SUO 20th Annual Scientific Meeting
Extraordinary Opportunities for Discovery
December 4 – 6, 2019
Renaissance Washington DC Downtown Hotel

Winter Scientific Program Co-Chairs:
Bradley C. Leibovich, MD, FACS
Edward M. Schaeffer, MD, PhD

#SUO19

PROGRAM BOOK
# Table of Contents

- **Board of Directors** ................................................................. 2
- **Committees** ........................................................................ 3
- **Faculty Listing** ................................................................. 4
- **Promotional Partners** ............................................................ 6
- **Contributors & Exhibitors** .................................................. 7
- **General Information** ............................................................ 8
- **CME Information** ................................................................. 9
- **Industry Satellite Symposium Events** ....................................... 12
- **General Scientific Program** .................................................. 13
- **Abstract Categories & Poster Maps** ........................................... 21
- **YUO Podium Session** ............................................................ 23
- **Oral Abstract Session** ............................................................ 27
- **Poster Session I – Summary** .................................................. 34
- **Poster Session I – Full Abstracts** ............................................ 48
- **Poster Session II – Summary** .................................................. 171
- **Poster Session II – Full Abstracts** ............................................ 184
- **Alphabetical Index of Authors** .................................................. 305
- **SUO Fellowship Programs** .................................................... 311
- **2021 SUO Fellowship Match Timeline** ........................................ 316
- **Mark Your Calendars** ............................................................. 317
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GENERAL INFORMATION

Attendee Participation
The meeting is designed to be a discussion of issues among members of the urologic oncology community. All attendees participate in the discussions and are encouraged to interact with program faculty.

Registration/Information Desk Hours
Wednesday, December 4, 2019  6:30 a.m. – 5:30 p.m.
Thursday, December 5, 2019 7:00 a.m. – 5:30 p.m.
Friday, December 6, 2019  7:00 a.m. – 3:45 p.m.

Exhibit Hall Hours
Wednesday, December 4, 2019 2:00 p.m. – 6:30 p.m.
Thursday, December 5, 2019 7:45 a.m. – 6:30 p.m.
Friday, December 6, 2019  7:45 a.m. – 11:00 a.m.

Poster Sessions
Wednesday, December 4, 2019 2:00 p.m. – 5:30 p.m.
Thursday, December 5, 2019 2:00 p.m. – 5:30 p.m.

SOCIAL FUNCTIONS

Welcome Reception
Date: Wednesday, December 4, 2019
Time: 5:30 p.m. – 6:30 p.m.
Location: Grand Ballroom
Attire: Business Casual

Young Urologic Oncologists (YUO) Dinner*
*YUO Members only.
Date: Wednesday, December 4, 2019
Time: 6:15 p.m. – 9:00 p.m.
Location: Congressional Ballroom
Cost: One ticket is included in the registration fee. Please RSVP to this event on your registration form.
Attire: Business Casual

The SUO’s subsection, the Young Urologic Oncologists (YUO) invites all YUO members, fellows and residents to join them at their Annual Dinner Program. Beginning with drinks and a plated dinner, the YUO program features lectures on mentorship, entrepreneurship and innovation, and other workforce issues in urologic oncology, as well as a special presentation by the winner of the “Paper of the Year” award.

SUO Reception & Awards
Date: Thursday, December 5, 2019
Time: 5:30 p.m. – 6:30 p.m.
Location: Grand Ballroom
Cost: Entrance is included in the registration fee.
Attire: Business Casual

SUO invites all of the attendees to visit with exhibitors, connect with fellow colleagues, and enjoy delicious appetizers and beverages while honor award winners and Board members.

Women in Urologic Oncology Reception
Date: Thursday, December 5, 2019
Time: 6:30 p.m. – 8:00 p.m.
Location: Meeting Rooms 12 - 14
Attire: Business Casual

The Women in Urologic Oncology invite all female trainees, physicians and scientists to join them for this unique networking event. There will be a cash bar available.

2019 AWARD WINNERS

2019 Huggins Medal:
Laurence Klotz, CM, MD, FRCSC
“My Active Surveillance Trajectory: A Literary Bibliography”
The Huggins Award is given annually in recognition of major lifetime contributions and achievements in research and clinical practice that has contributed to the progress in the treatment of genitourinary neoplasms.

2019 Richard D. Williams, MD
Prostate Cancer Research Excellence Award:
William J. Catalona, MD
“Prostate Cancer Screening”
Since 2013, the Urology Care Foundation has presented the Williams Award, named in honor of the late urologist, scientist, mentor, and humanitarian. The Williams Award is presented annually to an individual for outstanding and impactful research and work in the field of prostate cancer over the previous 10 years. Dr. Catalona was nominated by the SUO earlier this year.

2019 EAU Lecturer:
Arnulf Stenzl, MD
“How to Improve Uro-Oncological Surgery with Intraoperative Real-Time Multisensory Technology”
In 2016, the SUO and the EAU Section of Oncologic Urology (ESOU) established a lectureship-exchange program in order to strengthen the relationship between the two Societies and to facilitate collaborations between European and American physicians. The SUO and the EAU independently selects a representative of their Society to present as a guest speaker at the other organization’s Annual Meeting each year.

BOARD, COMMITTEE AND MEMBER MEETINGS

SUO/YUO Symposium on Clinical Research & Clinical Trials
Date: Wednesday, December 4, 2019
Time: 8:00 a.m. - 12:00 p.m.
Location: Mt. Vernon Square AB

SUO-CTC Board of Directors Meeting
Date: Wednesday, December 4, 2019
Time: 4:30 p.m. – 6:00 p.m.
Location: Mt. Vernon Square AB

SUO Board of Directors Meeting
Date: Wednesday, December 4, 2019
Time: 6:30 p.m. – 9:30 p.m.
Location: Meeting Rooms 12 - 14

SUO Fellowship Committee Meeting
Date: Thursday, December 5, 2019
Time: 6:30 a.m. – 7:45 a.m.
Location: Meeting Rooms 8 - 9

SUO Annual Business Meeting
Date: Thursday, December 5, 2019
Time: 10:10 a.m. – 10:30 a.m.
Location: Renaissance Ballroom

SUO Fellowship Program Directors’ Meeting
Date: Thursday, December 5, 2019
Time: 12:15 p.m. – 1:15 p.m.
Location: Mt. Vernon Square AB
EDUCATIONAL NEEDS

Kidney Cancer
Emerging data and new treatments continue to have a profound impact in treatment of urologic malignancies and particularly in field of kidney cancer management. Discussion and debate on these topics go hand-in-hand with the process of dissemination and implementation in the clinical care of patients with various forms of this challenging disease. Notably, an expanding armamentarium of molecular therapeutics for treatment of advanced and metastatic disease has sparked interest in the development of an array of neoadjuvant and adjuvant applications being tested in clinical trials with recently reported results becoming available. The results of such studies are open to careful interpretation and thoughtful discussion as additional studies develop.

Practicing urologists and medical oncologists need to be familiar with the genomic drivers for various forms of kidney cancers, the approach toward personalized medicine in this field, the novel pathways, mechanisms, safety profile and efficacy of available agents. Further, this understanding will support rational trial design and execution for the advancement of our patient care mission.

The standards of interventional treatment are shifting in the management of localized disease, not only through advances in surgical techniques and technologies but also through risk-stratified approaches to patient management. These approaches take into account features such as tumor aggressiveness, patient comorbidities and life-expectancy as well as the risks of contemporary interventions. Developed guidelines based on these variables require dissemination and discussion. Important as well is to understand the limitations of surgical techniques and areas in which data driven decisions regarding the appropriate application of surgical intervention warrant development and oversight.

Bladder Cancer
Organ preservation for muscle invasive bladder cancer is currently underutilized in the US. Results with trimodality therapy have been reported to be similarly to radical cystectomy in selected patients. The ideal patients for chemoradiation therapy, the rationale for the addition of chemotherapy and the best radiation therapy techniques are all important to understand when discussing this option with patients with muscle-invasive bladder cancer.

Transurethral resection of bladder tumor is the central surgical procedure for both the diagnosis and treatment of bladder cancer. Surprisingly, although this is a core technique taught in every residency program, there is wide variability in performance. Pathology review has demonstrated that detrusor muscle is often missing in the transurethral resection which means one of the key factors predicting outcomes and driving treatment decisions is missing. Video review of surgical technique has become an important educational tool, and can be applied to this very common procedure to try to improve outcomes.

Beyond TUR staging, standard evaluation of the extent of bladder cancer using imaging has been limited by the inability of standard CT scan to accurately predict muscle invasion, extravesical extension or nodal metastases. PET CT has not added much to date. Recent studies using multiparametric MRI have held out the promise of improving the accuracy of clinical staging. Finally, radical cystectomy continues to carry high morbidity and mortality in bladder cancer patients. Adoption of ERAS techniques for perioperative management has quite dramatically decreased length of stay but has not significantly impacted complication rates. In addition, adoption of these techniques has not been uniform or consistent. Identification of potentially modifiable patient–specific risk factors for complications and mortality is key along with prospective study of these interventions to evaluate their impact in the real world setting.

Prostate Cancer
The diagnostics and management of localized prostate cancer is complicated because of cancer heterogeneity and differentiated progression in various subgroups of patients. As a prostate cancer biomarker, FDA-approved detection assay for serum prostate specific antigen (PSA) and its derivatives are not potent enough to diagnose prostate cancer, especially high-grade disease (Gleason ≥7). To date, a collection of new biomarkers was developed. Some of these markers are superior for primary screening while others are particularly helpful for cancer risk stratification, detection of high-grade cancer, and prediction of adverse events.

The emergence of new drugs for mCSPC and mCRPC has dramatically improved treatment options for patients with advanced prostate cancer. Currently, systematic treatment options for mCSPC include hormonal therapy, chemotherapy, immunotherapy and radionuclide therapy as well as bone-modifying agents and palliative or supportive measures. Further, new genetically targeted agents (PARP inhibitors and PD-1 inhibitors) are on the horizon for certain subsets of biomarker-selected patients.

Penile Cancer
Penile cancer is a rare malignancy in most parts of the world resulting in significant heterogeneity and often non-evidence based diagnostic and therapeutic approaches to the care of penile cancer patients. Educational sessions such as this offer the opportunity to highlight recent advances in the management of penile cancer. In this regard, novel systemic approaches have been evaluated in optimizing the outcomes of patients suffering from advanced disease. In addition, the highly anticipated InPACT trial has been opened internationally to better define the effectiveness of systemic chemotherapy, radiotherapy, and pelvic lymph node dissection among patients with bulky nodal metastases. Lastly, supra-regionalization of care specifically aimed for rare malignancies such as penile cancer are occurring in Europe through efforts such as UROGEN highlight the opportunity to standardize treatment approaches and enhance research collaborations relevant to these rare malignancies.

Statistical Implications
Urologic oncology research studies often access secondary data sources such as national cancer registries or insurance billing claims to conduct comparative effectiveness research, epidemiological research, or to understand trends and variations in care. Understanding state-of-the-art statistical methods to extract meaningful results from these data sources enriches the quality of urologic research and helps avoid missteps in secondary data studies that lead to unintentionally erroneous inferences. In fact, in many observational studies, unmeasured confounding by factors that cannot be used as variables in the data can explain away many of the observed associations. Understanding econometric methods that are commonly used to analyze observational data, the importance of significance testing, and how to critically evaluate the results of secondary data analyses will promote higher quality urologic cancer research.
This session will review econometric methods that are commonly used to conduct comparative effectiveness research with observational data and discuss the indications, inferences, and pitfalls of each. We will then discuss how to generate estimates from models that allow for translation of data from these studies into clinically useful information. Lastly, we will discuss contemporary controversies with significance testing and methods to go beyond the p-value.

**Educational Objectives**
At the conclusion of the 2019 SUO Annual Meeting, attendees will be able to:

**Kidney Cancer**
- Describe the optimal imaging surveillance protocols for patients after treatment of kidney cancer.
- Recognize the emerging role of biomarkers for the future management of kidney cancer.
- Identify how building a surgical team may improve outcomes for complex kidney cancer surgeries.
- Review the potential for radiation in the future kidney cancer treatment paradigms.
- Explain diagnostic and treatment options for patients with small renal masses.
- Describe the evolution of genetic changes in kidney cancer progression and the clinical implication of landmark genetic events.
- Explain the rationale for neoadjuvant vs. adjuvant therapy using novel target and immune modulating agents.
- Identify the differences in clinical trial and real world evidence for kidney cancer.
- Recognize the importance of tracking institutional outcomes for quality improvement.
- Discuss the utility of multidisciplinary management of locally advanced and metastatic kidney cancers.
- Review the role of surgery with systemic therapies for metastatic kidney cancer.

**Bladder Cancer**
- Describe the basic steps of a properly performed TURBT.
- List the pros and cons of an en bloc approach to tumor resection.
- Identify the ideal patient for active surveillance of recurrent bladder tumors versus in-office treatment.
- Describe the current accuracy of multiparametric MRI in identification of muscle invasion and extravesical extension of primary bladder tumors.
- List 4 ways to decrease early and late complications from radical cystectomy, including the role of nutrition, prevention of infection and opioid-sparing pain management.
- Describe the short-term results of the S1314 COXEN clinical trial.
- List options for management of patients with muscle-invasive bladder cancer who are not eligible for surgery or chemotherapy and the expected outcomes of each.

**Prostate Cancer**
- Discuss the new biomarkers available to treat localized prostate cancer.
- Discuss the new medications available to treat advanced prostate cancer.

**Penile Cancer**
- Describe current and novel systemic therapies in the management of advanced penile cancer.
- Recognize the importance of the international InPACT trial and gain knowledge as to its inclusion/exclusion criteria as well as study endpoints. For any interested attendees and potentially eligible sites, this session will highlight opportunities they can participate and/or promote the trial within their medical community.
- Explain how efforts of supra-regionalization of care in the management of penile cancer through UROGEN have taken place including the potential opportunities it offers to enhance research collaborations and establish strict evidence based therapeutic approaches to managing this rare malignancy over broad geographical areas.

**Statistical Implications**
- Describe common techniques for survival analysis and the use of treatment selection models such as propensity score matching, instrumental variable analysis, and targeted maximal likelihood estimation.
- Discuss methods to generate interpretable estimates from model results that may allow for models derived from clinical trials or observational data to be more readily incorporated into clinical decision-making.
- List methods to critically evaluate the potential impact confounding by unmeasured variables could have in the results from models derived from clinical trials or observational data.
CONTINUING MEDICAL EDUCATION CREDIT INFORMATION

Accreditation
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The American College of Surgeons designates this live activity for a maximum of **15.00 AMA PRA Category 1 Credits™**. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

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The disclosure report for this meeting can be found at the following link: suonet.org/disclosures

Special Assistance
We encourage participation by all individuals. If you have a disability, advance notification of any special needs will help us better serve you. Call (847) 264-5901 if you require special assistance to fully participate in the meeting.
SYMPOSIUM EVENTS

WEDNESDAY, DECEMBER 4, 2019

12:00 p.m. - 1:00 p.m.

Industry Satellite Symposium Lunch
Location: Congressional Ballroom A
Sponsored by: Merck & Co., Inc.

“Treatment Approach for Certain Patients with Locally Advanced or Metastatic Urothelial Carcinoma”
Gautam Jayram, MD

THURSDAY, DECEMBER 5, 2019

7:00 a.m. - 8:00 a.m.

Industry Satellite Symposium Breakfast
Location: Congressional Ballroom A
Sponsored by: Creative Educational Concepts

“Expert Exchange: Examining the Use of Checkpoint Inhibitors in Bladder Cancer”
Ashish M. Kamat, MD, MBBS, FACS
Robert Dreicer, MD, MS, MACP, FASCO
Neal D. Shore, MD, FACS

12:10 p.m. - 1:25 p.m.

Industry Satellite Symposium Lunch
Location: Congressional Ballroom A
Sponsored by: Bayer HealthCare

“Now is the Time for Nubeqa”
David Morris, MD, FACS

12:10 p.m. - 1:25 p.m.

Industry Satellite Symposium Lunch
Location: Congressional Ballroom B
Sponsored by: Genomic Health

“Biomarkers for Early- and Advanced-stage Prostate Cancer”
Robert E. Reiter, MD

FRIDAY, DECEMBER 6, 2019

7:00 a.m. - 8:00 a.m.

Industry Satellite Symposium Breakfast
Location: Congressional Ballroom A
Sponsored by: Janssen Biotech, Inc.

“Treating Patients with Advanced Prostate Cancer: Metastatic and Non-Metastatic PC”
Robert W. Given, MD

12:00 p.m. - 1:15 p.m.

Industry Satellite Symposium Lunch
Location: Congressional Ballroom A
Sponsored by: Astellas Pharma and Pfizer Oncology

“Examining an Option for Castration-Resistant Prostate Cancer (CRPC)”
Larry Karsh, MD, FACS
20th Annual Meeting of the Society of Urologic Oncology
Extraordinary Opportunities for Discovery
December 4 - 6, 2019
Renaissance Washington DC Downtown Hotel
Washington, DC

General Scientific Program

Program Co-Chairs
Bradley C. Leibovich, MD, FACS
Edward M. Schaeffer, MD, PhD

Speakers and times are subject to change.
All sessions located in the Renaissance Ballroom unless otherwise noted.
WEDNESDAY, DECEMBER 04, 2019

OVERVIEW

6:30 a.m. - 5:30 p.m.  Registration/Information Desk Open
Location: Grand Registration Desk

7:00 a.m. - 5:00 p.m.  Speaker Ready Room
Location: Lafayette

7:00 a.m. - 12:00 p.m.  SUO Symposium on Clinical Research and Clinical Trials*
Location: Mt. Vernon Square AB
*Pre-registration required; not CME Accredited

2:00 p.m. - 6:30 p.m.  Exhibit Hall Open
Location: Grand Ballroom

2:00 p.m. - 5:30 p.m.  Poster Session I
Location: Grand Ballroom

5:30 p.m. - 6:30 p.m.  Welcome Reception
Location: Grand Ballroom

6:15 p.m. - 9:00 p.m.  *Young Urologic Oncologists (YUO) Dinner
Location: Congressional Ballroom
*YUO Members Only

GENERAL SESSION

12:00 p.m. - 1:00 p.m.  Industry Satellite Symposium Lunch*
Location: Congressional Ballroom A
*Not CME Accredited

1:00 p.m. - 2:30 p.m.  Organ Preservation in Urologic Cancers
Moderators: Edward M. Schaeffer, MD, PhD
Derya Tilki, MD

1:00 p.m. - 1:20 p.m.  Muscle-Invasive Bladder Cancer
Speaker: Robert Huddart, MA, MBBS, MRCP, FRCR

1:20 p.m. - 1:40 p.m.  Kidney Cancer
Speaker: Steven C. Campbell, MD, PhD

1:40 p.m. - 2:00 p.m.  Penile Cancer
Speaker: Philippe E. Spiess, MSc, MD

2:00 p.m. - 2:20 p.m.  Prostate Cancer
Speaker: Scott E. Eggener, MD

2:20 p.m. - 2:30 p.m.  Panel Discussion/Q&A

2:30 p.m. - 3:00 p.m.  Break/Visit Exhibits
Location: Grand Ballroom

3:00 p.m. - 4:00 p.m.  Statistical Implications in Urologic Cancer
Moderator: John L. Gore, MD, MS

3:00 p.m. - 3:15 p.m.  Treatment Selection Models for Comparative Effectiveness Research
Speaker: John L. Gore, MD, MS

3:15 p.m. - 3:30 p.m.  Clinically Interpretable Estimates from Statistical Models
Speaker: Jennifer R. Rider, ScD, MPH

3:30 p.m. - 3:45 p.m.  Critical Evaluation of the P-Value in Clinical Trials Reporting
Speaker: Sebastien Haneuse, PhD

3:45 p.m. - 4:00 p.m.  Panel Discussion/Q&A

4:00 p.m. - 5:00 p.m.  State-of-the-Art Lecture I: Future of Healthcare from an Economic Perspective
Speaker: R. Lawrence Van Horn, PhD, MPH, MBA
<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Location</th>
<th>Chairs/Authors</th>
</tr>
</thead>
<tbody>
<tr>
<td>5:00 p.m. - 5:30 p.m.</td>
<td>View Posters</td>
<td>Grand Ballroom</td>
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<tr>
<td>6:15 p.m. - 9:00 p.m.</td>
<td>*Young Urologic Oncologists (YUO) Dinner</td>
<td>Congressional Ballroom</td>
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<tr>
<td>6:30 p.m. - 6:40 p.m.</td>
<td>Welcome</td>
<td></td>
<td>E. Jason Abel, MD, FACS&lt;br&gt;Angela B. Smith, MD, MS</td>
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<tr>
<td>6:40 p.m. - 6:50 p.m.</td>
<td>Annual Business Meeting</td>
<td></td>
<td>E. Jason Abel, MD, FACS&lt;br&gt;Angela B. Smith, MD, MS</td>
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<tr>
<td>6:50 p.m. - 7:00 p.m.</td>
<td>Paper of the Year Presentation: Transcriptomic Heterogeneity in Multifocal Prostate Cancer</td>
<td></td>
<td>Simpa S. Salami, MD, MPH</td>
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<tr>
<td>7:00 p.m. - 9:00 p.m.</td>
<td>YUO Dinner Program</td>
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<tr>
<td>7:00 p.m. - 7:15 p.m.</td>
<td>Failing Forward: An Educational Perspective</td>
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<td>Kirsten L. Greene, MD, MS</td>
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<tr>
<td>7:15 p.m. - 7:30 p.m.</td>
<td>Failing Forward: A Clinical Perspective</td>
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<td>Tracy M. Downs, MD, FACS</td>
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<tr>
<td>7:30 p.m. - 7:45 p.m.</td>
<td>Failing Forward: A Research Perspective</td>
<td></td>
<td>Gennady Bratslavsky, MD</td>
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<tr>
<td>7:45 p.m. - 8:15 p.m.</td>
<td>Resilience: The Art of Failing Forward</td>
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<td>Sasha K. Shillcutt, MD</td>
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<tr>
<td>8:15 p.m. - 9:00 p.m.</td>
<td>Panel Discussion/Q&amp;A</td>
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<tr>
<td>THURSDAY, DECEMBER 05, 2019</td>
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**OVERVIEW**

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<tr>
<td>7:00 a.m. - 5:30 p.m.</td>
<td>Registration/Information Desk Open</td>
<td>Grand Registration Desk</td>
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<tr>
<td>7:00 a.m. - 5:00 p.m.</td>
<td>Speaker Ready Room</td>
<td>Lafayette</td>
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<td>7:45 a.m. - 6:30 p.m.</td>
<td>Exhibit Hall Open</td>
<td>Grand Ballroom</td>
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<tr>
<td>2:00 p.m. - 5:30 p.m.</td>
<td>Poster Session II</td>
<td>Grand Ballroom</td>
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<tr>
<td>5:30 p.m. - 6:30 p.m.</td>
<td>SUO Reception and Awards</td>
<td>Grand Ballroom</td>
<td></td>
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<tr>
<td>6:30 p.m. - 8:00 p.m.</td>
<td>Women in Urologic Oncology Reception</td>
<td>Meeting Rooms 12 - 14</td>
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**GENERAL SESSION**

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<tbody>
<tr>
<td>7:00 a.m. - 8:00 a.m.</td>
<td>Industry Satellite Symposium Breakfast*</td>
<td>Congressional Ballroom A</td>
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*Not CME Accredited
8:00 a.m. - 9:10 a.m.  
**Kidney Cancer Session I**

**Moderator:**  
**Robert G. Uzzo, MD**  
*Not CME Accredited*

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<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Speaker(s)</th>
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<tbody>
<tr>
<td>8:00 a.m. - 8:10 a.m.</td>
<td>Optimizing Imaging Surveillance After Treatment for Localized RCC</td>
<td>Suzanne B. Merrill, MD</td>
</tr>
<tr>
<td>8:10 a.m. - 8:20 a.m.</td>
<td>The Future of Predictive Biomarkers In RCC</td>
<td>Joshua M. Lang, MD</td>
</tr>
<tr>
<td>8:20 a.m. - 8:30 a.m.</td>
<td>Building a Surgical Team to Improve Outcomes for Complex Renal Surgery/IVC Thrombectomy</td>
<td>Viraj A. Master, MD, PhD, FACS</td>
</tr>
<tr>
<td>8:30 a.m. - 8:40 a.m.</td>
<td>Stereotactic Radiation For Treatment Of Renal Cell Carcinoma</td>
<td>Vitaly Margulis, MD</td>
</tr>
<tr>
<td>8:40 a.m. - 9:10 a.m.</td>
<td>Interactive Panel Discussion: Diagnostic and Treatment Options for Small Renal Masses</td>
<td>Antonio Finelli, MD, Mohamad E. Allaf, MD, Jeffrey A. Cadeddu, MD, Lindsey A. Herrel, MD, MS, Brian M. Shuch, MD</td>
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9:10 a.m. - 9:40 a.m.  
**SUO-CTC Session**

**Moderator:**  
**Robert G. Uzzo, MD**

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<thead>
<tr>
<th>Time</th>
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<th>Speaker(s)</th>
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<tbody>
<tr>
<td>9:10 a.m. - 9:17 a.m.</td>
<td>Overview of Challenges in Adjuvant RCC Trials</td>
<td>Naomi B. Haas, MD</td>
</tr>
<tr>
<td>9:17 a.m. - 9:24 a.m.</td>
<td>Update on Adjuvant Trials and the SUO-CTC</td>
<td>Gennady Bratslavsky, MD</td>
</tr>
<tr>
<td>9:24 a.m. - 9:40 a.m.</td>
<td>Upcoming Surgically Relevant Clinical Trials in RCC</td>
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<tr>
<td>9:24 a.m. - 9:32 a.m.</td>
<td>Cytoreduction Trial (SWOG)</td>
<td>Hyung L. Kim, MD</td>
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<td>9:32 a.m. - 9:40 a.m.</td>
<td>Ischemia Trial</td>
<td>Ithaar H. Derweesh, MD</td>
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</table>

9:40 a.m. - 10:10 a.m.  
**Break/Visit Exhibits**

*Location: Grand Ballroom*

10:10 a.m. - 10:30 a.m.  
**SUO Annual Business Meeting**

10:30 a.m. - 10:35 a.m.  
**NCI Update**

**Speaker:**  
**W. Marston Linehan, MD**

10:35 a.m. - 10:40 a.m.  
**SUO Fellowship Update**

**Speaker:**  
**Stephen A. Boorjian**

10:40 a.m. - 11:50 a.m.  
**Prostate Cancer Session I: Localized**

**Moderator:**  
**Martin E. Gleave, MD, FRCSC, FACS**

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<tr>
<th>Time</th>
<th>Topic</th>
<th>Speaker(s)</th>
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<tbody>
<tr>
<td>10:40 a.m. - 10:50 a.m.</td>
<td>Genomic Biomarkers</td>
<td>Daniel E. Spratt, MD</td>
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<tr>
<td>10:50 a.m. - 11:00 a.m.</td>
<td>What Can We Learn from the Breast Experience?</td>
<td>Matthew R. Cooperberg, MD</td>
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<tr>
<td>11:00 a.m. - 11:05 a.m.</td>
<td>Discussion/Q&amp;A</td>
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<td>11:05 a.m. - 11:15 a.m.</td>
<td>PUNCH</td>
<td>James A. Eastham, MD</td>
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<tr>
<td>11:15 a.m. - 11:25 a.m.</td>
<td>NHT + ARPI</td>
<td>Adam S. Kibel, MD</td>
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<tr>
<td>11:25 a.m. - 11:35 a.m.</td>
<td>GUNS and Other Biomarker Trials</td>
<td>Martin E. Gleave, MD, FRCSC, FACS</td>
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<tr>
<td>11:35 a.m. - 11:50 a.m.</td>
<td>Panel Discussion/Q&amp;A</td>
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<td>11:50 a.m. - 12:10 p.m.</td>
<td>2019 Richard D. Williams, MD Prostate Cancer Research Excellence Award Lecture: Prostate Cancer Screening&lt;br&gt;Speaker: William J. Catalona, MD</td>
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<tr>
<td>12:10 p.m. - 1:25 p.m.</td>
<td>Industry Satellite Symposium Lunch*&lt;br&gt;Location: Congressional Ballroom A&lt;br&gt;*Not CME Accredited</td>
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<tr>
<td>12:10 p.m. - 1:25 p.m.</td>
<td>Industry Satellite Symposium Lunch*&lt;br&gt;Location: Congressional Ballroom B&lt;br&gt;*Not CME Accredited</td>
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<tr>
<td>1:25 p.m. - 2:30 p.m.</td>
<td>Penile Cancer Session&lt;br&gt;Session Chair: Philippe E. Spiess, MSc, MD</td>
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<tr>
<td>1:28 p.m. - 1:43 p.m.</td>
<td>Novel Systemic Therapies in Penile Cancer&lt;br&gt;Speaker: Jad Chahoud, MD</td>
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<tr>
<td>1:43 p.m. - 2:03 p.m.</td>
<td>InPACT Trial Update&lt;br&gt;Speakers: Peter A. Johnstone, MD, FACS&lt;br&gt;Lance C. Pagliaro, MD&lt;br&gt;Curtis A. Pettaway, MD</td>
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<tr>
<td>2:03 p.m. - 2:18 p.m.</td>
<td>Lessons Learned from the euROGEN Initiative&lt;br&gt;Speaker: Vijay K. Sangar</td>
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<tr>
<td>2:18 p.m. - 2:30 p.m.</td>
<td>Questions and Answers</td>
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<td>2:30 p.m. - 3:00 p.m.</td>
<td>Huggins Lecture</td>
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<tr>
<td>3:00 p.m. - 3:30 p.m.</td>
<td>Break/Visit Exhibits&lt;br&gt;Location: Grand Ballroom</td>
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<td>3:30 p.m. - 5:00 p.m.</td>
<td>Bladder Cancer Session I: NMIBC&lt;br&gt;Session Chair: Eila C. Skinner, MD&lt;br&gt;Moderator: Cheryl T. Lee, MD</td>
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<td>3:30 p.m. - 4:19 p.m.</td>
<td>TURBT Technique</td>
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<td>3:30 p.m. - 4:00 p.m.</td>
<td>Evaluating TURBT Quality&lt;br&gt;Speaker: James O. Peabody, MD</td>
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<td>4:00 p.m. - 4:11 p.m.</td>
<td>Discussion&lt;br&gt;Panelists: Per-Uno Malmstrom, MD, PhD&lt;br&gt;Gary Steinberg, MD</td>
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<tr>
<td>4:11 p.m. - 4:19 p.m.</td>
<td>En Bloc Resection&lt;br&gt;Speaker: Georgios Gakis, Prof.</td>
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<tr>
<td>4:19 p.m. - 4:29 p.m.</td>
<td>Active Surveillance versus Office Fulguration or Laser Treatment&lt;br&gt;Speaker: Mark S. Soloway, MD</td>
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<tr>
<td>4:29 p.m. - 4:39 p.m.</td>
<td>The SUO-CTC Phase III Adstiladrin trial for BCG Unresponsive NMIBC&lt;br&gt;Speaker: Colin P. N. Dinney, MD</td>
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<tr>
<td>4:39 p.m. - 4:49 p.m.</td>
<td>MRI for Staging for Bladder Cancer &amp; ViRads System&lt;br&gt;Speaker: Neema Navai, MD</td>
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<tr>
<td>4:49 p.m. - 5:00 p.m.</td>
<td>Discussion</td>
<td></td>
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</table>
5:00 p.m. - 5:30 p.m.  View Posters  
Location: Grand Ballroom

5:30 p.m. - 6:30 p.m.  SUO Reception and Awards  
Location: Grand Ballroom

6:30 p.m. - 8:00 p.m.  Women in Urologic Oncology Reception  
Location: Meeting Rooms 12 - 14

FRIDAY, DECEMBER 06, 2019

OVERVIEW
7:00 a.m. - 3:45 p.m.  Registration/Information Desk Open  
Location: Grand Registration Desk

7:45 a.m. - 11:00 a.m.  Exhibit Hall Open  
Location: Grand Ballroom

GENERAL SESSION
7:00 a.m. - 3:30 p.m.  Speaker Ready Room  
Location: Lafayette

7:00 a.m. - 8:00 a.m.  Industry Satellite Symposium Breakfast*  
Location: Congressional Ballroom A  
*Not CME Accredited

8:00 a.m. - 8:30 a.m.  Young Urologic Oncologists (YUO) Program  
Chairs: E. Jason Abel, MD, FACS  
Angela B. Smith, MD, MS

8:00 a.m. - 8:07 a.m.  #1 ORIGIN OF GER TUMORS: SOMATIC TRANSFORMATION AND THE PRESENCE OF CANCER STEM-LIKE CELLS IN TERATOMA  
Presenter: Eric C. Umbreit, MD

8:07 a.m. - 8:14 a.m.  #2 PHASE I TRIAL OF INTRAVESICAL BACILLUS CALMETTE-GUÉRIN COMBINED WITH INTRAVENOUS PEMBROLIZUMAB IN HIGH GRADE NONMUSCLE INVASIVE BLADDER CANCER  
Presenter: Shaheen Alanee, MD, MPH, MBA

8:14 a.m. - 8:21 a.m.  #3 IMPLEMENTATION OF STANDARD OPIOID PRESCRIBING SCHEDULES FOLLOWING UROLOGIC SURGERIES REDUCES OPIOID PRESCRIPTIONS WITHOUT CHANGE IN PATIENT REPORTED OUTCOMES  
Presenter: Kathryn Hacker Gessner, MD, PhD

8:21 a.m. - 8:28 a.m.  #4 RISK OF MULTIPLE LEVELS OF RECURRENCE AND PROGRESSION AFTER INITIAL DIAGNOSIS OF NON-MUSCLE INVASIVE BLADDER CANCER IN A MULTI-SITE, COMMUNITY-BASED COHORT  
Presenter: Tullika Garg, MD, MPH

8:30 a.m. - 9:30 a.m.  Bladder Cancer Session II: MIBC/Metastatic  
Session Chair: Eila C. Skinner, MD

8:30 a.m. - 8:55 a.m.  Optimizing Surgical Outcomes for Cystectomy  
Moderator: Siamak Daneshmand, MD

8:30 a.m. - 8:35 a.m.  Immunonutrition  
Speaker: Jill Hamilton-Reeves, PhD, RD, CSO

8:35 a.m. - 8:40 a.m.  Preventing Readmission/Infections  
Speaker: Jen-Jane Liu, MD

8:40 a.m. - 8:45 a.m.  Opioid-Sparing Pain Management  
Speaker: Jay B. Shah, MD

8:45 a.m. - 8:50 a.m.  Does Maximal TURBT Improve Outcomes Prior to Cystectomy or Neoadjuvant Chemotherapy?  
Speaker: Trinity J. Bivalacqua, MD, PhD

8:50 a.m. - 8:55 a.m.  Discussion
<table>
<thead>
<tr>
<th>Time</th>
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</thead>
<tbody>
<tr>
<td>8:55 a.m. - 9:07 a.m.</td>
<td>S1314 Coxen Trial – Results and Next Steps in Personalized Systemic Therapy</td>
<td>Thomas W. Flaig, MD, Joshua J. Meeks, MD</td>
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<tr>
<td>9:07 a.m. - 9:12 a.m.</td>
<td>Discussion</td>
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<tr>
<td>9:12 a.m. - 9:20 a.m.</td>
<td>Options for Patients Not Eligible for Cystectomy or Chemotherapy</td>
<td>Per-Uno Malmstrom, MD, PhD</td>
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<tr>
<td>9:20 a.m. - 9:25 a.m.</td>
<td>Commentary</td>
<td>Ralph W. deVere White, MD</td>
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<tr>
<td>9:25 a.m. - 9:30 a.m.</td>
<td>Discussion</td>
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<tr>
<td>9:30 a.m. - 10:00 a.m.</td>
<td>State of the Art Lecture II: The Post TCGA Landscape Of Bladder Cancer</td>
<td>Seth P. Lerner</td>
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<tr>
<td>10:00 a.m. - 10:30 a.m.</td>
<td>Break/Visit Exhibits</td>
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<tr>
<td>10:30 a.m. - 11:30 a.m.</td>
<td>Kidney Cancer Session II: Advanced RCC</td>
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<tr>
<td>10:30 a.m. - 10:40 a.m.</td>
<td>Clinical Implications of Evolution Events in Renal Cell Carcinoma</td>
<td>Samra Turajlic, PhD</td>
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<td>10:40 a.m. - 10:50 a.m.</td>
<td>Comparing Outcomes for mRCC Patients Treated in Clinical Trials Versus Population Based Studies</td>
<td>Sumanta K. Pal, MD</td>
</tr>
<tr>
<td>10:50 a.m. - 11:00 a.m.</td>
<td>Better Outcomes at Higher Volume Centers: Evaluating Your Institution's Data</td>
<td>James Brugarolas, MD, PhD</td>
</tr>
<tr>
<td>11:00 a.m. - 11:30 a.m.</td>
<td>Interactive Panel Discussion: Integrating Surgery and Systemic Therapy for Locally Advanced and Metastatic RCC</td>
<td>Jose A. Karam, MD, James Brugarolas, MD, PhD, Sumanta K. Pal, MD, Bradley C. Leibovich, MD, Christopher G. Wood, MD</td>
</tr>
<tr>
<td>11:30 a.m. - 12:00 p.m.</td>
<td>EAU Lecture</td>
<td></td>
</tr>
<tr>
<td>11:30 a.m. - 11:35 a.m.</td>
<td>Introduction to the EAU Lecture</td>
<td>Christopher P. Evans, MD, FACS</td>
</tr>
<tr>
<td>11:35 a.m. - 12:00 p.m.</td>
<td>EAU Lecture: How to Improve Uro-Oncological Surgery with Intraoperative Real-Time Multisensory Technology</td>
<td>Arnulf Stenzl, MD</td>
</tr>
<tr>
<td>12:00 p.m. - 1:15 p.m.</td>
<td>Industry Satellite Symposium Lunch*</td>
<td></td>
</tr>
<tr>
<td>1:15 p.m. - 2:00 p.m.</td>
<td>Oral Abstract Session</td>
<td></td>
</tr>
<tr>
<td>#5</td>
<td>LIQUID BIOPSY ANALYSIS OF TERT PROMOTER AND FGFR3 MUTATIONS IN URINARY CELL-FREE DNA IN UPPER TRACT UROTHELIAL CARCINOMA*</td>
<td>Yujiro Hayashi, MD, FACS</td>
</tr>
<tr>
<td>#6</td>
<td>ON-TREATMENT CIRCULATING TUMOR CELL SUBTYPES AND BASELINE T-CELL POPULATION ARE BIOMARKERS FOR RESPONSE TO IMMUNOTHERAPY AND SURVIVAL IN METASTATIC GENITOURINARY CANCER PATIENTS</td>
<td>Timothy Clinton, MD, MPH</td>
</tr>
<tr>
<td>#7</td>
<td>RESPONSE OF FGFR3 ALTERATIONS IN HIGH-GRADE NON-MUSCLE INVASIVE BLADDER CANCER TREATED WITH INTRAVESICAL BACILLUS CALMETTE-GUERIN THERAPY</td>
<td>Timothy Chalfin, MD, MPH</td>
</tr>
<tr>
<td>#8</td>
<td>EVALUATION OF BIOMARKERS 4K SCORE, SELECTMDX AND EXODX, PSAD, TRUS AND MRI FOR THE DETECTION OF HIGH-GRADE PROSTATE CANCER</td>
<td>Claire M. De La Calle, MD</td>
</tr>
</tbody>
</table>
1:36 p.m. - 1:43 p.m.  #9 CHARACTERIZATION OF 68GA-PSMA AND 18F-FLUCICLOVINE (AXUMIN) TRANSPORTER GENE EXPRESSION IN LOCALIZED PROSTATE CANCER
Presenter: Carissa Chu, MD

1:43 p.m. - 1:50 p.m.  #10 SERUM microRNA-371a-3p LEVELS PREDICT VIABLE GERM CELL TUMOR IN CHEMOTHERAPY-NAIVE PATIENTS UNDERGOING RETROPERITONEAL LYMPH NODE DISSECTION
Presenter: Nirmish Singla, MD, MSCS

1:50 p.m. - 2:00 p.m.  Discussion/Q&A

2:00 p.m. - 3:00 p.m.  Prostate Cancer Session II: Advanced
Session Chair: Martin E. Gleave, MD, FRCSC, FACS

2:00 p.m. - 2:15 p.m.  Optimal Management of mCSPC
Speaker: Christopher Sweeney, MBBS

2:15 p.m. - 2:30 p.m.  Panel Discussion/Q&A
Moderator: Vivek K. Arora, MD, PhD
Panelists: Samuel Denmeade, MD
Christopher P. Evans, MD, FACS
Joaquin Mateo, MD, PhD
Christopher Sweeney, MBBS

2:30 p.m. - 2:45 p.m.  Bipolar AR Therapy
Speaker: Samuel Denmeade, MD

2:45 p.m. - 3:00 p.m.  PARPi
Speaker: Joaquin Mateo, MD, PhD

3:00 p.m. - 3:45 p.m.  Research Scholars Update

3:00 p.m. - 3:15 p.m.  CDKN1A Altered Urothelial Carcinoma
Speaker: Shawn Dason, MD, FRCSC

3:15 p.m. - 3:30 p.m.  Employing Multiparametric Profiling to Characterize Immunotherapy Responders in Clear Cell Renal Cell Carcinoma
Speaker: Brandon Manley, MD

3:30 p.m. - 3:45 p.m.  Impact of Surgery on Response to Cancer Immunology
Speaker: Karen M. Wheeler, MD, PhD, MS-CR

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General Session Recording
The general session will be video recorded. Please note that if you ask questions during the session, you may be video and/or audio recorded. Please see the registration/information desk should you have any concerns.
Grand Ballroom - Wednesday, December 4
Poster Session I

Exhibitor Booths

<table>
<thead>
<tr>
<th>Poster #s</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 - 36</td>
<td>Bladder</td>
</tr>
<tr>
<td>37 - 42</td>
<td>Health Services</td>
</tr>
<tr>
<td>43 - 66</td>
<td>Kidney</td>
</tr>
<tr>
<td>67 - 69</td>
<td>Other</td>
</tr>
<tr>
<td>70 - 72</td>
<td>Penile</td>
</tr>
<tr>
<td>73 - 114, 220</td>
<td>Prostate</td>
</tr>
<tr>
<td>115 - 121</td>
<td>Testis</td>
</tr>
<tr>
<td>115 - 121</td>
<td>Other</td>
</tr>
<tr>
<td>Podium #5</td>
<td>Other</td>
</tr>
</tbody>
</table>
Grand Ballroom - Thursday, December 5
Poster Session II

Poster #’s
122 - 157
158 - 163
164 - 186
187 - 189
190 - 191
79, 192 - 233
234 - 241

Category
Bladder
Health Services
Kidney
Other
Penile
Prostate
Testis

Exhibitor Booths
1. ORIGIN OF GERM CELL TUMORS: SOMATIC TRANSFORMATION AND THE PRESENCE OF CANCER STEM-LIKE CELLS IN TERATOMA

Eric Umbreit¹, Shi-Ming Tu², Andrew McIntosh², Mary Beth Westerman², Daniel Shapiro², Aron Joon², Jose Karam², Christopher Wood²

¹ MD Anderson Cancer Canter, ² MD Anderson Cancer Center

Presented By: Eric Umbreit

Introduction: Testicular germ cell tumor is the ideal model for the study of a genetic versus stem cell origin of cancer in solid tumors. Teratoma formation often develops in primary and metastatic germ cell tumors and is resistant to all systemic therapy, requiring surgical extirpation. There is controversy surrounding the genesis of germ cell-associated teratoma and the origin of its ability to transform into malignancy. It is unknown whether a mature teratoma dedifferentiates due to genetic mutations that reprogram a progeny cell into a progenitor cell, or teratoma develops from cancer stem cells, enabling it to differentiate into multiple lineages. The hypotheses of differentiation versus dedifferentiation in cancer cannot by more diametrically opposite and conceptually pivotal. We hypothesize that somatic transformation occurs by differentiation of a progenitor stem-like cell embedded in the teratoma rather than by dedifferentiation of a progeny differentiated cell from acquisition of a specific genetic mutation or activation of a specific stem-ness gene.

Methods: Two investigations where explored to further evaluate this hypothesis: (1) develop a post-chemotherapy teratoma primary culture and demonstrate a stem cell-like progenitor cell embedded within teratoma derived from surgically resected specimens, and (2) evaluate the genetic and molecular profiles of metastatic teratoma and corresponding malignant transformation in surgically resected specimens. After successful development of a teratoma primary culture, flow cytometry was performed on live cells for cell-surface stem-ness markers to identify a potential cancer stem cell within the teratoma. Subsequent implantation of in vitro primary cultures into SCID mice created in vivo patient derived xenograft (PDX) models. Second, archival tumor tissue from 7 patients with mapped H&E stained slides and unstained sections of the teratoma and its associated somatically transformed tumor was used for DNA and RNA sequencing. Genomic DNA and RNA library prep, and capture were performed using standard procedures and submitted to the MD Anderson Cancer Center IPCT Lab for whole genome and RNAseq sequencing.

Results: After screening numerous media, growth factors, and extracellular matrix, teratoma cells were successfully grown in primary culture from two patients, Tera13 and Tera22 (Pic 2). Cells were confirmed as teratoma by final pathology and primary culture analysis for i12p, SALL4, OCT3 and NANOG. By flow cytometry, Tera13 and Tera22, were found to have cells positive for the stem-ness markers CD24, CD26, CD34, CD44, CD90, CD117, Cripto-1, SSEA-1, and SSEA-4. The Tera13 cell line was engrafted into the subcutaneous flank of recipient SCID mice and PDX models revealed teratoma tumor at resection (Pic 1). In the second investigation arm using the T200 panel for DNA analysis, we identified 58 genes harboring mutations in 14 archived tumor samples (7 patients), of which 24 genes indicated discordance between teratoma and somatic transformation. None of the 24 genes were consistently altered between patients, thus, teratoma and transformed tissue had similar genetic profiles. RNA analysis revealed 7 significant genes with increased expression in teratoma tissue compared to somatic transformation, suggesting a different epigenetic profile between tissue types.

Conclusion: For the first time ever reported, we successfully created primary culture teratoma cell lines and subsequent PDX modeling. In addition, we have begun to identify cancer stem-like cells within mature teratoma, suggesting a new hypothesis for predicting teratoma behavior and somatic transformation. By demonstrating that metastatic teratomas and their corresponding somatic transformations had similar if not identical genetic profiles, we hypothesize they have a common clonal origin and question the theory of acquiring specific genetic mutations, which lead to dedifferentiation of teratomas during somatic transformation. We proposed an alternative hypothesis in which teratoma contains a stem-cell entity that could both differentiate into a teratoma or any other tumor phenotype. These entrenched stem-like progenitor cells embedded within the teratoma would account for the malignant potential of teratomas, the necessary extirpation with curative intent, the ability to differentiate and produce intratumoral heterogeneity (including somatic transformation), the propensity to metastasize and to develop late recurrences.
2. PHASE I TRIAL OF INTRAVESICAL BACILLUS CALMETTE-GUÉRIN COMBINED WITH INTRAVENOUS PEMBROLIZUMAB IN HIGH GRADE NONMUSCLE INVASIVE BLADDER CANCER.

Shaheen Alanee1, Ahmed El-Zawahry2, Kevin McVary3, Mustafa Deebajah4, Sherjeel Sana5, Kathy Robinson6, Krishna Rao7

1 ALANEE MD PLLC, 2 Department of Urology, University of Toledo, 3 Loyola University School of Medicine, 4 Department of Pathology, Beaumont Health System, 5 Aurora Health Care, Milwaukee, WI, 6 Southern Illinois University School of Medicine, Springfield, Illinois, 7 Southern Illinois University School of Medicine

Presented By: Shaheen Alanee

Introduction: A phase I trial of intravesical bacillus Calmette-Guerin (BCG) in combination with systemic pembrolizumab was conducted in patients with high grade non-muscle invasive bladder cancer who had persistent or recurrent disease after failing treatment with at least 2 courses of intravesical therapy (one of which had to contain BCG) or BCG followed by maintenance BCG. The primary objective was to determine the safety of this combination. Secondary end points included response to treatment at 19 weeks (end of treatment) and three months post treatment.

Methods: A total of 12 patients were enrolled, and nine patients with recurrent/persistent high-grade non-muscle invasive bladder cancer after at least two courses of intravesical therapy or one course of BCG treatment followed by one course of maintenance BCG finished treatment. Six doses of pembrolizumab (100 vs. 200 mg) were given every three weeks over 16 weeks given concurrently with six weekly doses of BCG beginning at week 7. Patient safety was evaluated during and for 30 days following pembrolizumab treatment. Preliminary combination efficacy was determined at 19 weeks using cystoscopy. Bladder biopsy was performed in patients with suspicious lesions.

Results: The combination of BCG and pembrolizumab was well tolerated at both 100mg and 200mg fixed doses. Fatigue and dysuria, spasm, urgency, sensitivity, and frequency were the most common adverse events reported. All AE were grade 1 or 2. Two patients died during the trial period. One patient died due to the progression of upper urinary tract urothelial carcinoma. The second patient died after cystectomy (for progressive disease) from a cardiovascular event. Of the nine patients treated, 7 (78%) had no evidence of disease in the bladder at 19 weeks, end of treatment.

Conclusion: The combination of BCG and Pembrolizumab was well tolerated. Intravesical BCG and pembrolizumab may have clinical activity in non-muscle invasive bladder cancer recurring after repeated intravesical therapy. A phase III trial is now open to test the clinical activity of this combination.

Funding: MERCK and Co. Inc.
3. IMPLEMENTATION OF STANDARD OPIOID PRESCRIBING SCHEDULES FOLLOWING UROLOGIC SURGERIES REDUCES OPIOID PRESCRIPTIONS WITHOUT CHANGE IN PATIENT REPORTED OUTCOMES
Kathryn Hacker Gessner, Jae Jung, J. Lee Graves, Hannah Cook, Peggy McNaull, Brooke Chidgey, Jami Mann, Matthew Coward, Bradley Figler, Kristy Borawski, Marc Bjurlin, Mathew Raynor, Ray Tan, Davis Vipraksit, Eric Wallen, Raj Pruthi, Angela Smith, Matthew Nielsen
University of North Carolina at Chapel Hill
Presented By: Kathryn Hacker Gessner

Introduction: The incidence of new persistent opioid use following surgery is approximately 6-10%, more common than any single post-operative complication. Additionally, a recent systematic review found 67-92% of patients report unused opioid medications after a surgical prescription. Reducing the oversupply of opioids may substantially impact the opioid epidemic as a primary and secondary prevention strategy. However, as the opioid prescribing practices are changing, there is a lack of data on how reduced prescription amounts may affect patient usage of opioids and patients’ post-operative pain control. We aimed to evaluate post-surgical opioid requirements of patients following urologic surgeries and create standard prescribing schedules to reduce oversupply of opioid prescriptions. Following implementation of these prescribing schedules, we sought to evaluate patient opioid usage and patient reported outcomes, including patient pain interference and patient satisfaction.

Methods: Patients undergoing urologic procedures at the University of North Carolina Hospitals associated with 49 specified CPT codes were identified. Details regarding medications prescribed for postoperative pain were obtained through our pharmacy database. Two weeks post-procedure, patients were either contacted via telephone or email to participate in a survey evaluating postoperative opioid usage, storage and disposal habits, and patient reported outcomes. This study included two time periods: following the first time period (7/2017-1/2018), usage amounts were analyzed and Standard Opioid Prescribing Schedules (SOPS) were developed and used to guide opioid prescribing amounts during the second time period (7/2018-1/2019). The following outcomes were measured: opioid prescribing amounts, patient opioid usage amounts, opioid disposal and storage patterns, patient satisfaction and need for additional pain medications, and pain interference (using the validated Promis 9b questionnaire). Prescribing and usage amounts were compared using a two-sided t-test.

Results: During the first time period, 678 qualifying urologic procedures were performed and 282 surveys completed. For all procedures, patient were prescribed significantly more 5 mg oxycodone tablets than they used (20.9 vs 7.8, respectively; p=8.08x10^-41). During the second study time period, 665 qualifying urologic procedures were performed and 156 surveys completed. Following implementation of the SOPS, patients were prescribed significantly fewer tablets (average of 12.7) and also used significantly fewer tablets (average of 5.3) compared to pre-SOPS amounts (p = 5.48x10^-24, p=0.0034, respectively). There was not a significant difference in pain interference scores, patients reporting they ran out of pain medication, or patient reported satisfaction.

Conclusion: Data-driven post-operative opioid prescribing schedules are effective in reducing the amount of opioids prescribed following urologic surgery and a reduction in prescribed amount may translate to fewer opioids being used. The prescription of fewer opioids following urologic surgery was not associated with more patients running out of opioid medications, increased pain interference, or reduced patient satisfaction.

Funding: N/A
4. RISK OF MULTIPLE LEVELS OF RECURRENCE AND PROGRESSION AFTER INITIAL DIAGNOSIS OF NON-MUSCLE INVASIVE BLADDER CANCER IN A MULTI-SITE, COMMUNITY-BASED COHORT

Tullika Garg 1, Carmit McMullen 2, Michael Leo 3, Maureen O’Keeffe-Rosetti 2, Sheila Weinmann 2, Matthew Nielsen 3

1 Geisinger, 2 Kaiser Permanente Northwest Center for Health Research, 3 Lineberger Cancer Center, University of North Carolina

Presented By: Tullika Garg

Introduction: Non-muscle invasive bladder cancer (NMIBC) has high rates of recurrence and low risk of progression. However, the natural history of NMIBC is heterogeneous with significant variation depending on stage and grade at diagnosis. Currently available risk calculators provide broad estimates of any recurrence and progression to muscle-invasive disease, but are not able to predict the stage and grade of the recurrence. Understanding the patterns of recurrence on a more granular level may enable risk-stratified NMIBC treatment and surveillance. The objective of our study was to predict the risk of multiple levels of recurrence and progression outcomes across NMIBC stage and grade in a large cohort from two community-based health systems.

Methods: The analysis cohort consisted of 2956 NMIBC (stage <T2) patients from Kaiser Permanente Northwest (KPNW) and Geisinger diagnosed between 1994-2015. Data were derived from tumor registries, electronic health records, membership files, and pathology records. Recurrences (n=1062) were identified using a computer algorithm and all pathology reports were annotated for stage and grade by two urologic oncologists (TG and MN). We defined initial NMIBC diagnosis as a composite stage and grade variable as follows: papillary urothelial neoplasm of low malignant potential (PUNLMP), Ta low grade, Ta high grade, Tis or Ta with carcinoma in situ (CIS), T1 low grade, and T1 high grade. Recurrences were defined as low risk (PUNLMP or Ta low grade), intermediate risk (Ta high grade, CIS, T1 low grade), or high risk (T1 high grade), or progression to muscle invasion. We defined four outcomes as follows: any recurrence, intermediate risk recurrence or higher, high risk recurrence or higher, and progression to muscle invasion. Separate Cox proportional hazards regressions were performed to determine the association between each initial stage/grade category and time to each ordered outcome. Multivariable models were adjusted for age, sex, health system (KPNW or Geisinger), initial tumor size (<3cm or >=3cm), initial number of tumors (unifocal vs. multifocal), perioperative intravesical chemotherapy (yes/no), and induction intravesical therapy (yes/no). We also computed 1- and 5-year risk estimates and associated 95% confidence intervals (CI) based on these models.

Results: Mean age at diagnosis was 69 years and the cohort was predominantly white (98.5%), male (79%), and from KPNW (66%). At initial diagnosis, nearly half (1420) of tumors were Ta low grade, 78% were unifocal, and 77% were less than 3cm in size. Over a median follow up of 29.4 months, there were 1062 recurrences (35.9% of the cohort) and a total of 111 patients had progression to muscle-invasion (3.8%). PUNLMP was associated with a decreased risk of any recurrence as compared to Ta low grade (adjusted HR 0.72, 95% CI 0.56-0.92, Table 1). The adjusted hazard of high risk recurrence (T1 high grade) or progression increased with increasing diagnosis stage/grade from Ta high grade (adjusted HR 2.60, 95% CI 1.62-4.15), Tis or Ta with CIS (adjusted HR 4.74, 95% CI 3.01-7.47), and T1 high grade (adjusted HR 7.14, 95% CI 4.97-10.26). Table 2 describes the predicted 1- and 5-year risk of each outcome by stage and grade at diagnosis. For example, the predicted risk of a high risk recurrence or progression was 4% at 1 year and 10% at 5 years.

Conclusion: In this large cohort of NMIBC patients from two community-based health systems, we assessed the predicted risks of new clinically relevant definitions of recurrence that incorporate stage and grade of the recurrence. To our knowledge, this is also one of the largest existing series of long-term PUNLMP outcomes. We found that the 1- and 5-year predicted risk of high risk recurrences (T1 high grade) and progression to muscle-invasive disease increased with higher composite stage and grade at diagnosis. The predicted risks of multilevel NMIBC recurrence and progression outcomes may be useful for counseling patients and for designing risk-stratified surveillance schedules.

Funding: NIH NCI 1R21CA191610-01 (PI: McMullen & Nielsen)
5. LIQUID BIOPSY ANALYSIS OF TERT PROMOTER AND FGFR3 MUTATIONS IN URINARY CELL-FREE DNA IN UPPER TRACT UROTHELIAL CARCINOMA

Yujiro Hayashi¹, Kazutoshi Fujita¹, Makoto Matsushita², Taigo Kato², Koji Hatano², Atsunari Kawashima², Takeshi Ujike², Motohide Uemura², Norio Nonomura²

¹ Department Urology, Osaka university , ² Department of Urology, Osaka University

Presented By: Yujiro Hayashi

This abstract will be presented as a podium during Poster Session I on Wednesday, December 4

Introduction: Upper tract urothelial carcinoma (UTUC) is a relatively uncommon malignancy, accounting for 5% of urothelial carcinoma (UC). Patients suspected of having UTUC need to receive invasive procedures such as CT urography, retrograde pyelography, or ureteroscopy for a definitive diagnosis. Many researchers have tried to develop useful urinary markers to detect UTUC, but urine cytology still remains as the only non-invasive diagnostic marker recommended by many guidelines although its sensitivity for detection of UTUC is as low as 40%. Cell-free DNA (cfDNA) in bodily fluids has huge potential in disease diagnosis. Cell-free tumor DNA (ctDNA) is shed into the urine or circulation along with DNA from normal cells. Even though ctDNA constitutes a small fraction of the total DNA, ctDNA is thought to be a promising diagnostic biomarker. Hotspot mutations of Telomerase Reverse Transcriptase (TERT) promoter and fibroblast growth factor receptor (FGFR3) (S249C) are frequently identified in UTUC specimens. To our knowledge, there is no research on the relationship between urinary cfDNA alteration of UTUC and clinical utility. In this study, we developed droplet digital polymerase chain reaction (ddPCR) assays for the detection of hotspot mutations of the TERT promoter region and FGFR3 and analyzed the diagnostic potential of urine supernatant cfDNA collected from patients with localized UTUC.

Methods: We investigated voided urine samples from four cohorts of patients: those with localized UTUC (UTUC cohort), those with microscopic or macroscopic hematuria without UC (Hematuria cohort), those who were treated with transurethral resection of bladder tumor (TURBT) or radical nephroureterectomy (RNU) and had no evidence of disease recurrence for at least one year (UC surveillance cohort), and a healthy control cohort (HC cohort) that included kidney transplantation donors, healthy volunteers, benign disease patients and patients with urological carcinoma other than UC. All patients in the UTUC cohort were histologically diagnosed as having UC, and urine samples were collected from patients within four days before RNU or transurethral biopsy. We excluded UTUC patients with concurrent bladder cancer. In 12 of the patients in the UTUC cohort, post-treatment urine samples were also collected about one week after RNU.

Results: Fifty-six UTUC patients (UTUC cohort), 50 patients with microscopic or macroscopic hematuria caused by other than UC (Hematuria cohort), those who were treated with transurethral resection of bladder tumor (TURBT) or radical nephroureterectomy (RNU) and had no evidence of disease recurrence for at least one year (UC surveillance cohort), and 26 healthy controls (HC cohort) were included in this study. The median age was 74.5 years (range 55–92 years) in the UTUC cohort, 68 years (range 33–89 years) in the Hematuria cohort, 70 years (range 47–89 years) in the UC surveillance cohort, and 57 years (range 31–81 years) in the HC cohort. The median follow-up time was 13 months (range 1–60 months). Of the 56 UTUC patients, 54 (96.4%) received RNU, 1 (1.8%) received Bacillus Calmette-Guérin therapy for carcinoma in situ of UTUC, and 1 (1.8%) received platinum-based chemotherapy for clinical T4 UTUC. We detected mutations of TERT C228T in 22/56 (39.3%), TERT C250T in 4/56 (7.1%), and FGFR3 S249C in 9/56 (16.1%) patients. FGFR3 mutation was found only in =pT1 tumors (positive predictive value: 100.0%). In combination with cytology results, the sensitivity was 78.6%, and the specificity was 96.0%.

Conclusion: We could detect TERT promoter and FGFR3 hotspot mutations in urinary cfDNA from UTUC patients. In combination with cytology results, the sensitivity of our non-invasive urinary test was high enough to apply this assay to the clinical setting. Liquid biopsy analysis of TERT promoter and FGFR3 mutations in urinary cfDNA could be a novel biomarker and a reliable factor for staging UTUC.
6. ON-TREATMENT CIRCULATING TUMOR CELL SUBTYPES AND BASELINE T-CELL POPULATION ARE BIOMARKERS FOR RESPONSE TO IMMUNOTHERAPY AND SURVIVAL IN METASTATIC GENITOURINARY CANCER PATIENTS

Heather Chalfin, Scot Niglio, Seth Steinberg, Lisa Cordes, Lisa Ley, Marissa Mallek, Olena Sierra Ortiz, Rene Costello, Jacqueline Cadena, Carlos Diaz, Jane Trepel, Don Bottaro, Andrea Apolo, Amir Mortazavi, Lincy Chu, Sumanta Pal, Primo Lara, Mark Stein

1 National Cancer Institute, Bethesda, MD, 2 The Ohio State University Comprehensive Cancer Center, Columbus, OH, 3 Epic Sciences, Inc., San Diego, CA, epicsciences.com, 4 City of Hope, Duarte, CA, 5 University of California, Davis, Sacramento, 6 Columbia University, New York, NY

Presented By: Heather Chalfin

Introduction: Circulating tumor cells (CTCs) are liquid biopsies currently under investigation that may improve risk stratification and optimize treatment selection for patients in a minimally invasive fashion. Beyond enumeration, CTCs uniquely allow for digital pathology characterization of individual malignant cell morphology and marker expression, and this technology has been successfully applied in prostate cancer to stratify response to chemotherapy vs. androgen receptor signaling inhibitors. Here, we examined the association between CTC digital pathology features and T-cell activation with overall survival (OS) in a cohort of metastatic genitourinary cancer (mGU) patients treated with immunotherapy combination (Clinical Trial ID NCT02496208).

Methods: 139 samples from N=61 mGU cancer patients undergoing CaboNivo or CaboNivolpi therapy were collected at baseline and on-therapy. Slides were processed with the Epic CTC platform and stained with pan-CK/CD45/PD-L1/DAPI for CTC detection or CD4/CD8/Ki-67/DAPI for T-Cell analysis. Approximately 3 million cells per slide were imaged through the advanced digital pathology pipelines to detect and assess CTC burden, as well as to quantify changes in immune cell populations.

Results: From 12/07/2016-01/22/2019, 61 pts [urothelial carcinoma (UC) N = 39; plasmacytoid UC N = 1; Clear cell renal cell carcinoma N = 4; bladder adenocarcinoma N = 8; bladder squamous cell carcinoma N = 3; bladder small cell N = 2; renal medullary N = 2; penile N=2] were treated. Median age was 61 years (range 20-82). N = 46 (75%) had visceral involvement, N = 19 (31%) had liver involvement, and N = 13 (21%) had bone involvement. CTCs were found in 70% of pts at baseline and Cycle 2. On treatment at Cycle 2, CTC burden was associated with resistance to therapy and shorter OS (5.1 vs 24.7 months, p = 0.015), and the presence of two specific CTC subtypes were also associated with shorter OS (2.27 vs 19.53 months, 1.71 vs 24.69 months, p<0.0001, p=0.0059). Features associated with these two CTC subtypes included CK intensity and speckling, circularity, cell size and nuclei count. Similar trends were observed with progression free survival. Low CD4 and CD8 T-cell counts at baseline were also associated with poor OS and response to therapy (%CD4<7, p 0.0001, %CD8<3, p=0.024).

Conclusion: Poor response to immunotherapy and shorter survival is associated with high CTC counts at Cycle 2, presence of specific CTC subtypes on therapy, and low %CD4 and %CD8 T-cells in mGU cancer patients. Ongoing efforts include digital pathology analysis of T-cell populations and single cell sequencing of CTC subtypes, as well as analysis of an additional 19 patients.

Funding: This project has been funded with federal funds from the National Cancer Institute, National Institutes of Health.
7. RESPONSE OF FGFR3 ALTERATIONS IN HIGH-GRADE NON-MUSCLE INVASIVE BLADDER CANCER TREATED WITH INTRAVESICAL BACILLUS CALMETTE-GUERIN THERAPY


Memorial Sloan Kettering Cancer Center

Presented By: Timothy Clinton

Introduction: The recent FDA approval of fibroblast growth factor receptor (FGFR)3 kinase inhibitors for use in metastatic urothelial carcinoma has increased interest in targeted therapy for bladder cancer. Additionally, FGFR3 alterations may be associated with lower response rates to immune checkpoint inhibition. It is known that FGFR3 mutations are more commonly identified in the non-muscle invasive bladder cancer (NMIBC) tumors. FGFR3 altered NMIBC tumors tend to be less likely to progress but their response to intravesical Bacillus Calmette-Guerin (BCG) immunotherapy is unknown. We sought to examine NMIBC tumors with FGFR3 alterations and determine the response of these tumors to BCG therapy. While assessing response, we will also identify any associated co-mutations that may be predictive genomic biomarkers of BCG response in these tumors.

Methods: We identified treatment naïve high-grade NMIBC patients enrolled on a prospective IRB-approved protocol for which targeted exon capture sequencing (MSK-IMPACT) was performed on pretreatment tumor DNA and matched germline DNA in a CLIA-certified laboratory and who were subsequently treated with intravesical BCG. Analysis of those tumors harboring a FGFR3 alterations was performed to compare response to BCG. Genomic alterations beyond FGFR3 were correlated to those who were BCG refractory versus BCG relapsing and those without any recurrence. Identified FGFR3 alterations were further evaluated for recurrence-free survival with Kaplan-Meier curves as they correlated to type of alteration (fusion vs hotspot).

Results: One-hundred nineteen patients with high-grade NMIBC who underwent BCG treatment were identified with fifty-one containing a FGFR3 alterations (43%). Thirty-nine patients (76%) were cTaHG and twelve (24%) were cT1HG at diagnosis. No patient with cTis contained a FGFR3 alteration. At a median 60-month (IQR 32-75) follow-up, 20 patients (39%) did not have a high-grade recurrence while 8 patients (16%) were deemed BCG refractory and 23 (45%) were BCG relapsing. Rate of progression was very low with only four patients (8%) with stage progression and only one patient to muscle-invasive disease. Assessment of the entire cohort for genomic alterations identified significant co-occurrence of FGFR3 mutations with cell cycle genes including CDKN2A (p=0.03) and MDM2 (p=0.03) and no FGFR3 mutated tumor contained an ERBB2 mutation. In Figure 1, we assessed the genomic alterations in the three responses to BCG for FGFR3 altered tumors. In an analysis of the types of FGFR3 alterations, we did identify four FGFR3-TACC3 and one FGFR3-TNIP2 fusions, but majority of the mutations were S249C hotspot mutations (n=34) and the remaining hotspot mutations in R248C, Y373C and K650E. Figure 2 demonstrates the recurrence-free survival of these FGFR3 alterations compared to FGFR3 wild-type.

Conclusion: FGFR3 alterations are relatively common in NMIBC where the standard of care is BCG immunotherapy. While FGFR3 altered NMIBC tumors have historically been associated with a favorable prognosis, our data demonstrates that FGFR3 altered tumors are associated with high recurrence rates similar to wild-type tumors. Given these findings further testing of FGFR3 altered tumors with FGFR3 inhibitors in the NMIBC setting are warranted. In this era of recurrent BCG shortages, patients with FGFR3 altered NMIBC tumors may benefit from the use of novel intravesical or systemic targeted agents and clinical trials of FGFR3 kinase inhibitors in NMIBC are currently underway.

Funding: This work was supported by the Sidney Kimmel Center for Prostate and Urologic Cancers, the Michael and Zena Wiener for Therapeutics Program in Bladder Cancer, Pin Down Bladder Cancer, Cycle for Survival, the Marie-Josee and Henry R. Kravis Center for Molecular Oncology, NIH/NCATS Grant Number UL1-TR002384, the National Cancer Institute Cancer Center Core Grant Number P30-CA008748 and by SPORE in Bladder Cancer P50-CA221745.
8. EVALUATION OF BIOMARKERS 4K SCORE, SELECTMDX AND EXODX, PSAD, TRUS AND MRI FOR THE DETECTION OF HIGH-GRADE PROSTATE CANCER
Claire de la Calle1, Janet Cowan1, Annika Herlemann1, Carissa Chu1, Adam Gadzinski1, Reuben Au Yeung1, Matthew Cooperberg1, Katsuto Shinohara1, Peter Carroll2, Hao Nguyen1, Vittorio Pasulo2, Alberto Saita3
1 University of California, San Francisco; 2 University of California, San Francisco; Istituto clinico Humanitas, Rozzano, Milan, Italy; 3 Istituto clinico Humanitas, Rozzano, Milan, Italy
Presented By: Claire de la Calle

Introduction: While PSA screening has resulted in decreasing prostate cancer mortality, PSA is also known to be a poorly specific test for the detection of clinically significant cancer and can lead to many unnecessary biopsies, over-detection of low risk prostate cancer or even miss aggressive disease. PSA’s lack of robustness as a screening biomarker has led to the development of new prostate cancer screening tools (urine, blood and imaging based) to add specificity to PSA for the detection of clinically significant prostate cancer. Here we aim to evaluate and compare three screening tools in the clinical setting: serum based 4K score and urine based SelectMDx and ExoDx and their added value when combined with multiparametric parametric MRI (mpMRI).

Methods: Patients referred to UCSF from 2016 to 2019 for consideration of biopsy were enrolled. Patients with PSA >20 ng/mL or with a prior positive prostate biopsy were excluded. 510 patients met inclusion criteria. All patients underwent DRE followed by urine collection for SelectMDx testing or underwent urine collection for ExoDx without pretesting DRE or had the serum based 4K score. SelectMDx scores were binary: low or high risk for prostate cancer. ExoDx was considered high prostate cancer risk if the IntelliScore was >15.6, and 4K scores >10% were considered high risk. 266 patients had a prostate biopsy. All biopsies were systematic 14 cores with or without targeted ultrasound or mpMRI fusion cores. We defined the sensitivity (SE), specificity (SP), negative and positive predictive values (NPV and PPV) of each biomarker, mpMRI, TRUS and PSAD for the detection of all prostate cancers and specifically high-grade prostate cancers (here defined as Gleason grade of 3+4 or higher). Multivariate logistic regression modeling adjusting for age, PSA, prostate volume, DRE, family history of prostate cancer and history of prior negative biopsy was performed to determine each biomarker’s ability to predict the presence of any cancer on biopsy or high-grade prostate cancer, with or without imaging. Statistical analyses were performed using SAS.

Results: Mean age was 66.2 years, 71% were Caucasian, 5% African American and 85% of had no family history of prostate cancer. 76% were biopsy naïve and median PSA was 6.4 ng/mL (IQR 4.7-8.6). 151 had the SelectMDx test, 196 ExoDx test and 209 4K score test. SE, SP, PPV and NPV of each biomarker, mpMRI, TRUS and PSAD for the detection of all prostate cancers and high-grade prostate cancers are listed in Table 1. ExoDx had the highest sensitivity overall, but the lowest specificity. SelectMDx had the lowest sensitivity but higher specificity than the other biomarkers for detecting clinically significant cancer. mpMRIs with a PIRADS 4/5 or a positive lesion on TRUS had the highest specificity but sensitivity was considerably lower than 4K or ExoDx sensitivities (Table 1). Multivariate logistic regression modeling showed that a positive result in any one of the biomarkers or imaging (mpMRI PIRADS 4/5 or positive lesion on TRUS) were strongly associated with finding high-grade disease. Furthermore, combining mpMRI with a biomarker increased predictive power for detecting clinically significant cancer as shown in Table 2. ExoDx had the highest AUC for performance in predicting high-grade disease of all the biomarkers (AUC 0.849 for ExoDx versus 0.835 for 4K and 0.699 for SelectMDx). The addition of PIRADS of 4 or 5 on mpMRI read increased the ExoDx AUC to 0.877 and the 4K AUC to 0.906 and the SelectMDx AUC increased to 0.805 (Table 2).

Conclusion: 4K score >10% or ExoDx >15.6 or PIRAD 4 or 5 on mpMRI all outperformed PSAD, TRUS and SelectMDX for the prediction of high-grade prostate cancer. High 4K scores and high ExoDx scores had high sensitivities while a PIRADS score 4/5 on mpMRI or positive lesion on TRUS had better specificity for high-grade prostate cancer. Combining the biomarkers with mpMRI resulted in the best predictive ability for detecting clinically significant cancer.

Funding: N/A
9. CHARACTERIZATION OF 68GA-PSMA and 18F-FLUCICLOVINE (AXUMIN) TRANSPORTER GENE EXPRESSION IN LOCALIZED PROSTATE CANCER

Carissa Chu¹, Martin Sjöström¹, Annika Herlemann¹, Jonathan Chou¹, Meera Chappidi¹, Matthew Cooperberg¹, Anthony Wong¹, Sima Porten¹, Thomas Hopeª, Peter Carroll¹, Felix Feng¹, Mohammed Alshalalfa², Shuang Zhao³, Daniel Spratt², Brandon Mahal³, Paul Nguyen⁴, Amar Kishan⁵, R. Jeffrey Karnes⁶, Elai Davicioni⁷, Edward Schaeffer⁸

¹ University of California, San Francisco, ² University of California, San Francisco, and Dana Farber Cancer Center, ³ University of Michigan, ⁴ Dana Farber Cancer Institute, Brigham and Women’s Hospital, ⁵ University of California, Los Angeles, ⁶ Mayo Clinic, ⁷ GenomeDx Biosciences, ⁸ Northwestern University

Presented By: Carissa Chu

Introduction: Molecular-based PET imaging for prostate cancer is transforming our ability to detect and target previously unknown sites of disease. While 18F-fluciclovine (Axumin) PET-CT is approved for use in the United States and recommended by the NCCN, prostate-specific membrane antigen (PSMA) PET-CT is more widely used in Europe/Australia and is recommended by the European Association of Urology. Less is known about the distinct biology of lesions detected by either modality or the optimal clinical setting for their use. While Axumin PET relies on radiotracer uptake by amino acid transporters (LAT1-4 and ASCT2), PSMA PET is dependent on surface expression of PSMA. Our objective was to compare relative expression of PSMA and Axumin transporter genes in a large cohort of radical prostatectomy (RP) samples to determine their distribution across molecular subtypes and correlation with long term clinical outcomes.

Methods: Gene expression data of 17,967 prospective RP samples generated from Decipher testing (GenomeDx Biosciences, San Diego, CA) and 1,135 retrospective samples with long term follow up were used in these analyses. All samples were from formalin-fixed paraffin-embedded tissues and the Affymetrix Human Exon 1.0 ST microarray (Affymetrix, Santa Clara, CA) was used for gene expression profiling. Associations between expression of PSMA and Axumin transporter genes (LAT1-4 and ASCT1-2) and pathologic variables, PAM50 molecular subtypes, and clinical outcomes were conducted. Multivariable analysis was performed to compare metastasis free survival and lymph node involvement.

Results: In RP specimens (n=17,967), all Axumin transporter genes (LAT 1-4, ASCT1-2) were expressed at lower levels when compared with PSMA (IQR -0.1-0.8 versus IQR 1.4-2.6, p <0.0001). LAT2 and ASCT2 were more highly expressed than other Axumin transporters (p<0.0001). While PSMA expression was positively correlated with metastatic genomic risk (Decipher), and pathologic Gleason score (GS) (p<0.0001 for both), LAT2, LAT3 and ASCT2 were inversely correlated with metastatic genomic risk in primary tumors (p<0.0001) and less expressed in GS 9-10 tumors (p<0.0001 for all). In one retrospective cohort of 780 men with >10 years of median follow up, higher PSMA expression was associated with poorer metastasis-free survival (MFS) (HR 1.45, p=0.001) and lymph node involvement (LNI, HR 2.14, p<0.0001), whereas high expression of LAT2, LAT3, ASCT2 expression was associated with better MFS (HR 0.85, p=0.04; 0.63, p<0.0001; 0.74, p<0.0001 respectively). In multivariable analysis adjusting for Gleason grade, stage, PSA at diagnosis, and LNI, high PSMA expression remained independently prognostic of MFS (HR 1.3, p=0.028) but did not reach significance for LNI (HR 1.3, p=0.09). After multivariable analysis, only LAT3 expression was prognostic of better MFS (HR 0.66, p<0.0001). With regard to molecular subtypes, Luminal B subtype was notable for overexpression of PSMA, while Luminal A was enriched in ASCT2 and LAT2 (p<0.0001). Basal subtype was notable for lowest expression of ASCT1 and LAT3 (p<0.0001). While PSMA expression did not correlate with ERG positive or negative prostate cancers, LAT2, ASCT1, and ASCT2 were overexpressed in ERG negative tumors (p<0.0001 for all).

Conclusion: In RP specimens, PSMA expression is positively correlated with genomic risk scores and predictive of poorer metastasis-free survival. After multivariate analysis, LAT3 expression was inversely correlated to metastatic risk. Molecular subtypes of prostate cancer variably express PSMA and Axumin transporter genes. While these findings suggest that gene expression analysis may have utility in selecting prostate cancer patients for different imaging modalities, further studies are necessary to validate the prognostic value of these imaging targets. Additional studies into the role of these targets in underlying tumor biology and metastatic disease are also warranted.

Funding: Prostate Cancer Foundation, NIH R01 CA235741, Benioff Initiative for Prostate Cancer Research
10. SERUM microRNA-371a-3p LEVELS PREDICT VIABLE GERM CELL TUMOR IN CHEMOTHERAPY-NAIVE PATIENTS UNDERGOING RETROPERITONEAL LYMPH NODE DISSECTION

John Lafin\textsuperscript{1}, Solomon Woldu\textsuperscript{1}, Yair Lotan\textsuperscript{1}, Cheryl Lewis\textsuperscript{1}, Kuntal Majmudar\textsuperscript{1}, Anna Savelyeva\textsuperscript{1}, Payal Kapur\textsuperscript{1}, Vitaly Margulis\textsuperscript{1}, Douglas Strand\textsuperscript{2}, James Amatruda\textsuperscript{1}, Aditya Bagrodia\textsuperscript{1}, Matthew Murray\textsuperscript{2}

\textsuperscript{1}University of Texas Southwestern Medical Center, \textsuperscript{2}University of Cambridge

Presented By: Nirmish Singla

Introduction: Serum microRNAs are candidate biomarkers for diagnosing and monitoring germ cell tumors (GCTs). The ability of miRNA to inform treatment in low-stage chemotherapy-naïve patients is unexplored. We sought to evaluate the performance characteristics of serum miRNA levels to predict viable GCT in chemotherapy-naïve patients undergoing primary retroperitoneal lymph node dissection (RPLND).

Methods: We prospectively collected presurgical serum samples and clinicopathologic characteristics from consecutive chemotherapy-naïve GCT patients undergoing primary RPLND from 2016-2019. Serum miRNAs (-367-3p/-371a-3p/-372-3p/-373-3p/-375) were isolated and quantified. RPLND histopathology was categorized as benign, viable GCT, or teratoma; miRNA levels were compared among groups. Performance characteristics, including receiver operating characteristic (ROC) curves, assessed the discriminative ability of each miRNA signature to predict viable GCT.

Results: 24 patients with stage I-II GCT underwent RPLND, revealing viable GCT in 11 (46%), teratoma in 3 (13%), and benign pathology in 10 (42%) patients. miR-371a-3p was the most discriminatory serum miRNA for viable GCT, exhibiting ~13,000-fold increase in expression over teratoma or benign pathology. On ROC analysis, miR-371a-3p had AUC=0.965, with sensitivity and specificity of 100% and 92%, respectively. The AUC for other serum miRNAs in predicting viable GCT were 0.874 (miR-367-3p), 0.846 (miR-372-3p), and 0.720 (miR-373-3p). These serum miRNAs were not predictive of pure teratoma.

Conclusion: Serum miRNAs, particularly miR-371a-3p, can accurately differentiate small-volume viable GCT from benign processes or teratoma in patients with negative serum tumor markers undergoing primary RPLND. If validated, these data suggest a basis to implement precision medicine strategies in treating patients with early-stage GCT.

Funding: NIH
POSTER SESSION I - SUMMARY

Poster Session I
Wednesday, December 4, 2019
2:00 p.m. - 5:30 p.m.
Grand Ballroom
See page 48 for full abstracts

1. PD-L1/PD-1 BIOMARKER FOR METASTATIC UROTHELIAL CANCER THAT PROGRESS POST-PLATINUM THERAPY: A SYSTEMATIC REVIEW AND META-ANALYSIS
Wei Phin Tan¹, Ankeet Shah¹, Gregory Barton¹, Brant Inman¹, Wei Shen Tan²
¹ Duke University Medical Center, ² University College London
Presented By: Wei Phin Tan

2. THE RISKS OF EPIDURAL ANESTHESIA IN CYSTECTOMY PATIENTS: A NSQIP ANALYSIS
Kirtishri Mishra¹, Amr Mahran², Laura Bukavina², Brittany Adamic³, Anjali Shekar¹, Vaishnavi Narayanamurthy¹, Richa Raina⁵, Carvell Nguyen⁶, Lee Ponsky⁷
¹ University Hospitals Cleveland Medical Center, ² University Hospitals Cleveland Medical Center, Urology Institute, Cleveland, Ohio, ³ University of Chicago Medical Center, Chicago, Illinois, ⁴ Case Western Reserve University School of Medicine, Cleveland, Ohio, ⁵ Northeast Ohio Medical University, Rootstown, Ohio, ⁶ Metro Health Medical Center, Cleveland, Ohio, ⁷ Case Comprehensive Cancer Center, Case Western Reserve University School of Medicine, Cleveland, Ohio
Presented By: Laura Bukavina

3. DOES ELECTROSTATIC COMPLEMENTARITY BETWEEN T-CELL RECEPTORS AND MACF1 MUTANTS CONFER A SURVIVAL BENEFIT IN PATIENTS WITH MUSCLE INVASIVE BLADDER CANCER?
Kyle Michelson¹, Boris Chobrutskiy², George Blanck², Ross Simon³, Jay Patel³, Trushar Patel³
¹ SUNY Downstate Medical Center, Department of Urology, ² University of South Florida, Department of Molecular Medicine, ³ University of South Florida, Department of Urology
Presented By: Kyle Michelson

4. DIGITAL PATHOLOGY OF CIRCULATING TUMOR CELLS WITH MORPHOLOGIC ANALYSIS IS FEASIBLE IN LOCALIZED AND METASTATIC BLADDER CANCER
Heather Chalfin¹, Kelly Harris², Stephanie Glavaris², Michael Gorin², Max Kates², Megan Fong³, Andres Matoso³, Michael Johnson², Kenneth Pienta², Jean Hoffman-Censits³, Trinity Bivalacqua¹, Noah Hahn², David McConkey², Megan Kearney³, Adam Jendrisak³, Vladimir Valera⁴, Andrea Apolo⁴
¹ National Institutes of Health, ² The James Buchanan Brady Urological Institute and Greenberg Bladder Cancer Institute, Johns Hopkins University School of Medicine, Baltimore, MD, USA., ³ Epic Sciences, Inc., San Diego, CA., ⁴ National Cancer Institute, Bethesda, MD.
Presented By: Heather Chalfin

5. VARIATION IN RADICAL CYSTECTOMY UTILIZATION IN PATIENTS WITH MUSCLE-INVASIVE BLADDER CANCER ACCORDING TO PATIENT, UROLOGIST AND HOSPITAL CHARACTERISTICS
Stephen B. Williams¹, Vishnukamal Golla², Karim Chemie³, Yong Shan⁴, Mohammed Ferdjallah⁵, Hemalkumar B. Mehta⁶, Yong-Fang Kuo⁷, Douglas S. Tyler⁸, Jacques Baillargeon⁹, Ashish M Kama³¹, Stephen J. Freedland¹, John L. Gore¹²
¹ The University of Texas Medical Branch, Division of Urology, ² Department of Urology, University of California, Los Angeles, CA, ³ The University of Texas Medical Branch, Division of Urology, Galveston, TX, ⁴ The University of Texas Medical Branch, Department of Surgery, Galveston, TX, ⁵ The University of Texas Medical Branch, Department of Surgery, Galveston, TX, ⁶ The University of Texas Medical Branch, Department of Preventive Medicine and Community Health, Galveston, TX, ⁷ Department of Urology, The University of Texas MD Anderson Cancer Center, Houston, TX, ⁸ Department of Urology, Cedars Sinai Medical Center, Los Angeles, CA, ⁹ Department of Urology, The University of Washington, Seattle, WA
Presented By: Preston S. Kerr

6. PROXIMITY TO OIL REFINERIES AND RISK OF BLADDER CANCER: A POPULATION-BASED ANALYSIS
Stephen B. Williams¹, Yong Chan², Mohammed Ferdjallah³, Jacques Baillargeon³, Yong-Fang Kuo³, Hemalkumar B. Mehta²
¹ The University of Texas Medical Branch, Division of Urology, ² The University of Texas Medical Branch, Division of Urology, Galveston, TX, ³ The University of Texas Medical Branch, Division of Urology, Galveston, TX
Presented By: Preston S. Kerr

7. COMPLETE TURBT PRIOR TO NEOADJUVANT CHEMOTHERAPY IMPROVES ONCOLOGICAL OUTCOMES IN PATIENTS WITH MUSCLE-INVASIVE BLADDER CANCER
Jamie Pak, Christopher Haas, Christopher Anderson, Helena Vila Reyes, G Joel DeCastro, Mitchell Benson, James McKiernan
Columbia University Irving Medical Center
Presented By: Jamie Pak
8. PLANNED SECONDARY ANALYSIS OF PURE-01: ROLE OF 18-FDG-PET/CT IN EVALUATING Lymph node INVOLVEMENT OF PATIENTS WITH MUSCLE-INVASIVE BLADDER CANCER RECEIVING NEOADJUVANT PEMBROLIZUMAB AND RADICAL CYSTECTOMY
Laura Marandino1, Antonella Capozza1, Daniele Raggi1, Elena Farè1, Patrizia Giannatempo1, Ettore Seregni1, Andrea Necchi1, Alessandra Alesi1, Alberto Briganti2, Filippo Pederzoli2, Andrea Gallina2, Marco Bandini2, Umberto Capitanio2, Marco Bianchi2, Giorgio Gangaglia2, Nicola Fossati2, Andrea Salonia2, Francesco Montorsi2
1 Fondazione IRCCS Istituto Nazionale dei Tumori, 2 Vita Salute San Raffaele University and Urological Research Institute (URI)
Presented By: Andrea Necchi

9. LONGITUDINAL HEALTH RELATED QUALITY OF LIFE AFTER RADICAL CYSTECTOMY UTILIZING THE FACT-BL-CYS INSTRUMENT: COMPARISON OF ILLIEAL CONDUIT, IANADIAN POUCH, AND ORTHOTOPIC NEOBLADDER.
Sean Kern, Ryan Speir, Hristos Kaimakliotis, Richard Foster, Timothy Masterson, Michael Koch, Clint Cary
Indiana University
Presented By: Sean Kern

10. INVESTIGATING THE SYNTHETIC LETHALITY OF EZH2 INHIBITION IN ARID1A MUTANT BLADDER CANCER
James Ferguson1, Hasib Rehman1, Darshan Chandrashekar2, George Netto2, Soory Varambally2, Guru Sonpavde3
1 UAB Urology, 2 UAB Pathology, 3 Dana Farber Cancer Institute
Presented By: James Ferguson

11. REOPERATION WITHIN 30 DAYS OF RADICAL CYSTECTOMY: IDENTIFYING HIGH-RISK PATIENTS USING THE AMERICAN COLLEGE OF SURGEONS NATIONAL SURGICAL QUALITY IMPROVEMENT PROGRAM DATABASE
Rashid Sayyid1, Diana Magee2, Amanda Hird2, Benjamin Harper3, Eric Webb3, Katherine Fratino3, Martha Terris3, Rabii Madi4, Zachary Claassen3, Raj Satkunasivam4, Christopher Wallis4
1 Augusta University, 2 Division of Urology, Department of Surgery, University of Toronto, Toronto, ON, Canada, 3 Section of Urology, Department of Surgery, Medical College of Georgia-Augusta University, Augusta, GA, 4 Department of Urology and Center for Outcomes Research, Houston Methodist Hospital, Houston, TX, 5 Department of Urology, Vanderbilt University, Nashville, TN
Presented By: Rashid Sayyid

12. RACE AND GUIDELINE-BASED TREATMENT: IMPLICATIONS FOR LONG-TERM SURVIVAL
Samuel Washington1, Maxwell Meng1, Anne Suskind1, Simon Porten1, Steven Gregorich2, Sikai Song2
1 Department of Urology, University of California San Francisco, 2 School of Medicine, University of California San Francisco
Presented By: Samuel Washington

13. RACE AND GUIDELINE-BASED TREATMENT: AN INTERSECTIONAL APPROACH TO INFORM INTERVENTIONS IN BLADDER CANCER
Samuel Washington1, Maxwell Meng1, Anne Suskind1, Sima Porten1, Steven Gregorich2, Sikai Song2
1 Department of Urology, University of California San Francisco, 2 School of Medicine, University of California San Francisco
Presented By: Samuel Washington

14. UNDERSTANDING THE BARRIERS TO NEOADJUVANT CHEMOTHERAPY AMONG MUSCLE-INVASIVE BLADDER CANCER PATIENTS: A QUALITY IMPROVEMENT INITIATIVE
Juan J Andino1, Christine Shafer1, Marissa Moore1, Udit Singhal1, Alon Weizer1, Sam Kaffenberger1, Lindsey Herrel1, Jeffrey Montgomery1, Daniel Wray2, Zachary Reichert3
1 Michigan Medicine Department of Urology, 2 Twine Clinical Consulting, LLC, 3 Michigan Medicine Department of Internal Medicine, Division of Hematology and Oncology
Presented By: Juan J Andino

15. THE ASSOCIATION OF TRAINEE INVOLVEMENT IN RADICAL CYSTECTOMY WITH PERIOPERATIVE AND ONCOLOGIC OUTCOMES
Matvey Tsivian, Vignesh Packiam, Stephen Boorjian, Prabin Thapa, Igor Frank, Matthew Tollefson
Mayo Clinic
Presented By: Svetlana Avulova

16. REGULATORY T CELLS PLAY A ROLE IN BLADDER CANCER DEVELOPMENT
Karen Wheeler, Niannian Ji, Neelam Mukherjee, Robert Svatek
University of Texas Health Center, San Antonio
Presented By: Karen Wheeler

17. RE-EXAMINATION OF THE DEPTH OF INVASION IN HIGH-GRADE T1 BLADDER CANCER AND CLINICAL OUTCOMES: AN INDEPENDENT PREDICTOR OF SURVIVAL
Mahmut Akgul1, Nafiseh Janaki2, Amr Mahran3, Kirtishri Mishra3, Danly Omil Lima3, Lee Ponsky3, Matt Bream4, Anjali Shekar5, Gregory MacLennan6, Laura Bukavina7
1 Indiana University School of Medicine, 2 Brigham and Women's Hospital, 3 University Hospitals Cleveland Medical Center, 4 Urological Associates, PC, 5 Case Western Reserve School of Medicine, 6 Case Western Reserve School of Medicine/University Hospitals Cleveland Medical Center, 7 Case Western Reserve/University Hospitals Cleveland Medical Center
Presented By: Laura Bukavina
18. USE OF A NOVEL MRNA BIOMARKER PANEL FOR BLADDER CANCER RISK STRATIFICATION
Eugene Shkolyar1, Qian Zhao1, Nicolas Teslovich1, Bharati Trivedi1, Ying Lu1, Kathleen Mach1, Joseph Liao1, Mandy Sin2
1 Stanford University, 2 Cepheid Inc.

Presented By: Eugene Shkolyar

19. PHASE 3 RESULTS OF VICINIUM IN BCG-UNRESPONSIVE NON-MUSCLE INVASIVE BLADDER CANCER (NIMBC)
Neal Shore1, Girish S. Kulkarni2, Michael Franks3, Rian Dickstein4, Fredrick N. Wol5, Barrett Cowan6, Curtis J. Dunseh7, Laurence Belkoff8, Rachelle L. Dillon9, Jeannick Cizeau9, Wassim Kassouf10
1 Carolina Urologic Research Center, 2 Division of Urology, Departments of Surgery and Surgical Oncology, Princess Margaret Cancer Centre, University Health Network, University of Toronto, Toronto, ON, 3 Virginia Urology Center PC, Richmond, VA, 4 Chief of Urology - University of Maryland Baltimore Washington Medical Center Medical Director of GU Oncology - Tame Cancer Center Clinical Assistant Professor - Department of Surgery at University of Maryland School of Medicine Director, Bladder Cancer Program - Chesapeake Urology, Hanover, MD, 5 Skyline urology, Director of Clinical Trials, Torrance, CA, 6 Urology associates of Denver, Englewood, CO, 7 Director of Research, Urological Associates of Southern Arizona, Tucson, AZ, 8 MidLantic Urology, Bala Cynwyd, Pa, 9 Senes Bio, Winnipeg, MB, 10 Stephen Jarislowsky Chair in Urology Professor and Associate Chair Dept. of Surgery, McGill University Head, Urologic Oncology McGill University Health Center, Montreal QC

Presented By: Neal Shore

20. SURVEILLANCE CYSTOSCOPY AMONG NON-MUSCLE INVASIVE BLADDER CANCER PATIENTS: FREQUENCY AND RISK FACTORS FOR LOW SURVEILLANCE LEVELS
Philip Kim1, Ronald Loo1, Stephen Williams1, Margo Sidell2, Tiffany Luong2, David Yi1, Aniket Kawatkar3, Kim Danforth2, Ayae Yamamoto3
1 Southern California Permanente Medical Group, 2 Kaiser Permanente Southern California, 3 Kaiser Foundation Hospital and Health Plan

Presented By: Philip Kim

21. PHASE 1 OUTCOMES OF A NOVEL THIRD GENERATION LIPOSOMAL PACLITAXEL FORMULATION (TSD-001) IN PATIENTS WITH LOW-INTERMEDIATE RISK NON-MUSCLE INVASIVE BLADDER CANCER (NMIBC)
Daniel Huynh1, Rian Dickstein1, Karl Bean1
1 Danny Huynh Urology, 2 Chesapeake Urology, 3 Lipac Oncology

Presented By: Michael Oefelein

22. SOS – A MULTI-INSTITUTIONAL EVALUATION OF RESCUES THERAPY WITH INTRAVESICAL GEMCITABINE AND DOCETAXEL FOR NON-MUSCLE INVASIVE BLADDER CANCER AFTER BCG FAILURE
Nathan Brooks1, Ryan Steinberg2, Lewis Thomas3, Sarah Mott4, Andrew Vitale5, Kenneth Nepple6, Michael O'Donnell7, Trafford Crump8, Eric Hyndman9, Marcus Daniels10, Max Kates11, Trinity Bivalacqua11, Jonathan Wang12, William DeWolf13, Supriya Nagaraju14, Ashish Kamat14, Donald Lamm15
1 The University of Texas MD Anderson Cancer Center, 2 University of Texas Southwestern Department of Urology, 3 Cleveland Clinic Foundation Department of Urology, 4 Holden Comprehensive Cancer Center University of Iowa, 5 University of Iowa Department of Urology, 6 University of Calgary Department of Urology, 7 Johns Hopkins University Department of Urology, 8 Beth Israel Deaconess Medical Center, 9 University of Texas MD Anderson Cancer Center, 10 BCG Oncology, Phoenix, AZ

Presented By: Nathan Brooks

23. SURVIVAL DIFFERENCES AMONG PATIENTS WITH NON-MUSCLE INVASIVE BLADDER CANCER
Adam Weiner1, Joshua Meeks1, Xiaosong Meng2, Solomon Woldu1, Yair Lotan2
1 Northwestern University, 2 UT Southwestern Medical Center

Presented By: Adam Weiner

24. SHORT-TERM OUTCOMES OF NOVEL COMBINATION REGIMEN OF INTRAVESICAL DOCETAXEL, GEMCITABINE, AND CISPLATIN IN PATIENTS WITH BCG-REFRACTORY NON-MUSCLE INVASIVE UROTHELIAL CARCINOMA OF THE BLADDER
Jamie Pak, Helena Vila Reyes, G Joel DeCastro, Christopher Anderson, Cory Abate-Shen, James McKiernan
Columbia University Irving Medical Center

Presented By: Jamie Pak

25. IMPACT OF STAGE PROGRESSION AS TRIGGER FOR CYSTECTOMY IN PATIENTS ON BCG THERAPY
Justin Matulay1, Nathan Brooks1, Courtney Chang1, Amy Lim1, Vikram Narayan1, Supriya Nagaraju1, Neema Navai1, Colin Dinney1, Ashish Kamat1, Roger Li1
1 University of Texas MD Anderson Cancer Center, 2 Moffitt Cancer Center

Presented By: Justin Matulay
26. GUIDELINES BASED MANAGEMENT OF NON-MUSCLE INVASIVE BLADDER CANCER AMONG SUO (SOCIETY OF UROLOGIC ONCOLOGY) MEMBERS
Justin Matulay1, Jonathan Duplisea1, Ashish Kamat1, William Tabayoyong2, Edward Messing3, Courtney Chang4, Siamak Daneshmand5, John Gore6, Jeffrey Holzbeierlein7, Lawrence Karsh8, Simon Kim9, Badrinath Konety10, Roger Li11, James McKiernan12, Gary Steinberg13, Stephen Williams13
1 University of Texas MD Anderson Cancer Center, 2 University of Rochester Medical Center, 3 University of Texas Health Sciences Center at Houston, 4 University of Southern California, 5 University of Washington, 6 University of Kansas Medical Center, 7 The Urology Center of Colorado, 8 Case Western Reserve University, 9 University of Minnesota, 10 Moffitt Cancer Center, 11 Columbia University Medical Center, 12 New York University Langone, 13 University of Texas Medical Branch
Presented By: Justin Matulay

27. FGFR3-TACC3 GENE FUSION AS THE SOLE DRIVER OF UROTHELIAL TRANSFORMATION AND TUMORIGENESIS
Aleksandra Walasek, Eugene Pietzak, Min Yuen Teo, Samuel Funt, Nikolaus Schultz, Wenhuo Hu, Dean Bajorin, Jonathan Rosenberg, Gopakumar Iyer, Bernard Bochner, David Solit, Hikmat Al-Ahmadie
Memorial Sloan Kettering Cancer Center
Presented By: Aleksandra Walasek

28. EFFECT OF PRE-EXISTING CONDITIONS ON BLADDER CANCER DIAGNOSIS: A COHORT STUDY USING ELECTRONIC PRIMARY CARE RECORDS
Madeline Carney1, Myra Quiroga2, Elizabeth Shepherd2, Luke Mounce2, Willie Hamilton2
1 USF Morsani College of Medicine, 2 University of Exeter Medical School
Presented By: Madeline Carney

29. 2019 BLADDER CANCER PATIENT SURVEY NETWORK RESULTS AND FUTURE DIRECTIONS
Judy Hamad1, John Gore2, Stephanie Chisolm3, Robert Lipman3, Angela Smith4
1 University of North Carolina at Chapel Hill School of Medicine, 2 Department of Urology, University of Washington Medical Center; Seattle, WA, 3 Bladder Cancer Advocacy Network; Bethesda, MD, 4 Department of Urology, University of North Carolina at Chapel Hill; Chapel Hill, NC
Presented By: Judy Hamad

30. TOTAL MEDICAL CARE COSTS IN THE YEAR FOLLOWING CYSTECTOMY AMONG BLADDER CANCER PATIENTS WITH A URINARY DIVERSION
Matthew Banegas1, Maureen O’Keeffe Rosetti1, Michael Leo1, Joanna Bulkley1, Sheila Weinmann1, Carmit McMullen1, Scott Gilbert2, Kim Danforth3, David Yi1, Marilyn Kwan1, Valerie Lee6
1 Kaiser Permanente Center for Health Research, 2 H. Lee Moffitt Cancer Center & Research Institute, 3 Kaiser Permanente Department of Research and Evaluation, 4 Kaiser Permanente Division of Research, 5 Kaiser Permanente Division of Research
Presented By: Matthew Banegas

31. SIMILAR SURVIVAL OUTCOMES AMONG CHEMORADIATION AND NEOADJUVANT CHEMOTHERAPY WITH RADICAL CYSTECTOMY FOR SMALL CELL BLADDER CANCER
Alejandro Abello1, Joseph Renzulli1, Michael Leapman1, Patrick Kenney1, Henry Park2
1 Yale School of Medicine, 2 Yale school of Medicine
Presented By: Alejandro Abello

32. GENDER DIFFERENCES IN PERIOPERATIVE CYSTECTOMY OUTCOMES IN NEW YORK STATE
Srinath Kotamarti1, Ervin Teper1, David Silver1, Ariel Schulman1, Joshua Bitran2, Alex Sherman3, Antonio Montgomery4, Frederick Greenstein4, Unni Mooppan4
1 Maimonides Medical Center, 2 Saint George’s University, 3 University of New England, 4 Brookdale Hospital Medical Center
Presented By: Srinath Kotamarti

33. PREDICTORS OF ADVERSE EVENTS FOLLOWING RADICAL CYSTECTOMY BY HIGH VOLUME SURGEONS IN NEW YORK STATE
Srinath Kotamarti1, Ervin Teper1, David Silver1, Ariel Schulman1, Joshua Bitran2, Alex Sherman3, Antonio Montgomery4, Frederick Greenstein4, Unni Mooppan4
1 Maimonides Medical Center, 2 St George’s University, 3 University of New England, 4 Brookdale Hospital Medical Center
Presented By: Srinath Kotamarti

34. BLADDER CANCER OUTCOMES FOLLOWING MEDICAID EXPANSION: NO INCREASE IN DIAGNOSIS AND TREATMENT?
Oliver Ko, Adam Weiner, Amanda Vo, Anuj Desai, Shilajit Kundu
Northwestern University Feinberg School of Medicine
Presented By: Oliver Ko
35. IMPLICATIONS OF DISCORDANT DIAGNOSTIC TO FINAL SURGICAL PATHOLOGY IN HIGH-GR ADE UPPER TRACT UROTHELIAL CARCINOMA
Ross Liao, Joseph Cheaib, Mohit Gupta, Max Kates, Michael Johnson, Noah Hahn, Jean Hoffman-Censits, Trinity Bivalacqua, Phillip Pierorazio
Johns Hopkins School of Medicine
Presented By: Ross Liao

36. PREDICTIVE MODEL FOR SYSTEMIC RECURRENCE FOLLOWING CISPLATIN-BASED NEOADJUVANT CHEMOTHERAPY AND RADICAL NEPHROURETERECTOMY FOR UPPER TRACT UROTHELIAL CARCINOMA
Rashed Ghandour1, Yuval Freidfeld2, Nirmish Singla1, Xiaosong Meng3, Aditya Bagrodia3, Solomon Woldu4, Vitaly Margulis3, Firas Petros2, Surena Matin2, Jay Raman3
1 UT Southwestern Medical Center, 2 MD Anderson Cancer Center, 3 Penn State Health Milton S. Hershey Medical Center
Presented By: Rashed Ghandour

37. DECISION FATIGUE CONTRIBUTES TO LOW-VALUE PROSTATE CANCER SCREENING PRACTICES BY OUTPATIENT PROVIDERS
Trevor C. Hunt1, Brock B. O'Neill1, Jacob P. Ambrose2, Benjamin Haaland3, Heidi A. Hanson4, Norman J. Waitzman5
1 Division of Urology, Department of Surgery, Huntsman Cancer Institute, University of Utah, Salt Lake City, UT, USA, 2 Division of Urology, and Population Sciences, Department of Surgery, Huntsman Cancer Institute, University of Utah, Salt Lake City, UT, USA, 3 Cancer Biostatistics Shared Resource, Huntsman Cancer Institute; and Division of Biostatistics, Department of Population Health Sciences, University of Utah, Salt Lake City, UT, USA, 4 Population Sciences, Department of Surgery, Huntsman Cancer Institute, University of Utah, Salt Lake City, UT, USA, 5 Department of Economics, University of Utah, Salt Lake City, UT, USA
Presented By: Trevor C. Hunt

38. CHANGES IN PROSTATE-SPECIFIC ANTIGEN AT TIME OF PROSTATE CANCER DIAGNOSIS FOLLOWING MEDICAID EXPANSION IN YOUNG MEN
Adam Weiner, Amanda Vo, Anuj Desai, Edward Schaeffer
Northwestern University
Presented By: Adam Weiner

39. CONTEMPORARY RACIAL DISPARITIES IN PSA SCREENING AND PROSTATE CANCER DIAGNOSIS IN A LARGE, INTEGRATED HEALTHCARE SYSTEM
Oluwaseun Adeyemi, William Anderson, Timothy Hetherington, Yhenneko Taylor, James Kearns
Atrium Health
Presented By: James Kearns

40. OFFICE CYSTOSCOPY: IS IT REALLY THE GOLD STANDARD?
Ralph Grauer1, Noah Shenkman2, Beth Horton3, Randy Jones1, Jennifer Lobo1, Tracey Krupski1, Jessica Rueb2
1 University of Virginia, 2 Cleveland Clinic
Presented By: Ralph Grauer

41. DIAGNOSTIC VALUE OF SERIAL PROSTATE MRI IN ACTIVE SURVEILLANCE
Carissa Chu1, Samuel Washington2, Janet Cowan2, Claire de la Calle2, Peter Carroll2
1 Carissa Chu, 2 University of California, San Francisco
Presented By: Carissa Chu

42. THE USE OF POSTOPERATIVE VIDEO VISITS TO REDUCE READMISSIONS IN PATIENTS UNDERGOING UROLOGIC SURGERY: A PILOT INITIATIVE
Lina Posada Calderon, Bashir Al Hussein Al Awamih, Jonathan Fainberg, Aleem I. Khan, Osamede Enobakhare, Douglas S. Scherr
Weill Cornell Medical College
Presented By: Lina Posada Calderon

43. IMPROVED SURVIVAL AFTER CYTOREDUCTIVE NEPHRECTOMY FOR METASTATIC RENAL CELL CARCINOMA IN THE CONTEMPORARY IMMUNOTHERAPY ERA: A NATIONAL POPULATION-BASED ANALYSIS
Nirmish Singla, Ryan Hutchinson, Rashed Ghandour, Yuval Freidfeld, Arthur Sagalowsky, Yair Lotan, Aditya Bagrodia, Vitaly Margulis, Hans Hammers, Solomon Woldu
University of Texas Southwestern Medical Center
Presented By: Nirmish Singla

44. ZHX2 DRIVES CELL GROWTH AND MIGRATION VIA ACTIVATION MEK/ERK1/2 SIGNAL AND INDUCE SUNITINIB RESISTANCE BY REGULATING THE AUTOPHAGY IN CLEAR CELL RENAL CELL CARCINOMA
Zongming Lin1, Jin Zhang2
1 zhongshan hospital, fudan university, 2 renji hospital, shanghai jiaotong university
Presented By: Liangsong Zhu
45. POOR RESPONSE TO IMMUNOTHERAPY IS ASSOCIATED WITH HIGH EXPRESSION OF NOVEL EPIDERMAL GROWTH FACTOR RECEPTOR SPLICE VARIANT IN PATIENTS WITH CLEAR CELL RENAL CELL CARCINOMA
Ali Hajiran1, Youngchul Kim2, Thushara Madanayake1, Timothy Robinson3, Philippe Spiess1, Manish Kohli4, Theresa Boyle5, James Mul6, Jamie Teer7, Brandon Manley3, Saif Zaman8, Shayan Falasiri2

1 Moffitt Cancer Center, 2 University of South Florida

Presented By: Ali Hajiran

46. IMPACT OF HOSPITAL VOLUME ON COMPLICATIONS FROM IMMUNOTHERAPY FOR RENAL CELL CARCINOMA
Eugene Cone1, Ye Yang2, Steven Chang3

1 Division of Urological Surgery and Center for Surgery and Public Health, Brigham and Women’s Hospital, Harvard Medical School; Department of Urology, Massachusetts General Hospital, Harvard Medical School; 2 Division of Urological Surgery, Brigham and Women’s Hospital, Harvard Medical School; 3 Division of Urological Surgery, Brigham and Women’s Hospital, Harvard Medical School; Division of Urologic Oncology, Dana Farber Cancer Center, Harvard Medical School

Presented By: Eugene Cone

47. CHARACTERIZATION OF THE METABOLOMIC PROFILE OF RENAL CELL CARCINOMA BY HIGH RESOLUTION MAGIC ANGLE SPINNING (HRMAS) MAGNETIC RESONANCE SPECTROSCOPY (MRS)
Melissa Huynh, Andrew Gusev, Francesco Palmas, Lindsey Vandergrift, Chiu-Lee Wu, Leo Cheng, Adam Feldman

Massachusetts General Hospital

Presented By: Melissa Huynh

48. EFFECTS OF CELL POLARITY ALTERATIONS ON TUMOR AGGRESSIVENESS IN RENAL CELL CARCINOMA
Xiaosong Meng1, Wan-Hsin Lin2, Panagiotis Anastasiadis2, Fang-Ming Deng3, Vitaly Margulis4

1 UT Southwestern Medical Center, 2 Department of Cell Biology, Mayo Cancer Center, Jacksonville, FL, USA, 3 Department of Pathology, NYU Langone Health, New York, NY, USA, 4 Department of Urology, UT Southwestern Medical Center, Dallas, TX, USA

Presented By: Xiaosong Meng

49. AUTOPHAGY BLOCKADE MEDIATES RESISTANCE TO MTOR INHIBITION OF RENAL CELL CARCINOMA VIA VHL-DEPENDENT NDRG1 EXPRESSION
Hua Chen, Kyle Potts, Allan Murray, Ronald Moore

University of Alberta

Presented By: Ronald Moore

50. ESTABLISHING A HEREDITARY RENAL SYNDROME CLINIC: ONE INSTITUTION’S EXPERIENCE IN PATIENT IDENTIFICATION, RISK ASSESSMENT, GENETIC TESTING AND SURVEILLANCE OUTCOMES
Sean Kern, Ryan Speir, Courtney Schroeder, Adam Calaway, Michael Koch, Gail Vance, Ronald Boris

Indiana University

Presented By: Sean Kern

51. SURVIVAL OUTCOMES AND NATIONAL PRACTICE TRENDS FOR ADJUVANT TARGETED THERAPY IN HIGH RISK LOCOREGIONAL RENAL CELL CARCINOMA
Nicholas Chakiryan, Ann Martinez-Acevedo, Mark Garzotto, Yiyi Chen, Jen-Jane Liu, Sudhir Isharwal, Christopher Amling, Ryan Kopp

Oregon Health & Science University

Presented By: Nicholas Chakiryan

52. KIDNEY CANCER INCIDENCE AND MORTALITY AMONG AMERICAN INDIANS/ALASKA NATIVES IN OKLAHOMA AND THE UNITED STATES
Michael Sufli1a, Amanda Janitz2, Janis Campbell3, Kelly Stratton4, Michael Cookson5, Daniel Parker6

1 The University of Oklahoma College of Medicine, 2 The University of Oklahoma College of Public Health, 3 The University of Oklahoma Department of Urology and the Stephenson Oklahoma Cancer Center

Presented By: Michael Sufli

53. CLINICAL FACTORS THAT PREDICT OUTCOMES FOR PATIENTS UNDERGOING CYTOREDUCTIVE NEPHRECTOMY FOR METASTATIC RENAL CELL CARCINOMA IN THE MODERN ERA OF SYSTEMIC THERAPEUTICS
Andrew McIntosh1, Eric Ubbret1, Cindy Gu1, Suresh Matin1, Jose Karam1, Christopher Wood2, Levi Holland3, Stephen Culp4

1 University of Texas MD Anderson Cancer Center, 2 University of Texas Health Science Center at Houston McGovern Medical School, 3 University of Virginia Health System

Presented By: Andrew McIntosh

54. POSITIVE VASCULAR MARGIN IS NOT prognostic IN NON-METASTATIC RENAL CELL CARCINOMA PATIENTS WITH TUMOR THROMBUS
Brittany Adamic1, Joshua Aizen1, Tatjana Antic1, Scott Eggenger1, Ryan Werntz2

1 University of Chicago, 2 University of South Carolina-Greenville

Presented By: Craig Labbate
55. NEPHROLOGY REFERRAL PATTERNS IN RENAL CANCER SURGICAL PATIENTS WITH PRE-EXISTING OR POST-OPERATIVE CHRONIC KIDNEY DISEASE
Julia Wainger¹, Joseph Cheaib¹, Hiten Patel¹, Mitchell Huang¹, Meredith Metcalf¹, Phillip Pierorazio¹, Joseph Canner²
¹ Brady Urological Institute, Johns Hopkins Hospital, Baltimore, MD, USA, ² Johns Hopkins Surgery Center for Outcomes Research, Johns Hopkins University School of Medicine, Baltimore, MD, USA
Presented By: Julia Wainger

56. EXAMINING THE ROLE OF CONTRAST-ENHANCED RENAL ULTRASOUND IN CHARACTERIZING INDETERMINATE RENAL LESIONS IN THE SETTING OF CHRONIC KIDNEY DISEASE
Ava Saidian¹, Taylor Tucker¹, Soroush Rais-Bahrami¹, Kristin Porter¹, Stephen Leahy²
¹ University of Alabama-Birmingham, ² Univeresity of Alabama-Birmingham
Presented By: Ava Saidian

57. CONTEMPORARY TRENDS IN PERCUTANEOUS RENAL MASS BIOPSY IN THE UNITED STATES
Manuel Ozambela, MD, Ye Wang, PhD, Steven L. Chang, MD, MS
Brigham and Women's Hospital / Harvard Medical School
Presented By: Manuel Ozambela, MD

58. SURVIVAL FOLLOWING CYTOREDUCTIVE NEPHRECTOMY: A COMPARISON OF EXISTING PREDICTIVE MODELS
Daniel Shapiro, Mary Beth Westerman, Jose Karam, Christopher Wood
The University of Texas M.D. Anderson Cancer Center
Presented By: Daniel Shapiro

59. OUTCOMES OF RENAL MASS BIOPSY IN ANATOMICALLY COMPLEX LESIONS
SELMA MASIC¹, Abhishek Srivastava², Marc Smaldone², Barton Milestone², Rosaleen Parsons², Rosalia Viterbo², Richard Greenberg², David Chen², Alexander Kutikov², Robert Uzzo²
¹ FOX CHASE CANCER CENTER, ² FCCC
Presented By: SELMA MASIC

60. COMPARING THE PROGNOSTIC VALUE OF PREOPERATIVE SERUM LABS AS BIOMARKERS FOR HIGH RISK RENAL CELL CANCER RECURRENT USING THREE INDEPENDENT COHORTS
Emily L. Davidson¹, Daniel D. Shapiro¹, Glenn O. Allen¹, David F. Jarrard¹, Kyle A. Richards¹, Tracy M. Downs¹, E Jason Abel¹, Jay D. Raman², Brian Sohi², Viral Master², Dattatraya Patil²
¹ University of Wisconsin School of Medicine and Public Health, ² Penn State Milton S. Hershey Medical Center, ³ Emory University School of Medicine
Presented By: Emily L. Davidson

61. AFRICAN AMERICANS AND RENAL CELL CARCINOMA: IS THE PATHOPHYSIOLOGIC PROCESS DIFFERENT?
Lina Posada Calderon, Bashir Al Hussein Al Awamleh, Jonathan Fainberg, Aleem I. Khan, Johannes C van der Mijn, Benjamin L. Taylor, Mark Alshak, Rahmi Elahjji, Hudson Pierce, Douglas S. Scherr
Weill Cornell Medical College
Presented By: Lina Posada Calderon

62. CLINICAL OUTCOMES OF LOW-STAGE SARCOMATOID RENAL CELL CARCINOMA
Alejandro Abello, Patrick Kenney, Michael Leapman
Yale School of Medicine
Presented By: Alejandro Abello

63. UROLOGIST-LEVEL VARIATION IN THE MANAGEMENT OF SMALL RENAL MASSES: A SEER-MEDICARE ANALYSIS
Joseph Cheaib¹, Hiten Patel¹, Meredith Metcalf¹, Michael Johnson¹, Mohamad Allaf¹, Phillip Pierorazio¹, Joseph Canner²
¹ Johns Hopkins University School of Medicine, ² Johns Hopkins Bloomberg School of Public Health
Presented By: Joseph Cheaib

64. PARTIAL VERSUS RADICAL NEPHRECTOMY FOR CLINICAL T2 RENAL MASSES
Matvey Tsivian, Vignesh Packiam, Svetlana Avulova, Christine Lohse, Stephen Boorjian, Bradley Leibovich, Aaron Potretzke
Mayo Clinic
Presented By: Matvey Tsivian

65. TREND AND CHARACTERISTICS OF SMALL RENAL MASSES
Francesco Claps¹, Nicola Pavan¹, Carmelo Morreale¹, Michele Rizzo¹, Matteo Boltri¹, Francesca Migliozzi¹, Giovanni Liguori¹, Carlo Trombetta¹, Venus Shafiei², Rossana Bussani²
¹ Urological Clinic, Department of Medicine, Surgery and Health Sciences - University of Trieste, ² Pathology Unit, Department of Medicine, Surgery and Health Sciences - University of Trieste
Presented By: Francesco Claps
66. INTRATUMORAL HETEROGENEITY OF PDL-1 EXPRESSION IN T3 RENAL CELL CARCINOMA
Allison May, Elizabeth Davaro, Katherine Schwetye, Coleman McFerrin, Facundo Davaro, Sameer Siddiqui, Zachary Hamilton
Saint Louis University
Presented By: Allison May

67. DETERMINING THE REPRESENTATION OF RACIAL MINORITIES WITH GENITOURINARY CANCERS IN THE NATIONAL CANCER DATABASE
Kyle Michelson¹, Danielle Gordon¹, Tashzna Jones¹, Thomas Monaghan¹, Raymond Khargi¹, Matthew Smith¹, Fenizia Maffucci¹, Hyezo Kwun¹, Nicholas Suss¹, Andrew Winer¹
¹ SUNY Downstate Medical Center, Department of Urology, ² Kings County Hospital, Department of Urology
Presented By: Kyle Michelson

68. IMPACT OF VARIANT HISTOLOGY ON SURVIVAL AND RESPONSE TO CHEMOTHERAPY IN PATIENTS WITH UPPER TRACT UROTHELIAL CELL CARCINOMA
Wilson Sui, Daniel A. Barocas, Sam S. Chang, David F. Penson, Matthew Resnick, Aaron A. Laviana
Vanderbilt University Medical Center Department of Urology
Presented By: Wilson Sui

69. SETTING THE STANDARDS: EXAMINING RESEARCH PRODUCTIVITY AMONGST ACADEMIC UROLOGISTS IN THE UNITED STATES AND CANADA IN 2019
Timothy Han¹, Lydia Glick¹, Joon Yau Leong¹, Seth Teplitzky¹, James Ryan Mark¹, Mark J. Mann¹, Edouard J. Trabulsi¹, Costas D. Lallas¹, Leonard G. Gomella¹, Thenappan Chandrasekar¹, Rodrigo Noorani², Zachary Klaassen⁴, Christopher JD Wallis³
¹ Department of Urology, Sidney Kimmel Cancer Center, Thomas Jefferson University, Philadelphia, PA, ² Division of Urology, Department of Surgery, University of Toronto, Toronto, Ontario, Canada, ³ Department of Urology, State University of New York Upstate Medical University, Syracuse, NY, USA, ⁴ Division of Urology, Department of Surgery, Augusta University – Medical College of Georgia, Augusta, GA; Georgia Cancer Center, Augusta, GA, ⁵ Division of Urology, Department of Surgery, University of Toronto, Toronto, ON, Canada; Department of Urology, Vanderbilt University Medical Center, Nashville, TN, USA
Presented By: Timothy Han

70. A NATION-WIDE ANALYSIS OF PALLIATIVE CARE USE IN PATIENTS WITH METASTATIC PENILE CANCER
Facundo Davaro¹, Allison May², Johar Syed², Sameer Siddiqui², Zachary Hamilton²
¹ Saint Louis University, ² Saint Louis University Department of Surgery, Division of Urology
Presented By: Facundo Davaro

71. NEOADJUVANT (NACT) VERSUS ADJUVANT CHEMOTHERAPY (ACT) FOR THE TREATMENT OF LOCALLY ADVANCED PENILE CANCER (PECA): A PROPORTIONAL META-ANALYSIS OF CASE SERIES STUDIES
Dr., Philip Haddad, Dr., Dalia Hammoud, Dr., Kevin Gallagher
LSUHSC-S, Overton Brooks VAMC
Presented By: Dr., Philip Haddad

72. MANAGEMENT OF LOCALIZED PENILE CANCER WITH AN ORGAN SPARING APPROACH USING SPLIT THICKNESS SKIN GRAFTING RESULTS IN EXCELLENT ONCOLOGIC AND FUNCTIONAL OUTCOMES
Ben Beech, Jan Rudzinski, Keith Rourke
University of Alberta
Presented By: Ben Beech

73. SYSTEMIC TREATMENT FOR METASTATIC CASTRATION RESISTANT PROSTATE CANCER (M-CRPC): DOES SEQUENCE MATTER?
Jack Andrews¹, Mohamed Ahmed¹, Robert Kames¹, Eugene Kwon¹, Alan Bryce²
¹ Mayo Clinic, ² Mayo Clinic Arizona
Presented By: Jack Andrews

74. SURVIVAL OUTCOMES FOR METASTATIC CASTRATION-RESISTANT PROSTATE CANCER WITH PSA LESS THAN 5.0 NG/ML TREATED WITH SIPULEUCEL-T, OVERALL AND BY RACE: DATA FROM THE PROCEED REGISTRY
Richard Tutrone¹, Christopher Pieczonka², Luke Nordquist³, Raoul Concepcion³, Scott Flanders³, Andrew Armstrong⁴
¹ Chesapeake Urology Research Associates, ² Associated Medical Professionals, Syracuse, NY, USA, ³ Department of Medical Oncology, GU Research Network, Omaha, NE, USA, ⁴ Director of The Comprehensive Prostate Center in Nashville, TN, USA; Clinical Associate Professor of Urology at Vanderbilt University School of Medicine, Nashville, TN, USA, ⁵ Department of Medical Affairs, Dendreon Pharmaceuticals LLC, Seattle, WA, ⁶ Divisions of Medical Oncology and Urology, Duke University Medical Center, Duke Cancer Institute, Duke University, Durham, NC, USA
Presented By: Richard Tutrone

75. SALVAGE RADICAL PROSTATECTOMY (SRP) AFTER ROBOT-ASSISTED LAPAROSCOPIC PROSTATECTOMY (RALP): CASE SERIES
Mohamed Ahmed, Jack Andrews, Giovanni Motterle, Marco Moschini, Eugene Kwon, Jeffery Karnes
Mayo Clinic
Presented By: Jack Andrews
<table>
<thead>
<tr>
<th>Poster Session I - Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>76. SYSTEMATIC REVIEW AND META-ANALYSIS OF TRIALS EVALUATING THE ROLE OF ADJUVANT RADIATION AFTER RADICAL PROSTATECTOMY FOR PROSTATE CANCER</strong></td>
</tr>
<tr>
<td>Bimal Bhindi, Zachary Klaassen, Soum Lokeshwar, Laurence Klotz</td>
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<tr>
<td>1 University of Calgary, 2 Medical College of Georgia At Augusta University, 3 Sunnybrook Health Sciences Centre</td>
</tr>
<tr>
<td><strong>Presented By:</strong> Christopher Wallis</td>
</tr>
<tr>
<td><strong>77. TIMING OF RADIATION AFTER RADICAL PROSTATECTOMY FOR MEN WITH PROSTATE CANCER MAY NOT AFFECT CLINICAL OUTCOMES</strong></td>
</tr>
<tr>
<td>Samuel Washington, Janet Cowan, Peter Carroll, Sikai Song, Felix Feng</td>
</tr>
<tr>
<td>1 Department of Urology, University of California San Francisco, 2 School of Medicine, University of California San Francisco, 3 Department of Radiation Oncology, University of California San Francisco</td>
</tr>
<tr>
<td><strong>Presented By:</strong> Samuel Washington</td>
</tr>
<tr>
<td><strong>78. C-11 CHOLINE PET FOLLOWING TAXOTERE IS A HELPFUL TOO TO PREDICT PROGRESSION-FREE SURVIVAL IN METASTATIC CASTRATE RESISTANT PROSTATE CANCER (MCRPC)</strong></td>
</tr>
<tr>
<td>Jack Andrews, Mohamed Ahmed, Masaya Jimbo, Michael Bold, Ayca dundar, Ayse Kendi, Eugene Kwon</td>
</tr>
<tr>
<td>Mayo Clinic</td>
</tr>
<tr>
<td><strong>Presented By:</strong> Jack Andrews</td>
</tr>
<tr>
<td><strong>79. EFFECT OF ENZALUTAMIDE ON PATIENT-REPORTED OUTCOMES, INCLUDING FATIGUE, IN METASTATIC HORMONE-SENSITIVE PROSTATE CANCER: ANALYSES FROM THE ARCHES STUDY</strong></td>
</tr>
<tr>
<td>Arnulf Stenzl, Curtis Dunshew, Ugo De Giorgi, Boris Alekseev, Taro Iguchi, Russell Z. Szmulewitz, Thomas W. Flagg, Bertrand F. Tomba, Robert Morlock, Cristina Ivanescu, Krishnan Ramaswamy, Fred Saad, Andrew J. Armstrong</td>
</tr>
<tr>
<td>1 University Hospital, Eberhard Karls University, 2 Urological Associates of Southern Arizona, 3 Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori (IRST) IRCCS, 4 Hertzen Moscow Cancer Research Institute, 5 Osaka City University Graduate School of Medicine, 6 The University of Chicago, 7 University of Colorado, 8 Cliniques universitaires Saint-Luc, 9 Astellas Pharma Inc., 10 IQVIA, 11 Pfizer Inc., 12 Centre Hospitalier de l’Université de Montréal, Université de Montréal/CRCUM, 13 Duke Cancer Institute Center for Prostate and Urologic Cancers</td>
</tr>
<tr>
<td><strong>Presented By:</strong> Arnulf Stenzl</td>
</tr>
<tr>
<td><strong>80. PATTERNS OF METASTASES OF PROSTATIC DUCTAL ADENOCARCINOMA</strong></td>
</tr>
<tr>
<td>Weranja Ranasinghe, Nathan Brooks, Mohamed Elsheshtawi, John Davis, Tharak Bathala, Patricia Troncoso, Ana Aparicio, Shi-Ming Tu, Brian F. Chapin</td>
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<tr>
<td>1 University of Texas, MD Anderson Cancer Center, 2 University of Texas, MD Anderson Cancer Center, Houston, Texas</td>
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<tr>
<td><strong>Presented By:</strong> Weranja Ranasinghe</td>
</tr>
<tr>
<td><strong>81. COMPREHENSIVE STEREOTACTIC BODY RADIOTHERAPY FOR HORMONE SENSITIVE OLIGOMETASTATIC PROSTATE CANCER (CROP)</strong></td>
</tr>
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<td>1 Sunnybrook Odette Cancer Centre, 2 Princess Margaret Cancer Centre, 3 Princess Margaret Cancer Centre</td>
</tr>
<tr>
<td><strong>Presented By:</strong> Patrick Cheung</td>
</tr>
<tr>
<td><strong>82. CLINICAL TRIAL PARTICIPATION BY INSURANCE STATUS, GEOGRAPHIC LOCATION, TREATMENT CENTER, AND GRADING IN PATIENTS WITH PROSTATE CANCER</strong></td>
</tr>
<tr>
<td>Mary Palmer, Meredith Ackerman, Amanda LeSeuer, PhD, Anthony Corcoran, MD</td>
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<td>NYU Winthrop Hospital,</td>
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<tr>
<td><strong>Presented By:</strong> Aaron Katz, MD</td>
</tr>
<tr>
<td><strong>83. ASSOCIATION BETWEEN INFLAMMATORY BOWEL DISEASE AND INCIDENT PROSTATE CANCER: A PROSPECTIVE, POPULATION-BASED STUDY USING COLORECTAL CANCER AS A COMPARATOR</strong></td>
</tr>
<tr>
<td>Adam Weiner, Anuj Desai, Shilajit Kundu, Travis Meyer, John Witte</td>
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<tr>
<td>1 Northwestern University, 2 UCSF</td>
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<tr>
<td><strong>Presented By:</strong> Adam Weiner</td>
</tr>
<tr>
<td><strong>84. NATIONAL TRENDS IN THE MANAGEMENT OF LOW RISK PROSTATE CANCER: ANALYZING THE IMPACT OF MEDICAID EXPANSION IN THE UNITED STATES</strong></td>
</tr>
<tr>
<td>Grant Pollock, Juan Chipollini</td>
</tr>
<tr>
<td>1 University of Arizona, Department of Urology, 2 University of Arizona, Department of Urology</td>
</tr>
<tr>
<td><strong>Presented By:</strong> Grant Pollock</td>
</tr>
</tbody>
</table>
85. LESION DETECTION EFFICACY OF 18F-RHPSMA-7.3 POSITRON EMISSION TOMOGRAPHY IN MEN WITH BIOCHEMICAL RECURRENT OF PROSTATE CANCER: INITIAL CLINICAL DATA FROM 285 CONSECUTIVE PATIENTS
Thomas Langbein¹, Markus Krönke¹, Wolfgang Weber¹, Matthias Eiber¹, Alexander Wurzer², Hans-Juergen Wester², Tobias Maurer³, Thomas Horn⁴
¹ Department of Nuclear Medicine, Klinikum rechts der Isar, Technical University of Munich School of Medicine, Munich, Germany, ² Chair for Pharmaceutical Radiopharmacy, Technical University of Munich, Garching, Germany, ³ Martini-Klinik and Department of Urology, University Hospital Hamburg Eppendorf, Hamburg, Germany, ⁴ Department of Urology, Klinikum rechts der Isar, Technical University of Munich School of Medicine, Munich, Germany
Presented By: Thomas Langbein

86. WHAT REALLY MATTERS WHEN PREDICTING OTHER CAUSE MORTALITY FOR MEN WITH PROSTATE CANCER: A MACHINE LEARNING APPROACH TO VARIABLE SELECTION
Brooke Namboodri¹, Xi Zhou, MS², Ethan Basch, MD, MS³, Angela B. Smith, MD, MS³, Marc Bjurlin, DO, MSc, FACOS³, Matthew E. Nielsen, MD, MS², Jennifer Lund, PhD², Hung-Jui Tan, MD, MSHPM², Alex Sox-Harris, PhD, MS³
¹ University of North Carolina at Chapel Hill, ² University of North Carolina at Chapel Hill, ³ Palo Alto Veterans Affairs Health Care System,
Presented By: Brooke Namboodri

87. UNDERSTANDING THE ROLE OF SELECTIVE BETA-BLOCKERS IN PATIENTS WITH ADVANCED PROSTATE CANCER ON ANDROGEN DEPRIVATION THERAPY
Natasza Posielski, Kyle Richards, Jinn-Ing Liou, E. Jason Abel, Tracy Downs, Tudor Borza, David Jarrard
University of Wisconsin School of Medicine and Public Health
Presented By: Natasza Posielski

88. DETECTION OF GERMLINE MUTATIONS IN LOCALIZED AND METASTATIC PROSTATE CANCER THROUGH GUIDELINE-BASED TESTING
Randy Vince Jr.¹, Jake Quarles², Mallory Luke³, Sanjay Das², Marissa Solorzano², Michelle Jacobs², Samuel Kaffengerter⁴, Simpa Salami⁴, Elena Stoffel⁴, Sofia Merajver⁵, Rachel Capra⁶, Todd Morgan⁷
¹ Michigan Medicine (University of Michigan), ² Research Assistant, ³ Genetic Counselor, ⁴ Assistant Professor of Urology, ⁵ Assistant Professor of Hematology Oncology, ⁶ Professor of Internal Medicine, Medical School and Professor of Epidemiology, School of Public Health, ⁷ Urologist, Michigan Institute of Urology, ⁸ Associate Professor of Urology, Chief of Urologic Oncology
Presented By: Randy Vince Jr.

89. TRENDS IN PATIENT OUT-OF-POCKET COSTS AND HOSPITAL AND PHYSICIAN REIMBURSEMENT FOR ROBOTIC AND OPEN RADICAL PROSTATECTOMY
Rodrigo Rodrigues Pessoa¹, Paul Maroni², Janet Kukreja², Simon Kim²
¹ University of Colorado Anschutz Medical Campus, ² University of Colorado - Anschutz Medical Campus
Presented By: Rodrigo Rodrigues Pessoa

90. NO ASSOCIATION BETWEEN PRE-TREATMENT POST-TRAUMATIC STRESS DISORDER OR DEPRESSION WITH BIOCHEMICAL RECURRENCE FOLLOWING RADICAL PROSTATECTOMY WITHIN THE VETERANS AFFAIRS HEALTH SYSTEM: RESULTS FROM SEARCH DATABASE
Rashid Sayyid¹, Za Klaassen², Benjamin Harper², Rashid Sayyid², Martha Terris², Lauren Howard³, Christopher Wallis³, Christopher Amling⁴, William Aronson⁴, Christopher Kane⁴, Matthew Cooperberg⁴, Jean Beckham⁵, Stephen Freedland⁶
¹ Augusta University, ² Department of Surgery, Section of Urology, August University, Augusta, GA, ³ Division of Urology, Durham Veterans Affairs Medical Center, Durham, NC, ⁴ Department of Urology, Vanderbilt University Medical Center, Nashville, TN, ⁵ Department of Urology, Oregon Health Sciences University, Portland, OR, ⁶ Division of Urology, West Los Angeles Veterans Affairs Medical Center, Los Angeles, CA, ⁷ Department of Urology, University of California, San Diego, CA, ⁸ Department of Urology, University of California, San Francisco, CA, ⁹ Durham Veterans Affairs Medical Center, Durham, NC, ¹⁰ Division of Urology, Cedars-Sinai Medical Center, Los Angeles, CA
Presented By: Rashid Sayyid

91. ROUTINE CLINICAL LABORATORY TESTS ASSOCIATED WITH OVERALL SURVIVAL IN PATIENTS WITH PROSTATE CANCER: APPLYING A SYSTEMATIC LABORATORY-WIDE ASSOCIATION STUDY (LWAS) METHOD
Ericka Sohlberg¹, Jaden Yang¹, Kristopher Kapphahn¹, Glenn Chertow¹, James Brooks¹, Manisha Desai¹, I-Chun Thomas², Chirag Patel³
¹ Stanford University, ² VA Palo Alto Health Care System, ³ Harvard University
Presented By: John Leppert

92. LONG-TERM OUTCOMES OF RADICAL PROSTATECTOMY IN MEN WITH A PREOPERATIVE SERUM PROSTATE-SPECIFIC ANTIGEN LEVEL ≤ 20 NG/ML
Jack Andrews, Rachael Carlson, Laureano Rangel, Stephen Boorjian, Jeffery Kames, Igor Frank, Matthew Tollefson, R. Houston Thompson, Matthew Gettman
Mayo Clinic
Presented By: Jack Andrews
93. PROGNOSTIC AND CLINICAL UTILITY CAPABILITIES OF CELL CYCLE PROGRESSION TESTING, PROSTATE IMAGING-REPORTING AND DATA SYSTEM SCORING, AND CLINICOPATHOLOGIC DATA IN MANAGEMENT OF LOCALIZED PROSTATE CANCER
David Morris¹, J. Scott Woods², Lauren Lenz², Jennifer Logan², Todd Cohen², Steven Stone²
¹ Urology Associates, PC, ² Myriad Genetics, Inc.
Presented By: David Morris

94. MANAGEMENT TRENDS AND SURVIVAL IN T1C PROSTATE CANCER AMONG MEN > 74 YEARS OF AGE
Stephanie Gleicher, Timothy Byler, Joseph M Jacob, Elizabeth Ferry
SUNY Upstate Medical University
Presented By: Stephanie Gleicher

95. DOWNGRADING OF GRADE GROUP 2 INTERMEDIATE-RISK PROSTATE CANCER FROM BIOPSY TO RADICAL PROSTATECTOMY: COMPARISON OF OUTCOMES AND PREDICTORS TO IDENTIFY POTENTIAL CANDIDATES FOR ACTIVE SURVEILLANCE
Zhuo Tony Su, Hiten Patel, Jonathan Epstein, Christian Pavlovich, Mohamad Allaf
James Buchanan Brady Urological Institute and Department of Urology, Johns Hopkins University School of Medicine
Presented By: Zhuo Tony Su

96. CONCORDANCE RATES BETWEEN MRI FUSION VERSUS TRUS PROSTATE BIOPSY AND PATHOLOGY AT RADICAL PROSTATECTOMY: DATA FROM THE PURC
Ruchika Talwar¹, Katharine Michel¹, Assem Malhotra¹, Daniel Lee¹, Thomas Guzzo¹, Bret Marlowe², Claudette Fonsel², John Danella³, Serge Ginzberg³, Thomas Lanchoney³, Jay Raman³, Adam Reese³, Jeffrey Tomaszewski³, Edouard Trabulsi³, Marc Smaldone⁴, Robert Uzzo⁴
¹ University of Pennsylvania, ² The Health Care Improvement Foundation, ³ Geisinger Health System, ⁴ Einstein Medical Center, ⁵ Urology Health Specialists, ⁶ Penn State Milton S. Hershey Medical Center, ⁷ Temple University Hospital, ⁸ MD Anderson at Cooper University Hospital, ⁹ Thomas Jefferson University Hospital, ¹⁰ Fox Chase Cancer Center
Presented By: Ruchika Talwar

97. RECOVERY OF SEXUAL FUNCTION IN MEN TREATED WITH ANDROGEN DEPRIVATION THERAPY FOR LOCALIZED PROSTATE CANCER
Daniel Joyce¹, Zighuo Zhao¹, Li-Ching Huang¹, Tatsuki Koyama¹, Ralph Conwill¹, David F. Penson¹, Daniel A. Barocas¹, Karen E. Hoffman²
¹ Vanderbilt University Medical Center, ² The University of Texas, MD Anderson Cancer Center
Presented By: Daniel Joyce

98. HOXB13 EXPRESSION CORRELATES WITH OUTCOMES AND PROGRESSION IN MEN WITH LOCALIZED PROSTATE CANCER
Adam Weiner¹, Edward Schaeffer¹, Farzana Faizal², Tamara Lotan³, Elai Davivioni³, R. Jeffery Karnes³
¹ Northwestern University, ² Johns Hopkins, ³ Decipher Biosciences, ⁴ Mayo Clinic
Presented By: Adam Weiner

99. RACIAL DISPARITIES IN YEARS OF POTENTIAL LIFE LOST SECONDARY TO UNTREATED LOW AND INTERMEDIATE RISK PROSTATE CANCER DEATHS
Mahmoud I Khalil¹, Milan Bimali², Rodney Davis³, Bruno Machado³, Mohamed H Kame³
¹ University of Arkansas for Medical Sciences, ² Department of Biostatistics, University of Arkansas for Medical Sciences, Little Rock, Arkansas, ³ Winthrop P. Rockefeller Institute, University of Arkansas for Medical Sciences, Little Rock, Arkansas, ⁴ Department of Urology, University of Arkansas for Medical Sciences
Presented By: Mohamed H Kamel

100. OUTCOMES OF ACTIVE SURVEILLANCE FOR MEN WITH LOCALIZED PROSTATE CANCER STRATIFIED BY AUA RISK GROUPING
Andrew Gusev¹, Keyan Salari¹, Edouard Nicaise¹, Alice Yu¹, David Kuppermann¹, Carl Ceraolo¹, Michael Blute¹, Douglas Dahl¹, Anthony Zietman¹, Adam Feldman¹, Timothy Baloda²
¹ Massachusetts General Hospital, ² University of Massachusetts Medical School
Presented By: Andrew Gusev

101. UROLOGIST-PATIENT SHARED DECISION IMPROVES PATIENT EXPERIENCE AND COST SAVINGS OF BIPARAMETRIC PROSTATE MRI
Andrew Gusev, Michelle Shabo, Scott Greenberg, Alan Goldstein, Jennifer Yates, Evan Ruppell, Ahmed Sobieh, Mitchell Sokoloff, Khashayar Rafatzand
University of Massachusetts Medical School
Presented By: Andrew Gusev
102. DOES PROSTATE VOLUME AFFECT CANCER DETECTION RATES FOR MRI-TARGETED BIOPSIES?
Luke P. O'Connor¹, Alex Wang¹, Michael A. Ahdoot, MD, MD², Nitin Yerram, MD², Andrew R. Wilbur³, Amir H. Lebastchi, MD⁴, Heather Chalfin, MD⁵, Sandeep Gurram, MD⁶, Patrick Gomella, MD⁷, Siobhan Telfer, MD⁸, Peter A. Pinto, MD⁹, Howard Parnes, MD⁹, Maria Merino, MD¹, Bradford J. Wood, MD¹, Baris Turkbey, MD⁹
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Presented By: Luke P. O'Connor

103. RACIAL DIFFERENCES IN ADVERSE PATHOLOGY AMONGST MEN WITH PROSTATE CANCER AT TIME OF RADICAL PROSTATECTOMY
Samuel Washington¹, Sikai Song², Janet Cowan³, Shoujun Zhao³, Matthew Cooperberg⁴, Peter Carroll⁵
¹ University of California San Francisco, ² School of Medicine, University of California San Francisco, ³ Department of Urology, University of California San Francisco
Presented By: Samuel Washington

104. THE NEW SURVEILLANCE, EPIDEMIOLOGY, AND END RESULTS PROSTATE WITH WATCHFUL WAITING DATABASE: OPPORTUNITIES AND LIMITATIONS
Chang Wook Jeong¹, Samuel Washington², Annika Herlemann Hermann², Peter Carroll², Matthew Cooperberg², Scarlett Gomez²
¹ Department of Urology, Seoul National University Hospital, Seoul, Republic of Korea, ² Department of Urology, University of California San Francisco, ³ Department of Epidemiology & Biostatistics, University of California, San Francisco, CA
Presented By: Samuel Washington

105. NATURAL HISTORY OF AN IMMEDIATELY DETECTABLE PSA FOLLOWING RADICAL PROSTATECTOMY: A DESCRIPTION OF A CONTEMPORARY COHORT
Peter E. Lonergan, Samuel L. Washington, Janet E. Cowan, Hao G. Nguyen, Matthew R. Cooperberg, Peter R. Carroll
University of California, San Francisco
Presented By: Peter E. Lonergan

106. POSTTRAUMATIC STRESS DISORDER AND SUICIDE AMONG VETERANS WITH PROSTATE CANCER
Maya Aboumrad¹, Brian Shiner¹, Talya Peltzman¹, Florian Schroek¹, Alexander Fuld¹, Ellyn Russo¹, Yinong Young-Xu¹, Lorelei Mucci², Zachary Kalessen³, Stephen Freedland⁴
¹ White River Junction Veterans Affairs Medical Center, ² Harvard T.H. Chan School of Public Health, ³ Medical College of Georgia at Augusta University, ⁴ Cedars-Sinai Medical Center
Presented By: Maya Aboumrad

107. UTILITY OF MULTIPARAMETRIC PROSTATE MRI IN PROSTATE CANCER ACTIVE SURVEILLANCE
Danly Omil-Lima, Albert Kim, Lee Ponsky
University Hospitals Cleveland Medical Center / Case Western Reserve University
Presented By: Danly Omil-Lima

108. AN UPDATE ON THE PROSTATECTOMY PATHOLOGIC FINDINGS OF A SERIES OF PATIENTS WITH PROSTATE CANCER AND NO SIGNIFICANT REGIONS OF INTEREST ON MAGNETIC RESONANCE IMAGING
Shaheen Alanee¹, Mustafa Deebayah², James Peabody², Mani Menon², Sean Williams³, Niles Gupta³, Ali Dabaja⁴
¹ ALANEE MD PLLC, ² Department of Pathology, Beaumont Health System, ³ Vattikuti Urology Institute, Detroit, MI, ⁴ Department of Pathology, Henry Ford Health System, ⁵ Vattikuti Urology Institute
Presented By: Shaheen Alanee
109. DIFFERENCES IN CONTEMPORARY BIOPSY GLEASON SCORE DISTRIBUTION IN MEN DIAGNOSED WITH PROSTATE CANCER FROM CHINA AND CANADA
Liang Dong1, Zehua Ma1, Baijun Dong1, Dixon Woon2, Wei Xu2, Michael Nesbit2, Girish Kulkarni2, Robert J Hamilton2, Antonio Finelli2, Neil E Fleschner2, Theodorus H van der Kwast2, Wei Xue3, Cynthia Kuk3, Annette Erlich3, Alexandre R Zlotta3, Oumin Shi4, Sigrid V Carlsson5
1 Renji Hospital, 2 University Health Network, 3 Sinai Health System, 4 Shenzhen Second People's Hospital, 5 Memorial Sloan Kettering Cancer Center
Presented By: Liang Dong

110. IMPLICATIONS OF OVERUTILIZATION OF IMAGING IN LOW RISK PROSTATE CANCER: MORE HARM THAN GOOD?
Justin Loloi1, Russel Owens1, Jay Raman2, Erik Lehman2, Matthew Kaag3, Suzanne Merrill4
1 Penn State Hershey College of Medicine, 2 Penn State Health Milton S. Hershey Medical Center, 3 ebl101@psu.edu, 4 mkaag@pennstatehealth.psu.edu
Presented By: Justin Loloi

111. IS PELVIC MRI SUFFICIENT AXIAL IMAGING FOR STAGING INTERMEDIATE (IR) AND HIGH-RISK (HR) PROSTATE CANCER?
Russel Owens1, Justin Loloi1, Jay Raman2, Erik Lehman2, Matthew Kaag2, Suzanne Merrill2
1 Penn State Hershey College of Medicine, 2 Penn State Health Milton S. Hershey Medical Center
Presented By: Russel Owens

112. USE OF ACTIVE SURVEILLANCE FOR BLACK MEN WITH LOW-RISK PROSTATE CANCER
Bashir Al Hussein Al Awamlh 1, Edward Schaeffer2, Yaw Nyame3, Xiaoyue Ma4, Peter Caif, Christopher Gaffney4, Jim Hu4, Jonathan Shoag4
1 Weill Cornell Medicine, 2 Northwestern, 3 University of Washington, 4 Weill Cornell Medicine
Presented By: Bashir Al Hussein Al Awamlh

113. EXTENDED VERSUS NON-EXTENDED PELVIC LYMPH NODE DISSECTION AMONG PATIENTS UNDERGOING RADICAL PROSTATECTOMY FOR LOCALIZED PROSTATE CANCER: A CAUSAL INERENCE-DRIVEN RETROSPECTIVE BI-CENTER COHORT STUDY
Marian S. Wettstein1, Luke A. David1, Aatif Qureshi1, Alex Zisman1, Michael Nesbit1, Ardalan Ahmad1, Robert J. Hamilton1, Alexandre R. Zlotta1, Neil E. Fleschner1, Antonio Finelli2, Girish S. Kulkarni3, Clinsky Pazhepurackel2, Karim Saba2, Christian D. Fankhauser2, Tullio Sulser2, Cédric Poyet2, Thomas Hermanns2
1 Division of Urology, Department of Surgery, Princess Margaret Cancer Centre, University Health Network, University of Toronto, Toronto, Ontario, Canada, 2 Department of Urology, University Hospital of Zurich, University of Zurich, Zurich, Switzerland
Presented By: Marian S. Wettstein

114. THE COMPARATIVE OUTCOMES OF RADICAL PROSTATECTOMY VERSUS RADIOThERAPY FOR NON-METASTATIC PROSTATE CANCER: A LONGITUDINAL, POPULATION-BASED ANALYSIS
Justin Oake1, Benjamin Shiff1, Jeff Saranchuk1, Rahul Bansal1, Darrel Drachenberg1, Jasmin Nayak1, Oksana Harasemiw1, Thomas Ferguson1, Navdeep Tangri2, Bimal Bhindi2
1 Section of Urology, University of Manitoba, 2 Chronic Disease Innovation Centre, Seven Oaks General Hospital; Department of Internal Medicine, University of Manitoba, 3 Chronic Disease Innovation Centre, Seven Oaks General Hospital; Department of Internal Medicine, University of Manitoba; Department of Community Health Sciences, University of Manitoba, 4 Section of Urology, University of Calgary
Presented By: Justin Oake
115. TRENDS IN EARLY MANAGEMENT OF STAGE 1 NON-SEMINOMA GERM CELL TESTICULAR CANCER
stephanie gleicher, Alexandr Pinkhasov, Oleg Shapiro, Elizabeth Ferry, Joseph M Jacob
SUNY Upstate Medical University
Presented By: stephanie gleicher

116. LEYDIG CELL TUMOR OF THE TESTIS: PATHOLOGICAL CHARACTERISTICS AND TREATMENT PATTERNS FROM THE NATIONAL CANCER DATABASE
Julie Nguyen¹, Kyle Hickey¹, Sanjay Pate², Tony Rodriguez²
¹ University of Oklahoma Health Sciences Center, ² OU Urology
Presented By: Julie Nguyen

117. TESTICULAR CANCER OUTCOMES FOLLOWING DEPENDENT COVERAGE AND MEDICAID EXPANSION: A NATIONAL RETROSPECTIVE COHORT STUDY
Adam Weiner¹, Ketan Jain-Porter¹, Oliver Ko¹, Anuj Desai¹, Shilajit Kundu¹, Stephen Jan²
¹ Northwestern University, ² University of Maryland School of Medicine
Presented By: Adam Weiner

118. MINIMALLY INVASIVE VS OPEN RPLND IN THE TREATMENT OF TESTICULAR CANCER: A COMPARISON OF CURRENT PRACTICE TRENDS AND OUTCOME MEASURES
Matthew Beamer, Stephanie Gleicher, Joseph Jacob
SUNY Upstate Medical University
Presented By: Matthew Beamer

119. PRIMARY ROBOTIC RETROPERITONEAL LYMPH NODE DISSECTION FOLLOWING ORCHIECTOMY FOR TESTICULAR GERM CELL TUMORS: A SINGLE-SURGEON EXPERIENCE
Andrew Supron, Joseph Cheaib, Mohamad Allaf, Phillip Pierorazio
Johns Hopkins University School of Medicine
Presented By: Andrew Supron

120. DOES PERCENTAGE OF SEMINOMA AT ORCHIECTOMY IMPACT PATIENT MORBIDITY AND PATHOLOGIC OUTCOMES AT POST-CHEMOTHERAPY RETROPERITONEAL LYMPH NODE DISSECTION FOR MIXED GERM CELL TUMOR?
Sean Kern, Ryan Speir, Richard Foster, Lawrence Einhorn, Clint Cary, Timothy Masterson
Indiana University
Presented By: Sean Kern

121. PERFORMANCE CHARACTERISTICS OF ANTI-18F-FACBC (AXUMIN) POSITRON EMISSION TOMOGRAPHY/COMPUTED TOMOGRAPHY PRIOR TO RETROPERITONEAL LYMPH NODE DISSECTION
Xiaosong Meng, Solomon Woldu, Daniel Wong, John Lafin, Vitaly Margulis, Jesse Conyers, Rathan Subramaniam, Aditya Bagrodia
UT Southwestern Medical Center
Presented By: Xiaosong Meng
1. PD-L1/PD-1 BIOMARKER FOR METASTATIC UROTHELIAL CANCER THAT PROGRESS POST-PLATINUM THERAPY: A SYSTEMATIC REVIEW AND META-ANALYSIS

Wei Phin Tan1, Ankeet Shah1, Gregory Barton1, Brant Inman1, Wei Shen Tan2

1 Duke University Medical Center, 2 University College London

Presented By: Wei Phin Tan

Introduction: Immune checkpoint inhibitors (ICI) are extremely expensive and most patients do not benefit significantly from their use. Identifying predictive biomarkers to determine patients most likely to respond to ICI therapy for metastatic urothelial carcinoma (UC) could dramatically decrease treatment cost. We performed a meta-analysis to determine response rate and survival outcomes on patients with metastatic UC progressing despite prior platinum-based chemotherapy receiving ICI stratified by biomarker status.

Methods: The study was registered in the International Prospective Register of Systematic Reviews (PROSPERO) registry. We performed a comprehensive literature search for all articles in PubMed and Embase up to 06/15/2019 to identify all studies pertaining to PD-L1/PD-1 targeted therapies for metastatic UC that reported biomarkers. Sample size of individual studies, demographic values were calculated based on percentages and summed up to obtain the values used for this cohort. Pooled averages were estimated using both the random-effects model proposed by DerSimonian and Laird. Proportions of complete response (CR, complete disappearance of tumor), partial response (PR, >30% reduction in tumor volume) and objective response rate (ORR, PR + CR) were pooled after arcsine transformation for variance stabilization. Published Kaplan–Meier plots from each trial were digitized using WebPlotDigitizer and survival probabilities extracted. Pseudo-individual patient survival data was then reconstructed for each study and pooling of survival curves done using the method of Combescure et al. to arrive at summary survival curves for each trial with accurate censoring information. To determine if the reconstructed survival curves accurately represented the primary data in each individual trial, intraclass correlation coefficients were calculated to assess the difference among reconstructed and published data. The meta-analyzed pseudo-IPD was then used to generate two overall pooled survival curves, one for OS and one for PFS, each stratified by PD-L1 biomarker status. Cox proportional hazards models were used to compare overall survival OS and PFS in biomarker negative and positive patients and the hazards ratio and its respective 95% CI reported.

Results: We identified 1429 manuscripts of which 8 met inclusion criteria. Pooled CR rate was 5% (95% CI 3% - 7%, I2 = 58%) overall, 8% (95% CI 5% - 10%, I2 = 43%) in PD-L1 positive biomarker and 3% (95% CI 1% - 4%, I2 = 48%) in PD-L1 negative biomarker patients. The intraclass correlation between published number-at-risk tables and those calculated from our pseudo-IPD was 1.0 (95% CI 1.0). Of the 1837 patients included in the analysis, 1760 (96%) patients were post-platinum therapy whereas 77 (4%) of patients have not received platinum therapy. Median age ranged from 66 to 68 years old, males were 1338 (77%) of patients, and 1117 (84%) of patients were Caucasian. A total of 726 (41%) and 1075 (59%) patients were Eastern Cooperative Oncology Group (ECOG) 0 and ECOG =1, respectively. On proportional hazards survival analysis, patients in the biomarker negative group were associated with a lower PFS (HR 1.48, 95% CI: 1.18 - 1.85, p<0.001) and lower OS (HR 1.54, 95% CI: 1.32 - 1.80, p<0.001) when compared to the biomarker positive group. Response data was available for 1641 patients and random effects proportion show complete response in 8% and 3% in biomarker positive and negative patients, respectively. Median OS for biomarker positive, biomarker negative and both is 10.6 months, 6.9 months and 8.6 months respectively. Median PFS for biomarker positive, biomarker negative and both is 3.3 months, 1.4 months and 2.7 months respectively.

Conclusion: ICI therapy for metastatic UC post platinum therapy has a higher overall response rate, OS and PFS in patients who are biomarker positive compared to those who are negative. However, some patients who are biomarker negative do achieve complete responses. Current PD-1/PD-L1 biomarkers are not ready for prime-time usage. A better biomarker for patient selection is essential before biomarkers can be used to stratify candidates for ICI therapy.
2. THE RISKS OF EPIDURAL ANESTHESIA IN CYSTECTOMY PATIENTS: A NSQIP ANALYSIS

Kirtishri Mishra\textsuperscript{1}, Amr Mahran\textsuperscript{2}, Laura Bukavina\textsuperscript{2}, Brittany Adamic\textsuperscript{3}, Anjali Shekar\textsuperscript{4}, Vaishnavi Narayanamurthy\textsuperscript{4}, Richa Raina\textsuperscript{5}, Carvell Nguyen\textsuperscript{6}, Lee Ponsky\textsuperscript{7}

\textsuperscript{1} University Hospitals Cleveland Medical Center, \textsuperscript{2} University Hospitals Cleveland Medical Center, Urology Institute, Cleveland, Ohio, \textsuperscript{3} University of Chicago Medical Center, Chicago, Illinois, \textsuperscript{4} Case Western Reserve University School of Medicine, Cleveland, Ohio, \textsuperscript{5} Northeast Ohio Medical University, Rootstown, Ohio, \textsuperscript{6} Metro Health Medical Center, Cleveland, Ohio, \textsuperscript{7} Case Comprehensive Cancer Center, Case Western Reserve University School of Medicine, Cleveland, Ohio

Presented By: Laura Bukavina

Introduction: Neuroaxial (i.e spinal, regional, epidural) anesthesia has been shown to be associated with reduced readmission rate, decreased hospital stay, and reduction in post operative complications in non urologic literature. Our aim was to identify differences in intra- and post-operative complications, length of stay, and readmission rates in cystectomy patients managed with different anesthesia modalities.

Methods: Utilizing the National Surgical Quality Inpatient Program (NSQIP) database, we identified patients who underwent a cystectomy with ileal conduit between 2014 and 2017. Patients were further subdivided based on additional anesthesia modality. We used the propensity score-matching (PSM) method to adjust for baseline differences between patients who received general anesthesia alone and those who received both general and epidural anesthesia using 1:1 caliper width of 0.15 for the propensity score through the nearest neighbor. Using step-wise multivariable logistic regression, we identified preoperative and intraoperative predictors associated with 30-day procedure related readmission, complications, and postoperative length of stay.

Results: Out of 4,843 patients identified, 2,956 patients met our inclusion and exclusion criteria and eligible for propensity score matching. Combined general with epidural anesthesia demonstrated no difference in length of stay, readmission or reoperation rate. Compared to GA adjuvant epidural anesthesia showed increased trend for development of pulmonary emboli (13(1.8%) vs 4(0.5%), p=0.051) as well as an increased odds of procedure related complications (aOR: 1.264, 95% CI: 1.019-1.567, p=0.033).

Conclusion: Using 2014-2017 NSQIP database we were able to demonstrate increased rates of procedure related complications, with no difference in hospitalization, readmission or reoperation rate as compared to general anesthesia alone. Future prospective trials with increased focus on postoperative opioid consumption, and early mobilization are encouraged.
3. DOES ELECTROSTATIC COMPLEMENTARITY BETWEEN T-CELL RECEPTORS AND MACF1 MUTANTS CONFER A SURVIVAL BENEFIT IN PATIENTS WITH MUSCLE INVASIVE BLADDER CANCER?

Kyle Michelson¹, Boris Chobrutskiy², George Blanck², Ross Simon³, Jay Patel³, Trushar Patel³

¹ SUNY Downstate Medical Center, Department of Urology, ² University of South Florida, Department of Molecular Medicine, ³ University of South Florida, Department of Urology

Presented By: Kyle Michelson

**Introduction:** Mutant amino acids in tumor cells are presumed to elicit an anti-tumor immune response, primarily mediated by T-cells. Thus, we sought to obtain the amino acid sequences for the T-cell receptors in muscle invasive bladder cancer (MIBC) patients to determine whether computational approaches could chemically link the T-cell receptors (TCR) to such mutant amino acids, similarly to a previously published protocol (1). We applied this novel approach to MIBC patients with mutations in the MACF1 gene, a microtubule-actin cross-linking factor and positive regulator of the Wnt signaling pathway, to determine if TCR-mutant amino acid chemical linkage correlates with clinical features and survival outcomes.

**Methods:** We acquired the amino acid sequences of the TCR-antigen binding site from T-cells of MIBC patients from The Cancer Genome Atlas (TCGA). We assessed the electrostatic charge of these amino acids sequences, termed the complementary determining region-3 (CDR3). We then obtained the net change in electrostatic charge caused by the mutant amino acids in the tumor cells of the matching patients. To determine whether the CDR3 electrostatic charges were complementary to the corresponding amino acids charges, we wrote an original Python program that outputted the charge relationships and their connection to survival rates. Overall and disease free survival were analyzed using Kaplan-Meier plots and a log rank-test was applied to assess for survival differences. Variations in clinical characteristics were examined using Chi-squared analysis.

**Results:** Of the 413 patients with MIBC in the TCGA, 53 had mutations in the MACF1 gene. Electrostatic complementarity for the MACF1 mutant amino acids and the corresponding TCR CDR3s (from the same patients) was found in 23 of these patients. Those with electrostatic complementarity had prolonged overall and disease free survival vs patients with non-complementary TCR CDR3-MACF1 mutants (p=0.007 and 0.016, respectively; Figures 1). Overall and disease free survival for patients with non-complementary TCR CDR3-MACF1 mutants were similar to that of all MIBC patients in the TCGA (p=0.233 and 0.888), whereas patients with complementarity had significantly improved survivals vs all patients (p=0.013 and 0.003). Patients with TCR-MACF1 complementarity were more likely to be male and white vs all other patients in TCGA dataset (p=0.049 and 0.025 respectively; Table 1). Of note, those with complementarity were more likely than non-complementary TCR CDR3-MACF1 mutants to have incidental prostate cancer (p=0.001).

**Conclusion:** Electrostatic complementarity between TCR CDR3 and MACF1 mutants is associated with improved survival odds in patients with MIBC. Further research is needed to explore whether complementarity between TCR and cancer mutants can reliably serve as a prognostic factor for bladder cancer patients and if complementarity contributes to disparate cancer survival outcomes. 1. Chobrutskiy BI, Zaman S, Diviney A, Mihyu MM, Blanck G. T-cell receptor-alpha CDR3 domain chemical features correlate with survival rates in bladder cancer. Journal of cancer research and clinical oncology. 2018. doi: 10.1007/s00432-018-2815-1. PubMed PMID: 30539280.
4. DIGITAL PATHOLOGY OF CIRCULATING TUMOR CELLS WITH MORPHOLOGIC ANALYSIS IS FEASIBLE IN LOCALIZED AND METASTATIC BLADDER CANCER

Heather Chalfin1, Kelly Harris2, Stephanie Glavaris2, Michael Gorin2, Max Kates2, Megan Fong2, Andres Matoso2, Michael Johnson2, Kenneth Pienta2, Jean Hoffman-Censits2, Trinity Bivalacqua2, Noah Hahn2, David McConkey2, Megan Kearney3, Adam Jendrisak3, Vladimir Valera4, Andrea Apolo4
1 National Institutes of Health, 2 The James Buchanan Brady Urological Institute and Greenberg Bladder Cancer Institute, Johns Hopkins University School of Medicine, Baltimore, MD, USA., 3 Epic Sciences, Inc., San Diego, CA., 4 National Cancer Institute, Bethesda, MD.
Presented By: Heather Chalfin

Introduction: Circulating tumor cells (CTCs) are promising biomarkers for risk stratification and prediction of therapeutic response in metastatic urothelial cancer (UC). Unfortunately, efforts to apply this technology in localized disease have largely been unsuccessful, in part due to low CTC enumeration in UC relative to other cancers, as well as limitations of the previous generation of detection technology. This older technology relies on counting cells after a selection step for epithelial-marker expression and does not consider CTC morphology. Here, we applied a novel selection-free digital pathology CTC detection platform with morphologic analysis for feasibility in a cohort of patients with localized UC. To date, this platform has associated CTC morphology with differential therapeutic response in metastatic bladder and castrate-resistant prostate cancer. If feasible in localized UC, we may potentially identify best candidates for novel adjuvant/neoadjuvant therapies, who may safely undergo bladder sparing, and enable sensitive monitoring for early recurrence.

Methods: Peripheral blood samples were collected at one time point from N=16 consecutive patients with UC including 8 (50%) with metastatic disease as controls, and 8 (50%) patients with localized UC (with 3 (37%) collected at TURBT and 5 (63%) at cystectomy prior to incision). Slides were processed with the Epic CTC platform and stained with pan-CK/CD45/PD-L1/DAPI for CTC detection. Approximately 3 million cells per slide were imaged through the advanced digital pathology pipelines to detect and assess CTC burden. Unsupervised clustering of CTC images was used to categorize CTCs into 5 subtypes based on 11 morphologic features including nuclear solidity, speckling, nucleoli and entropy; cytokeratin speckling and ratio; and cytoplasmic/nuclear circularity, area, and convex area ratio.

Results: A total of 119 CTCs were detected in 11/16 (69%) patients including 5/8 (63%) localized (2 NMIBC, 6 MIBC) and 6/8 (75%) metastatic. All patients with MIBC underwent cystectomy, 4/6 (67%) had neoadjuvant chemotherapy, 2 tumors were downstaged, 1 was upstaged, and 3 had stable disease. Patients with metastatic UC included those with upper tract UC (2), bladder cancer (5), and both upper and lower tract disease (1). Metastatic sites included: bone only 2/8 (25%), node only 1/8 (13%), and visceral 5/8 (62%). 3/8 (38%) patients had disease progression on current therapy, 2/8 (25%) had stable disease, and 3/8 (38%) had newly detected M1 disease prior to starting therapy. Median (range) CTC count/mL was similar for localized and metastatic patients (0.4 (0-58.6) and 0.75 (0-1.9) respectively). CTCs were detected in a patient with CIS, but not in a patient with TaHG disease. 1/16 (6.3%) patients had a single PD-L1+ CTC. CTCs were successfully assigned into 5 subtypes with predominant features of large cells, small cells, linear cells, high cytoplasmic circularity, and prominent nucleoli respectively.

Conclusion: Digital pathology and subtype assignment of circulating tumor cells is feasible in localized as well as metastatic bladder cancer. Ongoing efforts at our center include application of this technology in localized patients receiving investigational checkpoint inhibitor therapy to potentially predict best responders or conversely those at the highest risk for recurrence.

Funding: Greenberg Bladder Cancer Institute
5. VARIATION IN RADICAL CYSTECTOMY UTILIZATION IN PATIENTS WITH MUSCLE-INVASIVE BLADDER CANCER ACCORDING TO PATIENT, UROLOGIST AND HOSPITAL CHARACTERISTICS

Stephen B. Williams1, Vishnu Kamal Golla2, Karim Chamie2, Yong Shan3, Mohammed Ferjallah4, Hemalkumar B. Mehta3, Yong-Fang Kuo3, Douglas S. Tyler3, Jacques Baillargeon2, Ashish M. Kamat1, Stephen J. Freedland5, John L. Gore6

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2 The University of Texas Medical Branch, Division of Urology, Galveston, TX
3 The University of Texas Medical Branch, Department of Surgery, Galveston, TX
4 The University of Texas Medical Branch, Department of Urology, Galveston, TX
5 The University of Texas Medical Branch, Department of Preventive Medicine and Community Health, Galveston, TX
6 Department of Urology, The University of Texas MD Anderson Cancer Center, Houston, TX
7 Department of Urology, Cedars Sinai Medical Center, Los Angeles, CA
8 Department of Urology, The University of Washington, Seattle, WA

Presented By: Preston S. Kerr

Introduction: Previous studies have primarily evaluated patient characteristics associated with radical cystectomy (RC) use. The objective of this study is to determine the impact of patient, urologists, and hospital characteristics on variation in the use of RC.

Methods: Using the Surveillance, Epidemiology, and End Results Registry (SEER) Medicare linked database, we identified 7,097 patients, aged 66–85 years, diagnosed with clinical stage T2–4a muscle-invasive bladder cancer from January 1, 2002 through December 31, 2011. We identified 4,601 diagnosing urologists, 4,582 treating urologists and 822 hospitals and performed hierarchical modeling to determine variation in use of RC.

Results: Out of 7,097 patients, only 26% underwent RC. There was wide variation in RC use among hospitals (10–37%), even after adjusting for case-mix differences. The percentage of variance in RC use attributable to the hospital was 5%. Higher RC volume (10+ vs. 0 surgeries) by diagnosing urologists (odds ratio [OR], 2.18; 95% confidence interval [CI], 1.83–2.60) and hospitals (40+ vs. 0 surgeries) (OR, 1.62; 95% CI, 1.13–2.32) increased RC use. Patients diagnosed by female rather than male urologists were more likely to undergo RC (OR, 1.62; 95% CI, 1.31–2.01). Treating urologist volume (10+ vs. 0 surgeries) was associated with up to a 6-fold likelihood of undergoing RC (OR, 6.38; 95% CI, 5.31–7.67).

Conclusion: Use of RC was largely attributed to urologist surgical volume after controlling for patient and hospital characteristics. These findings further support centralization of RC to higher volume urologists to improve use.

Funding: This study was conducted with the support of a Department of Defense Peer Reviewed Cancer Research Program (PRCRP) Career Development Award (W81XWH1710576) and the Herzog Foundation (SBW). This study was supported by a Center for Translational Science Award by the NIH (TL1TR001440 and UL1TR001439) (MF). Yes

Table 1. Patient Demographic and Clinical Characteristics of Diagnosing Urologist and Treating Urologist

<table>
<thead>
<tr>
<th>Variable</th>
<th>Diagnosing Urologist</th>
<th>Treating Urologist</th>
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<tbody>
<tr>
<td>Age Group</td>
<td>Odd Ratio (95% CI)</td>
<td>Odd Ratio (95% CI)</td>
</tr>
<tr>
<td>70-74</td>
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<td>0.84 (0.7-0.93)</td>
</tr>
<tr>
<td>75-80</td>
<td>0.75 (0.6-0.9)</td>
<td>0.81 (0.69-0.93)</td>
</tr>
<tr>
<td>80-85</td>
<td>0.69 (0.59-0.9)</td>
<td>0.79 (0.61-0.99)</td>
</tr>
<tr>
<td>Sex</td>
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<td></td>
</tr>
<tr>
<td>Male</td>
<td>ref</td>
<td>ref</td>
</tr>
<tr>
<td>Female</td>
<td>1.02 (1.0-1.06)</td>
<td>1.01 (0.99-1.03)</td>
</tr>
<tr>
<td>Race</td>
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<tr>
<td>White</td>
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<td>ref</td>
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<tr>
<td>Black</td>
<td>0.96 (0.78-1.19)</td>
<td>0.98 (0.8-1.2)</td>
</tr>
<tr>
<td>Other</td>
<td>0.96 (0.77-1.22)</td>
<td>0.94 (0.77-1.17)</td>
</tr>
<tr>
<td>Mortality Status</td>
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<td></td>
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<tr>
<td>Low</td>
<td>ref</td>
<td>ref</td>
</tr>
<tr>
<td>High</td>
<td>0.87 (0.73-1.03)</td>
<td>0.84 (0.72-0.97)</td>
</tr>
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<td>Censored</td>
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<td>ref</td>
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<tr>
<td>Stage</td>
<td></td>
<td></td>
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<tr>
<td>T1</td>
<td>0.54 (0.42-0.69)</td>
<td>0.59 (0.48-0.73)</td>
</tr>
<tr>
<td>T2</td>
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<td>1.04 (0.98-1.09)</td>
</tr>
<tr>
<td>T4</td>
<td>0.94 (0.71-1.26)</td>
<td>0.95 (0.71-1.26)</td>
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<td></td>
</tr>
<tr>
<td>0</td>
<td>ref</td>
<td>ref</td>
</tr>
<tr>
<td>&gt;1</td>
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<td>0.81 (0.71-0.95)</td>
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<tr>
<td>Education</td>
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<td>&lt;12</td>
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<tr>
<td>&gt;12</td>
<td>0.98 (0.79-1.22)</td>
<td>0.98 (0.77-1.25)</td>
</tr>
<tr>
<td>Year of Diagnosis</td>
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<td></td>
</tr>
<tr>
<td>2002</td>
<td>1.05 (0.81-1.33)</td>
<td>1.22 (0.91-1.65)</td>
</tr>
<tr>
<td>2003</td>
<td>1.07 (0.84-1.35)</td>
<td>1.24 (0.95-1.63)</td>
</tr>
<tr>
<td>2004</td>
<td>1.09 (0.86-1.38)</td>
<td>1.28 (0.98-1.69)</td>
</tr>
<tr>
<td>2005</td>
<td>1.03 (0.81-1.31)</td>
<td>1.23 (0.95-1.58)</td>
</tr>
<tr>
<td>2006</td>
<td>1.02 (0.81-1.3)</td>
<td>1.20 (0.92-1.56)</td>
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<tr>
<td>2007</td>
<td>1.07 (0.86-1.34)</td>
<td>1.25 (0.97-1.63)</td>
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<td>2008</td>
<td>1.05 (0.83-1.32)</td>
<td>1.25 (0.97-1.62)</td>
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<td>2009</td>
<td>1.09 (0.87-1.36)</td>
<td>1.25 (0.98-1.63)</td>
</tr>
<tr>
<td>2010</td>
<td>1.02 (0.81-1.3)</td>
<td>1.21 (0.93-1.6)</td>
</tr>
<tr>
<td>2011</td>
<td>1.00 (0.8-1.2)</td>
<td>1.20 (0.92-1.53)</td>
</tr>
</tbody>
</table>

Table 2. Multivariable Model for Radical Cystectomy Utilization by Diagnosing and Treating Urologist Characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Diagnosing Urologist</th>
<th>Treating Urologist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician's Age</td>
<td>1.00 (0.98-1.03)</td>
<td>1.00 (0.97-1.03)</td>
</tr>
<tr>
<td>Practice year</td>
<td>0.99 (0.97-1.02)</td>
<td>0.99 (0.97-1.02)</td>
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<tr>
<td>Bed size</td>
<td>ref</td>
<td>ref</td>
</tr>
<tr>
<td>Physician Gender</td>
<td>1.00 (1.00-1.00)</td>
<td>1.00 (1.00-1.00)</td>
</tr>
<tr>
<td>Employment Group</td>
<td>ref</td>
<td>ref</td>
</tr>
<tr>
<td>1-2 physicians</td>
<td>1.03 (0.98-1.09)</td>
<td>0.95 (0.88-1.02)</td>
</tr>
<tr>
<td>Government</td>
<td>0.71 (0.55-0.92)</td>
<td>0.84 (0.65-1.07)</td>
</tr>
<tr>
<td>Medical School</td>
<td>0.90 (0.75-1.08)</td>
<td>0.91 (0.75-1.08)</td>
</tr>
<tr>
<td>Non government</td>
<td>1.01 (0.88-1.15)</td>
<td>1.01 (0.88-1.15)</td>
</tr>
<tr>
<td>Surgeon Volume</td>
<td>ref</td>
<td>ref</td>
</tr>
<tr>
<td>0</td>
<td>ref</td>
<td>ref</td>
</tr>
<tr>
<td>5+</td>
<td>2.38 (2.04-2.78)</td>
<td>3.52 (2.96-4.19)</td>
</tr>
<tr>
<td>10+</td>
<td>2.08 (1.61-2.69)</td>
<td>3.48 (2.63-4.52)</td>
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<td>Treatment center</td>
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<td>ref</td>
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<tr>
<td>Hospital Outpatient</td>
<td>2.18 (1.63-2.60)</td>
<td>6.38 (5.31-7.67)</td>
</tr>
<tr>
<td>Hospital Outpatient</td>
<td>2.18 (1.63-2.60)</td>
<td>6.38 (5.31-7.67)</td>
</tr>
</tbody>
</table>

Abbreviation: CI = confidence interval; NCI = National Cancer Institute; Yes = present; ref = reference; No = not present.

Yes
6. PROXIMITY TO OIL REFINERIES AND RISK OF BLADDER CANCER: A POPULATION-BASED ANALYSIS
Stephen B. Williams¹, Yong Chan², Mohammed Ferdjallah³, Jacques Baillargeon⁴, Yong-Fang Kuo⁴, Hemalkumar B. Mehta⁵
¹ The University of Texas Medical Branch, Division of Urology, ² The University of Texas Medical Branch, Division of Urology, Galveston, TX, ³ The University of Texas Medical Branch, Department of Medicine, Division of Epidemiology, Sealy Center on Aging, Galveston, TX, ⁴ The University of Texas Medical Branch at Galveston, Division of Biostatistics, Sealy Center on Aging, Galveston, TX, ⁵ The University of Texas Medical Branch, Department of Surgery, Galveston, TX
Presented By: Preston S. Kerr

Introduction: Incidence rates of bladder cancer according to proximity to oil refineries are largely unknown. We sought to determine proximity of oil refineries and bladder cancer incidence in the State of Texas which is home to the largest number of oil refineries in the United States.

Methods: We used the Texas Cancer Registry database to identify patients diagnosed with bladder cancer from January 1, 2001 to December 31, 2014. We linked this to the U.S. census data and County Health Ranking and Roadmaps database to control for smoking rates, atmospheric particulate matter (PM 2.5) and oil well distributions. Risk ratios were adjusted using a Poisson regression model.

Results: A total of 14,924 incident bladder cancer cases were identified. Patients living within 0-10 miles were older (71.0 vs. 69.6 yrs), more likely female (26.9% vs. 23.1%), African-American race/ethnicity (13.3% vs. 4.4%), and more advanced disease (distant/metastatic: 4.8% vs. 3.6%) than patients residing 20-30 miles from an oil refinery (all p<0.001). In adjusted analysis, patients living within 0-10 miles vs. 20-30 miles had an increased risk of bladder cancer (Risk Ratio (RR), 1.12: 95% Confidence Interval (CI), 1.07-1.17). Moreover, we observed further increased of advanced stage bladder cancer among patients living 0-10 miles vs. 20-30 miles from an oil refinery (distant/metastatic: RR 1.34: 95% CI 1.06-1.69).

Conclusion: These findings suggest increased risk of bladder cancer according to proximity to an oil refinery. Further research in additional cohorts using individual level data are needed to confirm these findings.

Funding: This study was conducted with the support of a Department of Defense Peer Reviewed Cancer Research Program (PRCRP) Career Development Award (W81XWH1710576) and the Herzog Foundation (SBW). This study was supported by a Center for Translational Science Award by the NIH (TL1TR001440 and UL1TR001439) (MF).

Table 1. Adjusted Risk Ratio of Bladder Cancer According to Proximity to an Oil Refinery.

<table>
<thead>
<tr>
<th>Proximity to oil refinery</th>
<th>Cancer cases</th>
<th>Population</th>
<th>Rate of cancer Per 10,000</th>
<th>Adjusted risk ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bladder Cancer - All cases</td>
<td>5537</td>
<td>2213854</td>
<td>25</td>
<td>1.1991</td>
</tr>
<tr>
<td>0-10 mile</td>
<td>5537</td>
<td>2213854</td>
<td>25</td>
<td>1.1991</td>
</tr>
<tr>
<td>10-20 mile</td>
<td>5615</td>
<td>2433988</td>
<td>23.1</td>
<td>1.0631</td>
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<tr>
<td>20-30 mile</td>
<td>3772</td>
<td>1504423</td>
<td>22.8</td>
<td></td>
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<tr>
<td>Bladder Cancer - Stage Localized</td>
<td>4114</td>
<td>2213854</td>
<td>18.6</td>
<td>1.0931</td>
</tr>
<tr>
<td>0-10 mile</td>
<td>4114</td>
<td>2213854</td>
<td>18.6</td>
<td>1.0931</td>
</tr>
<tr>
<td>10-20 mile</td>
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<td>2433988</td>
<td>19.0</td>
<td>1.0744</td>
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<td>20-30 mile</td>
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<td>17.7</td>
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<tr>
<td>Bladder Cancer - Stage regional</td>
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<td>1.0568</td>
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<tr>
<td>0-10 mile</td>
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<td>2213854</td>
<td>1.8</td>
<td>1.0568</td>
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<tr>
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<td>2433988</td>
<td>1.6</td>
<td>1.0112</td>
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<td>20-30 mile</td>
<td>265</td>
<td>1504423</td>
<td>1.6</td>
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<td>Bladder Cancer - Stage Distant</td>
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<td>2213854</td>
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<td>1.3389</td>
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<td>0-10 mile</td>
<td>267</td>
<td>2213854</td>
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<td>0.9967</td>
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<td>20-30 mile</td>
<td>138</td>
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<tr>
<td>Bladder Cancer - Stage Unstaged</td>
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<td>0-10 mile</td>
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<td>2213854</td>
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<td>1.3307</td>
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<td>10-20 mile</td>
<td>615</td>
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<tr>
<td>20-30 mile</td>
<td>444</td>
<td>1504423</td>
<td>2.7</td>
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</tbody>
</table>
7. COMPLETE TURBT PRIOR TO NEOADJUVANT CHEMOTHERAPY IMPROVES ONCOLOGICAL OUTCOMES IN PATIENTS WITH MUSCLE-INVASIVE BLADDER CANCER
Jamie Pak, Christopher Haas, Christopher Anderson, Helena Vila Reyes, G Joel DeCastro, Mitchell Benson, James McKiernan
Columbia University Irving Medical Center
Presented By: Jamie Pak

Introduction: Neoadjuvant chemotherapy (NAC) prior to radical cystectomy (RC) is the standard of care for muscle-invasive bladder cancer (MIBC), with absolute increase in overall survival (OS) ranging 5-10%. In a 2014 meta-analysis, NAC was associated with a pathologic complete response (pT0) in 29% of patients, who had improved OS compared to those without a complete response. Prior studies have shown that pT0 response can be attributed not only to NAC, but also to high-quality transurethral resections (TURBT) prior to NAC. In addition, several studies on bladder preserving trimodal therapy show about a 20% higher rate of local control after a visibly complete TURBT. Therefore, we sought to assess the association between completeness of pre-NAC TURBT and subsequent response and survival outcomes.

Methods: This was a single-institution, retrospective review of all patients who received NAC for clinically localized MIBC (=cT2, N0) from 2000 to 2017. Patients were excluded if they received non-cisplatin-based chemotherapy or external beam radiation either concurrent to chemotherapy or as adjuvant therapy (n=15), or had insufficient documentation on completeness of TURBT (n=26). A complete TURBT was defined as tumor resection in its entirety and/or resection down to normal appearing underlying bladder muscle as described in surgical operative reports; a negative bimanual examination and cross-sectional imaging without evidence of tumor invasion were also required. If repeat restaging TURBT prior to NAC revealed clinical T0 (cT0) status, this was also considered evidence of a complete pre-NAC TURBT. The precise platinum-based NAC regimen was left to the discretion of the treating oncologist. After completion of NAC, patients either underwent a repeat TURBT or proceeded immediately to RC, as per the treating physician. Patients ultimately refusing RC were placed on a strict active surveillance and delayed intervention (ASDI) protocol of cytology, cystoscopy with or without biopsy, and cross-sectional imaging at 3-4 month intervals. Primary endpoint was durable complete response (dCR), defined as either pT0 on RC specimen or remaining cT0 on the ASDI protocol for at least 1 year. Secondary endpoints included OS and durable down-staging (dDS), defined as patients with =pT1 on RC specimen or remaining =cT1 on ASDI protocol for at least 1 year.

Results: A total of 93 patients with MIBC met inclusion criteria. TURBT prior to NAC was described as complete in 67% (62/93) of patients. Patients with complete TURBT had lower rates of variant histology (13% vs 32%, p=0.03), had lower rates of hydronephrosis (15% vs 39%, p<0.01), and were more likely to pursue ASDI (60% vs 26%, p=0.01). Patients with complete pre-NAC TURBT were significantly more likely to attain a dCR (37% vs 13%, OR 4.04 [95% CI 1.3-13.1], p=0.01) and dDS (60% vs. 26%, OR 4.9 [95% CI 1.8 - 12.8], p<0.01) on univariate analysis. On multivariate analysis, complete TURBT was a significant predictor of dCR and dDS; this remained true on subset analysis excluding 11 patients with =cT3 on restaging TUR. On Kaplan-Meier analysis, patients with complete TURBT had improved OS (5-year OS 78% vs. 46%, p=0.01). On multivariate analysis controlling for variant histology, lymphovascular invasion, and hydronephrosis, complete TURBT was the only significant predictor of OS. Complete TURBT remained a significant predictor of OS in a subset analysis excluding the 11 patients with =cT3 on restaging TURBT.

Conclusion: A visibly complete TURBT prior to NAC is associated with a significant improvement in pathologic outcomes and OS in this single-institution cohort of patients with MIBC. The extent to which a complete pre-NAC TURBT represents a selection criterion for having lower clinical stage or a therapeutic advantage in response to NAC is difficult to isolate from a retrospective study. However, this report suggests a complete TURBT of muscle-invasive tumors should be pursued when feasible to potentially optimize outcomes after NAC.
8. PLANNED SECONDARY ANALYSIS OF PURE-01: ROLE OF 18-FDG-PET/CT IN EVALUATING LYMPH NODE INVOLVEMENT OF PATIENTS WITH MUSCLE-INVASIVE BLADDER CANCER RECEIVING NEOADJUVANT PEMBROLIZUMAB AND RADICAL CYSTECTOMY

Laura Marandino¹, Antonella Capozza¹, Daniele Raggi¹, Elena Farè¹, Patrizia Giannatempo¹, Ettore Seregni¹, Andrea Necchi¹, Alessandra Alessi¹, Alberto Briganti², Filippo Pederzoli², Andrea Gallina², Marco Bandini², Umberto Capitanio², Marco Bianchi², Giorgio Gangaglia², Nicola Fossati², Andrea Salonia², Francesco Montorsi²

¹ Fondazione IRCCS Istituto Nazionale dei Tumori, ² Vita Salute San Raffaele University and Urological Research Institute (URI)

Presented By: Andrea Necchi

Introduction: 18-Fluorodeoxyglucose Positron Emission Tomography/Computed Tomography (PET/CT) was reported to have limited utility in clinical N0 patients (pts) with muscle-invasive bladder carcinoma (MIBC) who received neoadjuvant chemotherapy and radical cystectomy (RC) or RC alone (Dason, AUA19). Early findings from the PURE-01 study (pembrolizumab before RC in cT2-3bN0M0 MIBC) reported pathologic complete responses (pT0) in 42% of patients. Herewith we present a secondary analysis aimed at evaluating the role of PET/CT imaging in lymph node involvement assessment.

Methods: In the PURE-01 study (NCT02736266), 3 courses of 200 mg pembrolizumab, every 3 weeks, were administered prior to RC. Adverse events (AE) were graded according to the Common Terminology Criteria for Adverse Events (CTCAE) classification, version 5.0. The patients were assessed with standard thorax-abdomen CT scan and with PET/CT scan during screening and after treatment, before RC. PET/CT scan was performed according to European guidelines. Images were acquired from the base of skull to mid-thigh. Imaging review and analysis was performed by two experienced nuclear medicine physicians blinded to clinical information. PET/CT images were evaluated qualitatively for increased or abnormal areas of FDG uptake with corresponding anatomic alterations in CT slices. Semiquantitative and volumetric analysis was performed. For each patient with nodal increased uptake in abdomino-pelvic area, the maximum standardized uptake value (SUVmax) and the short-axis size of the most intense lymph node were recorded. All pts underwent templated pelvic lymph node dissection (LND) with packeted node submission. PET/CT diagnostic ability was assessed using sensitivity, specificity, negative predictive value (NPV), positive predictive value (PPV), and accuracy.

Results: From 02/17 to 06/2019, 114 pts were enrolled and treated. 11 pts received additional chemotherapy post-pembrolizumab and were excluded from the analyses, resulting in 103 total evaluable pts, accounting for a total of 206 PET/TC scans. Six pts (5.8%) had positive nodes at baseline PET/CT: mean SUVmax=2.75; mean short axis: 6.2 mm. Eight pts (7.8%) had positive nodes at PET/CT post-pembrolizumab: mean SUVmax=4.21; mean short axis: 7.2mm. The rate of pathologic lymph node positive (pN+) disease was 15.5% (16 pts). The performance of post-pembrolizumab PET/CT in predicting pN+ disease is indicated in the Table. Considering pre-treatment PET/CT scan, 4/6 pts (66.7%) showing baseline FDG uptake revealed as pN+ vs 12/97 (12.4%) with no baseline FDG uptakes (p=0.005). A total of 39 pts (37.9%) developed inflammatory FDG-uptakes post-pembrolizumab in several target organs/regions: top 5 sites were thyroid (N=21, 61.8%), stomach and mediastinum (13 pts each, 12.6%), lung (N=10, 9.7%), other lymph nodes (N=4, 3.9%). These changes were clinically evident (signs/symptoms or laboratory changes) in 15 pts (38.5%).

Conclusion: In clinically N0 pts with MIBC, the features of PET/CT in response assessment post-pembrolizumab recapitulated those after chemotherapy, resulting in limited clinical utility. However, PET/CT scan may be useful to exclude the few pts who show any nodal FDG-uptake pre-treatment from single-agent checkpoint inhibitor trials, thus refining the conventional CT-scan based screening procedures. Three cycles of pembrolizumab determined profound inflammatory changes, whose long-term impact on safety is still to be determined.

Funding: MERCK

<table>
<thead>
<tr>
<th></th>
<th>Sensitivity</th>
<th>95% CI</th>
<th>Specificity</th>
<th>95% CI</th>
<th>NPV</th>
<th>95% CI</th>
<th>PPV</th>
<th>95% CI</th>
<th>Accuracy</th>
<th>95% CI</th>
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<td>Post-pembro PET/CT</td>
<td>37.5</td>
<td>15.2-64.6</td>
<td>97.7</td>
<td>91.9-99.7</td>
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<td>85.3-92.6</td>
<td>75</td>
<td>39.9-92.6</td>
<td>88.4</td>
<td>80.5-93.8</td>
</tr>
</tbody>
</table>

Abbreviations: CI: confidence interval; NPV: negative predictive value; PPV: positive predictive value
9. LONGITUDINAL HEALTH RELATED QUALITY OF LIFE AFTER RADICAL CYSTECTOMY UTILIZING THE FACT-BL-CYS INSTRUMENT: COMPARISON OF ILEAL CONDUIT, INDIANA POUCH, AND ORTHOTOPIC NEOBLADDER.

Sean Kern, Ryan Speir, Hristos Kaimakliotis, Richard Foster, Timothy Masterson, Michael Koch, Clint Cary
Indiana University

Presented By: Sean Kern

Introduction: With multiple options for urinary diversion following radical cystectomy, health related quality of life (HRQOL) is an important consideration during the shared decision-making process with patients being treated for bladder cancer. We aimed to characterize the HRQOL reported by patients who underwent a radical cystectomy for bladder cancer with respect to ileal conduit, Indiana pouch, or neobladder urinary diversion utilizing the Functional Assessment of Cancer Therapy-Bladder Cystectomy (FACT-Bl-Cys) validated patient health survey at various time points postoperatively.

Methods: The FACT-Bl-Cys survey was administered to 146 patients with bladder cancer undergoing radical cystectomy and urinary diversion at Indiana University from 2015-2018. Surveys were then completed prior to radical cystectomy and longitudinally throughout the post-operative course and retrospectively reviewed.

Results: Of the 146 patients completing questionnaires with a mean of over 12 months, 84 (57.6%) received an ileal conduit, 31 (21.2%) an Indiana pouch, and 31 (21.2%) an orthotopic neobladder. 76.7% of the patients were male. The mean (SD) FACT-Bl-Cys (0-168) pre- and post-operative scores amongst all diversion types were 120.15 (23.82) and 123.75 (22.88), possibly indicating perceived improvement in quality of life after treatment for bladder cancer with cystectomy. Patients who received an ileal conduit had the largest percent increase in HRQOL scores (5.96%), followed by Indiana Pouch (1.1%). Neobladder patients had an average decrease in HRQOL scores by (3.2%). There was no significant difference in Physical Well-Being subscores or the Social/Family Well-Being subscores between diversion types. The highest Functional Well-Being subscores were seen in the ileal conduit group, there was no change seen in the Indiana pouch group. In evaluating the treatment-specific cystectomy instrument results, the highest subscore increase was seen in the ileal conduit group and there was a decrease in subscores seen in the neobladder group. Emotional Well-Being scores increased amongst all diversion groups.

Conclusion: To our knowledge this is the first longitudinal analysis comparing quality of life in patients after receiving an ileal conduit, Indiana pouch, or neobladder urinary diversion utilizing a standardized, validated, treatment-specific patient health survey. Proper preoperative counseling is critical to ensure understanding about the benefits of continence vs noncontinent diversion types within the first year postoperatively.
10. INVESTIGATING THE SYNTHETIC LETHALITY OF EZH2 INHIBITION IN ARID1A MUTANT BLADDER CANCER

James Ferguson1, Hasib Rehman1, Darshan Chandrashekar2, George Netto2, Soory Varambally3, Guru Sonpavde3
1 UAB Urology, 2 UAB Pathology, 3 Dana Farber Cancer Institute

Presented By: James Ferguson

Introduction: Next generation sequencing of bladder cancer has revolutionized our understanding of the disease and promises to move the field towards better risk stratification, therapeutic target identification, and more personalized therapies for patients. Specifically, genes involved in epigenetic modifications have been shown to be frequently mutated in bladder cancer. In fact, over 90% of NMIBC harbor inactivating mutations in at least one chromatin modifying enzyme including ARID1A, KDM6A, and KMT2C/D. Among these, AT Rich Interactive Domain 1A (ARID1A), a member of the SWI/SNF chromatin modifying complex, harbors truncating/inactivating mutations in about 20% of both NMIBC and MIBC, making it the most frequently mutated epigenetic gene in bladder cancer and suggesting its mutation as an early event in bladder cancer tumorigenesis. Previously, Dr. Varambally and others have shown that the histone methyltransferase Enhancer Of Zeste Homolog 2 (EZH2), which is responsible for generating a transcriptionally repressive chromatin mark, is over expressed and required for growth of multiple aggressive cancers, including bladder cancer. EZH2 functions as the catalytic subunit of the polycomb repressive complex 2 (PRC2) which methylates lysine 27 on histone 3 (H3K27me), resulting in chromatin condensation and transcriptional silencing. Herein, we show that ARID1A mutations sensitize bladder cancer cells in vitro and in vivo to EZH2 inhibition with the small molecule GSK-126. We hope that these findings will help to elucidate the epigenetic molecular underpinnings of bladder cancer, and will result in new epigenetic therapeutic targets for patients.

Methods: In silico analysis using the TCGA dataset compared disease-free survival between ARID1A mutant (ARID1Amut) and wildtype (wt) tumors. Western blot was used to compare EZH2, ARID1A, and H3K27me3 protein levels between matched pairs of bladder cancer and normal urothelium from cystectomy specimens at our institution. Cell proliferation, viability, and colon formation assays were performed in the presence and absence of EZH2 inhibitor GSK-126 in bladder cancer cell lines with and without ARID1A mutations. Stable ARID1A knockdown cell lines were also tested to investigate causation. Murine xenograft experiments were performed using bladder cancer cell lines with and without ARID1A mutations to compare tumor growth inhibition by intraperitoneal GSK-126. In order to understand the molecular mechanisms behind differential GSK-126 sensitivity, RNA microarray was used to evaluate differentially expressed genes in bladder cancer cell lines with and without ARID1A mutations after treatment with GSK-126. Western blot and chromatin-immunoprecipitation analysis was performed to confirm the microarray findings.

Results: In silico analysis revealed that ARID1Amut bladder cancers show worse disease-free survival compared to ARID1Awt tumors (p-value: 0.007) [Fig1]. Western blot analysis revealed that EZH2 and resultant H3K27me3 levels are dramatically increased in bladder tumors compared with normal urothelium, with a concomitant decrease in ARID1A protein levels. Using 3 ARID1Awt bladder cancer cell lines (T-24, 5637, RT-112) and 3 ARID1Amut cell lines (HT-1197, HT-1376, VM-CUB1) we showed that the proliferation of only ARID1Amut cell lines is inhibited by EZH2 inhibitor GSK-126 [Fig2]. ARID1A knockdown in 5637 cells resulted in de novo GSK-126 sensitivity in proliferation assays. These findings were also recapitulated in vivo using murine xenograft models with intraperitoneal GSK-126 treatment for 3 weeks. To determine the molecular mechanisms behind the synthetic lethality of EZH2 inhibition in ARID1Amut cell lines, we performed transcriptomic analysis comparing ARID1Awt and mut cell lines in the presence and absence of GSK-126. Several genes were differentially expressed that could explain the differential sensitivity to GSK-126 inhibition including MTSS1 (or “missing in metastasis”), optineurin (OPTN), an autophagy regulator, and the tumor suppressor Protein Tyrosine Phosphatase, Receptor Type, R (PTPRR). The GSK-126 mediated induction of these proteins only in ARID1Amut cell lines was confirmed by western blot. ChIP analysis using antibodies to EZH2 and H3K27me3 in combination with PCR templates to the promoters of MTSS1, OPTN, and PTPRR showed that GSK-126 inhibition abrogated EZH2 binding to and methylation of those foci only in ARID1Amut cell lines.

Conclusion: ARID1A mutation is a reliable biomarker for EZH2 inhibitor sensitivity in bladder cancer cells. As EZH2 inhibitors are currently in phase I clinical trials with tolerable side effect profiles, these findings warrant further validation and future consideration for therapeutic intervention in early and late stage bladder cancer patients. Future experiments will include further investigation of the candidate genes MTSS1, OPTN, and PTPRR to determine if their induction is sufficient for the GSK-126 sensitivity of ARID1Amut cells. CRISPR-CAS9 correction of ARID1A mutations in ARID1Amut cell lines will be used to determine if this sensitivity to GSK-126 can be rescued. Furthermore, shRNA knockdown of other SWI-SNF components will be performed to determine if other mutations can similarly sensitize to GSK-126 treatment, and broaden the eligibility to future therapy. Xenograft studies are currently underway to compare the differential sensitivity of ARID1A mut and wt PDX models to GSK-126. Finally, we are investigating the utility of urinary cell free DNA in the detection of ARID1A mutations as a non-invasive eligibility screen for future therapeutics.
11. REOPERATION WITHIN 30 DAYS OF RADICAL CYSTECTOMY: IDENTIFYING HIGH-RISK PATIENTS USING THE AMERICAN COLLEGE OF SURGEONS NATIONAL SURGICAL QUALITY IMPROVEMENT PROGRAM DATABASE

Rashid Sayyid1, Diana Magee2, Amanda Hird2, Benjamin Harper2, Eric Webb3, Katherine Fratino3, Martha Tend3, Rabii Madi3, Zachary Naassen3, Raj Satkunasivam4, Christopher Wallis5
1 Augusta University, Division of Urology, Department of Surgery, University of Toronto, Toronto, ON, Canada, 2 Section of Urology, Department of Surgery, Medical College of Georgia-Augusta University, Augusta, GA, 3 Section of Urology, Department of Surgery, Vanderbilt University, Nashville, TN

Presented By: Rashid Sayyid

Introduction: Radical cystectomy (RC) remains the gold-standard treatment for muscle-invasive bladder cancer. This procedure, however, is highly morbid with 30-day peri-operative complication rates approaching 50% that may have significant medical and financial consequences. Identifying high-risk patients for such complications is thus essential. Our objective was to identify predictors of re-operation within 30 days of RC.

Methods: We identified 2608 patients who underwent RC for non-metastatic bladder cancer using the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) database. Our primary outcome was re-operation within 30 days of RC. Study variables included patient demographics, medical comorbidities, and post-operative hospitalization events. Univariate (Chi-square and Fisher’s exact tests), and multivariate regression analyses were used to evaluate predictors of re-operation.

Results: Median patient age was 69 years, 17.6% were female, and 79.5% received an ileal conduit. 152 patients (5.8%) were re-operated on within 30 days of their RC. On univariate analysis, race (10.9% of African-Americans vs. 5.1% of Caucasians and 4.0% of other races, p=0.04), history of chronic obstructive pulmonary disease (12.3% vs. 5.3%, p<0.01), and higher BMI (29.1 kg/m2 for those with re-operation within 30 days vs. 27.8, p=0.017) were associated with higher re-operation rates. Notably, type of diversion (ileal conduit vs. continent) and history of chemotherapy or radiotherapy within 30 days prior to RC were not associated with higher 30-day reoperation rates. On multivariate analysis, increasing BMI (OR 1.04, 95% CI 1.01-1.07) and history of COPD (OR 2.2, 95% CI 1.3-3.5) remained significant predictors of reoperation (Table 1). Patients who were reoperated on within this timeframe were more likely to experience mortality (4.0% vs. 1.6%, p=0.03), cardiac (7.2% vs. 1.9%, p<0.01), pulmonary (23.0% vs. 3.0%), neurologic (2.0 vs. 0.49%, p=0.02), and venous thromboembolic (10.5% vs. 5.4%, p<0.01) events, longer length of stay (16.5 days vs. 7.0, p<0.01), and infectious complications (64.5% vs. 24.1%, p<0.01) within this timeframe (Table 2).

Conclusion: Increasing BMI, history of COPD and possibly African-American race are associated with higher reoperation rates within 30 days of RC, with substantial health and financial consequences. These results will help urologists identify patients at higher risk of such adverse events and allow physicians to adopt more aggressive approaches to minimize post-operative surgical complications.

| Table 1. Multivariable regression model evaluating predictors of reoperation with in 30 days of radical cystectomy |
| Variable | Odds Ratio | 95% Confidence Interval |
| Age | 1.01 | 0.99-1.03 |
| Gender (male vs. female) | 1.34 | 0.84-2.13 |
| Race (African American vs Caucasian) | 2.29 | 1.71-34.34 |
| Race (Other vs Caucasian) | 0.70 | 0.31-1.52 |
| Body Mass Index | 1.04 | 1.02-1.07 |
| ASA (2 vs. 1) | 0.95 | 0.62-1.46 |
| Hx of diabetes mellitus | 0.88 | 0.57-1.34 |
| Active smoking | 1.46 | 0.99-2.17 |
| Hx of COPD | 2.33 | 1.45-3.74 |
| Chronic Steroid Use | 1.75 | 0.85-3.63 |
| Functional Status (Partially/totally dependent vs. independent) | 0.72 | 0.17-3.11 |
| Type of diversion (continent vs. ileal conduit) | 0.73 | 0.45-1.10 |

ASA: American Society of Anesthesiologists physical status classification system

<p>| Table 2. Adverse events following radical cystectomy for bladder cancer patients with and without reoperation within 30 days of surgery |</p>
<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Patients with reoperation (n=152)</th>
<th>Patients without reoperation (n=2456)</th>
<th>P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>6 (4.0%)</td>
<td>38 (1.6%)</td>
<td>0.03*</td>
</tr>
<tr>
<td>Cardiac Event</td>
<td>11 (7.2%)</td>
<td>46 (1.9%)</td>
<td>&lt;0.01*</td>
</tr>
<tr>
<td>Neurologic Event</td>
<td>3 (2.0%)</td>
<td>12 (0.5%)</td>
<td>0.02*</td>
</tr>
<tr>
<td>Pulmonary Event</td>
<td>35 (23.0%)</td>
<td>73 (3.0%)</td>
<td>&lt;0.01*</td>
</tr>
<tr>
<td>Venous Thromboembolic Event</td>
<td>16 (10.5%)</td>
<td>132 (5.4%)</td>
<td>0.01*</td>
</tr>
<tr>
<td>DVT</td>
<td>9 (5.9%)</td>
<td>89 (3.6%)</td>
<td>0.15</td>
</tr>
<tr>
<td>PE</td>
<td>9 (5.9%)</td>
<td>59 (2.4%)</td>
<td>0.01*</td>
</tr>
<tr>
<td>Any infection</td>
<td>90 (64.5%)</td>
<td>593 (24.1%)</td>
<td>&lt;0.01*</td>
</tr>
<tr>
<td>Sepsis</td>
<td>66 (43.4%)</td>
<td>293 (11.9%)</td>
<td>&lt;0.01*</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>20 (13.2%)</td>
<td>69 (2.8%)</td>
<td>&lt;0.01*</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>22 (14.5%)</td>
<td>210 (8.6%)</td>
<td>0.01*</td>
</tr>
<tr>
<td>Wound Infection</td>
<td>73 (48.0%)</td>
<td>271 (11.0%)</td>
<td>&lt;0.01*</td>
</tr>
<tr>
<td>Superficial SS-present (%)</td>
<td>20 (13.2%)</td>
<td>143 (5.8%)</td>
<td>&lt;0.01*</td>
</tr>
<tr>
<td>Deep incisional SS-present (%)</td>
<td>17 (11.3%)</td>
<td>34 (1.4%)</td>
<td>&lt;0.01*</td>
</tr>
<tr>
<td>Organ space SS-present (%)</td>
<td>40 (26.3%)</td>
<td>108 (4.4%)</td>
<td>&lt;0.01*</td>
</tr>
<tr>
<td>Prolonged hospital length of stay (%</td>
<td>124 (81.1%)</td>
<td>1164 (47.4%)</td>
<td>&lt;0.01*</td>
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<tr>
<td>Length of stay, median (IQ)</td>
<td>16.5 (8.0-26.5)</td>
<td>7.0 (6.0-10.0)</td>
<td>&lt;0.01*</td>
</tr>
</tbody>
</table>

*Denotes p-values <0.05

[Note: The table is incomplete and requires continuation for full context.]
12. RACE AND GUIDELINE-BASED TREATMENT: IMPLICATIONS FOR LONG-TERM SURVIVAL
Samuel Washington1, Maxwell Meng1, Anne Suskind1, Sima Porten1, Steven Gregorich2, Sikai Song2
1 Department of Urology, University of California San Francisco, 2 School of Medicine, University of California San Francisco
Presented By: Samuel Washington

Introduction: For individuals with muscle-invasive bladder cancer (MIBC), studies focused on racial disparities have shown black race is associated with 21% lower odds of guideline-based treatment (GBT) and differences in treatment explain 35% of observed black-white differences in survival. We aim to characterize how the interaction between race/ethnicity and receipt of GBT drive within- and between-race differences in survival for black, white, and Latino patients with MIBC.

Methods: We identified patients diagnosed with cT2-4 MIBC from 2004-2013 in the National Cancer Database. GBT was defined by American Urological Association guidelines. A Cox proportional hazards model of patient mortality estimated effects of patient GBT status, race/ethnicity, and the GBT-by-race/ethnicity interaction, adjusting for covariates.

Results: Of 60,566 MIBC patients with 125,821 person-years of post-treatment observation (max=11 years), 90.1% were white, 6.9% black, and 3.0% Latino. Half (50.2%) received GBT. Averaging across GBT status, Latino patients had lower hazard of death compared to black (HR 0.81, 95% CI 0.75-0.87) and white patients (HR 0.92, 0.86-0.98). Within racial/ethnic groups, GBT was associated with significantly lower hazard of death for black (HR 0.76, 0.70-0.82) and white (HR 0.78, 0.75-0.80), but not Latino patients (HR 0.90, 0.79-1.03). Lastly, mortality risk of black patients with GBT was nearly equivalent to Latino individuals receiving non-GBT (HR=1.02, 0.92-1.14).

Conclusion: Our study illustrates how race-based treatment disparities influence survival outcomes and extend beyond black-white comparisons. Even though there are race-based treatment disparities, they are meager relative to the generally low utilization of GBT and particular ‘under-allocation’ of GBT to vulnerable populations who arguably need it the most. Future efforts to improve the delivery of GBT, a factor directly impacted by urologic care providers, may mitigate the race-based survival differences observed in individuals with MIBC.

13. RACE AND GUIDELINE-BASED TREATMENT: AN INTERSECTIONAL APPROACH TO INFORM INTERVENTIONS IN BLADDER CANCER
Samuel Washington1, Maxwell Meng1, Anne Suskind1, Sima Porten1, Steven Gregorich2, Sikai Song2
1 Department of Urology, University of California San Francisco, 2 School of Medicine, University of California San Francisco
Presented By: Samuel Washington

Introduction: For patients with muscle-invasive bladder cancer, studies have shown black race is associated with 21% lower odds of guideline-based treatment (GBT) and differences in treatment explain 35% of observed black-white differences in survival. We aim to understand how the interaction between race/ethnicity and receipt of GBT drive within-race and between-race differences in survival for black, white, and Latino patients with muscle-invasive bladder cancer.

Methods: Using the National Cancer Database, we identified individuals diagnosed with cT2-4 muscle invasive bladder cancer (MIBC) from 2004-2013. Cox regression models included random effects to accommodate intra-facility correlations of outcome response. Models were adjusted for race, age at diagnosis, gender, histology, clinical T and N stages, treatment (GBT vs nonGBT), Charlson comorbidity index, insurance, and facility type with inclusion of the GBT-by-race/ethnicity interaction effect. Hazard ratios (HR) and 95% confidence intervals (CI) were reported. P value of 0.05 was considered statistically significant.

Results: Of the 60,566 individuals identified, 90.1% were white, 6.9% black, and 3% Latino. Most were 60 years or older (84.6%), had cT2 disease (76.4%), cT4a (92.9%) and had urothelial carcinoma (88.6%). Nearly one-third were female (28.3%). Most were treated at an academic center (34.9%) or comprehensive cancer center (46.3%). Half (50.2%) received GBT. On MV models clustered by treatment facility, GBT was associated with increased survival (HR 0.76, 95% CI 0.72-0.80) compared to nonGBT when averaged across all race groups. GBT benefit was similar for black and white individuals (black, HR 0.71, 95% CI 0.65-0.77; white, HR 0.72, 95% CI 0.70-0.74) but Latino individuals experienced less benefit (HR 0.85, 95% CI 0.74-0.97) compared to nonGBT. From the GBT-by-race interaction, the GBT effect was near equivalent for black race (HR 0.97, 95% CI 0.90-1.07) compared to white counterparts but stronger for both when compared to Latino individuals (black, HR 0.83, 95% CI 0.71-0.97; white, HR 0.85, 95% CI 0.74-0.97). Black individuals who received GBT had worse survival compared to white (HR 1.12, 95% CI 1.05-1.20) and Latino counterparts (HR 1.14, 95% CI 1.01-1.29). Of those with nonGBT, white (HR 1.20, 95% CI 1.09-1.32) and black individuals (HR 1.38, 95% CI 1.24-1.53) had worse survival compared to Latino individuals. Lastly, mortality risk of black individuals with GBT was near equivalent to Latino patients receiving nonGBT (HR 0.97, 95% CI 0.87-1.09).

Conclusion: The GBT effect was not uniform, with a 28-29% reduction in mortality risk experienced by white and black individuals but 15% reduction for Latino counterparts. Our study illustrates how race-based treatment disparities influence survival outcomes and extend beyond black-white comparisons. Future efforts to improve the delivery of GBT, a factor directly impacted by urologic care providers, may mitigate the race-based survival differences observed in individuals with MIBC.
14. UNDERSTANDING THE BARRIERS TO NEOADJUVANT CHEMOTHERAPY AMONG MUSCLE-INVASIVE BLADDER CANCER PATIENTS: A QUALITY IMPROVEMENT INITIATIVE
Juan J Andino, Christine Shafer, Marissa Moore, Udit Singhal, Alon Weizer, Sam Kaffenberger, Lindsey Herrel, Jeffrey Montgomery, Daniel Wray, Zachery Reichert
1 Michigan Medicine Department of Urology, 2 Twine Clinical Consulting, LLC, 3 Michigan Medicine Department of Internal Medicine, Division of Hematology and Oncology
Presented By: Juan J Andino

Introduction: Level 1 evidence supports the use of neoadjuvant chemotherapy (NAC) prior to cystectomy for muscle-invasive bladder cancer. Despite this, there is poor utilization of NAC, even at academic centers. It is crucial to gain a better understanding of existing treatment barriers. We sought to better understand NAC utilization at our institution, including factors associated with decreased use of NAC, as part of a quality improvement (QI) project.

Methods: We analyzed a pre-interventional data set of patients with ≥cT2 bladder cancer who consented to research and were treated with radical cystectomy at our institution between 2012-2017 (n=341) as part of this QI initiative. IRB approval was obtained. We assessed rate of referral for NAC; rate of NAC administration; demographic, geographic, patient and provider variables as well as patient outcomes (e.g. mortality, disease recurrence and progression). Rates were determined using point estimates (simple proportions). Bayesian logistic regression models with horseshoe prior were constructed to identify variables that were associated with NAC to inform future interventions.

Results: Out of 341 eligible patients, 241 (71%) patients with MIBC were referred to medical oncology for consideration of NAC and 202 (59%) received NAC. Considering the entire cohort, the 2-year all-cause mortality, disease-specific mortality, and disease recurrence rates were 36%, 32% and 18%, respectively; 90% had negative margins and 18% experienced a disease recurrence within 2 years. Using Bayesian logistic regression and comparing outcomes for patients who received NAC to those who did not at 2 years, the overall mortality rate was 29.4% vs 42.4% (98.3% probability), disease-specific mortality was 28.5% vs 32.5% (80.1% probability), disease recurrence 15.2% vs 17.3% (33.2% probability). The rates of negative margins were 93.0% vs 85.6% (97.8% probability). Figure 1 shows variables associated with the use of NAC. In red, renal insufficiency and hearing loss as well as treating urologist and medical oncologist are conclusively associated with decreased odds of receiving NAC. In green, diagnosis of heart failure and cM1 status is probably associated with decreased odds of receiving NAC. Finally, in black, age at diagnosis, ECOG score, and distance to UMHS are possibly associated with lower odds of receiving NAC while distance to nearest oncologist is possibly associated with increased odds of receiving NAC.

Conclusion: Renal insufficiency and hearing loss were associated with lower odds of NAC. There was also an association between the individual treating urologist and medical oncologist on the chance of having NAC. Congestive heart failure and cM1 status were probably associated with, while older age, higher ECOG, greater distance from our institution and higher BMI were possibly associated with lower odds of NAC. While expected medical contraindications were associated with decreased NAC use, there were provider and geographic variables identified which may have impacted NAC utilization. We are in the process of designing a provider focused intervention to improve the referral of patients to medical oncology for NAC when medically appropriate.

Funding: Twine Clinical Consulting, LLC
15. THE ASSOCIATION OF TRAINEE INVOLVEMENT IN RADICAL CYSTECTOMY WITH PERIOPERATIVE AND ONCOLOGIC OUTCOMES
Matvey Tsivian, Vignesh Packiam, Stephen Boorjian, Prabin Thapa, Igor Frank, Matthew Tollefson
Mayo Clinic
Presented By: Svetlana Avulova

Introduction: The impact of trainee involvement on surgical outcomes has been examined in various specialties, including urologic procedures, with mixed results. Herein, we assessed the impact of the level of trainees involved in surgery on perioperative and oncological outcomes of patients undergoing radical cystectomy (RC).

Methods: We reviewed the records of patients undergoing RC for urothelial carcinoma between 2000 and 2015 at Mayo Clinic. Trainee level was categorized as fellow, chief, senior and junior residents. In cases with multiple trainees, the highest level was considered. Demographic, perioperative and oncological outcomes were recorded and compared between the groups. Specifically, operative time, 30-day complications, severe complications (Clavien III-V) and oncological outcomes (overall, cancer-specific and recurrence-free survival) were assessed. Operative time model and complications were adjusted for known preoperative variables. Oncologic outcomes models were also adjusted for pathologic stage, nodal stage, margin status and perioperative blood transfusions.

Results: A total of 895 patients were included for study. Median operative time was 298 (251-352) minutes, 63% of patients experienced postoperative complications, 24% had severe complications. Median follow up among survivors was 5.9 years. On multivariable analysis, operative times were 30-40 minutes longer in procedures assisted by junior residents as compared to more senior trainees (table 1, p<0.001). Trainee level was not associated with overall or severe complications on multivariable analyses. Similarly, there were no significant associations between trainee level and overall, recurrence-free and cancer-specific survival.

Conclusion: While cases assisted by junior residents had longer operative times, complication rates and oncological outcomes were comparable across trainee groups. Trainee level does not appear to have an impact on perioperative and oncological outcomes of radical cystectomy for urothelial carcinoma.

<table>
<thead>
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<th>Variable</th>
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<tr>
<td>Fellow</td>
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CMI = Charlson comorbidity index
BMI = Body mass index
16. REGULATORY T CELLS PLAY A ROLE IN BLADDER CANCER DEVELOPMENT
Karen Wheeler, Niannian Ji, Neelam Mukherjee, Robert Svatek
University of Texas Health Center, San Antonio
Presented By: Karen Wheeler

Introduction: Regulatory T cells (Treg) are vital in the development and maintenance of immune tolerance. They function to dampen immune responses and their dysfunction leads to multi-organ autoimmune disease. In cancer, Treg are known to play key roles in the development of cancers including lung, breast, head and neck, and others. Treg are believed to be used by the tumors to aide in immune evasion. In bladder cancer, clinical studies have shown an increase in Treg in the tumor or blood of patients correlates with a worse prognosis. Herein we determine whether Treg play a key role in the development of bladder cancer.

Methods: Female wild type C57BL/6 mice or transgenic DEREG mice (that express a diptheria toxin [DT] receptor whenever Foxp3, the driver of a Treg phenotype, is expressed) were used for all experiments. Metastatic cancer was induced by injecting 0.5 x 10^6 MB49 bladder tumor cells via tail vein into mice on the day of surgery. Orthotopic (bladder) cancer was induced by catheterizing the bladders of female mice and injecting poly-L-lysine followed by 0.08x10^6 MB49 cells at day 0. Treg were depleted in DEREG mice with administration of 50g/kg DT given intraperitoneally every 4 days. Mice were sacrificed at days 21-26 and bladders, lungs, and bladder draining lymph nodes (BLN) were harvested for weight and flow cytometric analysis.

Results: In mice that received both orthotopic and intravenous bladder tumor challenge, Treg were highly present in the bladder tumors but not the lymph nodes or lung (Fig 1). In DEREG mice challenged with orthotopic bladder cancer, depletion of Treg with DT administration abrogated the development of bladder cancer (Fig 2A). Additionally, Treg depleted mice had an increase in the number and percentage of antigen specific CD8+ T cells in the bladder draining lymph nodes as well as an increase in activated CD4+ T cells (Fig 2B).

Conclusion: Regulatory T cells are necessary for bladder cancer development in the orthotopic model of bladder cancer. The Treg appear to function in an antigen-specific manner, but pan-T cell activation cannot be excluded. Development of immunotherapies targeting Treg in the bladder may represent a novel cancer therapeutics.

Funding: AUA Care Foundation and CPRIT Training Grant
17. RE-EXAMINING THE DEPTH OF INVASION IN HIGH-GRADE T1 BLADDER CANCER AND CLINICAL OUTCOMES: AN INDEPENDENT PREDICTOR OF SURVIVAL
Mahmut Akgul1, Nafiseh Janaki2, Amr Mahran3, Kirtishri Mishra3, Danly Omil Lima3, Lee Ponsky2, Matt Bream4, Anjali Shekar5, Gregory MacLennan6, Laura Bukavina7

1 Indiana University School of Medicine, 2 Brigham and Women’s Hospital, 3 University Hospitals Cleveland Medical Center, 4 Urological Associates, PC, 5 Case Western Reserve School of Medicine, 6 Case Western Reserve School of Medicine/University Hospitals Cleveland Medical Center, 7 Case Western Reserve/University Hospitals Cleveland Medical Center

Presented By: Laura Bukavina

Introduction: Background: There are approximately 400,000 new cases of bladder cancer worldwide, with 75% of patients having non-muscle-invasive bladder cancer (NMIBC), either above the urothelial basement membrane (Ta and carcinoma in situ) or invasive into the lamina propria (T1). High grade T1 bladder cancer is the most invasive of the NMIBC, with a significant proportion of patients experiencing upstaging at the time of surgery, with long-term rate of cancer specific mortality reaching up to 34%. Because T1 can exhibits such stark variability in biologic and histopathologic characteristics, we examined the clinical differences in mortality and recurrence-free survival in patients diagnosed with non-full thickness stage T1 bladder compared patients with full-thickness lamina propria stage T1 and stage T2 cancer.

Methods: We identified 2786 bladder cancer patients who underwent transurethral resection of bladder tumor (TURBT) at our institution between 1995 to 2015. Patients with pure transitional carcinoma only were included in the analysis, with adequate follow up, and presence of clearly visible detrusor muscle in the initial resection. Two pathologists independently reviewed the slides. Stage T1 bladder tumors were subclassified into two groups based on proximity of the tumor to the detrusor muscle: the advanced T1 (A-T1) tumor group, comprised of tumors that invaded the full thickness of lamina propria and were histologically immediately adjacent to but not demonstrably invasive into the detrusor muscle (DM); and the superficial T1 (S-T1) group, comprised of tumors that invaded the lamina propria but were not immediately adjacent to detrusor muscle. 154 patients were selected for the study, classified as S-T1 (n=79), A-T1 (n=20) and T2 (n=55). The variables were compared between the 3 groups using Fisher’s exact test, Chi-square test and Kruskal-Wallis. Recurrence free survival was assessed using Kaplan-Meier (KM) method and compared with the log-rank test. All tests were 2-sided and p<0.05 was considered statistically significant.

Results: The characteristics of 154 patients included in the study are summarized in Table 1. Only 11(25%) of patient underwent neoadjuvant chemotherapy prior to cystectomy, with additional 16 (36.4%) undergoing adjuvant therapy. Compared to S-T1 patients, A-T1 and T2 patients experienced an increased rate of mortality [25(31.6%) vs 10(50%) vs 30(54.5%), p=0.023] during the follow up period. Patients with A-T1 disease experienced worst survival out of the three cohorts, as evidence by Kaplan Meier curve, with only 28% (95% CI 13-54%) survival at 60 months after the diagnosis, as compared to 68% (95% CI 53-79%) in S-T1 and 49%(95% CI 35-62) in T2 disease. When evaluating risk factors responsible for increased mortality, age was found to be associated with increased risk of death with HR 1.054(1-026-1.083), while CIS, multifocality, and gender were not found to be predictors for worse outcomes. S-T1 was found to be protective with HR 0.346(0.161-0.743), as compared to A-T1 and T2 disease for mortality.

Conclusion: In conclusion our data points to strong evidence that increased depth of tumor invasion in T1 disease is a strong risk factor for increased mortality and decreased recurrence free survival.
18. USE OF A NOVEL MRNA BIOMARKER PANEL FOR BLADDER CANCER RISK STRATIFICATION

Eugene Shkolyar1, Qian Zhao1, Nicolas Teslovich1, Dharati Trivedi1, Ying Lu1, Kathleen Mach1, Joseph Liao1, Mandy Sin2
1 Stanford University, 2 Cepheid Inc.

Presented By: Eugene Shkolyar

Introduction: Over 2 million cystoscopies are performed annually in the United States and Europe for detection and surveillance of bladder cancer. Patients diagnosed with intermediate and high-risk non-muscle invasive bladder cancer are at high risk for disease progression and recurrence. Decisions regarding cystoscopy surveillance schedules, need for adjunct imaging technologies, and use of intravesical therapies are based upon presumed risk of cancer recurrence and progression. Thus, accurate risk stratification is critical in determining management strategies for patients with bladder cancer. Current risk-stratification models are constructed from clinical and histopathologic data, and thus rely on the availability of a thorough cystoscopy, histopathologic diagnosis, and time to establish a patient’s individual rate of recurrence. Urinary biomarkers have shown promise for bladder cancer detection however their clinical utility remains unknown. We aimed to develop a urinary biomarker model capable of detecting patients with increased risk bladder cancer.

Methods: With IRB approval, voided urine specimens were collected at Veterans Affairs Palo Alto Health Care System from subjects undergoing bladder cancer screening or surveillance cystoscopy between 2016 and 2019. All patients underwent white-light flexible cystoscopy. Subjects with bladder tumors identified on cystoscopy underwent transurethral resection of bladder tumor. Samples were categorized based upon tissue histopathologic diagnosis. Tumors were sub-categorized by stage and grade, and operative reports reviewed for tumor size and focality. AUA risk stratification defined as: low risk, solitary low-grade Ta < 3cm not recurrent within one year; high risk, high-grade T1, recurrent high-grade Ta, high-grade Ta > 3cm or multifocal, presence of CIS, BCG failure with high-grade disease, variant histology, LVI, or high-grade prostatic urethral involvement; intermediate risk, all others; was determined for all patients. Urine specimens (n=257) from 181 subjects were evaluated for expression of a 3-mRNA panel (ROBO1, WNT5A, CDC42BPB) for bladder cancer detection previously identified at VAPAHCS and the GeneXpert® Bladder Cancer Assay 5 mRNA panel (ABL1, CRH, IGF2, ANXA10, UPK1B). All mRNA expression was determined using the GeneXpert Dx automated multiplex RT-PCR platform using 2mL of urine per panel. Stepwise logistic regression analysis of the cycle threshold values of ABL1, CRH, IGF2, ANXA10, UPK1B, ROBO1, WNT5A, and CDC42BPB was done to create a diagnostic model to detect intermediate and high-risk bladder cancer. Ten-fold cross-validation was used to generate a receiver operating curve and a positivity threshold selected. Sensitivity and specificity for detection of intermediate and high-risk bladder cancer was determined.

Results: Urine specimens were collected from 76 patients undergoing screening evaluation for bladder cancer, 99 patients with a history of bladder cancer undergoing surveillance cystoscopy, and 6 patients found to have cancer on screening cystoscopy and then underwent subsequent surveillance cystoscopies. There was a total of 65 diagnoses of bladder cancer (27 low grade, 38 high grade). Twelve patients had low risk disease, 22 had intermediate risk disease, and 31 had high risk disease by AUA criteria. Stepwise logistic regression was used to create a diagnostic model for the detection of increased risk bladder cancer. ROBO1, CRH, and IGF2 were confirmed to correlate with the presence of intermediate and high-risk disease. Setting a P(IRBC) = .0903 as the cutoff for a positive test, the three-marker panel had a sensitivity of 93% (95% CI, 85%-98%) and specificity of 80% (95% CI, 74%-85%) for intermediate and high-risk bladder cancer. Among screening patients, 95% of intermediate and high-risk bladder cancers were detected, with all high-risk cancers (31/31) detected and 19 of 22 intermediate risk cancers detected.

Conclusion: A 3-marker urinary mRNA panel evaluating the expression of ROBO1, CRH, and IGF2 allows for automated, early identification of intermediate and high-risk bladder cancer. Biomarker based risk-stratification may allow clinicians to better triage cystoscopy scheduling for screening, guide frequency of surveillance cystoscopy, and identify patients who may benefit from adjunct imaging technology.
19. PHASE 3 RESULTS OF VICINIUM IN BCG-UNRESPONSIVE NON-MUSCLE INVASIVE BLADDER CANCER (NIMBC)
Neal Shore1, Girish S. Kutkarni2, Michael Franks3, Rian Dickstein4, Fredrick N. Wolk5, Barrett Cowan6, Curtis J. Dunshee7, Laurence Belkoff8, Rachelle L. Dillon9, Jeannick Cizeau9, Wassim Kassouf10
1 Carolina Urologic Research Center, 2 Division of Urology, Departments of Surgery and Surgical Oncology, Princess Margaret Cancer Centre, University Health Network, University of Toronto, Toronto, ON, 3 Virginia Urology Center PC, Richmond, VA, 4 Chief of Urology - University of Maryland Baltimore Washington Medical Center Medical Director of GU Oncology - Tate Cancer Center Clinical Assistant Professor - Department of Surgery at University of Maryland School of Medicine Director, Bladder Cancer Program - Chesapeake Urology, Hanover, MD, 5 Skyline urology, Director of Clinical Trials, Torrance, CA, 6 Urology associates of Denver, Englewood, CO, 7 Director of Research, Urological Associates of Southern Arizona, Tucson, AZ, 8 MidLantic Urology, Bala Cynwyd, Pa, 9 Senes Bio, Winnipeg, MB, 10 Stephen Jarislowsky Chair in Urology Professor and Associate Chair Dept. of Surgery, McGill University Head, Urologic Oncology McGill University Health Center, Montreal QC

Presented By: Neal Shore

Introduction: Vicinium is a recombinant fusion protein comprised of an anti-Epithelial Cell Adhesion Molecule (EpCAM) single chain antibody fragment genetically linked to a truncated form of Pseudomonas exotoxin A (ETA). Evidence to date is supportive of a dual mechanism of action. After intravesical dosing, Vicinium is internalized via EpCAM binding and the release of ETA into the cytosol results in inhibition of protein synthesis and ultimately apoptotic cell death. As a second mechanism, nonclinical studies have demonstrated that cells killed by Vicinium display immunogenic cell death signals that are known to promote the development of an adaptive T-cell mediated anti-tumor response. Results from the Phase 3 Vicinium trial, VISTA, in BCG-unresponsive NMIBC patients are presented.

Methods: BCG-unresponsive NMIBC patients defined as refractory or relapsing within 6 months (n = 126) and relapsing within 11 months (n = 7) after adequate BCG were accrued in a Phase 3 single-arm multicenter registrational trial (NCT02449239). During the induction phase, Vicinium (30 mg diluted in 50 mL PBS) was instilled for 2 hours twice weekly for 6 weeks, then weekly for 6 weeks. Patients who were disease-free at 3 months received maintenance every 2 weeks for up to 2 years. Evaluations were performed every 13 weeks. Treatment success was defined as negative cytology along with normal cystoscopy or negative or low-grade Ta disease on biopsy. Primary endpoints were complete response (CR) rate and duration of response (DoR) for CIS patients and time to recurrence for papillary patients.

Results: Of the evaluable CIS patients (n = 89), the overall 3-month CR rate was 40% and the median DoR was 9.4 months (95% CI, 5.1-NE). Subgroup analysis showed the median DoR was not reached for patients that had received only two courses of BCG prior to enrollment (n = 42) vs. 5.1 months in those who have received more than 2 courses of BCG (n=51). Of the evaluable papillary patients (n = 38), the recurrence-free rate at 3 months was 71% and median time to recurrence was 13.2 months (95% CI, 5.6-NE). On average, responders disease-free at 3 months remained cystectomy-free for 34.0 months vs. 20.7 months for non-responders (p = 0.001). Vicinium was well tolerated; approximately 50% of the patients (66 of 133) had treatment-related adverse events with the most common being dysuria (14%), hematuria (13%), urinary tract infection (12%), pollakuria (11%), micturition urgency (11%) and fatigue (8%). A total of 4 treatment-related severe adverse events were reported in 3 patients and included grade 4 cholestatic hepatitis, grade 5 renal failure, grade 3 acute kidney injury and grade 2 pyrexia. Only 3% of the patients discontinued treatment due to adverse events.

Conclusion: This Phase 3 study established that Vicinium was well-tolerated, demonstrated clinically meaningful anti-tumor activity and may both delay and/or prevent radical cystectomy.

Funding: Senes Bio
**20. SURVEILLANCE CYSTOSCOPY AMONG NON-MUSCLE INVASIVE BLADDER CANCER PATIENTS: FREQUENCY AND RISK FACTORS FOR LOW SURVEILLANCE LEVELS**

Philip Kim, Ronald Loo, Stephen Williams, Margo Sideli, Tiffany Luong, David Yi, Aniket Kawatkar, Kim Danforth, Ayae Yamamoto

1 Southern California Permanente Medical Group, 2 Kaiser Permanente Southern California, 3 Kaiser Foundation Hospital and Health Plan

**Presented By:** Philip Kim

**Introduction:** Tumor recurrence and progression are common among non-muscle invasive bladder cancer (NMIBC) patients. Timely surveillance is a critical component of high-quality care that allows for prompt identification and treatment of tumor recurrence and progression. However, studies report low and varied compliance with surveillance recommendations. Thus, we sought to determine the frequency of timely NMIBC surveillance in a large community-based cohort and to identify risk factors for low surveillance levels.

**Methods:** Adult NMIBC patients diagnosed from 1/1/2001-6/30/2015 within Kaiser Permanente Southern California (KPSC) were identified using data from the KPSC cancer registry, and patients who were health plan members at the time of diagnosis were eligible for the study. Patients were excluded if they had a diagnosis of cancer within the prior 5 years, other than non-melanoma skin cancer; radical cystectomy/urinary diversion (RC/UD) surgery, infusion chemotherapy, or hospice care within 3 months of diagnosis; or health plan membership loss or death within 12 months of diagnosis. Surveillance procedures were identified via codes for cystoscopy or tumor resections 61-365 days post-diagnosis. Tumor resection codes were included to minimize missing a surveillance episode (e.g., in case fulguration, rather than cystoscopy, was coded). Unique surveillance episodes/procedures had to be separated by >75 days to be counted. Outcome variables were >2 surveillance procedures (all patients) and >3 procedures for patients with high-risk tumors (T1, high grade, or carcinoma in situ tumors), which represent the minimum expected surveillance based on guidelines and clinician input. Patient and provider characteristics were extracted from the electronic health record and administrative databases. Multivariable odds ratios (ORs) and 95% confidence intervals (CIs) were estimated using generalized linear mixed models with a binary outcome and urologist as a random effect to account for clustering of patients within providers.

**Results:** Among 5,037 NMIBC patients, 13% had <2 surveillance procedures. Compared to patients 60-69, younger (<50, OR=0.58, 95% CI: 0.39-0.85) and older (≥80, OR=0.66, 95% CI: 0.51-0.85) patients were significantly less likely to receive at least 2 surveillance procedures in the first year after diagnosis. Hispanic patients were less likely than non-Hispanic white patients to receive at least 2 surveillance procedures (OR=0.76, 95% CI: 0.59-0.97). Patients with higher comorbidity levels (Charlson Comorbidity Index [CCI] score ≥2) were less likely to have at least 2 surveillance procedures in the year after diagnosis than patients with a CCI score of 0 (OR=0.64, 95% CI: 0.52-0.79; the CCI calculation ignored bladder cancer). The proportion of patients with >2 surveillance procedures increased over time (per-year OR=1.07, 95% CI: 1.05-1.10). Patients with high-risk tumors were more likely to receive at least 2 surveillance procedures (OR=1.38, 95% CI: 1.16-1.65). However, 40% of the 2,635 patients with high-risk tumors received <3 surveillance procedures. Among these high-risk patients, patients with greater comorbidity levels (CCI ≥2 vs. 0) were less likely to receive at least 3 surveillance procedures (OR=0.72, 95%; 0.59-0.89). Null associations with ≥3 surveillance procedures were observed for age, sex, race/ethnicity, neighborhood household income, oncology specialist, urologist years at KPSC, and urologist’s bladder cancer experience based on number of RC/UD surgeries in the prior year. Surveillance of ≥3 procedures in the year following diagnosis improved over the study years (per-year OR=1.04, 95% CI: 1.02-1.07) and was greater for patients with urothelial tumors (OR=1.97, 95% CI: 1.21-3.20).

**Conclusion:** Surveillance levels among higher-risk patients were lower than expected, with few identifiable predictors of low surveillance levels. Further exploration is needed, and next steps will include targeted chart reviews to determine potential causes. Additionally, while most patients received at least 2 surveillance procedures in the year following diagnosis, there are still some patients who did not receive this minimum expected surveillance. Thus, even for this level of surveillance, care could be improved further within a large, integrated delivery system. Additional research is needed to assess compliance with surveillance recommendations in other types of healthcare systems.

National Cancer Institute of the National Institutes of Health
21. PHASE 1 OUTCOMES OF A NOVEL THIRD GENERATION LIPOSOMAL PACLITAXEL FORMULATION (TSD-001) IN PATIENTS WITH LOW-INTERMEDIATE RISK NON-MUSCLE INVASIVE BLADDER CANCER (NMIBC)

Daniel Huynh¹, Rian Dickstein², Karl Bean³
¹ Danny Huynh Urology, ² Chesapeake Urology, ³ Lipac Oncology

Presented By: Michael Oefelein

Introduction: The purpose of this study (NCT 03081858) is to report phase 1 outcomes of a novel proliposomal formulation of paclitaxel (TSD-001), specifically designed for intravesical instillation for NMIBC.

Methods: This is the first in human exposure of TSD-001 (IND129419) in patients with low-intermediate risk NMIBC. The study design is prospective, non-randomized and adaptive, in which two cohorts (n=3, subjects each) received six escalating intravesical dose (range, 10-540 mg TSD-001) exposures every 2 weeks until Dose Limiting Toxicity (DLT, G3-4 AEs) is observed. Adverse events (AEs) were classified according the NCI CTCAE version 5.0. Urinary symptom bother was collected using the IPSS and OAB-q instruments. Bioanalytical measurement of paclitaxel urine and plasma concentration was performed using a validated assay. Bladder tumor recurrence was assessed by cystoscope and biopsy.

Results: A total of 5 AEs were reported, all of which were G1 or G2 in intensity and none of which met the criteria for DLT. There was no change from baseline in the IPSS or OAB-q scores. No measurable plasma concentrations of paclitaxel (LLQ <5.0 ng/mL) were reported over all doses (10-540 mg). Urine paclitaxel concentrations demonstrated proportional increase in concentration with increasing dose. No evidence of clinical recurrence has been identified in the 6 study subjects at a mean follow-up of 12 months.

Conclusion: NMIBC patients exposed to escalating TSD-001 dose (10-540 mg paclitaxel) until maximum deliverable dose (540 mg) demonstrated no DLT. Voiding function and bother were unchanged from baseline to completion. There was no evidence of systemic paclitaxel exposure based on a valid bioanalytical assess. No evidence of clinical recurrence or progression has been observed at a mean follow-up of 12 months. TSD-001 delivers high urinary concentrations of paclitaxel with no measurable systemic exposure, and is very well tolerated in NMIBC patients.

Funding: Lipac Oncology, LLC
22. SOS – A MULTI-INSTITUTIONAL EVALUATION OF RESCUES THERAPY WITH INTRAVESICAL GEMCITABINE AND DOCETAXOL FOR NON-MUSCLE INVASIVE BLADDER CANCER AFTER BCG FAILURE

Nathan Brooks1, Ryan Steinberg2, Lewis Thomas3, Sarah Mott4, Andrew Vitale5, Kenneth Nepple5, Michael O’Donnell6, Trafford Crump7, Eric Hyndman8, Marcus Daniels9, Max Kates1, Trinity Bivalacqua2, Jonathan Wang5, William DeWolf8, Supriya Nagaraju9, Ashish Kamat9, Donald Lamm10

1 The University of Texas MD Anderson Cancer Center, 2 University of Texas Southwestern Department of Urology, 3 Cleveland Clinic Foundation Department of Urology, 4 Holden Comprehensive Cancer Center University of Iowa, 5 University of Iowa Department of Urology, 6 University of Calgary Department of Urology, 7 Johns Hopkins University Department of Urology, 8 Beth Israel Deaconess Medical Center, 9 University of Texas MD Anderson Cancer Center, 10 BCG Oncology, Phoenix, AZ

Presented By: Nathan Brooks

**Introduction:** After the recurrence of NMIBC following initial BCG therapy, risk stratified management taking into account failure categorization, tumor characteristics, and patient factors includes radical cystectomy, clinical trial enrollment, and off-label use of intravesical chemotherapy. Many patients, however, remain unfit for or unwilling to have major extirpative surgery and thus identification of efficacious and safe alternatives to radical cystectomy is of paramount importance. Building on promising, single center data, we report the findings of a large, multi-institutional cohort of patients receiving intravesical Gemcitabine and Docetaxol after BCG failure for the first time.

**Methods:** IRB approval and data transfer agreements were established at each participating institution. Participating institutions retrospectively reviewed all patients treated with an induction course of sequential intravesical Gem/Doc for NMIBC between June 2009 and May 2018. De-identified data was maintained using REDCap software, supported by University of Iowa NIH/CTSA program grant 2UL1TR000442-06. Maintenance therapy was continued based on individual institutional protocols. Surveillance for recurrence was carried out per AUA guidelines. Recurrence and survival probabilities were plotted using the Kaplan-Meier methods and Cox regression models were used to evaluate the effect of patient, disease, and treatment variables on outcomes. Only patients with recurrent NMIBC and a history of prior BCG treatment were included in the analysis.

**Results:** Two hundred and seventy-six patients with a median follow-up of 22.9 months and a median number of 2 prior intravesical therapy induction courses were identified and included in the analysis. Only 3.3% of patients were unable to tolerate the full induction course of therapy. High grade recurrence free survival was 65% at 1 year and 52% at 2 years. Progression free survival was 97% and 93% at 1 and 2 years, respectively. On Cox regression analysis, clinical stage, number of prior BCG failures, BCG failure categorization, and treating institution did not impact disease recurrence. The addition of maintenance therapy was significantly associated with recurrence free survival (HR 2.37, 95% CI 1.36-4.11, p<0.01). Sixteen percent of patients underwent cystectomy at a median of 11.3 month from starting therapy. Bladder cancer specific mortality was 1% at 1 year and 5% at 2 years. There was no difference in outcome between patients with CIS and those with no CIS.

**Conclusion:** In this large, multi-institutional review of a heavily pretreated patient population with moderate duration follow-up, the intravesical administration of Gemcitabine and Docetaxol is safe, well tolerated, and appears efficacious in preventing recurrence without compromising progression free or cancer specific survival in patients with recurrent, NMIBC after BCG failure. It is notable that BCG failure number and category, clinical T stage, and the presence of CIS did not impact treatment success while the administration of maintenance therapy significantly improved recurrence free survival. In this era of BCG shortage and personalized medicine, prospective and mechanistic research is warranted.

**Funding:** Work supported by the John & Carol Walter Family Foundation
23. SURVIVAL DIFFERENCES AMONG PATIENTS WITH NON-MUSCLE INVASIVE BLADDER CANCER
Adam Weiner1, Joshua Meeks1, Xiaosong Meng2, Solomon Woldu2, Yair Lotan2
1 Northwestern University, 2 UT Southwestern Medical Center

Presented By: Adam Weiner

Introduction: We sought to assess contemporary survival rates for patients with non-muscle invasive bladder cancer (NMIB) using two, independently managed cancer registries in the United States.

Methods: From 2004 to 2016, we identified 110,548 patients with non-metastatic NMIBC from SEER and 321,650 from NCDB. Kaplan-Meier and Cox regression analyses stratified by clinical stage (Ta, CIS and T1) assessed overall survival (OS; SEER and NCDB) and cancer-specific survival (CSS; SEER only). Cox regressions accounted for age, race, and sex.

Results: Median age of diagnosis in NCDB was 72 years of age with median duration of follow-up of 4.3 years. Kaplan-Meier analysis showed significant differences by tumor stage (Figure 1A, Log-rank p<0.01). 10-year OS was 48%, 42% and 35% for Ta, CIS and T1, respectively. Upon multivariable analysis, OS was superior for Ta compared to CIS (hazard ratio [HR] 1.15; 95% CI: 1.12-1.18, p<0.001) and T1 (HR 1.52; 95% CI: 1.50-1.54, p<0.001). Median age of diagnosis in SEER was 67 years with median duration of follow-up of 5.6 years. Kaplan-Meier analysis showed significant differences in OS and CSS by tumor stage (Figure 1B and 2, both Log-rank p<0.01). 10-year OS was 65%, 59% and 52% and 10-year CSS was 92%, 85%, and 79% for Ta, CIS and T1, respectively. Upon multivariable analysis, CSS was superior for Ta compared to CIS (hazard ratio [HR] 1.93; 95% CI: 1.80, 2.10, p<0.001) and T1 (HR 3.30; 95% CI: 3.17, 3.44, p<0.001).

Conclusion: We provide contemporary survival rates for patients with NMIBC from two independently managed cancer registries in the US. Clinical stage prognosticates OS as a reflection of differing CSS.
Introduction: Bacillus Calmette-Guerin (BCG) is the standard of care for adjuvant intravesical therapy after transurethral resection (TURBT) of intermediate- and high-risk non-muscle invasive bladder cancer (NMIBC). However, up to 40% of high-risk patients treated with BCG will relapse. The preferred treatment for these patients is radical cystectomy (RC), though many patients refuse or are medically unfit for RC. Various intravesical therapies have been investigated for these patients, now more relevant than ever given the recent BCG shortages. Our institution recently reported a phase I study of combination cabazitaxel, gemcitabine, and cisplatin demonstrating encouraging recurrence-free rates of 89% and 83% at initial and 1-year evaluations, respectively, in a highly pretreated cohort. Off trial, our institution has begun using docetaxel in lieu of cabazitaxel given its high cost. The present study represents the first report of combination intravesical docetaxel, gemcitabine, and cisplatin (DGC) in the salvage setting for patients with BCG-refractory disease.

Methods: This was a retrospective review of all patients at our institution receiving the DGC regimen from January 2018 to July 2019. This regimen included a 6-week induction of separate-day weekly docetaxel (80mg), weekly gemcitabine (1000mg or 2000mg), and biweekly cisplatin (100mg) to reduce risk of platinum-induced hypersensitivity. In patients with treatment response, a maintenance regimen of separate-day monthly docetaxel (80mg) and monthly gemcitabine (1000mg) was initiated. Cystoscopy and urine cytology were performed every 3 months. All patients had normal CT or MRI upper urinary tract imaging within 3 months of starting the DGC regimen. Primary outcome was recurrence, defined as biopsy-proven cancer of any grade or stage. Progression was defined as =T2 disease or metastases as detected by biopsy, RC pathology, or imaging.

Results: A total of 10 patients received the DGC regimen, all of whom were male. Median age was 70 years (range 57-85 years). This highly pretreated cohort included 90% (9/10) of patients previously receiving at least two BCG induction courses +/- interferon and 30% (3/10) previously receiving intravesical chemotherapy. Prior to DGC, all patients had high-grade disease, with 2 patients having T1+Cis, 3 patients with Cis only, 1 patient with T1 only, 1 patient with Ta+Cis, and 3 patients with Ta only. Induction treatment was fully completed as planned in 80% (8/10) of patients, as one patient did not receive the last docetaxel and gemcitabine doses due to local symptoms (frequency, urgency, dysuria) and another patient stopped cisplatin after one treatment due to local symptoms (frequency, dysuria) and fatigue. Of the seven patients who have at least undergone the first surveillance cystoscopy (followup median 41 weeks, range 23-74 weeks), two patients have recurred: one at 17 weeks with LG Ta and was continued on maintenance, and the other at 26 weeks with HG T1 who underwent DGC reinduction with a response and was started on maintenance. At last followup, all seven patients were still on maintenance treatment. No patients have experienced progression nor undergone RC.

Conclusion: This novel salvage regimen of triple intravesical therapy has promising short-term results in a highly pretreated BCG-refractory patient cohort, with all patients experiencing initial downgrading and/or downstaging and all continuing on maintenance treatment. In this period of recent BCG shortages, this regimen may prove to be a reasonable treatment for BCG-naive and refractory patients.
25. IMPACT OF STAGE PROGRESSION AS TRIGGER FOR CYSTECTOMY IN PATIENTS ON BCG THERAPY
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Presented By: Justin Matulay

Introduction: Determining when BCG therapy for NMIBC has failed and when a patient should proceed with radical cystectomy (RC) is complex decision. While progression to muscle invasive bladder cancer (MIBC) from NMIBC is a definite indication for RC, more recent definitions have also suggested impact of stage/grade progression, even short of MIBC. Using a contemporary cohort of NMIBC patients who received – at a minimum – a full induction course of BCG, we aimed to explore disease outcomes related to progression to MIBC prior to definitive surgery.

Methods: We retrospectively identified all NMIBC patients treated with at least 1 full induction course of BCG (minimum 5 of 6 planned instillations) at our institution between 2006 and 2018 (n=583). Patients ultimately undergoing RC as definitive therapy were included in this analysis. Overall median follow-up was timed from first induction BCG instillation to last contact or death. Progression refers to the definition proposed by the International Bladder Cancer group, which includes any increase in stage (i.e. CIS to Ta, Ta to T1, etc.) or grade (low-grade to high-grade). Metastasis free survival (MFS) and overall survival (OS) were timed from the date of RC. Kaplan-Meier estimates with log-rank test were used to analyze MFS and OS outcomes with a p-value of less than 0.05 considered statistically significant.

Results: A total of 89 patients underwent RC with a median follow-up of 54.3 months. The median time from initiation of BCG to RC was 12.3 months, and did not differ significantly based on initial stage at diagnosis (cTa=11.8, cTis=11.3, cT1=14.0). Table 1 includes baseline clinicopathologic information. In the T1 patients, 22% (11/51) were clinically upstaged to MIBC before RC, whereas only 14% of Ta (4/29) and 11% of Tis (1/9) were. Pre-RC disease progression of any kind (stage and/or grade) occurred in 38% (34/89). Overall, any disease progression prior to RC did not have a statistically significant impact on MFS or OS on Kaplan-Meier analysis (log-rank p=0.20 and p=0.12, respectively). Similarly, patients progressing to a non-MIBC stage (i.e. Ta to T1; 5-yr MFS 93%, OS 77%) showed no difference in survival when compared to the non-progressors (5-yr MFS 85%, OS 72%). When clinically NMIBC (=cT1) was compared to clinically MIBC (=cT2), MFS was significantly longer in the former group (log-rank p=0.05; 5-year MFS 90% v. 67%); Figure 2. There was not a significant difference for OS (log-rank p=0.63) between groups despite an initial separation in curves around 5-years (5-year OS 76% v. 57%).

Conclusion: In this contemporary cohort of NMIBC patients treated with induction BCG followed by definitive RC upon BCG failure at a high-volume center, we have found that progression to muscle-invasive disease prior to RC is associated with worse 5-year MFS (90% v. 67%) and OS (76% v. 57%), though the latter difference was not statistically significant. Progression to anything less than MIBC before RC did not change survival outcomes significantly as compared to patients who did not progress. Our results suggest that there is a window of opportunity in which definitive surgical intervention for NMIBC provides a benefit that is otherwise lost after progression to MIBC, though progression to higher stage/grade NMIBC does not confer the same poor prognosis.

Funding: Wayne B. Duddleston Sr. Professorship
Introduction: The American Urological Association (AUA) introduced evidence-based guidelines for the management of non-muscle invasive bladder cancer (NMIBC) in 2016. These advocate a risk-adapted approach to NMIBC diagnosis, treatment, and surveillance, weighing the risk of progression to muscle-invasive disease against the cost and morbidity of specific interventions. Although not designed to replace clinical judgement, these guidelines provide a useful framework for managing NMIBC. We sought to assess the implementation of the AUA NMIBC guidelines in the three years since their release among urologists who are members of the Society of Urologic Oncology (SUO).

Methods: An SUO Survey Committee-approved survey was distributed to 747 members in December 2018, with a closing date in February 2019. This 14-question online survey (Qualtrics, SAP SE, Germany) consisted of 38 individual items addressing specific statements from the AUA NMIBC guidelines within 3 broad categories: initial diagnosis, surveillance, and imaging/biomarkers. Where applicable, questions included sub-categories for low-, intermediate-, and high-risk NMIBC. Adherence to guidelines was assessed by dichotomizing responses to each item that was related to recommended action statement within the guidelines. Statistical analysis was applied using Pearson’s chi-squared test, where a p-value of <0.05 was considered statistically significant.

Results: Complete survey responses were received from 121 (16.2%) members. One-hundred fourteen (94%) respondents listed their primary specialty as urologic oncology; 96 (84%) respondents completed urologic oncology fellowship (Figure 1). A total of 43 (35.5%), 45 (37.2%) and 86 (71.1%) of respondents were early career (1-5yrs), late career, and in academic practice, respectively. The mean individual rate of adherence to guidelines across all risk-categories was 71%, with better adherence for intermediate- and high-risk NMIBC (82% and 76%, respectively) than low-risk NMIBC (58%). The lack of adherence among low-risk patients tended to involve overtreatment: 77% of clinicians ordered routine upper tract imaging, 53% routinely ordered urinary cytology, and 51% performing follow-up surveillance at intervals of less than 1 year in the absence of recurrences. There were no statistically significant differences in adherence with regards to upper tract imaging and use of urine cytology for low-risk patients based on years in practice, fellowship training, or practice setting (Table 1). Adherence to guideline recommended cystoscopic surveillance intervals for low-risk disease differed based on clinical experience (60.9% [<10 years] v. 36.8% [=10 years], p=0.01) and type of fellowship training (55.2% [urologic oncology] v. 28.0% [none/other], p=0.02).

Conclusion: Of respondents, adherence to guidelines across all risk-categories was 71% with improved adherence among intermediate and high-risk patients. Decreased adherence observed among low-risk patients resulted in excessive use of cytology, imaging, and surveillance cystoscopy. These results support targeted interventions to support high-value care among low-risk patients.

Funding: Wayne B. Duddleston Sr. Professorship
27. FGFR3-TACC3 GENE FUSION AS THE SOLE DRIVER OF UROTHELIAL TRANSFORMATION AND TUMORIGENESIS
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Presented By: Aleksandra Walasek

Introduction: Due to the high frequency of dysregulated activity, mostly through activating mutations and over-expression, FGFR3 has been implicated to play a key oncogenic role in bladder cancer. The recent discovery of genomic FGFR3 rearrangements, mainly FGFR3-TACC3 fusions, identified in a subset of bladder tumors provides another mechanism for aberrant FGFR3 activation. In this study we sought to explore the role of activating FGFR3-TACC3 fusion in urothelial transformation and tumorigenesis using next-generation sequencing.

Methods: All patients with urothelial tumors that underwent next-generation sequencing using the Memorial Sloan Kettering-Integrated Mutation Profiling of Actionable Cancer Targets (MSK-IMPACT) assay were identified from our prospectively-maintained institutional database. We focused our analysis on genes available on our targeted panel, which have been shown to be commonly altered in urothelial carcinoma.

Results: A total of 985 samples from unique patients with non-muscle invasive and muscle invasive urothelial carcinoma were sequenced. FGFR3 alteration alone or with co-alterations was identified in 302 samples (31%) which was consistent with previous reports. Gene fusions were observed in 34 (4%) of the sequenced samples. FGFR3-TACC3 fusion was the most common gene rearrangement and was identified in 32 (3%) of the samples. Additional gene fusions observed in the cohort were FGFR3-JAKMIP1 and TNIP2-FGFR3 and occurred in single patient samples. Interestingly, tumors harboring FGFR3-TACC3 fusion as well as other genomic alterations ranged from low grade, non-invasive (pTa LG) to high grade, invasive (pT3 HG) tumors, while tumor samples with FGFR3-TACC3 fusion being the only alteration were all classified as low grade, non-invasive urothelial carcinoma (pTa LG).

Conclusion: Our study shows that FGFR3-TACC3 gene fusion may be sufficient to initiate the low grade, non-invasive urothelial carcinoma, however additional mutations are required to develop invasion. Currently we are evaluating other genetic alterations observed in high grade tumors with FGFR3-TACC3 fusion to understand how progression of bladder cancer can be more accurately predicted clinically.

Funding: This work was supported by the Sidney Kimmel Center for Prostate and Urologic Cancers, the Michael and Zena Wiener for Therapeutics Program in Bladder Cancer, Pin Down Bladder Cancer, Cycle for Survival, the Marie-Josee and Henry R. Kravis Center for Molecular Oncology, NIH/NCATS Grant Number UL1-TR002384, and the National Cancer Institute Cancer Center Core Grant Number P30-CA008748.

28. EFFECT OF PRE-EXISTING CONDITIONS ON BLADDER CANCER DIAGNOSIS: A COHORT STUDY USING ELECTRONIC PRIMARY CARE RECORDS
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Presented By: Madeline Carney

Introduction: Existing comorbid diseases may delay the diagnosis of bladder cancer. This study tested two hypotheses. First, there is an association between existing comorbidity burden and advanced-stage cancer, where the conditions compete for clinical attention and cancer symptoms are overlooked. Second, there is an association between the presence of comorbid conditions that mimic the patient’s first possible symptom of cancer and advanced-stage cancer, through symptom misattribution.

Methods: This population-based, observational study was set in The Clinical Practice Research Datalink (CPRD; a dataset of UK primary care medical records) with linkage to Public Health England National Cancer Registration and Analysis Service data. We studied adults (≥40 years) with an incident bladder cancer diagnosis (ICD10 code C67) between 01/01/2000 and 12/31/2015. CPRD records made in the year before cancer diagnosis were searched for codes indicating attendance for bladder cancer symptoms (hematuria, dysuria, and abdominal mass). CPRD records made in the 2 years before the earliest cancer symptom were searched for diagnostic codes for common comorbidity conditions (e.g., diabetes and cardiovascular diseases) and for conditions sharing symptoms with bladder cancer (urinary tract infection, sexually transmitted disease, kidney disease, tuberculosis, sickle cell disease, nephrolithiasis, prostatitis, menorrhagia, endometriosis, benign prostatic hyperplasia, uterine fibroids, aortic aneurysm, and retention). The data were analyzed using logistic regression. The outcome variable was stage of bladder cancer diagnosis: advanced (3 or 4) vs early (1 or 2). Explanatory variables included count of pre-existing comorbid conditions, and an “alternative-explanations” variable indicating when a patient’s comorbidity condition could explain their first possible bladder cancer symptom. The model adjusted for age, sex, and deprivation.

Results: The analysis included 1,469 (76.4% male) patients, of whom 270 (18.4%) had advanced-stage cancer. 1,178/1,469 (80.2%) patients (73.6% male) had 1 or more comorbid conditions. 616/1,469 (41.9%) patients (64.8% male) had alternative explanations for the first possible symptom of cancer. Women were more likely than men to be diagnosed with advanced-stage cancer (odds ratio 1.62; 95% confidence interval 1.20 to 2.18; <i>p</i>&lt;0.001). Alternative explanations for the first possible symptom of bladder cancer were strongly associated with advanced-stage diagnosis similarly in men and women (1.69, 1.20 to 2.39, <i>p</i>&lt;0.003). Count of conditions was not associated with stage at diagnosis (<i>p</i>&lt;0.64).

Conclusion: Existing comorbid diseases that mimic the presentation of bladder cancer are associated with advanced stage at diagnosis. Women are more likely than men to be diagnosed with advanced-stage cancer, but the effect is not driven by alternative explanations.

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29. 2019 BLADDER CANCER PATIENT SURVEY NETWORK RESULTS AND FUTURE DIRECTIONS
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Presented By: Judy Hamad

Introduction: Incorporating patients in the research process and including patient-centered outcomes in studies has become an important standard in research, as it leads to meaningful results that help patients make better healthcare decisions. The Bladder Cancer Advocacy Network’s (BCAN) Patient Survey Network (PSN) established a diverse and engaged bladder cancer patient population who contribute to the prioritization of bladder cancer research topics through annual surveys and summit meetings.

Methods: Through the PSN, patient participants were asked to report age, gender, race, highest level of education, household income, histology (if known), bladder cancer stage, treatments received, and date of last treatment. Caregiver participants were asked to report on these measures on behalf of their loved ones. Respondents were then asked to rank a series of stakeholder-identified research questions from most important (#1) to least important (#5). Respondents were limited to prioritizing questions within their own disease stage category and had the option to include their own prioritized question via free-text. Free-text questions were categorized by bladder cancer stage as well as by theme. Compared to years one and two of the PSN, this iteration of the PSN also included prioritization of upper tract urothelial cancer research topics.

Results: By year three of the PSN, the network enrolled over 1300 patients and caregivers. 405 patients and caregivers responded to the 2019 research prioritization survey. The average age of respondents was 67 years. The majority of respondents were male (62.5%) with non-muscle invasive bladder cancer (62.6%) diagnosed in the past five to ten years. 80.5% of respondents reported receiving greater than one form of treatment, with transurethral resection of bladder tumor (TURBT) and intravesical therapy being the most commonly received treatments. Prioritization rankings of research questions were stratified by disease stage: A) non-muscle invasive bladder cancer (NMIBC), B) muscle-invasive bladder cancer (MIBC), C) metastatic bladder cancer, and D) upper tract urothelial cancer (UTUC) (Figure 1). For NMIBC, the highest-ranked question involved the study of biomarkers to predict cancer recurrence (average rank of 1.82 on a scale of 1-5). Respondents with MIBC, metastatic bladder cancer, and UTUC all prioritized a similar research question regarding strategies to help patients understand their cancer prognosis (mean ranking 1.95 on a scale of 1-5 for MIBC; mean ranking 1.85 and 1.94 on a scale of 1-4 for metastatic bladder cancer and UTUC, respectively). Free-text questions submitted by respondents were similar to those included in previous PSN iterations.

Conclusion: Patients and caregivers are in a unique position to propose and advocate for inclusion of patient-center outcomes in research, given personal experience and stake in advancing care for the disease or treatment in question. The 2019 PSN highlights patient-prioritized research questions for a large group of bladder cancer patients and caregivers representing all bladder cancer disease stages. Prioritized research questions from this study, as well as a consolidated list of respondent-submitted research questions, will be distributed to funding agencies to guide future patient-centered bladder cancer studies.
30. TOTAL MEDICAL CARE COSTS IN THE YEAR FOLLOWING CYSTECTOMY AMONG BLADDER CANCER PATIENTS WITH A URINARY DIVERSION

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Presented By: Matthew Banegas

Introduction: In the United States (U.S.), bladder cancer is among the most costly cancers, with total national expenditures estimated at $3.98 billion in 2010 and projected to reach $5.38 billion by 2020. Approximately 80,470 individuals will be diagnosed with bladder cancer in 2019, among whom an estimated 10,000 will undergo a radical cystectomy and urinary diversion (UD) surgery. The majority of these patients will receive an ileal conduit, while about 20% will have a neobladder constructed. Though prior studies have estimated medical care costs of bladder cancer patients following radical cystectomy, there is limited information on costs by UD type, specifically. Efforts to understand the potential benefits and costs associated with different UD types are important to assess outcomes between treatment strategies among bladder cancer patients, and to inform efforts to reduce costs and burdens of care after cystectomy. To address the knowledge gap in this area, we estimated total health care costs in the year following radical cystectomy among bladder cancer patients treated with cystectomy and UD, comparing costs between ileal conduit and neobladder patients.

Methods: The Bladder Cancer Quality of Life (BCQOL) Study included patients diagnosed with bladder cancer who underwent radical cystectomy and received an ileal conduit (IC, n=821) or neobladder (NB, n=181) urinary diversion at one of three integrated health systems. Data for this study were obtained from clinical and administrative databases and included demographic, health plan coverage, clinical and utilization. For each patient, we summarized monthly counts of inpatient days, same day surgeries, hospital ambulatory encounters, emergency room visits, and outpatient clinic visits divided into the following groups: primary care, oncology, nephrology, urology, cardiology and other specialty visits. Cost coefficients were then applied to the utilization counts and summed to obtain total medical care costs, from the health system perspective. Monthly medical care costs per patient were estimated from the month of radical cystectomy through the 11 months following cystectomy, separated into quarters: Quarter 1=month of radical cystectomy (month 0) through month 2 following cystectomy; Quarter 2=months 3-5 following cystectomy; Quarter 3=months 6-8 following cystectomy; Quarter 4=months 9-11 following cystectomy. Multivariable generalized linear models with a gamma distribution and log link were used to estimate mean monthly total medical care costs per quarter (2012 USD$) and 95% confidence intervals [95% CI]. Cost estimates by UD type, tumor stage at cystectomy, presence of any complications, surgical approach, and death in quarter were obtained based on the marginal means from the multivariable model.

Results: Compared to patients who received an IC, those with an NB were more likely to be younger, female, have a lower comorbidity burden, have lower tumor stage at cystectomy and have underwent robotic surgery. In multivariable analysis, mean monthly cost totals per quarter were not significantly different between IC and NB patients in the 12 months following cystectomy. Overall, mean monthly total costs were highest in Quarter 1 (IC patients mean=$33,751 and NB patients mean=$37,061) and decreased each quarter thereafter: Quarter 2 (IC patients mean=$4,823 and NB patients mean=$3,621); Quarter 3 (IC patients=$3,630 and NB patients $3,018) and Quarter 4 (IC patients=$2,557 and NB patients $2,462). Patients with any complications had statistically significantly higher mean monthly total costs per quarter than those without complications (all p<0.001): Quarter 1 (any complications=$37,646 vs. no complications=$25,315); Quarter 2 (any complications=$5,562 vs. no complications=$1,705); Quarter 3 (any complications=$4,262 vs. no complications=$963); and Quarter 4 (any complications=$2,851 vs. no complications=$931). Compared to patients who underwent robotic surgery, those patients who did not undergo robotic surgery had similar mean monthly total costs in Quarter 1 (robotic mean=$33,108 vs. non-robotic mean=$34,479) and Quarter 2 (robotic mean=$5,298 vs. non-robotic mean=$4,486; although, mean monthly total costs for patients with robotic surgery were statistically significantly lower in Quarter 3 ($2,025) than for those without robotic surgery ($3,751, p<0.05) and remained lower (not statistically significant) in Quarter 4 (robotic mean=$1,895 vs. non-robotic mean=$2,636).

Conclusion: In this large retrospective, observational study assessing medical care costs of bladder cancer patients by type of continent urinary diversion, we found that costs in the year following radical cystectomy were similar between patients who received an ileal conduit and those who received a neobladder. Our study is among the first to estimate the economic burden to the health care system of bladder cancer patients who receive an ileal conduit or a neobladder, by UD type, addressing an important knowledge gap about cost patterns between different treatment approaches. We found that costs in the year following radical cystectomy were similar between patients who received an ileal conduit and those who received a neobladder, and that higher than average costs were driven, in part, by the occurrence of post-cystectomy complications. These findings highlight potential costs drivers that may serve as valuable targets for future cost containment strategies. Future research should explore patient reported outcomes and costs, by UD type, to further provide valuable information that may be used in treatment decision-making and cost conversations.

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31. SIMILAR SURVIVAL OUTCOMES AMONG CHEMORADIATION AND NEOADJUVANT CHEMOTHERAPY WITH RADICAL CYSTECTOMY FOR SMALL CELL BLADDER CANCER
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Presented By: Alejandro Abello

Introduction: Small cell bladder cancer is associated with highly aggressive clinical behavior and poor long-term survival. Nonetheless, in patients with clinically localized disease, local therapy has been historically recommended following initial systemic therapy. We aimed to assess differences in survival outcomes of systemic therapy followed by radical cystectomy or by radiation therapy.

Methods: We queried the National Cancer Database to evaluate patients with clinical stage I-III bladder cancer with small cell histology. The primary study outcome was overall survival between chemoradiation compared to neoadjuvant chemotherapy followed by radical cystectomy. We assessed overall survival during follow-up and performed multiple regression Cox models to adjust for the effects of independent variables that may affect clinical outcome and choice of therapy (age, race, Hispanic origin, tumor size, sex, median income, urban/rural habitation, Charlson comorbidity index, presence of lymph node positive disease).

Results: We identified 756 patients with stage I-III small cell bladder cancer treated with chemoradiation in 410 (54.23%) and neoadjuvant chemotherapy followed by cystectomy in 346 (45.77%). Compared to chemoradiation, patients that received neoadjuvant chemotherapy with cystectomy were younger (mean age: 65.2 ± 9.1 vs 71.2 ± 11.5; p <0.01) and had smaller tumor size (RT mean size in cm: 4.2 ± 2.4 vs 5.4 ± 7.7; P: 0.02). Distribution of sex, race, Charlson comorbidity index or stage was not significantly different between groups. During follow-up, 90-day mortality was significantly higher in the cystectomy group (4.79% vs 1.58%; P:0.02). After controlling for demographics, disease and treatment characteristics, hazard ratio for overall survival was not significantly different between treatment groups (HR: 0.91, CI: 0.66-1.25; P: 0.5).

Conclusion: Among patients with primary small cell bladder cancer overall survival appeared similar between radiation and radical cystectomy after systemic therapy.

32. GENDER DIFFERENCES IN PERIOPERATIVE CYSTECTOMY OUTCOMES IN NEW YORK STATE
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Presented By: Srinath Kotamarti

Introduction: Although bladder cancer and radical cystectomy is more common in men, females have worse oncologic outcomes. This has been attributed to both social factors including delayed diagnosis and biologic factors such as the presence of adverse histologic variants. On the other hand, less is known about outcomes after surgery. In this study, we examined gender differences in perioperative outcomes following radical cystectomies in New York State.

Methods: We examined the New York State Statewide Planning and Research Cooperative System (SPARCS) inpatient discharge database from 2010 to 2016. The database was searched for patients with a Clinical Classification Software (CCS) Diagnosis Code of Cancer of the Bladder and All Patient Refined Diagnosis Related Group (APR-DRG) of major bladder procedures. To mitigate the impact of surgeon experience, surgeons performing 4 or more cystectomies per year were included. Chi-Square analyses were performed to compare demographic and perioperative characteristics between males and females.

Results: We identified 3,439 surgeries including 622 (18.1%) in females and 2817 (81.9%) in males. Cases were performed by 37 high-volume surgeons with a median of 58 cases (IQR 42 to 98). Age and preoperative severity of illness were similar between genders (p>0.05). More females were non-Caucasian (19.8% vs. 16.4%, p=0.04). Female gender was associated with higher rates of discharge to extended post-admission care (16.1% vs 10.1%, p<0.0001) and higher rates of any adverse event [death, non-home discharge or extended LOS beyond 75th percentile] (30.9% vs 26.2%, p=0.017). Furthermore, female patients also were significantly more likely to accrue higher than average hospital charges (39.9% vs. 34.9%, p=0.021) and hospital costs (44.5% vs. 39.0%, p=0.011) during the hospitalization, as well.

Conclusion: Female patients undergoing radical cystectomies by high volume surgeons in New York State had higher adverse events and higher healthcare costs compared to males. These findings justify more rigorous study of the etiology of this gender discrepancy and its impact on bladder cancer survival outcomes.
33. PREDICTORS OF ADVERSE EVENTS FOLLOWING RADICAL CYSTECTOMY BY HIGH VOLUME SURGEONS IN NEW YORK STATE

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Presented By: Srinath Kotamarti

Introduction: Radical cystectomy (RC) with urinary diversion is the gold standard management of invasive bladder cancer. It has been shown that higher surgeon volume improves perioperative outcomes, but less is known about the impact of patient and social factors on outcomes in the high volume setting. We studied a contemporary, state-wide cohort of cystectomy patients to better define predictors of adverse events among high volume surgeons.

Methods: We examined the New York State Statewide Planning and Research Cooperative System (SPARCS) inpatient discharge database from 2010 to 2016. The database was searched for patients with a Clinical Classification System (CCS) Diagnosis Code of Cancer of the Bladder and All Patient Refined Diagnosis Related Group (APR-DRG) of major bladder procedures. Surgeons meeting previously described criteria for high volume (4-6 cases per year) or very high volume (at least 7 cases per year) were included. An adverse event was defined as mortality during admission, length of stay (LOS) beyond the 75th percentile or discharge to an extended care facility. Univariate and multivariate logistic regression were performed to identify significant predictors of adverse events.

Results: We identified 3,439 cystectomies in the 7-year period. 50.5% of patients were 70 years or older. 2817 (81.9%) were male. 83.0% of patients were Caucasian, 4.4% were African American and 12.6% were identified as neither. 61.8% of cases were performed in New York City. Cases were performed by 37 urologists, including 14 high volume and 23 very high volume surgeons. Median number of cases per surgeon was 58 (IQR: 42 to 98). There were 36 (1%) mortalities during the operative admission. Median LOS was 7 days (IQR: 6 to 11). 11.2% of patients were discharged to an extended care facility. On multivariate analysis, age 70 years or older (p<0.0001, OR 2.052), female gender (p=0.005, OR 1.332), preoperative severity of illness risk (p<0.0001, OR 4.661) and lower hospital volume (p<0.0001, OR 1.45) predicted an adverse event. Caucasian race and very high physician volume were associated with lesser adverse events on univariate, but not multivariate analysis.

Conclusion: Among high volume surgeons in New York State, patient factors including age, gender, and severity of illness impacted adverse events following cystectomy. While lower hospital volume contributed to adverse events, higher surgeon volume was not protective.
34. BLADDER CANCER OUTCOMES FOLLOWING MEDICAID EXPANSION: NO INCREASE IN DIAGNOSIS AND TREATMENT?
Oliver Ko, Adam Weiner, Amanda Vo, Anuj Desai, Shilajit Kundu
Northwestern University Feinberg School of Medicine
Presented By: Oliver Ko

Introduction: Patients with bladder cancer who have insurance coverage experience improved outcomes. Medicaid expansion under the Affordable Care Act aimed to increase insurance coverage and improve access to care. The association between Medicaid expansion and insurance coverage and time to treatment for those with bladder cancer has not been investigated.

Methods: A large, US-based cancer registry was utilized to evaluate the association between Medicaid expansion and rates of insurance, stage of cancer at diagnosis, and time to treatment for those diagnosed with bladder cancer. We compared these outcomes in patients aged 18-64 in non-expansion states (n = 16,602) to those in expansion states (n = 15,921) before (years 2012-2013) and after (years 2015-2016) Medicaid expansion by calculating adjusted difference-in-differences (DIDs) using multivariable linear regression.

Results: Overall percentage of those without insurance coverage did not change following expansion on multivariable regression (-0.65%, 95% confidence interval [CI] -1.71 to 0.41, p = 0.2). Similarly, the percentage of patients with bladder cancer presenting with Stage II disease (0.02%, 95% CI -1.91 to 1.95%, p = 0.9)) or metastatic disease (-0.07%, 95% CI -1.14 to 1.00%, p = 0.9) did not change. Treatment with cystectomy or systemic therapy >60 days after diagnosis of Stage II disease also did not change (1.48%, 95% CI -3.29 to 6.25%, p = 0.5). On subgroup analysis of a cohort of patients living in regions of low income, no changes were seen for rates of no insurance coverage, Stage II disease, metastatic disease, or time to treatment (all p > 0.1)

Conclusion: Medicaid expansion did not result in changes in insurance coverage, stage at diagnosis, or time to treatment for patients with newly diagnosed bladder cancer residing in expansion states relative to non-expansion states. Longer-term follow-up should investigate why insurance coverage following Medicaid expansion did not increase for bladder cancer.
35. IMPLICATIONS OF DISCORDANT DIAGNOSTIC TO FINAL SURGICAL PATHOLOGY IN HIGH-GRADE UPPER TRACT UROTHELIAL CARCINOMA
Ross Liao, Joseph Cheaib, Mohit Gupta, Max Kates, Michael Johnson, Noah Hahn, Jean Hoffman-Censits, Trinity Bivalacqua, Phillip Pierorazio
Johns Hopkins School of Medicine
Presented By: Ross Liao

Introduction: Accurate diagnostics to guide management are a technical challenge for many patients with upper tract urothelial carcinoma (UTUC). Some patients who undergo radical nephroureterectomy (RNU) and ultimately have high-grade (HG) UTUC can have non-diagnostic or low-grade (LG) UTUC (discordant pathology) at initial endoscopic evaluation. Stage distribution and survival of HG UTUC patients with discordant pathology may have important implications in the management of HG UTUC.

Methods: We retrospectively analyzed 191 UTUC patients with HG disease on surgical pathology who underwent endoscopic diagnostic biopsies prior to RNU from 2003 to 2018. The proportion of patients with locally-advanced (=pT2) disease on final pathology was compared in those with concordant versus discordant ureteroscopic pathology using Pearson’s chi-squared test. Overall survival estimates for the two groups were obtained using the Kaplan-Meier method and compared using the log-rank test.

Results: There were 58 patients (30.1%) with discordant pathology and 133 patients with concordant pathology between ureteroscopy and RNU. No significant difference in overall survival was found between the concordant and discordant groups [log rank P=0.9; HR=1.01 (95% CI: 0.62-1.66, P=0.95)]. Mean time from ureteroscopic biopsy to RNU was longer by 6 days for patients with discordant pathology (p=0.8). Proportion of locally-advanced (=pT2) disease was not significantly different between patients with concordant and discordant pathologies (55.6% and 48.3% respectively, P=0.3). This was also seen after controlling for neoadjuvant chemotherapy use. A sensitivity analysis using preoperative urine cytology grade rather than biopsy grade showed no significant difference in overall survival [log rank P=0.8; HR=0.93 (95% CI: 0.56-1.54, P=0.78)] or proportion of locally-advanced (=T2) disease (P=0.1) between discordant (high-grade urine cytology) and discordant (low-grade/ataypical/non-diagnostic urine cytology) groups. Three-group sensitivity analysis combining biopsy and urine cytology grades (both high-grade vs. both low-grade/ataypical/non-diagnostic vs. one high-grade and one low-grade/ataypical/non-diagnostic) also showed no significant difference (P=0.08).

Conclusion: Technical limitations in endoscopy can yield substantial rates of discordance between ureteroscopic and RNU pathology. HG UTUC patients with concordant compared to discordant pathology, however, have no significant differences in overall survival and =pT2 disease prevalence. These results suggest the importance of prompt evaluation and consideration for RNU in patients for whom there is a high clinical suspicion of HG disease, despite low-grade or non-diagnostic biopsy or urine cytology results.
36. PREDICTIVE MODEL FOR SYSTEMIC RECURRENCE FOLLOWING CISPLATIN-BASED NEOADJUVANT CHEMOTHERAPY AND RADICAL NEPHROURETERECTOMY FOR UPPER TRACT UROTHELIAL CARCINOMA

Rashed Ghandour, Yuval Freifeld, Nirmish Singla, Xiaosong Meng, Aditya Bagrodia, Solomon Woldu, Vitaly Margulis, Firas Petros, Surena Matin, Jay Raman

1 UT Southwestern Medical Center, 2 MD Anderson Cancer Center, 3 Penn State Health Milton S. Hershey Medical Center

Presented By: Rashed Ghandour

Introduction: Based on the established benefit of neoadjuvant chemotherapy (NAC) in urothelial cancer of the bladder, NAC is increasingly used prior to radical nephroureterectomy (RNU) for upper tract urothelial carcinoma (UTUC). Systemic recurrence (SR) following RNU carries a dismal prognosis. We sought to determine factors that predict higher risk of recurrence following NAC and RNU.

Methods: We retrospectively evaluated data from a multi-center database of UTUC patients who had NAC followed by RNU. Patients who received cisplatin-based NAC were included. Final pathology at RNU was dichotomized into less than pT2 versus pT2 or more, and used as such in the analysis. SR was defined as any recurrence outside the urinary tract. Univariate (UV) and multivariate (MV) Cox regression analysis was performed to identify factors associated with SR following NAC and RNU. Factors identified on UV analysis as significant for recurrence were grouped into 3 groups (0, 1, 2-4 risk factors) and evaluated for recurrence-free survival using the Kaplan-Meier analysis and log-rank test.

Results: 76 patients received cisplatin-based NAC prior to RNU between 2004 and 2016. Median age was 67.0 years (IQR=61.3-73.5), 46 (61%) and 30 (39%) patients received MVAC and GC, respectively. Final pathological stage was <T2 in 38 patients and =T2 in 37 patients. Overall 25% (19/76) had SR, 18 of those were within 19 months. On UV analysis, final specimen variables such as stage of T2 or more, lymphovascular invasion (LVI), nodal involvement, and positive surgical margin were all associated with higher recurrence. MV model including the identified pathological risk factors had an area under the curve of 0.862 suggesting high predictive ability. Stratifying according to number of risk factors, the 2-year recurrence-free survival was 100%, 80%, and 40.9% for zero, 1 and, 2-4 risk factors respectively (log-rank <0.001)

Conclusion: We created a predictive model for SR following NAC and RNU for UTUC to direct decision-making after surgery. Based on the above model, a pathology of muscle invasive UTUC is a strong predictors of SR. When combined with LVI, positive surgical margins and nodal involvement, the model can predict the risk of SR with high accuracy.
37. DECISION FATIGUE CONTRIBUTES TO LOW-VALUE PROSTATE CANCER SCREENING PRACTICES BY OUTPATIENT PROVIDERS

Trevor C. Hunt¹, Brock B. O’Neil¹, Jacob P. Ambrose², Benjamin Haaland³, Heidi A. Hanson⁴, Norman J. Waitzman⁵

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Presented By: Trevor C. Hunt

Introduction: Low-value prostate-specific antigen (PSA) testing generates financial waste and can be harmful to patients, yet it accounts for up to half of prostate cancer (PCa) screening. Decision fatigue, or the progressive decrease in consistency and favorability of choices with repetitive decision making, has been observed in breast and colorectal cancer care. We sought to determine whether low-value PSA testing patterns by outpatient providers are consistent with decision fatigue.

Methods: This retrospective cohort study included men without PCa from a large academic health system from July 1, 2011 through June 30, 2018. Outpatient encounters were stratified by clinical guidelines as whether a PSA test order would be appropriate or low-value. The primary endpoint was whether or not a PSA test was ordered. Descriptive statistics were compiled for patient, provider, and appointment factors. Logistic generalized estimating equations were used to analyze PSA test likelihood by appropriateness, with spline functions used to represent trends over the course of the day.

Results: A total of 1,667,628 outpatient encounters were included. A PSA test was ordered during 3.57% of encounters when it would be considered appropriate and during 1.72% when it was low-value. Overall, the greatest number of PSA tests were ordered during early morning encounters (Figure). After multivariable adjustment, the likelihood of an encounter resulting in a PSA test was greatest at 8:00 am, tapering off by 11:00 am (OR 0.6) and persisting through 4:00 pm (OR 0.6; Table). This sharp temporal decline was present for encounters where PSA testing was both appropriate and low-value.

Conclusion: Decision fatigue appears to play a role in low-value PSA testing practices as evidenced by a sharp decline in ordering as the day progresses. Decision fatigue appears to similarly affect PSA testing when it might be appropriate or low-value. Future efforts to improve PSA testing might employ clinical decision support, which has been shown to be effective in the setting of decision fatigue.

Funding: Research reported in this abstract was supported by the National Cancer Institute of the National Institutes of Health under Award Number K08CA234431. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.
38. CHANGES IN PROSTATE-SPECIFIC ANTIGEN AT TIME OF PROSTATE CANCER DIAGNOSIS FOLLOWING MEDICAID EXPANSION IN YOUNG MEN

Adam Weiner, Amanda Vo, Anuj Desai, Edward Schaeffer
Northwestern University

Presented By: Adam Weiner

Introduction: We hypothesized Medicaid expansion under the Affordable Care Act resulted in improved access to prostate cancer screening. We assessed this by measuring the percentage of men presenting with high-risk PSA (≥20 ng/ml) at the time of prostate cancer diagnosis in a national cohort.

Methods: From the National Cancer Database, we assessed 122,324 aged <65 years who were diagnosed with prostate cancer pre-(2012-2013) or post-expansion (2015-2016). Difference-in-difference (DID) analyses adjusting for sociodemographics using linear regression were used to compare PSA at diagnosis between patients living in states that did and did not expand Medicaid on January 1, 2014.

Results: The percentage of men presenting with PSA =20ng/mL at diagnosis was 19% in both expansion and non-expansion states (p=0.4). The percentage of men in expansion states presenting with PSA =20 ng/mL declined 2.33% (95% CI -3.21% to -1.44%, p<0.001) relative to that of men in non-expansion states. Medicaid expansion was not associated with significant changes in metastatic disease at diagnosis (p=0.3) or rates of no insurance (p=0.061). In subset analyses, men living in regions of low annual household income did not experience a change in PSA=20 ng/mL (-1.07%, 95% CI -3.29% to 1.14%, p=0.3) while there was a significant decline among Black men (-3.11%, 95% CI -5.25% to 0.96%, p=0.005).

Conclusion: Medicaid expansion was associated with a decrease in the percentage of young men presenting with PSA=20 ng/ml at the time of diagnosis of PCa. These results may be related to improvement in access to PCa screening.

Funding: 2019 Urology Care Foundation Residency Research Award Program and the Russell Scott, Jr., MD Urology Research Fund (ABW).
39. CONTEMPORARY RACIAL DISPARITIES IN PSA SCREENING AND PROSTATE CANCER DIAGNOSIS IN A LARGE, INTEGRATED HEALTHCARE SYSTEM

Oluwaseun Adeyemi, William Anderson, Timothy Hetherington, Yhenneko Taylor, James Kearns
Atrium Health

Presented By: James Kearns

Introduction: The USPSTF prostate cancer screening guidelines have changed significantly in the past decade, from a recommendation of do not screen in 2012 to a 2018 recommendation that focuses on shared decision making among men aged 55-69. In addition to making recommendations similar to the USPSTF, most guidelines further acknowledge that African American men should be screened more intensively than Caucasian men due to increased incidence of prostate cancer and increased prostate cancer mortality. Our objective was to characterize racial disparities in PSA screening and new prostate cancer diagnosis in a large healthcare system with a diverse patient population to understand contemporary trends.

Methods: This retrospective cohort study used data from the Atrium Health Enterprise Data Warehouse, which includes clinical records from over 900 care locations across North Carolina, South Carolina, and Georgia. Participants included all men ≥ 40 years seen in the ambulatory or outpatient setting during 2014-2018. Men were excluded if they had a prostate biopsy within 24 months or prostate cancer diagnosis within 18 months prior to their index encounter. PSA testing was determined through laboratory data. Prostate cancer diagnoses were determined using International Classification of Diseases 9th edition (ICD-9) and ICD-10 codes, with diagnoses confirmed by having relevant codes on at least two encounters after the index encounter. Clinical and demographic data were collected for all men, including age and race. Outcomes were reported for racial groups with > 2% representation in the population. Between-group comparisons were conducted using generalized estimating equations models to account for within-subject correlation. Statistical significance was defined as p < 0.05.

Results: There were 582,846 men seen in the outpatient or ambulatory setting from 2014-2018, including 416,843 Caucasians (71.5%) and 85,773 African Americans (14.7%). Screening rates declined among all age and racial groups from 2014-2018 (see figure). African American men were screened at a significantly lower rate than Caucasian men in each year (from 19.1% vs 19.8% in 2014 to 12.3% vs 12.9% in 2018 respectively, p<0.05 for all years). The prostate cancer diagnosis rate declined across all age groups, with the largest declines in men aged = 60. African American men had a significantly higher rate of prostate cancer diagnosis than Caucasian men in each year from 2014-2018.

Conclusion: PSA screening and prostate cancer diagnoses declined significantly between 2014 and 2018. African American men were less likely to be screened for prostate cancer but more likely to be diagnosed with prostate cancer. Given the general consensus that African American men should be more intensively screened for prostate cancer, significant racial disparities remain in prostate cancer screening. Further study is warranted to understand patient, provider, and system factors that contribute to disparities in prostate cancer care and outcomes.
40. OFFICE CYSTOSCOPY: IS IT REALLY THE GOLD STANDARD?
Ralph Grauer, Noah Schenkman, Beth Horton, Randy Jones, Jennifer Lobo, Tracey Krupski, Jessica Rueb
1 University of Virginia, 2 Cleveland Clinic
Presented By: Ralph Grauer

Introduction: Cystoscopy is the current gold standard for the evaluation of bladder cancer and is integral in the work-up of hematuria. As the elderly population of the United States grows, demand for urologists and cystoscopies is outpacing supply. One potential remedy is having advanced practice providers (APPs) perform cystoscopies. Reservations about APPs performing procedures center on the lack of standardized training and liability concerns over interpretation of cystoscopy. Before urologists can measure APPs competence, the inter-rater reliability of urologist-performed cystoscopy is needed. In other words, do urologists agree with one another on completeness, interpretation and resultant action of cystoscopy? To establish the baseline agreement of physician-performed cystoscopies, we examined the degree of consensus between urologists in the analysis of digitally-recorded, flexible cystoscopies.

Methods: As part of a more extensive IRB-approved protocol, flexible cystoscopies were performed on six patients by a board-certified urologist who trained in a Society of Urologic Oncology approved fellowship. The de-identified images were recorded from a Storz digital, high-definition flexible cystoscope. The cystoscopy was indicated for either work-up of hematuria or bladder cancer surveillance and was performed in standard fashion assessing ureteral orifices, side walls, dome, and retroflexion. The urethra was not always included in the video due to IRB constraints of the larger protocol. Two external, unique board-certified urologists reviewed each video and completed an online Qualtrics survey. Agreement rates between paired-reviewers were compared for 3 aspects of cystoscopy: completeness, diagnosis, and action taken.

Results: The results from the twelve expert reviews of six cystoscopies are summarized in Figure 1. For completeness of exam, 83% of reviewer pairs agree the cystoscopy was sufficiently thorough (90% confidence interval: 49.8%, 96.2%). In terms of diagnosis, 67% of reviewer pairs agreed that a diagnosis could be made using the video (90% confidence interval: 34.7%, 88.3%). One hundred percent of reviewer pairs were in agreement in the action to be taken after video review, despite the unique pathologies encountered in the six videos (90% confidence interval: 60.7%, 100%).

Conclusion: This pilot study found that board-certified urologists do not have high rates of inter-rater reliability when assessing diagnostic capability and completeness of cystoscopic examination. However, they were uniform in their actions based on the interpretation of the cystoscopy. This work has implications for both residency training programs and incorporation of APPs into office-based procedures. While the sample size is small, these findings suggest there is room for standardization in the way urologists perform, interpret, and teach cystoscopies.

<table>
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<th>Competence of exam: Did the cystoscopy thoroughly examine all major bladder landmarks?</th>
<th>Yes</th>
<th>No</th>
<th>Total</th>
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<tbody>
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<td>0</td>
<td>5</td>
</tr>
<tr>
<td>No</td>
<td>1</td>
<td>0</td>
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<tr>
<td>Total</td>
<td>6</td>
<td>0</td>
<td>6</td>
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</table>

<table>
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<tr>
<th>Can you make a diagnosis based on this video?</th>
<th>Yes</th>
<th>No</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
<tr>
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<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>6</td>
<td>0</td>
<td>6</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What action should be taken based on this video?</th>
<th>Continue with planned surveillance schedule</th>
<th>Biopsy/operative resection or Other</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continue with planned surveillance schedule</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Biopsy/operative resection or Other</td>
<td>0</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>2</td>
<td>4</td>
<td>6</td>
</tr>
</tbody>
</table>

Figure 1. Paired urologists’ response results from the online survey, following review of a digitally-recorded cystoscopy.
41. DIAGNOSTIC VALUE OF SERIAL PROSTATE MRI IN ACTIVE SURVEILLANCE
Carissa Chu1, Samuel Washington2, Janet Cowan2, Claire de la Calle2, Peter Carroll3
1 Carissa Chu, 2 University of California, San Francisco
Presented By: Carissa Chu

Introduction: Multiparametric MRI fusion biopsy can increase detection of clinically significant prostate cancer compared to standard systematic biopsy in men with low-risk prostate cancer. Men on active surveillance (AS) undergo multiple MRIs. Less is known about the stability of MRI PIRADS v.2 scoring over time and whether change in PIRADS score predicts biopsy upgrade or progression for men on active surveillance.

Methods: In a retrospective review of an institutional database, we identified men diagnosed with clinically localized prostate cancer, CAPRA score less than or equal to 5, absence of Gleason 5, two MRIs within three years of initial diagnosis, and initially managed with AS. Upgrade was defined as increase in biopsy Gleason grade to 3+4 or greater. Progression was defined as increase in biopsy Gleason grade and percentage positive cores. Cox proportional hazards regression was used to identify factors associated with the outcomes of interest.

Results: 193 men were evaluated in this study. Median time between MRIs was 19 months (range 8-36 months). Median follow up was 69 months (range 19-218 months). At MRI 1, 20% of patients had PIRADS 1-2 lesions, 21% PIRADS 3, and 48% PIRADS 4 or 5. At MRI 2, 13% of patients had PIRADS 1-2 lesions, 14% PIRADS 3, and 74% PIRADS 4 or 5. PIRADS score increase (from 1-3 to 4 or 5) occurred in 30% of patients. Only 18% of PIRADS 3 lesions remained stable on subsequent MRI; 74% increased to PIRADS 4 or 5 (51 and 23% respectively). 70% of PIRADS 4 lesions stayed PIRADS 4 and 14% increased to PIRADS 5. 65% of PIRADS 5 lesions remained PIRADS 5. At MRI 1, PIRADS 5 was predictive of biopsy upgrade (HR 2.4 95% CI 1.0-5.8, p=0.04), but not PIRADS 4 (p=0.42), when compared to PIRADS 1-3. At MRI 2, however, both PIRADS 4 and 5 were associated with biopsy upgrade (HR 2.7 95% CI 1.2-5.8 p=0.01; HR 4.8 95% CI 2.2-10.6, p<0.01, respectively) when compared to PIRADS 1-3. PIRADS 5 was associated with biopsy progression at both MRI 1 and MRI 2 (HR 2.6 95% CI 1.1-3.8, p=0.02; HR 4.3 95% CI 1.8-10.3, p<0.01, respectively), but not PIRADS 4 (p=0.89, 0.17). Overall PIRADS increase between MRI 1 and MRI 2 was associated with biopsy upgrade (HR 2.7, 95% CI 1.8-6.3), but not progression.

Conclusion: There is a high incidence of PIRADS score increase between prostate MRIs on men on active surveillance, which is associated with biopsy upgrade. Furthermore, PIRADS 4 and 5 lesions are more predictive of biopsy upgrade and progression at second MRI when compared to first MRI. Additional study into the role of MRI fusion biopsy for men on active surveillance is necessary.
42. THE USE OF POSTOPERATIVE VIDEO VISITS TO REDUCE READMISSIONS IN PATIENTS UNDERGOING UROLOGIC SURGERY: A PILOT INITIATIVE
Lina Posada Calderon, Bashir Al Hussein Al Awamlh, Jonathan Fainberg, Aleem I. Khan, Osamede Enobakhare, Douglas S. Scherr
Weill Cornell Medical College
Presented By: Lina Posada Calderon

Introduction: Hospital readmissions after major urologic oncological surgery range between 3% in robotic-assisted laparoscopic prostatectomy (RALP) and 30% in radical cystectomy (RC). Telemedicine is an innovative field that resulted in an increase in health care access and reduction of associated costs. The role of telemedicine in a postoperative setting and its impact upon readmission rates have not been studied. We aim to evaluate the feasibility of postoperative video visits and assess the impact in reducing readmissions following major urologic oncologic surgery.

Methods: Patients undergoing major urological surgery by a single provider (DSS) were screened to participate in our study. All patients with a compatible smartphone were included. At time of enrollment patients were instructed how to utilize the video-visit application. Instructions were also provided on how to measure liquid intake and urine output once discharged. Video visits began the day after discharge and were made every other day for a total of 2 weeks (7 visits per patient). In each visit, we assessed current medications, oral fluid intake, urine output, food intake, flatus/bowel movements, use of spirometer, daily activity, fever, and surgical wound appearance. Video call providers utilized a script designed to provide a consistent structure to each visit. Specific patient answers triggered either an intervention (done by video call providers) or a “red flag”, prompting video call providers to contact the attending surgeon for further management. The primary outcome was to assess the feasibility of post discharge video visits by number of completed calls as well as patient adherence to the post-operative care plan. Secondary outcomes were the impact upon the rate of thirty-day hospital readmission measured by comparing readmission rates to matched controls done before the study period, and patient satisfaction using a validated survey. Patients that were enrolled but in whom no calls were completed, were not included in the analysis.

Results: Out of the 78 screened patients, a total of 66 (84.6%) were enrolled and 53 (68%) completed more than one call. Of these, 16 (30.2%) were after RC, 11 (20.8%)after RALP, 14 (26.4%) after nephrectomy/ureterectomy and 12 (22.6%) after other procedures. A total of 243 calls (65.5% of expected calls and a mean 4.6 calls per patient) were completed. Overall, 83 interventions and 5 red flags were made (Figure 1). The most common reason for an intervention was poor oral fluid intake (24.1%) and for a red flag was poor bowel movements (60%). Oral intake was quantified for 73.3% of the calls and urine output for 67.1%. A total of 9 (17%) patients were readmitted within 30 days of surgery. The matched controls had a total of 13 (24.5%) readmissions, which translates into a 7.5% decrease in readmission rate in patients receiving video visits. As measured by the survey, the level of satisfaction among patients was 87%.

Conclusion: Postoperative video visits after major urological surgery are feasible, with 68% of all patients screened completing more than one call and 65.5% of planned calls completed. Additionally, we proved high patient adherence to the post-operative plan with a high percentage of oral fluid intake and urine output measurements. Video visits in post-operative patients seem to reduce 30-day readmissions. Further large, randomized studies should be done to assess if video visits have a significant effect on reducing readmissions and higher-grade complications post-discharge.

Funding: Supported by The Frederick J. and Theresa Dow Wallace Fund of the New York Community Trust
**43. IMPROVED SURVIVAL AFTER CYTOREDUCTIVE NEPHRECTOMY FOR METASTATIC RENAL CELL CARCINOMA IN THE CONTEMPORARY IMMUNOTHERAPY ERA: A NATIONAL POPULATION-BASED ANALYSIS**

Nirmish Singla, Ryan Hutchinson, Rashed Ghandour, Yuval Freifeld, Arthur Sagalowsky, Yair Lotan, Aditya Bagrodia, Vitaly Margulis, Hans Hammers, Solomon Woldu

*University of Texas Southwestern Medical Center*

**Presented By:** Nirmish Singla

**Introduction:** Immune checkpoint inhibitors (ICI) were approved for treating metastatic renal cell carcinoma (mRCC) in 2015. Current clinical use of cytoreductive nephrectomy (CN) is guided by extrapolation from studies using other classes of systemic therapy in mRCC. We sought to evaluate survival outcomes, timing, and safety of combining CN with modern immunotherapy (IO) approaches for mRCC.

**Methods:** We performed a population-based observational study using National Cancer Database (NCDB) data. From 96,329 renal cancer cases reported to the NCDB from 2015-2016, the final cohort for analysis included 391 surgical candidates diagnosed with clear cell mRCC who were treated with IO +/- CN and no other systemic therapies (Figure 1). Primary outcome was overall survival (OS) stratified by the performance of CN (CN+IO vs. IO alone). Secondary outcomes included whether the timing of IO administration in relation to CN impacts OS, pathologic findings, and perioperative outcomes.

**Results:** Of 391 patients included, 221 (56.5%) received CN+IO and 170 (43.5%) received IO only. Across a median follow-up of 14.7 months, patients who underwent CN+IO had significantly better OS (Figure 2; median NR vs. 11.6 mos.; HR 0.23 [95%CI 0.15-0.37], p<0.001), which was upheld on multivariable analyses. IO administration before CN resulted in lower pT stage, Fuhrman grade, tumor size, and frequency of lymphovascular invasion compared to upfront CN. Two of 20 patients (10%) undergoing CN post-IO with pT0 stage achieved complete pathologic response in the primary tumor (pT0). There were no positive surgical margins, 30-day readmissions, or prolonged inpatient length-of-stay in patients undergoing delayed CN.

**Conclusion:** Using a large, national, population-based database, we provide the first report of survival outcomes in mRCC patients treated with CN combined with modern IO approaches. Our findings support an oncologic role for CN in the modern IO era and provide preliminary evidence regarding the timing and safety of CN relative to IO administration.

**Funding:** NIH/NCI
44. ZHX2 DRIVES CELL GROWTH AND MIGRATION VIA ACTIVATION MEK/ERK1/2 SIGNAL AND INDUCE SUNITINIB RESISTANCE BY REGULATING THE AUTOPHAGY IN CLEAR CELL RENAL CELL CARCINOMA
Zongming Lin1, Jin Zhang2
1 zhongshan hospital, fudan university, 2 renji hospital, shanghai jiaotong university
Presented By: Liangsong Zhu

Introduction: Zinc fingers and homeboxes 2 (ZHX2) was found as a novel VHL substrate target, and it acted as an oncogenic driver in clear cell renal cell carcinoma (ccRCC). However, the detailed mechanism of ZHX2 in ccRCC development and proliferation remains elusive, and no research has focused on studying ZHX2 in drug resistance yet.

Methods: A tissue microarray with 358 ccRCC samples was used to determine the expression level of ZHX2 in ccRCC patients. VHL-deficient cell line 786-O was transfected with Lentivirus-ZHX2 to increase ZHX2 expression. And VHL-normal cell line CAKI-1 was used for lineage reprogramming with transfected with lentivirus-shVHL and lentivirus-ZHX2. The in vitro and in vivo experiments were performed with these new cell lines to determine the mechanism of ZHX2 in ccRCC development and drug resistance.

Results: Immunohistochemistry analysis showed that ZHX2 was not highly expressed in tumor tissues, only 33.2% (119/358) patients have high ZHX2 expression. However, high ZHX2 was significantly associated with advanced Fuhrman grade (p=0.004), and ZHX2 also proved to be an independent prognosis factor for progression-free survival (p=0.003), while there is no significant correlation with overall survival. We further discovered that ZHX2 overexpression transcriptional activate the MEK/ERK1/2 by using RNA-seq and ChIP-seq analysis, and ZHX2 promote its downstream targets, thus increase cell proliferation, migration and tube formation. We also found ZHX2 overexpression induce Sunitinib resistance though activating autophagy and the combination treatment of Sunitinib and autophagy inhibitor chloroquine could significantly rescue the phenomenon.

Conclusion: In summary, these results indicate that ZHX2 drives cell growth, migration and self-tumor angiogenesis though transcriptional activate MEK/ERK1/2 signaling pathway, and could increase Sunitinib resistance by regulating autophagy, these may provide new insight in advanced ccRCC treatment.

Funding: Shanghai Science and Technology Development Foundation (17JC1400904)
45. POOR RESPONSE TO IMMUNOTHERAPY IS ASSOCIATED WITH HIGH EXPRESSION OF NOVEL EPIDERMAL GROWTH FACTOR RECEPTOR SPLICE VARIANT IN PATIENTS WITH CLEAR CELL RENAL CELL CARCINOMA
Ali Hajiran¹, Youngchul Kim¹, Thushara Madanayake¹, Timothy Robinson¹, Philippe Spiess¹, Manish Kohli¹, Theresa Boyle¹, James Mule¹, Jamie Teer¹, Brandon Manley¹, Sait Zaman², Shayan Falasiri²
¹ Moffitt Cancer Center, ² University of South Florida
Presented By: Ali Hajiran

Introduction: Epidermal growth factor receptor (EGFR) is one of the most widely activated oncogenes associated with the development and progression of several types of cancer. We recently identified a previously unrecognized aberrant EGFR splice variant (EGFR-20-CTF) with specific expression in patients with clear cell renal cell carcinoma (ccRCC). The purpose of this study was to evaluate EGFR-20-CTF expression with response to immunotherapy.

Methods: We identified 88 patients with ccRCC in a prospective cohort hospital registry between 2004 and 2018 whose tumors had undergone RNA sequencing and characterization of the EGFR-20-CTF splice variant. In this cohort, 19 patients had received immunotherapy (IL-2 or checkpoint inhibitors). We divided the cohort into three tertiles based on levels of EGFR-20-CTF expression and measured time to death (months) following first immunotherapy treatment. A log-rank test was used to compare survival between the groups.

Results: EGFR-20-CTF expression was identified in 76.1% (n=67/88) of ccRCC tumors. Patients with the highest expression of the EGFR-20-CTF splice variant had a significantly lower survival at 48 months following immunotherapy compared to patients with the lowest expression of EGFR-20-CTF (p = 0.036). The average survival in patients with high EGFR-20-CTF expression was < 16 months.

Conclusion: This pilot study shows that the aberrant EGFR-20-CTF splice variant occurs frequently in patients with ccRCC and is enriched in patients who had a poor response to immunotherapy. This previously unrecognized splice variant presents a possible molecular marker of resistance and will need prospective validation.

Funding: This work was supported in part by the Urology Care Foundation Research Scholar Award Program and Society for Urologic Oncology. The content is solely the responsibility of the authors and does not necessarily represent the official views of the American Urological Association (AUA) or the Urology Care Foundation.
46. IMPACT OF HOSPITAL VOLUME ON COMPLICATIONS FROM IMMUNOTHERAPY FOR RENAL CELL CARCINOMA

Eugene Cone¹, Ye Yang², Steven Chang³

¹ Division of Urological Surgery and Center for Surgery and Public Health, Brigham and Women’s Hospital, Harvard Medical School; Department of Urology, Massachusetts General Hospital, Harvard Medical School; ² Division of Urological Surgery, Brigham and Women’s Hospital, Harvard Medical School; ³ Division of Urological Surgery, Brigham and Women’s Hospital, Harvard Medical School; Division of Urologic Oncology, Dana Farber Cancer Center, Harvard Medical School

Presented By: Eugene Cone

Introduction: The relationship of provider and hospital volume and outcomes from treatment has been studied for multiple medical and surgical conditions with better outcomes generally associated with high volume. However, there is a paucity of data regarding the relationship between hospital volume and treatment complications and outcomes for medical oncologic therapy. Many patients face significant geographic barriers to obtaining regular chemotherapy or immunotherapy infusions at high volume tertiary referral centers, perhaps more so than for a one-time major oncologic operation. As such, the question of whether hospital treatment volume is associated with treatment complication is fundamental to the practice of oncology. To explore this relationship, we conducted a retrospective cohort study of patients with metastatic renal cell carcinoma receiving immunotherapy and high and low volume hospitals.

Methods: We retrospectively analyzed the Premier Healthcare Database, which includes hospital administrative data for all payors from over 700 community and academic hospitals. The database captures 20% of all hospital discharges in the US, and includes data on infusions performed in hospital-operated clinics. This analysis was exempt from IRB approval, given the deidentified nature of the database. We identified patients with ICD9 diagnostic codes for both renal cell carcinoma and metastatic disease treated with nivolumab for metastatic renal cell carcinoma from 2015 (the first year of FDA approval) to 2017. Baseline clinicodemographic data were obtained for all patients and hospitals were characterized by number of beds, teaching status, rurality, and location. Hospital treatment volume was dichotomized as high volume (top quartile) as the primary exposure of interest. Outcomes of interest were immunotherapy-related complications and readmission. We identified immunotherapy complications via primary and secondary diagnostic codes present at re-presentation that were not present at initial infusion of immunotherapy. The list of complication codes was compiled using previously published compendiums supplemented with codes for complications mentioned on package inserts for the medications. We performed mixed effects logistic regression adjusting for sampling weight and hospital clustering to achieve a nationally representative estimate. Calculations were performed in SAS 9.4 (Cary NC) with an alpha of 0.05.

Results: Our study cohort included 3,335 patients, yielding 15,724 weighted hospital encounters (5,835 at low-volume hospitals and 9,889 at high-volume hospitals). Urban, teaching hospitals were more likely to be high volume infusers of immunotherapy (Table 1). A total of 3,191 complications were observed: 1,457 at high volume hospitals and 1,734 at low volume hospitals. There were no significant differences by volume of hospital in overall rates of complications or in rates of individual complications, with the exception of ocular complications which had a very low event rate and was not observed in the high volume sample (Table 2). We observed that high volume hospitals having a significantly reduced odds for readmission (OR 0.09, 95% CI 0.03-0.24) unrelated to immunotherapy-related complications.

Conclusion: Our retrospective cohort study of patients treated with nivolumab for metastatic renal cell carcinoma revealed no difference in immunotherapy-related complication rates between high and low volume hospitals. Although this is reassuring for community administration of immunotherapy, we also observed a significantly higher rate of readmission at lower-volume hospitals for reasons unrelated to immunotherapy. Further study in a larger cohort will be needed to better elucidate the reasons for this discrepancy.
**Introduction:** Renal cell carcinoma (RCC) is known to be a metabolic disease, with the various RCC subtypes exhibiting aberrations in several different metabolic pathways. Metabolomics measures global metabolite profiles from various metabolic pathways as these profiles are influenced across a pathological progression. Metabolomics tissue measurements also confer greater sensitivity for revealing disease biology than evaluations of tissue morphology. In this study, we characterized and compared the metabolomic profile of renal cell carcinoma to adjacent benign renal parenchyma using high resolution magic angle spinning (HRMAS) magnetic resonance spectroscopy (MRS).

**Methods:** Surgical tissue samples were obtained from partial and radical nephrectomy. Specimens were frozen and stored at -80°C for at least 24 hours. Tissue HRMAS-MRS was performed on a Bruker AVANCE spectrometer operating at 600 MHz. Three different spectra were recorded at 4°C: one without water suppression, one with water suppression and long T2 filters, and one with water suppression and short T2 filters. A MatLab-based curve fitting programme developed by our laboratory was used to process the spectra to produce relative intensities for each analyzed spectral region of interest. Comparisons of the metabolomic profiles of RCC and adjacent benign renal parenchyma were performed using JMP Pro 14. False discovery rates (FDR) were used from the response screening to account for multiple testing. Regions of interest (ROI) with FDR <0.05 were selected as potential predictors of malignancy, and from these results, the Wilcoxon rank sum test was used to compare the median MRS relative intensities for those metabolites that may differentiate between malignant and adjacent benign tissue. The Wilcoxon signed rank test was also used to compare paired RCC and adjacent benign samples. Logistic regression was employed to determine odds ratios for risk of malignancy based on the abundance of each metabolite.

**Results:** There were 38 RCC samples (16 clear cell, 11 papillary, 11 chromophobe) and 13 adjacent normal tissue specimens. Thirteen of these samples were matched pairs. Metabolites are presented as spectral ROIs in Tables 1 and 2. Those denoted as TBD (to be determined) are undergoing further study to definitively identify and associate specific metabolites to the corresponding spectral regions. Baseline characteristics and comparisons of median MRS relative intensities are presented in Table 2. Metabolites that were candidates for predictors of malignancy based on FDR p-values include histidine, phenylalanine, phosphocholine, serine, phosphocreatine, creatine, glycerophosphocholine, valine, glycine, myo-inositol, scylla-inositol, taurine, glutamine, spermine, acetoacetate, and lactate (Table 1). When we compared only matched pairs of malignant and adjacent benign parenchyma, the metabolic ROIs at 4.35-4.24, 3.8-3.78, 2.7-2.75, 1.91-1.89, and 1.49-1.46 parts per million (ppm) were also found to be potential predictors of malignancy (data not shown). Higher levels of spermine, histidine, and phenylalanine at 3.15-3.13 ppm appeared to be associated with a profound decrease in risk of RCC (OR 4 x10-5; 95% CI 7.42x10-8, 0.02), while 2.84-2.82 ppm significantly increased the risk of malignant pathology (OR 7158.67; 95% CI 6.3, 8.3x106), and the specific metabolites characterizing this region remain to be identified. Interestingly, tumor stage did not appear to have predictive value on the metabolomic profile of the malignant tumors, suggesting that the metabolites are more dependent on the specific histologic subtype rather than its aggressiveness as determined by stage.

**Conclusion:** HRMAS-MRS identified a number of metabolomic biomarkers that may be useful predictors of RCC. In particular, the metabolomic profile demonstrated that metabolites in the 3.14-3.13 ppm spectral region was present in lower levels in malignant tissue, while higher levels of metabolites in the 2.84-2.82 ppm region substantially increased the risk of RCC. These findings warrant further investigation in a larger population for validation.

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48. EFFECTS OF CELL POLARITY ALTERATIONS ON TUMOR AGGRESSIVENESS IN RENAL CELL CARCINOMA
Xiaosong Meng¹, Wan-Hsin Lin², Panagiotis Anastasiadis³, Fang-Ming Deng⁴, Vitaly Margulis⁴
¹ UT Southwestern Medical Center, ² Department of Cell Biology, Mayo Cancer Center, Jacksonville, FL, USA, ³ Department of Pathology, NYU Langone Health, New York, NY, USA, ⁴ Department of Urology, UT Southwestern Medical Center, Dallas, TX, USA
Presented By: Xiaosong Meng

Introduction: While remarkable advances have been made in understanding the molecular biology of renal cell carcinoma (RCC), there are still significant gaps of knowledge in how localized RCC progresses to invasive disease. Multiple recent studies have demonstrated that alterations in the expression of cell polarity proteins are associated with poor prognosis and invasive disease in multiple cancers. We hypothesize that alterations in cell polarity proteins and downstream effector proteins increase tumor aggressiveness and drive invasive potential and cancer progression in RCC. We seek to better characterize the cell polarity proteins alterations in RCC to help elucidate the potential role of this pathway in tumor invasion.

Methods: The TCGA level-3 RNA sequencing data for 473 primary clear cell RCC (ccRCC) tumors and 68 normal samples were downloaded and unsupervised hierarchical clustering was performed on both samples and genes. Expression levels of individual genes from primary tumor samples were compared with those from normal solid tissue using analysis of variance (ANOVA) for detection of differentially expressed genes between sample groups. Antibodies to Par-3, Rac1 and Tiam1 were optimized for immunohistochemistry using an institutional tissue microarray of formalin-fixed paraffin-embedded (FFPE) consisting of normal and malignant tissue specimen from multiple organs. After optimization, multiple primary ccRCC tumors of different Fuhrman grades and pathologic stages were stained and analyzed for initial pilot studies.

Results: Comparison of normal tissue with ccRCC tumor tissue demonstrates changes in expression levels of multiple genes for members of the Par, Scribble and Crumbs polarity complexes (Figure 1), with around five-fold decreases in the expression of the Crumbs 2 (CRB2) gene and Discs Large MAGUK Scaffold Protein 2 (DLG2) gene. Staining of FFPE tissue demonstrates increased levels of Par-3 and downstream effector protein Tiam1 in ccRCC tumors compared to normal kidney (Figure 2). Par-3 and Tiam1 staining also demonstrate intratumoral heterogeneity with increased expression in areas with higher grade nucleolar prominence and abnormalities compared to areas of low grade tumor (Figure not shown).

Conclusion: Preliminary data demonstrates changes to multiple cell polarity complex gene expression levels in ccRCC and alterations in cell polarity protein levels in tumors compared to normal tissue. How these gene expression changes correlate to polarity protein expression and downstream effector protein localization and tumor characteristics are still incompletely defined. Further studies using large multi-institutional ccRCC tumor microarrays to characterize changes among the expression of Par, Scribble and Crumbs polarity complexes proteins are ongoing. Further studies to characterize the location and function of these polarity complexes in live tumor cells are necessary to elucidate their role in tumor invasion.

Funding: This work was supported in part by the Urology Care Foundation Research Scholar Award Program and Society for Urologic Oncology Fund for Specialized Program of Research Excellence. The content is solely the responsibility of the authors and does not necessarily represent the official views of the American Urological Association or the Urology Care Foundation.
49. AUTOPHAGY BLOCKADE MEDIATES RESISTANCE TO MTOR INHIBITION OF RENAL CELL CARCINOMA VIA VHL-DEPENDENT NDRG1 EXPRESSION

Hua Chen, Kyle Potts, Allan Murray, Ronald Moore
University of Alberta

Presented By: Ronald Moore

Introduction: Autophagy is a lysosome-dependent degradative process, with reports indicating both tumor-suppressing and -promoting effects in cancer, including renal cancer (ccRCC). Loss of the Von Hippel-Lindau tumor suppressor gene (VHL) affects autophagy cellular function and promotes the expression of hypoxia-inducible protein N-myc downstream-regulated gene 1 (NDRG1); however, its regulatory role in the autophagic process is poorly understood. We investigated the influence of autophagy in concert of VHL expression to determine its cytotoxicity and activity associated with NDRG1 expression in ccRCC.

Methods: An isogenic matched 786-O cell line with restored wild-type VHL cell model was used for this study. These cells were stably lentiviral transduced with shRNA NDRG1 vector, or mCherry-EGFP tandem fluorescent-tagged LC3B reporter for studying autophagosome synthesis and lysosomal degradation (autophagy flux). Cell viability was evaluated by cytotoxic XTT assay. The efficacy of PI3K/AKT/mTOR pathway and its downstream targets inhibition by mTOR inhibitors everolimus (RAD001) and AZD8055 and/or autophagy inhibitors HCQ, bafilomycin A1, and Lys05 were evaluated by immunoblots, electron microscopy, and immunofluorescence.

Results: In an isogenic matched restored wild-type VHL 786-O cells, VHL downregulated the induction of NDRG1 protein levels, which were found to be modulated by hypoxia, intracellular iron and calcium levels. We demonstrated that VHL-deficient cells exhibited blockade of autophagy flux and impaired lysosomal function upon mTOR kinase inhibition to induce autophagy. These observed effects correlated with the induction of NDRG1 levels concurrent with increased autophagy flux marker p62 and the formation of cytoprotective autophagic vacuoles. Restored VHL in isogenic cells rescued the observed blockade in autophagy and reduced the induced NDRG1 levels to promote autophagy degradation. Interestingly, knockdown of NDRG1 sensitized mTOR-resistant 786-O deficient VHL cells to doxorubicin-induced apoptosis via PARP cleavage and had little effect on cytotoxicity but suppressed the initiation of autophagy induced by mTOR inhibitors. In contrast, silencing NDRG1 sensitized VHL-proficient cells to mTOR and/or autophagy inhibitors-induced cytotoxicity but not VHL-deficient cells. Similarly, combined treatment of mTOR and autophagy inhibitors augmented cytotoxic effects and promoted cell death in a VHL-dependent manner.

Conclusion: These results reveal that autophagy has different influences on cellular contexts in which autophagy inhibition to augment mTOR inhibition in the presence of VHL can lead to compensatory mechanisms enhancing tumor cell death.

Funding: Mr. Lube Foundation and Canadian Cancer Society
50. ESTABLISHING A HEREDITARY RENAL SYNDROME CLINIC: ONE INSTITUTION’S EXPERIENCE IN PATIENT IDENTIFICATION, RISK ASSESSMENT, GENETIC TESTING AND SURVEILLANCE OUTCOMES
Sean Kern, Ryan Speir, Courtney Schroeder, Adam Calaway, Michael Koch, Gail Vance, Ronald Boris
Indiana University
Presented By: Sean Kern

Introduction: Approximately 8-10% of patients with RCC may be linked to a hereditary predisposition. These estimates are speculated to be low due to few centers with established multidisciplinary clinics for hereditary RCC. We sought to establish a referral center for all patients with suspected hereditary conditions placing them at higher risk for kidney cancer. Our goals were to recognize patients with a potential hereditary condition, facilitate genetic counseling, provide informed consent and accurate genetic testing, and increase imaging compliance rates.

Methods: The Renal Hereditary Syndrome Clinic (RHSC) was established in 2016 and included a urologic oncologist, medical geneticist, and genetic counselor specializing in oncology. Intra-facility referral was facilitated using a database notification system. Patients were referred for a family history of kidney cancer or a kidney syndrome, multifocal renal cell carcinoma, or early onset renal cancer less than 46 years old. A monthly multidisciplinary RHSC tumor board reviewed histories, imaging, genetic risk, genetic testing, and management plans. The data from our initial experience was reviewed to establish the rate of positive genetic testing and surveillance compliance rates.

Results: The RHSC enrolled 46 patients over a 42 month period with an average age of 41.2 years. 21 patients (45.7%) enrolled were found to have predisposing germline variants. 9 patients declined genetic testing after being counseled in the RHSC or have pending genetic testing results. 25/46 patients (56.5%) were referred after renal tumor surgery. The pathologic diagnoses included clear cell (14), chromophobe (3), papillary type I (4), papillary type II (1), translocation RCC (1), renal angiomyolipoma (2), multifocal oncocytoma (1), and unclassified renal cell carcinoma (1). Twelve of the surgical patients (46.2%) had a family history significant for malignancies. 17/26 (65.4%) patient in the surgical group underwent genetic testing with four positive results (23.5%), two with FH mutations, and one VHL and TSC mutation. The remaining 20 patients (43.5%) were nonsurgical, referred for positive family history of a renal malignancy only (1/20); with a positive family history of genetic mutation(s) (10/20); associated features of hereditary renal disease (6/20), and (3/20) already diagnosed with a genetic mutation prior to being enrolled in the RHSC. In both the surgical and non-surgical groups, 21 (45.7%) patients seen in the RHSC have a hereditary cancer predisposition syndrome. The most common diagnoses were HLRCC (12), BHD (4), VHL (4), TSC (1).

Conclusion: The RHSC has served to identify surgical patients at risk for hereditary renal syndromes and to provide genetic counseling and testing for nonsurgical patients. In our surgical and non-surgical patients, genetic mutations were seen in 23.5% and 85%, respectively. Interestingly, the FH mutation and HLRCC was the most common syndrome identified. Among all patients followed in the RHSC with hereditary cancer predisposition syndromes, 95.2% of patients adhered to their recommended surveillance and follow up regimens. Early results suggest increased testing positivity and compliance rates compared to national averages. Evaluating patients with suspected hereditary renal diseases in a multidisciplinary clinic may increase imaging and follow-up compliance rates while better identifying at-risk patients with a strong family history. Clinicians should have a low threshold for referral to multi-disciplinary hereditary cancer clinics.
51. SURVIVAL OUTCOMES AND NATIONAL PRACTICE TRENDS FOR ADJUVANT TARGETED THERAPY IN HIGH RISK LOCOREGIONAL RENAL CELL CARCINOMA
Nicholas Chakiryan, Ann Martinez-Acevedo, Mark Garzotto, Yiyi Chen, Jen-Jane Liu, Sudhir Isharwal, Christopher Amling, Ryan Kopp
Oregon Health & Science University
Presented By: Nicholas Chakiryan

Introduction: The appropriate use of adjuvant targeted therapy (TT) for high-risk locoregional renal cell carcinoma (RCC) after nephrectomy is currently unclear due to mixed results from the relevant randomized controlled trials. National-level survival outcomes and practice trends for the use of adjuvant TT in the United States have not been reported.

Methods: Patients with non-metastatic clear cell RCC who underwent nephrectomy with either stage pT3a or greater or pN+ were identified in the National Cancer Database (2006 – 2015). Adjuvant TT was defined as receipt of TT within 3 months of RN. Baseline characteristics were described, and a multivariable analysis identified associations for receipt of adjuvant TT. Nearest-neighbor propensity matching was performed to create similar groups for comparison. A survival analysis was performed using Kaplan-Meier analysis and log-rank test.

Results: The final study population included 41,127 patients. 2,071 patients (5.04%) received adjuvant TT. Younger age, white race, private insurance, positive margins, pT4, and pN+ were associated with receipt of adjuvant TT. After nearest-neighbor propensity matching for clinically and statistically relevant covariates, 1,604 patients remained in the matched cohort, with statistically non-significant differences between the groups for all baseline characteristics. Median overall survival was 62 months for patients in the Adjuvant TT group versus 79 months for those who did not receive adjuvant TT (p < 0.001).

Conclusion: The propensity matched survival analysis revealed significantly decreased overall survival in patients who received adjuvant TT.
52. KIDNEY CANCER INCIDENCE AND MORTALITY AMONG AMERICAN INDIANS/ALASKA NATIVES IN OKLAHOMA AND THE UNITED STATES
Michael Suflita, Amanda Janitz, Janis Campbell, Kelly Stratton, Michael Cookson, Daniel Parker

The University of Oklahoma College of Medicine, The University of Oklahoma College of Public Health, The University of Oklahoma Department of Urology and the Stephenson Oklahoma Cancer Center

Presented By: Michael Suflita

Introduction: Racial disparities in the incidence and mortality of many cancers have been observed affecting American Indian/Alaska Native (AI/AN) populations. To date, few studies have examined the distribution of kidney cancer among AI/ANs compared to their white counterparts. Oklahoma is home to the second highest number of AI/AN peoples in the US, and data pertaining to our state’s AI/AN population is not typically included in national epidemiological studies. This study examines the incidence and mortality of kidney cancer among AI/ANs in Oklahoma and updates these trends for AI/AN and white populations nationally.

Methods: We queried the Oklahoma Central Cancer Registry through its web-based portal OK2SHARE for kidney cancer age-adjusted incidence rates (AAIRs) per 100,000 population and age-adjusted mortality rates (AAMRs) per 100,000 population. Indian Health Service-linked race was used to identify the AI/AN population. AAIR and AAMR data was obtained for the years 1999-2015. Rates were compared to those of the white population and further stratified by gender as well as Oklahoma Planning District for the same time periods. We then compared Oklahoma AAIRs and AAMRs to US national rates obtained from CDC Wonder for 1999-2015. Finally, temporal trends for the AAIR and AAMR, stratified by race, were analyzed using joinpoint regression modeling available from the National Cancer Institute.

Results: Incidence Rates
The overall AAIR among AI/ANs in Oklahoma was 30.8 (95% CI 29.4-32.2) per 100,000 population, compared to 15.6 (95% CI 15.3-15.9) per 100,000 for whites (rate ratio 1.97, 95% CI 1.88-2.08, Table 1). Nationally, the US AAIR for AI/AN and whites during the same period was 15.4 (95% CI 15.1-15.7) and 15.4 (95% CI 15.4-15.4) per 100,000 population, respectively. The AAIR for AI/ANs in Oklahoma increased annually by 2.69% per year (95% CI 1.4-4.0), despite a decline in the AAIR for all US AI/ANs since 2008 (-1.51% per year, 95% CI -3.4-0.4). For the Oklahoma white population, the AAIR has increased at a rate of only 2.06% per year since 2003 (95% CI 1.3-2.9) while national rates have plateaued since 2006 (0.36% per year, 95% CI 0.1-0.6, Figure 1).

Mortality Rates
The overall AAMR among AI/ANs in Oklahoma was 9.7 (95% CI 8.9-10.5) per 100,000 population, compared to 4.9 (95% CI 4.7-5.1) per 100,000 for whites (rate ratio 1.98, 95% CI 1.81-2.17, Table 1). Nationally, the US AAMR for AI/AN and whites during the same period was 4.4 (95% CI 4.2-4.6) and 4.1 (95% CI 4.1-4.1) per 100,000 population, respectively. The AAMR for AI/ANs and whites in Oklahoma did not change significantly throughout the study period (-0.27% per year, 95% CI -2.6-2.1) and 0.15% per year (95% CI -0.7-1.0), respectively. However, the AAMR among all US AI/ANs (-1.80% per year) and whites (-0.72% per year since 2001) declined significantly (p<0.05, Figure 1).

Conclusion: AI/ANs in Oklahoma are diagnosed with kidney cancer and die from it at nearly twice the rate of the white population. The rates of kidney cancer incidence are rising faster for Oklahoma AI/ANs than for their white counterparts. While national mortality rates for both AI/AN and white populations are declining, the mortality rates in Oklahoma are not significantly changing irrespective of race. These data highlight the need for public health initiatives aimed at resolving kidney cancer disparities among AI/ANs compared to whites, but also among Oklahomans compared to the rest of the country.

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<td>Mortality Rate</td>
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![Image of Age-Adjusted Incidence Rate](#)

![Image of Age-Adjusted Mortality Rate](#)
53. CLINICAL FACTORS THAT PREDICT OUTCOMES FOR PATIENTS UNDERGOING CYTOREDUCTIVE NEPHRECTOMY FOR METASTATIC RENAL CELL CARCINOMA IN THE MODERN ERA OF SYSTEMIC THERAPEUTICS

Andrew McIntosh1, Eric Umbreit1, Cindy Gu1, Surena Matin1, Jose Karam1, Christopher Wood1, Levi Holland2, Stephen Culp3

1 University of Texas MD Anderson Cancer Center, 2 University of Texas Health Science Center at Houston McGovern Medical School, 3 University of Virginia Health System

Presented By: Andrew McIntosh

Introduction: The management of metastatic renal-cell carcinoma (mRCC) with cytoreductive nephrectomy (CN) was historically supported by level 1 evidence. However, the available systemic therapeutics have evolved significantly in the years since. Furthermore, recent results from CARMENA, the only RCT in the targeted therapy (TT) era, now question the utility of cytoreductive nephrectomy (CN). The objective of this study was to examine overall survival (OS) and identify risk factors (RF) associated with patients not benefiting from CN in the TT era.

Methods: Using our institutional database, we identified mRCC patients undergoing CN from 2005-17. Clinicopathologic data was indexed for all patients in a comprehensive fashion, including clinical, peroperative, pre-operative laboratory, and final pathological data. Kaplan-Meier methods and Cox proportional hazards regression analyses were used to assess OS and risk stratify patients, respectively, based on pre-operative clinical and laboratory data.

Results: We identified 608 eligible patients with a median follow-up of 29.4 months. Some form of systemic therapy was administered to 81.1% (n=493) of patients, with the majority of these (n=481 or 97.6%) receiving post-CN systemic therapy. On multivariable analysis, RFs significantly associated with decreased OS included systemic symptoms at diagnosis, retroperitoneal and supra-diaphragmatic lymphadenopathy (LAD), bone metastasis, clinical T4 disease, hemoglobin less than lower limit of normal (LLN), serum albumin < LLN, serum LDH greater than the upper limit of normal (ULN), and neutrophil/lymphocyte ratio ≥ 4 (Table 1). Patients were stratified into three risk groups – Low (< 2 RF), intermediate (2-3 RF), and high (> 3 RF) with median OS of 58.9 (95% CI 44.3, 67.0), 31.2 (95% CI 27.1, 37.1) and 19.3 (95% CI 13.9, 22.6) months, respectively (p<0.0001) (Figure 1). There was no difference between the delivery and timing of post-operative systemic therapy between groups (p=0.949).

Conclusion: Patients with >3 of these RFs did not seem to benefit from CN. Importantly, OS in this group was equivalent to, if not higher than, patients in the CN+sunitinib arm of the CARMENA trial, thereby questioning the validity of those cohorts as representative of the general population.
54. POSITIVE VASCULAR MARGIN IS NOT PROGNOSTIC IN NON-METASTATIC RENAL CELL CARCINOMA PATIENTS WITH TUMOR THROMBUS
Brittany Adamic¹, Joshua Aizen¹, Tatjana Antic¹, Scott Eggener¹, Ryan Werntz²
¹ University of Chicago, ² University of South Carolina-Greenville
Presented By: Craig Labbate

Introduction: The vascular margin after radical nephrectomy with tumor thrombectomy for RCC is difficult to interpret clinically. We examined the prognostic implications of positive vascular margins (PVM) based on the strict definition of tumor cells invading the vein wall at the surgical margin.

Methods: Retrospective review identified 85 patients with pT3N0M0 renal cell carcinoma who underwent radical nephrectomy with tumor thrombectomy between 2001-2017 at the University of Chicago. Kaplan-Meier analysis was used to evaluate if a PVM was associated with recurrence-free survival (RFS) or overall survival (OS).

Results: Tumor invasion at the venous margin was identified in 39 patients (46%). Tumor thrombus level (Mayo) was 0 in 41 (48%), I in 11 (13%), II in 17 (20%), III in 10 (12%), and IV in 6 (7%). Patients with a PVM were more likely to have thrombus within the IVC, 74% level I or higher vs 33% in negative margin (NVM) group (p=0.002). At a median follow-up of 32 months, there was no difference in local recurrence: 8% PVM vs 11% NVM (p=0.7). Median RFS was 6.3 and 7.9 months, respectively (p-log-rank =0.7). The 2 and 5-year OS were 88% and 78% for NVM and 84% and 65% for PVM. (p-log-rank =0.6). Controlling for tumor diameter, margin status was not a predictor of RFS (p=0.8).

Conclusion: Recurrence-free and overall survival after radical nephrectomy with tumor thrombectomy for RCC do not appear to be impacted by a positive vascular margin. Vascular wall invasion is likely a surrogate of aggressive disease without prognostic impact.
55. NEPHROLOGY REFERRAL PATTERNS IN RENAL CANCER SURGICAL PATIENTS WITH PRE-EXISTING OR POST-OPERATIVE CHRONIC KIDNEY DISEASE
Julia Wainger1, Joseph Cheaib1, Hiten Patel1, Mitchell Huang1, Meredith Metcalf1, Phillip Pierorazio1, Joseph Canner2
1Brady Urological Institute, Johns Hopkins Hospital, Baltimore, MD, USA, 2Johns Hopkins Surgery Center for Outcomes Research, Johns Hopkins University School of Medicine, Baltimore, MD, USA
Presented By: Julia Wainger

Introduction: Chronic kidney disease (CKD) is a known sequela of renal surgery. The 2017 American Urologic Association (AUA) guidelines mention referral to nephrology for patients at significant risk for development or progression of CKD. Currently, data are limited describing the extent to which at-risk patients are being referred to nephrology pre-operatively and post-operatively. Our objective was to assess rates of nephrology referral amongst patients who had CKD pre-operatively or went on to develop CKD post-operatively, to identify predictors of referral, and to assess the association of nephrology referral with survival.

Methods: We obtained data from patients included in the SEER-Medicare database for patients =65 years of age who received surgery for renal parenchymal cancers and either had a diagnosis of CKD prior to surgery or developed CKD post-operatively between 1999 and 2014 (N=16,007). Referral data were derived from inpatient and outpatient nephrology claims. Patients were classified as follows: 1) having an established nephrologist if they had at least one nephrologist claim from six months or greater prior to their surgery; 2) having a pre-operative referral if they had a nephrology claim within six months prior to their surgery; 3) having an early post-operative referral if the first nephrology claim occurred within 3 months post-operatively; and 4) having a late post-operative referral for any first-time nephrology claims beyond 3 months after surgery. We 1) identified if and when patients were referred to nephrology by CKD disease status and surgery type, 2) used logistic regression to identify patient factors associated with nephrology referral pre- and post-operatively and 3) used a Cox proportional hazard regression model to assess associations between referral and survival. Logistic regression and survival analyses were conducted for patients who had surgery between 2004 and 2014 (N=11,510).

Results: Of 16,007 patients treated between 1999 and 2004, all of whom had CKD prior to surgery or developed CKD post-operatively, 10.3% had an established nephrologist and 7.2% had a pre-operative referral. See Figure 1 for referrals by CKD status and surgery type. Logistic regression demonstrated CHF (OR:1.2, 95% CI: 1.05-1.46, p=0.011), living in an urban area (OR: 1.4, 95% CI: 1.08-1.84, p<0.008), having a diagnosis of CKD prior to surgery (OR: 3.2, 95% CI: 2.71-3.70, P<0.001), and undergoing partial nephrectomy (OR: 1.63, 95% CI: 1.39-1.92, p<0.001) were associated with a pre-operative nephrology referral. Post-operative referrals by three months were associated with stage 3 disease (OR: 1.35, 95% CI: 1.17-1.55, <0.001), stage 4 disease (OR: 2.28, 95% CI: 1.89-2.78, p<0.001), and moderate to severe liver disease (OR:1.99, 95% CI:1.17-3.34, p<0.001). In an unadjusted model, there was an increased risk of death in patients who had a pre-operative nephrology referral (HR=1.28, p <0.001). However, after adjusting for age, sex, and clinical risk factors, there was no statistically significant survival difference (HR= 1.09, p=0.126). In both an unadjusted (HR= 2.1, p<0.001) and adjusted model (HR= 2.02, p<0.001), there was an increased risk of death in patients with a post-operative nephrology referral by three months. Both the rate of partial nephrectomies (13.5% to 19.3%, p<0.001) and pre-operative nephrology (6.6 to 9.8%, p<0.001) referrals increased over the first and second halves of the study period.

Conclusion: Few renal cancer patients at risk for CKD progression or development present to the urologist with an established nephrologist. Of patients with preexisting CKD, 41.1% of them do not have an established nephrologist or a referral to see one pre-operatively. Of the patients who present for surgery without CKD and develop CKD post-operatively, 88.4% do not see a nephrologist before surgery, suggesting missed opportunities to refer people at high risk of developing CKD or progression of CKD. Pre-operative nephrology referral did not appear to improve overall survival; however, referred patients may represent a higher risk subset, and other patients who may benefit appear under-referred. Of note, these data predate the 2017 guidelines, which specify clinical signs that may warrant referral.

Funding: This abstract was made possible by the Johns Hopkins Institute for Clinical and Translational Research (ICTR) which is funded in part by Grant Number TL1 TR003100 from the National Center for Advancing Translational Sciences (NCATS) a component of the National Institutes of Health (NIH), and NIH Roadmap for Medical Research. Its contents are solely the responsibility of the authors and do not necessarily represent the official view of the Johns Hopkins ICTR, NCATS or NIH.
56. EXAMINING THE ROLE OF CONTRAST-ENHANCED RENAL ULTRASOUND IN CHARACTERIZING INDETERMINATE RENAL LESIONS IN THE SETTING OF CHRONIC KIDNEY DISEASE
Ava Saidian1, Taylor Tucker1, Soroush Rais-Bahrami1, Kristin Porter1, Stephen Leahy2
1 University of Alabama-Birmingham, 2 University of Alabama-Birmingham

Presented By: Ava Saidian

Introduction: The prevalence of chronic kidney disease (CKD) in the United States is estimated to be over 14%. One particular difficulty, among the many issues that arise when caring for these patients, is accurate diagnosis of renal lesions without the use of intravenous contrast. Contrast Enhanced Renal Ultrasound (CERUS) is a diagnostic tool with the potential to allow for more precise imaging without the nephrotoxic effects of standard contrast in patients with indeterminate renal lesions and CKD.

Methods: A retrospective chart review of patients who underwent CERUS from 2014 to 2015 was performed at a single institution with data collection focused on renal function, prior imaging of renal lesions, and final clinical and pathological diagnoses. The main imaging modalities patients underwent prior to CERUS included Computed Tomography (CT), Magnetic Resonance Imaging (MRI), and non-contrast enhanced ultrasound. Patients were separated into two cohorts based on renal function with an eGFR<60 defining the CKD cohort. Comparisons were made between the two cohorts based on the results and findings of prior imaging modalities and follow-up CERUS performed.

Results: A total of 169 patients had a CERUS completed from 2014 to 2015 at a single academic institution. There were 104 patients with eGFR<60 who were classified as having CKD. A comparative analysis of categorical variables was done using chi-squared and Fisher’s exact test. CERUS provided specific diagnosis, new diagnosis and/or confirmed diagnosis of previously labeled “indeterminant renal lesions” by other imaging modalities in 41 (39.4%) of the CKD patients compared to 13 patients (20.0%) with normal renal function (p=0.0084). CERUS also resulted in a change in Bosniak classification of cysts in 2 (4.3%) of CKD patients compared to 8 (22.8%) patients with normal renal function (p=0.017). Finally, CERUS resulted in a change in the number of lesions in 2 (1.9%) CKD patients compared to 5 (7.7%) patients with normal renal function (p=0.11).

Conclusion: CERUS can be used to diagnose and follow renal lesions in patients with CKD who otherwise may not be able to undergo imaging with various forms of nephrotoxic contrast. Though US has its limitations, CERUS can help differentiate and further classify indeterminate renal lesions that may be concerning for malignancy. Perhaps patients with normal renal function have better complex cystic lesion characterization and detection of otherwise occult renal lesions based on improved blood flow characteristics. Further studies are necessary to validate these findings and further elucidate the mechanisms for the findings to optimize imaging selection in patients with compromised renal function.

Funding: UAB-UCSD O’Brien Center for Kidney Injury Research Summer Program
57. CONTEMPORARY TRENDS IN PERCUTANEOUS RENAL MASS BIOPSY IN THE UNITED STATES
Manuel Ozambela, MD, Ye Wang, PhD, Steven L. Chang, MD, MS
Brigham and Women’s Hospital / Harvard Medical School
Presented By: Manuel Ozambela, MD

Introduction: Unlike most other organ confined masses, patients discovered to have a renal mass traditionally proceed directly to extirpative surgery without a pre-operative tissue diagnosis confirming malignancy. Contemporary studies reveal that a sizable proportion of renal masses diagnosed today, particularly though that are incidentally detected, represent benign tumors or indolent malignancies on final pathology. This has lead to a growing body of literature supporting an expanded role for renal mass biopsy (RMB). However, it is unclear to what extent the medical community has incorporated RMB into practice. In this study, we aimed to characterize national trends in RMB utilization using a contemporary population-based cohort.

Methods: Patients who had undergone a renal biopsy between 2003 to 2017, in the Premier Hospital Database (Premier Inc, Charlotte, NC), a nationally representative hospital discharge database, were captured using International Classification of Diseases, Ninth Revision (ICD9) codes as well as Current Procedural Terminology (CPT) codes. We restricted our analysis to patients with a concurrent diagnosis of a renal mass and excluded those with metastatic disease. We determined utilization rate, 30-day RMB complication rate, and subsequent interventions within 90 days of biopsy. We applied sampling weights and adjusted for hospital clustering to achieve a nationally representative analysis.

Results: We identified 167,320 individuals who met the inclusion criteria and the annual number of RMB ranged from 7,200 to 15,500. After a period of stable to increasing utilization, we observed a steady decline in the annual number of RMB in the last three years of collected data (Figure 1). The majority of biopsies (56%) were performed in healthy patients (Charleston Comorbidity index =0), and there was an even distribution of ages with 27% of patients in this cohort younger than 55 years of age. Hematuria was the most common complication present in 7% of patients, but all other complications were rare (<0.4%) (Table 1). Overall, 73.7% of patients did not proceed to any intervention following biopsy, while 15.9% proceeded to either radical nephrectomy or partial nephrectomy and 10.4% underwent thermal ablation.

Conclusion: These findings suggest that despite multiple studies supporting the benefits of establishing a tissue diagnosis for renal masses, RMB is not being employed widely in the United States, and in fact utilization may be decreasing in recent years. This study confirms that RMB is safe with very low complication rates in the general population across a variety of care settings. Given the potential to guide therapy by possibly forgoing costly and invasive interventions in those with benign and indolent disease, coupled with a very low complication rate, additional studies are needed to determine the barriers to adoption.

<table>
<thead>
<tr>
<th>30-day RMB complications</th>
<th>Total cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>118 (0.38)</td>
</tr>
<tr>
<td>Hematuria</td>
<td>2588 (7.03)</td>
</tr>
<tr>
<td>Subcapsular Hematoma</td>
<td>44 (0.13)</td>
</tr>
<tr>
<td>Retroperitoneal Hematoma</td>
<td>26 (0.07)</td>
</tr>
<tr>
<td>Fistula</td>
<td>16 (0.06)</td>
</tr>
<tr>
<td>Colonic Injury</td>
<td>1 (0.002)</td>
</tr>
<tr>
<td>Splenic Injury</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Adrenal Injury</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Pneumothorax</td>
<td>92 (0.29)</td>
</tr>
</tbody>
</table>
58. SURVIVAL FOLLOWING CYTOREDUCTIVE NEPHRECTOMY: A COMPARISON OF EXISTING PREDICTIVE MODELS
Daniel Shapiro, Mary Beth Westerman, Jose Karam, Christopher Wood
The University of Texas M.D. Anderson Cancer Center
Presented By: Daniel Shapiro

Introduction: Currently, determining which patients are most likely to benefit from CN is poorly understood. Multiple prognostic models have been proposed but there is limited evidence of external validity and discriminatory capability of many commonly used models. We aimed to validate models currently used to predict renal cell carcinoma (RCC) outcomes in a cohort of patients undergoing cytoreductive nephrectomy (CN).

Methods: Ten RCC prognostic models (International Metastatic RCC Database Consortium [IMDC]; Memorial Sloan Kettering Cancer Center [MSKCC]; Culp; Leibovich; University of California at Los Angeles Integrated Staging System [UISS]; Stage, Size, Grade, and Necrosis [SSIGN]; Yaycioglu; Karakiewicz; Cindolo; and Margulis) were chosen based on clinical relevance and use in clinical trial design. Model validation was performed using patients who underwent CN at a single institution between 2005 and 2017 and model discrimination (ability to select patients at risk of death) was assessed. Concordance indices (c-indices) were calculated and compared with originally published c-indices (if known). The c-index ranges from 0.5 to 1, with 1 indicating a model has perfect ability to predict survival, and 0.5 is equivalent to a fair-coin toss.

Results: A total of 612 CN patients were stratified according to the prognostic models. A total of 444 (72.5%) died over the study period, with estimated 3-year survival of 46.2% (95% CI 42.0-50.2%). All models’ discriminatory capacity underperformed when compared to the originally published c-indices (Table 1) in our study cohort. The c-indices ranged from 0.55 (95% CI 0.52-0.58) for the Yaycioglu model to 0.64 (95% CI 0.62-0.67) for the SSIGN model. The MSKCC and IMDC models performed poorly with c-indices of 0.584 and 0.581, respectively.

Conclusion: Currently used predictive models have limited discriminatory capacity when applied to a modern cohort of patients undergoing CN. They are limited in their ability to risk stratify patients for randomization in prospective clinical trials of untreated metastatic RCC patients. Caution should be used when using these models for clinical decision making.

Table 1. Model Discrimination and c-index.

<table>
<thead>
<tr>
<th>Prediction Model</th>
<th>c-index</th>
<th>95% CI</th>
<th>Original Study c-index</th>
</tr>
</thead>
<tbody>
<tr>
<td>SSIGN</td>
<td>0.644</td>
<td>0.616-0.673</td>
<td>0.84</td>
</tr>
<tr>
<td>Leibovich</td>
<td>0.639</td>
<td>0.611-0.667</td>
<td>0.67</td>
</tr>
<tr>
<td>Karakiewicz</td>
<td>0.634</td>
<td>0.604-0.663</td>
<td>0.66</td>
</tr>
<tr>
<td>Culp</td>
<td>0.606</td>
<td>0.576-0.635</td>
<td>NR</td>
</tr>
<tr>
<td>Margulis</td>
<td>0.602</td>
<td>0.573-0.632</td>
<td>0.76</td>
</tr>
<tr>
<td>MSKCC</td>
<td>0.584</td>
<td>0.554-0.613</td>
<td>0.82</td>
</tr>
<tr>
<td>IMDC</td>
<td>0.581</td>
<td>0.551-0.611</td>
<td>0.73</td>
</tr>
<tr>
<td>UISS</td>
<td>0.573</td>
<td>0.549-0.597</td>
<td>0.73</td>
</tr>
<tr>
<td>Cindolo</td>
<td>0.555</td>
<td>0.525-0.584</td>
<td>0.67</td>
</tr>
<tr>
<td>Yaycioglu</td>
<td>0.554</td>
<td>0.524-0.584</td>
<td>0.65</td>
</tr>
</tbody>
</table>

c-index = concordance index, NR = not reported
59. OUTCOMES OF RENAL MASS BIOPSY IN ANATOMICALLY COMPLEX LESIONS
SELMA MASIC¹, Abhishek Srivastava², Marc Smaldone², Barton Milestone², Rosaleen Parsons², Rosalia Viterbo², Richard Greenberg², David Chen², Alexander Kutikov², Robert Uzzo²
¹ FOX CHASE CANCER CENTER, ² FCCC
Presented By: SELMA MASIC

Introduction: Renal mass biopsy (RMB) is increasingly used as a risk stratification tool to facilitate clinical decision making in patients with localized renal masses. The American Urological Association guidelines recommend core biopsies to optimize the diagnostic potential, but the decision to pursue a RMB is complex and often depends on multiple factors including the likelihood of diagnostic success based on a tumor’s anatomic complexity. Lower diagnostic yield has been associated with small, endophytic, hilar and anterior lesions. We compare diagnostic accuracy of core biopsies of anatomically complex renal masses as defined by their nephrometry score to their “non-complex” counterparts.

Methods: Our prospective, Institutional Review Board (IRB) approved renal cancer database was queried to identify all patients who underwent RMB between 2005-2018 and have an associated nephrometry score. Complex anatomy pertinent to RMB was defined as a renal mass that was (1) small (<2 cm), (2) entirely endophytic (nephrometry E=3), (3) hilar(h) or (4) partially endophytic (E=2) and anterior. RMBs obtained in the absence of these criteria were deemed “non-complex”. Demographic and pathologic data were compared between the groups. In cases where surgical pathology was available, biopsy data were compared to final surgical pathology for oncological (identification of malignancy), histological (RCC subtypes), and grade (low vs high) concordance. Pearson Chi-Square test was used for analysis with SPSS version 22 software.

Results: A total of 239 RMBs were identified, of which 146 (61%) were anatomically complex. Surgical pathology from eventual partial or radical nephrectomy was identified in 196 (82%) of the cases. Overall, core RMB was diagnostic in 97% (231/239) cases with concordance rates of 92% (181/196) for the diagnosis of cancer, 91% (179/196) for subclass histology and 67% (131/196) for nuclear grade compared with final surgical pathology. In comparison, there were different rates of oncologic concordance in 89% (106/119) for complex lesions and 97% (75/77) for “non-complex” lesions (p=0.03), histologic concordance 87% (104/119) for complex and 97% (75/77) for “non-complex” lesions (p=0.02), and grade concordance in 62% (74/119) versus 74% (57/77) (p=0.09).

Conclusion: RMB is diagnostic and accurate in small, endophytic, hilar and anterior anatomically complex renal masses, but the concordance rates with respect to identification of malignancy and histologic subtype are worse compared to “non-complex” masses. This may be due to confounding and unmeasured differences between the groups. Nonetheless, RMB should not be deferred in cases of anatomically complex lesions where additional data can improve clinical decision making. Appropriate patient counseling and management of expectations remain essential given the potential need for subsequent treatment plan adjustments.
60. COMPARING THE PROGNOSTIC VALUE OF PREOPERATIVE SERUM LABS AS BIOMARKERS FOR HIGH RISK RENAL CELL CANCER RECURRENCE USING THREE INDEPENDENT COHORTS

Emily L. Davidson1, Daniel D. Shapiro1, Glenn O. Allen1, David F. Jarrard1, Kyle A. Richards1, Tracy M. Downs1, E Jason Abel1, Jay D. Raman2, Brian Sohl2, Viraj Master3, Dattatraya Patil3

1 University of Wisconsin School of Medicine and Public Health, 2 Penn State Milton S. Hershey Medical Center, 3 Emory University School of Medicine

Presented By: Emily L. Davidson

Introduction: Multiple studies suggest that routinely collected preoperative serum labs have prognostic value to identify which patients are at increased risk for RCC recurrence. However, few studies have compared prognostic ability between lab values or among independent populations. The purpose of this study was to compare prognostic value of serum labs as biomarkers for recurrence in three independent cohorts of high risk non-metastatic RCC patients.

Methods: Clinical and pathologic data from non-metastatic =pT3a RCC patients who were treated surgically at 3 independent centers from 2000-2016 were analyzed. Cox proportional hazards analysis was used to evaluate associations of recurrence with preoperative serum lab values including: C-reactive protein (CRP), platelet count (PC), mean platelet volume (MPV), neutrophil: lymphocyte ratio (NLR), albumin, and hemoglobin (Hb).

Results: Of 746 patients with non-metastatic =pT3a RCC treated surgically at 3 institutions, the median 5-year recurrence free survival was 67%. Among individual cohorts, no differences in baseline age, gender or smoking history was identified but race and BMI were different among 3 populations (p<0.001, 0.005). Multivariate analysis was used to evaluate associations of race and BMI with baseline lab values considering differences in pT stage, grade, diameter, sarcomatoid features, thrombus, and systemic symptoms. Race was independently associated with Hb (p=0.002), and PC (p=0.003). BMI was independently associated with hemoglobin (p=0.02), albumin (p=0.02), and PC (p=0.02), and CRP (p=0.03). Per cohort analysis: NLR, CRP, MPV and albumin were prognostic in 1/3 cohorts. Hb was prognostic in 2/3 populations and PC was prognostic in all 3 cohorts. In combined cohort analysis: CRP, albumin, MPV, Hb, and PC were significant predictors of recurrence in univariate analysis. After multivariable analysis, independent predictors of recurrence included PC (HR 1.5, 95%CI 1.1-2.1, p=0.010), Hb (HR 1.5, 95%CI 1.0-2.2, p=0.034), tumor diameter (HR 1.1, 95%CI 1.1-1.2, p<0.001), and thrombus (HR 1.4 95%CI 1.2-1.5, p<0.001).

Conclusion: Preoperative platelet count and hemoglobin are prognostic factors for postoperative recurrence in high risk RCC patients. Baseline differences in labs values are associated race and BMI, and variability among independent cohorts may affect interpretation of prognostic ability within specific populations.

<table>
<thead>
<tr>
<th>Lab value prognostic?</th>
<th>Population 1</th>
<th>Population 2</th>
<th>Population 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albumin</td>
<td>+</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>CRP</td>
<td>+</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>+</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>MPV</td>
<td>-</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>N/L ratio</td>
<td>-</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Platelet count</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>
Introduction: The incidence of renal cell carcinoma (RCC) has been steadily increasing in the United States with a more rapid increase in the African American (AA) subgroup. Although different large population-based studies have tried to identify specific epidemiologic characteristics, data is still scant and controversial. The objective of this study was to describe the demographics, tumor characteristics and oncologic outcomes of AA and non-AA subpopulations in a RCC patient cohort with long-term follow up.

Methods: A retrospective review of patients who underwent partial or radical nephrectomy for renal masses between 2000-2015 was conducted. We collected preoperative, intraoperative and postoperative data and the cohort was divided into AA and non-AA. Patient demographics, tumor characteristics and oncological outcomes were compared between both groups.

Results: A total of 839 patients with an average follow-up of 72.5 months were identified and eligible for our cohort, with 37 (4.41%) being AA and 802 (95.59%) non-AA. African Americans were more likely to be younger at presentation (55.7 vs 62.1; p=0.0039) and male gender (89.2% vs 67.6%, p=0.0097) as compared to non-AAs. At baseline, AAs were more likely to have a history of hypertension (73.0% vs 55.4%, p=0.0341), chronic kidney disease (glomerular filtration rate <60ml/min; 51.3% vs 30.2%, p=0.0065) and be on dialysis at presentation (32.4% vs 2.0%, p<0.0001). Interestingly, variables associated with metabolic syndrome (BMI, obesity, diabetes and hypercholesterolemia) were not significantly different between both groups. Although clear cell RCC remained the most common histology (46.0%), AAs were found to have a greater percentage of papillary RCC (35.1% vs 16.8%, p=0.0043) than non-AAs. We found no differences in tumor stage and grade. There was no significant difference in recurrence rate, and overall survival (OS) between both groups (p=0.809 and p=0.689, respectively).

Conclusion: AA with RCC are younger in age at presentation, more likely to be male gender and have increased rates of hypertension and a higher renal disease burden. Additionally, papillary RCC is more common among AAs. These findings may suggest a different pathophysiologic process in RCC development among AA, with renal disease and hypertension likely playing a role.

Funding: Supported by The Frederick J. and Theresa Dow Wallace Fund of the New York Community Trust.
62. CLINICAL OUTCOMES OF LOW-STAGE SARCOMATOID RENAL CELL CARCINOMA
Alejandro Abello, Patrick Kenney, Michael Leapman
Yale School of Medicine

Presented By: Alejandro Abello

Introduction: Sarcomatoid features in renal cell carcinoma is a rare, adverse prognostic feature associated with higher tumor stage, metastatic risk, and poor survival. However, less is known about the clinical outcomes of low-stage tumors that have been treated with definitive surgical resection.

Methods: We queried the National Cancer Database, a hospital-based registry to identify patients who were treated with partial or radical nephrectomy for renal cell carcinoma for clinically localized tumors (stage =T1). We identified patients with clear cell carcinoma whose tumors displayed Sarcomatoid features. We compiled individual, demographic, clinical and pathologic data. We performed Cox regression hazard models to estimate overall survival during follow-up in patients with Sarcomatoid features including other disease characteristics that may affect clinical outcome such as tumor size, stage, age, histology, Charlson comorbidity index, race, sex, median income, urban/rural status, Hispanic heritage, and surgical approach. Our primary outcome corresponded to overall survival. Secondary outcomes corresponded to readmissions, 30 and 90-day mortality.

Results: We identified 68,845 patients with renal cell carcinoma cT1 and no evidence of metastatic disease treated with partial (52.74%) or radical nephrectomy (47.26%). From this cohort, 759 (1.1%) had evidence of sarcomatoid features. Compared to RCC with no sarcomatoid features, RCC with sarcomatoid was related to higher mean tumor size (46.7 ± 15.2 mm vs 35.5 ± 15.1 mm, P: <0.01), was seen more frequently in older population (63.1 ± 12.01 years/old vs 59.09 ± 12.5 years/old, P <0.01) and in males (65.48% vs 58.38%, P<0.01). After multiple variable Cox regression models, the presence of Sarcomatoid features increased the hazard for death during follow-up (HR 3.08, CI: 2.61-3.65; P<0.001) independently of surgical approach (Figure 1). 5-year overall mortality was 3.4-fold higher in patients with sarcomatoid. Readmission, 30-day and 90-day mortality were not statistically significantly different between groups.

Conclusion: Among patients with stage 1 tumors, the presence of sarcomatoid features was independently associated with shorter overall survival. Use of nephron sparing surgery was not associated with differences on survival.
63. UROLOGIST-LEVEL VARIATION IN THE MANAGEMENT OF SMALL RENAL MASSES: A SEER-MEDICARE ANALYSIS

Joseph Cheaib¹, Hiten Patel¹, Meredith Metcalf¹, Michael Johnson¹, Mohamad Allaf¹, Phillip Pierorazio¹, Joseph Canner²

¹ Johns Hopkins University School of Medicine, ² Johns Hopkins Bloomberg School of Public Health

Presented By: Joseph Cheaib

Introduction: Various strategies exist for the management of small renal masses, including active surveillance, thermal ablation, partial nephrectomy, and radical nephrectomy. Reporting individual urologist rates of the different approaches may be valuable to measure urologist performance and characterize unwarranted variation in the care of patients with small renal masses. Moreover, such data can have significant implications for patient and payer stakeholder groups. The urologist-level variation in the management of small renal masses has not been examined in the literature. In this study, we aimed to measure the variation in the use of each management approach at the urologist level for patients with small renal masses.

Methods: We performed a population-based study of patients diagnosed with small renal masses (cT1a tumors less than 4 cm in diameter) from January 1, 2004, to December 31, 2013, using the linked Surveillance, Epidemiology, and End Results (SEER)-Medicare database. Our outcome of interest was the management approach for the small renal mass, defined in SEER as either nonsurgical management (NSM), thermal ablation (TA), partial nephrectomy (PN), or radical nephrectomy (RN). Patients were assigned to a specific primary urologist using Medicare physician specialty codes. Separate multivariable mixed-effects logistic models were fit to evaluate the associations between each management approach and select patient characteristics, assuming a urologist-level random intercept to account for correlation among urologists and for calculation of urologist-level estimated probabilities of each approach. Each model adjusted for patient age at diagnosis, sex, race, Charlson comorbidity index, clinical tumor size, and year of diagnosis. From these models, predicted probabilities of each management approach along with 95% confidence intervals were obtained for each urologist, holding covariates constant at their frequency in the general population. Urologists were ranked based on their estimated probabilities for each management approach, and each point estimate was plotted relative to the overall mean estimated probability for that particular approach.

Results: A total of 12,738 patients with small renal masses (cT1a) along with 2791 primary urologists were identified. On average, each urologist saw 11 patients (median, 8 patients; interquartile range (IQR), 4-14 patients). The median age at diagnosis was 73 years (IQR, 69-78 years), and the majority of patients were males (N=7361, 57.8%), white (N=10870, 85.3%), and with a Charlson comorbidity index of 3 or higher (N=6622, 52%). The median clinical tumor size was 2.7 cm (IQR, 2.0-3.5 cm). 1775 (13.9%) patients underwent NSM, 1830 (14.4%) underwent TA, 4119 (32.3%) underwent PN, and 5014 (39.4%) underwent RN. The predictors of each management approach on multivariable mixed-effects logistic modeling are presented in Table 1. Interestingly, the likelihoods of undergoing NSM and PN were significantly associated with being diagnosed in 2009 and increased thereafter. At the individual urologist level, the estimated probability of NSM, TA, PN, and RN varied markedly: NSM (mean, 12.8%; range, 5.3-40.1%); TA (mean, 12.2%; range, 2.1-63.7%); PN (mean, 31.3%; range, 9.9-72.0%); RN (mean, 38.9%; range, 14.6-74.6%) (Figure 1A-D). Of the 2791 primary urologists, 1711 (61.3%) did not perform any NSM, 1910 (68.4%) did not perform any TA, 1148 (41.1%) did not perform any PN, and 900 (32.2%) did not perform any RN.

Conclusion: Considerable urologist-level variation exists in the management of small renal masses. An increase in NSM and PN was noted since the release of the 2009 American Urological Association (AUA) Guidelines for Clinical Stage I RCC and End-Stage Renal Disease (ESRD). Our study reveals the variable use of different management approaches among US urologists and establishes a framework for developing quality-improvement measures to improve the delivery of guideline-based care.
64. PARTIAL VERSUS RADICAL NEPHRECTOMY FOR CLINICAL T2 RENAL MASSES
Matvey Tsivian, Vignesh Packiam, Svetlana Avulova, Christine Lohse, Stephen Boorjian, Bradley Leibovich, Aaron Potretzke
Mayo Clinic
Presented By: Matvey Tsivian

Introduction: Only scarce data are available on the comparative outcomes of partial (PN) and radical nephrectomy (RN) in large (clinical T2) renal masses. We sought to evaluate functional and oncologic outcomes of these patients.

Methods: Patients undergoing PN and RN for clinical T2 renal masses between 2000 and 2016 were studied. Perioperative outcomes included overall and major (Clavien III-V) complications. Renal functional outcomes included changes in estimated glomerular filtration rate (eGFR) at diagnosis to 1 and 3 years postoperatively and new onset eGFR<60 and eGFR<15. Oncologic outcomes assessed in patients with renal cell carcinoma (RCC) included overall, cancer-specific, and metastases-free survival. Baseline features and outcomes were compared after adjusting for inverse probability weighted propensity scores.

Results: Out of 446 patients in the analytic cohort, 73 (16%) underwent PN. Clinical and radiographic features were well balanced between the groups. Overall and major complication rates were not significantly different between PN and RN patients: 21 vs 13%, p=0.10 and 4 vs 2%, p=0.16. Decline in eGFR at 1 and 3 years was more pronounced in RN: 16 vs 5 ml/min/m2, p<0.001 and 13 vs 2, p=0.009, respectively. A greater proportion of RN patients had new onset eGFR<60 at 1 and 3 years: 55 vs 17%, p<0.001 and 48 vs 17%, p=0.009, respectively. Among patients with RCC, overall, cancer-specific, and metastases-free survival were not significantly different.

Conclusion: These data support the use of PN in select patients presenting with clinical T2 renal masses.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Partial Nephrectomy</th>
<th>Radical Nephrectomy</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in eGFR at 1 year</td>
<td>-16 (-25 to -8)</td>
<td>-16 (-25 to -8)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Change in eGFR at 3 years</td>
<td>-13 (-23 to -2)</td>
<td>-13 (-23 to -2)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Any complication</td>
<td>35 (21)</td>
<td>47 (33)</td>
<td>0.10</td>
</tr>
<tr>
<td>High grade complication</td>
<td>3 (4)</td>
<td>3 (4)</td>
<td>0.16</td>
</tr>
<tr>
<td>eGFR at 1 year &lt;60*</td>
<td>1 (17)</td>
<td>87 (55)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>eGFR at 3 years &lt;60*</td>
<td>4 (17)</td>
<td>85 (48)</td>
<td>0.009</td>
</tr>
<tr>
<td>eGFR at 1 year &lt;15</td>
<td>0</td>
<td>1 (&lt;1)</td>
<td>NE</td>
</tr>
<tr>
<td>eGFR at 3 years &lt;15</td>
<td>3 (8)</td>
<td>2 (1)</td>
<td>NE</td>
</tr>
</tbody>
</table>

*Evaluated on the subset with eGFR at diagnosis <60.
†Evaluated on the subset with eGFR at diagnosis <15.
NE: Not evaluated because there were 5 or fewer patients with the outcome of interest.
65. TREND AND CHARACTERISTICS OF SMALL RENAL MASSES

Francesco Claps1, Nicola Pavan1, Carmelo Morreale1, Michele Rizzo1, Matteo Boltri1, Francesca Migliozzi1, Giovanni Liguori1, Carlo Trombetta1, Venus Shafiei2, Rossana Bussani2

1 Urological Clinic, Department of Medicine, Surgery and Health Sciences - University of Trieste, 2 Pathology Unit, Department of Medicine, Surgery and Health Sciences - University of Trieste

Presented By: Francesco Claps

Introduction: Doubtless, advances in imaging technology such as abdominal ultrasounds, computed tomography (CT) and magnetic resonance (MRI) are playing an important role in the diagnosis of renal masses (RM) and so of renal cell carcinoma (RCC) before the presence of clinical symptoms. This aspect has promised interest in active surveillance (AS) as a treatment option for the small masses, especially if supported by an imaging-guided biopsy that can characterize the tumor, that most likely will not contribute to cancer specific mortality. To the best of our knowledge, contemporary data evaluating the temporal trend of pathological characteristics and the relationship with cancer-related death of the incidental RM are not available. The aim of this study was to analyze incidence trend, changes in clinical characteristics, pathological features and cancer-related death of RM incidentally discovered at time of autopsy in a long period of time.

Methods: Data were retrieved from the autopsy register of the Pathology Department of a single tertiary referral center from 15086 consecutive autopsies performed between January 2004 and December 2017. Patients with previous history of primary RCC and patient with a kidney metastatic involvement from other tumors were excluded from this study.

Results: Overall, 184 (1.22%) RM were found. Benign and malignant lesions were respectively 32(17.4%) and 152(82.6%). The mean age at death was 82 years (SD 11.2) and the majority of patients were female (56.5%). Histologically were oncocytoma 13(7.1%), angiomyolipoma 13(7.1%), papillary adenoma 4(2.2%), cystic nephroma 3(1.6%), metanephric tumor 2(1,1%), clear-cell RCC 136 (73,9%) in which occurred 2(1,5%) sarcomatoid variant, papillary RCC 2(1,1%), chromophobe RCC 5(2,7%), carcinoma of the collecting ducts of Bellini 5(2,7%), nephroblastoma 1(0,5%). Considering the malignancies, pathological stage was: pT1 126(80,3%), pT2 10(6,4%), pT3 16(10,2%) and pT4 5(3,2%). In 16(10,2%) cases these were the cause of death. Temporal trend of incidence of RM and RCC decreased significantly over the years (p=0,01 and p=0,01 respectively). While the average age at death, sex and the distribution of the different histotypes remained constant over the time, RM found in the last years are increasing smaller (p=0,04) and only in one case in the last seven years RM was the cause of the patient's death.

Conclusion: The autopsy finding of incidental RM is decreasing. Although the distribution of the different kidney tumor histotypes appears constant, the mean size of the lesions that are incidentally identified at autopsy are increasingly smaller and more harmless. The incidental finding of RM is nowadays more common using the modern imaging techniques.
66. INTRATUMORAL HETEROGENEITY OF PDL-1 EXPRESSION IN T3 RENAL CELL CARCINOMA
Allison May, Elizabeth Davaro, Katherine Schwetye, Coleman McFerrin, Facundo Davaro, Sameer Siddiqui, Zachary Hamilton
Saint Louis University
Presented By: Allison May

Introduction: Recent studies have shown survival benefit for patients treated with PD-1 and PDL-1 inhibitors for advanced renal cell carcinoma. Interestingly, response to treatment has not been shown to be consistently related to PDL-1 expression of the tumor. We hypothesized that kidney tumors may exhibit intra-tumoral heterogeneity of PDL-1 expression, thus leading to variation of tumor staining.

Methods: All patients who underwent radical nephrectomy for stage T3 renal masses at our institution in the last 6 years were reviewed. Retrospective chart review was performed and tumor specimens were obtained from our pathology tumor bank. Tumors were stained for PD-L1 expression with 2 to 4 samples from each specimen. PDL-1 expression was classified as <1%, 1-5%, or >5%. Highest PD-L1 expression was used to correlate PDL-1 expression with covariables including demographics, tumor stage and grade, recurrence, and survival.

Results: We identified 23 patients who underwent radical nephrectomy for T3 tumors and had available tumor specimens. 15 tumors (65%) had positive PDL-1 staining in at least one sample (PDL-1 expression =1%). 13 tumors (56%) exhibited variation in PDL-1 expression between samples and 8 (35%) had at least one negative and one positive sample within the same tumor. PDL-1 expression varied based on location within the tumor (Figure 1), with the highest rates of positive expression from the mass involvement of the renal pelvis and the lowest rates of expression from the mass involvement of perirenal fat. PDL-1 expression was not found to be significantly related to age, race, sex, tumor grade, tumor recurrence or survival.

Conclusion: PDL-1 expression can vary significantly with T3 renal cell carcinoma, based on the area of tissue sampling. Further research is necessary to standardize methods of PDL-1 sampling and determine which patients may benefit from PDL targeted therapy.
67. DETERMINING THE REPRESENTATION OF RACIAL MINORITIES WITH GENITOURINARY CANCERS IN THE NATIONAL CANCER DATABASE

Kyle Michelson¹, Danielle Gordon¹, Tashzna Jones¹, Thomas Monaghan¹, Raymond Kharqi¹, Matthew Smith¹, Fenizia Maffucci¹, Hyezo Kwun¹, Nicholas Suss³, Andrew Winer²

¹ SUNY Downstate Medical Center, Department of Urology, ² Kings County Hospital, Department of Urology

Presented By: Kyle Michelson

Introduction: The National Cancer Database (NCDB) has provided data for numerous studies in urologic oncology. However, no study has examined the racial sampling bias of the NCDB in urologic cancer patients. Here we seek to delineate the racial bias present in five categories of genitourinary cancers in the NCDB by comparing it to the population-based United States Cancer Statistics (USCS) registry.

Methods: The NCDB covers cancer diagnoses at Commission of Cancer Centers, whereas the USCS covers 100% of the US population. The incidence of new diagnoses of primary urologic cancers stratified by race from 2004-2015 in the NCDB was compared to the same years in USCS in order to calculate a capture rate (percentage of diagnoses in USCS also represented in NCDB). Each race’s capture rate was compared to that of white patients in order to determine statistical difference. Renal and bladder cancer was further stratified by gender due to the male predominance of the malignancy. A chi-square test was performed to see if capture rates varied significantly by race.

Results: The NCDB captured 57.12% of the prostate cancer diagnoses for white patients found in the USCS versus 53.19% for black patients, 29.55% for Native American/Native Alaskan (NANA), and 50.23% for Asian or Pacific Islander (API) which were all statistically significant (p=< 0.0001). 73.25% of white vs 71.67% of black, 39.20% NANA, and 63.5% API renal cancer diagnoses were captured (p=< 0.0001). This difference remained when looking at black male renal cancer patients (p=< 0.0001), but not in females (p=0.5997). The capture rate was higher for black than white patients with bladder cancer (p=< 0.0001). However, NANA and API bladder cancer patients had significantly lower capture rates than their white counterparts (28.34% and 56.16% respectively, p=< 0.0001). No difference was found for penile (p=0.5153) and testis cancer (p=0.1024) in black patients, but the capture rate was lower for NANA and API patients for these cancers (p=< 0.0001).

Conclusion: Black patients in the USCS with prostate and renal cancers are less likely to be represented in the NCDB than white patients, whereas black patients with bladder cancer are overrepresented in the NCDB. NANA and API are universally underrepresented in NCDB for GU cancers. It is vital to consider this sample bias when interpreting NCDB-driven studies in urologic oncology.

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>White Capture Rate</th>
<th>Black Capture Rate</th>
<th>Asian or Pacific Islander Capture Rate</th>
<th>Native American/Alaskan Native Capture Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prostate</td>
<td>57.12%</td>
<td>53.19%</td>
<td>30.23%</td>
<td>29.55%</td>
</tr>
<tr>
<td>(112,639/1,971,925)</td>
<td>(192,786/362,429)</td>
<td>(24,651/49,077)</td>
<td>(2,971/5,939)</td>
<td></td>
</tr>
<tr>
<td>Renal (All)</td>
<td>73.25%</td>
<td>71.67%</td>
<td>39.20%</td>
<td>37.08%</td>
</tr>
<tr>
<td>(394,075/357,996)</td>
<td>(32,015/72,576)</td>
<td>(8,272/13,028)</td>
<td>(2,164/5,475)</td>
<td></td>
</tr>
<tr>
<td>Renal (Male)</td>
<td>78.87%</td>
<td>74.83%</td>
<td>41.69%</td>
<td>41.69%</td>
</tr>
<tr>
<td>(203,377/272,373)</td>
<td>(21,490/29,030)</td>
<td>(9,994/16,698)</td>
<td>(9,173/15,675)</td>
<td></td>
</tr>
<tr>
<td>Bladder (All)</td>
<td>63.36%</td>
<td>64.34%</td>
<td>56.18%</td>
<td>28.34%</td>
</tr>
<tr>
<td>(40,723/759,961)</td>
<td>(28,199/43,836)</td>
<td>(28,199/43,836)</td>
<td>(7,505/13,364)</td>
<td></td>
</tr>
<tr>
<td>Bladder (Male)</td>
<td>63.36%</td>
<td>64.34%</td>
<td>56.18%</td>
<td>28.34%</td>
</tr>
<tr>
<td>(36,338/578,811)</td>
<td>(28,199/43,836)</td>
<td>(28,199/43,836)</td>
<td>(7,505/13,364)</td>
<td></td>
</tr>
<tr>
<td>Bladder (Female)</td>
<td>63.36%</td>
<td>64.34%</td>
<td>56.18%</td>
<td>28.34%</td>
</tr>
<tr>
<td>(118,985/181,159)</td>
<td>(10,008/14,600)</td>
<td>(8,057/11,923)</td>
<td>(2,164/5,475)</td>
<td></td>
</tr>
<tr>
<td>Penile</td>
<td>65.64%</td>
<td>65.64%</td>
<td>65.64%</td>
<td>65.64%</td>
</tr>
<tr>
<td>(13,087/20,013)</td>
<td>(9,994/16,698)</td>
<td>(7,505/13,364)</td>
<td>(2,164/5,475)</td>
<td></td>
</tr>
<tr>
<td>Testis</td>
<td>63.36%</td>
<td>63.36%</td>
<td>63.36%</td>
<td>63.36%</td>
</tr>
<tr>
<td>(96,556/150,664)</td>
<td>(65,641/103,569)</td>
<td>(7,505/13,364)</td>
<td>(2,164/5,475)</td>
<td></td>
</tr>
</tbody>
</table>

*Patients for whom the race was unknown or unspecified were excluded from table.
68. IMPACT OF VARIANT HISTOLOGY ON SURVIVAL AND RESPONSE TO CHEMOTHERAPY IN PATIENTS WITH UPPER TRACT UROTHELIAL CELL CARCINOMA
Wilson Sui, Daniel A. Barocas, Sam S. Chang, David F. Penson, Matthew Resnick, Aaron A. Laviana
Vanderbilt University Medical Center Department of Urology
Presented By: Wilson Sui

Introduction: Upper tract urothelial carcinoma (UTUC) is a rare genitourinary malignancy that represents only 5-10% of all urothelial carcinoma (UC). While the majority of these cancers will be derived from urothelium, variant histology (VH) is reported in < 5% of these cases. We sought to identify prognostic and treatment factors for variant histology of UTUC using a nationwide database.

Methods: The National Cancer Database (NCDB) was queried for all cases of UTUC from 2004-2016. Patients with other cancer diagnoses, metastasis, and/or diagnosis on autopsy were excluded. Kaplan-Meier and Cox proportional hazards regression were used to identify independent predictors of overall survival.

Results: We identified 27,737 patients with UC versus 1,093 with VH, respectively. VH presented at both higher T and N stage versus UC and was more commonly metastatic. Not only was overall median survival significantly worse for VH (30 months, 95% CI 22.3 – 37.8 versus 67.5 months, 95% CI 63.3 – 73.0) but also inferior when stratified by stage. On multivariable cox proportional hazards analysis, VH was associated with worse hazards of survival versus UC (HR 1.341, 95% CI 1.196 – 1.504). On sub-analysis, patients who were =pT2N0/XM0/X or pN+M0/X after radical nephroureterectomy appeared to benefit from adjuvant chemotherapy across both UC and VH with improved hazards of survival.

Conclusion: Variant histology of the upper urinary tract is associated with later stage at presentation and worse survival when compared to UC, even when adjusted for stage. Adjuvant chemotherapy may improve survival in this cohort.

Figure 1. Kaplan-Meier curves detailing survival of patients with upper tract urothelial carcinoma. (A) Overall survival stratified by histology – urothelial carcinoma (UC) versus variant histology (VH). (B) Survival of =pT2N0/XM0/X patients after radical nephroureterectomy (RNUx) stratified by adjuvant chemotherapy (AC) and histology. (C) Survival of pN+M0/X patients after RNUx stratified AC and histology.
69. SETTING THE STANDARDS: EXAMINING RESEARCH PRODUCTIVITY AMONGST ACADEMIC UROLOGISTS IN THE UNITED STATES AND CANADA IN 2019
Timothy Han1, Lydia Glick1, Joon Yau Leong1, Seth Teplitzky1, James Ryan Mark1, Mark J. Mann1, Edouard J. Trabulsi1, Costas D. Lallas1, Leonard G. Gomella1, Thenappan Chandrasekar1, Rodrigo Noorani2, Hanan Goldberg3, Zachary Klaassen4, Christopher JD Wallis1

1 Department of Urology, Sidney Kimmel Cancer Center, Thomas Jefferson University, Philadelphia, PA, 2 Division of Urology, Department of Surgery, University of Toronto, Toronto, Ontario, Canada, 3 Department of Urology, State University of New York Upstate Medical University, Syracuse, NY, USA, 4 Division of Urology, Department of Surgery, Augusta University – Medical College of Georgia, Augusta, GA; Georgia Cancer Center, Augusta, GA, 5 Division of Urology, Department of Surgery, University of Toronto, Toronto, ON, Canada; Department of Urology, Vanderbilt University Medical Center, Nashville, TN, USA

Presented By: Timothy Han

Introduction: Research productivity amongst academic urologists is strongly encouraged, but little data is available on productivity metrics within the field of urology. We provide the first comprehensive survey of research productivity amongst academic urologists in the United States and Canada.

Methods: Using the Accreditation Council for Graduate Medical Education (ACGME) and individual program websites, all active accredited urology residency programs and their faculty were documented for demographics (program: AUA section, residents/year, fellowship status; physician: title, fellowship training, Scopus H-index and citations). Comprehensive searches were completed for all programs and physicians during March-May 2019. Descriptive statistics for demographic comparisons were performed using analysis of variance (ANOVA) for continuous variables and chi-square test for categorical variables. Multivariable logistic regressions were used to identify predictors of H-index greater than the median (> 12).

Results: 2214 academic urology faculty (2015 USA, 199 Canada) were identified. Median H-index for the entire cohort of physicians was 11 (Figure 1). Table 1 highlights the median H-index stratified by academic title, AUA section, gender, and fellowship training. On multivariable analysis, physicians in the North Central and Western Sections (vs. Mid-Atlantic), physicians who were fellowship-trained (vs. no fellowship training), and physicians of higher academic rank (Professor and Associate Professor vs. clinical instructor) were more likely to have H-index values greater than the median. Female physicians (vs. male) were more likely to have H-index values less than the median.

Conclusion: This study represents the first comprehensive assessment of research productivity metrics amongst academic urologists. These represent key benchmarks for trainees considering careers in academics and for practicing physicians gauging their own productivity in relation to their peers.
70. A NATION-WIDE ANALYSIS OF PALLIATIVE CARE USE IN PATIENTS WITH METASTATIC PENILE CANCER

Facundo Davaro¹, Allison May², Johar Syed², Sameer Siddiqui², Zachary Hamilton²
¹ Saint Louis University, ² Saint Louis University Department of Surgery, Division of Urology

Presented By: Facundo Davaro

Introduction: Advanced penile cancer is associated with a poor prognosis; therefore, providing patients with palliative therapy when appropriate is critical to appropriate quality of life. We aim to analyze the role and trends in use of palliative therapy in patients with metastatic penile cancer.

Methods: The National Cancer Database penile cancer dataset from 2004-2015 was queried for patients with metastatic disease (cTanyNanyM1). Patients were categorized based upon receipt of palliative treatment. Palliative care was catalogued as pain management therapy, surgery, radiation, systemic treatment, or any combination therapy. Our primary outcome was receipt of palliative treatment. Secondary outcome was the temporal trend in palliative care. Logistic regression (LR) was performed.

Results: 279 patients were identified with metastatic penile cancer with 49 (17.6%) of those receiving palliative care. The mean age of patients receiving palliative care was 61.9 and 67.1 years old who did not receive palliative therapy (p <0.011). Other patient specific demographics and clinical tumor characteristics were not significantly different between the two cohorts. Radiation (32.7%) and systemic therapy (24.5%) were the most prevalent choices for palliative treatment followed by combination treatment (16.3%), surgery (12.2%), pain management (10.2%), or unspecified palliation (4.1%). LR for the receipt of “any palliative therapy” revealed that increasing age (OR 0.97, p=0.03) decreased the likelihood of accepting palliative therapy. Meanwhile, African-American race (OR 2.5, p=0.025), Charlson score 1 (2.17, p=0.047) and 3+ (5.39, p=0.02) predicted an increased predilection for receiving palliative therapy. Interestingly, no statistically significant difference in mortality was noted between cohorts. No significant increase in the trend over time of palliative care administration was seen from 2004 to 2015 (p=0.94).

Conclusion: Metastatic penile cancer carries a high mortality rate yet only 17.9% of patients receive palliative treatments. Palliation is more common in younger patients, those with co-morbidities, and those of black race. Receipt of palliative care did not alter survival. No changes in the frequency of use were seen over time.
71. NEOADJUVANT (NACT) VERSUS ADJUVANT CHEMOTHERAPY (ACT) FOR THE TREATMENT OF LOCALLY ADVANCED PENILE CANCER (PCa): A PROPORTIONAL META-ANALYSIS OF CASE SERIES STUDIES

Dr., Philip Haddad, Dr., Dalia Hammoud, Dr., Kevin Gallagher
LSUHSC-S, Overton Brooks VAMC
Presented By: Dr., Philip Haddad

Introduction: Penile cancer (PeCa) is a rare but aggressive malignancy in industrialized countries. Despite surgical interventions, men who present with locally advanced disease have a relatively high risk of treatment failures with local and distant metastases. Given the overall poor prognosis for men with high-risk features, chemotherapy, be it in the neoadjuvant or adjuvant setting, may be of value in mitigating some of this risk. Currently, there are no large studies or randomized trials to provide solid evidence in that regard. Neoadjuvant chemotherapy in PeCa has been trending over time as it serves as cytoreductive approach to make surgical resection more feasible. However, there have been no direct head-to-head comparisons between these 2 chemotherapy approaches in PeCa with respect to surrogates of clinical efficacy. The purpose of this proportional meta-analysis is to compare death rates and recurrence rates of NACT versus ACT in locally advanced penile cancer patients.

Methods: A review of the literature was conducted and was restricted to the English language. Studies were obtained from the following sources: MEDLINE, EuropePMC, Cochrane database, article references, and Oncologic and Urologic Societies’ Proceedings. Inclusion criteria were (i) English language (ii) case series design reporting on more than 4 cases, (iii) use of NACT or ACT, (iv) patients with locally advanced PeCa and, (v) documentation of clinical outcomes of interest: death rates, recurrence rates, and NACT response rates. Proportional meta-analysis was conducted using the random-effects model. The respective 95% confidence intervals were calculated and funnel plots were constructed.

Results: Eighteen case series (12 NACT, 6 ACT) met all inclusion criteria. The pooled proportion (random effect) of death rates (DR), recurrence rates (RcR), and response rates (RR) were 58% (95%CI:52-64), 51% (95%CI:37-65), 52% (95%CI:46-59) in NACT from a total of 371 cases. The only statistically significant heterogeneity between these studies reflecting the inconsistency of clinical and methodological aspects was found in RcR analysis (I²=84.8% vs DR 20.8%, RR 27.5%). The pooled proportion (random effect) of DR and RcR were 37% (95%CI:24-48) and 46% (95%CI:38-54) in ACT from a total of 181 cases. The only statistically significant heterogeneity between these studies reflecting the inconsistency of clinical and methodological aspects was found in DR analysis (I²=63% vs RcR 0%). Using the proportional meta-analysis method, there was a significant difference with respect to DR between NACT and ACT but none was found with respect to RcR.

Conclusion: This proportional meta-analysis, which is the first of its kind in PeCa, shows that in locally advanced disease, NACT is associated with higher death rates but not recurrences than ACT. This finding may be the result of increased toxicity of NACT as it interacts with surgical morbidity and mortality. It may also be the result of an inherent selection bias where higher risk locally advanced PeCa are prescribed NACT in attempt to enhance surgical resectability and outcome. Prospective international clinical trials are expected to help clarify the role of chemotherapy, be it NACT or ACT, in locally advanced PeCa.
72. MANAGEMENT OF LOCALIZED PENILE CANCER WITH AN ORGAN SPARING APPROACH USING SPLIT THICKNESS SKIN GRAFTING RESULTS IN EXCELLENT ONCOLOGIC AND FUNCTIONAL OUTCOMES

Ben Beech, Jan Rudzinski, Keith Rourke
University of Alberta

Presented By: Ben Beech

Introduction: Penile cancer is an uncommon malignancy in North America, but can have devastating morbidity and mortality. Organ sparing approaches to the management of localized disease have become the new standard, in order to preserve urinary and sexual function, and to minimize the psychosocial impacts of treatment. Split thickness skin grafting (STSG) techniques have been successfully utilized for genital reconstruction and allow for an organ sparing approach in the treatment of localized penile cancer.

Methods: We present the case series of a single surgeon, with fellowship training in reconstructive urology. All patients who underwent resection and STSG reconstruction for localized penile cancer were identified. Baseline characteristics were recorded, as well as oncologic, and functional outcomes.

Results: We identified 12 patients who underwent resection and STSG reconstruction for localized penile cancer between June 2014 and June 2019. Median follow up was 14 months (range 1 to 59). The median age was 62 years old (range 32 to 85). All patients had a pathologic diagnosis of penile carcinoma in situ (CIS) or squamous cell carcinoma (SCC) from prior biopsy or resection. Seven patients had undergone prior therapy (topical therapy in 5, external beam radiotherapy in 1, attempted Moh’s microsurgery in one). The majority of patients were current or former smokers, were obese, and had not had a pediatric circumcision. In all cases, glansectomy was performed followed by the use of a STSG (harvested from the thigh) in order to reconstruct a neo-glans. Graft take was excellent in all cases when evaluated at the 4 week post-operative visit. There was no graft loss. The 90-day significant adverse event (SAE) rate was 0%. Standing voiding and erectile function were maintained in all patients. All patients had acceptable cosmesis and were satisfied with their outcome. A single patient required a subsequent meatal dilation, and 2 others required subsequent procedures for local recurrence. Final pathology ranged from pTis to pT2. Margins were positive in 2 of 12 patients. Local recurrence occurred in 2 patients at 2, and 5 months respectively. One of these patients underwent a repeat organ sparing procedure for salvage, while the other required a radical penectomy and lymph node dissection and unfortunately went on to developed metastatic disease.

Conclusion: We present our series of men treated with organ sparing surgery for localized penile cancer, utilizing STSG techniques. From a functional perspective, we were able to preserve excellent urinary and sexual function in all men. From an oncologic perspective, only 2 men developed local recurrence, 1 of whom was successfully salvaged with a repeat organ sparing procedure. We have demonstrated that STSG reconstruction is a viable technique for organ sparing in well selected men with localized penile cancer.
73. SYSTEMIC TREATMENT FOR METASTATIC CASTRATION RESISTANT PROSTATE CANCER (M-CRPC): DOES SEQUENCE MATTER?
Jack Andrews¹, Mohamed Ahmed¹, Robert Karnes¹, Eugene Kwon¹, Alan Bryce²
¹ Mayo Clinic, ² Mayo Clinic Arizona

Presented By: Jack Andrews

Introduction: Optimal sequencing of systemic therapy in the management of m-CRPC remains poorly elucidated. The CHAARTED and STAMPEDE studies have proven that early chemotherapy in the hormone-sensitive setting is superior to later chemotherapy. In a retrospective study, we attempt to investigate the two most common treatment sequences and investigate whether this holds true in the hormone-resistant setting.

Methods: Retrospectively, we identified 112 patients with m-CRPC. 80 patients (Group-A) received full course docetaxel chemotherapy followed by 2nd generation hormone therapy (2ndADT; Abiraterone or Enzalutamide). 32 patients (Group-B) received docetaxel after 2ndADT failed. The primary endpoint evaluated was 3-year cancer-specific survival.

Results: Median PSA was 5 in Group-A and 13.95 in Group-B. Bone-metastases were more prevalent in Group-B (87% vs 58%). All other clinicopathologic variables were statistically similar between Group-A and Group-B. (Table 1) Three-year cancer-specific survival was 87.4% and 64.1% for Group-A and Group-B, p=0.016. (Figure 1a) We report Hazard Ratio of 3.61 (95% CI 1.74-9.50, p=0.01). Three-year overall survival was 82.4% and 60.8% for Group-A and Group-B, p=0.01. (Figure 1b) These results held true when excluding patients with lymph node only metastasis.

Conclusion: Our data indicates that sequence of systemic therapy may influence outcomes for m-CRPC and that Docetaxel should be considered prior to 2nd generation ADT. Selection bias is inherent in retrospective studies such as this, however our results support the importance of earlier chemotherapy in the hormone-resistant state.
74. SURVIVAL OUTCOMES FOR METASTATIC CASTRATION-RESISTANT PROSTATE CANCER WITH PSA LESS THAN 5.0 NG/mL TREATED WITH SIPULEUCEL-T, OVERALL AND BY RACE: DATA FROM THE PROCEED REGISTRY

Richard Tutrone¹, Christopher Pieczonka², Luke Nordquist³, Raoul Concepcion⁴, Scott Flanders⁵, Andrew Armstrong⁶

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Presented By: Richard Tutrone

Introduction: Sipuleucel-T reduced risk of death by 22.5% (P = 0.032) in the IMPACT trial, which excluded men with baseline PSA <5.0 ng/mL. Lower baseline PSA levels are associated with lower disease burden and a greater benefit with sipuleucel-T, with greater benefits in black men. We examined overall survival in sipuleucel-T-treated mCRPC patients with baseline PSA <5.0 ng/mL in PROCEED (NCT01306890).

Methods: This exploratory analysis included 1,866 men who received 1 or more infusions of sipuleucel-T and had a reported baseline PSA. First, patients were grouped according to baseline PSA < 5.0 ng/mL (low PSA; n = 451 [23.9%]) or ≥ 5.0 ng/mL (high PSA; n = 1435 [76.1%]). Overall survival was calculated per Kaplan-Meier methods. Second, overall survival within these subgroups was analyzed by self-reported race.

Results: Demographics and baseline characteristics are described in Table 1. Median survival time was 47.9 months (95% CI: 43.8-52.0 months) and 26.4 months (95% CI: 24.7-27.7 months) in the low and high PSA groups, respectively (hazard ratio, 2.12, 95% CI: 1.83-2.46; P < 0.001). In the analysis by race, risk of death was 51% lower in low PSA black men (n = 35) vs white men (n = 407) (hazard ratio, 0.49; 95% CI: 0.26-0.92; P = 0.026) and 20% lower in high PSA black men (n = 185) vs white men (n = 1227) (hazard ratio, 0.80; 95% CI: 0.66-0.97; P = 0.024).

Conclusion: This post-hoc analysis demonstrates a survival of nearly 4 years when sipuleucel-T treatment is initiated in men with low PSA (<5.0 ng/mL) compared to patients with high PSA. Further, regardless of whether baseline PSA was above or below 5 ng/mL, treatment with sipuleucel-T resulted in a significant reduction in risk of death in black men as compared to white men. Use of sipuleucel-T in men with lower disease burden may improve their survival.

Funding: Dendreon Pharmaceuticals LLC

<table>
<thead>
<tr>
<th>Age, years</th>
<th>All Enrolled Men</th>
<th>White Men</th>
<th>Black Men</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline PSA</td>
<td>&lt; 5 ng/mL (N=451)</td>
<td>≥ 5 ng/mL (N=1435)</td>
<td>&lt; 5 ng/mL (N=407)</td>
</tr>
<tr>
<td>Median</td>
<td>70.0</td>
<td>72.0</td>
<td>70.0</td>
</tr>
<tr>
<td>(Q1, Q3)</td>
<td>(64.0, 76.0)</td>
<td>(66.0, 78.0)</td>
<td>(64.0, 76.0)</td>
</tr>
<tr>
<td>[Min, Max]</td>
<td>[43, 89]</td>
<td>[42, 97]</td>
<td>[43, 89]</td>
</tr>
<tr>
<td>Race, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>407 (90.2%)</td>
<td>1277 (85.5%)</td>
<td>407 (100.0%)</td>
</tr>
<tr>
<td>Black or African American</td>
<td>35 (7.0%)</td>
<td>105 (12.8%)</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>9 (2.0%)</td>
<td>23 (1.6%)</td>
<td>0</td>
</tr>
<tr>
<td>ECOG performance status score ≥ 1, n (%)</td>
<td>108 (23.9%)</td>
<td>502 (35.0%)</td>
<td>97 (23.8%)</td>
</tr>
<tr>
<td>Worst Gleason Score Sum ≥ 7, n (%)</td>
<td>391 (86.7%)</td>
<td>1113 (79.0%)</td>
<td>126 (66.2%)</td>
</tr>
<tr>
<td>Had Radical Prostatectomy, n (%)</td>
<td>193 (42.8%)</td>
<td>488 (34.0%)</td>
<td>176 (43.2%)</td>
</tr>
<tr>
<td>Had Local Radiation, n (%)</td>
<td>228 (50.6%)</td>
<td>709 (49.4%)</td>
<td>205 (50.4%)</td>
</tr>
<tr>
<td>Baseline PSA, ng/mL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>2.0</td>
<td>24.0</td>
<td>1.9</td>
</tr>
<tr>
<td>(Q1, Q3)</td>
<td>(0.3, 3.4)</td>
<td>(11.3, 65.3)</td>
<td>(0.8, 3.4)</td>
</tr>
<tr>
<td>[Min, Max]</td>
<td>[0.0, 5.0]</td>
<td>[5.1, 7497.3]</td>
<td>[0.0, 5.0]</td>
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75. SALVAGE RADICAL PROSTATECTOMY (SRP) AFTER ROBOT-ASSISTED LAPAROSCOPIC PROSTATECTOMY (RALP): CASE SERIES
Mohamed Ahmed, Jack Andrews, Giovanni Motterle, Marco Moschini, Eugene Kwon, Jeffery Karnes
Mayo Clinic
Presented By: Jack Andrews

Introduction: The use of salvage open-radical prostatectomy (SRP) has not been studied in patients whose primary treatment, Robot-assisted Laparoscopic prostatectomy (RALP), had failed. The aim of this study is to report our primary experience regarding technical feasibility and safety of salvage open radical prostatectomy (SRP) after robotic assisted laparoscopic prostatectomy (RALP).

Methods: We retrospectively reviewed the medical records of five patients (n=5) who had undergone SRP after RALP failure for clinically localized prostate cancer evidenced on imaging.

Results: The patients’ ages ranged from 53.1 to 65.4. They presented to us with raising PSA at their 1st post-RALP check. The median (IQR) post-RALP PSA was 1.98 (1.64 - 10) ng/ml with median (IQR) doubling time of 4 (1.8 -16.9) months. Patients underwent cross-sectional imaging (CT) and pelvic magnetic resonance imaging (MRI) that confirmed presence of residual prostatic tissue. Retropubic open salvage radical prostatectomy (SRP) was performed with no peri-operative or post-operative complications. One patient has reported mild/moderate stress incontinence since his original RALP which he managed by pelvic exercises. The median follow-up duration was 7.8 years. Only one patient required the addition of adjuvant salvage treatment after 9.3 yrs. for signs of cancer progression as evidenced on imaging and by rising PSA.

Conclusion: In this small case series, SRP was a safe and technically feasible option for management of locally recurrent prostate cancer with residual prostate left behind during primary RALP. Prolonged follow up and further studies are warranted to validate our findings.

| Table 1 - Demographics and preoperative/postoperative data for RALP: |
|------------------------|------------------------|
| Patients, n | 5 (100%) |
| Age, year median (range) | 60.9 (52.4-63.02) |
| BMI (kg/m²), median (range) | 27.13 (23.9-30.3) |
| Preoperative PSA (ng/ml), median (range) | 7.8 (5-11.5) |
| Pathological Gleason score | 3+3 (80%) |
| Clinical stage T2 | 5 (100%) |
| Pathological Stage at RALP pT2 | 5 (100%) |
| Surgical Margin Positive | 0 (0%) |
| Time elapsed between RALP and rising PSA (months), median (range) | 3 (1-3) |
| Time elapsed between RALP and SRP (months), median (range) | 6 (3-12) |
| Postoperative PSA (ng/ml), median (IQR) | 1.98 (1.48-17.4) |
| PSA doubling Time, median (range) months | 4 (3.8-16.9) |
| BMI = body mass index; PSA = prostate specific antigen; RALP = robotic assisted laparoscopic prostatectomy; NA= information not available |

| Table 2 - Perioperative and postoperative outcomes of patients that underwent salvage radical prostatectomy |
|------------------------|------------------------|
| Patients, n (%) | 5 (100%) |
| Median Age (range) | 61.4 (51.07-65.5) |
| Blood loss, liters (median, range), cc | 300 (250-850) |
| In Hospital Stay, days (median, range) | 4 (2-5) |
| Gleason Score at surgery | GS3+3 3 (60%) |
| Nocancer 1 (20%) |
| GS3+4 1 (20%) |
| Surgical specimens, grams (median, range) | 25.95 (12.3-58.8) |
| PSA at time of srR, median (range) | 2.7 (0.29-11.9) |
| PSA after surgery (ng/ml), median (range) | 0.1 (0.1-0.95) |
| PSA doubling Time, median (range) months | 19.9 (18-25) |
| Median Follow-up by years (range) | 7.8 (6.02-11.01) |
| Adjuvant therapies: total | 1 patient (20%) |
| RT | 1 (20%) |
| HT | 1 (20%) |
| BMI = body mass index; PSA = prostate specific antigen; RALP = radical prostatectomy; RT = radiation therapy; HT = hormonal therapy |
76. SYSTEMATIC REVIEW AND META-ANALYSIS OF TRIALS EVALUATING THE ROLE OF ADJUVANT RADIATION AFTER RADICAL PROSTATECTOMY FOR PROSTATE CANCER
Bimal Bhindi¹, Zachary Klaassen², Soum Lokeshwar², Laurence Klotz³
¹ University of Calgary, ² Medical College of Georgia At Augusta University, ³ Sunnybrook Health Sciences Centre

Presented By: Christopher Wallis

Introduction: Adjuvant radiation (aRT) for men with adverse pathologic features at radical prostatectomy has been associated with improved biochemical control in 3 previously published randomized controlled trials but the impact on survival remains unclear. With the recent publication new data, our objective was to reassess if aRT versus observation is associated with improved oncologic outcomes among these patients.

Methods: We performed a systematic review and meta-analysis of randomized trials. The primary outcome was overall survival (OS) and secondary outcomes were metastasis-free survival (MFS), loco-regional recurrence-free survival (RFS), biochemical progression-free survival (bPFS), and adverse events. Data were summarized using forest plots and synthesized using a random-effects meta-analysis.

Results: Based on 4 randomized trials including 2068 patients with a median follow-up of 8.7-12.6 years, no significant OS benefit was detected aRT versus observation, although it offered a consistent bPFS and local-RFS benefit. There is an uncertain MFS benefit with aRT, and the effect is largely driven by one trial (SWOG-8794) with a notable risk of bias. There was also a moderate risk of overtreatment, with 35-60% of patients being biochemical recurrence-free with observation alone. There was a greater risk of experiencing any adverse events and grade 3-4 adverse events affecting gastrointestinal, urinary, and erectile function with aRT versus observation. The number of adverse events per patients was also higher with aRT.

Conclusion: Although there is a consistent bPFS and local-RFS benefit with aRT, there is no clear OS benefit and the MFS benefit is uncertain. There is a greater risk of adverse events and a risk of overtreatment with aRT. These data may be helpful in reassessing the relative merits and harms of aRT in the contemporary era where early salvage radiotherapy is an alternate option.
77. TIMING OF RADIATION AFTER RADICAL PROSTATECTOMY FOR MEN WITH PROSTATE CANCER MAY NOT AFFECT CLINICAL OUTCOMES
Samuel Washington1, Janet Cowan1, Peter Carroll1, Sikai Song2, Felix Feng3
1 Department of Urology, University of California San Francisco, 2 School of Medicine, University of California San Francisco, 3 Department of Radiation Oncology, University of California San Francisco
Presented By: Samuel Washington

Introduction: For men with locally advanced disease, local therapy offers the opportunity for cure. Yet approximately 30,000 are diagnosed annually with recurrence after radical prostatectomy (RP), primarily as PSA failure without other evidence of disease. If left untreated, most with elevated PSA after RP will develop bone metastases within 10 years thus driving the need to identify factors impacting oncologic outcomes after secondary treatment (adjuvant or salvage therapy). We examine our institution’s outcomes after secondary treatment to identify whether margin status or pathologic stage/grade are associated with increased worse outcomes after secondary treatment.

Methods: Men with localized prostate cancer managed with primary RP were identified in our institutional database. Those with clinical evidence of metastatic disease or nodal disease on surgical pathology were excluded. Secondary treatment was defined as adjuvant or salvage RT after RP. Androgen deprivation therapy (ADT) was reported but not required for inclusion. Descriptive statistics were used to summarize the cohort. Surgical pathology findings (stage, Gleason grade, and margin status) were abstracted from the medical record. Patients were grouped by presence of low or high risk features on surgical pathology and surgical margin status. Low-risk features were defined as pathologic stage T2 or T3a and Gleason grade 4+3 or less. High risk features were defined as pathologic stage T3b, T4, or Gleason grade 4+4 or greater. Surgical margins (SM) were reported as positive or negative. Thus, groups of patients were classified as LOWNEG, LOWPOS, HIGHNEG, and HIGHPOS based on stage/grade risk and SM status. Kaplan-Meier survival analyses stratified by these 4 groups were used to examine differences in survival outcomes. Cox proportional hazards regression models were utilized to identify factors associated with biochemical recurrence-free survival (RFS), metastasis-free survival (MFS), and prostate cancer specific survival (CSS) after secondary treatment. Men with LOWPOS features were the referent group. Models were adjusted for age, PSA at diagnosis, and salvage (vs adjuvant) RT.

Results: Of 3919 patients with pN0 disease at RP, 467 (11.9%) underwent secondary treatment with or without ADT. Mean age at diagnosis was 61 years (SD 6.8) with a median PSA at diagnosis of 7.5 (IQR 5.4-11.1). One-third were LOWNEG, 30% LOWPOS, 25% HIGHNEG, and 12% HIGHPOS. SM+ status was more common amongst those receiving adjuvant compared to those receiving salvage RT (62% vs 34%). RFS, MFS, and CSS at 7 years after secondary treatment were 56%, 78%, and 96%, respectively. Compared to men with LOWPOS disease, all groups were associated with increased risk of recurrence after secondary treatment: LOWNEG, HR 2.1, 95% CI 1.3-3.3; HIGHNEG, HR 2.7, 95% CI 1.7-4.3; HIGHPOS, HR 2.4, 95% CI 1.4-4.3, p<0.01 for all. The stage/grade/margins groupings were not associated with risk of metastasis or cancer-specific mortality. For LOWPOS patients who did not receive adjuvant treatment RFS, MFS, and CSS were 64%, 98%, and 99%, respectively. Men with adjuvant RT had better outcomes at 7 years after secondary treatment compared to salvage RT (RFS, 87% vs 66%, log-rank p=0.01; MFS, 91% vs 85%, log-rank non-significant p=0.06; CSS, 100% vs 98%, log-rank p=0.05). Salvage RT was associated with increased risk of recurrence (HR 3.0, 95% CI 1.2-7.8, p=0.02) compared to adjuvant RT after adjusting for age and PSA at diagnosis. Type of secondary treatment was not associated with increased risk of metastasis. There were too few events to assess associations with cancer-specific mortality.

Conclusion: In a cohort of men undergoing secondary treatment after RP, SM+ was more common amongst those receiving adjuvant therapy and was associated with greater recurrence free survival at 7 years after secondary treatment compared to those with SM- and similar favorable pathologic features. Amongst LOWPOS patients, adjuvant RT was associated with better oncologic outcomes compared to salvage RT while salvage RT was associated with higher risk of metastasis. Further investigation into the impact of margin status and timing of secondary treatment may improve outcomes in men considering secondary treatment for recurrence after prostatectomy.
78. C-11 CHOLINE PET FOLLOWING TAXOTERE IS A HELPFUL TOOL TO PREDICT PROGRESSION-FREE SURVIVAL IN METASTATIC CASTRATE RESISTANT PROSTATE CANCER (MCRPC)

Mayo Clinic

Presented By: Jack Andrews

Introduction: Taxotere remains a common treatment modality for metastatic castrate resistant prostate cancer (mCRPC). Little data exists on the predictive value of C-11 choline PET following treatment with taxotere. We sought to investigate whether evaluation of patients with C-11 choline PET scan after a full course of taxotere was predictive of progression free-survival.

Methods: We retrospectively identified 77 mCRPC patients who were treated with a full course of 6 cycles of taxotere and were evaluated with a C-11 choline PET scan before treatment and after full course of taxotere chemotherapy between 2011-2017. Patients receiving or have received prior second generation ADT or prior chemotherapy were excluded. Complete response was defined as complete SUV resolution of the index lesion and a PSA nadir of =0.2 ng/ml following completion of a full taxotere course.

Results: A table of clinicopathologic variables is seen in Table 1. Median progression-free survival was 33.97 months (95% CI 26.02 - 38.57) in complete response group versus 9.53 months in incomplete response group (95% CI 5.09 - 11.49, p=0.001). Progression-Free survival is seen in Figure 1. Patients who respond incompletely to a full course of taxotere, have 2.4 times risk of developing progressive disease than patients who respond completely (p=0.001).

Conclusion: Predicting progression-free survival after treatment for mCRPC is a challenging endeavor. We provide our experience with C-11 choline PET scan to help guide post-taxotere treatment counseling. Patients with incomplete response, either biochemically or radiographically on C-11 Choline PET, after full course of taxotere treatment are at significantly higher risk or disease progression and may benefit from a change in treatment modality or combination therapy.

Table 1: Clinicopathologic Variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age (years +/- SD)</td>
<td>60.5 (59 +/- 7.3)</td>
</tr>
<tr>
<td>Median Gleason score (IQR)</td>
<td>8 (7-9)</td>
</tr>
<tr>
<td>Median Pre-Treatment PSA ng/mL (IQR)</td>
<td>4.5 (4.95 -10.7)</td>
</tr>
<tr>
<td>Median Pre-Tx SUVmax (IQR)</td>
<td>4.7 (3 - 6.3)</td>
</tr>
<tr>
<td>Volume of Mets</td>
<td>24 pts with 1-5 sites of metastasis, 53 pts with &gt;5 sites of metastasis</td>
</tr>
</tbody>
</table>
79. EFFECT OF ENZALUTAMIDE ON PATIENT-REPORTED OUTCOMES, INCLUDING FATIGUE, IN METASTATIC HORMONE-SENSITIVE PROSTATE CANCER: ANALYSES FROM THE ARCHES STUDY

Arnulf Stenzl1, Curtis Dunsehe2, Ugo De Giorgi3, Boris Alekseev4, Taro Iguchi5, Russell Z. Szmulewitz6, Thomas W. Flaig7, Bertrand F. Tombal8, Robert Morlock9, Cristina Ivanescu10, Krishnan Ramaswamy11, Fred Saad12, Andrew J. Armstrong13

1 University Hospital, Eberhard Karls University, 2 Urological Associates of Southern Arizona, 3 Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori (IRST) IRCCS, 4 Hertzen Moscow Cancer Research Institute, 5 Osaka City University Graduate School of Medicine, 6 The University of Chicago, 7 University of Colorado, 8 Cliniques universitaires Saint-Luc, 9 Astellas Pharma Inc., 10 IQVIA, 11 Pfizer Inc., 12 Centre Hospitalier de l’Université de Montréal, Université de Montréal/CRCHUM, 13 Duke Cancer Institute Center for Prostate and Urologic Cancers

Presented By: Arnulf Stenzl

Introduction: The Phase 3 ARCHES trial (NCT02677896) showed that enzalutamide + androgen deprivation therapy (ADT) improved radiographic progression-free survival (rPFS) versus placebo + ADT in men with metastatic hormone-sensitive prostate cancer (mHSPC). Here we report patient-reported outcome (PRO) data with a focus on fatigue up to week 73.

Methods: PROs, including the Functional Assessment of Cancer Therapy–Prostate (FACT-P) and Brief Pain Inventory–Short Form (BPI-SF), were assessed at baseline, week 13, and every 12 weeks until disease progression. Many patients initiated ADT for several months prestudy baseline (>20% of patients in each group had previously used ADT for >3 months). Most patients (63%) overall) had high-volume disease and about 20% of patients with high-volume disease initiated enzalutamide or placebo after docetaxel therapy. Change from baseline was assessed using mean scores and mixed model repeated measures. The proportion of patients scoring 0–4 on indicators of fatigue (FACT-P items GP1 ["I have a lack of energy"] and GP7 ["I am forced to spend time in bed"] were measured over time. The proportion of patients with item scores classified as worsening (by 1, 2, or =3 points versus baseline), stable, or improved (by 1, 2, or =3 points versus baseline) over time was also measured.

Results: Completion rates (.population scale with nonmissing values) were high (88-96%) for FACT-P and BPI-SF up to week 73. Both groups were generally asymptomatic at baseline, with good health-related quality of life (HRQoL) [mean (SD) FACT-P total score: placebo + ADT 112.7 (19.0); enzalutamide + ADT 113.9 (19.8)] and low pain (worst pain [item 3]: placebo + ADT 1.77 [2.3]; enzalutamide + ADT 1.80 [2.4]). HRQoL and pain scores remained stable over time, with no clinically meaningful between-group differences in change from baseline to week 73. Enzalutamide + ADT maintained HRQoL, as measured with FACT-P total score across 73 weeks, at the same level as placebo + ADT. For item GP1 at baseline, the proportion of patients with more than a little lack of energy (i.e., somewhat, quite a bit, or very much; item score >1) was similar between groups (35.9% of enzalutamide and 37.0% of placebo patients). At week 73, the proportion of patients with stable (enzalutamide 39.0%; placebo 36.4%) or improved (enzalutamide 41.5%; placebo 32.4%) lack of energy was similar in both groups (Figure 1). For GP7 at baseline, most patients were not forced to spend time in bed and this was similar between groups (76.4% of enzalutamide patients and 79.6% of placebo patients had a score of 0 [not at all]). At week 73, the proportion of patients who were stable (enzalutamide 73.2%; placebo 82.8%) or had improved (enzalutamide 12.1%; placebo 9.1%) regarding being forced to spend time in bed was similar in both groups (Figure 2).

Conclusion: Men with mHSPC were generally asymptomatic, with high HRQoL and low pain at baseline, likely due to many patients initiating ADT several months prestudy. No clinically meaningful differences in HRQoL were observed between enzalutamide and placebo. Similar proportions of patients in enzalutamide and placebo groups reported stable or improved fatigue item scores at week 73.

Funding: This study was funded by Astellas Pharma Inc. and Pfizer Inc., the co-developers of enzalutamide. Medical writing and editorial assistance were provided by Tom Lavelle from Bioscript and Folabomi Oladosu, PhD, and Jane Beck from Complete HealthVizion, funded by the study sponsors.
80. PATTERNS OF METASTASES OF PROSTATIC DUCTAL ADENOCARCINOMA
Weranja Ranasinghe1, Nathan Brooks2, Mohamed Elsheshtawi1, John Davis2, Tharak Bathala2, Patricia Troncoso2, Ana Aparicio2, Shi-Ming Tu2, Brian F. Chapin2
1 University of Texas, MD Anderson Cancer Center, 2 University of Texas, MD Anderson Cancer Center, Houston, Texas
Presented By: Weranja Ranasinghe

Introduction: Ductal Prostatic adenocarcinoma (DAC) is an aggressive histologic variant of prostate cancer (PCa) accounting for between 0.1-7% cases. DAC often presents as locally advanced or metastatic disease posing a significant challenge in management. In this study, we aim to investigate the patterns of metastases in men presenting with DAC, in order to further characterize this condition.

Methods: After obtaining IRB approval, the records of all patients referred to our institution with DAC from January 2005 to November 2018 were identified using natural language processing and electronic medical record verification. Patients with a new diagnosis of DAC with de novo metastatic disease, those with localized disease who developed metastases post-treatment and those who were free of disease post primary therapy were included. All patients had their pathology reviewed centrally at our institution to confirm the diagnosis. Patient data including age, tumor characteristics, presence of symptoms, PSA values, treatments, progression, sites and dates of metastases, and reported deaths were collected and analyzed. Student T tests, Chi-squared analysis, Kruskal-Wallis test and Kaplan Meier analyses were performed to assess the baseline demographic and tumor characteristics.

Results: 423 men with a new diagnosis of DAC were included. 164 (38.8%) had metastatic DAC (mDAC); 112 had de novo metastases while the remainder (52) developed metastases post-treatment. Men with de novo metastases had higher median PSA (36.4 vs 6) and higher ISUP grade group 4/5 disease (98.2% vs 86.3%) but lower cT3/T4 stage (28.6% vs 60%), compared to those with metastases post primary treatment (all p <0.05) (Table 1). Men with de novo mDAC and those who developed metastases post-treatment had multiple metastatic sites, commonly bone, lymph node and viscera, with higher rates of lung metastases seen in the post-treatment group (23.2% vs 44.2%, p=0.01) (Table 1). Eighty-seven percent of men with de novo metastases, required, on average, 3.2 lines of systemic treatment, comprised of chemotherapy, radiotherapy or surgical intervention for palliation of symptoms. The patients who initially presented with localized disease, 259 were free of disease post primary therapy, while 52 progressed to metastases. Of the latter group, 46 were treated with curative intent (34 radical prostatectomy and 12 radiotherapy) but developed metastases at a median time of 22 months (range 0.9 – 74.8 months) post-treatment. In this group, the median PSA at the time of metastases was 4 ng/ml (range 0.2 to 184). Men with de novo metastases had a worse overall 5-year survival (26%) compared to those who progressed to metastases post-treatment for localized DAC (63%) and those who did not develop metastases (74%) (p<0.001) (Figure 1).

Conclusion: This study describes the metastatic patterns of DAC. Despite aggressive therapy and palliation, DAC has a poor prognosis both in patients with de novo metastatic disease and those who later progress to metastases. Men who receive treatment for DAC with curative intent require stringent long-term follow up with imaging modalities including chest imaging given the predilection for lung metastases. The results from this study highlight the need for better understanding of the biology of DAC and the development of novel therapies.

Funding: AUA Urology Care Foundation Research Scholar Award
81. COMPREHENSIVE STEREOTACTIC BODY RADIOTHERAPY FOR HORMONE SENSITIVE OLIGOMETASTATIC PROSTATE CANCER (CROP)

Patrick Cheung¹, Gerard Morton¹, Hans Chung¹, Danny Vespri¹, William Chu¹, Stanley Liu¹, Chia-Lin Tseng¹, Arjun Sahgal¹, Hany Soliman¹, Sten Myrehaug¹, Ewa Szumacher¹, Urban Emmenegger¹, Darby Erler¹, Alexandre Mamedov¹, Senny Chan¹, Liying Zhang¹, Andrew Loblaw¹, Peter Chung², Joelle Helou³

¹ Sunnybrook Odette Cancer Centre, ² Princess Margaret Cancer Centre, ³ Princess Margaret Cancer Centre

Presented By: Patrick Cheung

Introduction: This prospective phase I study assessed the use of stereotactic body radiotherapy (SBRT) to treat all tumor sites along with intermittent androgen deprivation therapy (ADT) in patients with hormone sensitive oligometastatic prostate cancer. Primary endpoint was incidence of SBRT induced late toxicities. Secondary endpoints included various measures of treatment efficacy including cumulative incidence of developing of castration resistant prostate cancer (CRPC) and overall survival (OS).

Methods: Synchronous and metachronous metastatic disease presentations were eligible if there were = 5 metastases, with = 3 metastases in any single organ system. Conventional scans (CT/bonescan +/- MRI) were used to stage patients at baseline, although novel PET imaging was optional. SBRT was delivered to all sites of disease, including the prostate if not previously treated. SBRT dose was site dependent but was generally 30-35 Gy in 5 fractions for lymph nodes and non-spine bone, 24 Gy in 2 fractions for spine, and 35 Gy in 5 fractions to the prostate. Patients received ADT for 1 year before moving to an intermittent approach. ADT was not to be restarted until the PSA reached = 10 ng/mL or earlier if clinically indicated. Toxicity (CTCAE v4.0) and PSA measurements were collected every 4 months during follow-up. Conventional scans were performed at a minimum of once per year, although more frequent imaging was allowed at the discretion of the physician.

Results: 30 patients were accrued with a median age of 74 years. Median follow-up time was 34 months (range 15 – 51). Median baseline PSA was 8.0 ng/mL (range 1.0 – 148.6). 46.7% of patients had Gleason score of 8-10. 9 patients had synchronous disease presentation. Only 3 patients were staged with novel PET imaging. 47 metastases were irradiated, with 36 being in bone. 2 patients developed acute grade 3 GI toxicities. 1 patient developed late grade 3 GU toxicity and 1 patient developed a late SBRT induced bone fracture. There were no grade 4/5 toxicities. Median PSA nadir was 0.03 ng/mL. 46.6% of patients reached a PSA nadir of = 0.02 ng/mL, while 93% of patients reached a PSA nadir of < 1 ng/mL. The cumulative incidence (CI) of restarting ADT was 47.5% at 3 years. In those who restarted ADT, the median time to the event was 25.8 months. The CI of developing CRPC was 17.2% at 3 years. In those who developed CRPC, the median time to the event was 17.7 months. The CI of local failure of irradiated sites was 10.1% at 3 years. The CI of developing new metastases was 26.3% at 3 years. OS was 89.5% at 3 years.

Conclusion: Combining SBRT with an intermittent ADT approach for hormone sensitive oligometastatic prostate cancer is a novel approach. The vast majority of the patients in this study were staged conventionally without novel PET imaging and most had bone metastases as opposed nodal only disease. The incidence of grade = 3 toxicity was low. Efficacy appears to be promising compared to historical outcomes of using ADT alone, especially regarding the need to restart ADT and incidence of developing of CRPC. This study has since been expanded into a larger phase II design with 90 patients enrolled. Randomized trials such as Canadian Cancer Trials Group (CCTG) PR.20 are needed to properly quantify the potential benefits of local ablative therapy in this patient population.

Funding: Investigator initiated research grant from Abbvie
82. CLINICAL TRIAL PARTICIPATION BY INSURANCE STATUS, GEOGRAPHIC LOCATION, TREATMENT CENTER, AND GRADING IN PATIENTS WITH PROSTATE CANCER
Mary Palmer, Meredith Ackerman, Amanda LeSeuer, PhD, Anthony Corcoran, MD
NYU Winthrop Hospital,
Presented By: Aaron Katz, MD

Introduction: Utilizing information provided by the National Cancer Database (NCDB), we aim to evaluate whether clinical trial participation is influenced by several health factors including insurance status, treatment center, and grading of disease as well as evaluating if clinical trial involvement has a significant impact on survival outcomes in patients with prostate cancer.

Methods: Comparability of the two groups was evaluated using the two-sample t-test or Mann-Whitney test for continuous variables, and the chi-square test or Monte Carlo Estimate for the Fisher’s exact test, as deemed appropriate, for categorical variables. Variables associated with clinical trial participation in the univariate analysis (p<0.10) prior to propensity score matching (PSM) were included in a multivariable logistic regression model. Backwards selection was used to remove variables that did not significantly contribute information to the model, given other factors included in the model. In order to achieve comparability of the groups of interest with regard to potential confounding variables, PSM was implemented using the SAS macro OneToManyMTCH. The primary and secondary outcomes of interest after PSM were 30 and 90-day mortalities, vital status, treatment status, and overall survival. McNemar’s test for matched-pair samples was used to compare the rates of the categorical outcomes between the two matched groups. To estimate the effect of clinical trials participation on overall survival, Kaplan-Meier survival curves were generated and the stratified log-rank test was used to compare the equality of the survival curves in the matched sample. A result was considered statistically significant at the p<0.05 level of significance. All analyses were performed using SAS version 9.4 (SAS Institute Inc., Cary, NC).

Results: Patients with poorly differentiated or undifferentiated, anaplastic grade (OR = 13.78) were more likely to participate in clinical trials compared to those who had well differentiated, differentiated, not otherwise specified grading. Patients treated at a non-Academic/Research Program were less likely to participate in clinical trials than those from an Academic/Research Program. Patients from facilities located within East North/South Central (OR=16.31) and South Atlantic (OR=1.74) regions of the United States participated in clinical trials more than those from the New England region. Those with Private Insurance/Managed Care were more likely to participate in clinical trials as compared to those with other insurance (OR=5.03) (Table 1). Within the prostate subjects, 116 of 124 clinical trials participants were pair-matched with 116 of 290,476 non-clinical trials participants, yielding matches for 93.5% of clinical trials participants after PSM. After propensity score matching, there were no significant differences between the two groups with respect to 30-day mortality, 90-day mortality, vital status, treatment status, or overall survival (p<0.2926) (Table 2). However, the rate of survival at 4- and 5-years was higher in the non-clinical trial participating group as compared to the clinical trial participation group (100% vs. 93% respectively, p<0.0446).

Conclusion: Clinical trial participation options as primary treatment for prostate cancer patients may be difficult to find outside of an Academic/Research Program facility or within the New England region of the country, limiting the population served. It is interesting to note that more patients with private insurance/managed care coverage participate in clinical trials over those with other insurance options as many clinical trials cover cost of treatment and may alleviate cost as a barrier to care. Despite no significant differences between the clinical trial participant group and non-participant group in overall survival, mortality, vital, or treatment status, it may benefit clinicians to suggest clinical trial participation to prostate cancer patients based upon their grading, insurance status, and geographic location in order to achieve a more robust clinical trial participant population.

| Table 1 Multivariable Logistic Regression Model Predicting Clinical Trial Participation |
|---------------------------------|------------|-----------------|-----------------|---------------|
| Covariate                        | Odds Ratio (OR) | 95% Wald Confidence Limits | p-value |
| Grade                            |               |                  |                 |
| Well differentiated, differentiated, NOS | 1            | (0.98, 6.12)     | 0.3201         |
| Moderately differentiated, moderately well differentiated, intermediate differentiation | 3.33 | (0.98, 10.70) | 0.0519 |
| Poorly differentiated, undifferentiated, anaplastic | 13.78 | (3.39, 59.07) | 0.00015 |
| Facility Type                    |               |                  |                 |
| Academic/Research Program        | 0.02         | (0.01, 0.02)     | <0.0001        |
| New England                      | Reference     |                  |                 |
| East North/South Central         | 16.31        | (2.26, 117.08)   | <0.0001        |
| Middle Atlantic                  | 3.86         | (0.61, 209.00)   | 0.8857         |
| Mountain                         | 2.44         | (0.67, 12.00)    | 0.5704         |
| Pacific                          | 3.32         | (0.68, 16.57)    | 0.4077         |
| South Atlantic                   | 1.24         | (0.31, 4.84)     | 0.7584         |
| West North/South Central         | 5.71         | (0.76, 43.95)    | 0.1979         |
| Other                            | Reference     |                  |                 |
| Insurance Status                 |               |                  |                 |
| Medicare                         | 2.71         | (0.44, 11.37)    | 0.6423         |
| Private Insurance/Managed Care   | 3.33         | (1.74, 30.44)    | 0.00014        |
*compares lesions localized to test (p<0.0001, q=0.0001)

| Table 2 Propensity Score Matched Pair Analysis using McNemar’s Test |
|-----------------|-----------------|-----------------|---------------|
|                  | No Clinical Trial Participation | Clinical Trial Participation | Difference and 95% CI for Difference | p-value |
| 30-day Mortality | 0 (0.0%)        | 0 (0.0%)        | 0.0 (0.0, 0.0) | N/A |
| 90-day Mortality | 0 (0.0%)        | 0 (0.0%)        | 0.0 (0.0, 0.0) | N/A |
| Vital Status (alive) | 114 (95.3%) | 112 (95.6%) | 1.7 (2.5, 5.9) | 0.6875 |
| Treatment Status (Treatment Given) | 116 (100.0%) | 116 (100.0%) | 0.0 (0.0, 0.0) | N/A |
| *A positive (negative) difference indicates a larger (smaller) value for the No Clinical Trial Participation group.
83. ASSOCIATION BETWEEN INFLAMMATORY BOWEL DISEASE AND INCIDENT PROSTATE CANCER: A PROSPECTIVE, POPULATION-BASED STUDY USING COLORECTAL CANCER AS A COMPARATOR

Adam Weiner¹, Anuj Desai¹, Shilajit Kundu¹, Travis Meyer², John Witte²
¹ Northwestern University, ² UCSF

Presented By: Adam Weiner

Introduction: A diagnosis of inflammatory bowel disease (IBD) increases one’s risk of colorectal cancer (CRC), however recent data implicating IBD as a risk factor for prostate cancer (PC) requires validation in independent cohorts. We sought to evaluate the association between a diagnosis of IBD and incident PC in a prospectively maintained, population-based dataset.

Methods: From the UK biobank, we evaluated 472,463 participants aged 40-69 who entered the study between 2006 and 2010 with follow-up through mid-2015. Using multivariable Cox regression analyses adjusting for sociodemographics, lifetime exposures, and previous cancer screening, we assessed the association between a diagnosis of IBD and incident PC with incident CRC as a comparator.

Results: Mean age at study entry was 56 years, 94% were White, and 0.9% (n=4,383) had a diagnosis of IBD at study entry. After a median follow-up of 6.5 years, participants with IBD had an increased risk of CRC (Incidence 143 vs 92 cases per 100,000 person-years; HR 1.58, 95% CI 1.14-2.20). IBD was also associated with an increased risk of PC (Incidence 480 vs 341 cases per 100,000 person-years; HR 1.33, 95% CI 1.03-1.71). Ulcerative colitis but not Crohn’s disease was associated with increased risk of PC (HR 1.40, 95% CI 1.06-1.86 and HR 0.97, 95% CI 0.59-1.62, respectively).

Conclusion: Data from a prospective, population-based dataset demonstrate a diagnosis of IBD was associated with an expected increase in the risk of CRC incidence and validates prior findings of an association between IBD and incident PC.

Funding: NIH grants: NCI R25-CA112355 and NIA T32-AG049663
84. NATIONAL TRENDS IN THE MANAGEMENT OF LOW RISK PROSTATE CANCER: ANALYZING THE IMPACT OF MEDICAID EXPANSION IN THE UNITED STATES

Grant Pollock, Juan Chipollini

1 University of Arizona, Department of Urology, 2 University of Arizona, Department of Urology

Presented By: Grant Pollock

Introduction: We evaluated recent trends in the management of low risk prostate cancer (PCa) in the United States (US). Since little is known on factors affecting treatment patterns in era of the Affordable Care Act (ACA), our aims were to measure temporal trends and analyze factors contributing to adoption of surveillance based on state Medicaid expansion status.

Methods: Using the National Cancer Database, we identified men with PCa who resided in the 50 United States or District of Columbia with an incident diagnosis from 2012 to 2016. Men with histologically confirmed low risk PCa, defined as PSA less than 10 ng/ml, Gleason score 6 or less and cT1-T2a, were included. The Cochran Armitage test was used to evaluate trends in surveillance versus treatment across study period and comparisons between expansion and non-expansion states were performed. Univariable and multivariable logistic regression models were used to identify predictors for surveillance.

Results: The analytic cohort included 84,340 men. During the study period, surveillance as initial management in the US increased from 13.6% to 32.1% (p<0.01). When comparing by state Medicaid expansion status, expansion states had significantly higher rates of surveillance compared to non-expansion states (36.6 vs 28.5%, respectively). The expansion cohort had more white and Hispanic males, higher median income, lower morbidity and education status, and more privately insured and Medicaid patients compared to non-expansion states (all, p<0.05) (Table 1). After adjusting for clinical and demographic variables, Medicaid expansion was a significant predictor for surveillance (OR= 1.42, p<0.001) (Table 2).

Conclusion: Based on data from 2012-2016, there has been a temporal increase in surveillance as initial management for low risk prostate cancer in the US. State Medicaid expansion was significantly associated with increased rates of surveillance versus treatment. Understanding the impact of payer status on health outcomes can aid in the development of future health care policies aiming to mitigate disparities.
85. LESION DETECTION EFFICACY OF 18F-RHPSMA-7.3 POSITRON EMISSION TOMOGRAPHY IN MEN WITH BIOCHEMICAL RECURRENCE OF PROSTATE CANCER: INITIAL CLINICAL DATA FROM 285 CONSECUTIVE PATIENTS

Thomas Langbein¹, Markus Krönke¹, Wolfgang Weber¹, Matthias Eiber¹, Alexander Wurzer², Hans-Juergen Wester², Tobias Maurer³, Thomas Horn⁴

¹ Department of Nuclear Medicine, Klinikum rechts der Isar, Technical University of Munich School of Medicine, Munich, Germany, ² Chair for Pharmaceutical Radiopharmacy, Technical University of Munich, Garching, Germany, ³ Martini-Klinik and Department of Urology, University Hospital Hamburg Eppendorf, Hamburg, Germany, ⁴ Department of Urology, Klinikum rechts der Isar, Technical University of Munich School of Medicine, Munich, Germany

Presented By: Thomas Langbein

Introduction: Up to one-third of patients experience biochemical recurrence (BCR) of prostate cancer after curative-intent primary treatment. In this setting, early detection of malignant lesions allows interventions to be more precisely targeted and to take place when disease is more amenable to treatment. Early detection remains challenging, however, especially in patients with low prostate-specific antigen (PSA) levels. Investigational 68Ga-labeled prostate-specific membrane antigen (PSMA)-targeted radiotracers have demonstrated encouraging results in early detection of prostate cancer lesions underlying BCR. 18F-labeled PSMA-targeted radiotracers are also under clinical evaluation, since compared with 68Ga-labeled agents, they offer longer half-life with improved transportation logistics, and lower positron range with potentially enhanced spatial resolution and image quality. Radiolabeled PSMA ligands are a new class of diagnostic/therapeutic PSMA-targeting agents. Promising preliminary data have been reported for 18F-rhPSMA-7, which comprises four isomers, 18F-rhPSMA-7.1 through 18F-rhPSMA-7.4. Based on preclinical findings, 18F-rhPSMA-7.3 was selected as the lead rhPSMA compound for clinical development; it is now being assessed in a prospective Phase I clinical study, with Phase III trials anticipated to begin shortly. Here we report the first data regarding the lesion detection efficacy of 18F-rhPSMA-7.3 positron emission tomography (PET) in patients with BCR of hormone-sensitive prostate cancer, from a retrospective analysis of compassionate use experience at a tertiary referral center.

Methods: Datasets were reviewed from 285 consecutive patients with BCR of hormone-sensitive prostate cancer after radical prostatectomy (n = 247, 87%) or radiotherapy with or without brachytherapy (n = 38, 13%). Members of this cohort underwent 18F-rhPSMA-7.3 PET between 30 August 2018 and 15 February 2019, after providing written informed consent. The median (minimum – maximum) age at the time of 18F-rhPSMA-7.3 imaging was 71 (44–85) years. The median (minimum–maximum) last reported serum rhPSMA-7.3 PET between 30 August 2018 and 15 February 2019, after providing written informed consent. The median (minimum – maximum) 18F-rhPSMA-7.3 activity of 332 (204–454) MBq was administered via intravenous injection, and imaging started a median (minimum – maximum) 74 (57–117) min post-injection. Most patients (248/285, 87%) were injected, and imaging started a median (minimum – maximum) 74 (57–117) min post-injection. Most patients (248/285, 87%) were imaged using PET/computed tomography (CT) (Biograph mCT, Siemens, Erlangen, Germany), the remainder (37/285, 13%) using PET/magnetic resonance imaging (MRI) (Siemens Biograph mMR). As part of the analysis, images were re-read by an experienced nuclear medicine physician. To explore associations between pre-scan serum PSA concentration, primary histological differentiation, or treatment history and lesion detection rates, two-sample t-tests and Mann–Whitney U tests were used, as appropriate, to evaluate differences between subgroups.

Results: 18F-rhPSMA-7.3 PET identified 225/285 patients (79%) with pathological uptake (Table 1). Lesion detection rates tended to rise alongside pre-scan PSA levels, ranging from 45% (9/20) with PSA <0.2 ng/mL, to 97% (93/96) with PSA ≥2 ng/mL. In descending order of frequency, pathological uptake was most commonly detected in the prostate bed, pelvic lymph nodes, bones, retroperitoneal lymph nodes, supradiaphragmatic lymph nodes, and other distant sites. Distribution of involved regions was highly dependent on pre-scan PSA concentration (Figure 1). Mean ± standard deviation pre-PET PSA levels were significantly higher in patients with positive scans (n = 189) than in those with negative scans (n = 55): 6.88 ± 15.3 ng/mL vs. 0.69 ± 0.89 ng/mL, p <0.001. Interestingly, bone lesions were identified in 10% of patients (7/71) with PSA <0.5 ng/mL at the time of imaging. Primary Gleason Score (GS) category and history of androgen deprivation therapy (ADT) did not appear to be associated with detection efficacy: overall lesion detection rates were 67% (46/69) in patients with primary GS =7 vs. 80% (40/50) in those with primary GS =8, p = 0.109, and 84% (52/62) in patients receiving ADT within 6 months before imaging vs. 76% (134/177) in those not doing so, p = 0.183. In patients undergoing radical prostatectomy, history of external beam radiation therapy (EBRT; adjuvant or salvage) seemed to be related to scan positivity: lesions were found in 84% of patients (65/77) with prior EBRT vs. 70% of those without prior EBRT (95/136), p = 0.018.

Conclusion: These first reported data regarding lesion detection efficacy of 18F-rhPSMA-7.3 PET in patients with BCR of prostate cancer suggest that 18F-rhPSMA-7.3 PET offers high detection rates in this setting, including in men with low pre-scan PSA values; 18F-rhPSMA-7.3 PET detection efficacy broadly increases along with PSA concentration. The detection rates seen in this retrospective analysis appear to be higher than those reported in separate studies of 68Ga-PSMA-11, especially at low PSA values, and align with reported findings with 18F-rhPSMA-7 PET. Based on these promising results, prospective studies of 18F-rhPSMA-7.3 are now underway.

Funding: HJW and ME received funding from the SFB 824 (DFG Sonderforschungsbereich 824, Project B11) from the Deutsche Forschungsgemeinschaft, Bonn, Germany and Blue Earth Diagnostics (licensee for rhPSMA) as part of an academic collaboration. Blue Earth Diagnostics provided medical writing support for this abstract.
Table 1. Lesion detection efficacy of $^{18}$F-rhPSMA-7.3 PET in ZS5 consecutive patients: key findings

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detection rate by lesion site*</td>
<td>% (N)</td>
</tr>
<tr>
<td>Overall (pelvis/abdomen)</td>
<td>79% (222/280)</td>
</tr>
<tr>
<td>Local recurrence (prostate/bowel)</td>
<td>44% (125/285)</td>
</tr>
<tr>
<td>Lymph node metastases</td>
<td></td>
</tr>
<tr>
<td>Pelvis</td>
<td>19% (46/245)</td>
</tr>
<tr>
<td>Retroperitoneal</td>
<td>17% (49/289)</td>
</tr>
<tr>
<td>Supraaortic</td>
<td>8% (23/285)</td>
</tr>
<tr>
<td>Bone metastases</td>
<td>23% (65/285)</td>
</tr>
<tr>
<td>Other distant metastasis (lymph node)</td>
<td>8% (22/289)</td>
</tr>
<tr>
<td>Detection rate by PSA category (ng/mL)</td>
<td>% (95% CI)[N]</td>
</tr>
<tr>
<td>&lt;0.2</td>
<td>49% (26%-64%) (920)</td>
</tr>
<tr>
<td>0.5 - &lt;1.0</td>
<td>68% (59%-78%) (1010)</td>
</tr>
<tr>
<td>1.0 - &lt;2.0</td>
<td>56% (39%-72%) (3238)</td>
</tr>
<tr>
<td>2.0 -</td>
<td>83% (71%-95%) (5441)</td>
</tr>
<tr>
<td>≥2.0</td>
<td>97% (95%-100%) (9398)</td>
</tr>
</tbody>
</table>

*Due to rounding, percentages may not add to 100%.

Figure 1. $^{18}$F-rhPSMA-7.3 PET lesion detection rate by site and pre-scan PSA category.

Graph represents data from patients with available pre-scan PSA values: n = 244/285, 86%
86. WHAT REALLY MATTERS WHEN PREDICTING OTHER CAUSE MORTALITY FOR MEN WITH PROSTATE CANCER: A MACHINE LEARNING APPROACH TO VARIABLE SELECTION

Brooke Namboodri1, Xi Zhou, MS2, Ethan Basch, MD, MS2, Angela B. Smith, MD, MS2, Marc Bjurlin, DO, MSc, FACOS2, Matthew E. Nielsen, MD, MS2, Jennifer Lund, PhD2, Hung-Jui Tan, MD, MSHPM2, Alex Sox-Harris, PhD, MS3

1 University of North Carolina at Chapel Hill, 2 University of North Carolina at Chapel Hill, 3 Palo Alto Veterans Affairs Health Care System

Presented By: Brooke Namboodri

Introduction: Although prostate cancer is the most common cancer affecting men, the overwhelming majority of diagnosed patients will die from a competing cause within ten years of their diagnosis. As a result, predicting those who will die from non-cancer causes has become an essential consideration in the evaluation and management of this disease. To aid in decision-making, several prediction models have been developed. However, relatively few urologists use these existing tools. One limiting factor may be the number of input variables required. Existing comorbidity-based tools incorporate over a dozen medical conditions in addition to other variables. Less burdensome models that accurately predict other cause mortality (OCM) may better balance accuracy with usability.

LASSO (Least Absolute Shrinkage and Selection Operator) regression analysis, a technique used in machine learning, offers a strategy to model building that can perform variable selection in a way that yields simpler, more accurate models versus more conventional methods. In this context, we used LASSO regression to identify the most influential variables for predicting OCM for men newly diagnosed with prostate cancer.

Methods: Using SEER-CAHPS data, which links cancer registry information with Medicare claims and Consumers Assessment of Healthcare Providers and Systems survey responses, we identified men 65 years and older diagnosed with prostate cancer from 2004 through 2013. In total, we identified 76 candidate input variables inclusive of patient demographics, cancer information, claims-based health indicators, and patient-reported health measures. Next, we applied LASSO regression analysis to predict OCM. LASSO regression performs both shrinkage and variable selection for linear regression models to identify the core subset of predictive variables that minimize prediction error for a given outcome. Models were selected based on the Schwartz Bayesian information criterion (SBC) with lower values being preferable. Then, we fitted the model selected through LASSO regression and performed model diagnostics to evaluate its discriminatory ability.

Results: Among 3,240 men diagnosed with prostate cancer, 246 (7.62%) died of prostate cancer and 631 (19.48%) died of other causes. From the 76 variables, LASSO regression identified an 18-variable model consisting of 1 demographic variable (i.e., age), 3 cancer variables (i.e., PSA score, Gleason score, cancer stage), 10 claims-based variables (i.e., congestive heart failure [CHF], chronic obstructive pulmonary disease [COPD], arrhythmia, other neurological deficit, dementia, weight loss, bladder cancer, rehabilitation care, ambulance, and oxygen), and 4 patient-reported variables (i.e., general health status, mental health status, comorbidity count, and functional deficit). Among the 17 health measures in the Charlson Comorbidity Index, only CHF and COPD were selected. Similarly, only arrhythmia, neurological deficit, weight loss, dementia, CHF, and COPD were selected of the 30 health measures used by the Elixhauser Comorbidity Index. The top 6 variables in the LASSO regression model (i.e., age, CHF, general health, COPD, ambulance, and comorbidity count) accounted for most of the predictive performance, yielding a SBC of -5611.10 vs. -5701.93 for the full model (Figure). A model using just these 6 variables produced an AUC of 0.758 vs. 0.783 for the full model.

Conclusion: Estimating other cause mortality in men with prostate cancer can be accurately accomplished by using relatively few data inputs. This appears to be achieved through the inclusion of patient-reported health data and claims-based health measures related to functional status. Incorporating different types of data in combination with novel machine learning techniques may produce less burdensome tools that facilitate usability. Additional research should examine these models and focus on their dissemination and implementation into clinical practice.

Funding: Brooke Namboodri was supported by the AUA Summer Medical Student Fellowship Program by Herbert Brendler, MD, Research Fund. Hung-Jui Tan, MD, MSHPM was supported by a Mentored Research Scholar Grant in Applied and Clinical Research, MRSG-18-193-01-CPPB, from the American Cancer Society as well as the NIH Loan Repayment Program.
87. UNDERSTANDING THE ROLE OF SELECTIVE BETA-BLOCKERS IN PATIENTS WITH ADVANCED PROSTATE CANCER ON ANDROGEN DEPRIVATION THERAPY.
Natasza Posielski, Kyle Richards, Jinn-ing Liou, E. Jason Abel, Tracy Downs, Tudor Borza, David Jarrard
University of Wisconsin School of Medicine and Public Health
Presented By: Natasza Posielski

Introduction: Development of castration resistant prostate cancer (CRPC) is characterized by alterations in tumor cell signaling and metabolism which represent an opportunity for synergistic therapies to supplement androgen deprivation therapy (ADT) and delay disease progression. Recent work in Science found that endothelial β-adrenergic receptor signaling in the prostate stroma is critical for activation of an angiogenic switch and tumor progression suggesting an inhibitory role for beta-blockers (Zahalka, 2017). Epidemiological studies have shown a possible association between beta blocker use and improved prostate cancer (PCa) specific survival, but the data is limited and conflicting. To evaluate the role of selective beta-blocker use in advanced PCa, we interrogated the National Veterans Health Administration (VA) database to determine if metoprolol use at time of ADT initiation would result in improved oncologic outcomes.

Methods: We identified all men diagnosed with PCa in the VA Corporate Data Warehouse (CDW) from 2000 to 2008 and obtained pharmacy data for those with PSA >20 that initiated ADT during this time (n=39,198). Patients receiving < 6 months of ADT or ADT concurrently with primary radiation therapy were excluded. Pharmacy data was queried for use of metoprolol, a beta-1 selective beta blocker. Cox proportional hazards ratios were calculated for overall survival (OS), PCa specific survival (CSS) and skeletal related events (SREs).

Results: Of the final cohort of 39,198 patients with PCa on ADT and PSA >20, 10,223 (26.1%) had used metoprolol while 28,975 (73.9%) had not. Multivariable analysis found that utilization of metoprolol was not associated with improvement in OS (HR 0.97, CI 0.93-1.02, p=0.244) or CSS (HR 0.94, CI 0.85-1.04 p=0.213). When competing risk analysis was performed to account for death from other causes, metoprolol had no effect on PCa specific death (HR 0.98, CI 0.89-1.08, p=0.673). Metoprolol use was also not predictive of increased SREs (HR 1.0, CI 0.87-1.15, p=0.971).

Conclusion: In the largest cohort to date, metoprolol use in conjunction with ADT for advanced PCa was not associated with improvement in OS, CSS or risk of SREs. Our study suggests no survival benefit to beta blockers in advanced PCa. The role of these agents in limiting disease progression via blocking endothelial β-adrenergic receptor signaling in the prostate stroma in early PCa is being investigated.
**88. DETECTION OF GERMLINE MUTATIONS IN LOCALIZED AND METASTATIC PROSTATE CANCER THROUGH GUIDELINE-BASED TESTING**

Randy Vince Jr.¹, Jake Quarles², Mallory Luke², Sanjay Das², Marissa Solorzano², Michelle Jacobs³, Samuel Kaffenberger⁴, Simpa Salami⁴, Elena Stoffel⁵, Sofia Merajver⁶, Jason Hafron⁷, Todd Morgan⁸

¹ Michigan Medicine (University of Michigan), ² Research Assistant, ³ Genetic Counselor, ⁴ Assistant Professor of Urology, ⁵ Assistant Professor of Hematology Oncology, ⁶ Professor of Internal Medicine, Medical School and Professor of Epidemiology, School of Public Health, ⁷ Urologist, Michigan Institute of Urology, ⁸ Associate Professor of Urology, Chief of Urologic Oncology

Presented By: Randy Vince Jr.

**Introduction:** There’s increasing awareness that men with prostate cancer (PC) frequently harbor germline mutations (GM) that may carry important implications for them and their family members. Most studies evaluated GM rates in men with metastatic disease and a recent publication reported an overall detection rate of 17% in both metastatic and localized PC patients. Here, we sought to compare GM rates in metastatic and localized PC patients.

**Methods:** Between 2017 – 2019 men diagnosed with PC at Michigan Medicine and Michigan Institute of Urology (MIU) were offered genetic testing in accordance with NCCN guidelines. Patient data was tracked in a prospectively collected registry including multiple patient data points. Rates of pathogenic/likely pathogenic mutations and variants of uncertain significance (VUS) were compared according to patient demographic and disease characteristics.

**Results:** Overall, 310 patients underwent testing, including 139 men with metastatic PC and 171 with localized PC. Median age was 68 (24-99). 203 underwent testing at Michigan Medicine and 107 at MIU. 92% of patients were Caucasian. In metastatic PC patients, rates of pathogenic/likely pathogenic GM were 10.8% vs. 14.6% for localized PC patients. The most common mutations were in CHEK2 (27%), ATM(12%) and BRCA2(10%).

**Conclusion:** A large proportion of men with PC have mutations in key DNA damage repair genes. Screening all PC patients (irrespective of stage) and performing genetic testing for those with personal and family history meeting NCCN guidelines would increase identification of carriers, with potential implications for management of patients with metastatic or localized disease and cascade testing of at-risk family members.
89. TRENDS IN PATIENT OUT-OF-POCKET COSTS AND HOSPITAL AND PHYSICIAN REIMBURSEMENT FOR ROBOTIC AND OPEN RADICAL PROSTATECTOMY

Rodrigo Rodrigues Pessoa¹, Paul Maroni², Janet Kukreja², Simon Kim²
¹ University of Colorado Anschutz Medical Campus, ² University of Colorado - Anschutz Medical Campus

Presented By: Rodrigo Rodrigues Pessoa

Introduction: While health care costs attributable to robotic surgery for radical prostatectomy (RP) have been well described, actual reimbursements to hospitals and surgeons as well as the out-of-pocket costs for patients remain largely unknown. Thus, we sought to describe reimbursements to the health care system and costs to prostate cancer (PCa) patients among a privately-insured, population-based cohort.

Methods: Using MarketScan, a national private health insurance database, we identified all PCa patients who underwent open radical prostatectomy (ORP) or robotic-assisted laparoscopic prostatectomy (RALP) from 2010 to 2015. Patient-level reimbursements to hospitals and surgeons (technical fees) and out-of-pocket from patients (co-pay) represented the primary outcomes. Generalized estimating equations were used to provide estimates of each outcome adjusting for age, Elixhauser comorbidity index, postoperative complications, length of stay (LOS) and year of surgery.

Results: Among the 46,884 patients surgically treated for PCa, use of RALP increased from 40.6% in 2010 to 62.5% in 2015 (p < 0.001 for trend). The mean age was 58 years old (SD: 5.0). Compared to ORP, patients undergoing RALP had lower mean LOS (1.5 vs. 1.9 days; p < 0.001) and rates of postoperative complications (1.7% vs. 2.3%; p < 0.001). On multivariable analysis, RALP was responsible for higher adjusted hospital reimbursement compared to ORP and rose from 2010 ($16,919 vs. 15,701, p < 0.001) to 2015 ($20,197 vs. $18,979; p < 0.001). Conversely, physician reimbursement was higher each year for ORP relative to RALP ($3,272 vs. $2,931; p < 0.001 in 2010 to $3,914 vs. $3,572; p < 0.001 in 2015). Patient out-of-pocket costs were slightly higher for RALP ($188 vs. $164; p < 0.001) with no statistically significant change over time.

Conclusion: While higher hospital reimbursements were observed for RALP and accounted for a majority of the healthcare dollars spent overall, physician reimbursement was higher for ORP. Patient out-of-pocket costs were low for both surgical approaches. Further research is needed to better define the costs and reimbursement of RALP to identify opportunities to provide more cost-effective health care.
90. NO ASSOCIATION BETWEEN PRE-TREATMENT POST-TRAUMATIC STRESS DISORDER OR DEPRESSION WITH BIOCHEMICAL RECURRENCE FOLLOWING RADICAL PROSTATECTOMY WITHIN THE VETERANS AFFAIRS HEALTH SYSTEM: RESULTS FROM SEARCH DATABASE

Rashid Sayyid1, Za Klaassen2, Benjamin Harper2, Rashid Sayyid2, Martha Terris3, Lauren Howard3, Christopher Wallis3, Christopher Amling4, William Aronson5, Christopher Kane6, Matthew Cooperberg8, Jean Beckham9, Stephen Freedland10
1 Augusta University, 2 Department of Surgery, Section of Urology, Augusta University, Augusta, GA, 3 Division of Urology, Durham Veterans Affairs Medical Center, Durham, NC, 4 Department of Surgery, Vanderbilt University Medical Center, Nashville, TN, 5 Department of Urology, Oregon Health Sciences University, Portland, OR, 6 Division of Urology, West Los Angeles Veterans Affairs Medical Center, Los Angeles, CA, 7 Department of Urology, University of California, San Diego, CA, 8 Department of Urology, University of California, San Francisco, CA, 9 Durham Veterans Affairs Medical Center, Durham, NC, 10 Division of Urology, Cedars-Sinai Medical Center, Los Angeles, CA

Presented By: Rashid Sayyid

Introduction: Recent large-scale studies have demonstrated that pre-existing mental health illness burden has a negative impact on oncologic outcomes in men with urologic cancers. In addition to potential biologic reasons for such a discrepancy, it was suggested that such patients may be less likely to receive standard of care post-diagnosis. Our aim was to evaluate whether a known pre-cancer diagnosis of post-traumatic stress disorder (PTSD) or depression had an impact on post-radical prostatectomy biochemical recurrence rates within the confines of the equal-access Veteran Affairs health system.

Methods: The Shared Equal Access Regional Cancer Hospital (SEARCH) database was used to identify all men with prostate cancer who underwent radical prostatectomy (RP) between 2000-2017 at eight high-volume VA centers. A pre-cancer diagnosis of PTSD or depression was identified using ICD-9 and ICD-10 codes ascertained using a three-year look-back window. The primary outcome was biochemical recurrence (BCR), defined as PSA >0.2 ng/ml, 2 values at 0.2 ng/ml, or salvage treatment (radiation or hormonal therapy). Secondary outcome was all-cause mortality (ACM). Univariable and multivariable cox proportional hazards models, adjusting for baseline patient characteristics (age, body mass index, race), year of surgery, surgical center, pathologic variables (grade group, extracapsular extension, seminal vesicle invasion, lymph node status) and comorbidity burden quantified using the Charlson comorbidity index, were used to evaluate the association between PTSD and depression, separately, with BCR and ACM. Statistical significance was set at p<0.05.

Results: Our final cohort included 4,950 men. 735 (14.8%) and 398 (8.0%) patients had a known pre-prostate cancer diagnosis of PTSD and depression, respectively. Men with PTSD or depression were younger (61 vs. 62, p<0.001), had lower pre-RP PSA values (6.0 vs. 6.3, p=0.022), and had a lower comorbidity burden. Patients with PTSD were more likely to be African American (36% vs. 32%, p=0.022) and to have served in the Army (62% vs. 52%, p<0.001) or Marines (19% vs. 10%, p<0.001). No significant differences existed with regards to final pathologic variables or number of PSA checks between RP and BCR. On both univariable and multivariable analyses, both PTSD (adjusted HR 0.99, p=0.87) and depression (HR 0.89, p=0.25) diagnoses were not associated with rates of BCR. Similarly, PTSD (HR 1.07, p=0.54) and depression (HR 0.96, p=0.78) were not associated with ACM. Sensitivity analyses with one- and five-year look back windows for pre-RP diagnoses of PTSD and depression likewise demonstrated no associations with BCR or ACM.

Conclusion: Within the confines of an equal-access VA health system, pre-RP diagnosis of PTSD or depression does not impact BCR or ACM. These results suggest that differences in oncologic outcomes previously seen amongst patients with significant psychological burden in different healthcare systems may be related to disparities in access to care. These findings also highlight the quality of care received by veterans at the VA, which actively targets these patient populations in order to minimize health outcome discrepancies.
91. ROUTINE CLINICAL LABORATORY TESTS ASSOCIATED WITH OVERALL SURVIVAL IN PATIENTS WITH PROSTATE CANCER: APPLYING A SYSTEMATIC LABORATORY-WIDE ASSOCIATION STUDY (LWAS) METHOD

Ericka Sohberg1, Jaden Yang1, Kristopher Kapphan1, Glenn Chertow1, James Brooks1, Manisha Desai1, I-Chun Thomas2, Chirag Patel3

1 Stanford University, 2 VA Palo Alto Health Care System, 3 Harvard University

Presented By: John Leppert

Introduction: Risk stratification is an essential component of prostate cancer care, critical to identify patients at risk for progression, minimize overtreatment, plan treatment course, predict patient response, and compare cohorts of patients. However, no validated panel of routine clinical laboratory values exists that can be used to guide treatment decisions in patients with prostate cancer. Clinical laboratory values serve as ideal biomarkers due to their accessibility and low cost. Individual laboratory tests, such as albumin and C-reactive protein have been reported to be associated with survival outcomes in patients with localized prostate cancer. Similarly, hemoglobin and alkaline phosphatase levels have been linked with survival in patients with metastatic prostate cancer. However, there have not been efforts to validate these tests using real-world data, or to compare the relative strength of associations across multiple candidate laboratory tests. In order to systematically evaluate the laboratory tests associated with survival among patients with prostate cancer, we created the Laboratory-Wide Association Study (LWAS). The LWAS framework incorporates multiple methods to facilitate reproducibility including 1) using the false-discovery rate to simultaneously test the association of multiple laboratory values with survival outcomes, 2) requiring concordant results in training and testing sets, and finally 3) requiring each test to validate in a separate data set. We performed this within the Veterans Health Administration (VHA), the largest integrated healthcare system in the United States that cares for a large population of men with prostate cancer.

Methods: We identified a cohort of Veterans with incident prostate cancer between 2000-2013 within the VHA electronic health record. Patient demographics, tumor staging, and treatment data was obtained from the CDW Oncology database. Patients were then stratified into localized prostate cancer (Stage <T3) and metastatic prostate cancer risk groups (clinical stage M>0, T4 or N>0). We identified patient comorbidities using inpatient and outpatient diagnoses in the 2 years prior to the date of prostate cancer diagnosis. We calculated the Charlson Comorbidity Index using the Deyo-Romano methods for each patient. We then obtained all clinical laboratory data linked with each prostate cancer patient within 6 months of their prostate cancer diagnosis across the 153 VA hospitals and 414 clinical treatment sites in the VA. In order to include common routine clinical laboratory tests, we included only tests with results for at least 200 patients. 3,345,083 laboratory test values remained after this exclusion, from an initial pool of 12,559,629. We evaluated survival using the US Department of Veterans Affairs Vital Status File. Lab values were then normalized using z-standardization. The patients were randomly split into training (30%), testing (30%) and validation datasets (40%). We systematically fit proportional hazards models for each lab value, adjusting for relevant clinical characteristics. Each lab had to meet the FDR threshold, retain significance in the testing set and again in the validation set to meet the LWAS criteria. Final hazard ratios were calculated from the validation dataset.

Results: We identified 133,878 patients whom had had an outpatient lab within 6 months of their diagnosis. 92.7% of patients were diagnosed with localized disease and 7.3% with locally advanced or metastatic disease. The mean age of the cohort was 66.6 (+/-8.4) and the mean Charlson Comorbidity Index was 2.5 (+/-2.1). Each patient had a mean of 25 laboratory test results in the 6 months preceding the prostate cancer diagnosis, for a total 3,345,083 laboratory tests results after exclusion. In the analytic cohort, 60 laboratory tests met the FDR <0.05 threshold in the training set and 31 of these laboratory tests met significant thresholds in both testing and validation sets. Specifically, proB natriuretic peptide (proBNP) and gamma-glutamyl transferase (GGT) were most strongly associated with overall survival (HR 1.43 and 1.23 respectively). Albumin (HR 0.78) and hemoglobin (HR 0.81) were inversely associated with survival. Among patients with localized prostate cancer (N=124,089), 28 laboratory tests met LWAS criteria. Higher erythrocyte sedimentation rate (ESR) (HR 1.33), white blood cell count (HR 1.23) and alkaline phosphatase (HR 1.22) levels were most associated with worse survival, while higher albumin concentration (HR 0.78) and hemoglobin (HR 0.80) were associated with improved survival. Similarly, in LWAS analyses of patients with metastatic prostate cancer, 15 laboratory tests that passed LWAS criteria. Alkaline phosphatase (HR 1.33), ferritin (HR 1.23) and platelet count (1.22) were directly associated with survival, while albumin (HR 0.75), hemoglobin (HR 0.75) and hematocrit (HR 0.75) were indirectly associated.

Conclusion: Our proposal demonstrates the utility of LWAS to identify routine clinical laboratory tests associated with survival among men with prostate cancer using real-world data abstracted from the largest integrated national health care system. LWAS identified 31 common clinical laboratory tests associated with survival that may provide additional methods for risk stratifying patients and comparing disparate cohorts of patients in clinical trials. LWAS identified a different set laboratory tests important for patients with localized or metastatic prostate cancer, but pro-inflammatory laboratory markers were consistently associated with survival in all groups. In this era of personalized medicine, the addition of routine clinical laboratory data to survival models and clinical trial design has significant potential to improve and individualize prostate cancer treatment.

Funding: This work was supported in part by VA Merit Review (I01 HX0021261 to JL)
Figure. Clinical laboratory tests associated with survival across the entire cohort of 133,878 patients with prostate cancer. In this volcano plot, the effect size for each laboratory test is represented on the X-axis, while the strength of the association (the p value represented in -log10 scale) is shown on the Y-axis. We have colored and categorized all laboratory tests that met the LWAS criteria and demonstrated a potentially clinically significant effect size of greater than a HR of 1.1 or less than a HR of 0.9.
92. LONG-TERM OUTCOMES OF RADICAL PROSTATECTOMY IN MEN WITH A PREOPERATIVE SERUM PROSTATE-SPECIFIC ANTIGEN LEVEL = 20 NG/ML

Jack Andrews, Rachael Carlson, Laureano Rangel, Stephen Boorjian, Jeffery Karnes, Igor Frank, Matthew Tollefson, R. Houston Thompson, Matthew Gettman
Mayo Clinic

Presented By: Jack Andrews

Introduction: Few studies have investigated long-term outcomes of RP patients with extremely high PSA in the modern treatment era. We update here, our long-term outcomes in men treated with radical prostatectomy (RP) with preoperative serum prostate-specific antigen (PSA) between = 20 ng/mL.

Methods: We reviewed our institutional Prostatectomy Registry to identify 1307 men treated with RP with preoperative serum PSA greater than 20 ng/mL between 1987-2014. The study cohort was divided into 2 groups, high PSA (20 to 49 ng/mL, n=1051 patients) and extremely high PSA (=50 ng/mL, n=256 patients, range 50 - ...). Oncologic outcomes included biochemical recurrence (defined as two post-prostatectomy PSA values >0.2), systemic progression and cancer-specific mortality.

Results: Clinicopathologic variables are demonstrated in Table 1. Biochemical-recurrence rates in the groups of patients with a high PSA level and extremely high PSA were 59.6% and 63.2% at 20 years with a HR of 1.19 (0.98-1.44, p=0.08). Systemic-progression rates with a high PSA level and extremely high PSA 19.8% and 28.5% at 20 years with a HR of 1.24 (0.92-1.67, p=0.15). Cancer-specific mortality rates with a high PSA level and extremely high PSA 12.8% and 20.5% at 20 years with a HR of 1.34 (0.94-1.9, p=0.1), Figure 1.

Conclusion: Although PSA =20 ng/ml conveys high risk disease, long-term cancer-specific survival remains excellent when treated with RP. Additionally, we did not observe worse oncologic outcomes when comparing patients with PSA between 20-49 ng/mL and = 50 ng/mL. These data support the use of aggressive management in select men presenting with high PSA.
93. PROGNOSTIC AND CLINICAL UTILITY CAPABILITIES OF CELL CYCLE PROGRESSION TESTING, PROSTATE IMAGING-REPORTING AND DATA SYSTEM SCORING, AND CLINICOPATHOLOGIC DATA IN MANAGEMENT OF LOCALIZED PROSTATE CANCER

David Morris¹, J. Scott Woods¹, Lauren Lenz², Jennifer Logan², Todd Cohen², Steven Stone²
¹ Urology Associates, PC, ² Myriad Genetics, Inc.

Presented By: David Morris

Introduction: For men with newly diagnosed prostate cancer (PrCa), their families and health care providers, determining whether it is safe to pursue active surveillance (AS) can be a weighty decision, as the risk of overtreatment and adverse effects is balanced by the possibility of missing significant cancer. A well-informed decision depends on precise risk stratification. Multiparametric magnetic resonance imaging (mpMRI) with Prostate Imaging and Reporting and Data System (PI-RADS) scoring and the cell cycle progression (CCP) molecular prognostic test both have emerged as important tools for improving risk discrimination in PrCa diagnosis. It is important for clinicians to understand the capabilities and limitations of these tools, relative to each other and to other available clinicopathologic data, both in terms of prognosis and in terms of utility for guiding subsequent clinical management. This study aimed to evaluate and compare the prognostic and clinical utility capabilities among CCP testing, mpMRI with PI-RADS, and clinicopathologic data in selected medical management scenarios. Specifically, we assessed the distributions of molecular test scores and clinicopathologic data relative to PI-RADS scores to determine potential correlations, and we evaluated potential associations among these measures to predict tumor grade in both diagnostic biopsy and in post-radical prostatectomy (RP) tumor tissue. We also assessed the impact of these measures on the decision to pursue either AS or curative therapy among men who have PrCa.

Methods: This was a retrospective, observational, Institutional Review Board-approved analysis of data from patients ascertained sequentially (N=223, across two cohorts) from a single Urology community practice from January 2015-June 2018. Men were included in the study if they had been diagnosed previously with localized PrCa, had a PI-RADS version 2 score derived from mpMRI-ultrasound fusion targeted biopsy, and had a concomitant CCP test result from the biopsy. Cohort 1 (n=157) included men who had been newly diagnosed with localized PrCa, either with or without a previous negative biopsy. Cohort 2 (n=66) included men with localized PrCa who had initiated AS without CCP testing, but who subsequently received the test, with medical management informed by the result. The CCP score was calculated as the average expression of 31 CCP genes. The molecular score was combined in a validated model with the UCSF Cancer of the Prostate Risk Assessment (CAPRA) score to produce a clinical cell-cycle risk (CCR) score as described previously. The CCR score was reported to the provider and patient in the context of a validated AS threshold (CCR=0.8). Spearman’s rank correlation test was used to calculate the strength and significance of correlations between PI-RADS scores and CCP, CAPRA, or CCR scores. Generalized linear models were used to predict binary Gleason score category and also to predict medical management selection (either AS or curative therapy). Likelihood-ratio tests were used to determine predictor significance in both univariate and multivariate models.

Results: In combined Cohorts 1+2, weak but significant correlations were observed between PI-RADS score and CCP score (rs=0.24, p=4.1x10-4), CAPRA score (rs=0.36, p=3.0x10-8), or CCR score (rs=0.38, p=8.3x10-9), suggesting that much of the prognostic information captured by these measures is independent (Figure 1). CCP score was a significant predictor of higher-grade tumor (Gleason score =4+3) after RP, with the resected tumor approximately four times more likely to harbor a higher-risk Gleason score with every one-unit increase in CCP score in Cohort 1 (OR 4.39 [95% CI 1.62, 14.81], p=2.8x10-3) and in combined cohorts (OR 4.06 [95% CI 1.57, 12.69] p=3.0x10-3)(Table 1). PI-RADS score was not a significant predictor of post-RP Gleason score. Similar results were seen with CCP for predicting Gleason score at diagnostic biopsy (Table 1). On multivariate analysis, both CCP and CCR were significant and independent predictors of AS versus curative therapy in the newly diagnosed Cohort 1, with each one-unit increase in score corresponding to an approximately two-fold greater likelihood of selecting curative therapy (CCP OR 1.98 [95% CI 1.11, 3.67]; p=0.02)(CCR OR 2.23 [95% CI 1.49, 3.84], p=1.0x10-4). Having a CCR score at or below the AS threshold significantly reduced the probability of selecting curative therapy over AS (OR 0.29 [95% CI 0.14, 0.59], p=6.1x10-4), further validating the clinical utility of the AS threshold. PI-RADS scores showed no significant association with treatment selection.

Conclusion: These findings extend the validity and utility of the CCP test as an independent and accurate prognostic measure to aid in risk stratification and medical management of localized PrCa. Evidence presented here suggests that the CCP score is a better predictor of both tumor grade (at biopsy and after RP) and subsequent patient management than are mpMRI-derived PI-RADS scores. Therefore, a broad portfolio of measures, including targeted biopsy, clinicopathologic measures and molecular biomarker information, remains essential to ensure the most accurate and precise risk assessment to inform treatment selection for men with newly diagnosed, localized PrCa.

Funding: Funding for this work was provided by Myriad Genetics, Inc.
Figure 1. Distribution of cell cycle progression (CCP) score, UCSF Cancer of the Prostate Risk Assessment (CAPRA) score, and clinical cell-cycle risk (CCR) score across Prostate Imaging and Reporting and Data System (PI-RADS) score groups for patients in combined Cohorts 1 and 2 (N=223). Dotted line shows the CCR active surveillance (AS) threshold of 0.8.
94. MANAGEMENT TRENDS AND SURVIVAL IN T1C PROSTATE CANCER AMONG MEN > 74 YEARS OF AGE
Stephanie Gleicher, Timothy Byler, Joseph M Jacob, Elizabeth Ferry
SUNY Upstate Medical University
Presented By: Stephanie Gleicher

Introduction: Elderly men are underrepresented in prostate cancer (PCa) literature and management is based on individualized care pathways. In localized disease, reports have shown a survival benefit with surgery and radiation (XRT) among men 65-80 years, and XRT and androgen deprivation therapy (ADT) among men > 75 years. The objective of this study was to assess treatment trends and overall survival (OS) among men > 74 years of age with T1c PCa.

Methods: The National Cancer Database (NCDB) was queried to identify patients with stage cT1c adenocarcinoma PCa > 74 years of age between 2004-2016. We excluded all individuals with N1, M1, NX, MX disease, unknown treatment, treatment with both XRT and surgery, surgery other than radical prostatectomy (RP), PSA > 99ng/ml. We described 4 treatment cohorts: observation, XRT, surgery, and ADT alone. We compared demographic factors (age, race, insurance status, income, Charlson Comorbidity Index (CCI) and clinical factors (PSA, Gleason’s score (GS), treatment setting, distance traveled for care) with chi square and ANOVA. We generated Kaplan Meier survival curves and performed cox proportional hazards modeling. We generated trend charts to describe management patterns over time.

Results: Among 71,542 cases identified, 7% had surgery, 68% had XRT, 7% had ADT, and 18% were observed. We found a decrease in total diagnosed cases and total number treated over time. A decline in XRT was noted, with increases in RP and ADT. Significant differences among men undergoing surgery were noted for younger age, more white, lower PSA, income > $63K, travel further for care, more treatment at Academic centers, and less combination ADT (all p<0.001). Significant differences in OS were noted (log rank <0.001). Cox regression revealed significant survival benefit for XRT and ADT (HR 0.67 and 0.74, p-value<0.001 respectively); RP was not significantly associated with OS.

Conclusion: Fewer men > 74 years with T1c PCa are being diagnosed and treated, yet there has been a rise in the number of RPs performed. Survival benefit was seen for XRT and ADT among this age-based cohort of men. This discrepancy highlights the importance for prospective investigations and suggests a need for more guidance in managing this population.
95. DOWNGRADING OF GRADE GROUP 2 INTERMEDIATE-RISK PROSTATE CANCER FROM BIOPSY TO RADICAL PROSTATECTOMY: COMPARISON OF OUTCOMES AND PREDICTORS TO IDENTIFY POTENTIAL CANDIDATES FOR ACTIVE SURVEILLANCE

Zhuo Tony Su, Hiten Patel, Jonathan Epstein, Christian Pavlovich, Mohamad Allaf
James Buchanan Brady Urological Institute and Department of Urology, Johns Hopkins University School of Medicine
Presented By: Zhuo Tony Su

Introduction: Active surveillance (AS) is recommended for most men with low-risk (LR) prostate cancer. AS has also been suggested as a potential option for intermediate-risk (IR) men with certain “favorable” characteristics. However, to our knowledge, there remain no data to identify a subset of patients at IR at biopsy who will have a similar outcome on AS to patients with biopsy LR disease. We know however that some men with Grade Group (GG) 2 IR prostate cancer at biopsy downgrade to GG1 or harbor favorable pathology (FP), defined as GG1 or GG2 with <5% Gleason pattern 4 (GP4), at radical prostatectomy (RP). Prediction of downgrading or FP may help identify potential AS candidates within this group that have outcomes similar to patients with biopsy LR disease. In this study, we aimed to quantify the risk of and assess predictors for pathological downgrading to GG1 at RP for biopsy GG2 IR disease and compare with predictors of upgrading to GG>1 at RP for biopsy LR disease. Further, we sought to evaluate the impact of pathological downgrading and upgrading on recurrence-free survival (RFS). We hypothesized that prediction of pathological downgrading may help to identify a subset of patients with biopsy GG2 IR disease who will have similar outcomes to patients with biopsy LR disease and optimize their decision to pursue AS.

Methods: We performed a comparative cohort study of biopsy LR and IR men who underwent RP at the Johns Hopkins Hospital and Bayview Medical Center from January 2005 to December 2018. We evaluated pathological outcomes at RP and RFS after RP. We used multivariable Cox proportional hazards regression to compare RFS for the biopsy LR and GG2 IR cohorts and assess how RFS of these cohorts varies depending on pathological changes from biopsy to RP. We defined RFS as the interval from RP to the first of biochemical recurrence, prostate cancer metastasis, or death. In comparing RFS of various cohorts, we adjusted for covariates including patient age at RP, patient race, year of RP, preoperative prostate-specific antigen (PSA) level, and cancer volume at diagnosis. We utilized the concordance statistic (c-index) to assess the fitted models’ ability to discriminate GG changes from biopsy to RP. We calculated predicted probabilities of pathological downgrading, harboring FP, or upgrading, for individual patients using coefficients in the obtained final regression models.

Results: We identified 4,322 patients at IR and 1,325 patients at LR at biopsy who underwent RP during the study period. In our cohort of 2,943 biopsy GG2 IR patients, 223 (7.6%) experienced downgrading to GG1 and 525 (17.8%) harbored FP at RP. In our cohort of 1,325 biopsy LR patients, 730 (55.1%) experienced upgrading to GG>1 at RP. In multivariable Cox proportional hazards regression adjusting for covariates, biopsy GG2 IR patients downgrading to GG1 (adjusted hazard ratio (HR) 0.66 [95% confidence interval 0.30–1.48]) or harboring FP at RP (adjusted HR 0.58 [0.29–1.15]) had similar RFS to biopsy LR patients. Concordance statistics for the final predictive multivariable logistic regression models were 0.76 for downgrading and 0.64 for harboring FP at RP in biopsy GG2 IR patients and pathological upgrading to GG>1 at RP in biopsy LR patients. Evaluated predictors included patient age at RP, patient race, year of RP, family history of prostate cancer, preoperative PSA and PSA density levels, prostate size, and cancer volume at diagnosis. We utilized the concordance statistic (c-index) to assess the fitted models’ ability to discriminate GG changes from biopsy to RP. We calculated predicted probabilities of pathological downgrading, harboring FP, or upgrading, for individual patients using coefficients in the obtained final regression models.

Conclusion: Almost 8% of men with GG2 IR prostate cancer at biopsy downgrade and an even greater fraction (18%) harbor FP at RP. In contrast, over half of men with biopsy LR disease experience upgrading at RP. Biopsy GG2 IR patients who downgrade or harbor FP at RP have similar outcomes to biopsy LR patients. Furthermore, a cutoff of >10% predicted probability of downgrading to GG1 (24.7% of patients; adjusted HR 1.55 [0.89–2.68]) or >20% predicted probability of FP at RP (37.0% of patients; adjusted HR 1.35 [0.81–2.24]) led to similar RFS to biopsy LR patients.

Funding: SPORE grant P50CA58236 from the NIH
Table 1. Univariable and multivariable logistic regression evaluating preoperative factors for predicting pathological downgrading to Grade Group (GG) 1 and harboring favorable pathology (FP) at radical prostatectomy (RP) in men with GG2 intermediate-risk prostate cancer at biopsy

<table>
<thead>
<tr>
<th>Preoperative Factor</th>
<th>Downgrading to GG1 at RP</th>
<th>P Value</th>
<th>Harborng FP at RP</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>0.99 (0.97–1.01)</td>
<td>0.22</td>
<td>0.99 (0.96–1.01)</td>
<td>0.37</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>Referent</td>
<td></td>
<td>1.09 (0.47–2.52)</td>
<td>0.84</td>
</tr>
<tr>
<td>Asian</td>
<td>0.99 (0.78–0.99)</td>
<td>&lt;0.001</td>
<td>1.00 (0.99–1.01)</td>
<td>0.31</td>
</tr>
<tr>
<td>Black</td>
<td>0.94 (0.79–0.98)</td>
<td>&lt;0.001</td>
<td>1.00 (0.99–1.01)</td>
<td>0.31</td>
</tr>
<tr>
<td>Hispanic</td>
<td>0.81 (0.73–0.89)</td>
<td>&lt;0.001</td>
<td>1.00 (0.99–1.01)</td>
<td>0.31</td>
</tr>
<tr>
<td>Other/unknown</td>
<td>1.16 (1.07–1.26)</td>
<td>&lt;0.001</td>
<td>1.00 (0.99–1.01)</td>
<td>0.31</td>
</tr>
<tr>
<td>Age</td>
<td>0.98 (0.79–0.96)</td>
<td>&lt;0.001</td>
<td>0.99 (0.94–0.99)</td>
<td>0.01</td>
</tr>
<tr>
<td>Family history</td>
<td>0.89 (0.67–1.18)</td>
<td>0.42</td>
<td>1.00 (0.96–1.01)</td>
<td>0.12</td>
</tr>
<tr>
<td>PSA level (ng/mL)</td>
<td>0.83 (0.78–0.89)</td>
<td>&lt;0.001</td>
<td>0.84 (0.83–0.90)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Prostate size (g)</td>
<td>1.01 (1.00–1.01)</td>
<td>0.01</td>
<td>1.00 (0.99–1.01)</td>
<td>0.13</td>
</tr>
<tr>
<td>PSAD (per 0.01 ng/mL/g)</td>
<td>0.94 (0.91–0.98)</td>
<td>&lt;0.001</td>
<td>0.95 (0.94–0.97)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Positive cores</td>
<td>0.82 (0.76–0.89)</td>
<td>&lt;0.001</td>
<td>0.92 (0.88–0.96)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>≥1 positive core (vs. 1)</td>
<td>0.41 (0.28–0.60)</td>
<td>&lt;0.001</td>
<td>0.62 (0.46–0.83)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Maximum % core</td>
<td>0.98 (0.98–0.99)</td>
<td>&lt;0.001</td>
<td>0.99 (0.99–0.99)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Maximum % core ≥50 (vs. ≤50)</td>
<td>0.50 (0.37–0.67)</td>
<td>&lt;0.001</td>
<td>0.63 (0.52–0.77)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Multivariable  

\[c-index = 0.76\]

<table>
<thead>
<tr>
<th>Preoperative Factor</th>
<th>OR (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>0.98 (0.95–1.02)</td>
<td>0.07</td>
</tr>
<tr>
<td>RP Year</td>
<td>0.98 (0.95–1.02)</td>
<td>0.07</td>
</tr>
<tr>
<td>≥1 positive core (vs. 1)</td>
<td>0.61 (0.39–0.95)</td>
<td>0.03</td>
</tr>
<tr>
<td>Maximum % core</td>
<td>0.99 (0.98–0.99)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Abbreviations: c-index, concordance statistic; CI, confidence interval; OR, odds ratio; PSA, prostate-specific antigen; PSA-D, prostate-specific antigen density.

Table 2. Univariable and multivariable logistic regression evaluating preoperative factors for predicting pathological upgrading to Grade Group (GG) ≥1 at radical prostatectomy (RP) in men with low-risk prostate cancer at biopsy

<table>
<thead>
<tr>
<th>Preoperative Factor</th>
<th>OR (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>1.04 (1.01–1.06)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>Referent</td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>1.39 (0.60–1.20)</td>
<td>0.44</td>
</tr>
<tr>
<td>Black</td>
<td>1.32 (0.94–1.84)</td>
<td>0.10</td>
</tr>
<tr>
<td>Hispanic</td>
<td>0.61 (0.24–1.52)</td>
<td>0.28</td>
</tr>
<tr>
<td>Other/unknown</td>
<td>0.51 (0.27–0.97)</td>
<td>0.04</td>
</tr>
<tr>
<td>Age</td>
<td>1.16 (1.09–1.33)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Family history</td>
<td>1.03 (0.83–1.28)</td>
<td>0.81</td>
</tr>
<tr>
<td>PSA level (ng/mL)</td>
<td>1.19 (1.13–1.27)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Prostate size (g)</td>
<td>0.99 (0.98–0.99)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>PSAD (per 0.01 ng/mL/g)</td>
<td>1.10 (1.08–1.13)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Positive cores</td>
<td>1.18 (1.11–1.24)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>≥1 positive core (vs. 1)</td>
<td>2.36 (1.82–3.06)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Maximum % core</td>
<td>1.01 (1.01–1.03)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Maximum % core ≥50 (vs. ≤50)</td>
<td>2.08 (1.60–2.70)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Multivariable  

\[c-index = 0.70\]

<table>
<thead>
<tr>
<th>Preoperative Factor</th>
<th>OR (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>1.04 (1.01–1.06)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>RP Year</td>
<td>1.12 (1.04–1.22)</td>
<td>0.04</td>
</tr>
<tr>
<td>≥1 positive core (vs. 1)</td>
<td>1.68 (1.24–2.28)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Maximum % core</td>
<td>1.01 (1.00–1.02)</td>
<td>0.01</td>
</tr>
</tbody>
</table>

Abbreviations: c-index, concordance statistic; CI, confidence interval; OR, odds ratio; PSA, prostate-specific antigen; PSA-D, prostate-specific antigen density.

*An OR >1 in this column indicates a higher risk of pathological downgrading to GG1 at RP.

*An OR <1 in this column indicates a higher risk of harboring FP at RP.

*The final multivariable logistic regression model was obtained by selecting the fitted model that achieved the highest c-index value among all tested models.

*The final multivariable logistic regression model was obtained by selecting the fitted model that achieved the highest c-index value among all tested models.
96. CONCORDANCE RATES BETWEEN MRI FUSION VERSUS TRUS PROSTATE BIOPSY AND PATHOLOGY AT RADICAL PROSTATECTOMY: DATA FROM THE PURC
Ruchika Talwar1, Katharine Michel1, Aseem Malhotra1, Daniel Lee1, Thomas Guzzo1, Bret Marlowe2, Claudette Fonshell2, John Danella3, Serge Ginzberg4, Thomas Lanchoney5, Jay Raman6, Adam Reese7, Jeffrey Tomaszewski8, Edouard Trabulsi9, Marc Smaldone10, Robert Uzzo10
1 University of Pennsylvania, 2 The Health Care Improvement Foundation, 3 Geisinger Health System, 4 Einstein Medical Center, 5 Urology Health Specialists, 6 Penn State Milton S. Hershey Medical Center, 7 Temple University Hospital, 8 MD Anderson at Cooper University Hospital, 9 Thomas Jefferson University Hospital, 10 Fox Chase Cancer Center
Presented By: Ruchika Talwar

Introduction: In recent literature, multiparametric MRI has been shown to be of significant clinical value in the workup and staging of prostate cancer. Furthermore, MRI-targeted biopsies have been shown to be superior to the standard transrectal ultrasound technique. However, institutional and regional validation is important during the implementation of these newer techniques, such as MRI-fusion biopsies. Herein, we present the Pennsylvania Urologic Regional Collaborative (PURC) experience with MRI fusion biopsy. Our objective was to evaluate concordance rates between standard template transrectal ultrasound guided prostate needle biopsy versus MRI fusion biopsy and final pathology at the time of radical prostatectomy with our regional cohort. We hypothesized that MRI fusion biopsies would have significantly higher concordance rates.

Methods: Within the Pennsylvania Urologic Regional Collaborative (PURC), a prospective quality improvement collaborative of various urology practices in Pennsylvania and New Jersey formed in 2015, we identified all men who underwent either a transrectal ultrasound guided (TRUS) prostate needle biopsy, or an MRI fusion transrectal guided prostate needle biopsy, followed by radical prostatectomy for definitive treatment of prostate cancer from 2015 until 2018. We analyzed the pathology results from the time of biopsy and the final pathologic analysis at time of prostatectomy. We then calculated the concordance and upgrading rates at the time of biopsy versus final pathology at radical prostatectomy. Subsequently, we stratified our cohort by International Society of Urological Pathologists Grade Group (GG) and performed the same concordance testing. To assess for differences between our rates, we performed a test of equal proportions and a Pearson’s chi-squared test. We defined significance as p<0.05. All analyses were performed using STATA 15 (StataCorp).

Results: We identified 1,437 patients who underwent either traditional TRUS (n=1247) or MRI Fusion (n=196) biopsies, followed by radical prostatectomy in the PURC database. Within this cohort, 54.6% patients (n=784) identified as Caucasian, 20.2% (n=290) identified as African American, 5.4% (n=78) identified as other, while 20% (n=283) had no race recorded. Overall pathologic grading distribution at time of biopsy was as follows: 35.8% (n=515) Grade Group (GG) 1, 28.5% (n=409) GG 2, 13.3% (n=191) GG 3, 11.5% (165) GG 4, and 10.9% (n=157) GG 5. Median number of cores at time of TRUS biopsy was 12 (IQR: 12, 13), while median number of cores at time of MRI Fusion was 15 (IQR 13,18). Therefore, we inferred that patients who underwent MRI Fusion biopsy also underwent standard biopsy at the same time. On average, exact concordance rate between MRI Fusion biopsy and final pathology was 9.1% higher than concordance rate of TRUS biopsy (44.4% vs 35.3%, 95% CI: 1.6% - 16.5%, p < 0.01, Figure 1). Overall rate of upgrading on final pathology for MRI Fusion biopsies was 5.7% lower than for TRUS biopsies; however, this was not statistically significant (35.2% vs. 40.9%, 95% CI -1.5 – 13.0%, p = 0.06). When stratified by Grade Group, upgrading rate for MRI Fusion biopsies with GG 1 disease was 9.6% lower than upgrading rate for TRUS biopsies (91% vs 81.5%, 95% CI: 0.2% - 20.4%, Figure 2, p < 0.01). There was no significant difference between upgrading rates for GG 2 or 3 disease.

Conclusion: Within the PURC collaborative, MRI Fusion biopsies demonstrated significantly higher concordance rates with final pathology at the time of radical prostatectomy than TRUS prostate biopsies. When stratified by Grade Group, the rate of upgrading of GG 1 cancer was high overall (80-90%), but 9.6% lower in the MRI Fusion cohort than the TRUS biopsy cohort. This data provides relevant information with which to counsel our patients when considering the various biopsy techniques, especially when considering active surveillance versus definitive treatment. However, with regards to our Grade Group 1 cohort, based on the variables we analyzed, it is unclear what specific characteristics prompted urologists to elect radical prostatectomy over active surveillance, i.e, high risk genomic testing, which may explain our higher upgrading rates. This study has additional limitations. Given that it represents a regional cohort of practices, our experience may not be generalizable. Furthermore, it represents data from 2015 until 2018, at which point not all practices may have adopted MRI fusion technology. Despite these limitations, it provides meaningful data to guide quality improvement efforts within the collaborative to improve the utility of MRI fusion biopsies. Furthermore, this data can be used to leverage payers who may deny pre-biopsy MRI in our region. Future directions include identifying predictors for increased concordance rates, such as site and provider specific volume.

Funding: Data was provided with permission from the Pennsylvania Urology Regional Collaborative (PURC), funded by participating urology practices and the Partnership for Patient Care, a quality improvement initiative supported by the Health Care Improvement Foundation, Independence Blue Cross, and southeastern PA hospitals and health systems.
### Biopsy Grade Group 1

<table>
<thead>
<tr>
<th>Biopsy Type</th>
<th># Biopsies Upgraded</th>
<th>Total # Biopsies</th>
<th>Upgrading Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRUS</td>
<td>410</td>
<td>450</td>
<td>91.1%</td>
</tr>
<tr>
<td>MR Fusion</td>
<td>53</td>
<td>65</td>
<td>81.5%</td>
</tr>
<tr>
<td>Total</td>
<td>463</td>
<td>515</td>
<td>90.0%</td>
</tr>
</tbody>
</table>

On average, the upgrading rate for MR fusion biopsies with GS 6 is 9.6% lower (95% CI: -0.2% - 20.4%) than the rate for TRUS biopsies. \( p < 0.01 \)

Chi-Square test for Independence \( p \text{ value} = 0.02 \)

---

#### Table 1

<table>
<thead>
<tr>
<th>Biopsy Type</th>
<th>Number of Biopsies Concordant with Final Pathology</th>
<th>Total Number of Biopsies Performed</th>
<th>Percent Concordance</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRUS</td>
<td>438</td>
<td>1,241</td>
<td>35.3%</td>
</tr>
<tr>
<td>MR Fusion</td>
<td>87</td>
<td>196</td>
<td>44.4%</td>
</tr>
<tr>
<td>Total</td>
<td>525</td>
<td>1,437</td>
<td>36.5%</td>
</tr>
</tbody>
</table>

On average, the concordance rate for MR Fusion biopsy is 9.1% higher (95% CI: 1.6% - 16.5%) than the rate of TRUS biopsy. \( p < 0.01 \)

Chi-Square test for Independence \( p \text{ value} = 0.01 \)
97. RECOVERY OF SEXUAL FUNCTION IN MEN TREATED WITH ANDROGEN DEPRIVATION THERAPY FOR LOCALIZED PROSTATE CANCER
Daniel Joyce1, Zighuo Zhao1, Li-Ching Huang1, Tatsuki Koyama1, Ralph Conwill1, David F. Penson1, Daniel A. Barocas1, Karen E. Hoffman2

1 Vanderbilt University Medical Center, 2 The University of Texas, MD Anderson Cancer Center

Presented By: Daniel Joyce

Introduction: Decreased sexual function (SF) during androgen deprivation therapy (ADT) is well described; however, limited data exist assessing SF recovery following ADT use in treatment of localized prostate cancer. In this study, we compared SF in men who received ADT plus external beam radiation treatment (EBRT) to EBRT alone and identified patient-level predictors of SF recovery.

Methods: We prospectively enrolled a population-based cohort of men who underwent EBRT with and without ADT for intermediate or high risk localized prostate cancer as part of the Comparative Effectiveness Analysis of Surgery and Radiation (CEASAR) study. SF was assessed longitudinally out to 5 years using the validated Expanded Prostate Cancer Index Composite (EPIC-26) survey. Patients still receiving ADT at 5 years were excluded from analysis.

Results: A total of 167 patients were included. Of these, 73 underwent EBRT alone and 94 received ADT plus EBRT (51 with intermediate risk and 43 with high risk disease). Baseline SF was similar between groups (p=0.22). Compared to EBRT alone, ADT in high risk disease was associated with worse SF at 3 years but not at 5 years (Table 1). Neither baseline function, age, nor cardiovascular health influenced receipt of ADT.

Conclusion: ADT plus EBRT is associated with worse intermediate-term SF in men with high risk prostate cancer compared to EBRT alone. The addition of ADT in treatment of intermediate risk disease does not appear to result in worse intermediate-term SF compared to EBRT alone.

Funding: Funding for the study was provided by grants 1R01HS019356 and 1R01HS022640 from the Agency for Healthcare Research and Quality; UL1TR000011 to the Vanderbilt Institute of Clinical and Translational Research from the National Center for Advancing Translational Sciences; and 5T32CA106183 from the National Institute of Health and the National Cancer Institute. Research reported in this article was partially funded through a Patient-Centered Outcomes Research Institute (PCORI) award CE12-11-4667.

Table 1: Comparison of Sexual Function Between EBRT Alone and EBRT + ADT in Intermediate and High Risk Prostate Cancer Patients

<table>
<thead>
<tr>
<th></th>
<th>EBRT only</th>
<th>Int-Risk-EBRT-ADT</th>
<th>High-Risk-EBRT-ADT</th>
<th>Int-Risk-EBRT-ADT vs. EBRT only</th>
<th>High-Risk-EBRT-ADT vs. EBRT only</th>
<th>High-Risk-EBRT-ADT vs. Int-Risk-EBRT-ADT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>(N=73)</td>
<td>(N=51)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Erections Sufficient for Sex at 3-year</td>
<td>130</td>
<td>33 (57%)</td>
<td>23 (62%)</td>
<td>11 (31%)</td>
<td>1.8</td>
<td>[0.7, 4.7]</td>
</tr>
<tr>
<td>Erections Sufficient for Sex at 5-year</td>
<td>113</td>
<td>23 (45%)</td>
<td>18 (55%)</td>
<td>15 (52%)</td>
<td>1.6</td>
<td>[0.6, 4.1]</td>
</tr>
<tr>
<td>Sexual Function Score at 3-year, EPIC-26 (median, IQR)</td>
<td>129</td>
<td>69.4 (41.3, 84.6)</td>
<td>70.0 (42.1, 81.2)</td>
<td>28.3 (7.5, 70.0)</td>
<td>5.1</td>
<td>[-6.2, 16.6]</td>
</tr>
<tr>
<td>Sexual Function Score at 5-year, EPIC-26 (median, IQR)</td>
<td>112</td>
<td>65.0 (26.7, 82.5)</td>
<td>65.0 (38.3, 80.0)</td>
<td>43.8 (21.7, 70.0)</td>
<td>6.1</td>
<td>[-6.6, 19.3]</td>
</tr>
<tr>
<td>Recovery of Erections Sufficient for Sex by 5-year</td>
<td>68</td>
<td>12 (18%)</td>
<td>21 (31%)</td>
<td>5 (43%)</td>
<td>1.5</td>
<td>[0.4, 6.0]</td>
</tr>
</tbody>
</table>
98. HOXB13 EXPRESSION CORRELATES WITH OUTCOMES AND PROGRESSION IN MEN WITH LOCALIZED PROSTATE CANCER
Adam Weiner¹, Edward Schaeffer¹, Farzana Faizal², Tamara Lotan², Elai Davivioni³, R. Jeffery Karnes⁴
¹ Northwestern University, ² Johns Hopkins, ³ Decipher Biosciences, ⁴ Mayo Clinic
Presented By: Adam Weiner

Introduction: HOXB13 regulates prostate development and glandular homeostasis. Mutations in HOXB13 increase the risk of incident prostate cancer (PCa). Suppressed expression of the key HOXB13 binding partner, MEIS/2, correlates with worse oncologic PCa outcomes. Despite these key observations, expression of HOXB13 and its association with PCa outcomes has not been explored.

Methods: We utilized genome-wide expression profiles of prostate adenocarcinoma samples (pathology re-reviewed) from over 6300 cases including 5234 prospectively collected cases and 1135 cases from two institutional cohorts with long-term follow-up. We explored correlations between HOXB13 expression and a validated genomic risk score predicting metastasis (Decipher) following radical prostatectomy as well as actual metastasis-free survival (MFS) in those patients with follow-up. We also characterized HOXB13 expression in various publically available cohorts of castrate-resistant PCa (CRPC) and neuroendocrine PCa (NEPC) as well as a cell line modeling the transition from adenocarcinoma to CRPC and NEPC.

Results: Increased expression of HOXB13 was associated with high-risk of metastasis in the 5239 prospective cases (p<0.001). More specifically, high HOXB13 expression was associated with worse MFS in both cohorts with long-term follow-up (HR 1.73, 95% CI 1.23-2.44, p=0.001 and HR 2.34, 95% CI 1.35-4.09, p=0.002). We further found the combination of low MEIS1 and MEIS2 and high HOXB13 expression together further discriminated patients based on MFS (HR 1.99 and 2.6, respectively; Figure). HOXB13 expression decreased in the transition from adenocarcinoma to CRPC (p<0.001) and from CRPC to NEPC (p<0.001).

Conclusion: Increased HOXB13 expression correlates with worse MFS following prostatectomy, and to a greater degree in the setting of low MEIS1/2 expression. HOXB13 expression decreases as adenocarcinoma progresses to CRPC and subsequently NEPC.

Funding: the 2019 Urology Care Foundation Residency Research Award Program and the Russell Scott, Jr., MD Urology Research Fund (ABW).
99. RACIAL DISPARITIES IN YEARS OF POTENTIAL LIFE LOST SECONDARY TO UNTREATED LOW AND INTERMEDIATE RISK PROSTATE CANCER DEATHS

Mahmoud I Khalil1, Milan Bimali2, Rodney Davis3, Bruno Machado3, Mohamed H Kamel3
1 University of Arkansas for Medical Sciences, 2 Department of Biostatistics, University of Arkansas for Medical Sciences, Little Rock, Arkansas and Member, Winthrop P. Rockefeller Institute, University of Arkansas for Medical Sciences, Little Rock, Arkansas, 3 Department of Urology, University of Arkansas for Medical Sciences

Presented By: Mohamed H Kamel

Introduction: Active surveillance (AS) is becoming a widely adopted management option for patients with low-risk prostate cancer (Pca). African-American (AA) men have overall worse outcomes from Pca compared to Caucasian (CA) for a variety of socioeconomic, cultural and possibly biologic reasons, thus complicating the use of AS in this population. We aim to study racial disparities in Years of Potential Life Lost (YPLL) among CA and AA who were diagnosed with low and intermediate risk Pca and have not received any treatment modality. YPLL is defined as the difference between a predetermined end-point age (75 y) and the age at death for a death that occurred prior to that end age.

Methods: The Surveillance Epidemiology and End Results (SEER) database was used to identify low and intermediate risk Pca patients who were CA or AA and have not received treatment as a surrogate of active surveillance. The racial disparity in terms of YPLL was examined using a two-stage modeling approach. Of note, as of January 1st, 2003, Gleason score 7 has been moved from moderately to poorly differentiated group.

Results: 3,451 Pca patients (2725 CA and 726 AA) met inclusion criteria and were included in the study. Average age at diagnosis (years) was significantly different between the two groups (74.52 vs 71.46, P<0.01 for CA and AA, respectively). We observed significant association between race and marital status (P< 0.01) (Table 1). The majority of patients in the two groups (74.67%) survived 75 years or longer. AA had shorter mean survival time after Pca diagnosis compared to CA (5.8 vs 6.12 years, P=0.02). The two groups were similar in terms of tumor grade with most of the patients had a moderately differentiated tumor (92.09%). On the contrary, the two groups were significantly different (P<0.05) in tumor stage with T1 disease being prevalent in the AA group (55.51%) and T2 in the CA (52.29%). The unadjusted risk of having YPLL among AA is 70% (95% CI: 51%-91%, P<0.01) higher than CA. After adjusting for the effect of ethnicity, marital status, AJCC staging, and CHSDA (States and Contract Health Service Delivery Area) region, the risk of experiencing YPLL among AA is 63% (95% CI: 43%-85%, P<0.01) higher than CA. Among those who experienced YPLL (died before 75), the adjusted mean YPLL among AA was 12.72 months (95% CI: 11.4 – 14.3 months) higher compared to CA and this was not statistically significant (P<0.29).

Conclusion: In the setting of untreated low and intermediate risk Pca, racial disparity in risk of YPLL existed, with AA being more susceptible than CA. However among those who died before 75 years, the difference in estimated YPLL did not attain statistical significance between the two races. Regarding clinical significance, the relatively small difference in YPLL between AA and CA should be weighed against the potential side effects of surgery and radiation.

Table 1: Patient and tumor characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Level</th>
<th>Overall (n = 3451)</th>
<th>African American (n = 2725)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years, SD)</td>
<td>Mean ± SD</td>
<td>73.88 ± 8.61</td>
<td>71.46 ± 9.01</td>
<td>74.52 ± 8.39</td>
</tr>
<tr>
<td>Survival (years, SD)</td>
<td>6.05 (4.1)</td>
<td>5.84 (4.18)</td>
<td>5.78 (4.6)</td>
<td>0.02</td>
</tr>
<tr>
<td>Hispanic/Spanish Letters (a, %)</td>
<td>Yes</td>
<td>383 (11.1)</td>
<td>7 (0.96)</td>
<td>376 (13.8)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>1008 (29.4)</td>
<td>719 (9.04)</td>
<td>289 (8.59)</td>
</tr>
<tr>
<td>Marital Status (a, %)</td>
<td>Married/cohabitant</td>
<td>1983 (57.46)</td>
<td>333 (45.87)</td>
<td>1650 (60.5)</td>
</tr>
<tr>
<td></td>
<td>Divorced</td>
<td>256 (7.34)</td>
<td>72 (9.22)</td>
<td>184 (6.37)</td>
</tr>
<tr>
<td></td>
<td>Separated</td>
<td>26 (0.75)</td>
<td>19 (2.52)</td>
<td>7 (0.23)</td>
</tr>
<tr>
<td></td>
<td>Single Never Married</td>
<td>341 (9.88)</td>
<td>133 (15.6)</td>
<td>208 (8.37)</td>
</tr>
<tr>
<td></td>
<td>Widowed</td>
<td>348 (10.08)</td>
<td>69 (9.5)</td>
<td>279 (10.20)</td>
</tr>
<tr>
<td>Stage (a, %)</td>
<td>Well Differentiated</td>
<td>271 (7.91)</td>
<td>57 (7.85)</td>
<td>214 (7.93)</td>
</tr>
<tr>
<td></td>
<td>Moderately Differented</td>
<td>3378 (99.02)</td>
<td>680 (92.15)</td>
<td>2698 (92.97)</td>
</tr>
<tr>
<td>AJCC Stage (8th Edition) (a, %)</td>
<td>T1</td>
<td>1703 (49.30)</td>
<td>403 (51.51)</td>
<td>1300 (47.78)</td>
</tr>
<tr>
<td></td>
<td>T2</td>
<td>1348 (39.09)</td>
<td>323 (44.49)</td>
<td>1025 (37.32)</td>
</tr>
<tr>
<td>CHSDA Region (a, %)</td>
<td>East</td>
<td>1062 (30.77)</td>
<td>326 (44.9)</td>
<td>736 (26.00)</td>
</tr>
<tr>
<td></td>
<td>Southern Plains</td>
<td>374 (10.78)</td>
<td>131 (17.84)</td>
<td>243 (8.92)</td>
</tr>
<tr>
<td></td>
<td>Pacific Coast</td>
<td>1350 (39.49)</td>
<td>259 (33.87)</td>
<td>1291 (47.53)</td>
</tr>
<tr>
<td></td>
<td>Southwest</td>
<td>465 (13.47)</td>
<td>16 (1.83)</td>
<td>455 (16.7)</td>
</tr>
<tr>
<td>YPLL (a, %)</td>
<td>No YPLL</td>
<td>2177 (64.65)</td>
<td>454 (62.55)</td>
<td>2223 (77.92)</td>
</tr>
<tr>
<td></td>
<td>YPLL</td>
<td>874 (25.33)</td>
<td>272 (37.47)</td>
<td>602 (21.52)</td>
</tr>
</tbody>
</table>

1 The reported risks are based on: (1) Pca patients who were diagnosed at age ≥ 65 y and survived 75 y or longer; (2) Pca patients who were diagnosed at age ≥ 65 y and survived 50 y or longer. Pca patients who were diagnosed at age ≥ 65 y and survived 75 y or longer.
2 CHSDA Region - Does not include Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont. CHSDA Region - Does not include Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont. CHSDA Region - Does not include Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont. CHSDA Region - Does not include Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont. CHSDA Region - Does not include Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.
100. OUTCOMES OF ACTIVE SURVEILLANCE FOR MEN WITH LOCALIZED PROSTATE CANCER STRATIFIED BY AUA RISK GROUPING
Andrew Gusev1, Keyan Salari1, Edouard Nicaise1, Alice Yu1, David Kuppermann1, Carl Ceraolo1, Michael Blute1, Douglas Dahl1, Anthony Zietman1, Adam Feldman1, Timothy Baloda1
1 Massachusetts General Hospital, 2 University of Massachusetts Medical School

Presented By: Andrew Gusev

Introduction: Active surveillance (AS) is an accepted management strategy for very low risk, low risk, and select cases of favorable intermediate risk localized prostate cancer (PCa). Long term data, especially in intermediate risk, are critical for understanding which patients are suitable for this strategy and who should transition to treatment. We investigated our AS cohort to evaluate outcomes stratified by AUA risk groups with a focus on favorable intermediate risk.

Methods: We reviewed our institutional database of men enrolled in AS for localized PCa from 1996-2016. Our AS protocol includes prostate specific antigen (PSA) and digital rectal exam (DRE) every 4-6 months for 3 years, then annually if stable. Mandatory confirmatory 12 core biopsy is done at 12-18 months and since 2014, multiparametric magnetic resonance imaging (mpMRI) and MRI-fusion biopsy have become integral at confirmatory biopsy. Additional imaging and/or biopsies are done at the discretion of physician and patient. We evaluated freedom from treatment (FFT), treatment type and indication, biochemical recurrence (BCR), and freedom from metastasis (FFM). Survival analyses were conducted using the Kaplan-Meier method; comparisons between risk group outcomes were done with the Wilcoxon rank sum test.

Results: The cohort consisted of 1272 men (see Table 1). Unfavorable risk men were excluded from this analysis. Median follow-up time was 6.4 years (IQR 0.9-11.9). 1232 men (96.8%) had Grade Group (GG) 1, 39 (3.1%) had GG 2, and one had GG 3. For the favorable intermediate risk group, 100 (76.9%) were included due to PSA>10, 28 (21.5%) due to GG 2, and 2 (1.54%) due to cT2 disease. There was no statistically significant difference in the proportion of men progressing to treatment between risk groups (p = .24). Of those treated, compared to very low and low risk, the favorable intermediate risk group had a significantly larger proportion of men receiving external beam radiotherapy (p < .001) and a significantly smaller proportion of men receiving radical prostatectomy (p = .01). For very low, low, and favorable intermediate risk groups, respectively: 5 year FFT was 71.1%, 64.4%, and 65.7%; 10 year FFT was 56.9%, 55.1%, and 53.7%; 5 year BCR-free survival was 99.1%, 98.5%, 96.5%; 10 year BCR-free survival was 97.9%, 96.9%, 94.5%; 5 year FFM was 99.8%, 99.0%, and 100%; 10 year FFM was 98.2%, 95.4%, and 91.3%. There were no statistically significant differences in FFT (p = .10), BCR (p = .56), or FFM (p = .36) between risk groups. Within the favorable intermediate risk group, there were no statistically significant differences in FFT (p = .70) or FFM (p = .36) between men with GG 2 and those with PSA>10.

Conclusion: Our results suggest that carefully selected men with favorable intermediate risk PCa may be reasonable candidates for active surveillance, demonstrating no statistically significant difference in freedom from treatment, biochemical recurrence, or metastasis from that of very low and low risk men. AS remains a safe and viable option for men of all three risk groups with a 96.4% 10 year metastasis-free survival at our institution. Further study of the ideal inclusion criteria, surveillance strategy, triggers for intervention, and the role of advanced imaging and biomarkers is needed in this population.
101. UROLOGIST-PATIENT SHARED DECISION IMPROVES PATIENT EXPERIENCE AND COST SAVINGS OF BIPARAMETRIC PROSTATE MRI
Andrew Gusev, Michelle Shabo, Scott Greenberg, Alan Goldstein, Jennifer Yates, Evan Ruppell, Ahmed Sobieh, Mitchell Sokoloff, Khashayar Rafatizand
University of Massachusetts Medical School
Presented By: Andrew Gusev

Introduction: Prostate biparametric magnetic resonance imaging (bpMRI) has similar cancer detection rates to multiparametric MRI (mpMRI) without necessitating venipunctures or gadolinium contrast for dynamic contrast-enhanced imaging (DCE). DCE is utilized in mpMRI to differentiate between PIRADS-3 and PIRADS-4 lesions in the peripheral zone (PZ). However, if PZ PIRADS-3 lesions are biopsied similarly to PIRADS-4 or -5 lesions, characteristics of DCE would be inconsequential and bpMRI alone could guide management. Additionally, some patients are biopsy-keen and would favor biopsy for any PIRADS-3 lesion, further limiting the utility of mpMRI over bpMRI. Shared decision (SD) making between the patient and their urologist regarding biopsy preferences and physician’s suspicion of clinically significant cancer (CSC) may help identify those patients for which bpMRI is sufficient to guide management. This approach could save patients the discomfort of venipuncture, risk of contrast reactions, and cut down on healthcare associated costs. We investigated the effect of bpMRI with a SD pathway on patient experience, cost, and MRI throughput.

Methods: In an IRB approved retrospective study, we reviewed our institutional database of 287 treatment-naïve men undergoing mpMRI. We used decision trees to create three possible MRI work up scenarios. Scenario 1 (S1) was the current standard of care, mpMRI. Scenario 2 (S2) was initial bpMRI with decision to observe PIRADS-3, but biopsy PIRADS-4 and higher. Thus all patients with PZ PIRADS-3 were called back for re-imaging with DCE. Scenario 3 (S3) was initial bpMRI with SD protocol: of the patients with PZ PIRADS-3, only the subset determined to directly benefit from DCE were called back for re-imaging. We compared outcomes of system cost, patient cost, MRI throughput, and patient experience for each scenario. System cost was calculated as MRI and radiologist fee, obtained from Centers for Medicare and Medicaid Services. Patient cost was estimated as a half-day productivity loss, obtained from the US Department of Labor Statistics. MRI throughput was calculated using acquisition and room times from our facility. Patient unpleasant experiences were estimated by utilizing rates of adverse events for venipuncture and contrast administration described in the literature and rates of callbacks when initial bpMRI was insufficient in our cohort.

Results: Of 287 men, 50 (17.4%) had PZ PIRADS-3 lesions: DCE was negative for 36 (12 not biopsied) and positive with upgrade to PZ PIRADS-4 for 14 (11 biopsied). Combined, 23 of 287 men (8.0%) could have had management altered by DCE result. In S2, all patients with PZ PIRADS-3 (50) were called back to complete MRI work up with DCE. In S3, using the SD model, of the patients with PZ PIRADS-3, only the subset determined to directly benefit from DCE (23) were called back. When comparing outcomes for S2 and S3 with those for S1 (standard of care), system cost was reduced by both: S2 [-$32,646.75 (20%)] and S3 [-$36,366 (22.4%)]. Per patient cost was increased by both: S2 [+18 (17%)] and S3 [+8 (8%)]. Time to complete MRI workup was reduced by both: S2 [-1.3 days (8.0%)] and S3 [-4.2 days (25.9%)]. Number of unpleasant patient experiences was increased by S2 [+59.1 (13%)], but decreased by S3 [-25.2 (48.2%)]. Using S3 as a control due to its lowest number of unpleasant experiences, we calculated number needed to harm (NNH) for S1 to be 5.9 patients and S2 to be 58.8 patients.

Conclusion: Our results suggest that for treatment-naïve men, using bpMRI as the initial prostate imaging protocol combined with a SD on biopsy preferences and physician’s suspicion of CSC reduces patient unpleasant experiences, minimizes system cost, and maximizes MRI throughput, while having only a minor increase on per patient cost.

Table 1: Outcomes of Prostate MRI pathways

<table>
<thead>
<tr>
<th>N = 287</th>
<th>Scenario 1</th>
<th>Scenario 2</th>
<th>Scenario 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention Type</td>
<td>Current Practice</td>
<td>Proposed</td>
<td>Proposed</td>
</tr>
<tr>
<td>MRI type + Biopsy Strategy</td>
<td>mpMRI</td>
<td>bpMRI + biopsy PIRADS 4</td>
<td>bpMRI + SD Model</td>
</tr>
<tr>
<td>System Cost ($)</td>
<td>163,816.73</td>
<td>131,169.98</td>
<td>127,450.73</td>
</tr>
<tr>
<td>Difference from S1</td>
<td>0</td>
<td>-32,646.75 (-20.3%)</td>
<td>-36,366 (-22.4%)</td>
</tr>
<tr>
<td>Per Patient Cost ($)</td>
<td>103</td>
<td>121</td>
<td>111</td>
</tr>
<tr>
<td>Difference from S1</td>
<td>0</td>
<td>+18 (+17%)</td>
<td>+8 (+8%)</td>
</tr>
<tr>
<td>Time to complete MRI Eval (days)</td>
<td>16.2</td>
<td>14.9</td>
<td>12</td>
</tr>
<tr>
<td>Difference from S1</td>
<td>0</td>
<td>-1.3 (-8.0%)</td>
<td>-2.2 (-15.3%)</td>
</tr>
<tr>
<td>Number of unpleasant experiences</td>
<td>52.3</td>
<td>59.1</td>
<td>17.1</td>
</tr>
<tr>
<td>Difference from S1</td>
<td>0</td>
<td>+6.8 (+13%)</td>
<td>+25.2 (+48.18%)</td>
</tr>
<tr>
<td>Number needed to harm (NNH)</td>
<td>5.98</td>
<td>58.82</td>
<td>N/A (Control)</td>
</tr>
</tbody>
</table>
102. DOES PROSTATE VOLUME AFFECT CANCER DETECTION RATES FOR MRI-TARGETED BIOPSIES?
Luke P. O'Connor1, Alex Wang1, Michael A. Ahdoot, MD1, Nitin Yerram, MD1, Andrew R. Wilbur1, Amir H. Lebastchi, MD1, Heather Chaffin, MD1, Sandeep Gurram, MD1, Patrick Gornella, MD1, Siobhan Telfer, MD1, Peter A. Pinto, MD1, Howard Parnes, MD2, Maria Merino, MD3, Bradford J. Wood, MD4, Baris Turkbey, MD5

1 Urologic Oncology Branch, National Cancer Institute, National Institutes of Health, Bethesda, Maryland, 2 Division of Cancer Prevention, National Cancer Institute, National Institutes of Health, Bethesda, Maryland, 3 Translational Surgical Pathology Section, Center for Cancer Research, National Cancer Institute, National Institutes of Health, Bethesda, Maryland, 4 Center for Interventional Oncology, National Cancer Institute, National Institutes of Health, Bethesda, Maryland, 5 Molecular Imaging Program, National Cancer Institute, National Institutes of Health, Bethesda, Maryland

Presented By: Luke P. O’Connor

Introduction: MRI-US fusion biopsy (Fbx) demonstrates improved clinically significant prostate cancer detection rates (CDR) over 12-core systematic transrectal ultrasound (TRUS) biopsy. However, some have argued that among patients with smaller prostate glands, that targeted biopsy may not provide additional diagnostic value over TRUS biopsy.

Methods: Patients were enrolled in a prospectively designed cohort study assessing cancer detection rates by Fbx and TRUS. All patients underwent both biopsy modalities in the same setting and the CDR by each modality were assessed. Following data collection, patients were stratified in to quintiles by prostate volume and CDR by each modality were assessed. The primary outcome was the difference in CDR of clinically significant cancer, defined as Gleason =7. The difference in CDR between the two groups were compared using the chi-square test with a result of p < 0.05 considered statistically significant.

Results: Between 2007 and 2019, 2103 men underwent both TRUS and MRI-US fusion biopsy. Of these men, 1992 of them had a prebiopsy prostate volume measurement on MRI and were included in this study. Median age and median PSA at the time of biopsy were 64 (IQR 58-68) and 6.7 ng/dL (IQR 4.6-10.3), respectively. Median prostate volume on MRI (59 cc, IQR 37-71) and median number of Fbx targets (4 IQR 2-6) were assessed. The difference in CDR between TRUS biopsy and Fbx for the entire cohort was 6.8% (30.9% vs 37.8%, p < 0.001). Upon stratification of patients based on prostate volume, Fbx had superior CDR for prostates with volumes up to 30 cc (46.6% vs. 61.2%, p < 0.001), 31 to 60 cc (36.9% vs. 45.0%, p < 0.001), and 61 to 90 cc (18.8% vs. 24.6%, p = 0.044). Prostate volumes greater than 90 cc did not show a statistically significant difference in CDR between the two biopsy techniques. When analyzing CDR for Gleason 8 or greater disease, Fbx had improved cancer detection rates for prostates with volumes 0 to 30 cc (14.9% vs. 20.0%, p = 0.045) and 31 to 60 cc (11.3% vs. 17.7%, p < 0.001).

Conclusion: Contrary to common belief, MRI-targeted biopsy yields the highest cancer detection rates and greatest increase in cancer detection rates relative to TRUS biopsy among patients with a prostate volume of 0-60 cc. MRI targeted biopsies should not be skipped among patients with smaller prostate glands due to the belief that systematic biopsy adequately samples smaller prostates.
103. RACIAL DIFFERENCES IN ADVERSE PATHOLOGY AMONGST MEN WITH PROSTATE CANCER AT TIME OF RADICAL PROSTATECTOMY
Samuel Washington1, Sikai Song2, Janet Cowan3, Shoujun Zhao3, Matthew Cooperberg3, Peter Carroll3
1 University of California San Francisco, 2 School of Medicine, University of California San Francisco, 3 Department of Urology, University of California San Francisco
Presented By: Samuel Washington

Introduction: For black men, the concern that they are at greater risk of worse oncologic outcomes for prostate cancer compared to white counterparts may drive the greater push to surgery although reasons are likely multifactorial. While adverse pathology (AP) is associated with worse survival, data surrounding race-based differences in rates of adverse pathology is limited. We aim to examine the association between race and adverse pathology on surgical pathology among black and white men with prostate cancer.

Methods: Using our institutional prospective oncologic database, we identified 3,826 patients diagnosed with prostate cancer since 1990 and underwent primary RP. Adverse pathology was defined as GS>=4+3 or pT3/4 or pN1 on surgical pathology. Race was dichotomized as black or non-Hispanic white. Multivariable logistic regression modeling was utilized to examine the association between race and AP after adjusting for age, year of diagnosis, and clinical risk by UCSF-CAPRA category (low 0-2, intermediate 3-5, or high 6-10). PI-RADS and GPS scores were not included in the regression models due to the limited sample size. There was no significant effect of interaction between race and CAPRA, therefore no interaction term was included in the regression analysis.

Results: Of 3826 patients included, 3682 (96%) were white and 144 (4%) were black. At diagnosis, mean age was 60.4 years (SD 7.1), median PSA density was 0.19 (IQR 0.13-0.20), and most were intermediate- (44%) or high-risk (15%) by CAPRA. Mean GPS scores was 26.85 (SD 12). The majority of those who underwent prostate MRI had PI-RADS 4-5 lesions (89% vs 7% PI-RADS 3, 4% PI-RADS 1-2). Most had a systematic ultrasound-guided prostate biopsy alone (98%, 1% TRUS targeted alone, 1% MRI-TRUS fusion biopsy). Compared to white counterparts, black men were younger (53% <60 years vs 43%, p<0.02) with higher PSA density (PSAD 0.25 vs PSAD 0.19, p<0.01), and a larger proportion was high-risk by CAPRA (24% vs 15%, p=0.03) at diagnosis. PI-RADS at diagnosis, Genomic Prostate Score at diagnosis, and rate of targeted biopsy at did not differ significantly by race. Post-RP, pathologic Gleason grade, T-stage, and positive surgical margins rates were similar between races (p>0.05 for all). Nodal disease was more common in black men compared to white counterparts (8% vs 5%, p<0.01) On multivariate analysis, black race was not associated with higher risk of AP (OR 1.04, 95% CI 0.67-1.61, p=0.86) after adjusting for age, clinical CAPRA score, and year of diagnosis.

Conclusion: Black race was not associated with increased risk of AP at RP compared to white counterparts after adjusting for clinical factors. While race-based differences in oncologic outcomes exist, this study supports the growing body of research challenging the prior attribution of these differences solely on biology. Further investigation into how multiple factors such as biology/genetics, quality of care, social environment, and health-related behaviors may interact to contribute to these observations is warranted.

104. THE NEW SURVEILLANCE, EPIDEMIOLOGY, AND END RESULTS PROSTATE WITH WATCHFUL WAITING DATABASE: OPPORTUNITIES AND LIMITATIONS
Chang Wook Jeong1, Samuel Washington2, Annika Herlemann Herlemann2, Peter Carroll2, Matthew Cooperberg2, Scarlett Gomez2
1 Department of Urology, Seoul National University Hospital, Seoul, Republic of Korea, 2 Department of Urology, University of California San Francisco, 3 Department of Epidemiology & Biostatistics, University of California, San Francisco, CA
Presented By: Samuel Washington

Introduction: Active surveillance (AS)/Watchful waiting (WW) strategy for localized prostate cancer (PCa) is increasingly and broadly endorsed as a preferred option for initial treatment of men with very low- and low-risk PCa but outcomes can be difficult to analyze in traditional, population-based registries. The recently released Surveillance, Epidemiology, and End Results (SEER) prostate with WW dataset provides an opportunity to understand national patterns and trends in AS/WW, but the data source itself has not been well described.

Methods: Degree of missing data for each variable was measured. In order to examine bias due to missing data for cancer characterization, we compared two versions of the data: one which excluded cases with missing data and one dataset generated applying multiple imputation methods.

Results: We identified 316,724 patients in the entire cohort and 257,060 men with clinically localized PCa (T1-2N0M0) with data collected from 18 SEER registries between 2010 to 2015, with inclusion of a new, treatment variable for AS/WW. Only 46.2% cases had complete data on basic cancer characteristics for risk stratification. The excluded dataset (N=118,821) differed significantly from the multiple imputation dataset (N=257,060) in distribution of all reported variables (p<.001).

Conclusion: While the SEER Prostate with WW dataset offers a new method to describe treatment trends for men with PCa, including the use of AS/WW, the amount of missing data present should not be ignored. Our findings suggest that using a multiple imputation strategy can minimize potential bias due to missing data.
105. NATURAL HISTORY OF AN IMMEDIATELY DETECTABLE PSA FOLLOWING RADICAL PROSTATECTOMY: A DESCRIPTION OF A CONTEMPORARY COHORT

Peter E. Lonergan, Samuel L. Washington, Janet E. Cowan, Hao G. Nguyen, Matthew R. Cooperberg, Peter R. Carroll

University of California, San Francisco

Presented By: Peter E. Lonergan

Introduction: Radical prostatectomy (RP) can provide good long-term oncological outcomes in patients with localized and locally advanced prostate cancer (PCa). After RP, prostate specific antigen (PSA) represents the cornerstone for follow-up of patients. A persistently detectable PSA immediately following RP is an unfavourable prognostic factor. Potential explanations include: systemic, micro-metastatic disease that goes undetected preoperatively or the presence of residual prostate tissue. We described the natural history of the management and outcomes in men with a detectable PSA immediately following RP in an academic tertiary care center.

Methods: A retrospective review of prospectively collected clinical and pathologic data from consecutive patients who underwent RP for non-metastatic PCa at our institution between 2000 and 2018 was performed. A detectable PSA was defined as PSA > 0.05 ng/ml between 2-6 months post-surgery. Biochemical recurrence (BCR) was defined as two consecutive PSA values > 0.2 ng/ml after 6 months post-surgery or any salvage treatment for a rising PSA. Second recurrence was defined as additional treatment after post-RP salvage treatment. Outcomes were defined as time to other cause mortality (OCM) or prostate cancer specific mortality (PCSM).

Results: We identified 499 patients with a detectable PSA within 6 months following RP. The median age at diagnosis was 62 years (IQR 57-66) with a median PSA of 7.95 ng/ml (IQR 5.57-12.97). The median CAPRA-S score was 5 (IQR 2-7). The final pathology was Gleason score (GS) 3+3 in 52 (10%) men, GS 3+4 in 163 (33%), GS 4+3 in 143 (29%) and GS 8-10 in 141 (28%). Pathologic T-stage was T2 in 202 (40%), T3 in 283 (57%) and T4 in 14 (3%). Pathologic N1 disease was found in 81 (16%) men and N0/X in 418 (84%). The median follow-up was 41 months (IQR 20-77). 296 (59%) underwent salvage treatment at a median of 5 months. 33 (23%) of these men required further treatment (10 for bone metastases) at a median of 7 months. 203 (41%) of men with an immediately detectable PSA did not undergo any further treatment after RP. Treatment-free survival after post-RP salvage (31 on androgen deprivation therapy and 2 underwent salvage radiotherapy) in men with a detectable vs undetectable PSA was 86% vs 92% at 1 year, 78% vs 89% at 3 years, 72% vs 86% at 5 years and 70% vs 76% at 10 years (Log-rank p = 0.02). Prostate cancer specific survival in men with a detectable vs undetectable PSA was 100% vs 100% at 1 year, 99% vs 100% at 3 years, 96% vs 100% at 5 years and 91% vs 99% at 10 years (Log-rank p < 0.01).

Conclusion: This report describes the natural history of the management and outcomes in men with a detectable PSA following RP. We demonstrate that men with a detectable PSA after RP may have excellent long-term outcomes.
106. POSTTRAUMATIC STRESS DISORDER AND SUICIDE AMONG VETERANS WITH PROSTATE CANCER
Maya Aboumrad1, Brian Shiner1, Talya Peltzman1, Florian Schroeck1, Alexander Fuld1, Ellyn Russo1, Yinong Young-Xu1, Lorelei Mucci2, Zachary Klaassen3, Stephen Freedland4
1 White River Junction Veterans Affairs Medical Center, 2 Harvard T.H. Chan School of Public Health, 3 Medical College of Georgia at Augusta University, 4 Cedars-Sinai Medical Center
Presented By: Maya Aboumrad

Introduction: Prior studies have shown an excess risk of suicide following a prostate cancer diagnosis, which may be influenced by factors including age and cancer stage, grade, and treatment. However, the effect of mental health disorders, especially posttraumatic stress disorder (PTSD), on suicide risk among this population remains unknown. We sought to evaluate the impact of a pre-existing PTSD diagnosis on suicide and non-suicide mortality among men with newly diagnosed prostate cancer.

Methods: We used patient-level data from Veterans Health Administration (VHA) electronic medical records linked with Centers for Disease Control and Prevention (CDC) National Death Index cause of death records to assemble a cohort of men (age = 40 years) diagnosed with prostate cancer from 2004 through 2014. We used a retrospective window of one year to identify men with PTSD prior to their prostate cancer diagnosis. Cox proportional hazard models were used to identify risk factors for non-suicide and suicide mortality. We adjusted for age, race/ethnicity, marital status, military-related disability, homelessness, Agent Orange exposure, medical comorbidities (e.g., cardiovascular disease/coronary artery disease, sexual dysfunction), psychotropic medication use, health care service utilization, suicide attempts and ideation, National Comprehensive Cancer Network risk groups, metastases during the study period, and the year of prostate cancer diagnosis.

Results: Our cohort consisted of 242,653 men with prostate cancer, of whom 11,178 (4.6%) had a PTSD diagnosis prior to prostate cancer. The median follow-up time after cancer diagnosis was 4.7 years (IQR=4.7 years). Patients with PTSD were significantly more likely to be younger (age<65 years), non-white, married, and have more medical comorbidities compared to men without PTSD (p<0.001) (Table 1). Additionally, a significantly smaller proportion of patients with PTSD received any prostate cancer treatment (surgery, radiation, androgen deprivation therapy) compared to those without (PTSD: N=2,983, 27.0%; No PTSD: N=72,863, 31.8%) (Table 2). On multivariable analysis, having PTSD was associated with a lower rate of non-suicide mortality (HR=0.72; 95% CI: 0.67, 0.78; p<0.001). However, PTSD was an independent risk factor for suicide mortality even after controlling for important suicide risk factors such as major depressive disorder and substance abuse disorder (HR=2.42; 95% CI: 1.29, 4.52; p<0.001).

Conclusion: Men with pre-existing PTSD and a recent diagnosis of prostate cancer experienced improved overall survival despite being at greater suicide risk. Given the high prevalence of PTSD and prostate cancer in Veteran men, understanding the interplay between the two diseases warrants further study.

Funding: This project was funded intramurally by the VHA Office of Rural Health
Introduction: PSA-based screening has improved the early detection of prostate cancer, resulting in many more men being diagnosed and treated. Prospective cohort studies have shown that active surveillance is a safe management option for men with low and favorable-intermediate risk prostate cancer. Tools such as prostate biomarkers have been incorporated into the management of prostate cancer risk stratification, which in turn reassures the patient and clinician regarding appropriateness of active surveillance. Another such clinical tool is the multi-parametric prostate MRI. The NCCN guidelines’ active surveillance protocol previously recommended consideration of prostate MRI in response to PSA increase if an anterior lesion was suspected. These recommendations have recently changed in favor of expanded utilization of mpMRI. An unchanged mpMRI has been associated with an 80% negative predictive value for biopsy upgrading during AS (Henderson et al). However, prior studies have also demonstrated biopsy upgrading (> Gleason 6) in 27% of men with a negative mpMRI, suggesting that mpMRI alone cannot be used to monitor men on AS. The American Urological Association (AUA) Multiparametric Prostate MRI Consensus Panel deems current data to be insufficient regarding repeat MRI without a prostate biopsy for monitoring men on AS. Thus, given conflicting data and society stances, it is the goal of this study to evaluate the utility of prostate mpMRI for clinical decision making in patients on active surveillance.

Methods: The study was deemed exempt by the Institutional Review Board of University Hospitals, Cleveland Medical Center. Low and favorable-intermediate risk categories were defined according to National Comprehensive Cancer Network (NCCN) guidelines. A retrospective chart review was conducted to identify patients on active surveillance for low or favorable-intermediate risk prostate cancer receiving at least two prostate MRIs at University Hospitals Cleveland Medical Center from 2009-2016.69 patients on active surveillance with at least two prostate MRI and two prostate biopsies were identified. All MRIs were read and scored by board-certified radiologists using the Prostate Imaging Reporting and Data System (PIRADS) version 2. If the patient had multiple suspicious lesions, the lesion with the highest PIRADS score was included in the analysis and this index lesion was tracked throughout subsequent MRIs. The utility of prostate MRI was determined by calculating the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the change from the first to the second/subsequent MRI in relation to changes in biopsy pathology. MRI progression was defined as increase in PIRADS score of the previously existing index lesion or the appearance of a new high grade lesion. Noting that some patients had an initial mpMRI with a high risk lesion (PIRADS >3) that did not change, we then separately calculated the relative risk of biopsy upgrade among these patients with a high grade lesion at any time during AS compared to those without a high grade lesion.

Results: 19 out of 69 patients (28%) had progression of PIRADS lesion when followed with =2 mpMRI. 50 patients had no progression of MRI lesion (Figure 2). Of those with progression on MRI, 16 were found to have upgrade on prostate biopsy pathology, resulting in a positive predictive value of 84%. An upgrade in MRI lesion was noted to be 91% specific for biopsy progression (95% CI 76% to 98%). All patients who had an upgrade on pathology were noted to upgrade to intermediate risk disease (Gleason 3+4=7 or Gleason 4+3=7). Of the patients who had pathologic upgrade predicted by mpMRI, treatment change was noted in ~50% (data not shown). A total of 35 patients had biopsy progression on final pathology. Of these patients, 16 had upgrade of MRI lesion. Thus, the sensitivity of a change in MRI lesion was calculated at 46%. 44 patients had a high grade PIRADS lesion detected on mpMRI during AS. Amongst those patients who had a high grade lesion on any time, the relative risk of biopsy upgrade was 3.3 times greater than those without a high grade PIRADS lesion (95% CI 1.46-7.42; P<0.01).

Conclusion: When following patients on active surveillance with multiple prostate mpMRIs, most MRIs (~3/4) will not upgrade. A patient with a high risk lesion on mpMRI identified at any time while on surveillance has a 3.3-fold increased risk of progression on subsequent biopsy compared to those without a high risk lesion (PIRADS>3). If initial mpMRI demonstrates a high risk lesion, the majority of the benefit of imaging has been obtained. Clinicians should have a high suspicion for missed lesion and low threshold for re-biopsy. If a patient has upgrading of PIRADS lesion on MRI, there is a high likelihood of biopsy progression, often predicting treatment change (exit from AS). Thus the utility of mpMRI appears to be greatest when determining candidacy for active surveillance or when engaging in shared decision making on active surveillance to obtain additional information on the risk of pathologic upgrade prior to repeat biopsy.
108. AN UPDATE ON THE PROSTATECTOMY PATHOLOGIC FINDINGS OF A SERIES OF PATIENTS WITH PROSTATE CANCER AND NO SIGNIFICANT REGIONS OF INTEREST ON MAGNETIC RESONANCE IMAGING
Shaheen Alanee1, Mustafa Deebajah2, James Peabody3, Mani Menon3, Sean Williams4, Nilesh Gupta4, Ali Dabaja5
1 ALANEE MD PLLC, 2 Department of Pathology, Beaumont Health System, 3 Vattikuti Urology Institute, Detroit, MI, 4 Department of Pathology, Henry Ford Health System, 5 Vattikuti Urology Institute
Presented By: Shaheen Alanee

Introduction: We previously presented post prostatectomy pathology results from a small number of prostate cancer (PCa) patients who did not have findings suggestive of cancer on pre-operative pelvic magnetic resonance imaging (MRI). We update our series with results from more patients with the same imaging characteristics.

Methods: An institutional retrospective study for our database of mpMRI for clinical suspicion of prostate cancer from 2015 to 2018 was performed. Patients who underwent prostatectomy for prostate cancer were identified, and further analysis of their imaging and pathology findings were done. MRI was read by fellowship trained radiologist. Pathology was reviewed by fellowship-trained pathologist.

Results: 850 men underwent pelvic/prostate MRI performed between 2015 and 2018, and 156 patients underwent robotic assisted radical prostatectomy. Thirty three (21%) men (22 white, nine black, two other) had negative MRI for PIRAD 3 or greater. Their mean (range) age, PSA, and PSA density were 62.7 (50 - 86) years, 6.85 (0.2 - 32) ng/mL and 0.13 (0.06 – 0.22) ng/mL/cm2, respectively. On prostatectomy pathology, 27/33 (82%) men had PCA of Gleason score (GS) 7 or greater. These included 18 Grade Group 2, 5 Grade Group 3, 3 Grade Group 4 (2 with 4+4 and 1 with 3+5), and 1 Grade Group 5 (Gleason 5+5). The most common pattern was infiltrative growth with cancer glands intermingling between benign glands. Nine men had extra prostatic extension including 1 who had seminal vesicle extension.

Conclusion: With increasing the number of patients with prostate cancer not seen on MRI, we show an even higher percentage of clinically significant prostate cancer on final surgical pathology. This validates our previous findings that negative MRI should not be used in isolation of other clinical variables to decide on whether to perform a prostate biopsy or not.
109. DIFFERENCES IN CONTEMPORARY BIOPSY GLEASON SCORE DISTRIBUTION IN MEN DIAGNOSED WITH PROSTATE CANCER FROM CHINA AND CANADA

Liang Dong, Zehua Ma, Baijun Dong, Dixon Woon, Wei Xu, Michael Nesbitt, Girish Kulkarni, Robert J Hamilton, Antonio Finelli, Neil E Fleshner, Theodorus H van der Kwast, Wei Xue, Cynthia Kuk, Annette Erlich, Alexandre R Zlotta, Oumin Shi, Sigrid V Carlsson

1 Renji Hospital, 2 University Health Network, 3 Sinai Health System, 4 Shenzhen Second People’s Hospital, 5 Memorial Sloan Kettering Cancer Center

Presented By: Liang Dong

Introduction: The incidence of prostate cancer (PCa) in Asia is lower than in Western countries but has been increasing rapidly in the last decade. Studies have previously suggested that Asian men present more frequently with advanced stage and high-grade PCa than Caucasian men. The unfavorable risk profile in Asian men could be partly explained by differences in screening and early detection practices. Differences at the genomic level also exist such as TMPRSS2-ERG fusions (prevalence of 50% in Caucasian vs. ~20% in Asian). Risk calculators such as the ERSPC calculator have been recalibrated for Chinese populations, outlining possible risk differences compared to Caucasians. We investigated the impact of race (Asian or Caucasian) on biopsy Gleason Score (GS) distribution in men diagnosed with PCa in tertiary referral centers in Toronto and Shanghai.

Methods: We performed a retrospective study of 2175 men diagnosed with PCa at 2 tertiary referral centres, University Health Network, Toronto, Canada and Renji Hospital, Shanghai, China, between 2014 and 2017. The biopsy protocol between the two centres were similar (number of biopsy cores = 10-14). We compared the distribution of GS on biopsy between men in China and Canada. To take into account potential differences in biopsy grading between institutions, a pathologist in Toronto re-reviewed a random sample of 99 biopsies from Shanghai, blinded to institution, clinical information and GS. To study the association between race and GS at diagnosis, univariate and multivariable logistic regression analyses were performed adjusting for age, PSA and prostate volume.

Results: The study population comprised 1032 vs. 1143 men diagnosed with PCa in Shanghai and Toronto, respectively. Median age at diagnosis (69 vs 65 years) and PSA (19.08 vs 6.24 ng/ml) was higher in Asian men compared to Caucasian men (p<0.001) whereas their prostates were smaller (34.2 cc vs 38.0 cc, p<0.001). In the 99 biopsies re-reviewed, the kappa coefficient between Shanghai and Toronto was 0.72. On univariate analysis, more GS8-10 (28.1%% vs 8.5%, p<0.001) were found in Asian than Caucasian men. On multivariable analysis, adjusting for age, PSA and prostate volume, GS8-10 in Asian men was significantly higher than in Caucasian men (OR 2.93, 95% CI 2.206-3.902, p=0.001). In the subset of men with PSA<10 ng/ml, GS8-10 in Asian men was significantly higher than in Caucasian men (OR 2.712, 95%CI 2.055-3.579, p=0.001). Limitations include the retrospective nature of this study and that tertiary referral centers might not be representative of the entire population.

Conclusion: Our study confirms racial differences in PCa aggressiveness between Asian and Caucasian men. It is unclear why Asian men are diagnosed with higher GS on biopsy than Caucasian men but suggests that differences in screening might not be the sole explanation.
110. IMPLICATIONS OF OVERUTILIZATION OF IMAGING IN LOW RISK PROSTATE CANCER: MORE HARM THAN GOOD?
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Presented By: Justin Loloi

Introduction: Both the American Urological Association (AUA) and the National Comprehensive Cancer Network (NCCN) do not recommend staging imaging in very low risk (VLR) and low risk (LR) prostate cancer (PCa). Despite these explicit guidelines, there is concern for overutilization of imaging in these groups. To investigate this, we explored the utilization of staging imaging and the significance of the findings in newly diagnosed VLR and LR PCa patients.

Methods: 493 PCa patients diagnosed between 2011-2017 were stratified according to AUA and NCCN VLR and LR groups. Computed tomography (CT), magnetic resonance imaging (MRI) and bone scan performed at diagnosis was captured and compliance to guidelines was evaluated. The significance of radiologist interpreted imaging findings, by imaging type, were classified as non-urologic, non-significant urologic, and PCa significant.

Results: Greater than 75% of patients among each of these risk groups underwent imaging at time of diagnosis. Specifically, a total of 58 (75%) AUA VLR, 67 (75.3%) AUA LR, 51 (75%) NCCN VLR, and 74 (75%) NCCN LR had imaging and thus, showed non-compliance with guidelines. Bone scan was performed in up to 30 (30%) of patients with no scans showing PCa-significant findings and the majority being normal (Table). Six bone scans showed non-urologic findings necessitating further testing. CT was utilized in up to 38 (38%) of patients, with the majority being normal and only 3 showing PCa-significant findings. Ten CTs showed non-urologic/non-significant urologic findings causing further evaluation. MRI was the most utilized scan in low risk groups, occurring in up to 47 (70%) of patients. Although, the majority were normal, up to 25 scans showed non-significant urologic findings, and only 7 showed PCa significant findings.

Conclusion: Among VLR and LR PCa patients there is high overutilization of imaging at time of diagnosis despite AUA and NCCN recommendations against use. Most of such imaging yielded minimal PCa significant findings and caused further workup for incidental results. This exploratory analysis gives awareness that staging imaging in VLR and LR PCa patients may do more harm than good.

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<th>CT</th>
<th>MRI</th>
<th>Bone Scan</th>
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<tr>
<td></td>
<td>Total Patients</td>
<td>Non-urologic</td>
<td>Non-significant urologic</td>
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<tr>
<td>AUA VLR</td>
<td>58</td>
<td>35 (48.3)</td>
<td>0</td>
</tr>
<tr>
<td>AUA LR</td>
<td>51</td>
<td>32</td>
<td>1</td>
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<tr>
<td>NCCN VLR</td>
<td>74</td>
<td>51</td>
<td>3</td>
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<td>NCCN LR</td>
<td>74</td>
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<th></th>
<th>CT</th>
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<tr>
<td>AUA VLR</td>
<td>27</td>
<td>17</td>
<td>4</td>
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<tr>
<td>AUA LR</td>
<td>32</td>
<td>22</td>
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<td>NCCN VLR</td>
<td>21</td>
<td>16</td>
<td>3</td>
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<td>NCCN LR</td>
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Introduc...: The American Urological Association (AUA) and National Comprehensive Cancer Network (NCCN) provide highly recognized guidelines on staging imaging for prostate cancer (PCa). However, recommendations are vague as to type (CT vs MRI) and extent (abdomen vs pelvis) of axial imaging, raising concern for redundant imaging. To investigate if guidelines can become more specific, we explored the utilization and findings of staging imaging in IR and HR PCa patients.

Methods: 493 PCa patients diagnosed between 2011-2017 were stratified according to AUA and NCCN IR and HR groups. Staging imaging was captured and frequency of redundant (CT + MRI) and abdominal imaging determined. Significance of radiologist findings, for both redundant and abdominal imaging, were classified as non-urologic, non-significant urologic, and PCa significant.

Results: Among AUA and NCCN risk groups, 82 (35.7%) and 95 (37.3%) patients, respectively, experienced redundant imaging, of which only 7 patients in AUA and 9 patients in NCCN risk groups had an abnormal CT with normal MRI (Table 1). However, only 3 of these CTs had PCa significant findings, of which 2 identified bone mets, likely detectable on bone scan. In regards to the extent of imaging, a total of 157 (68.2%) AUA and 178 (69.8%) NCCN IR and HR patients received abdominal scans, of which only 35 and 38 were abnormal among AUA and NCCN risk groups, respectively (Table 2). Among these abnormal abdominal scans, only 8 showed PCa significant findings of which half were bone mets and again likely identifiable on bone scan.

Conclusion: Due to non-specific staging guidelines in IR and HR PCa regarding type and extent of axial imaging, patients are frequently receiving redundant imaging. Based on low occurrences of unique PCa significant findings in CT and abdominal imaging, our exploratory analysis suggests that narrowing initial recommendations to pelvic MRI and bone scan may reduce redundancy while maintaining sufficient staging.
112. USE OF ACTIVE SURVEILLANCE FOR BLACK MEN WITH LOW-RISK PROSTATE CANCER
Bashir Al Hussein Al Awamlh1, Edward Schaeffer2, Yaw Nyame3, Xiaoyue Ma4, Peter Cai4, Christopher Gaffney4, Jim Hu4, Jonathan Shoag4
1 Weill Cornell Medicine, 2 Northwestern, 3 University of Washington, 4 Weill Cornell Medicine

Presented By: Bashir Al Hussein Al Awamlh

Introduction: Active surveillance (AS) is recommended for men with low-risk prostate cancer. However, Black men are at risk of harboring high-grade disease at time of AS enrollment. It is unclear if the benefits of AS are equally distributed among Black men with low-risk disease in different regions of the US.

Methods: We used the Surveillance, Epidemiology, and End Results Active Surveillance/Watchful Waiting Dataset to characterize the utilization of AS among Black and non-Black men with very low and low-risk prostate cancer from 2010-15. Multivariable analysis was performed to determine factors associated with AS utilization within each census region and assess the impact of race on regional AS use.

Results: In 2010, AS utilization among Black men was highest in the West at 22.0%, and lowest in the Northeast at 7.0%. In 2015, rates had risen as high as 49.0% in the West and Midwest, and was lowest in the South at 34.0%. Among Black men, we found AS use to be lower in the Northeast compared to the West, p<0.001 for interaction. In a multivariable model controlling for socioeconomic, oncologic, and demographic characteristics, Black men in the Northeast were less likely to be placed on AS compared to non-Black men, OR 0.72, 95% CI 0.62-0.84, but more likely than non-Black men in West, OR 1.31, 95% CI 1.20-1.43.

Conclusion: Differences in regional utilization of AS have led to markedly disparate prostate cancer care for Black men. Understanding the causes of these geographic disparities has the potential to improve care.
113. EXTENDED VERSUS NON-EXTENDED PELVIC LYMPH NODE DISSECTION AMONG PATIENTS UNDERGOING RADICAL PROSTATECTOMY FOR LOCALIZED PROSTATE CANCER: A CAUSAL INFERENCE-DRIVEN RETROSPECTIVE BI-CENTER COHORT STUDY

Marian S. Wettstein1, Luke A. David1, Aatif Qureshi1, Alex Zisman1, Michael Nesbitt1, Ardalan Ahmad1, Robert J. Hamilton1, Alexandre R. Zlotta1, Neil E. Fleshner1, Antonio Finelli1, Girish S. Kulkarni1, Clinsky Pazhepurackel1, Karim Saba4, Christian D. Fankhauser2, Tullio Sulser2, Cédric Poyet2, Thomas Hermanns2

1 Division of Urology, Department of Surgery, Princess Margaret Cancer Centre, University Health Network, University of Toronto, Toronto, Ontario, Canada; 2 Department of Urology, University Hospital of Zurich, Zurich, Zurich, Switzerland

Presented By: Marian S. Wettstein

Introduction: The current guidelines of the European Association of Urology recommend an extended pelvic lymph node dissection (external iliac nodes, obturator nodes and internal iliac nodes up to the ureter crossing) in patients with a nomogram-based risk of nodal metastasis of higher than 5%. However, this recommendation is mainly based on the staging benefit of extended pelvic lymph node dissection (PLND) and not on any oncological outcome improvements as recently shown by a systematic review. The majority of the currently available literature compares patients who underwent PLND (extent often insufficiently classified) to patients that did not undergo PLND. Studies incorporating the anatomical extent of PLND are scarce and mainly underpowered due to a limited number of patients and/or short follow-up time. Furthermore, several studies lack a sufficient analytical framework to draw causal inference regarding the oncological benefit of extended versus non-extended PLND. Therefore, the aim of this study was to quantify the oncologic benefit of extended versus non-extended PLND in patients undergoing radical prostatectomy for localized prostate cancer. Specifically, we aimed to identify the direct effect of extended over non-extended PLND (i.e. the removal of occult micrometastases) that is not mediated through the detection of nodal disease and potential adjuvant therapy (indirect effect).

Methods: A retrospective bi-center cohort study involving a consecutive series of patients who underwent radical prostatectomy and PLND for localized prostate cancer between January 2006 and December 2016 in two tertiary referral centers with differing PLND templates (extended: University Hospital of Zurich, Zurich, Switzerland, non-extended: University Health Network, Toronto, Ontario, Canada) was performed. Patients were followed until April 2018 for the occurrence of either biochemical recurrence or secondary therapy (composite outcome). Formatted extended PLND patterns of the Swiss center to typical non-extended PLND patterns of the Canadian center, we excluded all surgeons who performed less than ten PLNDs during the study period as well as surgeons whose PLND template is not reflective of the center. Furthermore, we restricted the cohort to patients whose pelvic lymph node yield was between the 20th and the 80th percentile of the surgeon who performed the procedure. Time to biochemical recurrence or secondary therapy between extended and non-extended PLND was compared by Kaplan-Meier analysis/log-rank test and Cox proportional hazards regression, both unweighted and weighted by inverse probability weights. Balance of the weighted pseudo-cohort was assessed by the standardized difference of the mean (less than 0.2). The direct effect of extended over non-extended that is not mediated through the detection of nodal disease and potential adjuvant therapy was investigated by causal mediation analysis (natural effects Cox model with 5,000 bootstrap replications).

Results: During the study period of eleven years, 3,923 patients with available follow-up data were identified (Switzerland: 958 [24.4%]; Canada: 2,965 [75.6%]). After exclusion of 271 patients with missing covariates and 1,942 patients who did not receive PLND, a preliminary cohort of 1,710 males was available for the exploration of PLND patterns. Applying our above-mentioned PLND definitions yielded a final cohort of 1008 patients (extended PLND: 368 [36.5%]; non-extended PLND: 640 [63.5%]) and also confirmed our hypothesis regarding differential PLND patterns between two centers (see Figure 1). Unweighted and weighted survival analysis demonstrated results in favor of extended PLND (unweighted hazard ratio (HR): 0.77 [95% confidence interval: 0.59-1.01], p=0.056; weighted HR: 0.75 [0.56-0.99], p=0.044; see Figure 2). We observed a well-balanced weighted pseudo-population with standardized differences of the mean of less than 0.2. The causal mediation analysis confirmed the total effect of 0.77 [0.71-0.82]. After disentangling this total effect into an indirect effect (via detection of nodal disease and potential adjuvant therapy) and a direct effect (via removal of occult micro-metastases), we an even more protective direct effect of 0.69 [0.63-0.75].

Conclusion: Among patients undergoing radical prostatectomy and PLND for localized prostate cancer, extended versus non-extended PLND seems to be beneficial from an oncologic perspective. In our causal mediation analysis, the protective effect was even more pronounced after accounting for therapeutic impacts of improved staging. To our knowledge, this is the first study that used a purely causal inference-driven approach including causal mediation analysis to assess the oncologic benefit of extended versus non-extended PLND. Our results not only indicate the limited utility of non-extended PLND but also that the effect of extended PLND is not restricted to a staging benefit and probably involves a therapeutic benefit mediated through the removal of occult micrometastases. This study is obviously limited by its retrospective nature, unmeasured residual confounding, and the lack of power for mortality outcomes. Our results need to be confirmed in prospective studies sufficiently powered for mortality outcomes.
114. THE COMPARATIVE OUTCOMES OF RADICAL PROSTATEACTOMY VERSUS RADIOTHERAPY FOR NON-METASTATIC PROSTATE CANCER: A LONGITUDINAL, POPULATION-BASED ANALYSIS

Justin Oake¹, Benjamin Shift², Jeff Saranchuk¹, Rahul Bansal¹, Darrel Drachenberg¹, Jasmir Nayak¹, Oksana Harasemiw², Thomas Ferguson², Navdeep Tangri³, Bimal Bhindi⁴
¹ Section of Urology, University of Manitoba, ² Chronic Disease Innovation Centre, Seven Oaks General Hospital; Department of Internal Medicine, University of Manitoba, ³ Chronic Disease Innovation Centre, Seven Oaks General Hospital; Department of Internal Medicine, University of Manitoba; Department of Community Health Sciences, University of Manitoba, ⁴ Section of Urology, University of Calgary

Presented By: Justin Oake

Introduction: The comparative effectiveness of radical prostatectomy (RP) versus radiation therapy (RT) for prostate cancer remains a largely debated topic. Utilizing a provincial population-based linked dataset from an equal-access, universal health care system, we sought to compare outcomes among patients treated with either radiation or prostatectomy for non-metastatic prostate cancer.

Methods: We performed a retrospective cohort study by linking several administrative datasets to identify patients who were diagnosed with prostate cancer between 2004-2016 in Manitoba, Canada, and who were subsequently treated with either RP or RT. Cox proportional hazard models with inverse probability of treatment weighting (IPTW) were used to compare rates of all-cause mortality, as well as prostate cancer specific mortality between patients who underwent RP vs. RT.

Results: During the study period, 2,540 patients underwent RP and 1,895 underwent RT for prostate cancer. Unadjusted overall survival was higher for RP vs. RT (5-year OS 95.42% for RP compared with 84.55% for RT, p<0.001). In IPTW – adjusted Cox regression analysis, compared to patients in the RP groups, patients in the RT group had an increased rate of all-cause mortality (HR 1.93, 95% CI 1.63-2.26, p<0.0001), and prostate cancer cause of death (HR 3.98, 95% CI 2.89-5.49; p<0.0001).

Conclusion: RT was associated with inferior overall survival and higher prostate cancer mortality rates compared with RP. These findings highlight the importance of comparative effectiveness research to identify treatment disparities and warrant further investigation.

Funding: Funding for this study was provided by the University of Manitoba Department of Surgery.
115. TRENDS IN EARLY MANAGEMENT OF STAGE 1 NON-SEMINOMA GERM CELL TESTICULAR CANCER
stephanie gleicher, Alexandr Pinkhasov, Oleg Shapiro, Elizabeth Ferry, Joseph M Jacob
SUNY Upstate Medical University
Presented By: stephanie gleicher

Introduction: Stage 1 non-seminoma germ cell testicular cancer (NSGCT) is currently managed with primary orchiectomy, followed by surveillance, retroperitoneal lymph node dissection (RPLND), and/or chemotherapy. Given the data on long term side effects of chemotherapy, we hypothesized that more stage 1 NSGCT subjects are undergoing primary RPLND. The goal of this study was to assess trends in initial management for stage 1 NSGCT subjects.

Methods: The National Cancer Database (NCDB) was queried to identify subjects diagnosed with testicular cancer between 2004-2015. Inclusion criteria included pathologic stage 1 NSGCT disease. We excluded individuals with stage 1S, and unknown RPLND status, chemotherapy status, and pathologic staging data. We identified individuals who underwent chemotherapy at < 60 days from diagnosis, RPLND in staging/diagnostic setting, and individuals without RPLND or chemotherapy < 60 days (active surveillance). We used chi-square and ANOVA to compare demographic (age, race, geography, insurance status, income) and clinical factors (histology, distance traveled for care) among subgroups. We generated trend charts to describe management patterns over time.

Results: Of the 8253 subjects in this study, 60% enrolled in active surveillance (AS), 22% received chemotherapy < 60 days, and 18% underwent RPLND. An increase in the number of cases between 2004-2015 was noted. Treatment trends revealed a slight increase in AS and an increase in chemotherapy, with a decrease in RPLND. Individuals undergoing RPLND were more likely to travel further for care (p<0.001), receive care from > 1 facility (P<0.001), and be treated at an academic/research program (p<0.001) versus chemotherapy and AS. Individuals with embryonal histology and positive surgical margins were more likely to receive chemotherapy (p<0.001).

Conclusion: This study highlights a trend in increased primary chemotherapy for stage 1 NSGCT subjects with a decline in the rate of primary RPLND. Individuals undergoing RPLND were more likely to travel further for care and visit multiple facilities for care. Further studies should investigate factors influencing therapeutic pathways, as well as accessibility to care.
116. LEYDIG CELL TUMOR OF THE TESTIS: PATHOLOGICAL CHARACTERISTICS AND TREATMENT PATTERNS FROM THE NATIONAL CANCER DATABASE

Julie Nguyen1, Kyle Hickey1, Sanjay Patel2, Tony Rodriguez2

1 University of Oklahoma Health Sciences Center, 2 OU Urology

Presented By: Julie Nguyen

Introduction: Leydig cell tumors are a rare type of sex-cord stromal tumor that comprise 1-3% of all testicular neoplasms. Due to its rarity, limited data is available to guide treatment and management. Using the National Cancer Data Base (NCDB), we sought to determine the association of pathological characteristics, retroperitoneal lymph node dissection (RPLND), and overall survival.

Methods: We identified 309 patients from the National Cancer Database diagnosed with Leydig cell tumor from 2004 to 2015. Patients who did not receive orchiectomy were excluded. Pathologic characteristics and use of RPLND were determined. Overall survival was analyzed by Kaplan-Meier method for tumor size, pathologic tumor stage, and AJCC stage.

Results: Of the 66,042 cases of testicular cancer between 2004 and 2015, 309 (0.47%) were Leydig cell tumors. The median patient age of diagnosis was 47 years (IQR, 34-59) with a median follow-up of 51 months. Of the 309 patients, 75.7% were White, 19.1% were Black, and 5.2% were made up of other ethnic backgrounds. The majority of patients were Stage I (94.22%), with the remaining patients in Stage II (2.89%) and Stage III (2.89%). OS at 3 years was 97.1% (95% CI, 93.7-98.7), 60% (95% CI, 12.6-88.2), and 33.3% (95% CI, 4.61-67.6), respectively (p <0.0001). Median tumor size was 1.8 cm (IQR, 0.9 – 3.5). OS at 5 years for tumor sizes <=2.5 cm, >2.5 cm to <=5 cm, and >5 cm were 96.4% (95% CI, 91.4-98.5), 87.5% (95% CI, 73.6-94.3) and 73.5% (95% CI, 56.2-84.8), respectively (p < 0.0001). In patients with pTis/pT1, the 5 year OS is 96.1% (95% CI, 91.2-98.3) compared with pT2 OS of 45.9% (95% CI, 20.0-68.8) and pT3 OS of 40% (95% CI, 5.2%-75.3%) (p < 0.0001). Two of 7 patients with positive margins died. Twenty-seven patients received RPLND, of which 10 patients were node positive. The 3 year OS for patients who were N0 and N+ at the time of RPLND was 92.3% (95% CI, 56.6-98.9) and 50% (95% CI,11.1-80.4), respectively (p < 0.05). Four of 6 patients with metastatic disease died within 2 and 19 months.

Conclusion: Larger tumor size and higher pathological T stage were indicators of poorer overall survival in patients with Leydig cell tumors. Patients who received a retroperitoneal lymph node dissection had worse outcomes compared to those who did not. Further investigation is required to determine the optimal treatment for patients with these tumors.

![Overall Survival by Tumor Size](image1)

![Overall Survival by Pathological T Stage](image2)
117. TESTICULAR CANCER OUTCOMES FOLLOWING DEPENDENT COVERAGE AND MEDICAID EXPANSION: A NATIONAL RETROSPECTIVE COHORT STUDY
Adam Weiner1, Ketan Jain-Porter1, Oliver Ko1, Anuj Desai1, Shilajit Kundu1, Stephen Jan2
1 Northwestern University, 2 University of Maryland School of Medicine
Presented By: Adam Weiner

Introduction: The impact of the Affordable Care Act Dependent Care Expansion (ACA-DCE), which allowed adults aged 19-25 to continue on their parents’ insurance, and Medicaid expansion on outcomes for men with testicular cancer is unknown.

Methods: We used the NCDB to assess the impact of both insurance expansions on rates of no insurance, advanced stage at diagnosis (≥II), and days from diagnosis to orchiectomy or chemotherapy/radiotherapy. Adjusted difference-in-differences were calculated comparing these outcomes between men aged 19-25 and 26-64 pre- (2007-2009) and post-ACA-DCE (2011-2016; n=41,329) and between men residing in states that expanded Medicaid to those in states that did not (n=4,561) pre- (2011-2013) and post-Medicaid expansion (2015-2016).

Results: In ACA-DCE analyses, rates no insurance decreased 5.64% (95% CI -7.23 to -4.04%, p<0.001) among men aged 19-25. No change was seen in stage at diagnosis (p=0.9) or time to orchiectomy >14 days after diagnosis (p=0.6). Among men who received chemotherapy or radiotherapy as their first treatment, treatment >60 days after diagnosis decreased 4.84% (95% CI -8.22 to -1.45%, p=0.005). In the Medicaid expansion analyses, rates of no insurance decreased 4.20% (95% CI -7.67 to -0.73%, p=0.018) in expansion states. No change was seen in stage at diagnosis (p=0.8) or time to orchiectomy (p=0.109) while the rate of chemotherapy or radiotherapy >60 days after diagnosis decreased 8.76% (95% CI -17.13 to -0.38%, p=0.04).

Conclusion: ACA-DCE and Medicaid expansion were associated with decreases in the percentage of men with testicular cancer without insurance and time to delivery of chemotherapy or radiotherapy.

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Conclusion: ACA-DCE and Medicaid expansion were associated with decreases in the percentage of men with testicular cancer without insurance and time to delivery of chemotherapy or radiotherapy.
118. MINIMALLY INVASIVE VS OPEN RPLND IN THE TREATMENT OF TESTICULAR CANCER: A COMPARISON OF CURRENT PRACTICE TRENDS AND OUTCOME MEASURES
Matthew Beamer, Stephanie Gleicher, Joseph Jacob
SUNY Upstate Medical University
Presented By: Matthew Beamer

Introduction: Retroperitoneal Lymph Node Dissection (RPLND) is a treatment option for testicular cancer both in the primary and post-chemotherapy setting. Multiple single institution case series exist that examine outcomes for robotic and laparoscopic surgical approaches. Here we utilize the Nation Cancer Database (NCDB) to examine trends in the selection of surgical approach and respective outcome measures on a national level.

Methods: The NCDB was used to identify patients that received a RPLND following the diagnosis of testicular cancer. Only patients with data available regarding the surgical approach (robotic, laparoscopic, and open) were included. This included patients from 2010-2015. A minimal invasive group included both robotic and laparoscopic surgeries. This group was compared to open procedures. Demographic information, baseline health characteristic, cancer stage, surgical and survival outcomes were examined. Statistics were performed in SPSS. Student's t-test was used to analyze continuous variable and chi-squared test was used for categorical variables.

Results: A total of 2116 patient received a RPLND between 2010 and 2015. Minimally invasive procedures were performed in 94 patients and 2022 patients underwent an open surgical approach. There was no difference in age (minimally invasive 32.5 yrs, open 34.1yrs), race, insurance, income, distance traveled for surgery, regional population size, or education level between groups. There was no difference in Charlson-Deyo score with the majority of patient receiving a score of 1. The majority of RPLNDs were performed at academic centers in both groups with no difference identified based in geographic location. Pre-operative clinic stage did not play a role in selection of surgical approach. The majority of cases were performed open with minimal change in approach over the five-year period (Figure 1). There was no significant different in the number of lymph nodes collected or the number of positive nodes (Table 1). The rate of hospital readmission was low, with no significant difference between groups. Patients in the minimally invasive group tended to have a longer hospital stay but this was not significant. There was no difference in 30-day or 90-day mortality. The number of patients who received chemotherapy was not different between groups. Kaplan-Meyer analysis showed no difference in survival between groups.

Conclusion: The number of minimally invasive RPLND surgeries performed for testicular cancer remains small with little to no change over time. There appears to be no difference in survival between surgical approaches. In this time period, the minimally invasive cohort did not have decreased hospital stays or readmission rates.
Introduction: Following orchiectomy, men with non-seminomatous germ cell tumors of the testis must choose their next course of treatment from among active surveillance, platinum-based chemotherapy, and primary retroperitoneal lymph node dissection (RPLND). With the intention of reducing the morbidities of therapy, several surgeons have given new attention to robotic RPLND (R-RPLND). It is the intent of R-RPLND to replicate the open technique and its outcomes although limited data exist regarding long-term or comparative efficacy. Therefore, a more thorough analysis of a single surgeon’s experience over an extended period of time is warranted to assess the safety and feasibility of R-RPLND in the pre-chemotherapy setting.

Methods: A retrospective analysis was performed of all primary R-RPLND cases performed by a single surgeon, who performs both open and R-RPLND at high volume at an academic institution, between August 2013 and August 2019. Data on patient demographics, operative techniques, perioperative outcomes, and tumor characteristics were obtained.

Results: Twenty-eight men were identified who underwent primary R-RPLND. The baseline characteristics and subsequent outcomes of these primary R-RPLND patients are reported in Table 1. The median age at RPLND was 30 years (interquartile range [IQR]: 26-37 years), and the majority of patients (N=21, 75%) had clinical stage I disease. Most patients (N=13, 46%) underwent a bilateral template surgery. Of note, two cases involving clinical stage II disease were converted electively from robotic to open procedures at the discretion of the surgeon—one for body habitus, the second for more advanced disease than predicted by preoperative imaging; R-RPLND patients experienced no intraoperative complications and required no red blood cell transfusions. The median follow-up time after R-RPLND was 8 months (IQR: 4-29 months). Median node count was 31 (IQR: 19-43). 16 (57%) patients had node-positive disease; among these, pN1=6 (38%), pN2=8 (50%), and pN3=2 (12%). Embryonal carcinoma was the most common pathology. Of the 28 primary R-RPLND patients, 4 (14%) received adjuvant chemotherapy following surgery (pN1=1; pN2=2; pN3=1), 1 (4%) developed disease recurrence at 10 months after RPLND, and none required additional oncologic surgery. Postoperative complications included chylous ascites in 3 (11%) patients, nausea and abdominal pain in 2 (7%) patients, and retroperitoneal hematoma in 1 (4%) patient. Length of stay following R-RPLND was 2 days (IQR: 2-2.5 days). Ejaculatory function was retained in 12 (67%) of 18 patients who provided feedback on their ejaculation status.

Conclusion: With relatively short-term data, primary R-RPLND is safe and efficacious procedure for carefully selected men with stage I and II non-seminomatous germ cell tumors of the testis. Long-term data is needed to evaluate comparative oncologic efficacy with open surgery and a notably high rate of chylous ascites.
120. DOES PERCENTAGE OF SEMINOMA AT ORCHIECTOMY IMPACT PATIENT MORBIDITY AND PATHOLOGIC OUTCOMES AT POST-CHEMOTHERAPY RETROPERITONEAL LYMPH NODE DISSECTION FOR MIXED GERM CELL TUMOR?

Sean Kern, Ryan Speir, Richard Foster, Lawrence Einhorn, Clint Cary, Timothy Masterson
Indiana University

Presented By: Sean Kern

Introduction: Post-chemotherapy retroperitoneal lymph node dissections (PC-RPLND) for pure seminoma are widely considered to have an increased potential for complexity and morbidity, placing patients at increased risk and often finding only necrosis. We sought to determine if the percentage of seminoma in the orchiectomy specimen predicts necrosis on PC-RPLND for non-seminomatous germ cell tumors (NSGCT) and the associated impact on patient morbidity.

Methods: Patients with seminoma in the orchiectomy specimen who underwent PC-RPLND for NSGCT at Indiana University from 2009-2019 were identified to assess pathologic findings, required ancillary procedures at the time of PC-RPLND, and post-operative outcomes. Patients were categorized into quartiles to assess if increasing percentage of seminoma predicted necrosis.

Results: Of the 112 patients identified, pathologic analysis revealed necrosis in 30/112 (26.8%), malignancy 20/112 (19.9%), and teratoma 62/112 (55.4%). As percent seminoma increased by quartile, necrosis was more prevalent (23.7%, 25%, 31.6%, 35.7%), as was the size decrease in post-chemotherapy retroperitoneal masses. For patients with greater than 90% seminoma, necrosis was found almost 45% of the time. The incidence of concurrent nephrectomy during PC-RPLND was greatest in the 4th quartile. There was no significant difference in pre-operative serum tumor markers, patient age, length of stay, or Clavien-Dindo classification outcomes.

Conclusion: As percent seminoma in the orchiectomy specimen increased, the incidence of necrosis and the need for concurrent ancillary procedures increased. However, it did not seem to change the hospital course or post-operative morbidity. Unfortunately, these results show that PC-RPLND cannot be eliminated even in patients with very high orchiectomy seminoma percentages as over half of these patients had teratoma or viable malignant elements in the retroperitoneum.
121. PERFORMANCE CHARACTERISTICS OF ANTI-18F-FACBC (AXUMIN) POSITRON EMISSION TOMOGRAPHY/COMPUTED TOMOGRAPHY PRIOR TO RETROPERITONEAL LYMPH NODE DISSECTION
Xiaosong Meng, Solomon Woldu, Daniel Wong, John Lafin, Vitaly Margulis, Jesse Conyers, Rathan Subramaniam, Aditya Bagrodia
UT Southwestern Medical Center
Presented By: Xiaosong Meng

Introduction: There is no way to reliably differentiate between fibrosis/necrosis, teratoma, and viable germ cell tumor in patients receiving post-chemotherapy retroperitoneal lymph node dissection (RPLND) for non-seminomatous germ cell tumor (NSGCT). Functional imaging, including 18F-Fludeoxyglucose (18F-FDG) positron emission tomography (PET), has been disappointing in this space. Due to the need for better imaging modalities in patients receiving RPLND, we designed a prospective study using anti-1-amino-3-18F-fluorocyclobutane-1-carboxylic acid, a synthetic radiolabeled leucine amino acid analog which is commonly referred to as anti-18F-FACBC (AxuminTM, Blue Earth Diagnostics, Ltd. Oxford, UK). Our prospective study aims to investigate the accuracy of Axumin PET/CT in detecting residual tumor prior to retroperitoneal lymph node dissection (RPLND).

Methods: From March 2018 – May 2019, 10 eligible patients were enrolled and underwent pre-operative Axumin PET/CT prior to undergoing bilateral full template RPLND or excision of mass (in one case of re-do pelvic lymph node dissection). RPLND packets from each location were sent as separate specimens and appropriately labeled with the origin of the packet. Correlation between Axumin PET/CT and RPLND pathology were evaluated on per patient and per packet level.

Results: A total of 10 patients (age 29 ± 7.6 yrs) underwent Axumin PET/CT prior to surgery. 9/10 patients have undergone chemotherapy prior to RPLND (See Table 1 for baseline characteristics). Correlation between Axumin PET/CT and RPLND pathology was seen in 4/10 (40%) of patients. 6/10 patients (60%) with negative Axumin PET/CT were found to have residual disease on RPLND, with 1 patient with seminoma and 5 patients with teratoma (Table 2). Compared to the reference standard of RPLND, Axumin PET/CT has 14% sensitivity, 100% specificity, positive predictive value of 100% and negative predictive value of 33% in these 10 patients. No patients experienced any adverse events as a direct result of undergoing an Axumin PET/CT.

Conclusion: Current management of NSGCT is heavily reliant on sub-optimal imaging modalities that are unable to accurately distinguish between post-chemotherapy necrosis/fibrosis versus viable germ cell tumor and/or teratoma. Despite a different mechanism of action from 18F-FDG, anti-18F-FACBC has low sensitivity for residual teratoma in the retroperitoneum. However, one patient with positive Axumin PET/CT after prior RPLND had embryonal rhabdomyosarcoma on resection of the recurrent mass, suggesting the need for further evaluation of the role of Axumin PET/CT in NSGCT.
122. THE ROLE OF SURGICAL EXPERIENCE IN PATIENT SELECTION, SURGICAL QUALITY AND OUTCOMES IN ROBOT-ASSISTED RADICAL CYSTECTOMY
Bashir Al Hussein, Lina Posada, Jonathan Shoag, Neal Patel, Christopher Gaffney, Peter Cai, Douglas Scherr
Weill Cornell Medicine
Presented By: Bashir Al Hussein

123. RAPID ORGANOID DEVELOPMENT, DRUG SCREENING, AND NEOADJUVANT CHEMOTHERAPY RESPONSE PREDICTION FOR PATIENTS WITH LOCALLY-ADVANCED BLADDER CANCER
Kathryn Marchetti1, Nathan Merrill1, Nathalie Vandecan1, Xu Cheng1, Aaron Udager1, Lindsey Herrel1, Jeffery Montgomery1, Khaled Hafez1, Todd Morgan1, Alon Weizer1, Ajai Alva1, Matthew Soellner1, Sophia Merajver1, Samuel Kaffenberger1, Liwei Bao2
1 University of Michigan Health System, 2 lwbao@umich.edu
Presented By: Kathryn Marchetti

124. SARCOMATOID BLADDER CANCER: A VARIANT WITH WORSE PROGNOSIS AND A UNIQUE RECURRENCE PATTERN
Rishi Sekar1, Brian R. Winters1, Daniel W. Lin1, Jonathan L. Wright1, Lenoidas Diamantopoulos1, Bruce Montgomery2, Funda Vakar-Lopez2, Petros Grivas3, George Schade4
1 Division of Urology, Department of Surgery, University of Washington, 2 Division of Medical Oncology, 3 University of Washington, Department of Pathology, 4 University of Washington, Department of Medical Oncology, 5 Department of Urology, University of Washington
Presented By: Rishi Sekar

125. TRIMODAL THERAPY VERSUS RADICAL CYSTECTOMY FOR MUSCLE INVASIVE BLADDER CANCER - A MARKOV MICROSIMULATION MODEL
Diana Magee1, Douglas Cheung1, Amanda Hird1, Srikala Sridhar2, Padraig Warde3, Charles Catton3, Alejandro Berlin4, Peter Chung5, Alexandre Zlotta6, Neil Fleshner7, Girish Kulkarni8
1 Division of Urology, Department of Surgery, University of Toronto, 2 Division of Medical Oncology, Department of Internal Medicine, University Health Network, University of Toronto, 3 Department of Radiation Oncology, University Health Network, University of Toronto, 4 Division of Urology, Department of Surgery, University Health Network, University of Toronto
Presented By: Diana Magee

126. DISCOVERY OF A GENOMIC CLASSIFIER FOR PREDICTING CLINICALLY AGGRESSIVE LUMINAL BLADDER TUMORS WITH HIGHER RATES OF PATHOLOGICAL UPSTAGING
Yair Lotan1, Joep de Jong2, Joost Boormans3, Yang Liu4, Elai Davicioni5, Ewan Gibb6, Stephen Boorjian7, Trinity Bivalacqua8, Sima Porten9, Thomas Wheeler10, Seth Lerner11, Robert Svalik12, Peter Black13
1 University of Texas Southwestern Medical Center at Dallas, 2 Erasmus MC Cancer Institute, 3 Decipher Biosciences, 4 Mayo Clinic, 5 John Hopkins Medical Institute, 6 University of California San Francisco, 7 Baylor College of Medicine, 8 University of Texas Health San Antonio, 9 Vancouver Prostate Centre
Presented By: Yair Lotan

127. PROGNOSTIC SIGNIFICANCE OF PERIVESICAL LYMPH NODE STATUS IN PATIENTS WITH MUSCLE-INVASIVE BLADDER CANCER UNDERRIGHTING RADICAL CYSTECTOMY
Ghalib Jibara1, Melissa Assel1, Nathan Wong1, Cristina Falavolti1, Chun Huang1, Nima Almassi1, Daniel Sjoberg1, Nicole Benfante1, Hikmat Al-Ahmadie1, Guido Dalbaghi1, Andrew Vickers1, Eugene Cha1, Bernard Bochner1, Shawn Dason1, Victor McPherson1, Lucas Dean1
1 Memorial Sloan Kettering Cancer Center, 2 The Ohio State University, 3 McGill University, 4 University of Alberta
Presented By: Ghalib Jibara

128. VALIDATION OF COBRA NOMOGRAM IN THE CANCER GENOME ATLAS (TCGA) BLADDER CANCER COHORT
Meera Chappidi1, Maxwell Meng1, Sima Porten1, Christopher Welty2, Woonyoung Choi3
1 UCSF, 2 NorCal Urology, 3 Johns Hopkins Medical Institutions
Presented By: Meera Chappidi

129. ACTIVE CENTRALIZATION OF RADICAL CYSTECTOMY FOR BLADDER CANCER IN A UNIVERSAL HEALTHCARE SYSTEM: EARLY RESULTS FROM A CANADIAN ACADEMIC CENTER
Jan Rudzinski1, Benjamin Beech1, Niels-Erik Jacobsen1, Eric Estey1, Adrian Fairley1, Sunita Ghosh2, Scott North2, Naveen Basappa2, Michael Kolinsky2
1 Division of Urology, Department of Surgery, University of Alberta, 2 Medical Oncology, Department of Medicine, University of Alberta
Presented By: Jan Rudzinski
130. DOES GROSSLY COMPLETE TRANSURETHRAL RESECTION IMPROVE COMPLETE RESPONSE AFTER NEOADJUVANT CHEMOTHERAPY?  
Rashed Ghandour, Daniel Wong, Samuel Cusin, Nirmish Singla, Yuval Freifeld, Ryan Hutchinson, Aditya Bagrodia, Arthur Sagalowsky, Vitaly Margulis, Yair Lotan, Solomon Woldu  
UT Southwestern Medical Center  
Presented By: Rashed Ghandour

131. DETAILED CADAVERIC ANALYSIS FOR PERIVESICAL LYMPH NODES WITH POTENTIAL IMPLICATIONS IN BLADDER CANCER  
Muhammad Alsyouf1, Phillip Stokes1, Mohammad Hajija1, Jason Groegler1, Akin Amasyali1, Herbert Ruckle1, Brian Hu1, Laura Denham2  
1 Loma Linda University, Department of Urology, 2 Loma Linda University, Department of Pathology  
Presented By: Muhammad Alsyouf

132. INTERIM ANALYSIS OF PHASE I CLINICAL TRIAL OF INTRAVESICAL ONCOLYTIC MEASLES VIRUS PRIOR TO RADICAL CYSTECTOMY FOR UROTHELIAL CARCINOMA  
Tanner Miest, Shruthi Naik, Kevin Panikh, Stephen Boorjian, R. Jeffrey Karnes, R. Houston Thompson, Igor Frank, Matthew Tollefson, Paul Young, Bradley Leibovich  
Mayo Clinic  
Presented By: Tanner Miest

133. THE IMPACT OF URETERAL STENT VS NEPHROSTOMY TUBE PLACEMENT PRIOR TO RADICAL CYSTECTOMY ON POST-CYSTECTOMY UPPER TRACT UROTHELIAL CARCINOMA RATES  
Vidit Sharma1, Tanner Miest2, Luca Boeri2, Prabin Thapa2, Matthew K Tollefson2, R. Houston Thompson2, Stephen A Boorjian2, Igor Frank2, R. Jeffrey Karnes2  
1 UCLA, 2 Mayo Clinic  
Presented By: Vidit Sharma

134. EARLY COMPLICATIONS AS A RESULT OF INDIANA POUCH URINARY DIVERSION: A 7 YEAR EXPERIENCE  
Indiana University School of Medicine  
Presented By: Ryan Speir

135. 48-72 HOUR DISCHARGE FOLLOWING RADICAL CYSTECTOMY IS SAFE AND FEASIBLE  
Prithvi Murthy, Alice Crane, Michele Fascelli, Georges-Pascal Haber, Byron Lee  
Cleveland Clinic  
Presented By: Abhinav Khanna

136. COMPARING PROVIDER-LED SEXUAL HEALTH COUNSELING OF MALE AND FEMALE RADICAL CYSTECTOMY PATIENTS  
Natasha Gupta1, Lauren Kucirka1, Phillip Pierorazio1, Amin Heraati1, Trinity Bivalacqua1, Alice Semerjian2  
1 Johns Hopkins University School of Medicine, 2 IHA Urology/St. Joseph Mercy Hospital  
Presented By: Natasha Gupta

137. UPDATED RESULTS OF PURE-01 WITH PRELIMINARY ACTIVITY OF NEOADJUVANT PEMBROLIZUMAB IN PATIENTS WITH MUSCLE-INVASIVE BLADDER CARCINOMA WITH VARIANT HISTOLOGIES  
Andrea Necchi1, Danièle Raggi1, Maurizio Colecchia1, Patrizia Giannatempo1, Elena Ferre1, Laura Marandino1, Andrea Gallina2, Roberta Luciano2, Filippo Pederzoli2, Marco Bandini2, Giorgio Gandaglia2, Nicola Fossati2, Umberto Capitanio2, Andrea Salonia2, Alberto Briganti2, Francesco Montorsi2, Russell Madison3, Siraj Ali2, Jon Chung1, Jeffrey Ross3, Rodolfo Montironi4  
1 Fondazione IRCCS Istituto Nazionale dei Tumori, 2 San Raffaele Hospital and Scientific Institute, 3 Foundation Medicine, 4 Polytechnic University of the Marche Region  
Presented By: Andrea Necchi

138. AN EVALUATION OF MONTHLY MAINTENANCE THERAPY AMONG PATIENTS RECEIVING INTRAVESICAL COMBINATION GEMCITABINE/DOCETAXEL FOR NON-MUSCLE INVASIVE BLADDER CANCER  
Marcus Daniels1, Emily Barry1, Mark Schoenberg2, Trinity Bivalacqua1, Max Kates3, Alex Sankin5  
1 Johns Hopkins School of Medicine, 2 Albert Einstein College of Medicine, 3 Montefiore Medical Cent, 4 Johns Hopkins Medical Institutions, 5 Montefiore Medical Center  
Presented By: Marcus Daniels
139. REQUIRED EFFICACY FOR NOVEL THERAPIES IN BCG-UNRESPONSIVE NON-MUSCLE INVASIVE BLADDER CANCER: DO CURRENT RECOMMENDATIONS REALLY REFLECT CLINICALLY MEANINGFUL OUTCOMES?
Marian S. Wettstein\(^1\), Jaime O. Herrera-Caceres\(^1\), Ardalan Ahmad\(^1\), Michael A.S. Jewett\(^1\), Girish S. Kulkarni\(^1\), David Naimark\(^1\), Thomas Hermanns\(^3\)
\(^1\) Division of Urology, Department of Surgery, Princess Margaret Cancer Centre, University Health Network, University of Toronto, Toronto, Ontario, Canada, \(^2\) Division of Nephrology, Department of Medicine, Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada, \(^3\) Department of Urology, University Hospital of Zurich, University of Zurich, Zurich, Switzerland
Presented By: Marian S. Wettstein

140. PREDICTORS OF UPSTAGING AND SURVIVAL IN T1 UROTHELIAL CARCINOMA AFTER RADICAL CYSTECTOMY
Wesley Yip, Saum Ghodoussipour, Akbar Ashrafi, Jie Cai, Gus Miranda, Sumeet Bhanvadia, Hooman Djaladat, Anne Schuckman, Siamak Daneshmand
USC Institute of Urology
Presented By: Wesley Yip

141. SURVIVAL OUTCOMES OF HIGH RISK NON-MUSCLE INVASIVE BLADDER CANCER VERSUS DOWNSTAGED MUSCLE INVASIVE BLADDER CANCER AT THE TIME OF CYSTECTOMY
Shagnik Ray\(^1\), Marcus Daniels\(^1\), Aaron Brant\(^2\), Anthony De Felice\(^3\), Esther Lee\(^3\), Trinity Bivalacqua\(^3\), Max Kates\(^3\)
\(^1\) James Buchanan Brady Urological Institute at the Johns Hopkins University School of Medicine, \(^2\) Weill Cornell Medicine Urology, \(^3\) James Buchanan Brady Urological Institute at the Johns Hopkins University
Presented By: Shagnik Ray

142. MANAGEMENT OF HISTOLOGIC VARIANTS IN NON-MUSCLE INVASIVE BLADDER CANCER
Kris Prado, Daniel Greenberg, Andrew Sun, Eila Skinner
Stanford University School of Medicine
Presented By: Kris Prado

143. CHARACTERIZATION OF URINARY MICROBIOME IN PATIENTS WITH BLADDER CANCER: RESULTS FROM A SINGLE-INSTITUTION, FEASIBILITY STUDY
Juan Chipollini\(^1\), Justin Wright\(^2\), Hephzibah Nwanosike\(^2\), Regina Lamendella\(^2\), Carole Kepler\(^2\), Ken Batai\(^2\), Benjamin Lee\(^4\), David Stewart\(^6\)
\(^1\) The University of Arizona, \(^2\) Department of Biology, Juniata College, Huntingdon, PA, \(^3\) University of Arizona Cancer Center Biospecimen Repository, Tucson, AZ, \(^4\) Department of Urology, the University of Arizona, Tucson, AZ, \(^5\) Department of Surgery, the University of Arizona, Tucson, AZ
Presented By: Juan Chipollini

144. PATIENT MATCHED GENOMIC ANALYSIS OF HIGH-GRADE NON-MUSCLE INVASIVE BLADDER CANCER SPECIMENS PRE- AND POST-BCG IMMUNOTHERAPY
Timothy Clinton\(^1\), Nima Almassi\(^1\), Shawn Dason\(^1\), Victor McPherson\(^1\), Aditya Bagrodia\(^1\), Aleksandra Walasek\(^1\), Michal Wiseman\(^1\), Michael Berger\(^1\), Nikolaus Schutz\(^1\), Guido Dabagni\(^1\), David Solit\(^1\), Gopa Iyer\(^1\), Hikmat Al-Ahmadie\(^1\), Bernard Bochner\(^2\), Eugene Pietzak\(^2\)
\(^1\) Memorial Sloan Kettering Cancer Center, \(^2\) alahmadh@mskcc.org
Presented By: Timothy Clinton

145. CHARACTERIZING THE URINARY MICROBIOME OF PATIENTS WITH BCG-UNRESPONSIVE AND RESPONSIVE NON-MUSCLE INVASIVE BLADDER CANCER
Vikram Narayan, Amy Lim, Justin Matulay, Nathan Brooks, Chia-Chi Chang, Robert Jenq, Ashish Kamat, Colin Dinney, Neema Navai
University of Texas MD Anderson Cancer Center
Presented By: Vikram Narayan

146. COST-EFFECTIVENESS ANALYSIS OF MAINTENANCE BCG FOR INTERMEDIATE AND HIGH RISK NON-MUSCLE INVASIVE BLADDER CANCER
Vidit Sharma\(^1\), Christopher S. Saigal\(^1\), Mark S. Litwin\(^2\), Kevin Wymer\(^2\), Bijan J. Borah\(^2\), Vignesh T. Packiam\(^2\), R. Houston Thompson\(^2\), R. Jeffrey Karmes\(^2\), Stephen A. Boorjian\(^2\)
\(^1\) UCLA, \(^2\) Mayo Clinic
Presented By: Vidit Sharma

147. NOVEL IMIDAZLIUM COMPOUNDS FOR THE INTRAVESICAL TREATMENT OF SUPERFICIAL BLADDER CANCER
Uttam Satyal\(^1\), Rahmat Sikder\(^1\), Marie Southerland\(^2\), Michael Strohmeyer\(^2\), David Weader\(^2\), Jessie Baughman\(^2\), Claire Tessier\(^2\), Wiley Youngs\(^2\)
\(^1\) Fox Chase Cancer Center, \(^2\) University of Akron
Presented By: philip abbosh

148. PREDICTORS OF UPSTAGING AT THE TIME OF RADICAL CYSTECTOMY FOR PATIENTS WITH CLINICAL CARCINOMA IN SITU OR HIGH-GRADE NON-INVASIVE UROTHELIAL CARCINOMA REFRACTORY TO INTRAVESICAL THERAPY
Saum Ghodoussipour, Saum Ghodoussipour, Michael Basin, David Nusbaum, Juliet Han, Shane Pearce, Gus Miranda, Jie Cai, Sumeet Bhanvadia, Anne Schuckman, Siamak Daneshmand, Hooman Djaladat
University of Southern California
Presented By: Juliet Han
149. RACIAL AND SEX DIFFERENCES IN SOMATIC MUTATIONS IN BLADDER CANCER PATIENTS: AN ANALYSIS OF DATA FROM THE CBIOPORTAL FOR CANCER GENOMICS
Yaw NYame¹, Bruce Montgomery¹, Petros Grivas¹, Jonathan Wright¹, Kelsey Baker², Mary Redman²
¹ University of Washington, ² Fred Hutchinson Cancer Research Center
Presented By: Yaw NYame

150. DYNAMICS OF IMMUNE CELL POPULATIONS DURING BLADDER CANCER PROGRESSION SHOW AN ENRICHMENT OF DENDRITIC CELLS AND REGULATORY T CELLS IN RECURRENT NMIBC AND MIBC
Filipe Carvalho¹, Jillian Egan¹, Krithika Bhuvaneshwar², Yurii Gusev², Geoff Gibney², Lambros Stamatakis²
¹ MedStar Georgetown University Hospital, ² Georgetown University, ³ Georgetown Lombardi Comprehensive Cancer Center, ⁴ MedStar Washington Hospital Center
Presented By: Filipe Carvalho

151. IMPROVED LOW-GRADE BLADDER CANCER DETECTION FROM URINE SAMPLES: A CLINICAL STUDY USING BLADDER CARE TEST
Paolo Piatti¹, Taikun Yamada¹, Yap Ching Chew¹, Xi Yu Jia¹, Michiko Suwoto¹, Gangning Liang³, Saum Ghodossipour³, Siamak Daneshmand³
¹ Zymo Research Corp., ² Pangea Laboratory, LLC, ³ USC Norris Comprehensive Cancer Center
Presented By: Paolo Piatti

152. PRE-CLINICAL CELLULAR AND GENOMIC CORRELATES OF RESISTANCE TO IMMUNE CHECKPOINT BLOCKADE IN BLADDER CANCER
Debasish Sundi¹, Megan Duggan¹, Jing Zhao¹, William Carson III¹, Himanshu Savardekar², Thomas Mace²
¹ Ohio State University, ² Ohio State
Presented By: Debashis Sundi

153. SHOULD UROTHELIAL CARCINOMA BE CONSIDERED PART OF BRCA1 AND BRCA2 CANCER SYNDROMES?
Ankeet Shah¹, Dominic Grimberg², Hannah Berg³, Wei Phin Tan³, Brant Inman³
¹ Duke University, ² Duke University Division of Urology
Presented By: Ankeet Shah

154. IMPROVING COMPLIANCE WITH GUIDELINE RECOMMENDATIONS FOR HEMATURIA: ADDRESSING BARRIERS IN A LARGE ACADEMIC CENTER
Katharine Michel, Raju Chelluri, James Ding, Thomas Guzzo, Daniel Lee Penn
Presented By: Katharine Michel

155. GENOMIC BIOMARKERS OF RESPONSE TO IMMUNE-CHECKPOINT BLOCKADE IN METASTATIC UPPER TRACT UROTHELIAL CARCINOMA
Renzo G DiNatale¹, Diego Chowell², Andrew W Silagy², Vladimir Makarov², Eugene Pietzak², David Solit², Michael Berger², Hikmat Al-Ahmadi², A. Ari Hakimi², Ed Reznik², Dean F Barjorin², Timothy A Chan², Jonathan Coleman²
¹ Memorial Sloan Kettering Cancer Center, ² Memorial Sloan Kettering Cancer Center
Presented By: Renzo G DiNatale

156. FATE OF RESIDUAL URETERAL STUMP IN PATIENTS UNDERGOING ROBOT-ASSISTED RADICAL NEPHROROURETERECTOMY FOR HIGH-RISK UPPER TRACT UROTHELIAL CARCINOMA
Ram Pathak
Wake Forest University
Presented By: Ram Pathak

157. RADIOGRAPHIC PREDICTORS OF PATHOLOGIC RESPONSE TO NEOADJUVANT CHEMOTHERAPY IN PATIENTS WITH HIGH-GRADE UPPER TRACT UROTHELIAL CARCINOMA: RESULTS OF A PHASE II CLINICAL TRIAL
Andrew Tracey, Nathan Wong, Soleen Ghafoor, Daniel Sjoberg, Nicolas Silva, Bernard Bochner, Guido Dalbagni, S. Machele Donat, Harry Herr, Eugene Cha, Timothy Donahue, Eugene Pietzak, Hikmat Al-Ahmadi, Nicole Benfante, Gopa Iyer, Min Yuen Teo, Jonathan Rosenberg, H. Alberto Vargas, Dean Bajorin, Coleman Jonathan
Memorial Sloan Kettering Cancer Center
Presented By: Andrew Tracey

158. UROLOGY WORKFORCE CHANGES AND THEIR IMPLICATIONS ON PROSTATE CANCER CARE
Kathryn Marchetti, Brent K Hollenbeck, Mary Oerline, Samuel R Kaufman, Megan E V Caram, Vahakn B Shahinian, Parth K Modi
University of Michigan Health System
Presented By: Kathryn Marchetti

159. IMPLEMENTATION OF A REDUCED OPIOID UTILIZATION PROTOCOL FOR RADICAL CYSTECTOMY
Bogdana Schmidt, Daniel R. Greenberg, Jessica R Kee, Kerri Stevenson, Elizna Van Zyl, Anisia Dugala, Kris Prado, Eila C Skinner, Jay B Shah
Stanford University
Presented By: Bogdana Schmidt
160. OPIOID FREE POST-OPERATIVE RECOVERY: A ROBOTIC PROSTATECTOMY PILOT STUDY
Bogdana Schmidt, Alex Kasman, Charlene Chow, Alexa Sockell, Rebecca Hunt, Michelle Wu, Hurley Smith, Simon Conti, Jay Shah
Stanford University
Presented By: Bogdana Schmidt

161. LONG TERM PATTERNS OF COST AND UTILIZATION OF MEDICARE BENEFICIARIES WITH BLADDER CANCER
Ankeet Shah1, Frank A. Sloan2, Arseniy P. Yashkin1, Igor Akushevich1, Bant Inman1
1 Duke University, 2 Duke University Department of Economics, 3 Duke University Social Science Research Institute - Biodemography of Aging Research Unit, 4 Duke University Division of Urology
Presented By: Ankeet Shah

162. HETEROGENEITY IN POLICY EFFECT: CHANGES IN PROSTATE CANCER SCREENING ASSOCIATED WITH ACO PARTICIPATION
Amy N. Luckenbaugh, Christine P. Lai, Diane N. Haddad, Matthew J. Resnick
Vanderbilt University Medical Center
Presented By: Amy N. Luckenbaugh

163. TRANSPERINEAL VERSUS TRANSRECTAL ULTRASOUND-GUIDED SYSTEMATIC BIOPSY: UNDERSTANDING THE TRUE COSTS UTILIZING TIME-DRIVEN ACTIVITY-BASED COSTING
Aaron Laviana1, Eliza Cricco-Lizza1, Michael Tzeng2, Timothy McClure2, Jim Hu1, Michael Gross3, Michael Gorin4
1 Vanderbilt University Medical Center, 2 New York Presbyterian Hospital, Weill Cornell Medical College, New York, NY, USA, 3 Stony Brook Medicine, 4 Johns Hopkins School of Medicine
Presented By: Aaron Laviana

164. WHO DOES NOT RECEIVE A CYTOREDUCTIVE NEPHRECTOMY AMONG IMDC INTERMEDIATE-POOR RISK PATIENTS?
Skylar Iosepovici1, Andrew Silagy2, Roy Mano1, Renzo DiNatale2, Julian Marcon2, Robert Motzer2, Jonathan Coleman2, Paul Russo2, A. Ari Hakimi2, Kyrollis Attalla3
1 Memorial Sloan Kettering Cancer Center, 2 MSKCC, 3 MKSCC
Presented By: Skylar Iosepovici

165. MEDICAID EXPANSION DID NOT IMPROVE TIME TO TREATMENT FOR PATIENTS WITH METASTATIC RENAL CELL CARCINOMA
Anuj Desai, Adam B Weiner, Oliver Ko, Amanda Vo, Ketan Jain-Poster, Shilajit Kundu
Department of Urology, Feinberg School of Medicine, Northwestern University
Presented By: Anuj Desai

166. EXAMINING THE SURVIVAL BENEFIT OF CYTOREDUCTIVE NEPHRECTOMY IN THE SETTING OF TUMOR THROMBUS INVASION INTO VENA CAVA IN METASTATIC RENAL CELL CARCINOMA
Alexander Kenigsberg, Xiaosong Meng, Aditya Bagrodia, Yair Lotan, Vitaly Margulis, Solomon Woldu
UT Southwestern
Presented By: Alexander Kenigsberg

167. HIGH EXPRESSION OF TUMOR-ASSOCIATED MACROPHAGE (TAM) MARKERS WITHIN THE TUMOR MICROENVIRONMENT SIGNALS POOR OVERALL SURVIVAL IN PATIENTS WITH METASTATIC RENAL CELL CARCINOMA TREATED WITH IMMUNOTHERAPY
Ahmet Murat Aydin1, Ali Hajiran1, Philippe Spiess1, Manish Kohli1, Brandon Manley1, Shayan Falasiri2, SaiF Zaman3, Youngchul Kim4, Susan McCarthy4, Jonathan Nguyen5, James Mulé6
1 Department of Genitourinary Oncology, H. Lee Moffitt Cancer Center and Research Institute, 2 University of South Florida, 3 Department of Biostatistics, H. Lee Moffitt Cancer Center and Research Institute, 4 H. Lee Moffitt Cancer Center and Research Institute, 5 Department of Immunology, H. Lee Moffitt Cancer Center and Research Institute
Presented By: Ahmet Murat Aydin

168. FUSOGENIC LIPOSOMES AS A NOVEL NANOTHERAPY AGAINST METASTATIC CLEAR CELL RENAL CELL CARCINOMA
Jan Rudzinski1, Adrian Fairey1, Natasha Govindasamy2, Konstantin Stoletov2, Arun Raturi2, John Lewis2
1 Division of Urology, Department of Surgery, Faculty of Medicine and Dentistry, University of Alberta, 2 Department of Oncology, Faculty of Medicine and Dentistry, University of Alberta
Presented By: Jan Rudzinski

169. THE EMERGING ROLE OF POLY (ADP-RIbose) POLYMERASE INHIBITORS IN RENAL CELL CARCINOMA
Jerred Pletcher1, Jonathan Doan1, Sayani Bhattacharjee2, Puneet Sindhwani3, Nagesh Nadiminty3, Firas Petros1
1 College of Medicine and Life Sciences, The University of Toledo, 2 Cancer Biology Program, College of Medicine and Life Sciences, The University of Toledo, 3 Department of Urology, College of Medicine and Life Sciences, The University of Toledo Medical Center
Presented By: Firas Petros
170. THE IMPACT OF SURGICAL RESECTION ON CIRCULATING TUMOR-REACTIVE CYTOTOXIC T-CELLS FOR PATIENTS WITH RENAL TUMORS
Vignesh T. Packiam1, Henan Zhang1, Christine M. Lohse1, Matvey Tsivian1, Lance C. Pagliaro1, Brian A. Costello1, R. Houston Thompson1, Stephen A. Boorjian1, John C. Cheville1, Haidong Dong1, Bradley C. Leibovich1, Bimal Bhindi2, Paras Shah3
1 Mayo Clinic, 2 University of Calgary, 3 Albany Medical College
Presented By: Vignesh T. Packiam

171. PREVENTION OF BENIGN KIDNEY TUMOR RESECTION USING A COMBINATION OF ROUTINE BIOPSY AND TUMOR:CORTEX PEER: A 6-YEAR EXPERIENCE
Arun Menon, Tashionna White, Gaybrielle James, Eric Kauffman
Roswell Park Comprehensive Cancer Center
Presented By: Arun Menon

172. INITIAL OUTCOMES FOR UNIVERSAL ACTIVE SURVEILLANCE OF SMALL RENAL MASSES USING PRE-DEFINED PROGRESSION CRITERIA FOR TREATMENT CONVERSION
Arun Menon, Tashionna White, Gaybrielle James, Kristopher Attwood, Eric Kauffman
Roswell Park Comprehensive Cancer Center
Presented By: Arun Menon

173. ASSOCIATION OF DE RITIS RATIO AND NEUTROPHIL LYMPHOCYTE RATIO WITH RENAL FUNCTIONAL DECLINE AND ALL-CAUSE MORTALITY IN RENAL CELL CARCINOMA
Cathrine Keiner1, Margaret Meagher1, Devin Patel1, Fady Ghali1, Raksha Dutt1, Dattatraya Patil2, Viraj Master2, Kazutaka Saito3, Yosuke Yasuda3, Yasuhisa Fuji4, Nathan Miller4, Fang Wan4, Ithaa Derweesh5, Aaron Bradshaw6
1 University of California San Diego, 2 Emory, 3 Tokyo Medical and Dental University, 4 UCSD
Presented By: Cathrine Keiner

174. IMPACT OF ONCOLOGICAL VERSUS NON-ONCOLOGICAL FACTORS ON SURVIVAL OUTCOMES IN AFRICAN AMERICANS WITH RENAL CELL CARCINOMA
Margaret Meagher1, Aaron Bradshaw1, Britteny Cotta1, Ahmed Eldefrawy1, Stephen Ryan1, Ryan Nasseri1, Fang Wan1, Ithaa Derweesh1, Dattatraya Patil2, Viraj Master2, Kazutaka Saito3, Yosuke Yasuda3, Yasuhisa Fuji4
1 UC San Diego Health, 2 Emory Medical Center, 3 TMDU
Presented By: Margaret Meagher

175. PREOPERATIVE OPTIMIZATION OF PROMOTILITY, INVESTIGATION OF PREOPERATIVE CONSTIPATION SCORES AND DISCHARGE FOLLOWING NEPHRECTOMY AND PROSTATECTOMY
Derek Jensen, Alexandra Dahlgren, Katie Glavin, Will Parker, Jeffrey Holzbeierlein, Moben Mirza, David Duchene, Eugene Lee
University of Kansas, Department of Urology
Presented By: Derek Jensen

176. REDEFINING THE OBESITY PARADOX IN RENAL CELL CARCINOMA
Aleem Khan, Bashir Al Hussein Al Awamlh, Lina Posada, Jonathan Fainberg, Jonathan Shoag, Douglas Scherr
Weill Cornell Medical College Department of Urology
Presented By: Aleem Khan

177. STRATIFYING SIZE WITHIN RENAL CELL CARCINOMA STAGING GROUPS DOES NOT CORRELATE TO OUTCOMES; A SINGLE INSTITUTION EXPERIENCE WITH 870 PATIENTS OVER 15 YEARS
Aleem Khan, Lina Posada, Bashir Al Hussein Al Awamlh, Jonathan Fainberg, Douglas Scherr, Jonathan Shoag
Weill Cornell Medical College Department of Urology
Presented By: Aleem Khan

178. IMPACT OF DIABETES MELLITUS ON FUNCTIONAL AND SURVIVAL OUTCOMES IN RENAL CELL CARCINOMA: AN INTERNATIONAL MULTICENTER STUDY
Raksha Dutt, Margaret Meagher, Devin Patel, Fady Ghali, Cathrine Keiner, Nathan Miller, Aaron Bradshaw, Ithaa Derweesh
University of California, San Diego
Presented By: Raksha Dutt

179. IS RENAL VOLUME AND FUNCTION COMPROMISED IN ONCOCYTOMA PATIENTS ON ACTIVE SURVEILLANCE?
Amandip Cheema, Arun Menon, Sergei Kurenov, Tashionna White, Gaybrielle James, Eric Kauffman
Roswell Park Cancer Institute
Presented By: Amandip Cheema

180. NOT ALL RESECTED CYSTIC RENAL MASSES HARBOR INDOLENT PATHOLOGY
Randall Lee1, Benjamin Ristau1, Andrew Macintosh1, Lyudmila DeMora1, Robert Uzzo2, David Chen3, Richard Greenberg3, Rosalia Viterbo4, Marc Smaldone4, Alexander Kutikov4
1 Temple University Hospital, 2 University of Connecticut Health Center, 3 MD Anderson Cancer Center, 4 Fox Chase Cancer Center
Presented By: Randall Lee
181. IS THERE A BENEFIT TO ADDITIONAL NEUROAXIAL ANESTHESIA IN OPEN NEPHRECTOMY? A PROSPECTIVE NSQIP PROPENSITY SCORE ANALYSIS?
Laura Bukavina1, Lee Ponsky2, Kiritshri Mishra2, Jason Jankowski2, Amr Mahran3, Irma Lengu2, Robert Abouassaly2
1 Case Western Reserve University / University Hospitals Cleveland Medical Center, 2 University Hospitals Cleveland Medical Center, 3 Case Western Reserve University. Presented By: Danly Omil-Lima

182. LONG TERM ONCOLOGICAL OUTCOMES OF SURGICALLY TREATED ONCOCYTOMA
Matvey Tsivian, Vignesh Packiam, Christine Lohse, Svetlana Avulova, R Houston Thompson, Stephen Boorjian, John Cheville, Bradley Leibovich
Mayo Clinic. Presented By: Matvey Tsivian

183. DO THE METHODS FOR EVALUATING NECROSIS ON IMAGING AFFECT PREDICTION OF METASTATIC RENAL CELL CARCINOMA?
Skylar Iosepovici1, Roy Mano1, Cihan Duzgol1, Mazyar Ghanaati1, Andrew Silagy1, Kyle Blum1, Aleksandra Walasek1, Renzo DiNatale1, Julian Marcon1, Jonathan Coleman1, Paul Russo1, Oguz Akin1, A. Ari Hakimi1, Alejandro Sanchez2
1 Memorial Sloan Kettering Cancer Center, 2 Huntsman Cancer Institute. Presented By: Skylar Iosepovici

184. IMPACT OF AGE AT DIAGNOSIS ON CAUSE OF DEATH IN PATIENTS WITH KIDNEY CANCER
Ankur Choksi, Alexander Henry, Shu Wang, Michael Naslund, Mohummad Minhaj Siddiqui
University of Maryland School of Medicine. Presented By: Ankur Choksi

185. PREDICTORS OF NON-INTERVENTIONAL MANAGEMENT OF T1 RENAL MASSES: RESULTS FROM THE MUSIC-KIDNEY STATEWIDE COLLABORATIVE
Amit Patel1, Craig Rogers1, Anna Johnson1, Ji Qi2, Brian Lane3
1 Henry Ford Hospital, 2 University of Michigan, 3 Spectrum Health. Presented By: Amit Patel

186. PATTERNS OF CARE FOR KIDNEY CANCER IN MINORITY-SERVING HOSPITALS
Lina Posada Calderon, Bashir Al Hussein Al Awamleh, Alan L. Khan, Johannes C. van der Mijn, Bradley Mellis, Jonah Bernstein, Benjamin L. Taylor, Jonathan E. Shoag, Douglas S. Scherr
Weill Cornell Medical College. Presented By: Lina Posada Calderon

187. NEPHROURETERTECTOMY VS NEPHRON SPARING MANAGEMENT OF CLINICALLY LOCALIZED UROTHELIAL CARCINOMA OF THE URETER: PRACTICE PATTERNS AND OUTCOMES
Javier Piraino, Daniel Edwards, Zachary Snow, Gregory DiStefano
Main Line Health. Presented By: Javier Piraino

188. TWO CYCLES OF NEOADJUVANT CHEMOTHERAPY IMPROVES SURVIVAL OF UPPER TRACT UROTHELIAL CARCINOMA PATIENTS
Kenji Zennami1, Kiyoshi Takahara1, Nachiko Fukami1, Hitomi Sasaki1, Mamoru Kusaka1, Ryoichi Shiroki1, Makoto Sumitomo1
1 Fujita Health University, 2 Fujita Health University. Presented By: KENJI ZENNAMI

189. BLOCKADE OF THE IMMUNE CHECKPOINT B7-H3 SENSITIZES RHABDOMYOSARCOMA TO ANTI-TUMOR IMMUNE RESPONSE
Candace Granberg, Fabrice Lucien-Matteoni, Haidong Dong, Patricio Gargollo
Mayo Clinic. Presented By: Roxane Lavoie

190. PATHOLOGIC AND SURVIVAL OUTCOMES IN CT1 PENILE CANCER
Allison May, Coleman Mcderrm, Anirudh Guduru, Zachary Hamilton
Saint Louis University. Presented By: Allison May

191. ONCOLOGIC OUTCOMES OF ORGAN SPARING SURGERY FOR LOCALIZED PENILE CANCER: THE MD ANDERSON CANCER CENTER EXPERIENCE
Andrea Kokorovic, Jonathan Duplisea, Barrett McCormick, Mehrad Adibi, John N Papadopoulos, Curtis A Pettaway
The University of Texas MD Anderson Cancer Center. Presented By: Andrea Kokorovic
192. PATTERNS OF DRUG UTILIZATION FOR METASTATIC CASTRATION RESISTANT PROSTATE CANCER (MCRPC) MEDICARE BENEFICIARIES RECEIVING FIRST-LINE TREATMENT
Scott Flanders¹, Carol Bazell², Christine Ferro³, Kate Fitch¹, Jason Haftron², Rana McKay⁴
¹ Dendreon Pharmaceuticals, LLC, ² Milliman, Inc., ³ Department of Urology, Beaumont Health and Associate Professor of Urology, William Beaumont School of Medicine, ⁴ School of the Health Sciences, University of California at San Diego
Presented By: Scott Flanders

193. ALTERATIONS OF TUMOR MICROENVIRONMENT BY NITRIC OXIDE DONOR IMPEDES CASTRATION RESISTANT PROSTATE CANCER GROWTH
Himanshu Arora¹, Kush Panara¹, Manish Kuchakulla¹, Shathiyah Kalandavelu¹, Joshua M. Hare¹, Ranjit Ramasamy¹, Andrew V. Schally²
¹ University of Miami, ² University of Miami VA
Presented By: Himanshu Arora

194. INFLUENCE OF NODE-POSITIVE DISEASE AFTER RADICAL PROSTATECTOMY ON BIOCHEMICAL RECURRENCE AND EARLY ONCOLOGIC OUTCOMES IN MEN WITH PROSTATE CANCER
Samuel Washington¹, Janet Cowan¹, Annika Herlemann¹, Hoa Nguyen¹, Peter Carroll¹, Kyle Zuniga¹, Selma Masic⁴
¹ Department of Urology, University of California San Francisco, ² College of Physicians and Surgeons, Columbia University Medical Center, ³ Department of Surgical Oncology, Division of Urologic Oncology, Fox Chase Cancer Center
Presented By: Samuel Washington

195. TUMOR MULTIFOCALITY ON MULTI-PARAMETRIC MRI IS ASSOCIATED WITH INCREASED DETECTION RATE OF CLINICALLY-SIGNIFICANT PROSTATE CANCER IN LESIONS WITH PI-RADS SCORE 4
Ghazal Khajir¹, Kamyar Ghabili¹, Matthew Swallow¹, Jamil Syed¹, Michael Leapman¹, Preston Sprenkle¹, Rachael Sherrer¹, Soroush Rais-Bahrami²
¹ Department of Urology, Yale School of Medicine, ² Department of Urology, University of Alabama at Birmingham
Presented By: Ghazal Khajir

196. SALVAGE WHOLE GLAND CYROABLATION THERAPY VERSUS STANDARD OF CARE FOR PATIENTS FAILING INITIAL RADIATION THERAPY FOR PROSTATE CANCER
Shiva Nair¹, Andrew Warner², George Rodrigues², Joseph Chin³
¹ Western University, London Health Sciences Centre, ² Department of Radiation Oncology, Western University, London, Ontario, Canada, ³ Departments of Urology and Oncology, Western University, London, Ontario, Canada
Presented By: Shiva Nair

197. INITIAL SURGICAL RESULTS FROM PHASE II TRIAL OF NEOADJUVANT THERAPY, CONSOLIDATIVE SURGERY AND PSMA/PET IMAGING IN OLIGOMETASTATIC AND VERY HIGH RISK LOCALLY ADVANCED PROSTATE CANCER
David F. Jarrard¹, Christos Kyniakopoulos², Hamid Emamekhoo³, Joshua M. Lang³, Steve Cho¹, Shane Wells³, Brian Johnson¹, Alejandro Roldan¹, David J. Beebe¹, Wei Huang⁶
¹ University of Wisconsin-Madison, Department of Urology. UW Carbone Cancer Center, ² University of Wisconsin, Department of Medicine. UW Carbone Cancer Center, ³ University of Wisconsin, Department of Radiology, ⁴ University of Wisconsin, Department of Biomedical Engineering, ⁵ University of Wisconsin. Department of Biomedical Engineering, ⁶ University of Wisconsin, Department of Pathology
Presented By: Tariq A. Khemees

198. PROMPT - PROSTATE GENETIC SCORE IS A SENSITIVE TEST FOR MEN AT RISK OF METASTATIC PROSTATE CANCER
Stephen Ryan¹, Fady Ghali², Christopher Kane³, Andrew K Kader³, Sij Hema³, Brent Rose³, Frederick Millard³, James Randall³, Michael Liss⁷
¹ Department of Urology, UC San Diego, San Diego CA, ² Department of Urology, University of California San Diego, San Diego CA, ³ Department of Urology, Wake Forest University, Winston-Salem NC, ⁴ Department of Radiation Oncology, University of California San Diego, San Diego CA, ⁵ Department of Internal Medicine, Division of Oncology, University of California San Diego, San Diego CA, ⁶ Department of Urology, Washington University School of Medicine, St. Louis MI, ⁷ Department of Urology, University of Texas Health, San Antonio TX
Presented By: Fady Ghali

199. TRENDS IN INCIDENCE AND SURVIVAL AMONG MEN WITH METASTATIC PROSTATE CANCER: SEER ANALYSIS 2004-2015
Michael Feuerstein¹, Rehana Rasul², Anne Golden³
¹ Lenox Hill Hospital, ² Feinstein Institute for Medical Research, Northwell Health, ³ Department of Occupational Medicine, Epidemiology, and Prevention, Northwell Health
Presented By: Michael Feuerstein

200. CARDIOVASCULAR RISK FACTORS FOR PATIENTS WITH ADVANCED PROSTATE CANCER ON ANDROGEN DEPRIVATION THERAPY
Raju Chelluri, Kinnari Patel, Katharine Michel, James Ding, Thomas Guzzo, Daniel Lee
Penn
Presented By: Raju Chelluri
201. UTILITY AND PRECISION MEDICINE IMPLICATIONS OF COMBINED TUMOR AND GERMLINE GENETIC TESTING IN PATIENTS WITH PROSTATE CANCER
Edward Esplin, Daniel Pineda-Alvarez, Scott Michalski, Meaghan Russell, Shan Yang, Ihn Young Song, Robert Nussbaum

Invited

Presented By: Stephen Lincoln

202. WHEN CAN WE SKIP SYSTEMATIC PROSTATE BIOPSIEST?
Andrew Wilbur, Michael Ahdoot, Amir Lebastchi, Patrick Gomella, Sandeep Gurram, Peter Pinto, Sarah Reese, Sherif Mehralivand, Baris Turkbey, Minhaj Siddiqui, Paul Pinsky, Howard Parnes, Joanna Shi, Bradford Wood

1 Urologic Oncology Branch, National Cancer Institute, National Institutes of Health, Bethesda, Maryland, 2 General Dynamics Information Technology, 3 Molecular Imaging Program, Center for Cancer Research, National Institutes of Health, Bethesda, Maryland, 4 Director of Urologic Oncology and Robotic Surgery, VA Medical Center, University of Maryland, Baltimore, Maryland, 5 Division of Cancer Prevention, National Cancer Institute, National Institutes of Health, Bethesda, Maryland, 6 Biometric Research Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute, National Institutes of Health, Bethesda, Maryland, 7 Center for Interventional Oncology, National Cancer Institute, & Interventional Radiology, Radiology and Imaging Sciences, National Cancer Institute, National Institutes of Health, Bethesda, Maryland

Presented By: Andrew Wilbur

203. IMPACT OF PRE-BIOPSY MRI ON BIOPSY AND RADICAL PROSTATECTOMY GLEASON GRADE CONCORDANCE
Jonathan Shoag, Peter Cai, Christopher Gaffney, Bashir Al Hussein Al Awamlih, Michael Gross, Jim Hu, Dongze Li, Jialin Mao, Molly Nowels, Art Sedrakyan

1 Department of Urology, Weill Cornell Medicine, New York, NY, USA, 2 Department of Healthcare Policy and Research, Weill Cornell Medicine

Presented By: Peter Cai

204. ESTIMATING THE PREVALENCE OF PROSTATE CANCER GENOMIC SUBTYPES BY INVERSE PROBABILITY WEIGHTING
Jonathan Shoag, Peter Cai, Christopher Gaffney, Bashir Al Hussein Al Awamlih, Christopher Barbieri, Xiaoyue Ma

1 Department of Urology, Weill Cornell Medicine, New York, NY, USA, 2 Department of Healthcare Policy and Research, Weill Cornell Medicine

Presented By: Peter Cai

205. OTHER- AND ALL-CAUSE MORTALITY AMONG MEN WITH PROSTATE CANCER
Dudith Pierre-Victor, Paul F. Pinsky

National Cancer Institute, NIH

Presented By: Dudith Pierre-Victor

206. INTRA-LESIONAL PROSTATE CANCER HETEROGENEITY IN STEP-SECTIONED RADICAL PROSTATECTOMY SPECIMENS: IMPLICATIONS FOR TARGET BIOPSY STRATEGY
Andre Abreu, Tsuyoshi Iwata, Akash Sali, Chhavi Gupta, Alishaser Shakir, Alessandro Tafuri, Giovanni Cacciamaoni, Inderbir Gill

USC institute of Urology and Catherine & Joseph Aresty Department of Urology, University of Southern California

Presented By: Atsuko Fujihara

207. SYSTEMATIC REVIEW AND META-ANALYSIS COMPARING PROSTATE CANCER DETECTION RATES BETWEEN COGNITIVE AND MRI-ULTRASOUND GUIDED FUSION PROSTATE BIOPSY
Laena Frechette, Emily Barry, Matthew DeMasi, Ahmed Aboumohamed, Kara Watts, Ben Muller

1 Montefiore Medical Center, 2 Washington University at St Louis

Presented By: Ahmed Aboumohamed

208. WHY DOES MRI-TARGETED BIOPSY MISS CLINICALLY SIGNIFICANT CANCER?

1 National Institutes of Health, 2 Geisinger Commonwealth School of medicine, 3 Urologic Oncology Branch, National Cancer Institute, National Institutes of Health, Bethesda, Maryland, 4 Molecular Imaging Program, Center for Cancer Research, National Institute of Health, Bethesda, Maryland, 5 Division of Cancer Prevention, National Cancer Institute, National Institutes of Health, Bethesda, Maryland, 6 Biometric Research Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute, National Institute of Health, Bethesda, Maryland, 7 Center for Interventional Oncology, National Cancer Institute, & Interventional Radiology, Radiology and Imaging Sciences, National Cancer Institute, National Institutes of Health, Bethesda, Maryland

Presented By: Michael Ahdoot

209. OPIOID PRESCRIBING PATTERNS AFTER RADICAL PROSTATECTOMY AND LONG-TERM OPIOID USE
James Ding, Ruchika Talwar, David Lee, Bruce Malkowicz, Philip Mucksavage, Keith Van Arsdale, Alan Wein, Thomas Guzzo, Daniel Lee

1 University of Pennsylvania, 2 Penn

Presented By: James Ding
210. ASSOCIATION BETWEEN SOCIOECONOMIC STATUS AND PRIMARY TREATMENT CHOICE FOR LOCALIZED PROSTATE CANCER IN A UNIVERSAL HEALTHCARE SYSTEM: A POPULATION-BASED ANALYSIS
Justin Oake1, Jeff Saranchuk1, Rahul Bansal1, Darrel Drachenberg1, Jasmin Nayak1, Oksana Harasemiw2, Thomas Ferguson2, Navdeep Tangri3
1 Section of Urology, University of Manitoba, 2 Chronic Disease Innovation Centre, Seven Oaks General Hospital; Department of Internal Medicine, University of Manitoba, 3 Chronic Disease Innovation Centre, Seven Oaks General Hospital; Department of Internal Medicine, University of Manitoba; Department of Community Health Sciences, University of Manitoba
Presented By: Justin Oake

211. ARTIFICIAL INTELLIGENCE ACCURATELY AUTOMATES AND ACCELERATES IMMUNOFLUORESCENCE-BASED DISCOVERY INCLUDING THE VALIDATION OF NOVEL PROGNOSTIC AND PREDICTIVE BIOMARKERS IN PROSTATE CANCER
Hao Nguyen1, Lingru Xue1, Peter Carroll1, Matthew Cooperberg1, Ehsan Hosseini-Asl2, Clarence So2, Richard Socher2, Caiming Xiong2
1 University of California, San Francisco, 2 Salesforce Inc.
Presented By: Claire de la Calle

212. THE 4KSCORE TEST AND SELECTMDX DO NOT INFORM DECISION WHETHER TO OBTAIN A MULTI-PARAMETRIC MRI IN MEN WITH ELEVATED PSA
Jesse Persily1, Ezequiel Becher1, James Wysock2, Herbert Lepor2
1 New York University School of Medicine, 2 New York University
Presented By: Jesse Persily

213. THE IMPACT OF SERIAL MULTIPARAMETRIC MAGNETIC RESONANCE IMAGING TO PREDICT PATHOLOGICAL PROGRESSION DURING ACTIVE SURVEILLANCE WITH GLEASON 6 PROSTATE CANCER.
Andre Abreu1, Tsuoyoshi Iwata1, Aliagser Shakir1, Alessandro Tafuri1, Giovanni Cacciamani1, Luis Medina1, Mihir Desai1, Inderbir Gill1, Osamu Ukimura2, Vinay Duddalwar2, Manju Aron3, Suzanne Palmer4
1 USC Institute of Urology and Catherine & Joseph Aresty Department of Urology, University of Southern California, 2 Department of Urology, Kyoto prefectural university of medicine, 3 Departments of Radiology, Keck School of Medicine, University of Southern California, 4 Departments of Radiology, Keck School of Medicine, University of Southern California
Presented By: Atsuko Fujihara

214. FACTORS ASSOCIATED WITH DISEASE RECLASSIFICATION AND PROGRESSION TO DEFINITIVE TREATMENT IN MINORITY POPULATIONS ON ACTIVE SURVEILLANCE FOR PROSTATE CANCER
Matthew Loecher, Laura Kidd, Nahrin Ahmed, Joseph Terzian, Adam Reese
Temple University Hospital
Presented By: Matthew Loecher

215. INTRA-PRACTICE UROLOGIST-LEVEL VARIATION IN CANCER DETECTION RATES WITH TARGETED CORES ON FUSION BIOPSY
Apoorv Dhir, Chad Ellumoottil, Ji Qi, Jeff Montgomery, Simpa Salami, John Wei, Prasad Shankar, Matthew Davenport, Nicole Curci, Chen-Yu Wu, Anna Johnson, Arvin George
University of Michigan
Presented By: Arvin George

216. ASSESSING FOCALITY OF DOMINANT TUMOR ON SERIAL BIOPSY IN AN ACTIVE SURVEILLANCE COHORT - IMPLICATIONS FOR FOCAL THERAPY
Vittorio Fasulo1, Janet E. Cowan2, Samuel L. Washington III3, Hao G. Nguyen3, Katsuto Shinohara3, Peter R. Carroll3, Paolo Casale4
1 University of California, San Francisco – San Francisco, CA; Istituto clinico Humanitas – Rozzano, Milan, Italy, 2 University of California, San Francisco – San Francisco, CA; Istituto clinico Humanitas – Rozzano, Milan, Italy, 3 University of California, San Francisco – San Francisco, CA; Istituto clinico Humanitas – Rozzano, Milan, Italy
Presented By: Vittorio Fasulo

217. RADIOTHERAPY AFTER RADICAL PROSTATECTOMY: EFFECT OF TIMING OF POST-PROSTATECTOMY RADIATION ON FUNCTIONAL OUTCOMES
Heather Huelster1, Aaron Laviana1, Tatsuki Koyama1, Zhiguo Zhao1, Li-Ching Huang1, Ralph Conwill2, David Pensson1, Daniel Barocas3, Karen Hoffman4
1 Vanderbilt University Medical Center, 2 University of Texas MD Anderson Cancer Center
Presented By: Heather Huelster
218. ONE AND DONE? PSA DENSITY AS A PREDICTOR OF NUMBER OF CORES NEEDED TO DETECT CLINICALLY SIGNIFICANT PROSTATE CANCER
Amir Lebatschi1, Alex Wang2, Luke O’Connor2, Jonathan B. Bloom2, Michael Ahdoot2, Nitin Yerram2, Samuel A. Gold2, Kareem N. Rayn2, Sherif Mehdaviand2, Joanna Shih2, Thomas Sanford2, Peter A. Pinto2, Graham R. Hale2, Bradford J. Wood4, Baris Turkbey5
1 National Institutes of Health, National Cancer Institute, Urologic Oncology Branch, 2 National Institutes of Health, National Cancer Institute, Urologic Oncology Branch, Bethesda, MD, 3 National Institutes of Health, National Cancer Institute, Urology Oncology Branch, Bethesda, MD, 4 Center for Interventional Oncology, National Cancer Institute, National Institutes of Health, 5 Molecular Imaging Program, National Cancer Institute, National Institutes of Health
Presented By: Alex Wang

219. CAN A SEXTANT BIOPSY TEMPLATE BE USED INSTEAD OF EXTENDED 12-CORE TEMPLATE IN CONJUNCTION WITH MR/US FUSION PROSTATE BIOPSIES?
Vinson Wang, Michael Smigelski, Gen Li, Christopher Haas, Joseph Caputo, Hiram Shaish, Sven Wenske, Luis Alberto Pina Martina Columbia University Medical Center
Presented By: Luis Alberto Pina Martina

220. BODY MASS INDEX AND UPGRADING AT RADICAL PROSTATECTOMY AMONG MEN WITH LOCALIZED PROSTATE CANCER IN THE PROSTATE, LUNG, COLORECTAL AND OVARIAN CANCER SCREENING TRIAL
Amy Nemirovsky1, Kathryn Hughes Barry1, Sonja I. Berndt2, Amanda Black2, Wen-Yi Huang2
1 University of Maryland School of Medicine, 2 National Cancer Institute
Presented By: Amy Nemirovsky

221. FACTORS PREDICTING HIGHER BIOPSY YIELD WITH MRI-TARGETED VERSUS SYSTEMATIC PROSTATE BIOPSY: WHEN IS SOFTWARE FUSION MRI-TARGETING NECESSARY?
Grant Henning, Joel Vetter, Gerald Andriole, Eric Kim
Washington University School of Medicine
Presented By: Grant Henning

222. MRI FUSION BIOPSY CAN MISS APPROXIMATELY 2 IN 10 CLINICALLY SIGNIFICANT PROSTATE CANCERS
Brijesh Patel1, John Ogunkeye1, Eiftu Halie1, Pierce Massie1, Christopher Coogan1, Justin Cohen2, Paul Yonover2
1 Rush University Medical Center, 2 UroPartners
Presented By: Brijesh Patel

223. IMPACT OF AGE AT DIAGNOSIS ON CAUSE OF DEATH IN PATIENTS WITH PROSTATE CANCER
Ankur Choksi, Alexander Henry, Shu Wang, Michael Naslund, Mohummad Minhaj Siddiqui University of Maryland School of Medicine
Presented By: Ankur Choksi

224. INTERSECTION OF CONFIRM MDX HYPERMETHYLATION AND MULTIPARAMETRIC MRI IN MEN WITH PRIOR NEGATIVE PROSTATE BIOPSY
Daniel Artenstein1, Rex Parker2, Aaron Krug2, David Finley2, Margo Sidell3
1 Kaiser Permanente Los Angeles Medical Center, 2 Kaiser Permanente Los Angeles, 3 Kaiser Permanente Dept. of Biostatistics
Presented By: Daniel Artenstein

225. IDENTIFYING THE OPTIMUM DIAGNOSTIC PATHWAY IN MEN WITH SUSPECTED PROSTATE CANCER IN A US-BASED HEALTHCARE SYSTEM: A COST-EFFECTIVENESS ANALYSIS
Thomas Stonier4, Andrew Briggs4, Andrew Vickers4, Sigrid V. Carlson4, James Eastham5
1 Department of Surgery (Urology Service), Memorial Sloan Kettering Cancer Center, New York, NY, U.S.A, 2 1) Department of Epidemiology and Biostatistics, Memorial Sloan Kettering Cancer Center, New York, NY, U.S.A. 2) Department of Urology, Institute of Clinical Sciences, Sahlgrenska Academy at University of Gothenburg, Sweden, 3 Department of Epidemiology and Biostatistics, Memorial Sloan Kettering Cancer Center, New York, NY, U.S.A., 4 1) Department of Epidemiology and Biostatistics, Memorial Sloan Kettering Cancer Center, New York, NY, U.S.A. 2) Department of Urology, Institute of Clinical Sciences, Sahlgrenska Academy at University of Gothenburg, Sweden, 5 Department of Surgery (Urology Service), Memorial Sloan Kettering Cancer Center, New York, NY, U.S.A.
Presented By: Sigrid Carlson

226. PRIMARY CARE PHYSICIANS’ PERCEPTIONS OF AN ELECTRONIC MEDICAL RECORD-EMBEDDED DECISION SUPPORT TOOL FOR PROSTATE CANCER SCREENING: A FOCUS GROUP STUDY
Sigrid Carlson1, Tiffany Le1, Andrew Vickers1, Behfar Ebrahimi1, Junaid Nabi1, Mark Preston1, Michael Healey1, Adam Kibel2, Deepak Malhotra1
1 Memorial Sloan Kettering Cancer Center, 2 Brigham and Women’s Hospital, Harvard Medical School, 3 Harvard Business School
Presented By: Sigrid Carlson
227. REDACTED

228. GENOMIC HETEROGENEITY IN TISSUE-BASED PROGNOSTIC SIGNATURES FROM PROSTATE BIOPSIES; RESULTS FROM TWO PROSPECTIVE TRIALS
Venkatasai Atluri1, Nachiketh Soodana-Prakash1, Chad Ritch1, Bruno Nahar1, Mark Gonzalgo3, Bruce Kava1, Dipen Parekh1, Sanoj Punnen1, Radka Stoyanova2, Alan Pollack1
1 Department of Urology, University of Miami, 2 Department of Radiation Oncology, University of Miami
Presented By: Venkatasai Atluri

229. METABOLOMIX PROFILING OF PROSTATE CANCER UPGRADING DURING ACTIVE SURVEILLANCE
Bruce Trock1, Mufaddal Mamawala1, Sacha Wolfe1, Patricia Landis1, H. Ballentine Carter1, Edward Karoly2
1 Johns Hopkins School of Medicine, Department of Urology, 2 Metabolon, Inc.
Presented By: Bruce Trock

230. WIDESPREAD USE OF MULTIPARAMETRIC MRI IN AN ACTIVE SURVEILLANCE COHORT RESULTS IN EARLIER IDENTIFICATION AND TREATMENT OF CLINICALLY SIGNIFICANT PROSTATE CANCER
Alice Yu, Eduoard Nicaise, Andrew Gusev, Timothy Baloda, Amirkasra Mojtahed, Mukesh Harisinghani, Douglas Dahl, Matthew Wszolek, Anthony Zietman, Adam Feldman
Massachusetts General Hospital
Presented By: Alice Yu

231. RISK FACTORS WHICH PREDICT BIOPSY UPGRADING OVER TIME IN ACTIVE SURVEILLANCE FOR PROSTATE CANCER
Peter Lonergan, Samuel Washington, Shoujun Zhao, Janet Cowan, Hao Nguyen, Katsuto Shinozuka, Matthew Cooperberg, Peter Carroll
University of California, San Francisco
Presented By: Peter Lonergan

232. DOES TIME SPENT ON ACTIVE SURVEILLANCE ADVERSELY AFFECT THE PATHOLOGIC AND ONCOLOGIC OUTCOMES IN PATIENTS UNDERGOING DELAYED RADICAL PROSTATECTOMY?
Ardalan Ahmad1, Omar Alhunaidi1, Narhari Timilshina1, Maria Komisarenko1, Lisa Martin1, Girish Kulkarni1, Robert Hamilton1, Neil Flesher1, Antonio Finelli1, Patrick Richard2
1 Division of Urology, Department of Surgery, Princess Margaret Cancer Centre, University Health Network and University of Toronto, Toronto, Ontario, Canada, 2 Division of Urology, Department of Surgery, Princess Margaret Cancer Centre, University Health Network and University of Toronto, Toronto, Ontario, Canada, Division of Urology, Departments of Surgery, Centre Hospitalier Universitaire de Sherbrooke, Centre de Recherche du CHUS, Université de Sherbrooke, Sherbrooke, Quebec, Canada
Presented By: Ardalan Ahmad

233. PREOPERATIVE PROSTATE MAGNETIC RESONANCE IMAGING IMPROVES SURGICAL OUTCOME FOLLOWING RADICAL PROSTATECTOMY
Amir Lebastchi1, Samuel Gold1, Michael Ahdoot1, Sherif Mehralivand1, Jonathan Bloom1, Sandeep Gurram1, Patrick Gomella1, Joanna Shih1, Peter Pinto1, Minhaj Siddiqui3, Baris Turkbey2
1 National Cancer Institute, 2 University of Maryland, 3 National Cancer Institute
Presented By: Amir Lebastchi

234. HIGHER PREVALENCE OF BENIGN TUMORS IN MEN WITH TESTICULAR TUMORS AND HISTORY OF UNTREATED CRYPTORCHIDISM
Rachel Davis, Mahir Maruf, Joseph Cheaib, Phillip Pierorazio, Heather Di Carlo
Johns Hopkins University School of Medicine
Presented By: Joseph Cheaib
235. PRIMARY ROBOTIC-ASSISTED RETROPERITONEAL LYMPH NODE DISSECTION FOR NON-SEMINOMATOUS GERM CELL TUMOR: EXPERIENCE FROM A MULTI-INSTITUTIONAL SERIES
Jacob Taylor1, Ezequiel Becher2, James Wysock3, William C. Huang3, Andrew T. Lenis3, Mark S. Litwin3, Jacob Jipp4, Peter Langenstroer5, Marc A. Bjurlin6, Hung-Jui Tan7
1 New York University Langone Health, 2 Department of Urology, New York University Langone Health, 3 Institute of Urologic Oncology, Department of Urology, University of California Los Angeles, 4 Department of Urology, Medical College of Wisconsin, 5 Department of Urology, University of North Carolina Chapel Hill
Presented By: Jacob Taylor

236. PREDICTIVE CAPACITY OF miRNA-375 IN IDENTIFYING TERATOMA ON POST-CHEMOTHERAPY RETROPERITONEAL LYMPH NODE DISSECTION (PC-RPLND)
Alexander Kenigsberg, John Latin, Xiaosong Meng, Dreaux Abe, Anna Savalyeva, Nirmish Singla, Solomon Woldu, Yair Lotan, Payal Kapur, Vitaly Margulis, James Amatruda, Aditya Bagrodia
Presented By: Alexander Kenigsberg

237. EXPRESSION OF CIRCULATING MIR375 TO DETECT TERATOMA IN PATIENTS WITH GERM CELL TUMOR
Lucia Nappi1, Bernhard Eigl2, Kim Chi3, Christian Kollmannsberger4, Marisa Thr2, Martin Gleave2, Alan So2, Peter Black2, Robert Hamilton2, Siama Keshamand4, Craig Nichols5
1 British Columbia Cancer, 2 Vancouver Prostate Centre, 3 Princess Margaret Cancer Centre, 4 USC/Norris Comprehensive Cancer Center Institute of Urology, 5 South West Oncology Group
Presented By: Lucia Nappi

238. MANAGEMENT OF TESTICULAR GERM CELL TUMOR WITH SECONDARY SOMATIC MALIGNANCY
Nathan Wong1, Timothy Clinton1, Sumit Isharwal1, Mark Donoghue1, Sujata Patil1, Liwei Jia1, William Tap1, Gabriella Joseph1, Samuel Funt1, Deaglan McHugh1, Hikmat Al-Ahmadie1, Victor Reuter1, Robert Motzer1, George Bosl1, Joel Sheinfeld1, David Solit1, Darren Feldman1, Shawn Dason2, Lucas Dean3
1 Memorial Sloan Kettering Cancer Center, 2 The Ohio State University, 3 University of Alberta
Presented By: Nathan Wong

239. OUTCOMES FOLLOWING RETROPERITONEAL LYMPH NODE DISSECTION FOR CLINICAL STAGE II PATIENTS EXPERIENCING A LATE RELAPSE FOLLOWING UPFRONT PLATINUM BASED CHEMOTHERAPY
Ryan Speir, Sean Kern, Timothy Masterson, Richard Foster, Clint Cary
Indiana University School of Medicine
Presented By: Ryan Speir

240. ASSOCIATIONS OF PRE-ORCHIECTOMY HORMONE LEVELS TO TESTICULAR GERM CELL TUMOR PATHOLOGY, CLINICAL STAGE, AND SIZE
Kevin Pineault1, Joseph Cheaib2, Amin Herati2, Phillip Pierorazio2
1 Brady Urological Institute at Johns Hopkins Hospital, 2 Brady Urological Institute
Presented By: Kevin Pineault

241. CLINICOPATHOLOGIC PREDICTORS OF OUTCOMES IN CHILDREN WITH STAGE I GERM CELL TUMORS: A POOLED POST HOC ANALYSIS OF TRIALS FROM THE CHILDREN’S ONCOLOGY GROUP
Shyamli Singla1, Justin Wong2, James Amatruda1, Aditya Bagrodia2, Mark Krailo2, Li Huang3, Furqan Shaikh4, Deborah Billmire5, Frederick Ruisert6, Jonathan Ross2, Bryan Dicken2, A. Lindsay Frazier2
1 University of Texas Southwestern Medical Center, 2 University of Southern California, 3 Childrens Oncology Group, 4 The Hospital for Sick Children, 5 Indiana University, 6 Rainbow Babies and Childrens Hospital, 7 University of Alberta, 8 Dana-Farber Cancer Institute
Presented By: Nirmish Singla
Introduction: Robot-assisted radical cystectomy (RARC) remains one of the more complex procedures urologists perform. Due to the regionalization of bladder cancer care, there is likely a disproportion among urologists preforming RARC. We sought to evaluate the changes in patient selection, surgical quality surrogates and rates of complications with surgical experience.

Methods: We retrospectively reviewed 409 consecutive patients with bladder cancer who underwent RARC and pelvic lymph node dissection between 2006-2017 by a single surgeon. The cohort was divided into four groups (quartiles) according to surgical experience based on the chronologic order at which RARC was performed. Baseline, perioperative and pathologic characteristics of patients were compared among the four groups. Complications within 90 days of surgery were assessed using the Clavien-Dindo system. The association between surgical experience (quartile) and complications was assessed using logistic regression analyses adjusting for baseline, perioperative and pathologic characteristics.

Results: Median age (range from 70-73 years), BMI (range from 25 to 27 Kg/M2) and preoperative GFR (range from 59 to 65 ml/min/1.73m2) were similar among all four groups (all p> 0.05). Patients in the 4th quartile of RARC had higher rates of previous abdominal surgery (46% vs. 30.4%, p= 0.03) and ASA score of 3 or 4 (72% vs 47%, p= 0.03) compared to patients in the 1st quartile. Additionally, patients who were underwent RARC with more experience had less estimated blood loss (250cc in 4th quartile vs. 350cc in 1st quartile, p <0.0001), shorter operative time (346 in 4th quartile vs 360 minutes in 1st quartile, p <0.0001), and higher lymph node yield (22 vs. 17 nodes, p<0.0001, Figure). However, pathologic staging, positive surgical margin rate and choice of urinary diversion did not change significantly with experience. In total, 53% patients experienced any complication within 90 days of surgery and 16% had major complications (Grade =3). Complication rates were similar among all 4 groups within the first 30 days (p>0.05). However, patients in the 4th quartile had higher rate of any complication than those in the 1st quartile (74% vs 54%, p=0.01) within 90 days. All groups experienced similar rates of major complications within 30 and 90 days. Table shows multivariable analyses predicating factors associated with complications. Patients in the 4th quartile were more likely to experience any complication (OR 2.03 95%Cl 1.11- 3.70) within 90 days.

Conclusion: Our findings show that with surgeon comfort and experience, surgical quality surrogates such as operative time and lymph node yield improve. Additionally, there appears to be a trade-off between the increase in complexity of cases performed with experience and accepting higher rates of complications. Thus, complex cases are likely to benefit more from undergoing RARC in high-volume experienced centers that are capable of managing the associated complications.
123. RAPID ORGANOID DEVELOPMENT, DRUG SCREENING, AND NEOADJUVANT CHEMOTHERAPY RESPONSE PREDICTION FOR PATIENTS WITH LOCALLY-ADVANCED BLADDER CANCER

Kathryn Marchetti1, Nathan Merrill1, Nathalie Vandecan1, Xu Cheng2, Aaron Udager1, Lindsey Herrel1, Jeffery Montgomery1, Khaled Hafez1, Todd Morgan1, Alon Weizer1, Ajjai Alva1, Matthew Soellner1, Sophia Merajver1, Samuel Kaffenberger1, Liwei Bao2

1 University of Michigan Health System, lwbao@umich.edu

Presented By: Kathryn Marchetti

Introduction: Neoadjuvant chemotherapy prior to radical cystectomy (RC) for muscle-invasive urothelial carcinoma (UCCx) is the standard of care, though the absolute survival benefit is small, and some patients progress during chemotherapy. While progress has been made in the prediction of sensitivity to platinum-based chemotherapies, providing more accurate, personalized, and clinically-relevant chemotherapy response prediction is an unmet need. We present our early and ongoing experience with rapid, organoid-based drug-screening, which can be performed within 5-10 days of transurethral resection of bladder tumor (TURBT) or RC, and only requires only a small amount of tissue (~0.3 grams). This novel platform allows for the testing of a large number of drugs or drug combinations and is potentially informative for the prediction of neoadjuvant and adjuvant chemotherapy response.

Methods: After informed consent was obtained, approximately 1 gram of tumor was procured from patients undergoing TURBT or RC and divided between DNA/RNA sequencing, organoid drug-screening, and patient-derived xenograft model development. Briefly, tissue was dissociated, filtered, and resuspended in organoid media for serial passage and drug screening. Drugs were tested at a single “Cmax” concentration, which is the maximum plasma concentration in human trials so as to provide physiologic relevance. Testing was performed in duplicate and normalized to DMSO controls. For each drug tested at Cmax concentration, organoid viability was assessed, where 0 = complete response, and 100 = no response relative to DMSO controls. This was plotted on a red-green scale for ease of viewing in the Table where green indicates drug sensitivity, and red indicates drug resistance. The number of drugs tested per sample was dependent upon quantity of cells available upon tissue dissociation and subject to variability over the pilot period as the protocol was refined. Wherever possible, FDA-approved bladder cancer drugs and drug combinations were utilized including FGFR inhibitors. In addition, exploratory analyses with immuno-oncology agents were performed, given the innate advantages of retained tumor heterogeneity and possibility of retained immune cells within the organoid system. Anti-PD1, PDL1, and CTLA4 agents were tested alone and in combination.

Results: Drug response analyses were available 5-10 days following procedure. The first patient underwent RC for a locally-advanced pT3 UCCx with 75% squamous differentiation and dose response curves presented in the Figure, show a non-chemosensitive tumor. The second (TURBT for cT3N1 pure UCCx, sensitive to FGFR inhibition), third (RC for pure squamous cancer, sensitive only to doxorubicin), and fourth (TURBT for T4 UCCx, exquisitely sensitive to MVAC) patient tumor drug-response results are presented in the Table. The fifth patient underwent RC for pT2N1 UCCx after neoadjuvant gemcitabine-cisplatin. Interestingly, his tumor was MVAC-sensitive, while it was insensitive to gemcitabine-cisplatin. The sixth and seventh patients (RC for pT4, and pT2b, respectively UCCx with focal squamous) showed sensitivity to MVAC, and doxorubicin, respectively. Cell counts were lower for patients seven and eight necessitating the testing of fewer drugs. The eighth patient underwent TURBT for a locally advanced small cell cancer of urothelial origin (with adjacent CIS), and as expected, was cisplatin-sensitive. All organoids showed sensitivity to doxorubicin. DNA and RNA sequencing and PDX models are ongoing for all patients, as are clinical determinations of response to neoadjuvant and adjuvant chemotherapy, and immunotherapy.

Conclusion: This platform allows for the rapid determination of neoadjuvant chemotherapy response within 5-10 days of TURBT, and may further guide selection of therapeutic agents in patients with locally advanced bladder cancer. Correlation with clinical response to systemic therapies is ongoing as are comparisons with tumor FGFR status, PDL1 status, tumor mutational burden, and presence of DNA damage repair pathway mutations. Organoid-based drug testing has the potential for truly personalized therapeutics in bladder cancer, and may also facilitate future drug development and clinical trial efficiency.
124. SARCOMATOID BLADDER CANCER: A VARIANT WITH WORSE PROGNOSIS AND A UNIQUE RECURRENCE PATTERN

Rishi Sekar1, Brian R. Winters1, Daniel W. Lin1, Jonathan L. Wright1, Lenoidas Diamantopoulos2, Bruce Montgomery2, Funda Vakar-Lopez2, Petros Grivas3, George Schade5

1 University of Washington, Department of Urology, 2 University of Washington, Division of Medical Oncology, 3 University of Washington, Department of Pathology, 4 University of Washington, Department of Medical Oncology, 5 Department of Urology, University of Washington

Presented By: Rishi Sekar

Introduction: Sarcomatoid bladder cancer is a rare variant of urothelial carcinoma and is associated with aggressive tumor behavior and poor prognosis. Recent studies have also suggested chemo-resistance to standard neoadjuvant regimens and high recurrence rates after definitive intervention, therefore conferring a challenging treatment dilemma for urologist and patients. In this study, we retrospectively evaluate our institutional database to delineate survival outcomes and prognostic characteristics of muscle invasive sarcomatoid bladder cancer after cystectomy and describe a unique pattern of rapid abdomino-pelvic cystic recurrence.

Methods: Our institutional database at the University of Washington was queried to identify patients who underwent radical cystectomy for localized muscle invasive sarcomatoid and conventional (no variant histology present) urothelial carcinoma (UC) of the bladder from 2003 to 2018. Demographics, clinicopathologic characteristics, and treatment course were captured. Overall survival (OS) and recurrence-free survival (RFS) were calculated from time of cystectomy. T-test and chi-squared test were used for group comparison. Kaplan Meier method and life-table analysis were used for estimation OS and RFS, and Cox regression analysis (univariate and multivariate) was utilized for identification of prognostic factors related to OS. Variables significant in univariate Cox regression analysis were included in the final multivariate model. Log-rank test was used for comparison of OS and RFS between groups. A subgroup of patients with sarcomatoid histology was identified with a unique pattern of abdomino-pelvic cystic recurrence for comparison of prognostic outcomes, clinical course, as well as radiographic findings.

Results: Thirty-two consecutive patients with sarcomatoid variant and 287 with conventional urothelial histology were identified. Sarcomatoid histology was associated with significantly higher rates of extravesical disease (pT3/4) compared to conventional UC (64% vs. 35%, p = 0.001), but similar node positive disease (24% vs. 20%, p = 0.588) and positive surgical margins (6% in both groups, p = 0.999). ypT0N0 rates following neoadjuvant chemotherapy were lower for patients with sarcomatoid histology (7% vs 33%, p = 0.067). Five-year cumulative OS was significantly inferior in the sarcomatoid group (41% vs 69%, p = 0.001), and the same was true for RFS (43% vs. 61%, p = 0.005). In multivariate Cox regression analysis for OS in the entire cohort, sarcomatoid histology was significantly associated with worse OS (HR: 3.4, 95% CI: 1.5-7.7, p = 0.003). Thirteen (41%) patients with sarcomatoid histology recurred after cystectomy, with nine (28%) developing abdominopelvic recurrence. Among these, 5 patients presented with a unique pattern of rapid abdomino-pelvic cystic recurrence, with average time to recurrence of < 5 months and median survival of 13.8 months. The diagnosis of recurrence in these cystic recurrent patients was typically delayed due to the cystic/fluid collection appearance leading to interventions for possible abscess, prior to diagnosis of recurrence confirmed on biopsy or fluid cytology. Representative imaging was selected to characterize this unique recurrence pattern of abdominopelvic cystic masses and fluid collections. Images 1 and 2 represent two separate patients that developed abdominopelvic recurrence after radical cystectomy.

Conclusion: This represents the largest single institution series of patients with muscle invasive sarcomatoid bladder cancer treated with radical cystectomy. Sarcomatoid bladder cancer is associated with aggressive tumor behavior, with high rates of extravesical disease, limited response to neoadjuvant chemotherapy, and worse survival compared to conventional UC. Additionally, we identify a unique clinical pattern of rapid abdominopelvic cystic recurrence associated with very poor survival. Clinicians should have a high index of suspicion for disease recurrence in patients with sarcomatoid variant urothelial carcinoma that develop abdominopelvic fluid collections.
125. TRIMODAL THERAPY VERSUS RADICAL CYSTECTOMY FOR MUSCLE INVASIVE BLADDER CANCER - A MARKOV MICROSIMULATION MODEL

Diana Magee¹, Douglas Cheung¹, Amanda Hird¹, Srikala Sridhar², Padraig Warde³, Charles Catton³, Alejandro Berlin³, Peter Chung³, Alexandre Zlotta⁴, Neil Fleschner⁴, Girish Kulkarni⁴

¹ Division of Urology, Department of Surgery, University of Toronto, ² Division of Medical Oncology, Department of Internal Medicine, University Health Network, University of Toronto, ³ Department of Radiation Oncology, University Health Network, University of Toronto, ⁴ Division of Urology, Department of Surgery, University Health Network, University of Toronto

Presented By: Diana Magee

Introduction: Radical cystectomy (RC) is the historically accepted gold standard treatment for muscle invasive bladder cancer (MIBC), but trimodal therapy (TMT) has emerged as a valid therapeutic option. These two modalities however have not been directly compared. Therefore, we created a decision model assessing the effectiveness of TMT and RC using decision analysis methods.

Methods: A two-dimensional Markov microsimulation model was constructed using TreeAge Pro to compare RC and TMT for patients with newly diagnosed MIBC (Figure 1). Model probabilities and utilities were derived from published literature. Our primary outcome was quality adjusted life expectancy (QALE). Secondary outcomes included crude life expectancy (LE), and bladder cancer recurrences in the TMT arm. Markov cycle length was dynamic to mimic actual clinical practice. The base case for our model was an adult patient with MIBC (pT2-4 N0 M0) considered appropriate for either RC or TMT. Individual level sampling was completed for age, gender, and reconstruction type (ileal conduit vs neobladder) assigned in the RC arm.

Results: TMT was the preferred modality with an estimated mean QALE of 7.49 (95%CI: 6.89-7.86) versus 7.41 (95%CI: 6.95-7.86) for RC but mean LE for patients treated with TMT was lower (10.21 years, 95%CI: 9.3-10.7) compared with RC (10.74 years, 95%CI: 10.0-11.4). A sensitivity analysis evaluating the impact of age showed that younger patients treated with RC had greater QALE and longer LE than those treated with TMT. However, inverse findings were observed for elderly patients (Table 1). Overall, 39.4% of patients in the TMT arm experienced a bladder recurrence with 27% undergoing a salvage cystectomy.

Conclusion: Our study suggests that RC provides more unadjusted life years than TMT (0.53 years), but lower quality of life (-0.08). Differences in treatment preference were dependent on age. The younger patients are, the more likely they are to benefit from the oncological control derived from RC.

Table 1: Sensitivity analysis evaluating impact of starting age of patients in the microsimulation

<table>
<thead>
<tr>
<th>Starting Age of Patients</th>
<th>TMT (QALE)</th>
<th>RC (QALE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>45</td>
<td>8.26±11.56</td>
<td>8.45±12.87</td>
</tr>
<tr>
<td>55</td>
<td>8.10±11.20</td>
<td>8.13±12.17</td>
</tr>
<tr>
<td>65</td>
<td>7.68±10.45</td>
<td>7.57±11.68</td>
</tr>
<tr>
<td>75</td>
<td>6.67±8.97</td>
<td>6.41±9.13</td>
</tr>
<tr>
<td>85</td>
<td>5.58±7.43</td>
<td>5.19±7.26</td>
</tr>
</tbody>
</table>

QALE: quality adjusted life expectancy; LE: life years; TMT: trimodal therapy; RC: radical cystectomy
126. DISCOVERY OF A GENOMIC CLASSIFIER FOR PREDICTING CLINICALLY AGGRESSIVE LUMINAL BLADDER TUMORS WITH HIGHER RATES OF PATHOLOGICAL UPSTAGING

Yair Lotan1, Joep de Jong2, Joost Boormans2, Yang Liu3, Elai Davicioni3, Ewan Gibb3, Stephen Boorjian4, Trinity Bivalacqua5, Sima Porten5, Thomas Wheeler6, Seth Lerner7, Robert Svatek8, Peter Black9

1 University of Texas Southwestern Medical Center at Dallas, 2 Erasmus MC Cancer Institute, 3 Decipher Biosciences, 4 Mayo Clinic, 5 John Hopkins Medical Institute, 6 University of California San Francisco, 7 Baylor College of Medicine, 8 University of Texas Health San Antonio, 9 Vancouver Prostate Centre

Presented By: Yair Lotan

Introduction: Urothelial carcinoma (UC) of the luminal molecular subtype is associated with a lower rate of pathological upstaging from clinical stage T1-T2 to non-organ-confined (NOC; ≥pT3/pTanyN1-3) disease at radical cystectomy (RC). This suggests that neoadjuvant chemotherapy (NAC) may not be necessary in patients with luminal UC. However, approximately one-third of luminal UC were upstaged to NOC disease, and these patients may be undertreated if NAC is not administered. We therefore evaluated whether a refined model could be trained to accurately predict luminal NOC disease in cases diagnosed with clinically organ-confined (OC, cT1/T2) disease.

Methods: Microarray data was analyzed from bladder tumor specimens resected transurethrally (TURBT) in 206 patients with high grade cT1-T2 N0M0 UC who subsequently underwent RC without NAC. The primary endpoint was upstaging to NOC (≥pT3Nany/pTanyN1-3) in tumors of the luminal subtype that were selected using the Seiler 2017 genomic subtyping classifier (n=100). The luminal subset was randomly split into training (n=75) and testing (n=25) sets for the development of a single-sample luminal upstaging classifier (LUC) to predict upstaging to NOC disease at RC using lasso/ridge-penalized logistic regression. Differential signature/hallmark expression was conducted for identification of biological differences between luminal NOC and luminal OC disease.

Results: Upstaging to NOC occurred in 34% of luminal patients. The novel LUC further stratified luminal tumors predicting upstaging in 32/34 cases, with 6 false positives. The sensitivity for detection of luminal pN+ disease was 95% (20/21). On multivariable analysis, the LUC was found to be significantly associated with risk of upstaging (p<0.001) after adjusting for clinical variables (e.g., age, sex and smoking status) available at TURBT. Patients with predicted luminal NOC tumors had worse survival than the other luminal UC patients (p=0.001). Biologically, luminal NOC tumors had higher tumor purity (p=0.018), coupled with lower immune signature scores (p=0.05). A highly active metabolic state, as suggested by hallmark scores for mTORC1 signaling (p=0.006), unfolded protein response (p=0.026) and glycolysis (p=0.055), was seen for luminal NOC tumors.

Conclusion: A LUC was developed which distinguishes subsets of cT1-T2N0M0 luminal UC patients who are at higher risk of upstaging to NOC at RC, and mortality. Validation of this model in an independent large patient cohort is necessary to determine how molecular stratification of luminal tumors could be used to guide treatment of these patients.
127. PROGNOSTIC SIGNIFICANCE OF PERIVESICAL LYMPH NODE STATUS IN PATIENTS WITH MUSCLE-INVASIVE BLADDER CANCER UNDERGOING RADICAL CYSTECTOMY

Ghalib Jibara¹, Melissa Assel¹, Nathan Wong¹, Cristina Falavolti¹, Chun Huang¹, Nima Almassi², Daniel Sjoberg¹, Nicole Benfante¹, Hikmat Al-Ahmadie¹, Guido Dalbagni⁴, Andrew Vickers¹, Eugene Cha¹, Bernard Bochner¹, Shawn Dason⁵, Victor McPherson⁶, Lucas Dean⁷

¹ Memorial Sloan Kettering Cancer Center, ² The Ohio State University, ³ McGill University, ⁴ University of Alberta

Presented By: Ghalib Jibara

Introduction: Although the prognostic significance of pelvic lymph node metastasis at radical cystectomy is well described, the implications of positive perivesical nodes is less clear. Herein, we investigated the prognostic significance of perivesical nodal metastases detected at cystectomy.

Methods: We retrospectively reviewed patients who underwent radical cystectomy and packeted pelvic lymph node dissection at our institution between 2000 and 2015, excluding patients with locally advanced disease or who received non-standard preoperative systemic therapies. Nodes identified in the en bloc cystectomy specimen following node dissection were defined as perivesical. We calculated survival outcomes by nodal status and location (perivesical vs other pelvic) and compared hazard ratios for number of positive nodes by location.

Results: Of the 2,197 patients included, a median of 19 (IQR 12, 28) lymph nodes were removed, with 397 (18%) patients having nodal metastasis. The majority of node-positive patients had only positive pelvic nodes (306, 77%), while 29 (7%) had only positive perivesical nodes and 62 (16%) had both. Among node-positive patients, there was similar recurrence-free or overall survival based on location (log-rank p=0.4, and 0.8, respectively). For every additional positive node, the risk of recurrence (adjusted for consensus T-stage) was also similar regardless of location (HR 1.20 vs 1.09, p >0.2).

Conclusion: Positive perivesical lymph nodes identified at time of cystectomy carry similar prognostic implications as positive pelvic nodes found during templated packeted lymphadenectomy. Although infrequently found in the absence of positive pelvic nodes, the identification and reporting of perivesical nodes improves staging and can help guide use of adjuvant therapies to improve patient outcomes.

Funding: This research was supported by the Sidney Kimmel Center for Prostate and Urologic Cancers and funded in part through the NIH/NCI Cancer Center Support Grant P30 CA008748.
128. VALIDATION OF COBRA NOMOGRAM IN THE CANCER GENOME ATLAS (TCGA) BLADDER CANCER COHORT
Meera Chappidi1, Maxwell Meng1, Sima Porten1, Christopher Welty2, Woonyoung Choi3
1 UCSF, 2 NorCal Urology, 3 Johns Hopkins Medical Institutions
Presented By: Meera Chappidi

Introduction: Clinical nomograms can improve risk stratification and allow for earlier identification of candidates for adjuvant therapies and clinical trials following radical cystectomy (RC). The utility of clinical nomograms in The Cancer Genome Atlas (TCGA) bladder cancer cohort, which contains robust molecular subtype data for patients, has not been studied. Our objective was to validate the Cancer of the Bladder Risk Assessment (COBRA) score in the TCGA cohort and determine its clinical utility within the different molecular subtypes of bladder cancer.

Methods: Among the TCGA bladder cancer cohort (n=412), RC pathology reports were reviewed to determine number of lymph nodes removed, positive lymph nodes, and tumor T stage to calculate COBRA scores. Patients with missing data were excluded from analyses. The distribution of patient demographics and COBRA scores by molecular subtype were compared using the Chi-squared test. Kaplan-Meier survival curves were plotted by COBRA score in the overall cohort and within molecular subtypes. Univariable and multivariable Cox proportional hazard models were used to determine the clinical utility of the COBRA score to predict overall survival (OS) within the overall cohort and within each molecular subtype (if n>30 within subtype).

Results: The analytic cohort of 278 patients had median follow-up of 17.9 months. Within each molecular subtype the majority of patients had a COBRA score of 3 or 4 (Table 1). The luminal and luminal infiltrated subtypes had a trend towards higher COBRA scores with more patients having a COBRA score of 5 or higher. In survival analyses, higher COBRA score was associated with significantly worse 3-year OS (p=0.01) with COBRA 1 vs. COBRA 5 with rates of 63.1% [95% CI 44.9-76.7] vs. 11.7% [95% CI 8.3-38.2], respectively (Figure 1). In the overall cohort, higher COBRA score was associated with significant increased risk of death in univariable (HR=1.49 per point [PP] 95% CI [1.29, 1.72]) and multivariable models (HR=1.51 PP 95% CI [1.30, 1.75]) controlling for gender. This remained true in multivariable models stratified by molecular subtype for basal (HR=1.33 PP 95% CI [1.05, 1.68]), luminal infiltrated (HR=1.69 PP 95% CI [1.20, 2.39]), and luminal papillary (HR=1.59 PP 95% CI [1.23, 2.06]) tumors.

Conclusion: Our findings validate the COBRA score and its ability to predict OS following RC in the TCGA bladder cancer cohort. The predictive utility of the COBRA score remains within the molecular subtypes of bladder cancer, suggesting it can be used in conjunction with molecular subtyping information to help guide clinical decision-making following RC. The COBRA score is a simple, validated nomogram that clinicians can incorporate to improve risk stratification and allow for earlier identification of candidates for adjuvant therapies and clinical trials following RC.
129. ACTIVE CENTRALIZATION OF RADICAL CYSTECTOMY FOR BLADDER CANCER IN A UNIVERSAL HEALTHCARE SYSTEM: EARLY RESULTS FROM A CANADIAN ACADEMIC CENTER

Jan Rudzinski¹, Benjamin Beech¹, Niels-Erik Jacobsen¹, Eric Estey¹, Adrian Fairey¹, Sunita Ghosh², Scott North², Naveen Basappa², Michael Kolinsky³

¹ Division of Urology, Department of Surgery, University of Alberta, ² Medical Oncology, Department of Medicine, University of Alberta

Presented By: Jan Rudzinski

Introduction: Radical cystectomy for bladder cancer is a complex surgical oncology procedure. Accumulating data suggest variation in outcomes based on hospital and surgeon characteristics. Centralization of this procedure to high volume, fellowship-trained surgeons may improve clinical outcomes. High quality data examining the impact of radical cystectomy centralization are lacking. At the University of Alberta, radical cystectomy was centralized at a single institution and performed by 1 of 2 urologic oncologists starting in August 2013. Our objective was to compare outcomes of radical cystectomy before and after centralization of care.

Methods: A retrospective analysis of data from the University of Alberta Radical Cystectomy Database was performed. Eligible subjects were those with histologically proven urothelial carcinoma of the bladder (cTanyN1-3M0) undergoing curative intent surgery. Patients were classified into pre-centralization era (1994-2007; N=523) and post-centralization era (2013-present; N=134) cohorts for analyses. Pre-centralization era patients were treated by 1 of 11 urologic surgeons at 2 academic teaching hospitals. Post-centralization era patients were treated by 1 of 2 fellowship-trained urologic oncologists at 1 academic teaching hospital. Outcomes were overall survival, 90-day mortality rate, positive surgical margin (R1) resection rate, total number of lymph nodes evaluated, and 90-day blood product transfusion rate. The Kaplan-Meier method and multivariable regression analyses were used to analyze survival outcomes. Statistical tests were two-sided (p=0.05).

Results: The median follow-up duration in the pre- and post-centralization era was 33 months and 16 months, respectively. The predicted 2-year overall survival rate was 62% in the pre-centralization era and 84% in the post-centralization era (Log rank P=0.0007; multivariable HR 0.40, 95% CI 0.24 to 0.68, P<0.0001). Treatment in the post-centralization era was associated with lower 90-day mortality (6.3% versus 1.5%, multivariable OR 0.23, 95% CI 0.06 to 0.99, P=0.049), R1 resection (13.0% versus 1.5%; multivariable OR 0.07, 95% CI 0.01 to 0.51, P=0.009), and 90-day blood product transfusion (59% versus 6%, P<0.0001) as well as higher total number of lymph nodes evaluated (7 versus 30 lymph nodes, P<0.0001).

Conclusion: Surgical treatment in the post-centralization era was associated with superior survival, cancer control, and perioperative outcomes.
130. DOES GROSSLY COMPLETE TRANSURETHRAL RESECTION IMPROVE COMPLETE RESPONSE AFTER NEOADJUVANT CHEMOTHERAPY?
Rashed Ghandour, Daniel Wong, Samuel Cusin, Nirmish Singla, Yuval Freifeld, Ryan Hutchinson, Aditya Bagrodia, Arthur Sagalowsky, Vitaly Margulis, Yair Lotan, Solomon Woldu
UT Southwestern Medical Center
Presented By: Rashed Ghandour

Introduction: There is controversy regarding the benefit of a grossly complete transurethral resection of bladder tumor (TURBT) once the diagnosis of muscle-invasive bladder cancer (MIBC) has been made. Advocates for this approach suggest a higher complete response rate to neoadjuvant chemotherapy (NAC), while others suggest this can delay definitive therapy and subject the patient to risk of perforation for no clear benefit.

Methods: We retrospectively reviewed our institutional radical cystectomy (RC) database from 2011-2018 for patients who received a full course of cisplatin-based NAC for MIBC. Patients were excluded if they had non-muscle invasive or pure urothelial carcinoma, distant metastases at diagnosis, received preoperative radiotherapy, or had missing information on completeness of TURBT prior to NAC. Univariable and multivariable logistic regression analyses were performed to identify factors associated with complete response [pT0] or non-muscle invasive residual cancer [<pT2] following NAC based on clinicopathologic characteristics and grossly complete or incomplete TURBT.

Results: A total of 548 patients underwent an RC in our institution during the study period and were screened for inclusion. Of those, 167 patients received NAC followed by RC for MIBC and 100 patients satisfied the inclusion criteria. TURBT was described as complete in 49 patients (49%), and incomplete in 51 patients (51%) prior to initiation of NAC. There were no significant differences in baseline clinicopathologic characteristics between patients who had a complete or incomplete TURBT before NAC. At the time of RC, the overall pT0 rate was 25%, while the overall rate of non-muscle invasive disease was 75%. On logistic regression, there was no association between completeness of TURBT and response to NAC. Age, histology, and organ confined cancer were not significantly associated with response to NAC. Only the smoking status (current or prior history) was negatively associated with pathologic complete response on univariable (OR= 0.35, 95% CI: [0.14-0.88], p=0.026) and multivariable analysis (OR= 0.36, 95% CI: [0.14-0.91], p=0.031) (Tables 1 and 2).

Conclusion: We found no association between pT0 following TURBT and cisplatin-based NAC and completeness of TURBT in a cohort of MIBC patients. The negative finding suggests that tumor biology is likely the most relevant factor predicting pT0 rates at RC, and confirms that clinical staging is inadequate and that our perception of complete TURBT might be incorrect.
131. DETAILED CADAVERIC ANALYSIS FOR PERIVESICAL LYMPH NODES WITH POTENTIAL IMPLICATIONS IN BLADDER CANCER
Muhammad Alsyouf¹, Phillip Stokes¹, Mohammad Hajiha¹, Jason Groegler¹, Akin Amasyali¹, Herbert Ruckle¹, Brian Hu¹, Laura Denham²
¹Loma Linda University, Department of Urology, ²Loma Linda University, Department of Pathology
Presented By: Muhammad Alsyouf

Introduction: Perivesical lymph nodes were added to the 8th edition of AJCC staging for bladder cancer. In pN+ patients, positive perivesical lymph nodes are associated with even worse overall survival. Perivesical lymph nodes are inconsistently evaluated at the time of radical cystectomy and can be difficult to differentiate from perivesical fat. Currently, no studies have detailed the presence or anatomic location of perivesical lymph nodes.

Methods: Six un-embalmed cadavers (4 male, 2 female) with no prior pelvic malignancy or surgery were utilized. An open radical cystectomy was performed on all specimens with wide resection of perivesical tissue and meticulous care to separate the pelvic lymph nodes (e.g. obturator, external iliac) from the specimen. Due to the amount of perivesical fat, the specimens were fixed in a lymph node revealing solution (95% ethanol, diethyl ether, glacial acetic acid, buffered formalin) for 6 hours. Perivesical tissue dissection in 2 mm slices was performed. Lymph node identification and examination were performed grossly and microscopically in conjunction with a board-certified pathologist. Perivesical lymph node size and location in relation to bladder wall was recorded.

Results: Gross lymph nodes were identified in the perivesical tissue in 50% (3/6) of the specimens, with a total of 6 lymph nodes identified. The mean lymph node size was 7.5 mm (range 2-16 mm). The mean distance from bladder wall was 9 mm (range 3-15 mm). Ten potential anatomic locations for the perivesical lymph node location were developed: urachal, anterior bladder wall, posterior peritoneum, peri-prostatic/bladder neck, and bilateral peri-pedicile, bilateral peri-seminal vesicle, bilateral lateral bladder wall. Lymph nodes were identified in the following locations (Table): Right peripedicle (2 nodes), left lateral bladder wall (2 nodes), posterior peritoneum (1 node), anterior bladder wall (1 node). On histologic analysis, a total of 4 of the 6 (66%) grossly identified lymph nodes had confirmed lymphoid tissue.

Conclusion: In a cadaveric model with meticulous dissection, gross and histologically-confirmed lymph nodes were identified in the perivesical space in half of patients. When present, patients had an average of two lymph nodes that were distributed around the bladder and within 15mm of the bladder wall. This data, as well as the inclusion of perivesical lymph nodes in AJCC staging, argues for thorough evaluation of the radical cystectomy specimen for perivesical lymph nodes.
132. INTERIM ANALYSIS OF PHASE I CLINICAL TRIAL OF INTRAVESICAL ONCOlytic MEASLES VIRUS PRIOR TO RADICAL CYSTECTOMY FOR UROTHELIAL CARCINOMA

Tanner Miest, Shruthi Naik, Kevin Panikh, Stephen Boorjian, R. Jeffrey Karnes, R. Houston Thompson, Igor Frank, Matthew Tollefson, Paul Young, Bradley Leibovich
Mayo Clinic

Presented By: Tanner Miest

Introduction: Oncolytic virotherapy is a compelling experimental approach to achieve direct tumor lysis and stimulation of host adaptive immunity against tumor neoantigens. Here we describe interim results of a Phase 1 study designed to determine the tolerability, feasibility and preliminary efficacy of oncolytic measles virus (MV-NIS) after neoadjuvant intravesical administration prior to radical cystectomy (RC) for urothelial carcinoma (UC).

Methods: We initiated a phase 1 trial using MV-NIS as neoadjuvant therapy prior to RC for both non-muscle invasive and muscle invasive UC. A dose of 1x10^9 TCID/50 was instilled into the bladder as either a single dose or as two biweekly doses prior to RC. Patients receiving prior neoadjuvant cisplatin-based chemotherapy were excluded. Interim correlative studies include pRT-PCR for MV in voided urine samples and characterization of pre- and post-treatment immune cell infiltrate and pathology downstaging.

Results: Six patients have been treated to date with intravesical MV-NIS prior to RC, four with single dose treatments and two with dual treatments. No adverse events or dose limiting toxicities have been attributed to MV-NIS treatments. MV RNA was detectable in voided urine samples for up to two weeks after virus treatment. No infectious virus was recovered in the urine at any timepoint after MV-NIS treatment. Significant post-treatment lymphocytic tumor infiltrates were observed in residual UC tissue at the time of RC that were not observed in pretreatment UC biopsy samples. Four of six patients receiving MV-NIS had disease downstaging at RC, with both dual treatment patients having no residual disease at RC.

Conclusion: This Phase I clinical trial aims to determine the safety and efficacy of intravesical neoadjuvant MV-NIS in patients with UC of the bladder. Interim analysis of the first six patients show that treatment is well tolerated without dose limiting toxicities. MV RNA is detectable in the urine of treated patients for up to two weeks after treatment, and pathology downstaging at the time of RC has been observed for both non-muscle invasive and muscle invasive UC after MV-NIS treatment. With a planned accrual of 16 patients and future correlative studies, the relationship between MV-NIS treatment and UC disease response, as well as intratumoral immune activation, will be better elucidated.

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133. THE IMPACT OF URETERAL STENT VS NEPHROSTOMY TUBE PLACEMENT PRIOR TO RADICAL CYSTECTOMY ON POST-CYSTECTOMY UPPER TRACT UROTHELIAL CARCINOMA RATES

Vidit Sharma¹, Tanner Miest², Luca Boeri², Prabin Thapa², Matthew K Tollefson², R. Houston Thompson², Stephen A Boorjian², Igor Frank², R. Jeffrey Karnes²

¹ UCLA, ² Mayo Clinic

Presented By: Vidit Sharma

Introduction: Patients with hydronephrosis prior to radical cystectomy for urothelial carcinoma are variably treated with observation, ureteral stent, or nephrostomy tube. A recent study found that retrograde ureteral stent drainage in this setting was associated with a higher rate of post-cystectomy upper tract urothelial carcinoma (UTUC) compared to nephrostomy tube drainage. However, other large institutional studies are needed to corroborate these findings before they can be generalized and used to change management.

Methods: Patients undergoing radical cystectomy for bladder cancer for urothelial carcinoma (without prior UTUC) at our institution from 2000-2015 were identified. Pre-operative hydronephrosis and pre-operative upper tract drainage were assessed. The cohort of 1049 radical cystectomies was stratified into four groups: 1) no hydronephrosis (75%, N=787); 2) hydronephrosis without upper tract drainage (13%, N=132); 3) hydronephrosis treated with nephrostomy tube (3%, N=36); 4) hydronephrosis treated with ureteral stent (9%, N=94). The risk of UTUC post-cystectomy was compared using Kaplan-Meier analyses and multivariable Cox proportional hazard modeling. The risk of relevant complications was assessed using chi-square analyses and multivariable logistic regressions.

Results: In a cohort of 1049 radical cystectomies with a median follow up for survivors of 4.3 (interquartile range 1.2 – 8.4) years after cystectomy, the 5-year post-cystectomy UTUC rate was 6.6%, 10.2%, 17%, 18.7% for groups 1-4, respectively (p=0.127). After adjusting for age, comorbidities, tumor stage, nodal stage, neoadjuvant chemotherapy, lymphvascular invasion, margins, and year, multivariable Cox proportional hazard modeling found that relative to patients without pre-operative hydronephrosis, patients with hydronephrosis without upper tract drainage (hazard ratio (HR) 1.31, 1.08 -1.58, p=0.01) and hydronephrosis with percutaneous nephrostomy tubes (HR 1.49, 1.06-2.09, p=0.02) had higher post-cystectomy UTUC rates. Patients with hydronephrosis and a ureteral stent did not have higher post-cystectomy UTUC rates relative to patients without hydronephrosis (HR 0.90, 0.72 -1.12, p=0.33). The incidence of ureteroenteric anastomotic stricture and/or anastomotic leak did not differ significantly between groups (8.5%, 9.2%, 8.3%, 10.6%, respectively, p=0.918) and neither did the incidence of pyelonephritis (14.5%, 14.4%, 8.3%, 14.9%, respectively, p=0.778). Pre-operative hydronephrosis or upper tract drainage method did not emerge as a significant predictor for these complications on multivariable logistic regression analysis.

Conclusion: Pre-operative hydronephrosis was confirmed to be a risk factor for UTUC after radical cystectomy. However, after accounting for hydronephrosis, ureteral stent placement for managing hydronephrosis did not increase the risk of UTUC after cystectomy. The higher rate of UTUC seen with nephrostomy tube placement likely reflects higher underlying degree of obstruction from the primary tumor and other unmeasured confounders. Importantly, the method of upper tract drainage did not impact the incidence of ureteroenteric anastomotic complications or upper tract urinary infections. Thus, our data does not support the preferential use of either percutaneous nephrostomy tube placement or ureteral stent placement for hydronephrosis prior to radical cystectomy.
134. EARLY COMPLICATIONS AS A RESULT OF INDIANA POUCH URINARY DIVERSION: A 7 YEAR EXPERIENCE
Indiana University School of Medicine
Presented By: Ryan Speir

Introduction: Complication rates following cystectomy range from 40-80% with 75% of complications being related to the urinary diversion. Reported complication following continent cutaneous urinary reservoir creation has been reported to be higher than either ileal conduit or orthotopic neobladder creation. We sought out to describe the most recent 7 year experience with 137 consecutive Indiana pouch patients at a single institution. Our goal was to provide updated data on early complications with this type of urinary diversion during the first postoperative year.

Methods: Our prospectively maintained bladder cancer database was queried to identify all patients who underwent cystectomy who subsequently underwent an Indiana pouch continent urinary reservoir creation between 2012 -2018. Perioperative, intraoperative, and postoperative data were collected. The primary outcome was complication requiring readmission occurring during the first postoperative year. Secondary outcomes included rates of reoperation, pouch stones, febrile urinary tract infections, and overall mortality.

Results: 137 patient during the time period underwent cystectomy with Indiana pouch creation. 93% were radical cystectomies. Overall 54 (39%) patients suffered a complication during the first postoperative year. Intraoperative complications occurred in 3 (2.3%) patients. 41 (30%) of patients required readmission for various reasons including sepsis from urinary source, leak, wound infection, need for reoperation, and enterocutaneous fistula management. 15% of patients were treated for recurrent uncomplicated UTIs while 8% developed complicated UTIs requiring admission for intravenous antibiotics. Only 2 (1.5%) patients developed pouch or renal stones and 5 (3.6%) patients required stomal revisions. 23 patients (17%) required reoperation for multiple reasons including bowel perforations/leak, enterocutaneous fistula takedowns, ureteral strictures, and completion pelvic exenterations/urethrectomies. The overall one-year mortality rate for all causes was 3.7%.

Conclusion: Patients undergoing cystectomy with Indiana pouch urinary reservoir creation appear to have similar complications rates overall when compared with ileal conduit or orthotopic neobladder creation during the first postoperative year.
INTRODUCTION: Enhanced recovery protocols have reduced inpatient length of stay among cystectomy patients. A small subset of patients undergoing these pathways appear to have very rapid recovery and achieve discharge milestones within 48-72 hours of surgery. We report our experience with post-operative day (POD) 2 and 3 hospital discharge following radical cystectomy (RC) for bladder cancer.

METHODS: A prospectively maintained institutional database was used to identify patients undergoing RC for bladder cancer. A multi-faceted enhanced recovery protocol was implemented in October 2016. On this protocol, hospital discharge criteria included return of bowel function, tolerance to soft oral diet, adequate pain control with oral agents, demonstrated mobility, and fluency with stoma appliance or pouch irrigation. Clinical characteristics and perioperative outcomes of patients discharged on POD 2-3 were compared to those discharged POD 4 or later using Fisher exact and Wilcoxon rank sum tests.

RESULTS: A total of 264 patients underwent RC between October 2016 and May 2018. Of these, 33 (12.5%) patients were discharged on or before POD 3, including 8 (3.0%) patients discharged on POD 2. The only between-group difference observed in baseline characteristics was a higher pre-operative albumin in the early discharge group (median 4.3 [IQR 4.0-4.5] g/dL vs 4.1 [3.9-4.3] g/dL, p=0.01). Intraoperatively, early discharge patients were more likely to receive fully robotic cystectomy with intracorporeal diversion (87.9% vs 41.6%, p<0.0001) and had shorter operative duration (median 359 [IQR 336-396] minutes vs 405 [345-466] minutes, p=0.006). As shown in Table 1, the early discharge cohort had a lower readmission rate (p = 0.007), lower complication rate (p = 0.0002) and lower major complication rate (p = 0.002) than the traditional discharge cohort.

CONCLUSION: We report a subset of patients undergoing RC with an enhanced recovery pathway who define the ideal post-operative course. This cohort is ready for discharge within 48-72 hours of surgery and experiences low readmission and complication rates. These patients overwhelmingly undergo robotic cystectomy with intracorporeal diversion. As the urologic community strives to optimize outcomes for RC patients, this cohort should represent the target state that enhanced recovery pathways endeavor to achieve for all patients.

Table 1. Perioperative outcomes of patients undergoing radical cystectomy with early versus traditional hospital discharge.

<table>
<thead>
<tr>
<th></th>
<th>Discharge POD #2 or 3 (n=33)</th>
<th>Discharge POD #4 or later (n=231)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emergency room visits</td>
<td>6 (18.2)</td>
<td>28 (12.1)</td>
<td>0.40</td>
</tr>
<tr>
<td>Overnight 'observation' stays</td>
<td>2 (6.1)</td>
<td>9 (3.9)</td>
<td>0.63</td>
</tr>
<tr>
<td>Hospital Readmission</td>
<td>0 (0)</td>
<td>37 (16.02)</td>
<td>0.007</td>
</tr>
<tr>
<td>Any complication</td>
<td>3 (9.1)</td>
<td>94 (40.7)</td>
<td>0.0002</td>
</tr>
<tr>
<td>Major complication*</td>
<td>0 (0)</td>
<td>33 (14.3)</td>
<td>0.02</td>
</tr>
</tbody>
</table>

All outcomes are within 30-days from hospital discharge, reported as n (%)  
POD=post-operative day  
* Major complication defined as Clavien 3 or higher
**136. COMPARING PROVIDER-LED SEXUAL HEALTH COUNSELING OF MALE AND FEMALE RADICAL CYSTECTOMY PATIENTS**

*Natasha Gupta¹, Lauren Kucirka¹, Phillip Pierorazio¹, Amin Herati¹, Trinity Bivalacqua¹, Alice Sererjlan²*  
¹Johns Hopkins University School of Medicine, ²IHA Urology/St. Joseph Mercy Hospital

**Presented By:** Natasha Gupta

**Introduction:** Sexual dysfunction is a common quality of life issue and source of symptom-induced distress among both male and female patients undergoing radical cystectomy (RC) for bladder cancer. Therefore, sexual health counseling (SHC) is an important part of the informed consent process for patients undergoing RC. While prior studies have demonstrated that patients undergoing RC report a lack of provider-led counseling about intimacy-related issues, specific deficiencies and differences in provider-led sexual health counseling of male and female patients have not been previously explored. Therefore, we sought to compare national practice patterns among urologists regarding counseling of male and female RC patients about sexual health topics in the preoperative and postoperative setting, with a particular focus on identifying specific areas of deficiencies, gender disparities, and barriers to counseling.

**Methods:** We conducted a national survey of members of the Society of Urologic Oncology to assess topics routinely included in sexual health counseling of male and female RC patients in the preoperative and postoperative setting as well as barriers to SHC of female patients. For each sexual health topic assessed, the frequency of non-routine SHC of preoperative and postoperative female versus male patients was compared using chi-squared tests.

**Results:** Overall, 168 of 723 members responded. The mean age was 44.6 ± 11.0 years, 7.8% were female, 69.6% completed a urologic oncology fellowship, and 68.1% were in academic practice. The median time in practice was 9 years (interquartile range [IQR]: 4-17). The median number of female RC's performed in the 12 months preceding the survey was 5 (IQR: 3-10). When comparing preoperative SHC of sexually active female versus male patients, the majority of providers did not routinely discuss sexual orientation (74.8% vs. 75.8%, respectively, p=0.9), partner sexual dysfunction (79.4% vs. 75.8%, respectively, p=0.8), or referral options to psychological and sexual health services (85.5% vs. 77.4%, respectively, p=0.6) (Figure 1). Preoperatively, providers were significantly more likely to not provide routine SHC to sexually active female versus male patients for specific topics, including baseline sexual dysfunction (60.8% vs. 20.8%, respectively, p<0.001), the risk of sexual dysfunction after RC (20.0% vs. 7.3%, respectively, p=0.01), and the potential for a nerve-sparing approach (70.8% vs. 36.0%, respectively, p=0.002) (Figure 1).

Additionally, 41.2% of urologists did not routinely inform sexually active female patients about the potential for pelvic organ-preserving RC. Postoperatively, providers were significantly more likely to not provide routine SHC to sexually active female patients compared to sexually active males (42.6% vs. 21.1%, respectively, p=0.01). Regarding provider-reported barriers to SHC of females, 67.0% listed older patient age, 62.3% said there was not enough time, and 49.1% listed uncertainty about patients’ baseline sexual function. However, 93.3% reported that SHC was within the scope of their practice.

**Conclusion:** We identified key deficiencies in SHC of male and female RC patients, specific disparities in provider-led sexual health counseling of female RC patients, and common provider-reported barriers to counseling female patients. Since RC has a significant impact on sexual health, it is critical to address these deficiencies and disparities by improving provider awareness and education about sexual health counseling and by addressing barriers to counseling female patients.

**Funding:** Greenberg Bladder Cancer Institute
137. UPDATED RESULTS OF PURE-01 WITH PRELIMINARY ACTIVITY OF NEOADJUVANT PEMBROLIZUMAB IN PATIENTS WITH MUSCLE-INVASIVE BLADDER CARCINOMA WITH VARIANT HISTOLOGIES

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1 Fondazione IRCCS Istituto Nazionale dei Tumori, 2 San Raffaele Hospital and Scientific Institute, 3 Foundation Medicine, 4 Polytechnic University of the Marche Region

Presented By: Andrea Necchi

Introduction: Patients with predominant variant histologies (pVH) of bladder tumors, usually defined as involving >50% of the tumor specimen, are typically excluded from clinical trials, and for these patients there is no standard neoadjuvant therapy, defining an unmet medical need. We aimed to evaluate the activity of neoadjuvant pembrolizumab in patients with muscle-invasive bladder carcinoma (MIBC) and variant histologies, enrolled within the PURE-01 study (NCT02736266).

Methods: In the PURE-01 study, 3 courses of 200 mg pembrolizumab, every 3 weeks, preceding radical cystectomy (RC) were administered in clinical T2-4aN0M0 MIBC. The amended study design included patients with pVH. Pathologic complete response (pT0) in intentio-to-treat population was the primary endpoint. Logistic regression models evaluated clinical variables (clinical T-stage and histology) and biomarkers in association with the pathologic response. Biomarker analyses included PD-L1 expression using the combined positive score (CPS, Dako 22C3 antibody) and comprehensive genomic profiling (FoundationONE assay).

Results: From 02/2017 to 06/2019, 114 patients have been enrolled: 34 (29.8%) presented with VH, including 19 (16.7%) with pVH (Figure). In total, the pT0-rate was 36.8% (95% confidence interval [CI]: 28-46.4) and the pT<=1 rate was 55.3% (95%CI: 45.7-64.6). The majority of pVH patients presented with squamous-cell carcinoma (SCC, N=7), and 6/7 (85.7%) had a downstaging to pT<=1, with one pT0; 2/3 lymphoepithelioma-like (LEL) variants had a pT0 response. None of the remaining 9 pVH had a response. On multivariable logistic regression analyses, tumor mutational burden (TMB) and CPS were associated with pT<=1 response (p=0.015 and p=0.032, respectively), together with the clinical T-stage (p=0.004), regardless of tumor histology (pVH: p=0.32; VH: p=0.92). Differences in genomic alterations between pVH and UC subgroups involved RB1 (36.8% vs 22.5%, respectively) and ERBB2 copy number alterations (25% vs 7.5%, respectively), whereas FGFR3 alterations were equally observed across the histologic subgroups: 15.5%, 13.3% and 17.5% in pVH, VH, and UC, respectively.

Conclusion: The updated PURE-01 results confirm the activity of neoadjuvant pembrolizumab in MIBC. Patients with SCC and LEL features should be considered for inclusion in neoadjuvant immunotherapy trials. PD-L1 CPS and TMB may predict the pathological response to pembrolizumab and provide a rationale for selecting patients according to these features instead of the histological bladder cancer subtypes. Furthermore, pVH tumors revealed different opportunities for targeted therapies and a non-overlapping genomic alterations landscape compared to UC or VH.

Funding: Merck
138. AN EVALUATION OF MONTHLY MAINTENANCE THERAPY AMONG PATIENTS RECEIVING INTRAVESICAL COMBINATION GEMCITABINE/DOCETAXEL FOR NON-MUSCLE INVASIVE BLADDER CANCER
Marcus Daniels¹, Emily Barry², Mark Schoenberg³, Trinity Bivalcqua⁴, Max Kates⁵, Alex Sankin⁶
¹ Johns Hopkins School of Medicine, ² Albert Einstein College of Medicine, ³ Montefiore Medical Center, ⁴ Johns Hopkins Medical Institutions, ⁵ Montefiore Medical Center

Presented By: Marcus Daniels

Introduction: Increasingly, intravesical chemotherapy with Gemcitabine/Docetaxel (GEM/DOCE) has been utilized in the salvage setting for non-muscle invasive bladder cancer (NMIBC). We sought to report our experience with sequential maintenance intravesical GEM/DOCE for patients with NMIBC.

Methods: Fifty-nine patients who received full GEM/DOCE for NMIBC between 2013 and 2018, per the protocol adapted from University of Iowa, were identified and characterized. Patients were treated with 6 weekly instillations of GEM/DOCE and subsequent monthly maintenance installations for those with no evidence of disease at 1st surveillance. Student’s t-test and χ² test were used to compare continuous and categorical variables as appropriate. For survival analyses, Kaplan-Meier (KM) curves were created to assess disease-free survival (DFS). Overall comparisons of KM survival analysis were conducted using the Wilcoxon test.

Results: Across all patients, median follow-up was 24 months. Sixty-six percent of patients received ≥2 intravesical induction therapies prior to receiving GEM/DOCE. Thirty-one patients (63%) failed ≥2 induction courses of BCG before receiving GEM/DOCE. Overall DFS was 48% at 1-year and 28% at 2-years. For patients who failed ≥1 induction courses of BCG, overall DFS was 48% at 1-year and 32% at 2-years. GEM/DOCE appears to be effective for therapy naïve and patients who have failed previous intravesical therapies (p=0.39). There were 41 (69.5%) patients who had no evidence of disease at 1st surveillance and were eligible for maintenance therapy. Among these patients, 24 were managed with observation alone and 17 with monthly maintenance. Median follow-up for observed patients was 36 months and 26 months for patients with maintenance. DFS at 1 year was 42% for observed patients and 81% for patients receiving maintenance (p=0.04). DFS at 2 years was 32% for observed patients and 59% for patients receiving maintenance therapy (p=0.45). For maintenance eligible patients who received ≥1 induction courses of BCG, DFS was 42% for observed patients and 81% for patients receiving maintenance therapy at 1 year and 34% for observed patients and 59% for patients receiving maintenance therapy at 2 years. Pathologic stage at recurrence was similar between observed patients and those receiving maintenance (p=0.83). KM analyses showed greater DFS for patients receiving maintenance therapy compared to observed patients (p=0.04).

Conclusion: Patients who demonstrate initial complete response to GEM/DOCE may benefit from maintenance GEM/DOCE.
139. REQUIRED EFFICACY FOR NOVEL THERAPIES IN BCG-UNRESPONSIVE NON-MUSCLE INVASIVE BLADDER CANCER: DO CURRENT RECOMMENDATIONS REALLY REFLECT CLINICALLY MEANINGFUL OUTCOMES?
Marian S. Wettstein1, Jaime O. Herrera-Caceres1, Ardalan Ahmad1, Michael A.S. Jewett1, Girish S. Kulkarni1, David Naimark2, Thomas Hermanns3
1 Division of Urology, Department of Surgery, Princess Margaret Cancer Centre, University Health Network, University of Toronto, Toronto, Ontario, Canada, 2 Division of Nephrology, Department of Medicine, Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada, 3 Department of Urology, University Hospital of Zurich, University of Zurich, Zurich, Switzerland
Presented By: Marian S. Wettstein

Introduction: Single-arm trials are currently an accepted study design to investigate the efficacy of novel therapies (NT) in non-muscle invasive bladder cancer (NMIBC) unresponsive to intravesical Bacillus Calmette-Guérin (BCG) immunotherapy as randomized controlled trials are either unfeasible (comparator: early radical cystectomy; ERC), or unethical (comparator: placebo). To guide the design of such single-arm trials, two expert groups (IBCG: International Bladder Cancer Group; FDA/AUA: United States Food and Drug Administration/American Association of Urology) published recommendations for clinically meaningful outcomes. The aim of this study was to quantitatively verify the appropriateness of these two recommendations.

Methods: We used a discrete simulation framework in combination with the infrastructure of a supercomputer to find the required efficacy at which a NT can compete with ERC when it comes to quality-adjusted life expectancy (QALE). Each sampled individual was modeled by distinct age, sex and tumor characteristics. Model inputs were obtained from systematic literature search. In total, 24 different efficacy thresholds (including the recommendations) were investigated. To account for the uncertainty of input parameters, each efficacy threshold was explored with 1000 probabilistic input sets.

Results: After ascertaining face validity with content experts, repeated verification, external validation, and calibration we considered our model as valid (see Figure 1). Both recommendations rarely showed an incremental benefit of the NT over ERC (see Figure 2). In the most optimistic scenario, an increase of the IBCG recommendation by 10% and an increase of the FDA/AUA recommendation by 5% would yield results at which a NT could compete with ERC from a QALE perspective.

Conclusion: This simulation study demonstrated that the current recommendations regarding clinically meaningful outcomes for single-arm trials evaluating the efficacy of NT in BCG-unresponsive NMIBC are too low. Based on our quantitative approach, we propose increasing these thresholds to at least 45-55% at 6 months and 35% at 18-24 months to promote the development of clinically truly meaningful NT.
140. PREDICTORS OF UPSTAGING AND SURVIVAL IN T1 UROTHELIAL CARCINOMA AFTER RADICAL CYSTECTOMY

Wesley Yip, Saum Ghodoussipour, Akbar Ashrafi, Jie Cai, Gus Miranda, Sumeet Bhanvadia, Hooman Djaladat, Anne Schuckman, Siamak Daneshmand
USC Institute of Urology
Presented By: Wesley Yip

Introduction: T1 urothelial carcinoma remains a complex disease to manage due to its clinical variability with high rates of recurrence and progression. Optimal treatment strategies are not well-defined, in part due to the difficulty in appropriate staging and risk stratification. As there is a significant difference between the management of nonmuscle invasive and muscle invasive disease, there is a need for a better understanding of the patients who can undergo conservative management and those who would be best treated with timely radical cystectomy. Thus, we sought to determine the clinical characteristics that are predictors of upstaging and survival in patients with pure T1 urothelial carcinoma undergoing radical cystectomy.

Methods: Our IRB-approved bladder cancer database was reviewed to identify patients who had undergone radical cystectomy for pure T1 urothelial carcinoma. Patients without detrusor muscle in transurethral resection specimens, variant histology, or any pathology worse than T1, were excluded. Univariate and multivariate analyses were used to determine predictors of upstaging, and Cox regression modeling was used to determine prognostic indicators of recurrence free survival (RFS).

Results: From 1984 to 2018, 261 patients with no worse than T1 urothelial carcinoma, with detrusor muscle included in their transurethral resection specimens, underwent radical cystectomy at our institution. Median age was 69 years, median follow-up was 4.7 years, 223 patients (85%) were male, and 203 patients (78%) underwent cystectomy within 1 year of diagnosis. The 5 year RFS rate was 80.3%. Our multivariate analysis revealed that lymphovascular invasion (LVI) (Odds Ratio (OR) 2.6, Confidence Interval (CI) 1.2-6.9), over 1 year from diagnosis to cystectomy (OR 3.8, CI 1.4-10.2), and intravesical chemotherapy (OR 3.9, CI 1.5-11.0) were associated with upstaging from nonmuscle invasive to muscle invasive disease at the time of cystectomy. BCG therapy was associated with less risk of upstaging (OR 0.61, CI 0.3-1.4), and waiting between 3 months to 1 year from diagnosis to cystectomy had no statistically significant effect (OR 1.5, CI 0.7-2.9). Our Cox regression model revealed that female sex (Hazard Ratio (HR) 2.3, CI 1.0-5.0), Charlson Comorbidity Index (HR 3.2, CI 1.8-5.7), more than 5 transurethral resections (HR 3.8, CI 1.4-10.1), cystectomy after 1 year from diagnosis (HR 2.5, CI 1.5-4.4), upstaging at cystectomy (HR 2.1, CI 1.2-3.6), extravesical disease (HR 8.7, CI 4.1-18.9), lymph node positivity (HR 7.7, CI 3.1-19.3), and LVI (HR 2.2, CI 1.1-4.5) were all associated with worse RFS.

Conclusion: While the optimal management of T1 urothelial carcinoma remains debatable, our contemporary series of patients with confirmed T1 disease with muscle in their resection specimens elucidates several variables that are predictors of upstaging and survival. These factors can be useful in counseling patients and updating our guidelines to better identify high-risk disease. Moreover, our data suggests that timely cystectomy may be of benefit in this population.
141. SURVIVAL OUTCOMES OF HIGH RISK NON-MUSCLE INVASIVE BLADDER CANCER VERSUS DOWNSTAGED MUSCLE INVASIVE BLADDER CANCER AT THE TIME OF CYSTECTOMY

Shagnik Ray¹, Marcus Daniels¹, Aaron Brant², Anthony De Felice³, Esther Lee³, Trinity Bivalacqua³, Max Kates³
¹ James Buchanan Brady Urological Institute at the Johns Hopkins University School of Medicine, ² Weill Cornell Medicine Urology, ³ James Buchanan Brady Urological Institute at the Johns Hopkins University

Presented By: Shagnik Ray

Introduction: Introduction: Neoadjuvant chemotherapy has been shown to improve overall survival in patients who undergo cystectomy for muscle invasive bladder cancer (MIBC). To date, it is unclear whether select patients with high-risk non-muscle invasive bladder cancer (HR NMIBC) could benefit from NAC. In this study, we analyze recurrence and survival post-cystectomy outcomes for HR NMIBC, MIBC responsive to NAC, and MIBC responsive to TURBT. We additionally analyze risk factors for recurrence in patients with HR NMIBC.

Methods: Methods: We performed a retrospective review of our institution’s cystectomy database from database inception in February 2000 to August 2019 to identify patients with pN0 and pT0, pTa, pT1, or pTis urothelial carcinoma on cystectomy pathology. Comparisons were made between patients with HR NMIBC, MIBC that downstaged with NAC, and MIBC that downstaged with TURBT without NAC. Kruskal Wallis and Chi-Squared tests were used to compare continuous and categorical variables respectively. Log Rank and Cox Regression tests were used to analyze recurrence-free and overall survival outcomes for all three groups.

Results: Results: We identified 512 patients with pN0 and pT0, pTa, pT1, or pTis urothelial cell carcinoma on cystectomy pathology. 249 patients had clinical HR NMIBC that remained pathologic NMIBC on cystectomy, 190 patients had MIBC that downstaged with NAC, and 73 patients had MIBC that downstaged with TURBT without NAC. Patients with HR NMIBC, MIBC downstaged with NAC, and MIBC downstaged with TURBT without NAC had significantly different times to cystectomy (685.25 months, 297.18, 283.72, p<0.001), rates of intravesical therapy (73.39%, 15.26%, 18.06, p=0.001), rates of pathologic T stage pT0 (15.26%, 45.79%, 45.21%, p<0.001), rates of carcinoma in situ (CIS) (67.07%, 45.79%, 49.32%, p<0.001), and rates of tumor size > 2 cm (62.65%, 36.84%, 36.99%, p<0.001). Location of recurrence was not significantly different between groups (p=0.834). Kaplan-Meier curves comparing overall survival and recurrence-free survival for each patient group are shown in Figure 1. Of note, HR NMIBC patients had significantly different recurrence-free survivals compared with MIBC downstaged with NAC and MIBC downstaged with TURBT respectively (p=0.004, p=0.014 respectively), but did not have significantly different overall survival (p=0.078, p=0.386 respectively). The MIBC groups were not significantly different in terms of recurrence-free and overall survival (p=0.576 and p=0.752 respectively).

The results of Cox Regression analysis for patients with HR NMIBC are depicted in Table 1. Of note, age at cystectomy (HR=1.0351,p=0.032), time to cystectomy (HR=1.0005,p=0.003), and lack of intravesical therapy (HR=2.308,p=0.017) predicted recurrence while age at cystectomy (HR=1.0460,p=0.004) and smoking (HR=1.2713,p=0.019) predicted death.

Conclusion: Conclusions: Patients from our cohort with HR NMIBC had worse post-cystectomy outcomes relative to MIBC downstaged with NAC or with TURBT without NAC in terms of recurrence-free survival but did not have significantly different overall survival. Patients with NAC responsive and TURBT responsive MIBC had similar recurrence-free and overall survival outcomes. Further work is needed to determine why certain patients with HR NMIBC recur more frequently than downstaged MIBC patients and whether NAC can be useful in certain settings for patients with HR NMIBC.

Table 1: Cox Hazard Analysis for Patients with High Risk Non-Muscle Invasive Bladder Cancer

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Hazard Ratio</th>
<th>p-value</th>
<th>Hazard Ratio</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at Cystectomy</td>
<td>1.051</td>
<td>0.032</td>
<td>1.060</td>
<td>0.004</td>
</tr>
<tr>
<td>BMI</td>
<td>0.967</td>
<td>0.232</td>
<td>0.967</td>
<td>0.229</td>
</tr>
<tr>
<td>Time to Cystectomy</td>
<td>1.0005</td>
<td>0.003</td>
<td>1.009</td>
<td>0.001</td>
</tr>
<tr>
<td>Female Sex</td>
<td>0.932</td>
<td>0.761</td>
<td>0.926</td>
<td>0.186</td>
</tr>
<tr>
<td>Non-White Race</td>
<td>0.959</td>
<td>0.940</td>
<td>1.1447</td>
<td>0.331</td>
</tr>
<tr>
<td>Smoking</td>
<td>1.1594</td>
<td>0.248</td>
<td>1.2725</td>
<td>0.019</td>
</tr>
<tr>
<td>Charlson ≥ 3</td>
<td>0.6186</td>
<td>0.219</td>
<td>1.2875</td>
<td>0.407</td>
</tr>
<tr>
<td>Intravesical Therapy</td>
<td>0.4832</td>
<td>0.017</td>
<td>0.7439</td>
<td>0.298</td>
</tr>
<tr>
<td>Path T Stage pT0</td>
<td>0.4347</td>
<td>0.077</td>
<td>0.5571</td>
<td>0.352</td>
</tr>
<tr>
<td>Carcinoma In Situ</td>
<td>0.5574</td>
<td>0.084</td>
<td>0.7000</td>
<td>0.253</td>
</tr>
<tr>
<td>Tumor Size &gt; 2cm</td>
<td>0.9574</td>
<td>0.843</td>
<td>1.3696</td>
<td>0.302</td>
</tr>
</tbody>
</table>

Figure 1: Kaplan-Meier Curves comparing HR NMIBC, NAC Responsive MIBC, and TURBT Responsive MIBC in terms of overall survival and recurrence free survival.
142. MANAGEMENT OF HISTOLOGIC VARIANTS IN NON-MUSCLE INVASIVE BLADDER CANCER

Kris Prado, Daniel Greenberg, Andrew Sun, Eila Skinner
Stanford University School of Medicine

Presented By: Kris Prado

Introduction: Histologic variants in non-muscle invasive bladder cancer have been associated with a worse prognosis compared to pure urothelial carcinoma (UC). The 2016 update of the World Health Organization (WHO) pathology guidelines for classification of bladder tumors emphasized the reporting of histologic variants. However, it is unclear if modern classification of histologic variants has the same clinical significance as seen in prior studies. The purpose of this study is to determine if variant histology, as defined by current WHO guidelines, in patients with NMIBC is associated with a higher recurrence rate after treatment with Bacillus Calmette-Guérin (BCG) compared to UC.

Methods: We retrospectively reviewed the charts of 347 patients with high grade Ta or T1 bladder tumor pathology (with or without carcinoma in situ) reviewed between January 2013 and March 2018. We included patients who had transurethral resection of bladder tumor (TURBT) pathology that was reviewed by Stanford Health Care. Patients were excluded if they did not have any follow-up records, if a restaging TURBT was upgraded to muscle-invasive disease, or if the pathology was not reviewed by Stanford Health Care. Patients with variant histology were identified from TURBT pathology and were compared to those with UC, and the outcomes measured were recurrence-free survival after treatment with BCG as well as cystectomy-free survival.

Results: Of the 347 patients included in this study, 59 patients had variant histology, and 288 patients had UC, with mean follow up of 1.9 and 2.1 years, respectively. Of the patients with variant histology, 14 (23.7%) patients had more than one variant present, and this mixed histology group was the most common among the variant histology group. The remaining histologic variants consisted of squamous (9, 15.3%), glandular (8, 13.6%), micropapillary (7, 11.9%) plasmacytoid (7, 11.9%), sarcomatoid (6, 10.2%), nested (3, 5.1%), adenocarcinoma (2, 3.4%), lipid rich (1, 1.7%), giant cell (1, 1.7%), and trophoblastic (1, 1.7%). Patients with variant histology received BCG in 35/59 (59.3%) cases, and patients with UC received BCG in 213/288 (74.0%) cases. Radical cystectomy was performed for non-muscle invasive bladder cancer with variant histology based on clinical judgement. The rate of radical cystectomy was higher in the variant histology group compared to UC (40.7% vs. 26.0%, p < 0.05). Recurrence-free survival after treatment with BCG was greater in the variant histology group compared to the UC group (62.1% vs 38.0%, p <0.05).

Conclusion: In contrast to prior studies, our study demonstrates that patients with non-muscle invasive bladder cancer with variant histology treated with BCG had better recurrence-free survival compared to patients with UC. Our findings suggest that a select subgroup of patients with non-muscle invasive bladder cancer with variant histology may benefit from treatment with BCG.
143. CHARACTERIZATION OF URINARY MICROBIOME IN PATIENTS WITH BLADDER CANCER: RESULTS FROM A SINGLE-INSTITUTION, FEASIBILITY STUDY
Juan Chipollini1, Justin Wright2, Hephzibah Nwanosike2, Regina Lamendella2, Carole Kepler3, Ken Batai4, Benjamin Lee4, David Stewart5
1 The University of Arizona, 2 Department of Biology, Juniata College, Huntingdon, PA, 3 University of Arizona Cancer Center Biospecimen Repository, Tucson, AZ, 4 Department of Urology, the University of Arizona, Tucson, AZ, 5 Department of Surgery, the University of Arizona, Tucson, AZ

Presented By: Juan Chipollini

Introduction: The human microbiome has been linked to development of several malignancies, but there is scarcity of data on the impact of the urine microbiome in bladder cancer. Thus far, the role of microorganisms in bladder cancer has not been fully elucidated. An important and clinically relevant question would be whether the urinary microbiome has any effect on bladder carcinogenesis. The aim of this study was to assess different microbial taxa among prospectively collected urine samples from patients undergoing evaluation for newly diagnosed non-muscle invasive bladder cancer (NMIBC). Our goal was to provide results that could expand our understanding of microbial taxa as a novel biomarker with potentially diagnostic and therapeutic implications.

Methods: A prospective cohort study was conducted after obtaining institutional review board approval. Urine samples were collected from 20 patients undergoing cystoscopic evaluation. Each patient signed an IRB approved consent form prior to urine collection for use in this study. All were required to have negative standard urine cultures. DNA was extracted and processed for 16S rRNA sequencing. Observed species richness and evenness were analyzed. Principal coordinates analyses (PCoA) plots and ANOSIM tests for significance were generated from a weighted UniFrac distance matrix made within QIIME from a cumulative sum scaled (CSS) normalized amplicon sequence variant table. Linear discriminant analysis Effect Size (LEfSe) analysis was used to identify microbial organisms whose sequences were more abundant. An alpha level of 0.05 was used for comparisons and bacteria markedly increased were defined as linear discriminant analysis (LDA) score >2. Features were plotted on a logarithmic scale according to the group with which they were significantly associated.

Results: Median age was 75 years old. Ten patients had high grade urothelial carcinoma (UC) while 8 patients had low grade UC. Samples with less than 1000 sequences per sample were excluded from analyses. In total, 16 samples contained high quality sequence data for subsequent analyses. Two patients had benign pathology and used as a qualitative control group. Global bacterial composition demonstrated high patient specific variability across groups (Figure 1). High proportions of Bacteroidaceae and Lachnospiraceae were seen across cancer and non-cancer samples. Additionally, relative abundance of Pseudomonadaceae was seen in all risk groups. When comparing observed species richness and evenness, no significant differences were found between pairwise cancer risk cohorts (all pairwise p > 0.05). Beta diversity did not reveal any distinct clustering (anosim p=0.554). No significant differential diversity was observed when comparing high versus low grade tumors (anosim p=0.882). Methylobacterium was found to be significantly enriched in intermediate risk patients (Figure 2A). When comparing high versus low grade samples, LEfSe analysis revealed significant enrichment of Sphingomonadaceae, Sphingomonadales, Sphingomonas, Veillonella, Flavobacteriales, Rhodocista and Thermoleophilia (p < 0.05, LDA > 2.0). No taxa were enriched in the low grade samples. Significant differential abundance of Sphingomonas was observed in patients with high grade tumors (Figure 2B). Conclusion: In this proof of concept study, we report the status of a urinary microbiome in patients presenting with newly diagnosed NMIBC and standard negative urine culture. Compositional differences in urine microbes were observed among different cancer risk groups as well as high versus low grade tumors. Whether cause and effect can be established will require continued research and collaboration to further expand our understanding on molecular and biological factors of bladder carcinogenesis.

Funding: This study was funded by the University of Arizona Department of Surgery Faculty Seed Grant
Figure 1: Global composition of bacteria at family level. Control and cancer groups are labeled on the X-axis and expressed as relative amplicon sequence variants (ASVs) abundance per case.

Figure 2: Bacterial enrichment. (A) Barcharts display of *Methylobacterium* individually represented for each patient differentially enriched in intermediate risk bladder cancer samples. (B) Differential abundance of *Sphingomonas* in high grade versus low grade samples.
144. PATIENT MATCHED GENOMIC ANALYSIS OF HIGH-GRADE NON-MUSCLE INVASIVE BLADDER CANCER SPECIMENS PRE- AND POST-BCG IMMUNOTHERAPY

Timothy Clinton, Nima Almassi, Shawn Dason, Victor McPherson, Aditya Bagrodia, Aleksandra Walasek, Michal Wiseman, Michael Berger, Nikolaus Schultz, Guido Dalbagni, David Solit, Gopa Iyer, Hikmat Al-Ahmadi, Bernard Bochner, Eugene Pietzak

1 Memorial Sloan Kettering Cancer Center, 2 alahmadh@mskcc.org

Presented By: Timothy Clinton

Introduction: Over seventy percent of bladder cancer presents as non-muscle invasive bladder cancer (NMIBC). The standard of care for high-grade NMIBC is intravesical Bacillus Calmette-Guerin (BCG) immunotherapy. Unfortunately, forty percent of patients do not respond to BCG therapy and experience recurrence or progression of disease. Identifying genomic alterations in high-grade bladder cancer associated with clinical response to BCG immunotherapy can provide clinical utility for both prognostic purposes and for identifying novel targeted therapy. Our group has previously identified an association between ARID1A mutations and an increased risk of recurrence after BCG therapy. By utilizing next-generation sequencing to evaluate pretreatment and posttreatment specimens from BCG therapy within the same patient, we can identify resistance patterns within tumors.

Methods: We identified high-grade NMIBC patients who underwent BCG immunotherapy who were enrolled on a prospective IRB-approved protocol for which targeted exon capture sequencing (MSK-IMPACT) was performed on pretreatment and posttreatment tumor DNA and matched germline DNA in a CLIA-certified laboratory. The primary endpoint of analysis was high-grade recurrence following intravesical BCG therapy. Patients were classified as having BCG refractory, BCG relapsing, and/or BCG unresponsive disease. BCG refractory defined as failure to be disease free within 6 months after initial BCG with maintenance or re-treatment at 3 months due to rapid recurrence, BCG relapsing is tumor recurrence after 6 months of BCG with early (<12 months) or late (>12 months) and BCG unresponsive as recurrent CIS (within 12 months) or Ta/T1 (within 6 months) after completion of adequate BCG. Genomic alterations and tumor mutational burden (TMB) were correlated with BCG refractory versus BCG relapsing disease.

Results: Thirteen patients with high-grade recurrence following BCG treatment were identified who had their pretreatment and posttreatment specimens undergo genomic analysis. The median age at diagnosis was 57 years (IQR 48-76) with ten patients (77%) male. Nine patients (69%) were cTaHG, 3 patients (23%) cT1 and 1 patient (8%) cTis with median follow-up of 57 months (IQR 42-67). As demonstrated in Figure 1, the concordance between pretreatment BCG and posttreatment BCG specimens was very high with only select cases of unique mutations between matched specimens. One select case in the late BCG relapsing cohort (Patient 13) with a known FGFR3-TACC3 fusion had a pretreatment CDKN1A mutation and after BCG treatment had two unique secondary CDKN1A mutations. Another case in the late BCG relapsing cohort (Patient 10) was found to have both ARID1A, PIK3CA and FGFR3 hotspot mutations. As a tumor harboring an ARID1A mutation there is an increased risk of recurrence and with two actionable mutations in PIK3CA and FGFR3 this may have implications for possible targeted therapy in the future. When comparing genomic alterations between BCG refractory/relapsing cohorts only TP53 (HR 4.5 (1.1-18.3), p=0.03) and KMT2D (HR 4.4 (1.4-13.8), p=0.01) were significantly associated with BCG refractory disease. The numbers are very small but comparing genomic alterations between BCG unresponsive to remainder of cohort identified CDKN2A and BRCA2 to be significantly associated. There was no significant difference in the TMB between BCG refractory and BCG relapsing (13.5 vs 12.1, p=0.8) nor between pre-treatment versus post-treatment specimens (12.5 vs 13.0, p=0.9).

Conclusion: BCG recurrence can be prevalent in NMIBC and with recurrent BCG shortages further knowledge of resistance patterns can ultimately help guide clinical practice. On the whole we found the concordance to be exceptionally high between pretreatment and posttreatment specimens. The cohort identified here is small but there are some select differences between pretreatment and posttreatment specimens that may warrant more evaluation. While we are looking at only patients with BCG recurrences, there are a number of actionable mutations that serve as a potential for novel targeted therapies. These recurrent tumors after BCG therapy are being explored further with whole-exome sequencing and other next-generation sequencing to analyze expression across the transcriptome. The ability to sequence tumors within the same patient at different temporal points after treatments allows for further elucidation of clonal evolution of tumors.

Funding: This work was supported by the Sidney Kimmel Center for Prostate and Urologic Cancers, the Michael and Zena Wiener for Therapeutics Program in Bladder Cancer, Pin Down Bladder Cancer, Cycle for Survival, the Marie-Josee and Henry R. Kravis Center for Molecular Oncology, NIH/NCATS Grant Number UL1-TR002384, the National Cancer Institute Cancer Center Core Grant Number P30-CA008748 and by SPORE in Bladder Cancer P50-CA221745.
145. CHARACTERIZING THE URINARY MICROBIOME OF PATIENTS WITH BCG-UNRESPONSIVE AND RESPONSIVE NON-MUSCLE INVASIVE BLADDER CANCER
Vikram Narayan, Amy Lim, Justin Matulay, Nathan Brooks, Chia-Chi Chang, Robert Jenq, Ashish Kamat, Colin Dinney, Neema Navai
University of Texas MD Anderson Cancer Center

Presented By: Vikram Narayan

Introduction: Recent data have challenged the idea that the urinary tract is “sterile,” with molecular studies demonstrating the presence of microbial DNA even within the urine of patients with negative urine cultures by traditional testing. These microbial communities, collectively referred to as the “urinary microbiome,” may originate from anywhere within the urinary tract and their impact on urothelial carcinoma pathogenesis and therapy is of great interest. Given evidence suggesting that BCG response may in part be due to trained immunity, we hypothesized that the urinary microbiome may influence one’s response to BCG immunotherapy for the treatment of non-muscle invasive bladder cancer (NMIBC), and sought to characterize the urinary microbiota of a cohort of patients with BCG-responsive and unresponsive disease.

Methods: A total of 52 individuals were identified from an institutional cohort of patients with NMIBC, and included individuals with TaHG, T1HG, and CIS who underwent BCG intravesical therapy and for whom banked urine was available. Urine was collected uniformly through a voided, clean-catch method, with samples centrifuged and stored at -80 degrees C with DMEM in 1 mL aliquots. Pelleted urine samples were then used for DNA extraction with PCR amplification of 16S rDNA. Diversity within samples (alpha diversity) was evaluated with the Simpson index, which considers both the richness and abundance of unique operational taxonomic units (OTUs). Descriptive statistical analyses were performed using SPSS v24 to characterize the clinical cohort. “BCG-unresponsive disease” was characterized by the definitions provided in the 2018 FDA Guidance for Industry statement for NMIBC.

Results: Of the 52 samples analyzed, 24 were from patients with BCG-unresponsive NMIBC while 25 were from BCG responders. Median age of the cohort was 66.3 years (range 35-87 years). CIS was present in 33% of BCG-responsive patients and 79% of BCG-unresponsive patients. Two samples did not yield adequate quality DNA for amplification and were excluded in the analysis. There was no statistically significant difference between the groups with respect to mean microbial alpha diversity, represented by the Simpson index (11.1 for BCG-unresponsive vs 11.5 for BCG-responsive, p=0.66). The most abundant phyla among BCG-unresponsive samples were Firmicutes, Actinobacteria, and Bacteroidetes. Among BCG responder samples, in addition to the latter phyla, Parcubacteria and Proteobacteria were more commonly encountered. A notable feature of both cohorts was the high degree of variability within each individual’s microbial community composition, regardless of one's BCG-responder status.

Conclusion: Overall microbial diversity is similar within the urines collected from BCG-unresponsive and BCG-responsive patients, although operational taxonomic units belonging to certain phyla may be more enriched in patients with BCG-responsive disease. Efforts to correlate these findings with immune responses will be required before a true link between the urinary microbiome and immunotherapy response can be established.

Funding: MD Anderson GU SPORE in Bladder Cancer
Introduction: Intravesical induction BCG once weekly for six weeks is the mainstay of initial treatment for intermediate or high risk non-muscle invasive bladder cancer (NMIBC). However, the value of ongoing maintenance BCG for one to three years is unclear. In a meta-analysis of 20 randomized clinical trials examining maintenance BCG, Sylvester et al found that maintenance BCG was associated with reduced bladder cancer recurrence and progression to MIBC. A subsequent patient level meta-analysis of BCG maintenance trials demonstrated reduced recurrence but no difference in progression with maintenance BCG. Given the unclear effect on progression, limited supply, and increased cost and toxicity of maintenance BCG, 50% of urologists do not use maintenance BCG for intermediate and high risk NMIBC patients. In a resource constrained health care infrastructure plagued by BCG shortages, it is critical to understand the value of maintenance BCG. Herein, we conduct a comprehensive cost-effectiveness analysis on maintenance BCG using Markov modeling. Such a model could provide valuable insight on balancing the costs and benefits of maintenance BCG. Furthermore, it could identify thresholds for reduction in both recurrence and progression at which maintenance BCG would be considered cost-effective.

Methods: A Markov model was constructed to compare the cost-effectiveness of maintenance BCG relative to no-maintenance BCG after successful completion of induction BCG for intermediate and high risk NMIBC. A simplified model schematic is shown in Figure 1. Analysis was from a US payer perspective using Medicare costs, and utility values were obtained from the literature. The following maintenance BCG schedule was followed: once weekly instillations for 3 weeks at 3, 6, 12, 18, 24, 30, and 36 months after induction BCG completion. Intermediate risk patients were scheduled to receive 1 year of maintenance BCG and high risk patients 3 years. Surveillance consisted of guideline based cystoscopy intervals and annual CT urograms in both the maintenance and no-maintenance BCG arms of the model. Maintenance BCG side effect and drop-out rates were taken from large randomized trials. 5-year recurrence, progression to MIBC, metastasis, and mortality rates were extracted from meta-analyses and randomized trials. In the base case, maintenance BCG was associated with 20% improved 5-year recurrence free survival but not progression free survival. We then identified a threshold of reduction in recurrence alone below which maintenance BCG would be cost-effective. Next we identified a threshold of reduction in progression below which maintenance BCG would be cost-effective. Other unvariable sensitivity analyses were performed for all relevant variables in our model. Multivariable sensitivity analyses were performed using 10,000 Monte-Carlo microsimulations at a willingness-to-pay threshold of $100,000 per quality adjusted life year (QALY).

Results: At 5 years after randomization, mean costs and QALYs per patient were $10,069 and 2.73 QALYs for maintenance BCG and $8,901 and 2.73 QALYs for no-maintenance BCG, respectively. In the base model, assuming a 20% 5-year recurrence free survival benefit for maintenance BCG and no progression free survival benefit, the excess costs of maintenance BCG and the associated lower utility from BCG related side effects balanced out the costs and lower utility associated from increased recurrence in the no-maintenance BCG arm. On sensitivity analysis, maintenance BCG became cost-effective using a willingness-to-pay threshold of $100,000/QALY if its absolute 5 year recurrence rate was 24% lower than no-maintenance BCG (assuming no difference in MIBC progression) or if the 5 year progression rate to MIBC was 2.4% lower for maintenance BCG vs no-maintenance BCG. Figure 2 displays a Tornado diagram to demonstrate the impact of varying individual model variables on the net-monetary benefit of maintenance BCG, in which variables that significantly altered maintenance BCG cost-effectiveness are marked with a vertical black bar. In addition to recurrence and progression, maintenance BCG became cost-effective if its 5-year overall mortality rate was 0.5% lower than no-maintenance BCG. On multivariable sensitivity analysis using 10,000 Monte-Carlo microsimulations of the base case (20% difference in 5 year recurrence and no difference in progression or mortality), maintenance BCG was cost-effective in 22% of microsimulations at a willingness-to-pay threshold of $100,000/QALY.

Conclusion: Maintenance BCG has a low chance of being cost-effective for intermediate/high risk NMIBC at traditional willingness-to-pay thresholds assuming a 20% reduction in 5-year recurrence and no difference in progression to MIBC relative to no-maintenance BCG. Maintenance BCG became cost-effective if it reduced 5-year recurrence rates by 24% or more, and thus efforts to sub-stratify the impact of maintenance BCG on recurrence for intermediate and high risk NMIBC are warranted to improve patient selection for maintenance BCG. Maintenance BCG also became cost-effective if it was associated with a 2.4% 5-year progression-free survival benefit. A traditional meta-analysis found a statistically significant 4% 5-year progression benefit (driven largely by an old trial in which repeat transurethral resection for high risk NMIBC was not employed) but an individual patient-data meta-analysis found no significant difference in progression. Given this ambiguity, our model supports further high quality studies that clarify the impact of maintenance BCG on progression to MIBC for intermediate and high risk NMIBC. In the present milieu of chronic BCG shortages, our study supports the American Urologic Association’s current position of prioritizing BCG for induction courses over maintenance regimens.
147. NOVEL IMIDIAZLUM COMPOUNDS FOR THE INTRAVESICAL TREATMENT OF SUPERFICIAL BLADDER CANCER

Uttam Satyal1, Rahmat Sikder1, Marie Southerland2, Michael Strohmeyer2, David Weader2, Jessie Baughman2, Claire Tessier2, Wiley Youngs2

1 Fox Chase Cancer Center, 2 University of Akron

Presented By: philip abbosh

Introduction: Ongoing BCG shortages have crippled the treatment of patients with high NMIBC. Second line therapies such as intravesical chemotherapy are ineffective, likely relating to their mechanism of action and the relatively short practical intravesical dwell time. Without better approaches, many patients will require radical cystectomy for disease that would otherwise have been managed with intravesical therapy. We therefore developed a novel series of imidazolium compounds which are highly effective in cell line models and in mice with BBN-induced bladder tumors and describe herein the first in the series, TPP1.

Methods: Treatments: In all cases, cells were plated the night before the experiment began, then treated for 1h (or less). Determination of growth inhibition: Bladder cancer cell lines (n=8) were treated with TPP1 for 1h, 30min, 15 min, or 5 min. CellTiter Glo assay was performed 24h later. Treatments were done on 4 wells for each dose and luminescence was normalized to an untreated control. Sub-G1 analysis: Cells and debris were collected from triplicate wells and washed, then fixed in ethanol and stained with propidium iodide. Flow cytometry was used to determine the sub-G1, G1, S, and G2 fractions. Sub-G1 fraction was compared to untreated control.

Colony formation assay: 10 days after treatment, the wells were stained with crystal violet dissolved in water/MeOH and visualized. Western blot: Extracts were made from cells+debris or mitochondrial pellets or their supernatants and resolved using PAGE and transferred to PVDF membranes then immunoblotted.

Mitochondrial toxicity: Mitochondria were isolated from RT112 cells and treated in isolation with TPP1. The supernatants and pellets were then subjected to Western blot using antibodies raised against Cytochrome C.

Mouse studies: BBN-induced tumors were measured using excretory CT urography. After filling defects were identified, mice were treated with intravesical TPP1 for 1h on consecutive days. 24h later, the bladder was collected for histopathology. Normal C57B6 mice were treated with TPP1 or vehicle for 1h. 24h later, the bladder was collected for histopathology. Studies were approved by the Fox Chase IACUC (#19-03).

Results: TPP1 induced growth inhibition with IC50 in the 200 micromolar range after 1h exposure. Interestingly, IC99 doses induce significant growth inhibition (70%) in as little as 5 minutes. Colony formation assay showed that TPP1 is highly effective and cytotoxic. It was an efficient inducer of apoptosis as measured by sub-G1 analysis and induction of cleaved PARP1 and cleaved Caspase-9 by western blot. Based on the structure of this delocalized lipophilic cation (DLC) and the known SAR of other DLCs, we hypothesized that TPP1 localizes to mitochondria to induce mitotoxicity. Isolated mitochondrial suspensions treated with TPP1 rapidly extrude Cytochrome C into the supernatant, confirming that the compounds distinctly target the mitochondria. Normal C57B6 mice were intravesically treated with 750 or 1500 micromolar TPP1. Histology of the bladder showed that there was little urothelial damage compared to vehicle-treated mice. Histopathology showed no evidence of inflammation. This was confirmed by anti-myeloperoxidase immunostaining. To determine direct antitumor activity, FVB mice with BBN-induced filling defects were treated with TPP1 or vehicle on consecutive days for 1h. 24h later, the bladder was collected for histopathology. There apoptosis was occurring in the tumors from TPP1-treated mice but not pre-treatment mice, confirmed with anti-cleaved caspase 3 immunostaining. Also, normal adjacent urothelium did not have any evidence of cell death in either TPP1 or pretreatment mice.

Conclusion: These results suggest that TPP1 may be an efficacious intravesical therapy with little toxicity, although this needs to be more rigorously proven in long-term mouse studies with better defined toxicology. Intravesical TPP1 has several potential advantages over BCG including a clearly delineated and rapid mechanism of action and little apparent inflammation. Intravesical TPP1 has several potential advantages over BCG and other novel biological therapeutics currently in clinical trials because of its ease of manufacture. Lastly, TPP1 has significant advantages over intravesical cytotoxic chemotherapy because it appears to have a rapid and cell cycle-independent onset of effect on the mitochondria rather than cell cycle-specific effects that require prolonged exposures to achieve cytotoxicity. We therefore nominate TPP1 as a novel intravesical therapy which we will continue to develop in anticipation of human clinical trials or as a tool compound for further modifications to enhance its functionality.
148. PREDICTORS OF UPSTAGING AT THE TIME OF RADICAL CYSTECTOMY FOR PATIENTS WITH CLINICAL CARCINOMA IN SITU OR HIGH-GRADE NON-INVASIVE UROTHELIAL CARCINOMA REFRACTORY TO INTRAVESICAL THERAPY

Saum Ghodoussipour, Saum Ghodoussipour, Michael Basin, David Nusbaum, Juliet Han, Shane Pearce, Gus Miranda, Jie Cai, Sumeet Bhanvadia, Anne Schuckman, Siamak Daneshman, Hooman Djaladat

University of Southern California

Presented By: Juliet Han

Introduction: Carcinoma in situ (CIS) and high-grade papillary urothelial carcinoma (Ta) of the bladder are non-invasive malignancies with risk of progression. The recommended treatment of these diseases is intravesical therapy (IVT) with BCG or other chemotherapeutic agents. Various options are available for patients who fail to respond to IVT including clinical trials, but cystectomy remains the gold standard. In this study we look to identify rates of upstaging of disease at the time of cystectomy for IVT-refractory CIS or Ta disease, and predictors of such upstaging in patients referred to a tertiary referral center.

Methods: Using an IRB approved, prospectively maintained bladder cancer database, we identified all patients with clinical CIS or high grade Ta disease (cTis/Ta/N0M0) who underwent radical cystectomy after failure of IVT. Final pathology and clinical variables were compared with Chi square analysis for categorical variables and with Kruskal Wallis test for continuous variables. Multivariable logistic regression was used to control for significant differences.

Results: We identified 264 patients in our cohort. IVT was BCG in 200 patients and other (chemotherapy, interferon) in 64 patients. Final pathology was down staged (pT0N0) in 26 (9.9%), remained same stage (pTis/TaN0) in 141 (53.4%) and upstaged in 97 (36.7%) patients (51 pT1, 17 pT2, 6 pT3, 12 pT4, 11 pN+). Age, current smoking and low albumin were all significantly associated with upstaging on univariate analysis (Table 1). On multivariate analysis, age over 71 years (OR 3.43, 95% CI 1.8-6.9, p<0.01), current smoking status (OR 9.01, 95% CI 2.8-35.5,p<0.01) and having an albumin <3.4 (OR 7.34, 95%CI 1.6-52.7, p=0.02) independently increased the chance of upstaging disease.

Conclusion: A significant proportion of patients with clinical non-invasive CIS or Ta disease will have adverse pathology at the time of cystectomy following failed IVT. Older age, smoking and malnutrition may serve as predictors of such upstaging. These results underscore the importance of aggressive management of such patients.
149. RACIAL AND SEX DIFFERENCES IN SOMATIC MUTATIONS IN BLADDER CANCER PATIENTS: AN ANALYSIS OF DATA FROM THE CBIOPORTAL FOR CANCER GENOMICS

Yaw NYame¹, Bruce Montgomery¹, Petros Grivas¹, Jonathan Wright¹, Kelsey Baker², Mary Redman²

¹ University of Washington, ² Fred Hutchinson Cancer Research Center

Presented By: Yaw NYame

Introduction: Disparities in bladder cancer outcomes seen in African Americans and women in the US are a result of a complex relationship between social, healthcare, and biologic factors. To date, there is limited data on potential molecular differences in urothelial cell carcinoma of the bladder by race/ethnicity and gender.

Methods: This is a retrospective analysis of non-synonymous mutational data from the cBioPortal for Cancer Genomics open access platform. A total of eight unique cohorts were identified within the cBioPortal system. The cohort was divided into groups by gender (male/female) and race (white/non-white). Somatic mutations were selected from those with frequency > 7% from The Cancer Genome Atlas (TCGA) and DNA damage repair (DDR) genes. Univariate analysis to determine differences in mutational frequency by race, sex and age was performed using Student’s t-test and Fischer’s exact test. For those genes with significant differences, multivariate Cox regression analysis (adjusting for age, sex and race) was performed, including a test for interaction for genes that had a significant association with race or sex.

Results: A total of 917 unique patients were identified from cBioPortal for this analysis. Median age for the cohort was 68 years (range: 25-98) and 227 (25%) were identified as female. The cohort was majority white (n = 426, 85%). TP53 (54% vs. 31%, p < 0.001), ARID1A (29% vs. 7%, p < 0.001), ERBB3 (12% vs. 3%, p = 0.01) and CDKN1A (8% vs 18%, p = 0.02) were differentially mutated in white tumors compared to non-white tumors. ERBB2 was more common among male (13%) compared to female (6%) patients in the cohort (p < 0.01). There were no differences in DDR genes by race/ethnicity and gender, but the median age for those with ERCC2 (70.4 vs. 66.8 years) and RAD51 (76.3 vs. 67.0 years) mutations was higher compared to those without the mutations, respectively. In the multivariate analysis, ERCC2 (HR 0.45, 95% CI 0.25, 0.80), SPTAN1 (HR 0.50, 95% CI 0.29, 0.84), and EP300 (HR 0.60, 95% CI 0.39, 0.92) were significantly associated with survival. There was a significant interaction between white race and CDKN1A in the survival analysis. In non-white patients with CKDN1A mutations, the HR for mortality was 3.1 (95% CI 1.14 – 8.42) whereas there was no association seen in white patients with the mutation (HR 0.86, 95% CI 0.50 – 1.50).

Conclusion: Somatic mutational differences existed by both race and sex in a large cohort of patients with bladder cancer. These findings are limited by poor representation of non-white patients and retrospective design, and advocate for prospective, representative patient cohorts to assess tumor biology in bladder cancer disparities research.
150. DYNAMICS OF IMMUNE CELL POPULATIONS DURING BLADDER CANCER PROGRESSION SHOW AN ENRICHMENT OF DENDRITIC CELLS AND REGULATORY T CELLS IN RECURRENT NMIBC AND MIBC
Filipe Carvalho¹, Jillian Egan¹, Krithika Bhuvaneshwar², Yuriy Gusev², Geoff Gibney³, Lambros Stamatakis⁴
¹ MedStar Georgetown University Hospital, ² Georgetown University, ³ Georgetown Lombardi Comprehensive Cancer Center, ⁴ MedStar Washington Hospital Center
Presented By: Filipe Carvalho

Introduction: Bladder cancer is one of the tumor types that best responds to immunotherapy where a plethora of immunotherapy strategies are currently under investigation. However, it is unclear which specific immune cell populations infiltrate bladder tumors during their progression from non-muscle invasive bladder cancer (NMIBC) to muscle invasive bladder cancer (MIBC). Our goal is to characterize how the immune system adapts to tumor progression and identify potential targets for immune therapies.

Methods: We analyzed microarray gene expression data (accession number GSE13507) in normal bladder mucosa, normal mucosa surrounding a bladder tumor, primary NMIBC, recurrent NMIBC and invasive bladder cancers. CIBERSORT analytical tool was used to estimate the frequency of B cells, CD8+, CD4+ naïve and memory, regulatory T cells (Tregs), gdT cells, dendritic cells, NK cells, monocytes, macrophages and all the polymorphonuclear populations in the different stages of bladder cancer progression.

Results: We found that normal mucosa is enriched for resting memory T cells and M2 Macrophages, and is depleted of CD8+ T cells, Tregs, and dendritic cells. Interestingly, recurrent NMIBC and muscle-invasive bladder cancer have low numbers of resting memory T cells, M2 Macrophages and almost absence of CD8+ T cells, but have 10 times more Tregs and activated DCs compared with normal bladder mucosa.

Conclusion: Our results show an enrichment of Tregs and activated DCs as bladder tumors progress to recurrent NMIBC and MIBC. Validation of these results may allow to identify novel immunological signatures to manipulate the immune response in early tumor stages and prevent recurrence or progression to advance stages.

Funding: Department funds
151. IMPROVED LOW-GRADE BLADDER CANCER DETECTION FROM URINE SAMPLES: A CLINICAL STUDY USING BLADDER CARE TEST
Paolo Piatti¹, Taikun Yamada¹, Yap Ching Chew¹, Xi Yu Jia¹, Michiko Suwoto², Gangning Liang³, Saum Ghodossipour³, Siamak Daneshmand³
¹ Zymo Research Corp., ² Pangea Laboratory, LLC, ³ USC Norris Comprehensive Cancer Center
Presented By: Paolo Piatti

Introduction: Bladder cancer (BC) is the 5th most common cancer in the USA, with 81,190 new cases and 17,240 deaths annually, and an incidence of 2.4% within the population. The high recurrence rate of BC requires a lifelong patient follow-up with cystoscopy. However, the invasiveness of cystoscopy and the high costs associated to this procedure, poses a significant burden on patients as well as on the healthcare system. Several tests for the non-invasive detection of BC have been developed in the past years however, because of relatively low sensitivities and/or specificities (especially for low-grade tumors), these tests have not been adopted for the routine clinical use. Therefore, a non-invasive, simple and sensitive test for detection and routine monitoring of BC is needed.

Methods: Bladder CARE is a new non-invasive and quantitative test that allows measurement of the methylation levels of three BC specific biomarkers in urine samples. In this clinical study, we evaluated the performance of this test using voided urine samples collected from 136 healthy individuals, 77 BC patients with no prior history of bladder cancer, and 24 patients that previously underwent Transurethral Resection of Bladder Tumor (TURBT). Urine specimens were collected and stabilized using Bladder CARE at-home urine sample collection kit and BC detection was performed by a CLIA-certified and CAP-accredited laboratory (Pangea Laboratory LLC) using Bladder CARE. The results were then compared to the clinical information (cystoscopy). Additionally, the test linearity and limit of detection (LOD) were determined by analyzing artificial samples with Bladder CARE test.

Results: Bladder CARE was able to discriminate BC from healthy control samples with a sensitivity of 93.5%, a specificity of 92.6%, and a positive and negative predictive value of 87.8% and 96.2%, respectively. Remarkably, low-grade tumors were detected with a sensitivity of 90%. We also found that Bladder CARE test has a LOD of 0.046% (the equivalent of detecting 1 cancer cell in a sample containing 2,200 normal cells). In addition, contrary to many other epigenetic tests, Bladder CARE test is based on a bisulfite-free technology that allows an increase the cancer signal ~10-fold compared to standard DNA methylation detection methods that use bisulfite treatments.

Conclusion: While cystoscopy remains the gold standard to confirm the presence of BC, the superior sensitivity of Bladder CARE test, together with its low LOD, make this test an effective early indicator of low-grade tumors and for routine recurrence monitoring of BC patients. In addition, Bladder CARE urine collection kit allows to collect and stabilize the urine specimen comfortably at-home and mail it to the testing laboratory at room temperature, streamlining the patients’ detection and monitoring process.
152. PRE-CLINICAL CELLULAR AND GENOMIC CORRELATES OF RESISTANCE TO IMMUNE CHECKPOINT BLOCKADE IN BLADDER CANCER
Debasish Sundi¹, Megan Duggan¹, Jing Zhao¹, William Carson III¹, Himanshu Savardekar², Thomas Mace²
¹ Ohio State University, ² Ohio State

Presented By: Debasish Sundi

Introduction: Resistance to immune checkpoint blockade is an important challenge for patients with bladder cancer. Approximately 25-35% of patients have objective responses in the 2nd-line metastatic setting and 40% have pathologic complete response during neoadjuvant treatment. Studies in other solid tumor types have identified immune suppressor cells that are associated with resistance to immune checkpoint blockade, and sometimes targeting these immune suppressor cells can increase therapeutic responses. The purpose of his study was to determine cellular and bulk gene expression correlates of resistance to anti-PD-L1 therapy in immune competent murine bladder cancer models.

Methods: C57BL6 female mice were subcutaneously inoculated with 1 million cells from the BBN963 and UPPL1541 cell lines. Once tumors reached 3-5mm in size, subjects were treated three times weekly with anti-PD-L1 monoclonal antibody (BioXCell, 5mg/kg, intraperitoneal administration). In combination therapy studies, subjects were also treated with the tyrosine kinase inhibitor ibrutinib (25mg/kg/day oral). Tumor volumes were monitored over time based on 2-dimensional caliper measurements and subjects were classified as responders (complete or partial) or non-responders (stable disease or progression) based on RECIST criteria. At end of study, tumors were excised and flash frozen for subsequent immune gene expression profiling and/or digested into single-cell suspensions for subsequent surface antibody staining and flow cytometry. Spleens were processed into single-cell suspensions that were also subject to surface antibody staining for lineage immune markers followed by flow cytometry. Proportions of cell populations were compared via two-tailed t-testing, and immune gene expression differences after quantile normalization were considered significant between treatment groups if at least 2-fold differences in expression were detected at a p<0.01.

Results: In the BBN936 (basal) model, the response rate (partial or complete) in control subjects was 0% (0/10) and among anti-PD-L1 treated subjects, 73% (16/22). Comparing control (IgG-treated) subjects to non-responder (anti-PD-L1 treated) subjects, non-responders had a greater proportion of monocytic myeloid derived suppressor cells (M-MDSC) in the tumor microenvironment (TME) and less M-MDSC in the spleen, suggesting a shift into tumors of macrophage-like MDSC are a biomarker of resistance to anti-PD-L1 treatment. In the UPPL1541 (luminal) model, the opposite effect was observed: non-responders had lower levels of M-MDSC in the TME. When bulk tumor was processed into RNA and analyzed on the Nanostring Immune Panel gene expression platform, basal bladder tumors treated with anti-PD-L1 in combination with the MDSC-inhibitor ibrutinib demonstrated lower levels of macrophage markers Ptgs2 and Serpinb2 compared to control, suggesting that targeted therapy has the potential to remodel the TME in the setting of immune checkpoint blockade.

Conclusion: In a basal model of bladder cancer, macrophage like immune suppressor cells (M-MDSC) appear to be a biomarker of resistance to immune checkpoint inhibitor (anti-PD-L1) treatment. This does not appear to be the case in a luminal bladder cancer model. The macrophage content of non-responder tumors can be potentially decreased by combination treatment incorporating ibrutinib, which inhibits MDSC signaling.

Funding: Urology Care Foundation
153. SHOULD UROTHELIAL CARCINOMA BE CONSIDERED PART OF BRCA1 AND BRCA2 CANCER SYNDROMES?

Ankeet Shah¹, Dominic Grimberg², Hannah Berg², Wei Phin Tan², Brant Inman²
¹ Duke University, ² Duke University Division of Urology

Presented By: Ankeet Shah

Introduction: Germline BRCA1 and BRCA2 mutations are known to be associated with breast, ovarian, cervical, stomach, pancreatic, and prostate cancer. Urothelial carcinomas are not usually considered part of the BRCA spectrum of tumors. However, we have identified several patients in whom urothelial carcinoma was part of a germline BRCA mutation phenotype. We present our experience with such cases and compare our findings with those from The Cancer Genome Atlas (TCGA). Identifying germline BRCA mutations in patients with urothelial carcinoma not only affects screening for, and the prevention of, other non-urothelial cancers in these patients but might also affect their disease course.

Methods: After IRB approval, we identified 5 patients with a personal history of urothelial carcinoma as well as a germline BRCA1 or BRCA2 mutation. The specific BRCA1 or BRCA2 mutations were compared to somatic mutations in the same genes in the 412 patient TCGA muscle-invasive bladder cancer cohort using cbioPortal and the associated MutationMapper. Presumptive protein-level modifications from such germline mutations were identified from DNA mutation data using Ensembl and ClinVar datasets. We also evaluated the pathogenic and nominated pathogenic BRCA mutations found in a similar but distinct 411 patient TCGA (PanCancer Atlas) cohort focused specifically on germline mutations in the context of our own cohort. Mutations of uncertain significance were excluded from our analysis.

Results: Within our institutional cohort of five patients, we identified three patients with mutations in BRCA1 and two with mutations in BRCA2. These patients were younger at presentation than typical urothelial carcinoma patients (median = 59). Four had non-muscle invasive bladder cancer and one had muscle-invasive bladder cancer. Four patients in our cohort had family histories of BRCA-associated malignancies, including one patient with a family member with bladder cancer. In contrast to our institutional cohort, none of the pathogenic or likely pathogenic somatic mutations in the TCGA cohort were identified in patients with low grade cancer (Figure 1a). However, one of the two nominated variants in the TCGA (PanCancer Atlas) germline cohort was associated with low grade cancer. We compared our five patients with 17 patients in the TCGA (Cell, 2017) and four patients in the TCGA (PanCancer Atlas) cohorts with known or nominated pathogenic BRCA mutations. We depicted these mutations by BRCA gene (Figure 1b). All documented mutations were unique across cohorts aside from two patients with the same BRCA2 mutation in our institutional cohort. With respect to influence on behavior, we noted in our institutional cohort that two of the five patients were diagnosed with their BRCA mutation in their 30s, and before diagnosis of any other malignancy. As a consequence, they initiated screening for BRCA-associated malignancies as per guidelines.

Conclusion: We identified four unique germline BRCA mutations associated with urothelial carcinoma. The association of these mutations with treatments and outcomes are limited by the early stage in genomic characterization of urothelial carcinoma, as well as their infrequency and variability. Although rare, germline BRCA mutations are observed in bladder cancer patients, and identification of this mutation could impact the patient’s overall screening. Further study may elucidate whether patients who are diagnosed with BRCA mutations should be monitored more closely for urothelial carcinoma with the aim of shifting diagnosis earlier in the disease pathway.
154. IMPROVING COMPLIANCE WITH GUIDELINE RECOMMENDATIONS FOR HEMATURIA: ADDRESSING BARRIERS IN A LARGE ACADEMIC CENTER
Katharine Michel, Raju Chelluri, James Ding, Thomas Guzzo, Daniel Lee
Penn
Presented By: Katharine Michel

Introduction: Hematuria is associated with 5-10% risk of urothelial malignancy and is the most common symptom in bladder cancer. The American Urological Association (AUA) recommends that gross and microscopic hematuria be evaluated with cross-sectional imaging and a cystoscopy. Many providers and patients are not compliant with this recommendation, as there are significant delays from the time of hematuria to the diagnosis and treatment of bladder cancer. Moreover, the barriers and facilitators for improving compliance have not been well examined. Therefore, we sought to evaluate existing practice patterns, and implemented a 3 month pilot to address the specific barriers to care to evaluate how compliance with guideline recommendations can be improved.

Methods: In cooperation with the Center for Digital Health Innovation, and after receiving approval from the University of Pennsylvania Quality Improvement institutional review board, we reviewed patient charts from June 2018 to January 2019, and evaluated existing referral systems from the Emergency Department (ED) and primary care providers to all Urology physicians and advanced practice providers. A mixed methods approach using in-depth semi-structured interviews of patients with gross or microscopic hematuria, and shadowing of patient evaluations was performed to identify potential barriers and facilitators to compliance. In total, 37 patients were interviewed for this initiative. Patients were identified according to the AUA guideline recommendations of 3+ red blood cells, without any known apparent causes such as a urinary tract infection. Utilizing these findings, a pilot project was initiated from March to June 2019 to specifically address these barriers to compliance with guideline recommendations.

Results: Overall, there were many points from the identification of hematuria to the evaluation where people were lost to follow up. Only 15% of patients with microscopic or gross hematuria in the ED were notified of the finding or had documented acknowledgement of the hematuria findings, only 10% were scheduled or referred to a Urologist, and only 7% actually followed through with a Urologist evaluation. For all new patient visits for hematuria, we found an alarming no-show rate of 30%, and of those who do present for the consultation, only 50% complete the full axial imaging and cystoscopy evaluation. On in-depth examination, we found that 80% of the patients surveyed did not recognize the importance and need for follow-up. There was also significant stigma about the evaluation with a cystoscopy that was a barrier. Only 30% of the patient cohort had a smartphone, but 60% had a primary caregiver who helped provide rides. Twenty-seven percent noted difficulty with transportation as a significant barrier. Based off of patient responses, we created a calendar and infographic that describes possible reasons for hematuria, but also lists the upcoming appointments. We generated a separate order set that would automatically generate a referral order and appointment, imaging preference, and patient education material. The calendar and infographic was also sent to the patient a week before the scheduled appointment. With this simple nudge, the patient notification and education increased from 15% to 100%, and the no-show rate decreased from 30% to 9% over 3 months.

Conclusion: There are significant barriers to implementing guideline-concordant care for patients with hematuria. Applying simple changes to the electronic health record and patient notifications can help to provide substantial impact in decision support, to make the right choice the easy choice for both providers and patients. By applying these simple “nudges,” there were significant and immediate improvements in guideline-concordant care and evaluation for hematuria. Future studies may provide evidence to substantiate this approach and scale to other applications for an elderly population.

Funding: Center for Digital Health Innovation Grant
155. GENOMIC BIOMARKERS OF RESPONSE TO IMMUNE-CHECKPOINT BLOCKADE IN METASTATIC UPPER TRACT UROTHELIAL CARCINOMA

Renzo G DiNatale, Diego Chowell, Andrew W Silagyi, Vladimir Makarov, Eugene Pietzak, David Solit, Michael Berger, Hikmat Al-Ahmadie, A. Ari Hakimi, Ed Reznik, Dean F Barjorin, Timothy A Chan, Jonathan Coleman

1 Memorial Sloan Kettering Cancer Center, 2 Memorial Sloan Kettering Cancer Cancer

Presented By: Renzo G DiNatale

Introduction: Multiple factors have been shown to be associated with response to immune-checkpoint blockade (ICB) across different cancer types. However, no reliable biomarkers of response have been described for metastatic upper tract urothelial carcinoma (UTUC). We explored the association between several immunogenomic biomarkers of response to ICB and survival in this context.

Methods: Next-generation DNA sequencing was performed on 131 pretreatment tumor samples from 121 patients using our institutional sequencing platform (MSK-IMPACT). Raw data was processed using our previously-validated pipeline. Tumor mutation burden (TMB), copy-number alterations (CNAs), microsatellite instability (MSI), HLA class I diversity (germline and somatic) and specific mutations were analyzed with regards to prognosis. The primary outcome was overall survival (OS), calculated from the date of metastasis to the date of death or last follow-up. Estimates were computed using the Kaplan-Meier method and associations were tested using Cox regression models.

Results: Of the 121 patients included in the study, 62 received ICB therapy (table 1). A higher fraction of the genome bearing CNAs (FCNAg) was found to be associated with poor prognosis in univariate analysis (HR: 1.01 [1.00, 1.02], p=0.03). This finding was specific to patients treated with ICB (interaction, p=0.001) and was independent of other prognostic variables (figure 1). Previously-reported biomarkers of response to ICB such as TMB (HR: 0.99 [0.96, 1.01], p=0.2) and HLA class I homozygosity (HR: 1.2 [0.57, 2.52], p=0.6) were not significantly associated with OS.

Conclusion: Even after adjusting for other prognostic factors, a higher burden of CNAs in the genome was significantly associated with poor prognosis in patients receiving ICB therapy for metastatic UTUC.

Funding: Thompson family foundation and NIH grant T32

Table 1. Baseline characteristics of the metastatic UTUC cohort treated with ICB.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Levels</th>
<th>n=62</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years) (median [IQR])</td>
<td>69 (56, 76)</td>
<td></td>
</tr>
<tr>
<td>Gender (%)</td>
<td>Female</td>
<td>22 (35.5)</td>
</tr>
<tr>
<td>Primary tumor site (%)</td>
<td>Renal pelvis</td>
<td>41 (66.1)</td>
</tr>
<tr>
<td>M1 at diagnosis (%)</td>
<td>M0</td>
<td>40 (77.4)</td>
</tr>
<tr>
<td>Surgery for primary tumor (%)</td>
<td>No</td>
<td>21 (33.9)</td>
</tr>
<tr>
<td>ICB line of therapy (%)</td>
<td>First-line</td>
<td>17 (27.4)</td>
</tr>
<tr>
<td>ICB regimen (%)</td>
<td>Single agent Combo</td>
<td>49 (79.0)</td>
</tr>
<tr>
<td>Microsatellite instability (MSI=10) (%)</td>
<td>Low</td>
<td>66 (90.2)</td>
</tr>
<tr>
<td>Tumor mutation burden (mut/Mb), median (IQR)</td>
<td>6.72 (2.95, 14.94)</td>
<td></td>
</tr>
<tr>
<td>DNA damage repair deleterious mutations (%)</td>
<td>WT</td>
<td>50 (82.0)</td>
</tr>
<tr>
<td>Percent of genome CN-altered (median [IQR])</td>
<td>6.64 (10, 84.6)</td>
<td></td>
</tr>
<tr>
<td>Whole-genome doubling events (%)</td>
<td>No</td>
<td>35 (56.5)</td>
</tr>
<tr>
<td>Germline HLA class I homozygosity (%)</td>
<td>Heterozygous</td>
<td>43 (69.4)</td>
</tr>
<tr>
<td>Somatic loss-of-heterozygosity in HLA (%)</td>
<td>WT</td>
<td>51 (80.3)</td>
</tr>
</tbody>
</table>

Figure 1. Forest plot showing the results of multivariable Cox regression analysis. A higher fraction of the genome bearing copy-number alterations (CNA) was found to be independently associated with worse prognosis.
156. FATE OF RESIDUAL URETERAL STUMP IN PATIENTS UNDERGOING ROBOT-ASSISTED RADICAL NEPHROURETERECTOMY FOR HIGH-RISK UPPER TRACT UROTHELIAL CARCINOMA

Ram Pathak  
Wake Forest University  
Presented By: Ram Pathak

Introduction: Management of the distal ureter in radical nephroureterectomy and bladder cuff excision (RNUBCE) is paramount, directly influencing oncologic outcomes. Herein, we analyze the natural history of patients who have undergone robotic radical nephroureterectomy without formal bladder cuff excision and retained ureteral stump and compare this cohort with patients undergoing formal RNUBCE for high-risk upper tract urothelial carcinoma (UTUC).

Methods: From January 2006 to December 2018, all patients who underwent robotic RNUBCE for high-risk UTUC were reviewed. Preoperative, perioperative, and postoperative variables were investigated. Overall survival, cancer specific survival, local recurrence-free survival, distant recurrence-free survival, and bladder recurrence-free survival were compared between the two cohorts. Further management treatments were explored for patients with retained ureteral stump. Follow-up consisted of abdominopelvic/chest imaging and cystoscopy at regular intervals.

Results: A total of 105 patients underwent robotic RNU during the above time period. Of patients with documented 6 month follow-up, approximately 6.6% of patients had retained ureteral stump. Median follow-up for the entire cohort was 31.5 months with a range of 6 to 114.2 months. Factors that precluded formal BCE were densely, fibrotic reaction near the ureterovesical junction due to prior vascular or pelvic surgery in 5 patients, severe pyonephrosis and continued anesthetic risk in one patient, and surgeon choice (patient co-morbidities) in another patient. Three patients died with metastatic disease and one patient succumbed to cardiovascular compromise. 2 additional patients developed local recurrence only at the level of the ureteral stump, with one patient undergoing eventual distal excision, contralateral RNUBCE and radical cystectomy with urinary diversion.

Conclusion: In these cases responsibilities assumed by the surgeon demand the utmost in judgement and skill; however, at times, circumstances prevail such as patient factors and nature/biology of the disease. These factors may prevent adequate excision of bladder cuff at the time of RNU. In this robotic cohort of patients undergoing RNUBCE for UTUC, not excising the bladder cuff directly translates to inferior oncologic outcomes. Complete ureteral excision with bladder cuff should be performed where possible as this is an integral part of the surgery. Also, if feasible, adjunctive treatments should be considered.
157. RADIOGRAPHIC PREDICTORS OF PATHOLOGIC RESPONSE TO NEOADJUVANT CHEMOTHERAPY IN PATIENTS WITH HIGH-GRADE UPPER TRACT UROTHELIAL CARCINOMA: RESULTS OF A PHASE II CLINICAL TRIAL
Andrew Tracey, Nathan Wong, Soleen Ghafoor, Daniel Sjoberg, Nicolas Silva, Bernard Bochner, Guido Dalbagni, S. Machele Donat, Harry Herr, Eugene Cha, Timothy Donahue, Eugene Pietzak, Hikmat Al-Ahmadie, Nicole Benfante, Gopa Iyer, Min Yuen Teo, Jonathan Rosenberg, H. Alberto Vargas, Dean Bajorin, Coleman Jonathan
Memorial Sloan Kettering Cancer Center
Presented By: Andrew Tracey

Introduction: Neoadjuvant chemotherapy (NAC) has established survival benefits prior to radical cystectomy for invasive urothelial carcinoma, yet its role in managing high risk upper tract urothelial carcinoma (UTUC) prior to nephroureterectomy (NU) is less clear. We performed a phase II clinical trial of NAC with gemcitabine and cisplatin (GC) in patients with UTUC to evaluate pathologic response. Herein, we investigated where radiographic responses could predict pathologic response at time of NU.

Methods: Patients with high-risk localized UTUC (high grade disease on biopsy and/or radiographic evidence of cT2-4 disease with positive select cytology) were recruited to receive 4 cycles of GC prior to planned nephroureterectomy or distal ureterectomy with the primary objective of the phase 2 study being pathologic response rate, defined as £pT1N0. All patients underwent imaging (CTU unless contra-indicated) at baseline and after 4 chemotherapy and were reviewed by a dedicated GU radiologist. All baseline imaging studies were categorized as: (i) no visible abnormality, (ii) focal nodular/polypoid mass or (iii) focal or diffuse thickening/fat stranding without discrete mass. Post-chemotherapy imaging studies were categorized as: (i) stable disease, (ii) progression of disease, (iii) partial response or (iv) complete response. Radiographic responses were correlated with final pathologic staging.

Results: A total of 43 patients (pT0N0 = 9, £pT1N0 = 18 and >pT1N0 = 16) had CT scans performed pre- and post-chemotherapy. All patients had a visible lesion seen on imaging (mass = 34 and thickening = 9). The median pre-chemotherapy mass size was 3.1cm (IQR 1.8, 4.1). The majority of UTUC disease was found in the renal pelvis alone (N = 25), followed by the ureter alone (N = 13) and then both renal pelvis and ureter (N = 5). Approximately 60.5% of patients (N = 26) had evidence of hydronephrosis prior to chemotherapy. Following chemotherapy, 10 patients had a complete response, 20 had a partial response and 13 had stable disease. No patients progressed radiographically while on chemotherapy. Patients who had a complete radiographic response were more likely to have a pathologic response (£pT1N0 = 90%), compared to a partial response (90% vs 65%, P = 0.21) and stable disease (90% vs 38%, P = 0.01).

Conclusion: Radiographic response following NAC for UTUC appears to be correlated with pathologic response at time of surgery. Radiographic response, in addition to other pre-operative predictors, may play a useful role in counseling and optimizing management of patients with UTUC.

Funding: This research was supported by the Sidney Kimmel Center for Prostate and Urologic Cancers and funded in part through the NIH/NCI Cancer Center Support Grant P30 CA008748.
158. UROLOGY WORKFORCE CHANGES AND THEIR IMPLICATIONS ON PROSTATE CANCER CARE
Kathryn Marchetti, Brent K Hollenbeck, Mary Oerline, Samuel R Kaufman, Megan E V Caram, Vahakn B Shahinian, Parth K Modi
University of Michigan Health System
Presented By: Kathryn Marchetti

Introduction: Within the United States, a shift in the organization of medical practice is ongoing. As independently owned groups merge and are acquired by larger hospitals systems, physicians are working in increasingly larger group practices and those employed by hospital systems. These changes have implications on the management of men with prostate cancer. Yet, the extent to which urology practices are changing is not well understood.

Methods: Using Medicare claims data from the Medicare Data on Provider Practice and Specialty file, we identified all urologists billing Medicare and the practice with which they were affiliated from 2010 through 2016. Based on number and specialty of included physicians, we characterized groups as solo (1-2 urologist in practice of at least half urologists), small single specialty (3-9 urologists in practice of at least half urologists), large single specialty (10 or more physicians in practice with at least half urologists), specialist only (less than half urologists and no primary care physicians), and multispecialty groups (less than half urologists and at least one primary care physician). We identified hospital-owned groups as those that had at least a 3:1 ratio of services that were billed with a “hospital outpatient department” versus “office” place of service. Using a sample of national Medicare claims, we identified all patients with incident prostate cancer, as well as each patient’s urologist, treatment received, and total standardized Medicare spending within 1 year of diagnosis.

Results: The number of urologists increased from 9,305 in 2010 to 9,570 in 2016, while the number of practices decreased from 3,588 to 2,861 in the same period. The proportion of urologists in a multispecialty group increased from 17.1% in 2010 to 28.2% in 2016, while those within smaller groups declined (Figure 1). Hospital-owned groups included 4.6% of all urologists in 2010 but increased to include 7.9% of urologists by 2016. In each year, hospital-owned practices had the lowest mean spending per patient with incident prostate cancer, while large single specialty groups had the highest. Hospital-owned groups provided observation and surgery more often than other groups, while large single specialty groups used more radiation therapy than other group types.

Conclusion: Urology group practice organization trends appear to be mirroring those of the medical profession as a whole. Increasingly, urologists are employed in multispecialty and hospital-owned groups. As previous studies have demonstrated there is an association between practice type and treatment decisions. It is important to understand this shift and its implications on the management of prostate cancer and other urologic disease.
159. IMPLEMENTATION OF A REDUCED OPIOID UTILIZATION PROTOCOL FOR RADICAL CYSTECTOMY
Bogdana Schmidt, Daniel R. Greenberg, Jessica R Kee, Kerri Stevenson, Elizna Van Zyl, Anisia Dugala, Kris Prado, Eila C Skinner, Jay B Shah
Stanford University
Presented By: Bogdana Schmidt

Introduction: Radical cystectomy (RC) often requires a prolonged course of opioid medications for postoperative pain management. We implemented a Reduced Opioid Utilization (ROU) protocol to decrease exposure to opioid medications. Our objective was to determine the impact of the ROU protocol on opioid exposure, pain control, inpatient recovery, and complication rates among patients who underwent RC.

Methods: The ROU protocol includes standardized recovery pathways, a multimodal opioid-sparing pain regimen, and improved patient and provider education regarding non-opioid medications. Opioid exposure was calculated as morphine equivalent dose (MED), and was compared between RC patients following the ROU protocol and patients who previously followed our traditional pathway. Opioid-related adverse drug events (ORADEs), pain scores, length of stay, and 90-day complications, readmission, and mortality were also compared between cohorts.

Results: 104 patients underwent RC, 54 (52%) of whom followed the ROU protocol. ROU patients experienced a statistically significant decrease in opioid exposure in the post-anesthesia care unit (p = 0.003) and during their postoperative recovery (85.7 ±21.0 MED vs 352.6 ±34.4 MED, p<0.001). The ROU protocol was associated with a statistically significant decrease in ORADEs after surgery. There was no significant difference in average pain scores, length of stay, readmissions, or 90-day complication or mortality rates.

Conclusion: The ROU protocol decreased opioid use by 77% without compromising pain control or increasing the rate of complications. This study demonstrates the efficacy of non-opioid medications in controlling postoperative pain, and highlights the role providers can play to decrease patient exposure to opioids after RC surgery.
Introduction: Opioids are routinely overprescribed after surgery, and their use has not significantly decreased after adoption of minimally invasive techniques. For previously opioid-naïve patients who receive opioids after major or minor surgery, over 6% become chronically opioid dependent. In an era of increasing drug addiction and overdose surgeons are gatekeepers to the opioid epidemic. We have a responsibility to our patients to be stewards of appropriate post-operative opioid use. Over 90,000 robotic assisted laparoscopic prostatectomy (RALP) surgeries are performed annually in the United States. We sought to explore the feasibility of an opioid-free protocol at discharge for patients undergoing RALP at a single academic institution.

Methods: In July 2019, we initiated an opioid-free protocol consisting of multi-phase interventions in the clinic, pre-operative staging area, operating room, post-operative recovery, and at discharge (Figure 1). Data were prospectively collected on morphine equivalent doses (MED) prescribed at discharge, opioid type, post-operative phone calls, clinic visits, and emergency room (ER) visits related to pain. The prospective cohort was compared to a historical control cohort managed according to individual surgeon preferences. Patients with a history of chronic opioid use or GFR <60 mL/min were excluded. Patient characteristics were compared using the Mantel-Haenszel chi-square test for trend and analysis of variance.

Results: 65 patients who underwent RALP from October 2017 through January 2018 comprise the historical control cohort. Comparing this historical group to the 12 eligible patients that underwent RALP since institution of the protocol, there were no differences in patient demographics (age, p=0.97; BMI, p=0.25; ASA, p=0.69; history of chronic pain, p=0.326; prior abdominal/hernia surgery, p=0.39; pathologic stage, p=0.69). Among the historical cohort, mean amount of opioids prescribed at discharge was 163 morphine equivalent doses (MED), compared to 20 MEDs in the intervention group. After initiation of the opioid-free protocol, 2 patients (17%) received a narcotic prescription at discharge. There has been no increase in the number of pain-related phone calls to the clinic after surgery (2 after initiation of the opioid-free pathway versus 8 in the control group, (p=0.66)). None of the patients in the intervention group required a subsequent opioid prescription, an additional clinic visit, or ER visit related to pain.

Conclusion: These preliminary data suggest that institution of an appropriate multi-modal pain management protocol can result in rapid decrease in opioid over-prescription. Patients undergoing RALP can be discharged without an opioid without compromising patient experience with no significant increase in post-operative phone calls, clinic visits, or ER visits.
Introduction: Bladder cancer (BC) is highly prevalent in the elderly and costly to treat. The financial burden of improved survivorship and advancing treatments for this disease will likely be borne out by Medicare. Limited data is available regarding the long-term costs of treating BC. This study documented cost and use of services for BC care and for other (non-BC) care received over a 15-year follow-up period by a cohort of Medicare beneficiaries diagnosed with BC in 1998.

Methods: The Surveillance, Epidemiology and End Results (SEER) Program linked to Medicare claims was evaluated with respect to diagnoses, services provided, and Medicare Parts A and B payments. Cost was defined as actual Medicare payments to providers, adjusted to 2018 US$. These were broken out to BC-related if the associated claim contained a relevant BC diagnosis code. Payments without relevant diagnoses were considered non-BC care. Data were further stratified by site of disease, with local disease comprising in-situ and stage I disease, regional disease comprising stage II-IV with limited extent of disease codes, and distant disease comprising stage IV with advanced extent of disease codes. To assess utilization, Part B-covered services were grouped into 6 mutually-exclusive categories, and utilization rates were identified after normalizing to the number of beneficiaries with BC surviving to the year-end.

Results: The SEER population was largely white (92%) and male (73%), with approximately 70% of the population falling between 70-85 years of age. One-year survival was 81% all stages, 90% localized BC, 60% regional BC, and 14% distant BC. Over 15 years, total BC-related cost per beneficiary was $42,011 (95% Confidence Interval (CI): $42,405-$43,417) across all stages combined. Non-BC care cost was approximately double that. Intensity of BC-related care was highest during the first year following BC diagnosis, falling substantially thereafter. After follow-up year 5, there was equilibration of costs between survivors treated for local and regional disease. The costs were largely driven by non-BC care costs. Patients with distant disease had similarly high costs of treatment seen in those with regional disease, but few survived beyond the first year. There were few statistically significant changes in BC-related utilization beyond year 5 across utilization categories, including physician visits, laboratory test and imaging. This was consistent across stage-specific stratum. Utilization of non-BC care remained constant during follow-up or increased.

Conclusion: We evaluated the 15-year costs of care as well as Medicare utilization for BC patients. Substantial cumulative costs were incurred for non-BC care, and represented a major portion of overall cost of care after 5 years of follow up. While increasing BC survivorship is an important objective, non-BC care will remain a burden to Medicare and will need to be accounted for with the expected population trends.
162. HETEROGENEITY IN POLICY EFFECT: CHANGES IN PROSTATE CANCER SCREENING ASSOCIATED WITH ACO PARTICIPATION

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Presented By: Amy N. Luckenbaugh

Introduction: Evidence suggests that Accountable Care Organization (ACO) participation may improve the value of health care through improving quality while reducing cost. Prior data has demonstrated small magnitude changes in PSA testing for ACO beneficiaries; however, little is known about individual ACO performance. In this context, we evaluated the variation in prostate cancer screening across among individual Medicare Shared Savings Program (MSSP) ACOs.

Methods: We performed a retrospective cohort study using national Medicare data from 2007-2017, evaluating the rates of change in PSA testing across ACOs, controlling by HRR and year. We examined the mean rate of change in PSA testing for men ≥75 years of age versus those <75 by ACO. We repeated the same for beneficiaries with high predicted 5-year survival versus low predicted 5-year survival. Using the number of ACO participation years, defined as years from January 1, 2013, we evaluated whether there was a correlation between ACO maturity and screening changes.

Results: We identified 21,050,902 eligible ACO-attributed beneficiaries. The overall trend was a reduction in PSA testing; however, there was wide variation (Figure 1) with some ACOs reducing screening, and others increasing screening (mean rate of change: -24.5%, -70.45-72.2%). Among beneficiaries ≥75 years there was a mean 30.3% reduction in PSA screening, with a 13.8% reduction for those ≥75 (p<0.0001). Similarly, for those with low predicted 5-year survival there was a mean 40.8% reduction in PSA screening, with an 11.1% reduction among those with high predicted 5-year survival (p<0.0001). When evaluating the impact of ACO maturity, we found no observable difference in the use of PSA screening.

Conclusion: There is wide variation in PSA performance between ACOs, even when controlling for age and predicted life expectancy status. Overall, ACOs reduce PSA performance even for those who are most likely to benefit from PSA testing. ACOs ability to reduce low value testing, while simultaneously improving high value testing did not improve as ACOs matured. Although the aggregate effect of ACOs on prostate cancer screening is small, there are a small number of ACOs in which the effect is large. Going forward, honing in on what makes these high performing ACOs successful will be valuable in order to improve the value in the prostate cancer screening landscape.

Relative Change in Mean PSA Test Performance by ACO
163. TRANSPERINEAL VERSUS TRANSRECTAL ULTRASOUND-GUIDED SYSTEMATIC BIOPSY: UNDERSTANDING THE TRUE COSTS UTILIZING TIME-DRIVEN ACTIVITY-BASED COSTING
Aaron Laviana1, Eliza Cricco-Lizza2, Michael Tzeng2, Timothy McClure2, Jim Hu2, Michael Gross3, Michael Gorin4
1 Vanderbilt University Medical Center, 2 New York Presbyterian Hospital, Weill Cornell Medical College, New York, NY, USA, 3 Stony Brook Medicine, 4 Johns Hopkins School of Medicine
Presented By: Aaron Laviana

Introduction: Diagnostic prostate biopsy (PnBx) options include transrectal ultrasound-guided (TRUS), transperineal (TP) template-guided, and multiparametric MRI (mp-MRI) fusion-guided targeted TP or TRUS. Although post-biopsy infection rates appear less with TP, many patients require an anesthetic. Our objective was to calculate the actual upfront cost of each PnBx approach using time-driven activity-based costing (TDABC).

Methods: We utilized TDABC for six PnBx modalities, factoring in personnel, equipment, and material costs to derive capacity cost rates, which were then multiplied by the relevant process times. TDABC was defined as the sum of its resources, and the costs of mp-MRI fusion-guided TP under general anesthesia (GA), in-office template-guided TP, in-office systematic TRUS, in-office mp-MRI fusion-guided TRUS, in-office mp-MRI fusion-guided TP, and in-office mp-MRI cognitive-fusion TP were calculated.

Results: TDABC assessment demonstrated the following costs: in-office TRUS PBx, $229.61; in-office template-guided TP, $335.30; in-office MRI cognitive-fusion TP $1005.30; in-office mp-MRI fusion-guided TRUS $1072.88; in-office mp-MRI fusion-guided TP $1098.25; and mp-MRI fusion-guided TP under GA $1994.36. Both MRI ($670) and the added costs of the operating room were significant cost drivers. Time to perform TP versus TRUS was similar (10.1 minutes versus 10.0 minutes, respectively), which mirrored the length for mp-MRI fusion-guided TP versus mp-MRI fusion-guided TRUS (23 minutes versus 20 minutes, respectively).

Conclusion: When performed in clinic, the cost of TP versus TRUS PnBx is similar. Determining methods to increase the percentage of TP PnBx performed in clinic may lead to its continued adoption, and further investigation into cost-effectiveness after accounting for differences in post-biopsy sepsis rates is needed.

Funding: Aaron A. Laviana was supported by the Paul Calabresi Career Development Award for Clinical Oncology (PCACO) K12 (NIH Institutional Research Career Development K12 grant mechanism).
164. WHO DOES NOT RECEIVE A CYTOREDUCTIVE NEPHRECTOMY AMONG IMDC INTERMEDIATE-POOR RISK PATIENTS?
Skylar Iosepovic1, Andrew Silagy2, Roy Mano2, Renzo DiNatale2, Julian Marcon2, Robert Motzer2, Jonathan Coleman2, Paul Russo2, A. Ari Hakimi2, Kyrollis Attalla3
1 Memorial Sloan Kettering Cancer Center, 2 MSKCC, 3 MKSCC

Presented By: Skylar Iosepovic

Introduction: Retrospective studies of surgical cohorts are limited because patients are selected for surgery as a prerequisite for inclusion. Therefore, we aimed to evaluate the preoperative decision-making that determines patient selection for cytoreductive nephrectomy.

Methods: We reviewed 284 IMDC intermediate-poor risk patients with metastatic renal cell carcinoma who were all referred to urologists at a single institution for consideration of a cytoreductive nephrectomy between 2009 and 2019. We compiled baseline patient and tumor characteristics and compared these factors in patients that were and were not selected for cytoreductive nephrectomy. For non-operative patients, we performed an iterative thematic analysis of the reasons for recommending non-surgical management.

Results: There were 211 patients who received a cytoreductive nephrectomy and 73 patients managed non-operatively. Non-operative patients had more metastatic disease sites (p = 0.007), specifically bone metastases (p = 0.016), and a higher proportion of poor risk IMDC status (p = 0.003). There was no significant difference between the patient groups regarding smoking history, eGFR at encounter, diabetes, and primary tumor size. (Table 1) There were seven distinct themes for recommending non-operative management. These were a combination of patient and tumor factors. (Figure 1)

Conclusion: While IMDC poor risk group patients were less likely to be selected for surgery, this was not an exclusive classification for patient selection. Operative selection is a nuanced process, with detailed consideration given to evaluating each individual patient.

Table 1 - The reasons a patient was considered suitable for non-operative management

<table>
<thead>
<tr>
<th>Factor</th>
<th>Non-operative</th>
<th>Operative</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cohort</td>
<td>73</td>
<td>211</td>
<td></td>
</tr>
<tr>
<td>Male gender (%)</td>
<td>33 (72.6)</td>
<td>58 (74.9)</td>
<td>0.756</td>
</tr>
<tr>
<td>Age (median [IQR])</td>
<td>64.00 (56.00, 71.00)</td>
<td>61.00 (53.00, 69.00)</td>
<td>0.169</td>
</tr>
<tr>
<td>Patient race (%)</td>
<td></td>
<td></td>
<td>0.647</td>
</tr>
<tr>
<td>Asian</td>
<td>2 (2.7)</td>
<td>5 (2.4)</td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>5 (6.8)</td>
<td>8 (3.8)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>2 (2.7)</td>
<td>5 (3.4)</td>
<td></td>
</tr>
<tr>
<td>Patient Refused/Unknown</td>
<td>6 (7.2)</td>
<td>11 (5.2)</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>58 (79.5)</td>
<td>182 (86.3)</td>
<td></td>
</tr>
<tr>
<td>Smoking history (%)</td>
<td></td>
<td></td>
<td>0.517</td>
</tr>
<tr>
<td>Current</td>
<td>12 (16.4)</td>
<td>30 (14.2)</td>
<td></td>
</tr>
<tr>
<td>Former</td>
<td>30 (41.1)</td>
<td>86 (40.4)</td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>30 (41.1)</td>
<td>83 (39.3)</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>1 (1.4)</td>
<td>12 (5.7)</td>
<td></td>
</tr>
<tr>
<td>eGFR (median [IQR])</td>
<td>72.63 (54.22, 93.00)</td>
<td>71.11 (59.11, 89.49)</td>
<td>0.665</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>15 (20.5)</td>
<td>41 (20.4)</td>
<td></td>
</tr>
<tr>
<td>Radiographic tumor size (median [IQR])</td>
<td>7.50 (5.30, 8.30)</td>
<td>7.20 (5.40, 9.20)</td>
<td>0.6</td>
</tr>
<tr>
<td>No. of metastatic organs (median [IQR])</td>
<td>2.00 (1.00, 3.00)</td>
<td>2.00 (1.00, 2.00)</td>
<td>0.007</td>
</tr>
<tr>
<td>IMDC Risk Profile (%)</td>
<td></td>
<td></td>
<td>0.003</td>
</tr>
</tbody>
</table>

Legend of reasons to not operate:
P = Oncological prioritization
R = Rate of disease progression
F = Tumor-driven frailty
B = Significant disease burden
C = Pre-existing comorbidities
S = Surgically unrespectable
K = Poor renal function
165. MEDICAID EXPANSION DID NOT IMPROVE TIME TO TREATMENT FOR PATIENTS WITH METASTATIC RENAL CELL CARCINOMA
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Presented By: Anuj Desai

Introduction: Lower socioeconomic status and the absence of health insurance coverage has been associated worse outcomes in renal cell carcinoma (RCC). Medicaid expansion was an important provision of the Affordable Care Act and increased the number of people eligible for coverage under Medicaid starting in January, 2014 in several states. While coverage rates in the general population have improved, the effects of medicaid expansion on RCC outcomes are unknown. We hypothesized that following Medicaid expansion, patients with metastatic RCC would have reduced time to treatment.

Methods: We performed a retrospective cohort study on 6844 patients age <65 years diagnosed with metastatic RCC at the time of diagnosis within the National Cancer Database (NCDB) to assess the impact of Medicaid expansion on rates of no insurance and days from diagnosis to treatment (surgery or systemic therapy). We compared these outcomes in the pre-expansion (2012-2013) and post-expansion (2015-2016) eras between patients living in states that expanded and did not expand Medicaid using difference-in-difference (DID) analyses. DIDs were calculated using linear regressions adjusting for sociodemographic covariates.

Results: Rate of no insurance did not change in expansion states compared to non-expansion states (DID -0.55%, 95% Confidence Interval [CI] -3.32 to 2.21%, p = 0.7) in all patients with metastatic RCC or when limiting the analysis to patients living in regions of low income (DID 1.73%, CI -5.35 to 8.81%, p=0.6). There was no change in treatment within 60 days of diagnosis among all patients (DID 2.81%, CI -2.61 to 8.22%, p=0.3) or among those living in low income regions (DID 8.86%, CI -3.48 to 21.20%, p=0.16).

Conclusion: Medicaid expansion was not associated with higher rates of health insurance coverage or decreased time to treatment in patients with metastatic RCC.

![Diagram of Rates of No Insurance and Time to Treatment < 60 Days](image-url)
166. EXAMINING THE SURVIVAL BENEFIT OF CYTOREDUCTIVE NEPHRECTOMY IN THE SETTING OF TUMOR THROMBUS INVASION INTO VENA CAVA IN METASTATIC RENAL CELL CARCINOMA

Alexander Kenigsberg, Xiaosong Meng, Aditya Bagrodia, Yair Lotan, Vitaly Margulis, Solomon Woldu
UT Southwestern

Presented By: Alexander Kenigsberg

Introduction: The role of cytoreductive nephrectomy (CN) for metastatic renal cell carcinoma (mRCC) is controversial in the setting of novel systemic therapies. Little is known about the survival benefit in the setting of tumor thrombus invasion into the vena cava (IVC-TT).

Methods: The National Cancer Database was queried from 2006-2016 for patients with mRCC under the AJCC 7th edition, and cT3a, cT3b, or cT3c disease. Patients with significant comorbidities (Charlson-Deyo >/= 2) were excluded. Univariate and multivariable analysis (MVA) was performed to analyze association of CN with overall survival (OS).

Results: 4,533 met inclusion criteria, with median follow-up of 9.72 months. Median OS of those in the CN versus no surgery cohort (Figure 1) was 22.05 vs. 4.83 months for T3a (p<0.001), 19.71 vs. 4.96 months for T3b (p<0.001), and 13.17 vs. 4.86 months for T3c (p<0.001), with diminishing survival improvement as IVC-TT level increased. In the overall MVA, the following were associated with increased risk of death: age (p=0.003), female sex (p=0.021), median income in bottom two quartiles (p=0.001), no high school education (p=0.001), Charlson-Deyo score 1 (p=0.027), non-clear cell histology (p=0.001), poorly differentiated disease (p=0.045), clinical N1 (p<0.001). CN was independently associated with significantly decreased risk of death (HR 0.413, 95% CI 0.372-0.459, p<0.001) and remained so in subgroup analysis (cT3a-HR 0.425, cT3b-HR 0.370, and cT3c-HR 0.355).

Conclusion: In patients who are surgical candidates, there appears to be a benefit to CN despite IVC-TT, with diminishing improvement in OS with increased level of TT. Further analysis is needed to determine optimal sequencing of CN and systemic therapy.
167. HIGH EXPRESSION OF TUMOR-ASSOCIATED MACROPHAGE (TAM) MARKERS WITHIN THE TUMOR MICROENVIRONMENT SIGNALS POOR OVERALL SURVIVAL IN PATIENTS WITH METASTATIC RENAL CELL CARCINOMA TREATED WITH IMMUNOTHERAPY
Ahmet Murat Aydin1, Ali Hajiran1, Philippe Spiess1, Manish Kohli1, Brandon Manley1, Shayan Falasiri2, Saif Zaman2, Youngchul Kim3, Susan McCarthy4, Jonathan Nguyen4, James Mulé5
1 Department of Genitourinary Oncology, H. Lee Moffitt Cancer Center and Research Institute, 2 University of South Florida, 3 Department of Biostatistics, H. Lee Moffitt Cancer Center and Research Institute, 4 H. Lee Moffitt Cancer Center and Research Institute, 5 Department of Immunology, H. Lee Moffitt Cancer Center and Research Institute
Presented By: Ahmet Murat Aydin

Introduction: Tumor-associated macrophages (TAMs) have been associated with tumor progression and metastasis in breast, ovarian and gastric cancers. Based on response to microenvironmental stimuli, TAMs may differentiate into two different types of macrophages: tumor resisting type 1 (M1) and tumor promoting type 2 (M2) macrophages. Using the pan-macrophages marker CD68 and M2 markers CD163 and CD206, we aimed to evaluate the clinical significance of TAM location mapping within the tumor in patients with metastatic renal cell carcinoma (mRCC) treated with immunotherapy.

Methods: A total of 26 patients treated with immunotherapy for mRCC were included in this pilot study. Patients received either IL-2 (n =20) or checkpoint inhibitors (n=6) as first immune agent. Using quantitative multiplex immunofluorescence (Opal™; PerkinElmer), expression levels of CD68, CD163 and CD206 markers within the tumor nest, at the tumor-stroma interface, and within the surrounding stroma were evaluated in formalin-fixed paraffin-embedded primary tumor samples. Expression densities of CD68+, CD68+/CD163+ and CD68+/206+ TAMs were calculated and patients were grouped into low and high expression subgroups stratified by median expression level of each marker. Survival from the date of first immunotherapy was compared between patients with low and high biomarker expressions using a Log-rank test.

Results: Our findings (Table 1) demonstrate that high expression of pan-macrophage marker, CD68 within the mRCC microenvironment and high expression of M2 marker of CD68/CD163 in surrounding stroma was associated with poor overall survival of the patients.

Conclusion: Certain TAM expression markers correlate with survival of patients with mRCC. High co-expression of TAMs markers within the tumor microenvironment and their location associates with poor survival. Whether or not TAM markers can aid in the treatment decision making process in mRCC remains to be further investigated.

Table 1. Median overall survival (OS) after date of first immunotherapy in 26 patients with mRCC

<table>
<thead>
<tr>
<th>Marker and location</th>
<th>Median OS, low marker expression (months)</th>
<th>Median OS, high marker expression (months)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CD68+ CD206+</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tumor nest</td>
<td>53.1</td>
<td>46.7</td>
<td>0.527</td>
</tr>
<tr>
<td>Interface</td>
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168. FUSOGENIC LIPOSOMES AS A NOVEL NANOTHERAPY AGAINST METASTATIC CLEAR CELL RENAL CELL CARCINOMA
Jan Rudzinski1, Adrian Fairey1, Natasha Govindasamy2, Konstantin Stoletov2, Arun Raturi2, John Lewis2
1 Division of Urology, Department of Surgery, Faculty of Medicine and Dentistry, University of Alberta, 2 Department of Oncology, Faculty of Medicine and Dentistry, University of Alberta
Presented By: Jan Rudzinski

Introduction: We conducted a whole human genome short hairpin RNA (shRNA) screen on highly motile human squamous cell carcinoma (Hep3) cells and identified a panel of novel functional genes that are required for successful metastatic dissemination in vivo. One such novel target gene encodes for C14orf142 which is upregulated in metastatic clear cell RCC. Short interfering RNA (siRNA) are double stranded RNAs capable of binding to and inducing the degradation of complementary messenger RNAs in the cytoplasm leading to silencing of functional proteins. Fusogenic liposome platform is formulated with fusion associated small transmembrane proteins such as P14 which ensures highly efficient siRNA delivery directly into the cellular cytoplasm. Our objective is to investigate whether a novel P14 armored LNPs encapsulating custom siRNA against C14orf142 could interfere with clear cell RCC experimental metastasis.

Methods: Custom designed siRNAs targeted against C14orf142 were encapsulated in P14 armoured fusogenic lipid nanoparticles (LNP) using the Precision Nanosystems Nanoassemblr TMbenchtop system. 786-0 cell lines (clear cell RCC) were transfected and successful protein knock-down was validated using western blot analysis. To measure cellular invasion and motility we utilized modified Boyden chamber and the Matz assay. The avian embryo model was used to evaluate the impact of P14 armored fusogenic liposomes encapsulating siRNA against C14orf142 in prevention of 786-0 vascular extravasation in vivo. T-test was used to evaluate differences between groups with p value of <0.05 accepted as statistically significant.

Results: Transfection of 786-0 cell line with 4µg of custom siRNA against C14orf142 with P14 LNPs demonstrate significant reduction in expression of C14orf142 compared to scramble transfected cells (32.67±9.52% vs 100%, respectively, p<0.05) without compromise in cellular viability. 786-0 silenced for expression of C14orf142 demonstrate significant reduction in % invasion (72.33±4.87%) and cellular migration (46.33±8.37%) compared to scramble clones (100%) (p<0.05). 786-0 transfected with P14 armored fusogenic liposomes encapsulating 4µg ofsiRNA against C14orf142 demonstrate significant reduction in vascular extravasation in vivo compared to scramble clones (15.43±3.45% vs100%, respectively, p<0.05).

Conclusion: P14 armoured fusogenic lipid nanoparticles encapsulating siRNA against C14orf142 could potentially pave the way for novel therapeutic approaches in management of metastatic clear cell RCC.

Funding: Kidney Cancer Research Network Canada
**169. THE EMERGING ROLE OF POLY (ADP-RIBOSE) POLYMERASE INHIBITORS IN RENAL CELL CARCINOMA**

Jerred Pletcher, Jonathan Doan, Sayani Bhattacharjee, Puneet Sindhwani, Nagalakshmi Nadiminty, Firas Petros

*1 College of Medicine and Life Sciences, The University of Toledo, 2 Cancer Biology Program, College of Medicine and Life Sciences, The University of Toledo, 3 Department of Urology, College of Medicine and Life Sciences, The University of Toledo Medical Center*

**Presented By:** Firas Petros

**Introduction:** Renal cell carcinoma (RCC) is the sixth most common cancer in the US, but no significant changes in management have occurred since tyrosine kinase era until the recent breakthrough with checkpoint inhibitors. Hence, the need for more therapeutic options is paramount. One therapeutic option not yet explored is poly (ADP-ribose) polymerase (PARP) inhibitors (PARPi). The objective of this study was to determine whether PARP inhibition represents a novel therapeutic option for RCC.

**Methods:** We used publicly available databases such as COSMIC, GDC Data Portal, and cBioPortal to explore the rate of mutations in DNA repair genes in RCC tissues from the TCGA cohort. To test the efficacy of PARPi against RCC cells, we treated a human normal renal cell line RPTEC/TERT1 and two human renal cancer cell lines ACHN and CAK1-2 with varying concentrations of PARPi niraparib, olaparib, rucaparib, veliparib, and talazoparib. Cell survival, cell proliferation, and apoptosis were assessed. Xenografts of ACHN cells in SCID mice were treated with PARPi to assess their efficacy in vivo.

**Results:** Data mining revealed that ~27-32% of RCC contain mutations in homologous recombination genes. Niraparib and talazoparib were the most effective at reducing the cell survival and proliferation of RCC cells in vitro. Treatment with PARPi induced caspase-mediated apoptosis in the RCC cell lines. Niraparib, talazoparib, and rucaparib were the most effective in reducing the growth of ACHN xenografts in vivo.

**Conclusion:** Agents that exploit mutations in DNA damage repair genes such as PARPi may be effective therapeutic options for RCC.

**Funding:** Frank Stranahan Foundation
170. THE IMPACT OF SURGICAL RESECTION ON CIRCULATING TUMOR-REACTIVE CYTOTOXIC T-CELLS FOR PATIENTS WITH RENAL TUMORS
Vignesh T. Packiam1, Henan Zhang1, Christine M. Lohse1, Matvey Tsivian1, Lance C. Pagliaro1, Brian A. Costello1, R. Houston Thompson1, Stephen A. Boorjian1, John C. Cheville1, Haidong Dong1, Bradley C. Leibovich1, Bimal Bhindi2, Paras Shah2
1 Mayo Clinic, 2 University of Calgary, 3 Albany Medical College
Presented By: Vignesh T. Packiam

Introduction: The impact of surgical resection of renal tumors on peripheral immune related cells is not well characterized, and has potential implications as biomarkers for systemic immune therapy are being developed. We sought to assess the effect of surgical resection on circulating cytotoxic T-cells (CTLs) for patients with renal tumors.

Methods: We prospectively enrolled 40 patients undergoing partial, radical, or cytoreductive nephrectomy (PN, RN, CN) for unilateral primary renal tumors between 2016 and 2018. We excluded immunosuppressed patients. Blood draws were performed preoperatively, 1 day post-operatively, and 3 months post-operatively. Peripheral blood mononuclear cells (PBMCs) were isolated and flow cytometry was performed. The % of PBMCs expressing CD11a/CD8 (CTLs) were assessed. The % of CTLs expressing PD-1, Bim (a downstream PD-1 pathway pro-apoptotic mediator), CX3CR1/GZMB (an effector memory T-cell phenotype), and Ki67 (a proliferation marker) were assessed. Median changes in % of CTLs from before surgery to the 1 day and 3 month time points were evaluated with the Wilcoxon signed rank test. Comparisons between aggressive (pT3-4, N1, M1, or aggressive histology (high-grade, coagulative necrosis, sarcomatoid dedifferentiation, or specific RCC-variant histologies)) versus indolent tumors were assessed using the Wilcoxon rank sum test.

Results: Twenty, 12, and 8 patients underwent RN, PN, and CN, respectively. Thirty, 7, and 3 patients had clear-cell RCC, non-clear cell RCC, and oncocytoma, respectively. Twenty-three and 17 patients had aggressive and indolent tumors, respectively. While there was no significant change at 1 day, by 3 months there were significantly increased CTLs among PBMCs (+1.3%; p=0.004). At 1 day there was significant decrease in CX3CR1+GZMB+ CTLs (-2.9%; p=0.001) and significant increase in Bim+ CTLs (+3.0%; p=0.03). However, these changes were no longer significant by 3 months. Interestingly, Ki67+ CTLs increased at day 1 (+0.6%; p<0.001) but decreased by 3 months (-0.6%; p=0.001). There were no significant changes in PD-1+ CTLs at either time point. There were no significant changes in any CTL characteristics at 1 day or 3 months between aggressive and indolent tumors.

Conclusion: These findings characterize changing CTL profiles over time with surgical resection of renal tumors. These data may help guide biomarker development for utilization of systemic immune therapies.

171. PREVENTION OF BENIGN KIDNEY TUMOR RESECTION USING A COMBINATION OF ROUTINE BIOPSY AND TUMOR:CORTEX PEER: A 5-YEAR EXPERIENCE
Arun Menon, Tashionna White, Gaybrielle James, Eric Kauffman
Roswell Park Comprehensive Cancer Center
Presented By: Arun Menon

Introduction: The tumor:cortex peak early-phase enhancement ratio (PEER) using multiphase CT has been prospectively validated for discerning CD117(+) chromophobe renal cell carcinoma from CD117(+) oncocytoma (RO). We evaluate the effectiveness of routine preoperative biopsy and PEER evaluation to prevent resection of benign kidney tumors.

Methods: Retrospective study of oncologic outcomes was performed for all fat-poor renal cortical tumor patients seen over a 5 year period at a National Comprehensive Cancer Network institute by a single surgeon who used routine biopsy combined with oncocytic tumor:cortex PEER evaluation to guide patient selection for surgical resection. Biopsy was recommended for all renal cortical tumors with suspected chance of benign histology of at least 1% based on radiographic appearance and symptomology. Tumor:cortex PEER was measured prospectively from multiphasic CT imaging for all CD117-positive tumors with a biopsy favoring RO, in order to support (PEER >0.55) or challenge (PEER <=0.50) RO diagnosis. Patients with RO diagnosis supported by biopsy and PEER value were surveyed. The primary outcome measure was the incidence of benign histology among surgically resected tumors. The secondary outcome measure was the rate of metastasis among patients with biopsy favoring benign tumor histology who were managed with active surveillance.

Results: 383 consecutive patients with clinically localized renal cortical tumors presenting over a 6 year period were included in the study. Renal mass biopsy was performed for 246 (64.2%) patients. 36 (9.4%) patients were determined to have benign renal tumor histology on biopsy and PEER evaluation. These patients did not undergo surgery and were placed on surveillance. 171 patients with a preoperative diagnosis of renal cell carcinoma underwent surgery, of these 110 (64.3%) patients were diagnosed as malignant renal tumor on preoperative biopsy and 61 (35.7%) patients had frank features of malignancy clinically or on imaging and directly proceeded to surgery without a biopsy. On review of the final resected tumor histopathology, no instance of resection for a benign tumor was found. One patient with a preoperative diagnosis of spindle cell tumor was found to have epithelioid Angiomyolipoma with necrosis and indeterminate malignant potential on final pathology. Over a median follow up of 24 months, no patient with a benign tumor on active surveillance developed metastasis.

Conclusion: Among nearly 400 clinically localized renal tumor patients seen, there have been no cases of benign tumor resection. We conclude that routine biopsy combined with tumor:cortex PEER measurement for discerning CD117(+) oncocytoma from CD117(+) chromophobe RCC is effective for avoiding resection for benign tumors.
172. INITIAL OUTCOMES FOR UNIVERSAL ACTIVE SURVEILLANCE OF SMALL RENAL MASSES USING PRE-DEFINED PROGRESSION CRITERIA FOR TREATMENT CONVERSION

Arun Menon, Tashioanna White, Gaybrielle James, Kristopher Attwood, Eric Kauffman
Roswell Park Comprehensive Cancer Center

Presented By: Arun Menon

Introduction: Metastatic risk for small renal mass (SRM) patients on active surveillance (AS) is low and often outweighed by treatment morbidity/mortality. Current AS literature is confounded by highly selected SRM patients who are unfit for treatment, hence neither treatment rates nor standardized progression criteria for triggering treatment in healthier SRM patients are well defined. We report our initial experience with a novel SRM management approach that includes: 1) universal AS recommendation for all SRM patients without progression at presentation, and 2) AS management using specific prospectively applied progression criteria for triggering treatment recommendation.

Methods: All non-end stage renal disease patients with enhancing SRM tumors and no prior renal cell carcinoma (RCC) history who presented from January 2013 to January 2017 to a single urologic oncologist at a National Comprehensive Cancer Network institute were recommended AS if pre-defined progression criteria were not met at presentation. Progression criteria for recommending treatment at presentation or during AS were the absence of benign tumor biopsy histology + presence of any of the following: longest tumor diameter (LTD) > 4 cm; growth rate > 5 mm/year; LTD > 3 cm + growth rate = 3 mm/year; high risk biopsy histology; > cT3a stage; or symptoms. SRM biopsy was recommended for LTD > 2 cm. The primary outcome measure was 1 and 3-year progression-free survival (PFS); the secondary outcome measure was metastasis-free survival (MFS).

Results: Of 127 SRM patients with > 3 months follow-up, 4 met progression criteria at presentation and were recommended treatment. All remaining 123 SRM patients (median initial LTD 2.2, range 0.9-3.9 cm) were managed with initial AS. Median follow up for these 123 AS patients was 30 (range 6-68) months, during which 35 (29%) met at least 1 progression criterion. 1 and 3-year PFS rates were 92%, and 70%, respectively. Shorter PFS was associated with initial LTD (3-year PFS 83%, 75%, 45% for < 2 cm, 2.1-3 cm, >3cm, respectively) and clear cell RCC biopsy histology (3-year PFS 45%). Most (28/35; 80%) progressing patients converted to treatment (27 surgery, 1 ablation). Only 1/88 (1%) non-progressing patients converted to treatment for anxiety or other causes. Benign tumor resection incidence was 0%, and most (61%) resected tumors had adverse RCC pathology (high grade and/or pT3a). MFS for progressing or non-progressing patients was 100%.

Conclusion: Universal initial AS for SRM patients using these specific progression criteria significantly delays or avoids treatment for most patients with initial LTD < 3 cm, and overall improves identification of aggressive vs. indolent tumors for treatment selection by avoiding benign tumor removal and enriching resection for adverse RCC pathology. Longer PFS and MFS rates are needed to better assess the durability and oncologic safety of universal AS.
173. ASSOCIATION OF DE RITIS RATIO AND NEUTROPHIL LYMPHOCYTE RATIO WITH RENAL FUNCTIONAL DECLINE AND ALL-CAUSE MORTALITY IN RENAL CELL CARCINOMA

Cathrine Keiner¹, Margaret Meagher¹, Devin Patel¹, Fady Ghali¹, Raksha Dutt¹, Dattatraya Patil², Kazutaka Saito³, Yosuke Yasuda⁴, Yasuhisa Fuji⁴, Nathan Miller⁴, Fang Wan⁴, Ithaar Derweesh⁴, Aaron Bradshaw⁴

¹ University of California San Diego, ² Emory, ³ Tokyo Medical and Dental University, ⁴ UCSD

Presented By: Cathrine Keiner

Introduction: Extirpative renal surgery may be associated with renal functional decline and increased risk of mortality in patients with renal cell carcinoma (RCC). RCC is a metabolically driven disease and a number of markers of inflammation have been associated with oncologic outcomes. Predictive markers for renal functional decline and association with mortality are not well-defined. We sought to investigate the utility of pre-operative neutrophil-lymphocyte ratio (NLR), platelet-lymphocyte ratio (PLR), and De Ritis Ratio as predictors of renal functional decline and overall survival (OS) in RCC.

Methods: Multi-institutional (UC San Diego, Emory, Tokyo Medical Dental University) retrospective analysis of patients undergoing extirpative renal surgery for renal cell carcinoma. Primary outcome was all-cause mortality (ACM)/overall survival (OS). Secondary outcomes included development of de novo estimated glomerular filtration rate (eGFR)<45 ml/min/1.73m² (eGFR<45) and eGFR<30 ml/min/1.73m² (eGFR<30). Logistic regression multivariable analysis (MVA) was conducted to elucidate independent risk factors for ACM, eGFR<45 and eGFR<30. Kaplan-Meier analysis (KMA) was used to investigate OS, and freedom from de novo eGFR<45 and eGFR<30.

Results: 2928 patients were analyzed (1850 Male/1078 Male, median age 60 years, median follow up 30.5 months); 1741 patients underwent partial nephrectomy (PN), while 1187 underwent radical nephrectomy (RN). Median tumor size was 4.5 cm. 690 patients had NLR = 3, while 208 patients had NLR = 6; 110 patients had PLR = 3; and 474 patients had De Ritis Ratio = 3. MVA for risk factors associated with worsened ACM included male sex (OR=1.60, p=0.020), HTN (OR=2.14, p=0.001), increasing tumor size (OR=1.12, p<0.001), clear cell histology (OR=1.98, p=0.001), RN (OR=1.56, p=0.048), NLR= 6 (OR=2.43, p=0.001), Di Ritis Ratio =3 (OR=2.38, p<0.001), and de novo eGFR<45 (OR=1.64, p=0.015). Variables associated with risk of development of eGFR<45 included increasing age (OR=1.03, p<0.001), male (OR=1.54p=0.009), HTN (OR=2.30, p<0.001), clear cell RCC (OR=2.16, p<0.001), RN(OR=6.8, p=0.030), NLR=6 (OR=1.999, p=0.002), and Di Ritis Ratio=3 (OR=0.226, p<0.001). Variables associated with development of eGFR<30 included increasing age (OR=1.05, p<0.001), DM (OR=3.01, p<0.001), African American (OR=1.93, p=0.005), Di Ritis Ratio=3 (OR=1.99, p=0.001), and NLR=6 (OR=2.123, p=0.002). PLR was not independently associated with overall survival, development of de novo eGFR<45, or development of de novo eGFR<30. On KMA, NLR=6 was associated with worse OS (p<0.001). Di Ritis ratio ( =1.5) was associated with worse OS (p<0.001) and Di Ritis ratio ( =3) was associated decreased freedom from of de novo eGFR<45 (p=0.026).

Conclusion: Preoperative elevated NLR and De Ritis Ratio were independent risk factors for functional decline and worsened OS in RCC patients, while PLR in our sample was not predictive of both outcomes. When safe and feasible, nephron preserving management strategies should be considered in patients with elevated NLR and De Ritis Ratio to reduce risk of functional decline and potential mortality.
174. IMPACT OF ONCOLOGICAL VERSUS NON-ONCOLOGICAL FACTORS ON SURVIVAL OUTCOMES IN AFRICAN AMERICANS WITH RENAL CELL CARCINOMA

Margaret Meagher1, Aaron Bradshaw1, Brittney Cotta1, Ahmed Eldefrawy1, Stephen Ryan1, Ryan Nassen1, Fang Wan1, Ithaar Derweesh1, Dattatraya Patil2, Viraj Master2, Kazutaka Saito3, Yosuke Yasuda2, Yasuhisa Fujii3
1 UC San Diego Health, 2 Emory Medical Center, 3 TMDU

Presented By: Margaret Meagher

Introduction: African-Americans have an increased incidence of renal cortical tumor subtypes of lower oncological potential in the setting of lower risk disease when compared to other ethno-racial groups. On the other hand, survival outcomes are similar. We investigated the impact of African-American race on overall survival, oncological outcomes, functional outcomes, and non-cancer mortality.

Methods: Multi-institutional (Emory, TMDU, UCSD) retrospective analysis of patients who underwent partial or radical nephrectomy between 1998-2018. The cohort was divided into African-American and Non-African American subgroups for descriptive analyses. Patients were analyzed for demographics, clinical parameters, and post-surgical outcomes. Primary outcome was overall survival (OS). Secondary outcomes included non-cancer mortality (NCM), recurrence free survival (RFS), and estimated glomerular filtration rate (eGFR) decline. Multivariable logistic regression analyses (MVA) were used to elucidate predictive factors for OS, NCM, and RFS, and de novo eGFR <45 and <30 ml/min/1.73m2.

Results: 3632 patients who received either partial or radical nephrectomy for renal masses were grouped into African American (AA, n=531) and Non-African American (NAA, n=3101) sub-groups for analysis. No difference was noted between groups with respect to mean tumor size (p=0.31). Non-African Americans had a higher proportion of metastases at presentation (9.9% vs. 7.0%, p=0.04). African-American race was an independent risk factor for functional decline to de novo eGFR <45 (OR=1.43, p=0.04) and de novo eGFR<30 (OR 2.01, p<0.001). MVA for worsened NCM demonstrated African-American race (OR=1.63, p=0.02), increasing age (OR=1.05, p<0.001), male sex (OR=1.56, p=0.01), and hypertension (OR=1.73, p=0.001) to be independent risk factors. Significant factors on MVA for worsened OS included increasing age (OR=1.03, p<0.001), radical nephrectomy (OR=1.47, p=0.013), increasing tumor size (OR=1.11, p<0.001), hypertension (OR=2.63, p<0.001), high tumor grade (OR=1.97, p<0.001), and post-operative eGFR <45 (OR=1.50, p=0.006). MVA for worsening RFS demonstrated high tumor grade (OR=2.04, p<0.001) and increasing clinical tumor size (OR=1.15, p<0.001) to be independent risk factors.

Conclusion: African Americans undergoing renal surgery for RCC appear to have similar OS and RFS, but poorer NCM than non-African American patients. The cause of these disparities is multifaceted but is likely associated with functional decline. Nephron-sparing management when feasible and appropriate should be considered in African-American patients presenting with renal cortical tumors.

Funding: Stephen Weissman Kidney Cancer Research Fund
175. PREOPERATIVE OPTIMIZATION OF PROMOTILITY, INVESTIGATION OF PREOPERATIVE CONSTIPATION SCORES AND DISCHARGE FOLLOWING NEPHRECTOMY AND PROSTATECTOMY

Derek Jensen, Alexandra Dahlgren, Katie Giavin, Will Parker, Jeffrey Holzbeierlein, Muben Mirza, David Duchene, Eugene Lee
University of Kansas, Department of Urology

Presented By: Derek Jensen

Introduction: At our institution, the target length of stay following robotic partial nephrectomy, laparoscopic radical nephrectomy, and robotic prostatectomy is discharge on post-operative day 1 (POD#1). We hypothesized that treating preoperative constipation will help combat the rate of postoperative ileus—one of the leading reasons for increased lengths of stay. Before launching a trial to treat preoperative constipation, we conducted a prospective observational study to determine the baseline level of constipation amongst this patient population as well as investigate a relationship between preoperative constipation and increased length of stay. The Patient Assessment of Constipation Symptoms (PAC-SYM) is a validated patient questionnaire that assesses constipation symptom burden on a spectrum with higher scores representing higher levels of constipation, but no specific threshold for diagnosis of constipation.

Methods: Patients were asked to complete PAC-SYM surveys at a preoperative visit. Peri-operative data was collected prospectively including demographics, procedure performed, PAC-SYM scores, and length of stay.

Results: A total of 99 patients met trial criteria. 31 patients underwent laparoscopic or robotic radical nephrectomy, 34 underwent robotic partial nephrectomy, and 34 underwent robotic prostatectomy. 18/99 (18%) patients stayed longer than POD #1. The overall pre-operative PAC-SYM score was 4.4. 32% (10/31) of lap nephrectomy patients, 24% (8/34) of partial nephrectomy patients, and 0% (0/34) radical prostatectomy patients stayed longer than POD #1. Preoperative PAC-SYM scores for lap nephrectomy, robotic partial nephrectomy, and robotic prostatectomy were 4.7, 4.1, and 4.2, respectively. Radical and partial nephrectomy patients with a PAC-SYM score of 5 or greater had a 36% chance of staying longer than POD#1 compared to 23.3% with a PAC-SYM score <5. Overall, patients who discharged on POD#1 had an average preoperative PAC-SYM score of 4.1 compared to 5.3 for those who did not, although this was not statistically significant. The reasons for delay in discharge were abdominal distension/pain (10), nausea (4), and post-operative complication (2), dizziness (1), and patient preference (1).

Conclusion: On average, patients with delayed discharge after minimally invasive surgery had higher PAC-SYM scores compared to those discharged on post-operative day #1. Patients with a PAC-SYM score <5 undergoing nephrectomy (radical or partial) were 11% more likely to discharge on POD#1. Further studies will elucidate the potential role of treating constipation preoperatively to decrease post-operative length of stay.
176. REDEFINING THE OBESITY PARADOX IN RENAL CELL CARCINOMA

Aleem Khan, Bashir Al Hussein Al Awamlh, Lina Posada, Jonathan Fainberg, Jonathan Shoag, Douglas Scherr
Weill Cornell Medical College Department of Urology

Presented By: Aleem Khan

Introduction: Obesity is among the established risk factors for development of renal cell carcinoma but has also been associated with lower stage and grade of disease as well as improved survival compared to patients with normal body weight, a phenomenon often referred to as the Obesity Paradox. In this study we compared differences oncological outcomes between BMI extremes following nephrectomy for renal cell carcinoma.

Methods: We performed a retrospective study of patients at a single, large academic institution who underwent surgical management of RCC from 2000-2015. We collected preoperative, intraoperative and postoperative data including pathologic reviews according to the World Health Organization 2004 classification of renal tumors. Overall survival was calculated from time of nephrectomy to cancer-specific death or last follow up. Data analysis was done using Kaplan-Meier log-rank estimates for survival comparisons. Multivariable Cox proportional hazards regression controlling for age, gender, ASA class, tumor grade, and histology subtype was used to determine factors associated with recurrence-free survival.

Results: We identified 870 patients who underwent surgical management of renal tumors between the years 2000-2015. A total of 180 patients were used for the analysis comparing the 10th and 90th percentiles, with 60 (7%) lean patients (BMI<20) and 190 (22%) obese patients (BMI>31). The median age at presentation was 66 years and 60 years for lean and obese patients, respectively and median follow-up time for both groups was 6 years. Clear cell carcinoma comprised 155 (62%) of the patient group, while papillary (34, 13.6%), chromophobe (26, 10.4%), Oncocytoma (19, 7.6%) and other (16, 6.4%) comprised the rest. There was no significant difference in overall survival between the two groups (HR 0.217, 95% CI 0.029-1.64) with 98% and 92% cumulative survival at 6 years for lean and obese patients, respectively. There was a significant difference in recurrence (HR 2.859, 95% CI 1.203-6.797) between lean and obese patients, with lean patients having a higher likelihood of recurrence at 3 years, with a median time to recurrence of 10 months compared to 35 months for obese patients. On multivariable Cox regression, lean BMI (HR 3.13, 95% CI 1.15-8.53), increasing pathologic stage (HR 2.4, 95% CI 1.01-5.55), and clear cell subtype (HR 3.2, p=0.001) were associated with decreased recurrence-free survival.

Conclusion: Leaner patients were significantly more likely to recur independent of tumor histologic subtype, stage, and grade at time of nephrectomy compared to obese patients. We observed no differences in the cancer specific survival, indicating that the difference in relapse risk may be a key mediator in explaining the obesity paradox.

177. STRATIFYING SIZE WITHIN RENAL CELL CARCINOMA STAGING GROUPS DOES NOT CORRELATE TO OUTCOMES; A SINGLE INSTITUTION EXPERIENCE WITH 870 PATIENTS OVER 15 YEARS

Aleem Khan, Lina Posada, Bashir Al Hussein Al Awamlh, Jonathan Fainberg, Douglas Scherr, Jonathan Shoag
Weill Cornell Medical College Department of Urology

Presented By: Aleem Khan

Introduction: Tumor size is a well-established prognostic biomarker in patients with renal cell carcinoma (RCC). While compelling evidence has previously shown prognostic relevance of dividing T2 tumors into T2a (>7cm and <10 cm) and T2b (>10cm), there is a paucity of evidence to support the subcategorization of tumors into T1a and T1b. This study aimed to determine the prognostic relevance of these subcategories.

Methods: We performed a retrospective study of patients at a single, large academic institution who underwent surgical management of RCC from 2000-2015. We collected perioperative and pathologic data. Overall survival (OS) was calculated from time of nephrectomy to cancer-specific survival (CSS) or death from any cause. Survival analysis was done using Kaplan-Meier log-rank estimates for survival comparisons. Multivariable Cox proportional analysis was used to assess the association between obesity and recurrence-free survival (RFS), adjusting for age, gender, ASA class, tumor grade, and histology subtype.

Results: We identified 870 patients who underwent surgical management of renal tumors. On final pathology 615 patients had pT1 disease, of which 456 (74.1%) had T1a and 159 (25.9%) with T1b. The median follow-up was 6 years (IQR 1.8-10.5), and the median age at presentation was 62 and 64 for T1a and T1b, respectively. Of patients with T1a disease, 223 (48.9%), 108 (23.7%), 49 (10.7%), and 76 (16.7%) had clear cell, papillary, chromophobe, or other type of tumor, respectively. There was no significant difference in OS between the two groups (p=0.680) at 6-year (99% vs.97%) for T1a and T1b tumors, respectively. Similarly, at 6-years there was no difference in RFS between T1a and T1b (95% vs 88%, p=0.246). Across all T1 disease, there was no significant association with maximum tumor dimension in OS (p=0.790) or CSS (p=0.385). On multivariable Cox regression, T1b was not associated with worse OS than T1a (HR 1.28, 95% CI 0.515-3.163).

Conclusion: There were no differences in oncological outcomes between T1 patients in a contemporary cohort for patients with a long-term follow up. Our results indicate that subcategorizing T1 tumors has no prognostic relevance, and suggests a simplification of the current AJCC staging system for RCC may be warranted.
178. IMPACT OF DIABETES MELLITUS ON FUNCTIONAL AND SURVIVAL OUTCOMES IN RENAL CELL CARCINOMA: AN INTERNATIONAL MULTICENTER STUDY

Raksha Dutt, Margaret Meagher, Devin Patel, Fady Ghali, Cathrine Keiner, Nathan Miller, Aaron Bradshaw, Ithaar Derweesh
University of California, San Diego
Presented By: Raksha Dutt

Introduction: Functional decline is an important consideration in the surgical treatment of renal cell carcinoma (RCC), especially in those patients with diabetes mellitus (DM) who are at increased risk of kidney disease. While radical nephrectomy (RN) may be associated with increased risk of functional decline in kidney function compared to partial nephrectomy (PN), the modifying effect of DM is not completely understood. We sought to investigate the relationship between DM and decline in kidney function following surgery for RCC and explore the risk of DM on overall survival (OS) in patients with RCC.

Methods: A multicenter dataset (UC San Diego, Emory, TMDU) of RCC patients undergoing PN and RN was utilized. The cohort was divided based on DM status (DM=diabetes mellitus, NDM=no diabetes mellitus). Demographic factors and clinical parameters were analyzed for each patient. Multivariable analysis (MVA) was run to elucidate potential variables associated with decline in kidney function and increased mortality. Kaplan-Meier analysis (KMA) was used to investigate 5-year OS rates.

Results: 2928 patients were analyzed (DM=406, NDM=2522). On MVA, variables associated with risk of development of de novo eGFR<45 mL/min/1.73m2 included increasing age (OR=1.070, p<0.001), presence of DM (OR=1.883, p<0.001), greater clinical tumor size (OR=1.033, p=0.032), and PN surgery type (OR=1.543, p<0.001). Variables associated with risk of development of de novo eGFR<30 mL/min/1.73m2 included increasing age (OR=1.046, p=0.001), African American race (OR=2.183, p=0.001), and presence of DM (OR=2.092, p<0.001). MVA revealed increasing age (OR=1.022, p=0.002), presence of HTN (OR=2.469, p<0.001), higher BMI (OR=0.976, p=0.036), greater clinical tumor size (OR=1.118, p<0.001), higher grade tumor (OR=1.869, p<0.001), PN surgery type (OR=1.554, p=0.011), and post-operative eGFR<30 mL/min/1.73m2 (OR=1.876, p=0.026) to be independent risk factors for decreased OS. On KMA, 5-year OS stratified by DM status showed that DM is associated with worse OS for patients treated with RN (p=0.047), but not for patients treated with PN (p=0.944).

Conclusion: Presence of DM is an independent risk factor for renal functional decline to de novo chronic kidney disease (CKD) Stages IIIa, IIIb, and IV. While development of CKD is a risk factor for worse OS, decreased survival in DM patients was associated with radical nephrectomy recipients but not with partial nephrectomy recipients. Presence of DM may be considered a strong indicator for nephron preservation management strategies when safe and feasible in RCC patients.
179. IS RENAL VOLUME AND FUNCTION COMPROMISED IN ONCOCYTOMA PATIENTS ON ACTIVE SURVEILLANCE?
Amandip Cheema, Arun Menon, Sergei Kurenov, Tashionna White, Gaybrielle James, Eric Kauffman
Roswell Park Cancer Institute

Presented By: Amandip Cheema

Introduction: The oncologic safety of active surveillance (AS) in renal oncocytoma has been widely reported. However, a remaining concern of surveying all oncocytoma patients is the hypothetical possibility of renal functional deterioration due to mechanical effects of an enlarging tumor on normal renal parenchyma. Here we tested this hypothesis by evaluating renal functional outcomes of oncocytoma tumors on AS, including 3-dimension (3-D) imaging software to measure ipsilateral renal parenchymal volumetric changes in patients with large and/or actively growing oncocytoma tumors.

Methods: A renal tumor AS database at Roswell Park Comprehensive Cancer Center was queried to identify all renal oncocytoma patients with at least 18 months follow up on AS. Renal functional outcomes (Cr, GFR) were retrospectively reviewed to determine changes during AS. Tumor volume was calculated using the formula \(0.5362 \times x \times y \times z\) when 3 dimensions were available and \(0.5362 \times x \times y \times (x+y/2)\) when two dimensions were available. Oncocytoma patients with an estimated volume increase on AS of at least 20 cm\(^3\) were selected for automated 3-D volumetric assessment of the tumor and ipsilateral renal parenchyma using CT images with Myrian \(^\text{®}\) software. Ipsilateral renal parenchymal volume and tumor volume were compared between first and last available CT images.

Results: Among a total of 32 oncocytoma patients on AS, 22 with at least 18 months follow up were identified (median 33, mean 37.5, range 19-95 months). Median (mean) estimated tumor volume for these 22 patients was 8.5 cm\(^3\) (27.3 cm\(^3\)) at AS initiation compared to 16.8 cm\(^3\) (42.7 cm\(^3\)) at last follow up. Median (mean) Cr and GFR for these 22 patients was 1.02 mg/dl and 70.9 ml/min/1.73 m\(^2\) (1.0 and 68.6) at AS initiation compared to 0.89 mg/dl and 79.5 ml/min/1.73 m\(^2\) (0.9 and 74.2) at last follow up. A total of 9 patients were identified with estimated volume increase of at least 20 cc on AS, most of whom had tumor size >5 cm at last follow up. Tumor volumes calculated for these 9 patients using 3-D imaging software (range 11.3-222) correlated well with estimated tumor volumes (range 9.2-232). The median change in 3-D tumor volume on AS was 26.1 cm\(^3\) (mean 40.5, range 20.2-106), while the median change in normal renal parenchymal volume was -8.0 cm\(^3\) (mean -6.1, range -35-23). 6/9 (67%) tumors had minimal-to-no decrease (10 cm\(^3\) or more) in 3-D renal parenchymal volume on AS.

Conclusion: Loss of renal parenchyma and function may be uncommon in oncocytoma patients regardless of tumor growth and size. This result supports the renal functional safety of AS for oncocytoma, however larger studies with longer follow up and larger tumor volume increases are needed.
180. NOT ALL RESECTED CYSTIC RENAL MASSES HARBOR INDOLENT PATHOLOGY

Randall Lee¹, Benjamin Ristau², Andrew Macintosh³, Lyudmila DeMora⁴, Robert Uzzo⁴, David Chen⁴, Richard Greenberg⁴, Rosalia Viterbo⁴, Marc Smaldone⁴, Alexander Kutikov⁴

¹ Temple University Hospital, ² University of Connecticut Health Center, ³ MD Anderson Cancer Center, ⁴ Fox Chase Cancer Center

Presented By: Randall Lee

Introduction: Cystic renal cell carcinomas (cRCC) are suggested to be clinically indolent. As such, a distinct pathologic staging category for these lesions was recently proposed. These recommendations fail to account for limitations in the ability of modern imaging to differentiate cRCC from the rare more biologically aggressive mimics. We evaluated the frequency of high-grade kidney cancer in the highly selected cohort of surgically resected renal masses having cystic appearance on pre-operative radiographic imaging.

Methods: A prospectively maintained institutional database was queried for clinically cystic renal masses that underwent surgery from January 2000-June 2016 (n=2,729 kidney surgeries). Patient and tumor characteristics including age at surgery, smoking history, Charlson comorbidity index (CCI), gender, race, BMI, laterality, Bosniak classification, histology, grade, size, and nearness to the collecting system were recorded. Associations between tumor grade and patient/tumor characteristics were evaluated using generalized estimating equations.

Results: Eighty-nine patients (n=102 cystic lesions) met strict inclusion criteria; the majority (77%) were older than 50 years of age with a median Charlson comorbidity index was 1.15 (SD1.48). Of the 102 clinically cystic renal masses, 26% were pathologically confirmed as high grade RCC, while 74% were low grade RCC (n=50) or benign (n=26). CCI was associated with high grade surgical pathology (OR 1.37, 95% CI 1.05-1.79, p = 0.02). There was no association between tumor grade and the remainder of the patient/tumor characteristics analyzed.

Conclusion: Proposed changes to the kidney cancer staging system define a tumor’s cystic nature based on pathologic examination, however the decision for surgical intervention is based on preoperative radiographic evaluation. Proceeding with surgery for a radiographically “cystic” renal mass was a rare event in our cohort; however, among those who were selected for surgery, about one fourth harbored high-grade pathology. Before making changes to the clinical RCC staging system, a better understanding of the limitations inherent to radiographic characterization of cystic renal masses is necessary.
Introduction: Optimal anesthesia is an essential component of the enhanced recovery pathway after surgery (ERAS) as it has the potential to facilitate earlier mobilization, expedite the return of bowel function—leading to shorter length of stay, and accelerated convalescence. Neuroaxial (i.e. spinal, regional, epidural) anesthesia has also been associated with lower 30-day readmission rates. Furthermore, a reduction in hospital mortality has also been reported, in particular due to decreased deep venous thromboembolism. Prior studies have promoted the combination of spinal and general anesthesia as providing a more predictable analgesic effect, lesser hemodynamic and respiratory side effects in patients undergoing cardiac, vascular, orthopedic, pelvic and abdominal surgery. Indeed, local anesthetics interfere with blood clotting and prevent hypercoagulability, which can reduce incidence of post-operative DVT. Based on the above-mentioned considerations, the National Institute of Health and Care Excellence (NICE) in the United Kingdom recommends including neuroaxial anesthesia as part of venous thromboembolism (VTE) prevention in patients undergoing non-cardiac surgery. Radical nephrectomy is a commonly performed urologic surgery in the United States. Given the unique benefits provided by neuroaxial anesthesia in orthopedic and cardiac literature, we aimed to evaluate the benefits of adjunct anesthesia in the open nephrectomy cohort. Specifically, the objective of the present study was to identify differences in intra- and post-operative complications, length of stay and readmission rates between patients managed with general anesthesia alone as compared to general + neuroaxial (spinal, regional and epidural) anesthesia.

Methods: The NSQIP database includes over 150 perioperative data elements, which were collected from over 600 hospitals. Patients were included in the study if they were 18 years or older at the time of surgery between 2014 and 2017. CPT codes were used to identify patients having undergone open nephrectomy. Patients were further subdivided based on anesthesia modality: general anesthesia alone vs in combination with neuroaxial anesthesia. Data elements that were collected included age, race/ethnicity, body mass index (BMI), smoking status, diabetes mellitus, hypertension on medications, dyspnea, chronic obstructive pulmonary disease, bleeding disorders, steroid use, greater than 10% weight loss within 6 months before surgery, preoperative hematocrit, American Society of Anesthesiology (ASA) physical status, blood transfusion within 72 hours prior to surgery, congestive heart failure, and functional status. Functional status was defined as dependent (partial or total) versus independent. Patients were excluded if they had preoperative ascites, disseminated cancer or sepsis, or on mechanical ventilation at the time of surgery. Patients with missing values (preoperative hematocrit, height, weight, and those with unknown or unassigned ASA status), older than 90 years old, or undergoing emergent nephrectomy were excluded. Patients with any additional concurrent general surgery procedures (i.e. cholecystectomy, appendectomy, colectomy, etc) were also excluded. Intraoperative variables that were evaluated in the analysis included procedure type, total operating time, and wound classification, defined using the National Healthcare Safety Network. Postoperative variables included postoperative length of hospital stay, total length of stay, complications, readmission, procedure related readmissions and reoperation rates.

Results: 2,346 out of 3633 patients were included. Before propensity score matching, patients in the two groups were unevenly matched for BMI (p=0.031), race (p<0.001), and hypertension (p=0.033). After 1:1 propensity score matching, 1090 patients were evenly distributed in each category, with no demographic differences between the two groups. The differences previously seen prior to matching were no longer significant. The remainder of the descriptive statistics were equally distributed among the groups. Compared to GA alone after multivariable logistic regression, adjuvant neuroaxial anesthesia showed increased odds ratio of prolonged post-operative stay [aOR: 1.107, 95% CI: 1.042-1.176, p=0.001] (Table 3C) after adjusting for age, dyspnea, CHF, COPD, ASA status, ARF, dialysis, operative time, and preoperative hematocrit value. The addition of neuroaxial anesthesia was not associated with decreased procedure related readmission rate (aOR 0.966, 0.537-1.736, p=0.909), or a decrease in the complication rate (aOR 0.9, 0.659-1.227, p=0.505) when compared to general anesthesia alone. (Table 3A & 3B) Overall, the complication rate was 23.9 %, with no differences in complications between GA alone vs adjuvant neuroaxial anesthesia group, p=0.434. The most common complication after open nephrectomy in the GA cohort was a urinary tract infection, seen in 11(2%) patients. Pneumonia was more common in the NA group, 15 (2.8%)—although these differences were not significant. Both groups experienced a high rate of intra and postoperative transfusion requirements 101(18.5%) and 94(17.2%), p=0.635, as well as all-readmissions 25(4.6%) vs 24(4.4%), p=0.096, albeit the differences again were not significant in either of the postoperative outcomes.

Conclusion: Using the 2014-2017 NSQIP database, we were able to demonstrate no difference in procedure related readmissions and complications in the neuroaxial anesthesia group. Furthermore, patients who received neuroaxial anesthesia experienced a longer postoperative stay. Future prospective trials with increased focus on postoperative opioid consumption and early mobilization are encouraged.
### Table 2: Intra/postoperative outcomes

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<th>General Ancestral</th>
<th>Additional Ancestral</th>
<th>p</th>
<th>95% CI</th>
<th>After FSH</th>
<th>Overall</th>
<th>General Ancestral</th>
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<td>2059</td>
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<td>Transfusion (Units or percent) (%)</td>
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<td>Length of stay (days)</td>
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<td>Mortality (%)</td>
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<td>Severe Mortality (%)</td>
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*FSH: surgical site infection
*CSA: cardiovascular accident

### Table 3A: Procedure-related readmissions: multivariable logistic regression analysis

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<th></th>
<th>OR</th>
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<td>Additional anesthesia</td>
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<td>0.537 - 1.716</td>
<td>0.869</td>
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<td>Age</td>
<td>1.051</td>
<td>0.994 - 1.113</td>
<td>0.123</td>
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<tr>
<td>BMI</td>
<td>0.943</td>
<td>0.923 - 0.965</td>
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### Table 3B: Any complication: multivariable logistic regression analysis

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<tr>
<td>Age</td>
<td>1.052</td>
<td>0.997 - 1.108</td>
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### Table 3C: Post-operative stay negative Binomial Regression analysis

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<td>0.815 - 0.876</td>
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<td>Age</td>
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<td>0.001</td>
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<td>Dyspnea</td>
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<td>1.645 - 2.150</td>
<td>0.001</td>
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<tr>
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<td>Operative time</td>
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<tr>
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</tbody>
</table>
182. LONG TERM ONCOLOGICAL OUTCOMES OF SURGICALLY TREATED ONCOCYTOMA
Matvey Tsivian, Vignesh Packiam, Christine Lohse, Svetlana Avulova, R Houston Thompson, Stephen Boorjian, John Cheville, Bradley Leibovich
Mayo Clinic
Presented By: Matvey Tsivian

Introduction: The available data on long term outcomes of surgically treated renal oncocytoma (RO) are scant and largely outdated. Herein we describe our institutional outcomes of surgically treated RO.

Methods: We included patients who underwent surgical resection of a renal mass with a pathologic diagnosis of RO as confirmed by genitourinary pathology review. Disease recurrence was recorded as new radiographic evidence of a concerning renal mass warranting surveillance or intervention, and recurrence-free survival was estimated using the Kaplan-Meier method.

Results: A total of 561 patients underwent resection of RO between 1970 and 2012 (Table 1). Of these, 102 (18%) were multifocal, including 52 classified as multifocal because of bilateral tumors at diagnosis. Clinical stage was T1 in 87% of patients. Median follow up was 10.6 years. Twenty-four patients experienced recurrence at a median of 6 years. Recurring tumors were RO in 12, renal cell carcinoma in 2, and unknown in 10. Recurrence-free survival rates at 5, 10, and 20 years following surgery were 98, 96, and 94%, respectively. For patients presenting with multifocal disease, recurrence-free survival rates at these time points were 95, 87, and 87%, respectively. Multifocal disease at presentation was significantly associated with recurrence (HR=3.92, 95%CI 1.75-8.75, p<0.001; Figure 1).

Conclusion: While RO has excellent oncologic outcomes, a subgroup of patients presenting with multifocal disease are at significant risk of recurrence. These data support revisiting guidelines for follow-up for RO after surgical resection.
183. DO THE METHODS FOR EVALUATING NECROSIS ON IMAGING AFFECT PREDICTION OF METASTATIC RENAL CELL CARCINOMA?
Skylar Iosepovici, Roy Mano, Cihan Duzgol, Mazyar Ghanaat, Andrew Silagy, Kyle Blum, Aleksandra Walasek, Renzo DiNatale, Julian Marcon, Jonathan Coleman, Paul Russo, Oguz Akin, A. Ari Hakimi, Alejandro Sanchez

1 Memorial Sloan Kettering Cancer Center, 2 Huntsman Cancer Institute

Presented By: Skylar Iosepovici

Introduction: Previous studies have shown an association between pathological tumor necrosis and adverse outcome in patients with RCC. Reported rates of tumor necrosis on preoperative imaging range from 10% - 92% and their association with outcome is less studied. We aimed to evaluate the association between tumor necrosis on preoperative imaging and outcome of localized renal masses when evaluated using imaging reports and radiology re-review of the images.

Methods: After obtaining IRB approval, we identified patients who underwent nephrectomy for a localized renal mass between the years 2005 – 2011 and had preoperative axial imaging available for review. The presence of necrosis on imaging was determined based on the original radiology report and by an independent radiology re-review of the images. Kaplan-Meier curves were plotted to evaluate metastatic free probability stratified by the presence of necrosis on imaging. Multivariable Cox regression models were used to evaluate the association between necrosis on imaging and metastatic free probability when controlling for gender, mode of presentation, lymphadenopathy and tumor size.

Results: A total of 758 men and 470 women with a median age of 61 years (IQR 52, 70) were included in the study cohort. Most patients (1029, 84%) presented incidentally, 41 patients (3%) had lymphadenopathy and the median tumor size was 3.7cm (IQR 2.5, 5.7). Necrosis was found in 114 tumors (9%) when determined by the original imaging report and 651 tumors (53%) when the images were re-reviewed by a radiologist. A total of 105 patients (9%) had evidence of necrosis on both the original report and the image re-review, 555 patients (45%) had evidence of necrosis on one of the two methods and 568 patients (46%) did not have evidence of necrosis. Patients who had evidence of necrosis by both definitions had the highest rate of metastatic disease (Figure 1). Necrosis on preoperative imaging remained a significant predictor of outcome on multivariate analysis when controlling for known preoperative predictors of metastatic free probability, using either of the definitions for necrosis.

Conclusion: Tumor necrosis on imaging is a significant preoperative predictor of metastatic free probability irrespective of the way it is evaluated. Ongoing studies are assessing whether the degree of necrosis on preoperative imaging as a continuous variable may better predict metastatic free probability in this group of patients.

Funding: This work was supported by The Sidney Kimmel Center for Prostate and Urologic Cancers. This research was funded in part through the NIH/NCI Cancer Center Support Grant P30 CA008748.
184. IMPACT OF AGE AT DIAGNOSIS ON CAUSE OF DEATH IN PATIENTS WITH KIDNEY CANCER
Ankur Choksi, Alexander Henry, Shu Wang, Michael Naslund, Mohummad Minhaj Siddiqui
University of Maryland School of Medicine
Presented By: Ankur Choksi

Introduction: It is presumed that older patients are more likely to die from other causes of death than the cancer itself and hence the age at which a patient is diagnosed with cancer is a key determinant in the treatment modalities offered to a patient. The relationship between age at diagnosis and cause of death has not been well described for genitourinary cancers. The objective of this study is to examine the variation in causes of death with respect to age at diagnosis for patients diagnosed with non-metastatic kidney cancer.

Methods: We retrospectively analyzed the records of patients diagnosed with localized (N0M0) kidney cancer (ICD-O-3 8260, 8310-8312, 8316-8317, 8319, 8323, 8480, and 8510) between the ages of 45 and 74 in the US Surveillance, Epidemiology and End Results Program (SEER) from 2003 to 2015. Patients with multiple primary tumors and unknown details regarding cause of death were excluded. Univariate and multivariate Cox proportional hazards regression was performed to investigate mortality and cause of death. Kaplan – Meier survival estimates were obtained for kidney cancer – specific and all cause of death at 5 and 10 years from diagnosis to calculate attributable cause of death to kidney cancer by age at diagnosis.

Results: We identified 87,953 patients diagnosed with localized kidney cancer between 2003 and 2015. Treating age as a continuous variable, kidney cancer-specific hazards ratio is 1.032 (95% CI: 1.028 – 1.037, p<0.001) and all-cause hazards ratio is 1.041 (95% CI: 1.038 – 1.043, p<0.001) at 5 years after diagnosis while kidney cancer-specific hazards ratio is 1.031 (95% CI: 1.027 – 1.035, p<0.001) with an all-cause hazards ratio of 2.73 (95% CI: 2.50 – 2.97, p<0.001) at 10 years after diagnosis. On multivariate analysis, patients diagnosed between the ages of 70 – 74 had a kidney cancer-specific hazards ratio of 2.65 (95% CI: 2.43 – 2.88, p<0.001) with an all-cause hazards ratio of 2.90 (95% CI: 5.88 – 6.80, p<0.001) when compared to patients diagnosed between the ages of 45 – 49. Figure 1: Kaplan-Meier Survival Estimates showing kidney cancer-specific vs other causes of death at 10 years (top) and 15 years (bottom) from diagnosis

Conclusion: The attributable cause of death to kidney cancer for patients diagnosed with kidney cancer at a younger age is similar to that of patients diagnosed at an older age.
Introduction: Whilst surgical excision remains the principal management strategy for T1 renal masses, the rates of active surveillance (AS) and other non-interventional approaches are not well known. Although the most recent AUA and ASCO guidelines include AS as a treatment option for T1a lesions, most single-institution and population-based series suggest rates well below 10%. We hypothesized that use of non-interventional approaches in academic and community-based practices for patients diagnosed with new T1 renal masses is much higher than prior reports.

Methods: Proposed and approved in 2015, MUSIC KIDNEY (Kidney mass: Identifying and Defining Necessary Evaluation and therapy) commenced data collection in September 2017. Data abstractors recorded clinical, radiographic, pathologic, and short-term follow-up data for patients with newly-diagnosed T1 RM at 13 diverse MUSIC practices with 45 physicians. The 965 patients with complete data were analyzed according to whether treatment (T) or no treatment (NT) was performed within 90 days of initial evaluation.

Results: NT was employed in 46% of patients (n=438), ranging from 0% to 57% at each of the 13 evaluated practices. Patient, physician and tumor characteristics for the NT and T cohorts are demonstrated in table 1. Factors significantly associated with NT (vs. T) in multivariable analysis included age (p<.0001), tumor type (complex cystic > indeterminate or solid, p=0.003), clinical impression (indeterminate > suspicious for RCC, p<.001), and T1a (vs. T1b, p<.0001). Factors not associated with NT vs. T included practice type (academic vs. community-based), practice location (southeast vs. other parts of MI), insurance type, race, gender, and renal mass biopsy (all p>0.4).

Conclusion: The MUSIC-KIDNEY quality improvement collaborative provides an opportunity to assess the factors that influence management of T1 RM across a range of practice types. NT is employed widely across our statewide collaborative; factors associated with NT appear to be appropriate. Management after the initial decision to perform NT (active surveillance, vs. surveillance vs. reassurance) will be a focus of subsequent study.

Funding: Blue Cross Blue Shield of Michigan
186. PATTERNS OF CARE FOR KIDNEY CANCER IN MINORITY-SERVING HOSPITALS
Lina Posada Calderon, Bashir Al Hussein Al Awamlh, Aleem I. Khan, Johannes C. van der Mijn, Bradley Mellis, Jonah Bernstein, Benjamin L. Taylor, Jonathan E. Shoag, Douglas S. Scherr
Weill Cornell Medical College
Presented By: Lina Posada Calderon

Introduction: Minority serving hospitals (MSH) serve the highest percentage of black and Hispanic patients. Independent of patient and provider factors, treatment at MSH may result in lower quality of care. As black and Hispanic patients reportedly die more from kidney cancer, understanding the origin of the disparity is crucial to addressing it. Here, we assess whether kidney cancer care differs between minority-serving hospitals (MSH) and non-MSH.

Methods: Using the National Cancer Data Base (NCDB) from 2004 to 2015 we identified 240,527 adult patients diagnosed with non-metastatic kidney cancer. MSH were defined according to the proportion of Black and Hispanic patients treated at each facility. We used validated metrics for kidney cancer care, namely the odds of undergoing surgery for kidney cancer (partial or radical nephrectomy) and time from diagnosis to surgery, to measure the impact of treatment at MSH.

Results: 19,701 (8.2%) patients were treated at MSH and 220,826 (91.8%) at non-MSH of which 15,807 (80.2%) and 181,359 (82.1%) underwent renal surgery, respectively, p<0.001. In multivariable analysis, patients treated at MSH had lower odds of undergoing renal surgery as compared to patients treated at non-MSH, Odds Ratio (OR) 0.93, 95% CI 0.89 to 0.98; p=0.002. There was no difference in time from diagnosis to surgery, mean difference -0.47 days, 95% CI -1.38 to 0.44, p=0.307. In subset analysis, white and Hispanic patients had lower odds undergoing surgery when treated at MSH, OR 0.88, 95% CI 0.82 to 0.94 and OR 0.88, 95% CI 0.79 to 0.97, respectively. Further, when MSH were low-volume facilities, patients also had a decreased odds of undergoing surgery, OR 0.76, 95% CI 0.72 to 0.81; p<0.001.

Conclusion: Treatment at MSH is associated with a lower likelihood of receiving surgery for kidney cancer. This effect is modified by race/ethnicity and by facility volume, which suggests a combination of health access, patient, and facility factors contribute to racial disparities in kidney cancer care.
187. NEPHROURETERECTOMY VS NEPHRON SPARING MANAGEMENT OF CLINICALLY LOCALIZED UROTHELIAL CARCINOMA OF THE URETER: PRACTICE PATTERNS AND OUTCOMES

Javier Piraino, Daniel Edwards, Zachary Snow, Gregory Diorio
Main Line Health
Presented By: Javier Piraino

Introduction: Upper tract urothelial carcinoma (UTUC) accounts for 5-6% of urothelial tumors and is characterized by rates of recurrence up to 90% with 5-year cancer-specific survival (CSS) ranging from 30-60%. Therefore, despite low prevalence, UTUC has a significant impact on both patient quality of life (QoL) and healthcare socioeconomic.Nephroureterectomy (NU) with bladder cuff excision has historically been the gold standard therapy for UTUC, but is associated with increased risk of chronic kidney disease (CKD), as well as other risks associated with a solitary kidney. Consequently, nephron-sparing management (NSM), such as segmental ureterectomy (SU) and endoscopic management (EM), have become an attractive alternative in appropriately selected patients. Currently, studies examining the comparative efficacy of NU versus NSM have been relegated to retrospective examinations of small institutional patient cohorts, or retrospective analyses of larger administrative datasets, representing but a small portion of comparative efficacy research performed in the genitourinary oncology domain. Furthermore, there is limited data regarding ureteral UTUC, an entity that has been increasing in incidence over the past thirty years and is uniquely suited to NSM approaches.Considering the relative absence of robust comparative efficacy research, as well as poorly characterized treatment trends, NSM for ureteral UTUC deserves greater evaluation. The primary objective of the current study is to analyze the NCDB to identify patterns in selection of surgical approach that may be influenced by patient-specific and facility-related factors. We also present a comparison of outcomes for these surgical modalities.

Methods: We queried the NCDB between 2004-2015 for patients with clinically-localized (=cT2N0M0) primary ureteral UTUC managed principally with NU, SU or EM. Patients with a previous cancer diagnosis (contralateral UTUC, recurrent UTUC or urothelial carcinoma of the bladder) and non-urothelial tumor histology were excluded from our analysis. Patient and disease-specific data indexed included age, gender, race, comorbidities (measured as a Charlson-Deyo score) tumor size (mm) and tumor grade (high/low). Treatment variables considered included surgical approach (NU/SU/EM) and volume of UTUC cases performed at the operating facility stratified by quintile. Statistical analysis was performed using IBM® SPSS® Statistics 24.0. Data were summarized and compared using medians, interquartile ranges and the Kruskall-Wallis ANOVA for continuous variables, while categorical variables were reported and compared using frequencies and Pearson’s chi-square. For variables demonstrating significance on ANOVA, Dunn’s post hoc tests were carried out pairwise with a Bonferroni adjustment. Multivariable logistic regression was employed to determine factors associated with likelihood of receipt of a given surgical intervention. Overall survival was estimated using standard Kaplan-Meier methods and compared using the log rank test. Multivariate survival analysis was performed using Cox proportional hazards regression. Significance was determined at p<0.05 with confidence intervals of 95%.

Results: Of the 7,121 patients that met our inclusion criteria, 57.9% (n=4,121) were managed with NU, 23.3% (n=1,658) with SU and 18.8% (n=1,342) with EM. The median patient age was 72 years old (65-80) and 58.8% of patients were male compared to 41.6% female. The median tumor size was 28mm (1.8-4.0) of which 58.4% were classified as high grade, compared to 41.6% low grade tumors. Facility volume quintiles were defined as 1st (<7 cases), 2nd (7-9 cases), 3rd (10-14 cases), 4th (15-21 cases) and 5th (>21 cases). On univariate analysis, it was noted that patients undergoing EM were older than patients undergoing SU or NU (75y vs 72y vs 72y; p<0.001). There were no apparent differences between race (p=0.619) and Charlson-Deyo score (p=0.761) among the different surgical approaches. Proportions of patients undergoing NU and SU differed significantly between males and females, with females receiving slightly more NU (59.3% vs 56.8%) and less SU (21.2% vs 24.7%) than males (p=0.002). Rates of EM were similar at 18.4%. With regard to pathologic characteristics, patients undergoing EM had smaller tumor sizes than those undergoing NU and SU (20mm vs 24mm vs 30mm; p<0.001). Similarly, patients with high grade tumors underwent NU more frequently than SU or EM (64.7% vs 24.1% vs 11.2%), while low grade tumors underwent NU less frequently, with similar rates of SU and increased rates of EM. With regards to overall survival (OS), there was no difference in median OS among patients undergoing NU, SU or EM.

Conclusion: The current retrospective analysis of a large sample of patients in the NCDB demonstrates similar overall survival patients undergoing NSM of ureteral UTUC compared to radical NU. Practice patterns appear consistent with guideline recommendations, but treatment disparities may exist among facilities based on the volume of UTUC treatment performed. Considering that retrospective studies have demonstrated comparable outcomes, future prospective trials may better elucidate patient and disease factors amenable to NSM. Improved dissemination of knowledge regarding practice patterns and outcomes of NSM for UTUC has the potential to improve delivery of NSM in appropriate patients.
### Table 1. Baseline patient, disease, treatment and site-specific characteristics

<table>
<thead>
<tr>
<th>NU</th>
<th>SU</th>
<th>EM</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y)</td>
<td>72 (64-79)</td>
<td>72 (64-79)</td>
<td>75 (60-82)</td>
</tr>
<tr>
<td>Tumor size (mm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td>Male</td>
<td>2375 (20-45)</td>
<td>1095 (15-35)</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>1743 (20-45)</td>
<td>623 (15-35)</td>
</tr>
<tr>
<td>Race</td>
<td>Black</td>
<td>153 (57.3)</td>
<td>5 (24.4)</td>
</tr>
<tr>
<td></td>
<td>Caucasian</td>
<td>3510 (56.8)</td>
<td>1366 (25.1)</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>178 (56.0)</td>
<td>25 (26.7)</td>
</tr>
<tr>
<td>Charlson-Deyo Score</td>
<td>0</td>
<td>2707 (20-45)</td>
<td>1067 (15-35)</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>1033 (20-45)</td>
<td>464 (15-35)</td>
</tr>
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<td></td>
<td>2</td>
<td>341 (20-45)</td>
<td>11 (24.4)</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>91 (56.0)</td>
<td>3 (26.7)</td>
</tr>
<tr>
<td>Tumor Grade</td>
<td>Low Grade</td>
<td>716 (47.2)</td>
<td>329 (21.7)</td>
</tr>
<tr>
<td></td>
<td>High Grade</td>
<td>1775 (54.7)</td>
<td>614 (24.1)</td>
</tr>
<tr>
<td>Volume Quintile</td>
<td>1st</td>
<td>916 (52.9)</td>
<td>407 (23.3)</td>
</tr>
<tr>
<td></td>
<td>2nd</td>
<td>766 (56.8)</td>
<td>282 (20.4)</td>
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<tr>
<td></td>
<td>3rd</td>
<td>609 (56.8)</td>
<td>266 (25.2)</td>
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<td></td>
<td>4th</td>
<td>819 (51.6)</td>
<td>262 (25.2)</td>
</tr>
<tr>
<td></td>
<td>5th</td>
<td>724 (56.8)</td>
<td>411 (25.2)</td>
</tr>
</tbody>
</table>

*Notes: Bold values indicate statistical significance. NU, SU, and EM refer to various treatment groups.*

### Figure 1. Kaplan-Meier Curve Demonstrating Comparative Overall Survival (OS) Among Nephroureterectomy (NU), Segmental Ureterectomy (SU) and Endoscopic Management (EM) of Ureteral UTUC.

*Graph showing the survival rates over time for different surgical approaches.*
188. TWO CYCLES OF NEOADJUVANT CHEMOTHERAPY IMPROVES SURVIVAL OF UPPER TRACT UROTHELIAL CARCINOMA PATIENTS

Kenji Zennami1, Kiyoshi Takahara1, Nachiko Fukami1, Hitomi Sasaki1, Mamoru Kusaka1, Ryoichi Shiroki1, Makoto Sumitomo2

1 Fujita Health University, 2 Fujita Health University

Presented By: KENJI ZENNAMI

Introduction: Upper tract urothelial carcinoma (UTUC) is frequently upstaged after surgery and is associated with poor prognosis. Several retrospective studies reported that neoadjuvant chemotherapy (NAC) induced pathological downstaging (pDS) including pathological complete response (pCR) and improved clinical outcomes. Most of the studies used 4 or more cycles of NAC. In this study, we evaluated if two cycles of NAC improves survival of UTUC patients in our institute.

Methods: A total of 167 patients who underwent radical nephroureterectomy at Fujita Health University between November 2005 and December 2018 were retrospectively analyzed. The study group comprised 114 patients with UTUC who received NAC followed by surgery. The control group consisted of 53 patients who underwent initial surgery without NAC. We compared two groups in overall survival (OS), cancer specific survival (CSS), recurrence free survival (RFS; urinary tract or visceral) and independent prognostic factors. Kaplan-Meier methods, log-rank test and cox proportional-hazards models were used for statistical analysis.

Results: The regimens in the NAC group were gemcitabine plus cisplatin (GC) in 87 patients (76%), gemcitabine plus carboplatin (GCcarbo) in 10 patients (9%) and methotrexate, vinblastine, doxorubicin plus cisplatin (MVAC) in 17 patients (15%). Median follow up was 1108 days, and there were no significant differences in preoperative patient characteristics between NAC group and initial surgery (IS) group. NAC had significantly improved 5-year OS (75% vs 55%, p=0.004) and 5 year CSS (84% vs 65%, p=0.024). That is more significant in the analysis with cT3 patients (p=0.0002). NAC also significantly improved visceral RFS (p=0.001). However, NAC does not affect urinary tract RFS (p=0.96) when compared to IS. pDS were observed in 55 out of 114 (48%) in NAC group, and 12 out of 53 (22%) in IS group. Comparison of OS between with pDS and without pDS demonstrated significantly better OS in with pDS group (p=0.0001). Multivariate cox proportional-hazards models identified NAC, pDS, resection margin, pN and cT3 as independent prognostic factors for OS.

Conclusion: Two cycles of NAC induced pDS and improved survival of UTUC patients. Reduced number of NAC cycles may offer clinical benefits of low chemo-associated toxicity, appropriate surgery without delay in chemo-resistant case and sufficient cancer regression with pDS. Further prospective studies are needed to identify the clinical benefit of NAC and optimal number of NAC cycles for UTUC.
189. BLOCKADE OF THE IMMUNE CHECKPOINT B7-H3 SENSITIZES RHABDOMYOSARCOMA TO ANTI-TUMOR IMMUNE RESPONSE

Candace Granberg, Fabrice Lucien-Matteoni, Haidong Dong, Patricio Gargollo
Mayo Clinic
Presented By: Roxane Lavoie

Introduction: Rhabdomyosarcoma (RMS) is the most common soft tissue tumor in children and up to 20% of children may present with aggressive and/or metastatic disease. Multimodal therapies including chemotherapy and radiotherapy have improved patient survival in the last few decades, yet the 5-year overall survival rate is less than 40%. Additionally, the therapeutic regimen for RMS patients is extremely toxic, resulting multiple deleterious long-term effects in surviving patients. This highlights the urgent need to develop novel therapeutic approaches for pediatric RMS (pedRMS). Since immunotherapy has been introduced to the armamentarium of oncologists, unprecedented clinical responses have been observed in adult cancers. In contrast, immunotherapy is at its infancy in pedRMS, and significant efforts are required to characterize the tumor immune microenvironment and assess the clinical utility of immunotherapy. Immune checkpoint molecules such as B7-H1 (PD-L1) are highly expressed by cancer cells to evade the host's immune system, and blockade of immune checkpoint molecules with neutralizing antibodies have demonstrated positive clinical responses in several cancers. Our group sought to assess the therapeutic potential of immune checkpoint blockade in pedRMS.

Methods: Expression profiles of immune checkpoint molecules in pedRMS patient-derived cell lines were analyzed by qPCR, western-blot and flow cytometry and confirmed by proteomic profiling. Immunohistochemistry was employed to validate expression of immune checkpoint molecules in patient-derived tumor sections. We developed an in vitro T-cell killing assay to determine the functional impact of immune checkpoint molecule expression on the anti-tumor immune response. Finally, we performed in vivo experiments with two animal models to evaluate the efficacy of immune checkpoint blockade to enhance T-cell mediated antitumor immune response and therapeutic response in pedRMS.

Results: We determined expression profiles of B7 immune checkpoint molecules by flow cytometry of patient-derived RMS cells and observed no expression of B7-H6 and B7-H7, weak/moderate expression of B7-H1 (PD-L1) or PD-L2 and high expression of B7-H3 (Fig 1A). B7-H3 expression was confirmed by cell-surface proteomic profiling and immunohistochemistry of patient-derived xenograft (Fig 1B) and patient-derived fresh tumor sections. Knockdown of B7-H3 was associated with decreased pedRMS tumor cell viability when co-cultured with T-lymphocytes (Fig 1C). In animals bearing pedRMS tumors, B7-H3 knockdown resulted in greater tumor infiltration of immune cells and reduction of tumor burden.

Conclusion: B7-H3 is constitutively expressed in pedRMS and participates to immunosuppression and disease progression. Blockade of B7-H3 restores anti-tumor immune response in vitro and in vivo. This work highlights the therapeutic potential of targeting B7-H3 and supports the implementation of immunotherapy for the treatment of pediatric rhabdomyosarcoma.
190. PATHOLOGIC AND SURVIVAL OUTCOMES IN CT1 PENILE CANCER
Allison May, Coleman Mcferrin, Anirudh Guduru, Zachary Hamilton
Saint Louis University
Presented By: Allison May

Introduction: Penile cancer is a rare, but often aggressive disease. Due to the low number of cases, pathologic outcomes such as upstaging are not well documented in the literature. We sought to evaluate the pathologic and survival outcomes in T1 penile cancer using the National Cancer Database (NCDB).

Methods: All men diagnosed with clinical stage T1a or T1b penile cancer were identified in the NCDB from 2004–2015. Demographic data was compared between patients with cT1a and cT1b to determine any associations with stage at diagnosis. Pathologic outcomes were examined, including the risk of upstaging to pT2 or higher. Logistic regression was performed to determine any association between demographics or tumor characteristics with pathologic upstaging. Survival outcomes were analyzed with Kaplan Meier estimates.

Results: During the study period, 2484 men were diagnosed with T1 penile cancer, 2237 with T1a and 247 with T1b. The majority of patients were treated with local excision or partial penectomy. 8.5% of cT1a patients and 26.4% of cT1b patients were upstaged to T2 – T4. Black patients were less likely to be upstaged (OR 0.4, p=0.02). The presence of high grade disease or lymphovascular invasion (LVI) was associated with upstaging (OR 3.6 and 15.7, p<0.001, respectively). With an average follow up of 48 months, there was a 30.3% mortality rate in the cT1a group and 46.2% in the cT1b group. Including all patients, 5 year overall survival decreased with increasing pathologic stage and was 62.3% for pT1, 46.8% for pT2, and 52.5% for pT3 (log-rank p=0.04).

Conclusion: Clinical T1 penile cancer has a high rate of upstaging at surgery, particularly with cT1b disease and presence of LVI, suggesting an underlying risk of understaging. More aggressive pathologic factors as well as non-black race are correlated with upstaging. The overall mortality rate is high and correlates with pathologic T stage.
191. ONCOLOGIC OUTCOMES OF ORGAN SPARING SURGERY FOR LOCALIZED PENILE CANCER: THE MD ANDERSON CANCER CENTER EXPERIENCE
Andrea Kokorovic, Jonathan Duplisea, Barrett McCormick, Mehrad Adibi, John N Papadopoulos, Curtis A Pettaway
The University of Texas MD Anderson Cancer Center
Presented By: Andrea Kokorovic

Introduction: Organ-sparing surgery (OSS) has emerged as an attractive therapeutic option for patients with localized penile cancer due to perceived cosmetic and functional benefits. Given the rarity of this disease however, OSS has not been widely investigated in the literature and its oncologic efficacy remains elusive. The primary purpose of this study is to describe characteristics and oncologic outcomes of patients with penile cancer treated with OSS at a large tertiary referral center.

Methods: Patients undergoing OSS for penile carcinoma from January 1996 to January 2018 at the University of Texas MD Anderson Cancer Center were identified using a prospectively maintained database. OSS included wide local excision (WLE), glans sparing partial penectomy, laser ablation, circumcision or combination of excisional surgery with laser therapy. Clinical and pathologic data were collected to perform descriptive analysis. All patients were re-staged according to American Joint Committee on Cancer (AJCC) 8th Edition TNM staging. Kaplan Meier estimates were used to determine cancer specific survival outcomes.

Results: 129 patients with penile cancer undergoing OSS were identified over a 22-year period. Median age at time of diagnosis was 61.4 years (IQR 26.4-87.8). The majority of patients presented with a penile lesion (79.8%), and the glans was the most frequently involved site (39.5%). The most commonly performed OSS was combined excisional and laser treatment (34.1%), followed by glans-sparing partial penectomy (30.2%), WLE (24.0%), laser ablation (7.8%) and circumcision (3.9%). Most patients had pT1a disease at presentation (36.4%). 43 patients (33.3%) had non-invasive disease (pTis or pTa), while 14.7%, 14.7% and 0.78% were stage pT1b, pT2 and pT3, respectively. 36 patients (27.9%) underwent a lymph node dissection, 5 of which occurred in the setting of recurrence. Of patients undergoing nodal dissection, the majority had pN0 disease (72.2%); pN1, pN2 and pN3 disease occurred in 8.3%, 2.8% and 16.7% of patients, respectively. Median follow-up time was 28.0 months (IQR 0.17-188.17). 21 patients had recurrence of disease following OSS. At initial presentation, 14 recurrences were local, 6 regional and 1 local+regional. Salvage treatments included additional glans sparing surgery (15 patients; 71.4%), nodal dissection (5 patients; 32.8%) and radical surgery (1 patient; 0.48%). 3 patients developed metastatic disease and died as a result. The remainder had no evidence of disease at last known follow-up. 66.7% of patients recurred within 24 months of the initial OSS, and there was no significant difference in cancer specific survival between patients that recurred versus those that did not (median survival 126.1 months vs 195.5 months, respectively; p=0.62).

Conclusion: OSS provides effective local control and should be considered in the therapeutic armamentarium for localized penile cancer in appropriately selected patients wishing to preserve function and cosmesis. Importantly, most patients recur within 2 years of therapy and can be salvaged with additional organ sparing procedures. Stringent routine follow-up protocols are important in the detection of recurrent lesions.
192. PATTERNS OF DRUG UTILIZATION FOR METASTATIC CASTRATION RESISTANT PROSTATE CANCER (MCRPC) MEDICARE BENEFICIARIES RECEIVING FIRST-LINE TREATMENT

Scott Flanders1, Carol Bazell2, Christine Ferro2, Kate Fitch2, Jason Haftron3, Rana McKay4

1 Dendreon Pharmaceuticals, LLC, 2 Milliman, Inc., 3 Department of Urology, Beaumont Health and Associate Professor of Urology, William Beaumont School of Medicine, 4 School of the Health Sciences, University of California at San Diego

Presented By: Scott Flanders

Introduction: Six products approved for first-line treatment of mCRPC have been available in the U.S. since 2012 including abiraterone acetate plus prednisone, cabazitaxel, docetaxel, enzalutamide, radium-223 and sipuleucel-T. Given the evolving treatment landscape for patients with metastatic prostate cancer, we sought to examine patterns of first-line mCRPC treatments utilizing a Medicare Fee for Service (FFS) claims database of over 40 million patients.

Methods: Using the 2013-2017 Medicare FFS 100% Part A, B and D Identifiable Research data, we identified all Medicare beneficiaries having Part A, B and D eligibility and no HMO enrollment in all months through 2017 or until death. For each calendar year, we identified patients with prostate cancer as men having 1+ qualifying claim coded with prostate cancer (ICD-9 185, ICD-10 C-61) in any position of the claim. Men with treatment naïve mCRPC were defined as individuals not having received a mCRPC approved therapy 12 months prior to their first mCRPC therapy during each indexed year. Utilization of mCRPC approved drug therapies was identified using HCPCS codes for infused products and NDC codes for oral products. Patients were grouped into cohorts based on first-line mCRPC treatment utilized and followed for 12 months after their index date. The index date was defined as the first mCRPC approved therapy claim in each indexed year. The proportion of patients receiving a first-line treatment without a subsequent second-line treatment within 1-year of the initial treatment index date was described.

Results: The proportion of prostate cancer men receiving an approved mCRPC drug therapy during each year remained relatively constant over the four year period at 3.2%-3.6%; the proportion receiving first-line therapy fell slightly between 2014 and 2017 (47.4% to 44.6%). Abiraterone had the highest utilization in all years except 2016, enzalutamide had the highest use in 2016 and second highest for all other years evaluated. In order of decreasing use across years, the remaining products were docetaxel followed by sipuleucel-T, radium-223 and cabazitaxel (Table 1). A proportion of mCRPC men were treated with combination therapy; however, sample sizes fell below CMS suppression requirements. Table 2 shows the proportion of patients having received first-line with no subsequent second-line mCRPC therapy within 1 year. Patterns of use of abiraterone and enzalutamide as first-line treatments were relatively constant during 2014-2016. For mCRPC men using abiraterone and enzalutamide as a first-line treatment, the proportion not having second line therapy within 1-year of the index date remained consistent from 2014-2016, increasing at 0.9% and 2.2%, respectively. Over this same time period, the proportion of docetaxel and cabazitaxel first-line use with no second-line therapy rose +8.7% and +6.9% respectively. Utilization of sipuleucel-T in first-line without receiving a second-line therapy rose +15.3% from 26.0% (2014) to 41.3% (2016). Finally, the proportion of men receiving first-line radium-223 treatment with no second-line treatment within one year of index fell by -3.2% (2015-2016). Use of docetaxel and abiraterone may be overreported given these may be used in castration-sensitive prostate cancer.

Conclusion: The proportion of prostate cancer men receiving an approved mCRPC drug therapy during each year remained relatively constant over the four year period at 3.2%-3.6%; the proportion receiving first-line therapy fell slightly between 2014 and 2017 (47.4% to 44.6%). Abiraterone had the highest utilization in all years except 2016, enzalutamide had the highest use in 2016 and second highest for all other years evaluated. In order of decreasing use across years, the remaining products were docetaxel followed by sipuleucel-T, radium-223 and cabazitaxel (Table 1). A proportion of mCRPC men were treated with combination therapy; however, samples sizes fell below CMS suppression requirements. Table 2 shows the proportion of patients having received first-line with no subsequent second-line mCRPC therapy within 1 year. Patterns of use of abiraterone and enzalutamide as first-line treatments were relatively constant during 2014-2016. For mCRPC men using abiraterone and enzalutamide as a first-line treatment, the proportion not having second line therapy within 1-year of the index date remained consistent from 2014-2016, increasing at 0.9% and 2.2%, respectively. Over this same time period, the proportion of docetaxel and cabazitaxel first-line use with no second-line therapy rose +8.7% and +6.9% respectively. Utilization of sipuleucel-T in first-line without receiving a second-line therapy rose +15.3% from 26.0% (2014) to 41.3% (2016). Finally, the proportion of men receiving first-line radium-223 treatment with no second-line treatment within one year of index fell by -3.2% (2015-2016). Use of docetaxel and abiraterone may be overreported given these may be used in castration-sensitive prostate cancer.

Funding: Medical Affairs, Dendreon Pharmaceuticals, LLC
<table>
<thead>
<tr>
<th>Therapy</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abiraterone</td>
<td>50.00%</td>
<td>54.70%</td>
<td>51.40%</td>
<td>42.40%</td>
</tr>
<tr>
<td>Cabazitaxel</td>
<td>0.50%</td>
<td>0.40%</td>
<td>0.80%</td>
<td>0.90%</td>
</tr>
<tr>
<td>Docetaxel</td>
<td>18.10%</td>
<td>19.50%</td>
<td>23.90%</td>
<td>18.10%</td>
</tr>
<tr>
<td>Enzalutamide</td>
<td>21.70%</td>
<td>33.70%</td>
<td>31.80%</td>
<td>26.80%</td>
</tr>
<tr>
<td>Radium223</td>
<td>0.00%</td>
<td>3.50%</td>
<td>3.40%</td>
<td>3.90%</td>
</tr>
<tr>
<td>Sipuleucel-T</td>
<td>9.50%</td>
<td>8.10%</td>
<td>8.60%</td>
<td>7.90%</td>
</tr>
</tbody>
</table>

**Medicare Population Denominators**

- Prostate cancer diagnosis during index year: 452,718
- mCRPC approved drug therapy utilization during index year: 14,351
- No mCRPC approved drug therapy during 12 months prior to first mCRPC approved drug therapy during index year: 6,800

<table>
<thead>
<tr>
<th>Therapy</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abiraterone</td>
<td>63.7%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cabazitaxel</td>
<td>55.6%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Docetaxel</td>
<td>65.8%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enzalutamide</td>
<td>71.2%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radium223</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sipuleucel-T</td>
<td>26.0%</td>
<td></td>
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</tbody>
</table>

**Table 2. Proportion of mCRPC First Line Therapy Men Not Receiving 2nd Line Therapy Within 12 Months (2014-2016)**

<table>
<thead>
<tr>
<th>First Line Therapy</th>
<th>No Second Line Therapy in 12 Months After First Line Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abiraterone: n = 3,403</td>
<td>63.7%</td>
</tr>
<tr>
<td>Cabazitaxel: n = 36</td>
<td>55.6%</td>
</tr>
<tr>
<td>Docetaxel: n = 1,228</td>
<td>65.8%</td>
</tr>
<tr>
<td>Enzalutamide: n = 1,476</td>
<td>71.2%</td>
</tr>
<tr>
<td>Radium223: n = 0</td>
<td>-</td>
</tr>
<tr>
<td>Sipuleucel-T: n = 649</td>
<td>26.0%</td>
</tr>
</tbody>
</table>

**Table 2. Proportion of mCRPC First Line Therapy Men Not Receiving 2nd Line Therapy Within 12 Months (2014-2016)**

<table>
<thead>
<tr>
<th>First Line Therapy</th>
<th>No Second Line Therapy in 12 Months After First Line Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abiraterone: n = 2,592</td>
<td>65.0%</td>
</tr>
<tr>
<td>Cabazitaxel: n = 32</td>
<td>90.6%</td>
</tr>
<tr>
<td>Docetaxel: n = 1,458</td>
<td>71.5%</td>
</tr>
<tr>
<td>Enzalutamide: n = 2,514</td>
<td>70.8%</td>
</tr>
<tr>
<td>Radium223: n = 263</td>
<td>60.7%</td>
</tr>
<tr>
<td>Sipuleucel-T: n = 603</td>
<td>35.5%</td>
</tr>
</tbody>
</table>

**Table 2. Proportion of mCRPC First Line Therapy Men Not Receiving 2nd Line Therapy Within 12 Months (2014-2016)**

<table>
<thead>
<tr>
<th>First Line Therapy</th>
<th>No Second Line Therapy in 12 Months After First Line Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abiraterone: n = 2,129</td>
<td>65.6%</td>
</tr>
<tr>
<td>Cabazitaxel: n = 56</td>
<td>62.5%</td>
</tr>
<tr>
<td>Docetaxel: n = 1,621</td>
<td>74.5%</td>
</tr>
<tr>
<td>Enzalutamide: n = 2,154</td>
<td>73.4%</td>
</tr>
<tr>
<td>Radium223: n = 233</td>
<td>57.5%</td>
</tr>
<tr>
<td>Sipuleucel-T: n = 583</td>
<td>41.3%</td>
</tr>
</tbody>
</table>

**Table 2. Proportion of mCRPC First Line Therapy Men Not Receiving 2nd Line Therapy Within 12 Months (2014-2016)**

1 Urban vs rural based on beneficiary zip code and CMS “Zip Code to Census Locality” file.
2 Based on review of provider specialty reported on evaluation and management services provided in an office setting.
193. ALTERATIONS OF TUMOR MICROENVIRONMENT BY NITRIC OXIDE DONOR IMPEDES CASTRATION RESISTANT PROSTATE CANCER GROWTH

HIMANSHU ARORA¹, Kush Panara¹, Manish Kuchakulla¹, Shathiyah Kulandavelu¹, Joshua M. Hare¹, Ranjith Ramasamy¹, Andrew V. Schally²

¹ University of Miami, ² University of Miami VA

Presented By: HIMANSHU ARORA

Introduction: Immune targeted therapy of nitric oxide synthases are being considered as a potential frontline therapeutics to treat patients diagnosed with locally advanced and metastatic prostate cancer. However, the role of nitric oxide (NO) in castration resistance prostate cancer (CRPC) is controversial because NO can increase in nitrosative stress while simultaneously possessing anti-inflammatory properties. Accordingly, we tested the hypothesis that increased NO will lead to tumor suppression of CRPC through tumor micro environment.

Methods: S-Nitrosoglutathione (GSNO), an active NO donor, is a potent therapeutic agent that has been safely used in human clinical trials for pre-eclampsia and persistent pulmonary hypertension. We treated CRPC murine models and 22Rv1 cells with GSNO and studied effects of increased NO levels, mechanism of action and its long term efficacy. Animal experiments were carried out in compliance with the Institutional Animal Care and Use Committee of University of Miami. Molecular analyses were performed using standard procedures.

Results: S-nitrosoglutathione (GSNO), an NO donor decreased the tumor burden in murine model of CRPC by targeting tumors in a cell non autonomous manner. GSNO inhibited both the abundance of anti-inflammatory (M2) macrophages and expression of pERK indicating that tumor associated macrophages activity is influenced by NO. Additionally GSNO decreased IL-34 indicating suppression of tumor associated macrophage differentiation. Cytokine profiling of CRPC tumor grafts exposed to GSNO revealed a significant decrease in expression of G-CSF and M-CSF as compared to grafts not exposed to GSNO. We verified the durability of NO on CRPC tumor suppression by using secondary xenograft murine models.

Conclusion: This study validates the significance of NO on inhibition of CRPC tumors through TME. These findings may facilitate the development of previously unidentified NO-based therapy for CRPC.

Funding: CTSI
194. INFLUENCE OF NODE-POSITIVE DISEASE AFTER RADICAL PROSTATECTOMY ON BIOCHEMICAL RECURRENCE AND EARLY ONCOLOGIC OUTCOMES IN MEN WITH PROSTATE CANCER

Samuel Washington1, Janet Cowan1, Annika Herlemann1, Hao Nguyen1, Peter Carroll1, Kyle Zuniga2, Selma Masic3

1 Department of Urology, University of California San Francisco, 2 College of Physicians and Surgeons, Columbia University Medical Center, 3 Department of Surgical Oncology, Division of Urologic Oncology, Fox Chase Cancer Center

Presented By: Samuel Washington

Introduction: The diagnostic and therapeutic value of pelvic lymph node dissection (PLND) at radical prostatectomy (RP) remains unclear. Given that the prevalence of nodal disease remains low (0.37-12.4%), there is concern of overtreatment relative to its utilization (40-94%). Thus, we aim to characterize the prognostic value of PLND and secondary treatment on oncologic outcomes for a contemporary cohort of men with nodal disease on surgical pathology at RP.

Methods: Men who underwent primary RP with PLND for prostate cancer (PCa) were identified in our institutional prospective database. Patients were stratified by nodal status for comparison of clinical and pathologic data. Detectable prostate-specific antigen (PSA) was defined as a PSA>0.05 ng/ml within 2-6 months after RP. For those without a reported PSA in this time period, men with a PSA>1 ng/ml between 0-2 months after RP or a PSA between 0.05 to 1 ng/ml and subsequent treatment within 6 months of RP were coded as having a detectable PSA. Separate multivariable Cox proportional hazards regression models were fit for the following outcomes: biochemical recurrence-free survival (bRFS), overall survival (OS), and PCa-specific mortality (PCSM). Adjuvant treatment was partly defined by detectable PSA and thus excluded from multivariable models. Each model was adjusted for age at diagnosis, PSA at diagnosis, pathologic Gleason grade, surgical margin status, post-RP PSA (undetectable (UDT) vs detectable), and post-RP PSA with adjuvant treatment.

Results: Of 1,635 identified men, 167 (10.2%) had nodal disease (pN1). Mean age at diagnosis was 62 years (standard deviation (SD) 7.1). Median follow-up after RP was 31 months (interquartile range (IQR) 13-58). Adverse pathology was more common in pN1 patients (pathologic Gleason grade >4+3, 86% vs 50%, p<0.01; >pT3 (90% vs 50%, p<0.01) compared to pN0. Using a cutoff of 14 LNs dissected for men with nodal disease, 7-year outcomes were similar (p>0.05 for all) but those with >25 LNs dissection had worse bRFS compared to those with less dissected (57% vs 30%, log-rank p=0.03). The number of positive LNs was associated with worse 7-year outcomes [RFS, HR 1.2, 95% CI 1.1-1.2, p<0.01; OS, HR 1.2, 95% CI 1.1-1.4, p=0.01] but not PCSM (p=0.2) after adjustments. Median number of positive LNs was 1 (IQR 1, 3) in pN1 patients. At 7 years, bRFS differed significantly between these groups (78% for UDT PSA, 84% for UDT and adjuvant therapy, 38% for detectable PSA, log-rank p<0.01) but OS and PCSM were not significantly different. On multivariable analysis, number of positive LNs (HR 1.1, 95% CI 1.0-1.2, p=0.02) and detectable PSA (vs UDT, HR 5.1, 95% CI 1.8-14.3, p=0.01) were associated with increased risk of recurrence after RP but not OS (p>0.05 for all). After salvage treatment, 7-year bRFS, OS, and PCSM did not differ significantly between men with an UDT PSA, those with an UDT PSA who underwent adjuvant treatment, and those with a detectable PSA (p>0.05 for all).

Conclusion: In a contemporary cohort of men with pN1 disease, more extensive LND was not associated with improved oncologic outcomes. Interestingly, the extent of nodal involvement was associated with greater risk of biochemical recurrence but no other oncologic outcomes. Amongst those who underwent secondary treatment after RP, UDT PSA after RP conferred greater bRFS at 7 years. In this subset of men, adjuvant treatment was not associated with improved post-salvage biochemical or treatment-free survival. Further investigation into the potential therapeutic benefit of PLND at RP is warranted to better estimate the potential risk of overtreatment of men with nodal disease.
195. TUMOR MULTIFOCALITY ON MULTI-PARAMETRIC MRI IS ASSOCIATED WITH INCREASED DETECTION RATE OF CLINICALLY-SIGNIFICANT PROSTATE CANCER IN LESIONS WITH PI-RADS SCORE 4

Ghazal Khajir1, Kamyar Ghabili1, Matthew Swallow1, Jamil Syed1, Michael Leapman1, Preston Sprenkle1, Rachael Sherrer2, Soroush Rais-Bahram2

1 Department of Urology, Yale School of Medicine, 2 Department of Urology, University of Alabama at Birmingham

Presented By: Ghazal Khajir

Introduction: Magnetic resonance imaging (MRI)/ultrasound fusion targeted biopsy of a lesion with prostate imaging reporting and data system (PI-RADS) score 4 (P4) is associated with a high positive predictive value (~ 45%) for clinically-significant prostate cancer. However, it is unknown if multifocality on multi-parametric MRI (mpMRI) could further risk stratify P4 lesions. We sought to assess the detection of the clinically-significant prostate cancer in P4 lesions stratified by tumor multifocality on mpMRI.

Methods: Using the MRI-ultrasound fusion prostate biopsy databases at the Yale University and the University of Alabama at Birmingham (UAB), we identified patients with at least one PI-RADS 4 (P4) lesion on mpMRI who underwent targeted biopsy of those lesions. Each patient meeting the above criteria was grouped into one of three lesion MRI classifications – P4+P2/P3 (P4 lesion and an additional PI-RADS 3 or 2 lesions), single P4, or P4+P4/P5 (=2 P4 lesions or a lesion with a P4 and an index lesion with PI-RADS 5). The rate of grade group (GG)=2 pathology on targeted biopsy of the P4 lesions was compared between the MRI classification groups. The clinical and radiological factors associated with finding GG =2 in P4 lesions were also evaluated.

Results: In total, 345 (Yale) and 300 (UAB) patients with at least one lesion with P4 were identified. The studied MRI classification groups P4+P2/P3, single P4, and P4+P4/P5 included 184, 267 and 194 men, respectively. For the combined cohorts, the rate of GG=2 biopsy pathology in the groups P4+P2/P3, single P4 and P4+P4/P5 was 21.7%, 36.3%, and 46.4%, respectively (p<0.001). On multivariable analysis, age (OR 1.08, 95%CI 1.05-1.11, p<0.001), prostate volume (OR 0.79 per 10mL, 95%CI 0.70-0.89, p<0.001), and MRI classification group (single P4 vs. P4+P2/P3, OR 2.17, 95%CI 1.34 -3.49, p=0.001; and P4+P4/P5 vs. P4+P2/P3, OR 2.56, 95%CI 1.54-4.25, p<0.001) were significantly associated with the risk of GG=2 pathology on targeted biopsy of the P4 lesion.

Conclusion: Our data indicated that detection of clinically-significant (GG=2) prostate cancer on biopsy of the high-risk lesion (P4) on mpMRI might be influenced by tumor multifocality on imaging.

196. SALVAGE WHOLE GLAND CYROABLATION THERAPY VERSUS STANDARD OF CARE FOR PATIENTS FAILING INITIAL RADIATION THERAPY FOR PROSTATE CANCER

Shiva Nair1, Andrew Warner2, George Rodrigues2, Joseph Chin3

1 Western University, London Health Sciences Centre, 2 Department of Radiation Oncology, Western University, London, Ontario, Canada, 3 Departments of Urology and Oncology, Western University, London, Ontario, Canada

Presented By: Shiva Nair

Introduction: Men who experience prostate cancer recurrence after radiotherapy usually progress to systemic therapies. Some of these may be candidates for local salvage therapy, avoiding and delaying such therapies. We compared long-term outcomes of salvage cryoablation (SCT) versus standard of care without local salvage therapy in a large radiation therapy database (EBRT).

Methods: Men undergoing SCT for localized radiorecurrent prostate cancer at Western University between 1995 and 2004 were identified. The EBRT group was identified from the pan-Canadian Prostate Cancer Risk Stratification (ProCaRS) database treated between 1994 and 2008. Men were matched using propensity scores based on age at radiation, pre-radiation PSA, Gleason score and T-stage and hormone therapy prior to salvage treatment. Primary end points were overall survival (OS) and cancer specific survival (CSS).

Results: A total of 982 men treated with EBRT developed biochemical failure and 186 men were treated with SCT. Median follow-up from radiation treatment was 11.6 years for EBRT and 25.1 years for SCT. The propensity matched cohorts consisted of 196 EBRT versus 98 SCT. Fifty-six men in the SCT group experienced secondary biochemical failure and 48 received salvage hormone therapy. In the EBRT group there were 78 deaths and 49 prostate cancer deaths compared with 80 deaths and 24 prostate cancer deaths. There was a significant benefit in OS (p=0.004) and CSS (p=0.003) favoring SCT.

Conclusion: In carefully selected men with localized recurrent prostate cancer post radiation, further local salvage treatment may lead to benefits in CSS and OS.
197. INITIAL SURGICAL RESULTS FROM PHASE II TRIAL OF NEOADJUVANT THERAPY, CONSOLIDATIVE SURGERY AND PSMA/PET IMAGING IN OLIGOMETASTATIC AND VERY HIGH RISK LOCALLY ADVANCED PROSTATE CANCER

David F. Jarrard 1, Christos Kyriakopoulos 2, Hamid Emamekhoos 2, Joshua M. Lang 2, Steve Cho 3, Shane Wells 3, Brian Johnson 4, Alejandro Roldan 5, David J. Beebe 5, Wei Huang 6

1 University of Wisconsin-Madison, Department of Urology. UW Carbone Cancer Center, 2 University of Wisconsin, Department of Medicine. UW Carbone Cancer Center, 3 University of Wisconsin, Department of Radiology, 4 University of Wisconsin, Department of Biomedical Engineering, 5 University of Wisconsin. Department of Biomedical Engineering, 6 University of Wisconsin, Department of Pathology

Presented By: Tariq A. Khemees

Introduction: Previous studies have shown that addition of docetaxel to standard androgen deprivation therapy (ADT) significantly improves progression-free survival (PFS) and overall survival (OS) compared to standard ADT alone in men with metastatic hormone-sensitive prostate cancer. Further evidence suggest that removal of the primary may improve outcomes by reducing the risk of tumor self-seeding. Tumor resistance remains a major issue in the treatment of advanced cancer. We are conducting a Phase II trial enrolling men with very high risk localized, locally advanced or oligometastatic prostate cancer (PC) patients to examine the feasibility of neoadjuvant chemohormonal therapy, tumor response and molecular mechanisms of resistance.

Methods: UW17009 is an IRB-approved open-label, single-arm trial recruiting 30 patients with newly diagnosed locally advanced PC. Patients receive ADT and docetaxel for three cycles (3 months) followed by prostatectomy. The primary endpoint is pathologic complete response rates. Secondary clinical objectives are rate of patients with PSA recurrence at month 12 after surgery as well as safety and tolerability. Exploratory interventions include PSMA PET/MRI imaging as a method for determining treatment response and response heterogeneity in primary prostate cancer and metastatic lesions performed before and after chemohormonal therapy. In addition, evaluation of genomic and gene expression signatures in cancer cells, prostate stroma, bone marrow microenvironment and circulating tumor cells in responding and resistant lesions is ongoing.

Results: To date, 26 of 30 patients have enrolled and undergone neoadjuvant treatment and radical prostatectomy (RP) with lymph node dissection. The mean age is 61 year, 96% are Caucasian with mean BMI of 28.35. The mean PSA at diagnosis was 32.1 ng/dl and 88.5% had Grade Group 5 cancer. Metastatic disease at baseline was identified in 6/26 patients (5 in lymph nodes and bone, 1 in LN only) using standard conventional imaging. Neoadjuvant therapy was overall well tolerated with expected toxicities including fatigue and neutropenia. All but two patients received all 3 cycles of docetaxel chemotherapy. All patients had multi-focal primary PC detected on PSMA PET/MRI. All patients underwent planned surgery (24 robotic and 2 open RP). Mean OR time was 169 minutes and mean estimated blood loss was 226 mL. One patient received a blood transfusion following open RP. Mean length of stay was 1.6 days (1-7 days). Grade 3-4 postoperative complications were seen in 7% (2/26). Mean number of lymph nodes removed was 13.4 and ten patients had node positive disease. The rate of negative surgical margins was 73% and 80% of patient had = pT3 on final pathology. No patient achieved a complete pathologic response, however 91% (24/26) had undetectable PSA on week 6 after surgery. The two patients with persistent PSAs following surgery received salvage ADT with Abiraterone. Mean follow-up is 8 months (1.6-12 months) and rate of biochemical failure 23% (6/26).

Conclusion: Neoadjuvant chemohormonal therapy prior to definitive surgery for very high risk localized and/or oligometastatic PC generates a high rate of local tumor control with a heterogeneity of tumor response between foci. The treatments are well tolerated with side effects similar to those previously described with chemohormonal therapy. Further characterization of tumor heterogeneity and molecular imaging is ongoing.

Funding: Urology Care Foundation, Research Scholar Award (TK), The 2016 Debbie and Mark Attanasio-PCF Young Investigator Award (C.E.K.), DOD IMPACT Award 191341- Partnering PI (J.M.L., D.J., D.B)
198. PROMPT - PROSTATE GENETIC SCORE IS A SENSITIVE TEST FOR MEN AT RISK OF METASTATIC PROSTATE CANCER
Stephen Ryan1, Fady Ghali2, Christopher Kane2, Andrew K Kader2, Sij Hemal3, Brent Rose4, Frederick Millard5, James Randall6, Gerald Andriole6, Michael Liss7
1 Department of Urology, UC San Diego, San Diego CA, 2 Department of Urology, University of California San Diego, San Diego CA, 3 Department of Urology, Wake Forest University, Winston-Salem NC, 4 Department of Radiation Oncology, University of California San Diego, San Diego CA, 5 Department of Internal Medicine, Division of Oncology, University of California San Diego, San Diego CA, 6 Department of Urology, Washington University School of Medicine, St. Louis MO, 7 Department of Urology, University of Texas Health, San Antonio TX
Presented By: Fady Ghali

Introduction: Prostate cancer (PCa) screening may be improved by focusing screening efforts on men that are at high risk. We investigated the sensitivity of a germline marker of PCa risk (Prompt - PGS) alone and in combination with family history (FH) to identify men at risk for metastatic PCa.

Methods: After IRB approval, 100 men presenting to the University of California San Diego oncology clinic with metastatic PCa were prospectively enrolled. Baseline clinical characteristics and saliva were collected on all patients. DNA was harvested from saliva and the Prompt - PGS calculated based on genotype at 33 single nucleotide polymorphisms and weighted by odds ratio (OR) and allele frequency. Based on previous studies, a Prompt score < 0.6 indicated low, 0.6 to 1.3 intermediate and >1.3 high risk of PCa. Men with a FH were considered at least intermediate risk. Sensitivity calculations were based on a hypothetical screening algorithm whereby low risk patients would not be screened, and intermediate/high risk men underwent screening.

Results: 100 men were enrolled at a median age of 63.3 years old (IQR 60.1-71.1) and followed for a median of 100.8 months (IQR 57-166.4). 21% of men in this cohort had a FH, 6%, 50% and 44% of men had low, intermediate and high Prompt scores respectively. When FH is added, this climbs to 95%. The high-risk cohort was older at the time of metastasis, and for most of the analysis comparative statistics could not be reliably employed given the very low number of false negatives. 59 men died during the study period at a median time of 100.8 month (IQR 52.3-171.4). Of those, 4 (6.8%), 27 (45.7%), and 28 (47.5%) were in the low, intermediate, and high-risk groups respectively. Within the high-risk group, Prompt - PGS without FH accounted for 71.4% of the patients. Sensitivity for death during study period was 93.2% for the hypothetical PCa screening paradigm. A majority of men that presented with metastatic PCa did not undergo routine PSA based screening (68% vs 32%). Of the 68 men that did not undergo not-for-cause PSA screening, 64 (94.1%) would be included in our hypothetical PCa screening paradigm. Of the 59 men that died during our study period, a majority 40 (67.8%) did not undergo routine not-for-cause PSA screening. Of the 40 men that did not undergo PSA screening and passed away, 37 (92.5%) would be included and 3 (7.5%) would be excluded from our hypothetical PCa screening paradigm.

Conclusion: We present, to our knowledge, the only analysis of the performance of a low penetrance germline genetic risk score stratification of a cohort of men with known metastatic PCa. In a cohort of men with metastatic PCa at presentation, only 5% were identified as low risk by our criteria, and the majority (55%) fell within the high-risk group. Of the men with a high Prompt - PGS, 77.3% had a negative family history. 68% of the men in this analysis did not undergo regular PSA screening; based on Prompt alone, 94.1% of these men would have been flagged for screening. We demonstrate that a screening strategy based on our proposed risk grouping would have missed 5% and captured 95% of a metastatic PCa cohort. Of the men that died in our study period, only 6.8% would have remained unscreened under our hypothetical paradigm. Prompt-PGS alone and together with FH is a sensitive means of identifying men who should consider PCa screening.
### Table 1 – Comparison of Low and Intermediate/High risk groups

<table>
<thead>
<tr>
<th>Risk Group</th>
<th>Low</th>
<th>Intermediate/High</th>
<th>p</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>38</td>
<td>64</td>
<td></td>
<td>102</td>
</tr>
<tr>
<td>Median Age at enrollment (yrs)</td>
<td>64 (60-67.5)</td>
<td>66 (60-71.5)</td>
<td>0.038</td>
<td>63.3 (60.2-70.3)</td>
</tr>
<tr>
<td>Median Follow-up months (IQR)</td>
<td>120 (66-267)</td>
<td>88.5 (57-168)</td>
<td>0.372</td>
<td>99.4 (57-166.4)</td>
</tr>
<tr>
<td><em>Family History</em></td>
<td>N/A</td>
<td>21</td>
<td>22.11%</td>
<td>43.11%</td>
</tr>
<tr>
<td>POS Group</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>3</td>
<td>100%</td>
<td>1</td>
<td>0.05%</td>
</tr>
<tr>
<td>Intermediate</td>
<td>30</td>
<td>52.63%</td>
<td>50</td>
<td>36.00%</td>
</tr>
<tr>
<td>High</td>
<td>N/A</td>
<td>44</td>
<td>46.52%</td>
<td>44.66%</td>
</tr>
</tbody>
</table>

*High and Neg FH

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Low</th>
<th>Intermediate/High</th>
<th>p</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hx PSA Screening (yes)</td>
<td>1</td>
<td>20%</td>
<td>31</td>
<td>32.63%</td>
</tr>
<tr>
<td>Hx Definitive Therapy (yes)</td>
<td>2</td>
<td>40%</td>
<td>44</td>
<td>46.32%</td>
</tr>
<tr>
<td>Surgery</td>
<td>1</td>
<td>30%</td>
<td>25</td>
<td>36.32%</td>
</tr>
<tr>
<td>Radiation</td>
<td>0</td>
<td>0%</td>
<td>18</td>
<td>18.95%</td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>1</td>
<td>30%</td>
<td>1</td>
<td>1.05%</td>
</tr>
<tr>
<td>ADT (Yes)</td>
<td>5</td>
<td>100%</td>
<td>93</td>
<td>97.90%</td>
</tr>
<tr>
<td>Medical</td>
<td>5</td>
<td>100%</td>
<td>89</td>
<td>93.68%</td>
</tr>
<tr>
<td>Responsive?</td>
<td>3</td>
<td>100%</td>
<td>87</td>
<td>91.38%</td>
</tr>
<tr>
<td>Surgical</td>
<td>0</td>
<td>0%</td>
<td>4</td>
<td>4.52%</td>
</tr>
<tr>
<td>Developed CRPC</td>
<td>4</td>
<td>85%</td>
<td>69</td>
<td>72.63%</td>
</tr>
<tr>
<td>Death during follow-up</td>
<td>4</td>
<td>85%</td>
<td>55</td>
<td>57.89%</td>
</tr>
</tbody>
</table>

*Family History of PCs in first degree relative.

POS: Prostate Specific Score
ADT: Androgen deprivation therapy
CRPC: Castrate Resistant PCs
NOTE: Statistical Test = Independent Samples Mann-Whitney U Test

### Table 2 – Comparison of Low and Intermediate/High risk groups in men that died during study period

<table>
<thead>
<tr>
<th>Risk Group</th>
<th>Low</th>
<th>Intermediate/High</th>
<th>p</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>38</td>
<td>64</td>
<td></td>
<td>102</td>
</tr>
<tr>
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<td>0.038</td>
<td>63.3 (60.2-70.3)</td>
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<td>0.372</td>
<td>99.4 (57-166.4)</td>
</tr>
<tr>
<td><em>Family History</em></td>
<td>N/A</td>
<td>21</td>
<td>22.11%</td>
<td>43.11%</td>
</tr>
<tr>
<td>POS Group</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>4</td>
<td>6.58%</td>
<td>1</td>
<td>4.60%</td>
</tr>
<tr>
<td>Intermediate</td>
<td>50</td>
<td>50.00%</td>
<td>50</td>
<td>36.00%</td>
</tr>
<tr>
<td>High</td>
<td>N/A</td>
<td>44</td>
<td>44.66%</td>
<td>44.66%</td>
</tr>
</tbody>
</table>

*High and Neg FH

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Low</th>
<th>Intermediate/High</th>
<th>p</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hx PSA Screening (yes)</td>
<td>1</td>
<td>20%</td>
<td>18</td>
<td>21.45%</td>
</tr>
<tr>
<td>Hx Definitive Therapy (yes)</td>
<td>2</td>
<td>30%</td>
<td>30</td>
<td>21.45%</td>
</tr>
<tr>
<td>Surgery</td>
<td>1</td>
<td>30%</td>
<td>17</td>
<td>21.45%</td>
</tr>
<tr>
<td>Radiation</td>
<td>1</td>
<td>30%</td>
<td>12</td>
<td>21.45%</td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>1</td>
<td>30%</td>
<td>1</td>
<td>1.48%</td>
</tr>
<tr>
<td>ADT (Yes)</td>
<td>1</td>
<td>50.0%</td>
<td>1</td>
<td>1.48%</td>
</tr>
<tr>
<td>Medical</td>
<td>4</td>
<td>100%</td>
<td>55</td>
<td>100.00%</td>
</tr>
<tr>
<td>Responsive?</td>
<td>4</td>
<td>100%</td>
<td>52</td>
<td>94.55%</td>
</tr>
<tr>
<td>Surgical</td>
<td>3</td>
<td>54.35%</td>
<td>3</td>
<td>5.16%</td>
</tr>
<tr>
<td>Developed CRPC</td>
<td>2</td>
<td>35.7%</td>
<td>40</td>
<td>87.09%</td>
</tr>
<tr>
<td>Death during follow-up</td>
<td>5</td>
<td>25.8%</td>
<td>58</td>
<td>25.8%</td>
</tr>
</tbody>
</table>

*Family History of PCs in first degree relative.

POS: Prostate Specific Score
ADT: Androgen deprivation therapy
CRPC: Castrate Resistant PCs
**Title:** TRENDS IN INCIDENCE AND SURVIVAL AMONG MEN WITH METASTATIC PROSTATE CANCER: SEER ANALYSIS 2004-2015

**Authors:** Michael Feuerstein¹, Rehana Rasul², Anne Golden³

¹ Lenox Hill Hospital, ² Feinstein Institute for Medical Research, Northwell Health, ³ Department of Occupational Medicine, Epidemiology, and Prevention, Northwell Health

**Presented By:** Michael Feuerstein

**Introduction:** Since docetaxel was approved in 2004, several new drugs have been approved demonstrating efficacy and improved survival for metastatic prostate cancer patients. In the past decade prostate cancer screening has decreased, in part due to the USPSTF recommendation in 2012. This study evaluated the impact of these developments on population trends in metastatic prostate cancer incidence and survival.

**Methods:** Men >18 years diagnosed with de novo stage M1 prostate cancer from 2004-2015 were identified from SEER 18 Registries. M1 was classified as non-regional lymph nodes (M1a), bone metastasis with or without lymph nodes (M1b) and distant metastatic disease (M1c). Age-adjusted incidence rates per 100,000 were calculated. Unadjusted 2-year overall and prostate cancer mortality rates by year of diagnosis were calculated using the Kaplan Meier method.

**Results:** We identified 34,888 men with M1 prostate cancer with median age of 72 years. From 2004-2015, there was a slight increase in de novo M1 disease from 10.2 per 100,000 to 12.1 per 100,000 (Figure). M1b prostate cancer rates increased, while M1a and M1c rates remained stable. 2-year overall mortality for M1 disease decreased from 0.50 (±0.01) to 0.46 (±0.01) from 2004-2014, while 2-year prostate cancer mortality decreased from 0.40 (±0.01) to 0.37 (±0.01).

**Conclusion:** As might be expected from decreased screening, there was an increase in diagnosis of de novo metastatic prostate cancer from 2004-2015. Population data also demonstrated a modest improvement in survival from 2004-2015. These trends may be less pronounced than expected due to decreased screening and later diffusion of effective treatments.
200. CARDIOVASCULAR RISK FACTORS FOR PATIENTS WITH ADVANCED PROSTATE CANCER ON ANDROGEN DEPRIVATION THERAPY
Raju Chelluri, Kinnari Patel, Katharine Michel, James Ding, Thomas Guzzo, Daniel Lee
Penn
Presented By: Raju Chelluri

Introduction: Cardiovascular and metabolic changes are a common and serious problem for patients with prostate cancer receiving androgen deprivation therapy (ADT). There is a high prevalence co-morbid cardiovascular disease in this at-risk elderly male population, and exposure to ADT contributes to a metabolic syndrome characterized by sarcopenic obesity, insulin resistance, arterial stiffness, and lipid derangements. Importantly, novel androgen signaling inhibitors, such as enzalutamide and abiraterone acetate, are commonly used life-prolonging ADT therapies for advanced prostate cancer, but have been associated with an almost 40% increase in cardiovascular toxicity. Provider awareness of cardiac risk factors is also low, as more than half of those who meet criteria for statin use are actually prescribed the medications. Therefore, it is essential to evaluate cardiovascular risks and statin prescription utilization for men on ADT.

Methods: In cooperation with the Center for Digital Health Innovation, and after receiving approval from the University of Pennsylvania Quality Improvement institutional review board, we identified 1,944 patients who were prescribed ADT for advanced prostate cancer from 2010 to 2019 at the University of Pennsylvania Health System. The 10-year Atherosclerotic cardiovascular disease risk (ASCVD) was calculated using the ASCVD risk calculator from the American College of Cardiology. Cardiac risk factors such as weight, body mass index (BMI), comorbidities such as diabetes, blood pressure, and cholesterol levels were reviewed. The American College of Cardiology 2019 guidelines recommended starting a statin with a low density lipoprotein (LDL-C) above 70mg/dL and above a 5% ten-year ASCVD risk. A significant blood pressure change of 20mmHg systolic or 10mmHg diastolic increases the risk of stroke or cardiovascular disease by two-fold.

Results: Overall, the median age of the cohort was 73 (IQR 67-80), with ADT treatment for a median duration of 18.5 months (IQR 4.6-45.9). Regarding antiandrogen utilization, 63% (1146/1818) were primarily on bicalutamide, 24.4% (443/1818) on abiraterone, 11.4% (208/1818) on enzalutamide, and 1% (18/1818) on apalutamide. Overall, 72% (1400/1944) of the population had an ASCVD risk score of 5% and above and should be on statin therapy according to guidelines. However, 48.2% (674/1400) of those who should have received statins did not receive statin therapy. The median total cholesterol levels were 166 (142-193) and median LDL were 92 (70-117). The median BMI was 28 (IQR 25-31), with 21% of the cohort as obese and 12.5% as severely or morbidly obese. Of the patients on abiraterone, enzalutamide, or apalutamide, 15.9% (103/650) had weight gain of 10 or more pounds. Fifty eight percent (57.6%) of the cohort had at least stage I hypertension. Of the 658 patients on the newer agents such as abiraterone, enzalutamide, or apalutamide, 25.8% (170/688) reported a significant blood pressure change of 20mmHg systolic or 10mmHg diastolic while on the new generation ADT.

Conclusion: This study highlights several cardiovascular risk factors for patients on ADT that are not receiving guideline concordant care. Approximately fifty percent of the patients on androgen deprivation therapy with significant ASCVD risk factors did receive guideline concordant statin therapy. In addition, more than a quarter of the patients on advanced ADT noted a high increase in their blood pressures. We will be utilizing these findings to create an intervention to improve decision support, which will automatically highlight the ASCVD risk and change the electronic medical record ordering system to facilitate improved cholesterol and blood pressure monitoring. By providing subtle “nudges” to providers, we hope to make the “right” choice the “easy” choice, and improve guideline concordant care.
201. UTILITY AND PRECISION MEDICINE IMPLICATIONS OF COMBINED TUMOR AND GERMLINE GENETIC TESTING IN PATIENTS WITH PROSTATE CANCER

Edward Esplin, Daniel Pineda-Alvarez, Scott Michalski, Meaghan Russell, Shan Yang, Ihn Young Song, Robert Nussbaum

Invitae

Presented By: Stephen Lincoln

Introduction: DNA testing has emerged as a cornerstone of precision medicine in prostate cancer diagnosis and treatment. Multiple types of DNA tests are used in this setting to inform care, including (a) tumor DNA tests, intended to detect somatic mutations in a tumor specimen, as well as (b) germline tests intended to detect inherited mutations that predispose to cancer, typically using blood or saliva specimens. Compared to somatic mutations, germline findings can suggest additional management actions for both the patient as well as their family members. Recent publications show that actionable germline mutations in cancer patients are far more prevalent than was once thought, and 5-10% of all prostate cancers are believed to have a hereditary component. Nevertheless, most tumor mutations are somatic, not germline. Confusingly, germline mutations are present in tumor tissue and are often reported by tumor tests, although these tests typically cannot accurately determine whether any given mutation is of somatic or germline origin. Moreover, most tumor tests are not optimized to detect or interpret germline DNA alterations, and these tests can fail to report clinically important germline events. A third type of DNA testing, (c) "liquid biopsy" tests of circulating tumor DNA are also emerging but are not considered herein. In this study, we investigated the utility of combined tumor and germline testing in a cohort of prostate cancer patients who had been referred for both test types.

Methods: We analyzed de-identified data from a consecutive series of 110 patients who met all of the following criteria: (a) the patient had a current diagnosis or personal history of prostate cancer (any type or grade); (b) the patient had been referred for germline genetic testing for a panel of hereditary cancer genes; and (c) the patient was known, at the time of that germline test, to have previously received tumor testing and summarized results of that tumor test were available for this analysis. The specific reasons for ordering each germline test varied, and included the personal/family history of the patient, tumor test results of potential germline significance, and other clinical factors. Although the genes included in the germline and somatic panels were not identical, and the specifics of both tests varied from patient to patient at physician discretion, the tests overlapped for most known prostate cancer genes. In addition, we reviewed patient indications to determine which patients met criteria for germline testing on the basis of personal and family history of cancer alone.

Results: All patients in this study had at least one finding from tumor testing and almost half (51/110, 46%) harbored one or more germline mutations. These germline findings included pathogenic or likely pathogenic variants in BRCA2 (31 patients), BRCA1 (3), ATM (4), APC (4), CHEK2 (3), as well as BLM, CDH1, CDKN2A, HOXB13, MSH2, NBN, NTHL1, PALB2, PMS2 (1 each). Five of the 51 germline positive patients (9.8%) carried clinically relevant germline mutations not reported by the tumor test. In the remaining cases, although the germline mutation was reported by the tumor test, it was not always reported as being potentially germline in origin. One additional finding was a mosaic (i.e. present in less than 100% of the body’s cells) TP53 mutation that was likely a result of CHIP (clonal hematopoiesis of indeterminate potential), a condition which increases the risk of leukemia and other diseases. Most (46/51, 90%) of the germline findings were considered potentially actionable under current management guidelines for familial disease, indications for approved therapies and/or clinical trial eligibility. Eight of the 51 positives (16%) did not meet criteria for germline testing based on their personal/family history. Seven of the 51 (14%) had received germline testing only at the time of a secondary cancer diagnosis. Considering the most commonly mutated genes, the fraction of all reported mutations determined to be germline was 46% for BRCA2, 44% APC, 38% CHEK2, 36% ATM, and 18% BRCA1.

Conclusion: Patients with positive tumor tests often (46%) harbored pathogenic germline variants, findings that can alter management compared with tumor testing alone. For example, patients with germline mutations in BRCA2 risk additional pancreatic and male breast cancers. Mutation-positive female relatives risk breast and ovarian cancers. Increased screening, preventative actions, cascade testing of relatives, and reproductive counseling may be appropriate in such cases, in addition to precision therapy and clinical trial eligibilities. Additionally, inherited prostate cancers can have poor prognosis compared to sporadic cancers, an observation which may also influence clinical decisions. Although mutations in certain genes were more likely than others to be germline, most mutations were somatic and recommendations for managing familial disease often would not apply to these cases. Germline tests disambiguated such findings and helped optimize clinical decisions. However, almost 10% of germline mutations were not reported by tumor testing, 16% were in patients who did not meet personal/family history criteria for germline testing, and 14% were in patients tested only after a secondary cancer appeared, reinforcing the utility of germline tests in diverse patient situations. Our study has an obvious bias in that germline tests were most commonly ordered by clinicians for patients with high suspicion of harboring a germline mutation. In a broader populations the germline positive rate is lower. Nevertheless, many results from this study likely still apply, suggesting that germline testing has high clinical utility within, and also independent of, the population of patients receiving tumor tests as part of their care.
202. WHEN CAN WE SKIP SYSTEMATIC PROSTATE BIOPSIES?
Andrew Wilbur 1, Michael Ahdoot 1, Amir Lebastchi 1, Patrick Gomella 1, Sandeep Gurram 1, Peter Pinto 1, Sarah Reese 2, Sherif Mehralivand 1, Baris Turkbey 3, Minhaj Siddiqui 1, Paul Pinsky 4, Howard Parnes 5, Joanna Shih 6, Bradford Wood 7
1 Urologic Oncology Branch, National Cancer Institute, National Institutes of Health, Bethesda, Maryland, 2 General Dynamics Information Technology, 3 Molecular Imaging Program, Center for Cancer Research, National Institutes of Health, Bethesda, Maryland, 4 Director of Urologic Oncology and Robotic Surgery, VA Medical Center, University of Maryland, Baltimore, Maryland, 5 Division of Cancer Prevention, National Cancer Institute, National Institutes of Health, Bethesda, Maryland, 6 Biometric Research Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute, National Institutes of Health, Bethesda, Maryland, 7 Center for Interventional Oncology, National Cancer Institute, & Interventional Radiology, Radiology and Imaging Sciences, National Cancer Institute, National Institutes of Health, Bethesda, Maryland
Presented By: Andrew Wilbur

Introduction: Multiple recent studies have suggested the most sensitive technique for prostate cancer diagnosis consists of combined MRI-targeted fusion and 12-core systematic biopsies. However, increasing the number of cores taken during biopsy has been shown to increase rates of urinary and infectious complications. In this study, we sought to determine if patients with high-risk prostate MRI lesions (PIRADS 5) can safely forego the systematic biopsy in favor of the MRI-targeted biopsy alone.

Methods: Between 2015 and 2019, patients enrolled in a prospective clinical trial evaluating the use of MRI-targeted fusion biopsy. All patients with MRI visible lesions underwent MRI-targeted and systematic biopsies during the same setting for prostate cancer diagnosis. The highest Gleason Grade(GG) cancer detected by each modality was recorded and stratified by MRI PIRADS v2 score. All data was collected prospectively as part of a nationally registered clinical trial(NCT00102544).

Results: In total, 723 men with PIRADS=2 lesions underwent subsequent prostate biopsy. A total of 51(7.1%), 87(12.0%), 346(47.9%), and 239(33.1%) biopsied men had a lesion with a greatest PIRADS score of 2, 3, 4, and 5, respectively. Of these men, 185(25.6%) were biopsy naïve. Among patients whose greatest lesion was PIRADS 5 (n=239), 226(94.6%) cancer diagnoses were made. Of these, 217(98.0%) were made by MRI-targeted biopsy, as opposed to 194(85.8%) by systematic biopsy. Of the 9 cancers missed by MRI-targeted biopsy, zero were clinically significant (GG=3). In regard to upgrading events, MRI-targeted biopsy upgraded 39(16.3%) clinically significant cancers which were either missed or graded as clinically insignificant by systematic biopsy. Conversely, systematic biopsy was responsible for upgrading 2(0.8%) patients, both of which were upgrades from GG=2 on MRI-targeted biopsy to GG=3 on systematic biopsy.

Conclusions: For men with PIRADS 5 lesions on prostate MRI, omission of systematic biopsies in favor of MRI-targeted biopsy alone leads to a marginal (<1%) decline in cancer diagnosis. However, for PIRADS 2-4 lesions, systematic biopsy adds significant diagnostic value and should be considered in combination with MRI-targeted biopsy.

Funding: NIH Intramural Grant

<table>
<thead>
<tr>
<th>Cancer Detection Rate by Biopsy Method and PIRADS Score</th>
<th>Greatest PIRADS Score of Lesions Biopsied</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PIRADS 2</td>
</tr>
<tr>
<td>Systematic Biopsy Only</td>
<td></td>
</tr>
<tr>
<td>No Cancer</td>
<td>34 (66.7%)</td>
</tr>
<tr>
<td>GG=1</td>
<td>9 (17.6%)</td>
</tr>
<tr>
<td>GG = 2</td>
<td>8 (15.7%)</td>
</tr>
<tr>
<td>GG = 3</td>
<td>3 (5.9%)</td>
</tr>
<tr>
<td>MRI-Targeted Biopsy Only</td>
<td></td>
</tr>
<tr>
<td>No Cancer</td>
<td>42 (82.4%)</td>
</tr>
<tr>
<td>GG=1</td>
<td>4 (7.8%)</td>
</tr>
<tr>
<td>GG = 2</td>
<td>5 (9.8%)</td>
</tr>
<tr>
<td>GG = 3</td>
<td>3 (5.5%)</td>
</tr>
<tr>
<td>Combination</td>
<td></td>
</tr>
<tr>
<td>No Cancer</td>
<td>32 (62.7%)</td>
</tr>
<tr>
<td>GG=1</td>
<td>10 (19.6%)</td>
</tr>
<tr>
<td>GG = 2</td>
<td>9 (17.6%)</td>
</tr>
<tr>
<td>GG = 3</td>
<td>4 (7.5%)</td>
</tr>
</tbody>
</table>
203. IMPACT OF PRE-BIOPSY MRI ON BIOPSY AND RADICAL PROSTATECTOMY GLEASON GRADE CONCORDANCE
Jonathan Shoag1, Peter Cai1, Christopher Gaffney1, Bashir Al Hussein Al Awamlh1, Michael Gross1, Jim Hu1, Dongze Li2, Jialin Mao2, Molly Nowels2, Art Sedrakyan2
1 Department of Urology, Weill Cornell Medicine, New York, NY, USA, 2 Department of Healthcare Policy and Research, Weill Cornell Medicine
Presented By: Peter Cai

Introduction: The use of multiparametric MRI prior to biopsy has allowed clinicians to target regions of interest for biopsy and has resulted in the detection of more high-grade cancers on biopsy, and less low-grade cancers, than TRUS biopsy alone. However, it remains unclear whether targeting detects higher grade lesions that are otherwise occult, or if this increase in biopsy grade is resultant from selective sampling of higher grade areas within an otherwise lower grade cancer. Distinguishing between these two possibilities is important, particularly as the safety of active surveillance was demonstrated in the pre-MRI era. In order to address this question, we examined the effect of pre-biopsy MRI on the rate of pathologic upgrading and downgrading at prostatectomy in the SEER-Medicare linked data from 2010 to 2015.

Methods: Prostate cancer patients were identified from the SEER-Medicare database (International Classification of Diseases site code (ICD-O-3) C61.9). Both transrectal ultrasound biopsy and MRI in-bore biopsies were identified by CPT codes and included. Among 82,483 patients identified in the study, 11,028 had both a Gleason grade for biopsy and prostatectomy. Logistic regression was performed to assess the effect of MRI use on the Gleason grade change between biopsy and prostatectomy. Patients were considered to have a prior negative biopsy if they had a prostate biopsy prior to the index biopsy which diagnosed prostate cancer. All p-values were two-sided with statistical significance, evaluated at the 0.05 alpha level. Ninety-five percent confidence intervals for odds ratios were calculated to assess the precision of the obtained estimates. All analyses were performed using SAS v9.4 (SAS Institute Inc., Cary, NC, USA).

Results: Among biopsy naïve men, those who had a pre-biopsy MRI had a higher odds of downgrading at prostatectomy, OR 1.32, 95% CI 1.05 to 1.66. In contrast, the odds of upgrading were significantly lower for men who had an MRI, OR 0.78, 95% CI 0.61 to 0.99 (Figure 1, Table 1). This suggests that pre-biopsy MRI is associated with both oversampling of high grade areas, resulting in downgrading at prostatectomy, and the detection of otherwise occult higher-grade lesions, resulting in less upgrading.

Conclusion: Men who have an MRI prior to their first prostate biopsy are more likely to be downgraded at radical prostatectomy and less likely to be upgraded. As MRI-targeted biopsy is increasingly adopted, re-evaluating risk stratification tools developed in the pre-MRI era will be critical.
204. ESTIMATING THE PREVALENCE OF PROSTATE CANCER GENOMIC SUBTYPES BY INVERSE PROBABILITY WEIGHTING

Jonathan Shoag¹, Peter Cai¹, Christopher Gaffney¹, Bashir Al Hussein Al Awamlh¹, Christopher Barbieri¹, Xiaoyue Ma²
¹ Department of Urology, Weill Cornell Medicine, New York, NY, USA, ² Department of Healthcare Policy and Research, Weill Cornell Medicine

Presented By: Peter Cai

Introduction: The delineation of distinct, reproducible genomic subclasses of primary prostate cancer has been a major advance. Such subclasses, defined by rearrangement in ERG or other ETS transcription factors, SPOP mutation, and IDH1 and FOXA1 mutations, have distinct biology and clinical behavior. Studies used to define genomic subtypes, such as The Cancer Genome Atlas (TCGA), are often assumed to be representative of the population with the disease. However, molecularly profiled cohorts are likely enriched for patients who have more aggressive disease. We sought to determine the true prevalence of prostate cancer genomic subtypes by weighting patients from TCGA to nationally representative data based on clinico-pathologic features.

Methods: Two separate data sources were used in this study: TCGA and the Surveillance Epidemiology and End Results (SEER) registry. Individual records from patients with prostate cancer who underwent prostatectomy were extracted from SEER. A multivariable logistic regression model using demographic and oncologic characteristics including age, race, year of diagnosis, lymph nodes, pathological stage, Gleason score from prostatectomy specimen, surgical margin status, and PSA, was used to predict the probability of a subject being incorporated in TCGA, and inverse probability weighting performed. After weighting, the chi-squared test and two-sample t-tests were performed to confirm balance on the above variables. Adjusted percentages of genomic subtypes in TCGA, and the proportion of subjects with ERG rearrangements by age were conducted using scaled-weights.

Results: Patients in TCGA were more likely to have lymph node metastases, and higher T stages and Grade Groups as compared to patients undergoing prostatectomy in SEER over the same time period. Multivariable logistic regression including clinical and pathologic data generated an area under the receiver operating characteristic curve of 0.88. After weighting, the number of patients with the most common primary prostate cancer subtype, ERG fusions, decreased from 151 (46%) to 117 (35.7%) and the number of unclassified patients increased from 84 (25.6%) to 134 (40.9%), Figure 1B, p=0.0069. In the unweighted cohorts, there was a decrease in percentage of ERG mutation frequency with increasing age (p=0.047), however this trend was not statistically significant in the weighted cohorts (0.071), Figure 1C.

Conclusion: Genomically profiled cohorts are not generalizable. Estimating the distribution of prostate cancer genomic subtypes in the US by inverse probability weighting suggests a markedly divergent distribution than the TCGA cohort. The proportion with ERG fusions appears lower than commonly cited, particularly in older men, with important implications for biomarkers based on ERG overexpression. Further, the proportion of subjects without a known subtype is over 40%, highlighting the need for increased studies. Overall, these results suggests the need for caution in generalizing the results of molecular profiling to the general population.
205. OTHER- AND ALL-CAUSE MORTALITY AMONG MEN WITH PROSTATE CANCER
Dudith Pierre-Victor, Paul F. Pinsky
National Cancer Institute, NIH
Presented By: Dudith Pierre-Victor

Introduction: Although prostate cancer (PCa) is the most commonly diagnosed solid tumor among American men, most men diagnosed do not succumb to PCa specific death. This high incidence to mortality ratio is due, in part, to the indolent nature of disease and to advances in screening and treatment. While PCa specific mortality has been the topic of numerous investigations, mortality from other causes has received less attention. This study aimed to investigate other- and all-cause mortality among men with PCa.

Methods: The Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial was designed to test the efficacy of screening for PLCO cancers among individuals 55-74 years. From the PLCO cohort, we selected men diagnosed with PCa from 1994-2014. To compare other- and all-cause survival of PCa cases to that of non-cases, we matched four controls to each case. We performed Cox proportional hazards modeling with matched case-control sets, controlling for age, randomization arm, and race in Model I and additionally for education, marital status, BMI, smoking status, pre-trial PSA screening behavior, and major comorbidities in Model II. Similar models were developed among the PCa cases, examining survival as a function of prognostic categories (low, intermediate and high- D’Amico risk and advanced disease) and Gleason score.

Results: Of the 76,672 men enrolled in PLCO, there were 11004 PCa cases. The median (25th/75th) follow-up time from diagnosis was 9.6 (6.1/13.6) years. The 15-year survival rates were 93.1% for PCa-specific survival, 63.4% for other-cause survival, and 58.1% for all-cause survival. Compared to non-cases, PCa cases had 21% (HR=0.79; 95% CI: 0.75-0.83) and 15% (HR=0.85; 95% CI: 0.81-0.89) lower other-cause mortality in Models I and II, respectively. The all-cause mortality risk was 1% (HR=0.99; 95% CI: 0.95-1.04) lower and 8% (HR=1.08; 95% CI: 1.03-1.13) higher for Models I and II, respectively, among cases compared to controls. Within PCa cases, compared to the low-risk group, HRs for other-cause mortality were 1.17 (95% CI: 1.06-1.29), 1.48 (95% CI: 1.32-1.67), and 1.78 (95% CI: 1.45-2.18) for intermediate-risk, high-risk, and advanced disease, respectively, in Model I. These HRs were similar in Model II, which controlled for all covariates (Table 1). For all-cause mortality, Model I HRs were 1.26 (95% CI: 1.16-1.38), 1.92 (95% CI: 1.73-2.14), and 4.73 (95% CI: 1.45-5.40) for intermediate-risk, high-risk, and advanced disease, respectively, in Model I. These HRs were similar in Model II, which controlled for all covariates (Table 1).

Conclusion: Over the 15-year follow-up period, among PCa cases the mortality risk from other causes exceeded that of PCa. However, the risk of other-cause mortality was consistently lower among PCa cases compared to that of non-cases even after controlling lifestyle and behavioral characteristics. Within cases, higher risk groups had higher other-cause mortality compared to low-risk group even after adjusting for comorbidities. These results warrant further investigations to elucidate the reasons for lower other-cause mortality among PCa cases compared to non-cases and higher other-cause mortality among those with higher risk PCa.

Other- and All-cause Mortality among Men with Prostate Cancer

<table>
<thead>
<tr>
<th>Cases vs. Controls</th>
<th>Other Cause</th>
<th>All-cause</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model I</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-Cases</td>
<td>HR (95%CI)</td>
<td>HR (95%CI)</td>
</tr>
<tr>
<td>Cases</td>
<td>0.79 (0.75-0.83)</td>
<td>0.99 (0.95-1.04)</td>
</tr>
<tr>
<td>Model II</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-Cases</td>
<td>HR (95%CI)</td>
<td>HR (95%CI)</td>
</tr>
<tr>
<td>Cases</td>
<td>0.85 (0.81-0.89)</td>
<td>1.08 (1.03-1.13)</td>
</tr>
<tr>
<td>Within Cases</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Model I</td>
<td>Risk group</td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>HR (95%CI)</td>
<td>HR (95%CI)</td>
</tr>
<tr>
<td>Intermediate</td>
<td>1.17 (1.06-1.29)</td>
<td>1.26 (1.16-1.38)</td>
</tr>
<tr>
<td>High</td>
<td>1.48 (1.32-1.67)</td>
<td>1.92 (1.73-2.14)</td>
</tr>
<tr>
<td>Advanced</td>
<td>1.78 (1.45-2.18)</td>
<td>4.73 (3.45-5.40)</td>
</tr>
<tr>
<td>Model II</td>
<td>Risk group</td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>HR (95%CI)</td>
<td>HR (95%CI)</td>
</tr>
<tr>
<td>Intermediate</td>
<td>1.17 (1.06-1.23)</td>
<td>1.27 (1.16-1.38)</td>
</tr>
<tr>
<td>High</td>
<td>1.42 (1.26-1.60)</td>
<td>1.86 (1.67-2.06)</td>
</tr>
<tr>
<td>Advanced</td>
<td>1.66 (1.35-2.03)</td>
<td>4.47 (3.92-5.11)</td>
</tr>
<tr>
<td>Model I</td>
<td>Gleason Score</td>
<td></td>
</tr>
<tr>
<td>GS 6</td>
<td>Ref</td>
<td>Ref</td>
</tr>
<tr>
<td>GS 7</td>
<td>1.19 (1.08-1.32)</td>
<td>1.32 (1.21-1.45)</td>
</tr>
<tr>
<td>GS 8-10</td>
<td>1.32 (1.18-1.50)</td>
<td>1.83 (1.63-2.07)</td>
</tr>
<tr>
<td>Model II</td>
<td>Gleason Score</td>
<td></td>
</tr>
<tr>
<td>GS 6</td>
<td>Ref</td>
<td>Ref</td>
</tr>
<tr>
<td>GS 7</td>
<td>1.20 (1.08-1.34)</td>
<td>1.36 (1.23-1.51)</td>
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<tr>
<td>GS 8-10</td>
<td>1.32 (1.13-1.53)</td>
<td>1.85 (1.62-2.10)</td>
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</table>
Introduction: Recently there is increasing evidence which suggests that prostate cancer (PCa) exhibits intratumor histological heterogeneity. Mesko et al. demonstrated that Gleason heterogeneity is detectable on biopsy in study of 53 patients and reported a 55% rate of Gleason heterogeneity, defined as a difference in Gleason scores between two cores within a single target. The impact of multiparametric magnetic resonance imaging (mpMRI) on PCa diagnosis has been growing. Using mpMRI-transrectal ultrasound (TRUS) fusion guided biopsy, the addition of two biopsy cores to lesions visible with MRI resulted in 30% higher rate of detection of high-risk and 17% less detection of low-risk tumors. However, the optimal strategy for placement and number of cores within the targeted lesion has not been generalized for the cancer detection. Our goal of target biopsy is to get the accurate Gleason score which represents the Gleason score of the whole lesion. The purpose of this study is to analyze the intra-lesional heterogeneity in prostate cancer with radical prostatectomy (RP) specimen for the optimization of target biopsy.

Methods: Among 162 consecutive men who underwent RP between January 2015 and August 2018 and consented for research, 96 men were analyzed. Patients who had prior treatment history, patients with inadequate tumor sampling during grossing, or patients with small tumor size (<1cm) were excluded. Lesions on RP specimens were included if they were =1cm in maximum diameter. The tumor was divided in three equal parts along the largest tumor diameter. The peripheries were the two ends of the largest diameter while center of the tumor was area in the central part along the largest diameter that had the maximum tumor amount. At each three points a circle area of 3mm (C, P1, and P2) was examined for the evaluation of the Gleason Score by a pathologist. Intra-lesional heterogeneity was defined as a difference in Grade group (GG) between three cores within a single lesion. The concordance of GG in any considered area (GG in peripheral areas: GG in P1 and GG in P2, GG in central area: GG in C) with GG for the whole lesion was analyzed. JMP® 14(SAS Institute Inc., Cary, NC, USA) is utilized for statistical analysis. In comparison between the lesions with and without heterogeneity, the Mann-Whitney’s U test or Fisher’s exact test were appropriately used. A 2-sided significance test is used. P<0.05 is considered significantly different.

Results: 120 lesions in 96 patients were identified. Median (IQR) diameter was 2.1(1.8-2.8) cm and median GG for whole lesion was 3(2-3). Among 120 lesions, 85 lesions (71%) had intra-lesional heterogeneity. In comparison of clinical characteristics of lesions with and without heterogeneity, there were no significant differences in median PSA value, prostate volume, PSA density, clinical/pathological T stage, largest diameter of the lesion, and PIRADS in mpMRI. Lesions with intra-lesional heterogeneity had higher median (IQR) GG for whole lesion than those without intra-lesional heterogeneity (3(2-3) vs 2(2-3), p=0.003). The concordance rate of GG at sampled area with GG for the whole lesion was as follows, P1:58%, P2:54%, C: 70%, C+P1:86%, C+P2: 82%, and C+P1+P2: 92% (Fig.1). The discordance rate of GG in C with GG for whole lesion was 30%, with lower GG in C accounting for 15% and with higher GG in C accounting for 15%.

Conclusion: The intra-lesional heterogeneity in prostate cancer was 71%. Lesions with intra-lesional heterogeneity had higher GG for whole lesion than those without intra-lesional heterogeneity. The concordance of GG at central area with GG for the whole lesion was higher than GG at peripheries. If we apply these results to biopsy simulation, the addition of one peripheral sampling to one central sampling increased concordance with GG for whole lesion in 12 or 18%. The addition of two peripheral sampling to one central sampling increased concordance with GG for whole lesion in 22%, resulting in the best concordance 92%.
207. SYSTEMATIC REVIEW AND META-ANALYSIS COMPARING PROSTATE CANCER DETECTION RATES BETWEEN COGNITIVE AND MRI-ULTRASOUND GUIDED FUSION PROSTATE BIOPSY
Laena Frechette¹, Emily Barry¹, Matthew DeMasi¹, Ahmed Aboumohamed¹, Kara Watts¹, Ben Muller²
¹ Montefiore Medical Center, ² Washington University at St Louis
Presented By: Ahmed Aboumohamed

Introduction: With increasing utilization of image-guided fusion prostate biopsy (FB) platforms, a plethora of studies have emerged demonstrating an increase in the sensitivity of prostate cancer detection for the FB approach compared to standard transrectal-ultrasound guided prostate biopsy. More recently, studies comparing rates of cancer detection between FB and cognitive fusion biopsy (CB) have emerged, particularly as the cost and availability of an image-guided fusion biopsy platform precludes its universal availability. We conducted a systemic review and meta-analysis of current literature to compare the rates of overall prostate cancer and clinically significant prostate cancer detection between FB and CB.

Methods: Pubmed, EMBASE, MEDLINE, and Cochrane Library databases were searched to identify prospective studies in which both FB and CB modalities were compared and published through June 24, 2019. Search terms utilized were (“prostate cancer OR prostate tumor OR prostate biopsy OR prostate biopsies”) AND (“fusion biopsy OR fusion OR fusion target OR image-guided OR imaging-ultrasound fusion OR software fusion OR imaging-targeted”) AND (“cognitive OR visual estimation OR cognitive-registration OR cognitive targeting”) AND (“MRI or magnetic resonance imaging OR nuclear magnetic resonance imaging OR mpMRI”). Retrospective studies, published abstracts, and manuscripts written in a language other than English were excluded. All studies were reviewed by two investigators and the following data were extracted: population statistics, patient demographics, MRI protocol, biopsy protocol including navigation systems used, and rates of overall and clinically significant prostate cancer detection for both FB and CB modalities. RevMan5 software was used to conduct the meta-analysis and generate forest plots. Heterogeneity was assessed using X² and I² statistics.

Results: A total of 192 unique manuscripts and abstracts were identified using our search criteria. 152 were excluded based on their title or abstract not adequately reflecting the scope of this study. 40 full text manuscripts were reviewed for content and availability of data. Of these, nine prospective studies comparing rates of prostate cancer detection between FB to CB for suspicious prostate lesions on MRI were analyzed and incorporated into the analysis. A total of 1714 men with mean age 64.6 years and mean PSA 8.2 ng/dl comprised the composite study population. The average rates of overall prostate cancer detection (Figure 1; 49.1% for CB vs. 53.4% for FB; [OR]: 1.11, 95% [CI] 0.91-1.36, p = 0.30) and clinically significant prostate cancer detection (Figure 2; 34.2% for CB vs. 35.1% for FB; OR: 1.13, 95% CI 0.89-1.44, p = 0.32) were comparable between the two modalities, respectively. I² test for heterogeneity among studies was 45%, suggesting moderate heterogeneity between studies. Among all studies reviewed, only one study reported ethnicity data.

Conclusion: Results from this analysis demonstrate a minimal trend toward improved rates of overall and clinically significant prostate cancer detection by MRI-US image-guided fusion biopsy compared to cognitive fusion biopsy in men with MRI-identifiable lesions, although results did not reach statistical significance. Data regarding outcomes in various ethnic groups is markedly under-reported among the studies reviewed. Larger comparative studies may help to further elucidate this comparison and overcome the moderate degree of between-study heterogeneity.
208. WHY DOES MRI-TARGETED BIOPSY MISS CLINICALLY SIGNIFICANT CANCER?

Michael Ahdoot¹, Christian Hague², Andrew Wilbur², Amir Lebatschi², Patrick Gomella³, Sandeep Gurram³, Peter Pinto³, Sherif Mehralivand², Baris Turkbey⁴, Paul Pinsky⁵, Howard Parnes⁶, Joanna Shih⁷, Bradford Wood⁸

¹ National Institutes of Health, ² Geisinger Commonwealth School of Medicine, ³ Urologic Oncology Branch, National Cancer Institute, National Institutes of Health, Bethesda, Maryland; ⁴ Molecular Imaging Program, Center for Cancer Research, National Institute of Health, Bethesda, Maryland, ⁵ Division of Cancer Prevention, National Cancer Institute, National Institutes of Health, Bethesda, Maryland, ⁶ Biometric Research Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute, National Institute of Health, Bethesda, Maryland, ⁷ Center for Interventional Oncology, National Cancer Institute, & Interventional Radiology, Radiology and Imaging Sciences, National Cancer Institute, National Institutes of Health, Bethesda, Maryland

Presented By: Michael Ahdoot

Introduction: MRI-Targeted Fusion prostate biopsies have demonstrated improved clinically significant cancer compared to systematic biopsy. However, despite MRI-targeted biopsy improved detection there remain critically important cases of missed clinically significant cancer. We seek to understand the reason for these “MRI-Targeted biopsy misses”.

Methods: Patients were enrolled in a prospective study comparing transrectal MRI-targeted fusion biopsy with systematic 12 core biopsy. Patients with an elevated PSA, abnormal rectal exam, or imaging finding concerning for prostate cancer underwent prostate MRI followed by MRI-targeted and systematic biopsies, in the same setting, if a prostate lesion was detected on MRI. The subset of patients with clinically significant (GG=3) cancer found on systematic biopsy and GG=2 cancer on MRI-targeted biopsy were classified as MRI-targeted biopsy misses. A retrospective analysis of the MRI lesion with an expert genitourinary radiologist was performed to assess for the cause of MRI-targeted biopsy miss. The possible reasons for biopsy misses included MRI-invisible lesions, MRI-Invisible lesions, and MRI-visible lesions missed on biopsy.

Results: Over the study period of 2007 to 2019, 2103 patients met study inclusion criteria and underwent combine MRI-targeted and systematic prostate biopsies. 42 (2.0%) men demonstrated clinically significant cancer detected on systematic biopsy only. The majority of MRI targeted biopsy misses were due to errors in lesion targeting (n=22, 52.4%), followed by MRI-invisible lesions (n=17, 40.5%). MRI lesions missed by the radiologist accounted for a 7.1% (n=3) of MRI-targeted biopsy misses. Of the lesions missed due to targeting errors, 29.4% (n=5) were due to poor co-registration of the MRI with the ultrasound.

Conclusion: MRI-targeted biopsies can miss clinically significant cancers. Most of these misses are due to errors in lesions targeting, which highlights the importance of accurate co-registration and targeted when using software based fusion platforms. Additionally, some patients will harbor MRI-invisible lesions which are un-targetable by MRI-targeted platforms. Among highly experienced genitourinary radiologists, the rates of MRI visible lesion misses of clinically significant cancer can be low.

Funding: NIH Intramural Fund

<table>
<thead>
<tr>
<th>Table 1. Patient Demographics</th>
<th>All patients</th>
<th>MRI negative biopsy cohort</th>
<th>MRI positive biopsy cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total N (%) total</td>
<td>2103 (100%)</td>
<td>2081 (100%)</td>
<td>122 (100%)</td>
</tr>
<tr>
<td>Race, N (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>122 (74.2)</td>
<td>122 (58.9)</td>
<td>20 (62.5)</td>
</tr>
<tr>
<td>Black</td>
<td>8 (4.7)</td>
<td>8 (3.8)</td>
<td>0 (0.0)</td>
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<tr>
<td>Asian</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>5 (2.4)</td>
<td>5 (2.4)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Other</td>
<td>24 (11.4)</td>
<td>24 (11.4)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Age, mean (SD)</td>
<td>72.12 (5.91)</td>
<td>72.12 (5.91)</td>
<td>63.35 (7.42)</td>
</tr>
<tr>
<td>PSA, mean (mg/dl)</td>
<td>8.45</td>
<td>8.45</td>
<td>8.45</td>
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<tr>
<td>Tumor stage, N (%)</td>
<td></td>
<td></td>
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<tr>
<td>T1c</td>
<td>30 (14.3)</td>
<td>30 (14.3)</td>
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<tr>
<td>T3c</td>
<td>30 (14.3)</td>
<td>30 (14.3)</td>
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<tr>
<td>T3a</td>
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<tr>
<td>T3b</td>
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<td>T3c</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>MRI prostate volume, mean, mg/dl</td>
<td>39.98</td>
<td>39.98</td>
<td>39.98</td>
</tr>
<tr>
<td>Number of Targeted Biopsies, mean</td>
<td>17.41</td>
<td>17.41</td>
<td>17.41</td>
</tr>
<tr>
<td>Number of Systemic Biopsies, mean</td>
<td>3.92</td>
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<tr>
<td>Prostate Targeted</td>
<td>0.42</td>
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<tr>
<td>Malignant</td>
<td>0.42</td>
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<tr>
<td>Number of Postive Random Biopsies, mean</td>
<td>3.52</td>
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</tr>
<tr>
<td>Number of Men with MRI visible, N (%)</td>
<td>41 (19)</td>
<td>41 (19)</td>
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<td>Number of Men with MRI visible, N (%)</td>
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<td>Number of Men with MRI visible, N (%)</td>
<td>1 (0)</td>
<td>1 (0)</td>
<td>1 (0)</td>
</tr>
</tbody>
</table>

Reasons for MRI-Targeted Biopsy to Miss Clinically Significant Cancers

MRI invisible: 52%, Missed by radiology on MRI: 41%, Missed on targeting: 7%
209. OPIOID PRESCRIBING PATTERNS AFTER RADICAL PROSTATECTOMY AND LONG-TERM OPIOID USE

James Ding1, Ruchika Talwar2, David Lee2, Bruce Malkowicz2, Philip Mucksavage2, Keith Van Arsdalen2, Alan Wein2, Thomas Guzzo2, Daniel Lee2

1 University of Pennsylvania, 2 Penn

Presented By: James Ding

Introduction: More than 40 people die daily from an overdose involving prescription opioids, with over 4 million Americans engaged in non-medical use of prescription opioids each month. Opioid stewardship is therefore essential to help eliminate the crisis, as prescriptions over 50 morphine milligram equivalents per day (MME) increases the risk of overdose by two-fold. Previous studies based off of electronic orders may underestimate opioid usage if patients seek other providers or pharmacies. Little is known about the prescribing practices after prostatectomy and the long-term usage of opioids. Therefore, we sought to characterize existing practice patterns and opioid use characteristics in a large tertiary academic center.

Methods: After receiving approval from the University of Pennsylvania's Quality Improvement Institutional Review Board, opioid prescriptions from 1,574 consecutive patients who underwent a radical prostatectomy for localized prostate cancer at a single institution from June 2015 to October 2018 were evaluated utilizing the Pennsylvania Prescription Drug Monitoring Program (PDMP). All drug strengths were converted to MME to facilitate comparison, with 50 MME being roughly equivalent to 10 tablets of Vicodin (5/300). Prolonged opioid use was defined as opioid use for 3 months or more.

Results: A median of 210 MME (IQR 210-337.5) were prescribed postoperatively, equaling 52.5 MME (IQR 30-70) per day. More than half of the patients (56%) were prescribed more than 50 MME per day. There was extensive variation in prescribing patterns among different providers, with median values ranging from 42 to 84 MME per day. Overall, 34.2% (447/1308) of the patients were prescribed an opioid at least once before undergoing a prostatectomy, with 3.6% (47/1308) having prolonged use before prostatectomy. After prostatectomy, 5.3% (69/1308) of the patients had prolonged use of opioids. Of the patients who had prolonged use after prostatectomy, 53.6% (37/69) of the patients had their initial opioid exposure with the postoperative prescription. Those with prolonged opioid use after prostatectomy used more pharmacies (median 3, IQR 2-5) than those without chronic use (median 1 (IQR 1-2) to fill the opioid prescriptions (p<0.01). The amount of opioids prescribed daily (MME per day) did not differ according to the patient's previous opioid exposure (p=0.56) or history of prolonged opioid use (p=0.25). Patient demographic and operative factors, such as age, race, and length of stay, were not associated with prolonged opioid use after prostatectomy.

Conclusion: There was a significant quantity of opioids prescribed after prostatectomy, with significant variation among different providers. More than half of the patients using opioids for prolonged periods received their first prescription after prostatectomy. Future studies to improve PDMP surveillance and implementation of non-opioid alternatives would be required to help improve opioid stewardship after prostatectomy.

210. ASSOCIATION BETWEEN SOCIOECONOMIC STATUS AND PRIMARY TREATMENT CHOICE FOR LOCALIZED PROSTATE CANCER IN A UNIVERSAL HEALTHCARE SYSTEM: A POPULATION-BASED ANALYSIS

Justin Oake1, Jeff Saranchuk1, Rahul Bansal1, Darrel Drachenberg1, Jasmir Nayak1, Oksana Harasemiw2, Thomas Ferguson2, Navdeep Tangri2

1 Section of Urology, University of Manitoba, 2 Chronic Disease Innovation Centre, Seven Oaks General Hospital; Department of Internal Medicine, University of Manitoba

Presented By: Justin Oake

Introduction: A large body of research has shown that there are strong socioeconomic disparities in access to cancer treatment. However, whether these inequalities persist among men with prostate cancer has not been previously explored in the equal-access, universal Canadian health care system. The aim of this study is to compare whether socioeconomic status (SES) is associated with the type of treatment received (radical prostatectomy (RP) versus radiation therapy (RT)) for men diagnosed with nonmetastatic prostate cancer in Manitoba, Canada.

Methods: Men who were diagnosed with non-metastatic prostate cancer between 2004 and 2016 and subsequently treated with RP or RT were identified using the CancerCare Manitoba Registry and linked to provincial databases. SES was defined as neighbourhood income by postal code and divided into income quintiles (Q1 - Q5, with Q1 the lowest quintile and Q5 the highest). Multivariable logistic regression nested models were used to compare whether SES was associated with treatment type received.

Results: We identified 4,560 individuals between 2004-2016 who were diagnosed with non-metastatic prostate cancer, and who were subsequently treated with RP (n=2,554) or RT (n=2,006). Among socioeconomic income quintiles, as income quintile increased, men were more likely to undergo RP than RT (Q3 vs Q1: aOR 1.45, 95% CI 1.09-1.92; Q5 vs Q1: aOR 2.17, 95% CI 1.52-2.86).

Conclusion: In our universal healthcare system, patients from a higher SES were significantly more likely to undergo RP compared with RT despite equal access to both modalities. Patient-centred policies ensuring more equitable counselling and treatment are needed to diminish these disparities.

Funding: Funding for this study was provided by the University of Manitoba Department of Surgery.
211. ARTIFICIAL INTELLIGENCE ACCURATELY AUTOMATES AND ACCELERATES IMMUNOFLUORESCENCE-BASED DISCOVERY INCLUDING THE VALIDATION OF NOVEL PROGNOSTIC AND PREDICTIVE BIOMARKERS IN PROSTATE CANCER

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1 University of California, San Francisco, 2 Salesforce Inc.

Presented By: Claire de la Calle

Introduction: Immunofluorescence (IF) performed on tissue microarrays (TMA) is a proven platform for both rapid and cost-effective screening and validation of biomarkers but is limited by thearduous and subjective human visual assessment with an IF microscope. We aim to implement deep learning-based artificial intelligence (AI) models to automate and speed up the analysis of numerous biomarkers such as Ki 67, Erg, PTEN, c-MYC, AR (androgen receptor), by using various algorithms to recognize specific patterns of expression in epithelial cells and normal stromal tissue for each marker of interest in order to translate the findings into prediction models of recurrence and metastasis after surgery.

Methods: A TMA was constructed consisting of 648 samples (424 tumor, 224 normal tissue) generated from radical prostatectomy specimens done for localized prostate cancer. Each had been previously subjected to RNA-based biomarker assessment. IF staining was performed on the TMA using antibodies against Ki 67, ERG, PTEN, c-MYC, AR and CK8 (cytoskeleton 8) and analyzed for differential expression using “gold standard” standardized manual microscopy and using a deep learning-based algorithm. Analysis was done blinded to any clinicopathological data. For the manual microscopy, relative mean fluorescence intensity was used to extrapolate the differential expression in normal adjacent tissue to that of cancerous tissue. Then, AI algorithms were designed to recognize both broad patterns and specific details of the digitized images at pixel level, by discriminating epithelium, stroma, and artifacts, using a training cohort. During its development, the model learns to accurately disentangle overlapping regions and touching cells, by leveraging prior information of cell structure computed by pixel-intensity based algorithms. To do so, the Otsu method thresholding algorithm combined with mean shift clustering was employed, to find the cell centers, followed by a level-set algorithm, to compute the initial cell boundaries. These predictions were then combined with pixel predictions of a fully-convolutional deep model to refine the regions of three overlapping tissues, i.e. epithelium, stroma, and artifacts (Figure 1). DAPI was used for nuclear staining. The trained model was then validated using a separate cohort from the TMA. Predicted data from the algorithm were then compared to the data from the manual microscopy.

Results: We started with Ki-67 and ERG stainings of the constructed TMA. The analysis using Ki-67 and ERG positivity and expression levels generated by the AI algorithm showed only a 5% variance compared to the manually generated “gold standard” results. The AI algorithm was able to pick out which tumor were positive for ERG with 100% accuracy, meaning accuracy was maintained despite data variance from artifacts. Furthermore, the AI program had the ability to improve its accuracy after each iteration of modifications and feedback through the training cohort. Figure 1: ERG expression pipeline showing original staining of ERG expression (red), artifact (green), DAPI nuclear staining (blue) and decomposed image in black and white and final composite with quantification from the AI algorithm.

Conclusion: We demonstrated that our new AI algorithm produces similar outcomes with high accuracy and robustness when compared to manual quantification but with more efficiency, cost effectiveness, and objectivity. We are now developing more complex algorithms that will include the differential pattern of expression of PTEN, MYC and AR in regions high grade cancer, as well as CK8 (to help better distinguish epithelial cells from stromal cells), with the objectives of streamlining discovery and validation of novel biomarkers for lethal prostate cancer.
212. THE 4KSCORE TEST AND SELECTMDX DO NOT INFORM DECISION WHETHER TO OBTAIN A MULTI-PARAMETRIC MRI IN MEN WITH ELEVATED PSA

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¹ New York University School of Medicine, ² New York University

Presented By: Jesse Persily

Introduction: Historically, approximately 70% of men with an elevated PSA did not have any prostate cancer (PCa) following trans -rectal ultrasound guided systematic biopsy (SB). Today, the consensus amongst the urology community is the need to improve the specificity of PSA testing for detecting clinically significant prostate cancer (csPCa). mpMRI and/or various biomarkers are being recommended as reflex tests to better select men with elevated PSA levels for prostate biopsy with the objective of increasing specificity of PSA screening for detecting csPCa. The advantage of mpMRI is that PIRADS scoring is directly proportional to risk of detecting csPCa and MRI guided biopsy increases detection of csPCa and decreased risk of low risk cancer compared to SB. The advantages of both blood-based and urine-based PCa biomarkers include lower costs, simplicity of testing, and a standard, quantitative result. The optimal utilization of mpMRI and biomarkers to inform decision to perform prostate biopsy is not well defined. The objective and unique aspect of the present study is to compare the performance of two biomarkers (4Kscore Test and SelectMDx) individually and in combination to predict PI-RADS score in a group of men with an elevated serum PSA under consideration for prostate biopsy.

Methods: Between November 2018 to April 2019, all men presenting with the diagnosis of elevated PSA to two uro-oncologists (JW and HL) were advised to undergo a 4Kscore Test, SelectMDx, and mpMRI in order to inform decision whether to perform prostate biopsy. All patients who completed all three tests were included in the study. The total PSA level reported as part of the 4Kscore represented the baseline serum PSA. mpMRI was performed using the 3T clinical instrument and an external phased – array coil and included T2 weighted images, axial diffusion weighted imaging using b values of 50 and 1000 s/mm² with generation of the apparent diffusion coefficient maps and calculated b-1500 images and dynamic contrast enhancement imaging after intravenous gadolinium chelate. A PI-RADS score was assigned by one of several board certified radiologists with expertise interpreting prostate mpMRI. Risk cut-off points of 7.5% for detecting a csPCa (i.e., GGG >1) derived from the 4Kscore and SelectMDx tests were compared for their ability to predict mpMRI PI-RADS scores. Positive Predictive Value, (PPV), Negative Predictive Value (NPV), Sensitivity, and Specificity were calculated, setting PI-RADS >2 as a positive mpMRI result. The predictive performance of these biomarkers, as well as PSA and PSAD, were evaluated using the area-under-the receiver operator curve. To combine these two continuous biomarker tests into a signal predictor, a predicted probability was calculated using logistic regression for both mpMRI cut-offs, and then this predicted probability was evaluated as the AUC of the ROC curve.

Results: Of the 124 men who were advised to undergo both biomarker tests and mpMRI, 103 (83%) completed all three tests. The median age was 63 years (IQR: 58-69) and median PSA was 5.61ng/ml (IQR: 4.12-8.26). Thirty men had a family history of PCa and 16 patients had abnormal DRE. Biomarker characteristics included median 4Kscore of 11% risk of csPCa (IQR: 6-24) and median SelectMDx risk score of <2% of csPCa (IQR: 2-13). After mpMRI, 30, 22, 36, 13, and 2 patients were found to have PI-RADS scores of 1, 2, 3, 4 and 5, respectively. The positive predictive value (PPV), negative predictive value (NPV), sensitivity, and specificity for the individual biomarkers to predict PI-RADS scores are shown in Table 1. The positive and negative predictive value of the individual biomarkers to predict mpMRI was consistently between 50 to 60%. The superior sensitivity the 4Kscore Test and specificity of SelectMDx, respectively is likely attributed to twice number of 4K tests that were positive (69% vs. 29%). The ROC curves and AUC values are shown for the serum PSA, PSAD, 4Kscore Test and SelectMDx to discriminate between PI-RADS 1-2 and 3-5 is shown in Figure 1. The rank order of AUC (highest to lowest) was the combination of 4Kscore Test + SelectMDx, 4Kscore Test, PSAD, SelectMDx, and PSA. The increase in the AUC by adding of SelectMDx to the 4Kscore Test was marginal and clinically insignificant.

Conclusion: Our study provides compelling evidence that biomarkers do not reliably inform decisions whether to obtain an mpMRI in men with elevated PSA. The present study was not designed to determine whether biomarkers or mpMRI is the preferred reflex test to inform decisions whether to proceed with prostate biopsy in men with elevated PSA since it would require all these men undergoing biopsy independent of mpMRI and biomarker findings. Our study was designed to address whether biomarkers can be used in order inform decisions whether to proceed with an mpMRI assuming discriminating between PI-RADS 1,2 vs 3-5 was clinically relevant. Additional follow-up and a prospective trial design will be necessary to provide insight about optimal implementation of biomarkers and mpMRI in order to maximize the sensitivity and specificity of prostate biopsy for detecting csPCa.
Table 1. Performance of 4Kscore and Select MDx to Predict mpMRI

<table>
<thead>
<tr>
<th></th>
<th>MRI+</th>
<th>MRI-</th>
<th>PPV</th>
<th>Sensitivity</th>
<th>Specificity</th>
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<tbody>
<tr>
<td>SelectMDx +</td>
<td>18</td>
<td>15</td>
<td>54.5</td>
<td>52.9</td>
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<td>50.3</td>
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<tr>
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<td>34</td>
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<td>52.9</td>
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<tr>
<td>4Kscore Test -</td>
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<td>18</td>
<td>68.6</td>
<td>34.6</td>
<td>68.6</td>
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<tr>
<td>SelectMDx+/4Kscore +</td>
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<td>11</td>
<td>59.3</td>
<td>53.9</td>
<td>31.4</td>
</tr>
<tr>
<td>SelectMDx - and/or 4Kscore -</td>
<td>55</td>
<td>41</td>
<td>68.6</td>
<td>78.8</td>
<td>68.6</td>
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</tbody>
</table>

A positive MRI was PI-RADS > 2. Positive SelectMDx or 4Kscore Test >75% risk of cPca.

Figure 1. ROC for 4KScore and Select MDx Tests to Predict mpMRI PI-RADS > 2

<table>
<thead>
<tr>
<th>Source of the Curve</th>
<th>AUC (95% Confidence Interval)</th>
</tr>
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<tbody>
<tr>
<td>SelectMDx</td>
<td>.565 (.452-.677)</td>
</tr>
<tr>
<td>4Kscore Test</td>
<td>.625 (.514-.736)</td>
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<tr>
<td>SelectMDx + 4Kscore Test</td>
<td>.629 (.519-.739)</td>
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<td>PSA Density</td>
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</table>
213. THE IMPACT OF SERIAL MULTIPARAMETRIC MAGNETIC RESONANCE IMAGING TO PREDICT PATHOLOGICAL PROGRESSION DURING ACTIVE SURVEILLANCE WITH GLEASON 6 PROSTATE CANCER.

Andre Abreu1, Tsuyoshi Iwata1, Aliasger Shakir1, Alessandro Tafuri1, Giovanni Cacciamani1, Luis Medina1, Mihir Desai1, Inderbir Gill1, Osamu Ukimura2, Vinay Duddalwar3, Manju Aron4, Suzanne Palmer5

1 USC Institute of Urology and Catherine & Joseph Aresty Department of Urology, University of Southern California, 2 Department of Urology, Kyoto prefectural university of medicine, 3 Departments of Radiology, Keck School of Medicine, University of Southern California, 4 Department of Pathology, Keck School of Medicine, University of Southern California, 5 Departments of Radiology, Keck School of Medicine, University of Southern California

Presented By: Atsuko Fujihara

Introduction: The purpose of this study is to investigate the utility of multiparametric magnetic resonance imaging (mpMRI) in the reassessment of patients on active surveillance (AS) for prostate cancer.

Methods: Men who were enrolled on AS between June 1999 and November 2018 with Gleason score (GS) 3+3 prostate cancer were included if they underwent confirmatory biopsy and mpMRI prior to any biopsy. A subset analysis was performed among patients with serial MRI during AS. A lesion with score of ≥ 3 on Prostate Imaging Reporting and Data System (PIRADS) version 1.0 or 2.0 was considered an MRI-positive lesion. MRI progression was defined as an increase in PIRADS score, or the appearance of any new lesion with PIRADS ≥ 3, or lesion enlargement detected on follow up MRI. Pathological progression (PP) was defined as the increase of GS at biopsy. Multivariate logistic regression analysis was performed to evaluate predictors of PP.

Results: 54 out of 181 (30%) patients with PP were identified. Higher PSA density (p=0.0001) and positive MRI (p=0.0003) at last biopsy were significantly associated with PP. 70 patients who underwent serial MRI were examined as a subset analysis. Only MRI progression was significantly associated with PP (p=0.0003) (Fig.1). The major limitation of this study is its retrospective nature and its relatively small sample size.

Conclusion: We demonstrated that the utility of mpMRI for reassessment of patients on AS for GS 3+3 prostate cancer is significant. MRI progression was a strong predictor for pathological progression. (245 words)
Introduction: There is now a large body of literature supporting the use of active surveillance (AS) for the management of men with low risk prostate cancer, however the majority of these studies are primarily composed of Caucasian men. Our institutional AS series is unique in that > 80% of our AS patients are racial minorities. We aimed to characterize factors associated with disease reclassification and progression to definitive treatment in this unique AS cohort.

Methods: Men on AS at our institution are typically followed with biannual PSA testing and repeat biopsy 6-12 months following initial biopsy (typically with MRI/US fusion). Subsequent MRI and surveillance biopsies are performed on an annual to bi-annual basis. Patients with Gleason upgrading or a significant increase in number of positive biopsy cores on surveillance biopsy are deemed to have reclassified and are typically encouraged to undergo definitive treatment with either radical prostatectomy or radiation therapy. We performed a retrospective analysis of our institutional prospectively-maintained active surveillance database. We characterized demographic and disease-specific variables associated with progression to definitive treatment. Cox proportional hazards, Kaplan Meier, and log rank testing were used to perform univariate analysis of factors associated with progression. Multivariable assessment of these factors was performed using Cox proportional hazards analysis.

Results: Our AS cohort includes 138 patients with a median follow-up of 23 months (range: 6-69 months). The racial breakdown of our cohort is as follows: 86 (62.3%) African American, 31 (22.5%) Hispanic, and 21 (15.2%) Caucasian. Median patient age at initial biopsy was 62 years (range 50-78 years) and median PSA was 5.2 (range 1.0 – 12.0). 129 men (93.5%) had grade group 1 tumors at diagnosis and the remainder grade group 2. AUA risk group at diagnosis included 57 (42.2%) with very-low risk disease, 64 (47.4%) with low risk, and 14 (10.4%) with favorable intermediate risk. During follow-up, 46 of 138 (33.3%) men progressed to definitive treatment. Median and 3-year treatment-free survival for the cohort were 49 months and 73%, respectively. The Table shows univariate and multivariable factors associated with progression to definitive treatment. The Figure shows Kaplan Meier curves of progression-free survival for several variables associated with progression on univariate analysis.

Conclusion: We investigated factors associated with progression to definitive treatment among patients managed with AS at our institution, a large percentage of whom are racial minorities. The majority of demographic and disease-specific factors studies were not associated with progression to treatment. In our multivariate analysis, only the Genomic Health Oncotype GPS score was associated with progression to treatment. These findings suggest that the GPS score is a useful tool when counseling minority patients enrolled in AS regarding their likelihood of progression to treatment.
215. INTRA-PRACTICE UROLOGIST-LEVEL VARIATION IN CANCER DETECTION RATES WITH TARGETED CORES ON FUSION BIOPSY

Apoorv Dhir, Chad Ellimoottil, Ji Qi, Jeff Montgomery, Simpa Salami, John Wei, Prasad Shankar, Matthew Davenport, Nicole Curci, Chen-Yu Wu, Anna Johnson, Arvin George
University of Michigan
Presented By: Arvin George

Introduction: There is Level-1 evidence supporting the use of multiparametric MRI and transrectal ultrasound-guided prostate biopsy (fusion biopsy) in the prostate cancer diagnostic pathway. While it is evident that fusion biopsy outperforms transrectal ultrasound guided biopsy in cancer detection, significant variation in cancer detection rates exists, ranging from 46-70%. Prior studies have found several factors impacting fusion biopsy outcomes including patient and tumor specific characteristics and imaging specifications. However, it is unknown the degree to which differences in biopsy technique contribute to variation in cancer detection. As fusion biopsy becomes ubiquitous, it is essential to determine whether there is an ideal approach to optimize cancer detection. For instance, subtle differences across providers in sampling methods and techniques may introduce significant variation in cancer detection at the provider level. In this study, we used data from a cohort of experienced urologists at a single institution to investigate provider-level variation in cancer detection rate.

Methods: All men in the Michigan Urological Surgery Improvement Collaborative (MUSIC) clinical registry who underwent fusion biopsy at Michigan Medicine from August 2017 to March 2019 were included. The MUSIC clinical registry is maintained by trained data abstractors who enter a set of data elements for all men in MUSIC practices who undergo a prostate biopsy. Provider level outcomes were analyzed. The primary outcome was defined as cancer detection rate by targeted cores. Secondary outcomes included GGG=2 cancer detection rate on targeted cores stratified by PIRADS score and meeting of MUSIC fusion biopsy scorecard benchmark measures. Bivariate and multivariable logistic regression analyses was performed to assess variation in cancer detection rates at the fusion biopsy provider level controlling for patient age, PSA, race, family history, clinical stage, and PIRADS score.

Results: We identified 708 patients in the MUSIC registry who underwent fusion biopsy at Michigan Medicine during the study period. Biopsies were performed by five providers, whose volumes ranged from 77-199 fusion biopsies. There was no significant difference in distribution of age, race, family history, or PSA across patients treated by the five providers. However, there were statistically significant differences in DRE, maximum PIRADS score, prior diagnosis of prostate cancer, and number of cores biopsied across patients treated by the five providers. There was no significant difference in targeted cancer detection rates across the five fusion biopsy providers in our study. (Figure 1) Adjusted overall cancer detection rate by targeted cores on fusion biopsy ranged from 54-74% across the five providers (adjusted p = 0.60) with an average cancer detection rate of 62.6%. Cancer detection rates for all providers surpassed the MUSIC quality benchmark of >45%. GGG=2 detection in PIRADS 3 lesions ranged from 0-15% across the five providers (unadjusted p = 1.000) with an average GGG=2 cancer detection rate of 10.5%. Risk adjusted GGG=2 detection of prostate cancer in PIRADS 4 lesions ranged from 34-59% across the five providers (adjusted p = 0.134) with an average GGG=2 detection rate of 34.8%. Risk adjusted GGG=2 detection in PIRADS 5 lesions ranged from 70-86% across the five providers (adjusted p = 1.000) with an average GGG=2 detection rate of 70.2%.

Conclusion: In this study, we found no difference in cancer detection rates in targeted lesions across fusion biopsy providers at a single institution. Furthermore, all providers met the established MUSIC benchmark rates for high quality care, and we found no statistically significant difference in GGG=2 detection rates for PIRADS 3, 4, and 5 lesions. Collectively, these findings suggest that, among experienced providers, variation in fusion biopsy technique may not contribute to overall variation in cancer detection rates with targeted cores on fusion prostate biopsy.

Funding: Blue Cross Blue Shield of Michigan
216. ASSESSING FOCALITY OF DOMINANT TUMOR ON SERIAL BIOPSY IN AN ACTIVE SURVEILLANCE COHORT - IMPLICATIONS FOR FOCAL THERAPY

Vittorio Fasulo1, Janet E. Cowan2, Samuel L. Washington III2, Hao G. Nguyen2, Katsuto Shinohara2, Peter R. Carroll2, Paolo Casale3
1 University of California, San Francisco – San Francisco, CA; Istituto clinico Humanitas – Rozzano, Milan, Italy, 2 University of California, San Francisco – San Francisco, CA, 3 Istituto clinico Humanitas – Rozzano, Milan, Italy

Presented By: Vittorio Fasulo

Introduction: Active surveillance (AS) remains a safe option for selected men with clinically localized prostate cancer (PCa). Focal therapy (FT) has been proposed by some as an alternative. To what extent such patients are at risk of major changes in tumor volume and/or grade outside of the dominant lesion is of importance when considering FT in such a population of men. We aim to understand the progression of the dominant tumor in terms of focality and histologic grading in men who have undergone serial biopsy of prostate (Bx) to identify how many could be reasonable candidates for FT.

Methods: Men enrolled on AS at UCSF between 1996 and 2017 with low-intermediate risk PCa at diagnosis (PSA < 20ng/ml, clinical stage T1–2, Gleason score (GS) 3+3/3+4), at least 10 biopsy cores taken at diagnosis, and at least 1 biopsy after diagnosis were included. All biopsies were systematic biopsy. Changes in biopsy laterality and/or grade over time were assessed. Dominant tumor (DT) was defined as the tumor with highest GS and size on biopsy confined to 1 or 2 contiguous sextants. In addition those with these characteristics and only a small volume of GS 3+3 on the contralateral side were also considered candidates.

Results: Among 1272 men, mean patient age was 62 years and median PSA was 5.42 ng/ml. Median follow up was 78 months (IQR 46-108). Median number of biopsies was 3 (min 2, max 12) and 18% had 5 Bx or more. At diagnosis 1142 (90%) and 130 (10%) patients had GS 3+3 and GS 3+4 disease respectively. At first surveillance Bx (fsBX) findings were negative in 255 (20%), unchanged in 711 (56%), and upgraded in 306 (24%). Proportions of findings were similar at the following 3 biopsies. Across all biopsies 27% were negative and 7-year upgrade-free survival was 39%. At diagnosis, 88% of tumors were in locations viable for FT (50% unifocal (Un) and 38% multifocal in contiguous sextants (Mc) versus 12% multifocal in non-contiguous sextants (Mn-c)). At fsBX, 21% of biopsies were negative and 85% of the remainder were viable for FT (29% Un and 56% Mc versus 15% Mn-c). Across all biopsies DT remained stable in 592 (47%), changed prostate side or expanded to bilateral in 128 (10%), upgraded on the original dominant side in 407 (32%), and upgraded on the opposite side in 145 (11%). Of those upgraded on the non-dominant side, 74% were GS 3+4, 21% were GS 4+3 and 5% were GS>=4+4.

Conclusion: Findings on serial biopsy in men with low risk disease on AS suggest that tumor location remains relatively stable and that significant changes in grade and/or volume occur in the dominant tumor focus. A low percentage of patients show significant progression outside the dominant tumor. Such information is relevant when considering FT in this patient population.
217. RADIOTHERAPY AFTER RADICAL PROSTATECTOMY: EFFECT OF TIMING OF POST-PROSTATECTOMY RADIATION ON FUNCTIONAL OUTCOMES

Heather Huelster¹, Aaron Laviana¹, Tatsuki Koyama¹, Zhiguo Zhao¹, Li-Ching Huang¹, Ralph Conwill¹, David Penson¹, Daniel Barocas¹, Karen Hoffman²

¹Vanderbilt University Medical Center, ²University of Texas MD Anderson Cancer Center

Presented By: Heather Huelster

Introduction: The effect of timing on post-prostatectomy radiotherapy on patient-reported sexual-, urinary-, and bowel-related functional outcomes is controversial. This study seeks to compare outcomes after radical prostatectomy (RP) and post-prostatectomy radiation and elucidate the timing of radiation to allow optimal recovery of function.

Methods: The Comparative Effectiveness Analysis of Surgery and Radiation (CEASAR) study is a prospective, population-based, observational study of men with localized prostate cancer enrolled from 2011 to 2012. Patient-reported sexual, urinary, and bowel functional outcomes were measured using the 26-item Expanded Prostate Index Composite (EPIC-26) at baseline and at 6, 12, 36, and 60 months after enrollment. Changes in functional outcome domain scores from baseline compared by timing of radiation after RP were evaluated using continuous and comparative multivariable and linear regression models.

Results: Among 1482 CEASAR participants initially treated with radical prostatectomy for clinically localized prostate cancer, 11.5% (N=170) were subsequently treated with adjuvant (N=57) or salvage (N=113) external beam radiotherapy. Compared to men treated with RP alone in an adjusted linear model, salvage radiation was associated with significantly worse domain scores for sexual function (-11.1, 95% CI 5.3-17.0, p=0.001), incontinence (-7.6, 95% CI 1.6-13.6, p=0.014), urinary irritation (-6.1, 95% CI 2.4-9.7, p=0.001), bowel irritation (-4.5, 95% CI 1.7-7.4, p=0.002), and hormonal function (-3.3, 95% CI 0.6-6.0, p=0.017). Adjuvant radiation was associated with worse incontinence (-11.9, 95% CI 3.1-20.7, p=0.008), urinary irritation (-5.9, 95% CI 0.6-11.2, p=0.030), and hormonal function (-7.3, 95% CI 1.0-13.6, p=0.023) domain scores compared to RP alone at 5 years of follow up.

Post-prostatectomy radiation has a significant effect on EPIC-26 sexual, urinary, and bowel function domain scores. On multivariable analysis, time from surgery to radiation was associated with a significant change in sexual domain score from post-RP baseline (-5.3, 95% CI -9.5 to 20.0, p=0.016) with this effect most mitigated for radiation administered 24 months after prostatectomy.

Conclusion: Post-prostatectomy radiation has a significant effect on EPIC-26 sexual, urinary, and bowel function domain scores.
218. ONE AND DONE? PSA DENSITY AS A PREDICTOR OF NUMBER OF CORES NEEDED TO DETECT CLINICALLY SIGNIFICANT PROSTATE CANCER

Amir Lebatsch1, Alex Wang2, Luke O’Connor2, Jonathan B. Bloom2, Michael Ahdoot2, Nitin Yerram2, Samuel A. Gold2, Kareem N. Rayn1, Sherif Mehralivand2, Joanna Shih2, Thomas Sanford2, Peter A. Pinto2, Graham R. Hale3, Bradford J. Wood4, Baris Turkbey5
1 National Institutes of Health, National Cancer Institute, Urologic Oncology Branch, 2 National Institutes of Health, National Cancer Institute, Urologic Oncology Branch, Bethesda, MD, 3 National Institutes of Health, National Cancer Institute, Bethesda, MD, 4 Center for Interventional Oncology, National Cancer Institute, Bethesda, MD, 5 Molecular Imaging Program, National Cancer Institute, Bethesda, MD

Presented By: Alex Wang

Introduction: MRI/US fusion guided prostate biopsy (FBx) has been shown to detect clinically significant prostate cancer (csCaP) at higher rates and with fewer cores than standard prostate biopsy. However, the number of targeted cores needed to characterize lesions identified on multiparametric MRI (mpMRI) is unknown. This study sought to determine factors that predict the number of cores needed to characterize lesions during FBx.

Methods: A retrospective analysis of a prospectively maintained database of all patients undergoing FBx at an academic referral center between May 2014 and January 2018 was conducted. At least two FBx cores were taken from each lesion identified on mpMRI. Patient and lesion specific factors were analyzed to determine factors that predict the necessity to obtain additional cores to detect csCaP. GEE-based univariate logistic regression model with exchangeable correlation was used to estimate the effects of clinical characteristics including race, BMI, PSA, PSA density (PSAD), lesion location, and PI-RADS score on the proportion of positive and negative agreement. Predictability of a significant continuous predictor was quantified by AUC. The most significant patient-level predictor (PSAD) was further analyzed to determine thresholds at which multiple cores per lesion are needed to avoid missing csCaP.

Results: An analysis of a total of 1135 FBx were performed during the study time interval. PSA (OR=1.57, 1.20-2.05, p<0.01) and PSAD (OR=1.43, 1.11-1.85, p<0.01) significantly predicted positive agreement of csCaP. AUC for positive and negative agreement was 57.4 and 61.0 for PSA and 56.4 and 72.3 for PSAD, respectively. PSAD density thresholds allowing for a 20% discordance rate and missing up to 2.4% of csCaP are displayed in Figure 1. Using these thresholds, 53% lesions from 56% patients could receive single core targeted biopsy.

Conclusion: These data indicate that in patients with a PSAD less than 0.11ng/ml2 or greater than 0.26ng/ml2, lesions may be acceptably characterized with a single targeted biopsy core.
219. CAN A SEXTANT BIOPSY TEMPLATE BE USED INSTEAD OF EXTENDED 12-CORE TEMPLATE IN CONJUNCTION WITH MR/US FUSION PROSTATE BIOPSIES?
Vinson Wang, Michael Smigelski, Gen Li, Christopher Haas, Joseph Caputo, Hiram Shaish, Sven Wenske, Luis Alberto Pina Martina
Columbia University Medical Center
Presented By: Luis Alberto Pina Martina

Introduction: Sextant prostate biopsies have previously been extended to 12-core template biopsies (TBx) to improve detection rates of prostate cancer (PCa). It is unclear if this holds true in the current era when 12-core TBx are being performed in conjunction with MRI/ultrasound fusion biopsies (FBx). The 2016 AUA consensus statement on FBx suggests the continued synchronous performance of a 12-core TBx due to the risk of missing clinically significant PCa (csPCa) in up to 23% of patients. We sought to determine if the number of TBx cores could be reduced in order to decrease patient discomfort (and possibly risk of infection and bleeding) without affecting detection rates in the setting of combined TBx/FBx.

Methods: A retrospective analysis was performed on patients undergoing first time combined 12-core TBx/FBx at Columbia University Medical Center by a single Urologist for elevated PSA or abnormal digital rectal exam from 2015-2018. The medial and lateral 6 cores of the 12-core TBx were separately censored to simulate biopsy results of a 6-core TBx. McNemar’s test was performed to assess if FBx plus 6-core biopsy had similar diagnostic ability as FBx plus 12-core biopsy.

Results: Overall, 395 patients were identified. Figure 1 shows the distribution of pathologic findings for three groups, panel a-c (FBx plus 12-core TBx, and the two sets of FBx plus 6-core TBx). Of 209 patients with benign findings or Gleason 3+3 disease on targeted FBx only, csPCa (defined as Gleason =3+4) was detected in 31 patients (15%) on 12-core TBx (panel a). When the medial vs. lateral 6 cores of the 12-core TBx were censored, clinically significant disease would have been missed in 11 (35%) vs. 8 (26%) of the 31 patients (panel b and c). McNemar’s test confirmed that omitting 6 of the 12 template biopsy cores resulted in a statistically significant decrease of csPCa detection rates (p=0.0026 and p=0.013 for medial and lateral templates, respectively).

Conclusion: A reduction in the number of template biopsy cores from 12 to 6 at the time of fusion biopsy would result in a decreased ability to detect csPCa. Therefore, continued performance of 12-core TBx is required even in conjunction with a commonly performed MRI/US FBx. However, a prospective randomized study would need to be performed to confirm these findings in a true sextant vs 12-core TBx/FBx setting.
Introduction: About one third of prostate cancer (PCa) patients who undergo radical prostatectomy (RP) are upgraded between biopsy and RP. Improved prediction of upgrading is needed to inform treatment decisions. We investigated whether body mass index (BMI) is associated with upgrading in a large, multi-center study.

Methods: We included 1,586 men with localized PCa who received RP as initial treatment within one year of biopsy in the Prostate Cancer Progression Study in the Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial. Using self-reported, pre-diagnostic BMI, we evaluated any upgrading compared to no change in Gleason score (GS), and separately analyzed upgrading in men with GS 6 at biopsy and GS 7 at biopsy. We used logistic regression to estimate odds ratios (OR) and 95% confidence intervals (95% CI) for BMI and upgrading, adjusting for age at diagnosis (continuous), race (white, non-white, missing), RP year (1994-2004 and 2005-2010) and smoking (never, former, current, missing). We ran separate models additionally adjusting for time from biopsy to RP to assess its potential role as a mediator of the association between BMI and upgrading. We also assessed interactions between BMI and age, race, RP year and smoking. We computed p-values for interaction using likelihood ratio tests comparing nested models with and without the interaction terms.

Results: Upgrading occurred in 27.2% of our study population. The median age of PCa diagnosis was 66 years for both men who were upgraded and those who were not, with an age range of 55-84 years. The majority of men in our sample were white (90.1%). About 60.8% of the men had a clinical T stage of T1, and 39.2% had T2 disease. Most of the men in our sample had a prostate-specific antigen (PSA) concentration <10 ng/mL at diagnosis (77.7%). There tended to be a longer time between biopsy and surgery for those who were upgraded (median=56 days) than those who were not (median=54 days; Wilcoxon p-value=0.08). Comparing obese to normal weight men, we observed borderline significantly increased odds of any upgrading (OR=1.24, 95% CI: 0.90-1.70) and upgrading from GS 6 to 7 or greater (OR=1.34, 95% CI=0.91-1.97), but no association for GS 7 to 8 or greater (OR=1.49, 95% CI=0.70-3.19). Additional adjustment for time from biopsy to RP did not appreciably alter the results (OR for any upgrading=1.24, 95% CI=0.90-1.70). We observed some evidence of differences in the association between obesity and upgrading by RP year, with a positive association for men who underwent RP in 1994-2004 (OR for any upgrading=1.41, 95% CI=0.97-2.04), but not for 2005-2010 (OR=0.82, 95% CI=0.44-1.55; p-interaction=0.05). There were no differences by age, race or smoking (p-interaction=0.63, 0.88 and 0.54, respectively).

Conclusion: Our results suggest a positive association between obesity and upgrading, which could not be explained by a delay in the time from biopsy to surgery and may in part reflect increased disease progression associated with obesity. These findings may help inform the patient-provider treatment decision making process.
221. FACTORS PREDICTING HIGHER BIOPSY YIELD WITH MRI-TARGETED VERSUS SYSTEMATIC PROSTATE BIOPSY: WHEN IS SOFTWARE FUSION MRI-TARGETING NECESSARY?

Grant Henning, Joel Vetter, Gerald Andriole, Eric Kim
Washington University School of Medicine

Presented By: Grant Henning

Introduction: Although the use of magnetic resonance imaging (MRI) for the detection of prostate cancer (PCa) is now widespread, the optimal approach for prostate biopsy following MRI remains unclear. For patients with a positive MRI, combining a systematic template biopsy with an MRI-targeted biopsy is currently considered standard of care. We analyzed clinical and imaging factors to predict when a biopsy strategy utilizing software fusion MRI-targeting is beneficial compared to systematic template biopsy alone.

Methods: We analyzed our PCa database from July 2015 to December 2017 and identified 373 men who had Prostate Imaging Reporting and Data System (PIRADS) classification 3 or greater and underwent a subsequent systematic template and software fusion MRI-targeted biopsy with the UroNav platform (Invivo, Cambridge, MA). For our analysis, we compared the Gleason score of biopsy cores obtained in systematic fashion to those obtained using MRI-targeting. Using multivariate analysis, we examined clinical and imaging factors that predict higher Gleason Grade Group (GGG) disease in cores obtained using MRI-targeting compared to those obtained using the systematic template.

Results: Overall, the detection rate of GGG2 or higher PCa was 30.3% (113/373) for systematic template biopsy compared to a detection rate of 35.4% (132/373) for software fusion MRI-targeted biopsy. 14.2% of men (53/373) were found to have higher GGG in targeted biopsy specimens than those obtained systematically. Factors that predicted targeted biopsy showing higher GGG disease than systematic biopsy included age = 70 compared to < 60 years (OR 3.79, p=0.02), anterior lesion location (OR 3.33, p=0.01), and multiple lesions on MRI (OR 2.70, p=0.01). Notably, factors which were not found to predict improved biopsy yield with the addition of MRI-targeting included prostate volume per cubic centimeter (cc) on MRI (OR 0.99, p=0.15), MRI lesion size per cc (OR 0.92, p=0.35), PIRADS classification 5 compared to 3 (OR 2.47, p=0.08), previous negative biopsy (OR 1.69, p=0.19), and transitional zone lesion location (OR 0.90, p=0.84).

Conclusion: A biopsy strategy utilizing software fusion MRI-targeting offers benefit for PCa risk stratification in older men, those with an anterior MRI lesion, and those with multiple lesions on MRI. For other patients, we should consider systematic template biopsy alone or with cognitive MRI-targeting. Our results may assist in the development of a personalized approach when deciding which biopsy strategy to employ for a given patient.

222. MRI FUSION BIOPSY CAN MISS APPROXIMATELY 2 IN 10 CLINICALLY SIGNIFICANT PROSTATE CANCERS

Brijesh Patel1, John Ogunkeye1, Eiftu Halie1, Pierce Massie1, Christopher Coogan1, Justin Cohen2, Paul Yonover2
1 Rush University Medical Center, 2 UroPartners

Presented By: Brijesh Patel

Introduction: Magnetic Resonance Imaging (MRI) fusion technology, wherein MRI imagery and live ultrasound (US) images are “fused” to allow targeting of identified abnormalities, is being increasingly used to improve the accuracy of needle biopsies of the prostate. Our understanding of the diagnostic yield of MRI-guided targeted biopsies (TB) versus a 12 core trans-rectal US systematic biopsy (SB) continues to evolve. With this in mind, we used our UroPartners Cancer of the Prostate (UROCaP) Registry to evaluate MRI fusion biopsy accuracy in a large practice setting.

Methods: Between January 2015 and July 2018, 2,134 patients with Prostate Imaging Reporting and Data System version 2 (PIRADS) 3, 4, or 5 lesions underwent SB immediately followed by TB using the UroNav System at a single center by multiple urologists in a large, community-and-academic integrated urology group. We analyzed data for PIRADS designation and Gleason grade grouping (GG) among patients with a positive SB and negative TB.

Results: Of the 2,134 patients, prostate cancer (CaP) was identified in 1054 (50.9%) overall. The concordance rates between SB and TB are listed in Table 1. Amongst the 1054 patients with prostate cancer, SB was positive while TB was negative in 247 (23.4%) whose MRIs showed a total of 352 lesions; 275 PIRADS 3 lesions, 67 PIRADS 4 lesions, and 10 PIRADS 5 lesions. 59 of 275 (21.4%) PIRADS 3 lesions were associated with clinically significant (Grade Groups 2-5) CaP detected on SB alone, 15 of 67 (22.4%) for PIRADS 4 lesions, and 3/10 (30%) for PIRADS 5 lesions. Notably, none of these CaP were detected on TB in this subset.

Conclusion: These findings demonstrate that MRI-fusion targeted biopsies can fail to detect CaP in at least 23.4% of patients who have PIRADS 3, 4 or 5 lesions identified on prostate MRI. While MRI fusion biopsy is an advanced technology which improves our ability to detect and monitor prostate cancer, it remains imperfect, and relying solely on targeted biopsies risks missing clinically significant prostate cancer. Our data emphasize the need to combine systematic and targeted biopsies. We believe that our findings represent the limitations in current MRI imagery, the PIRADS system, and the state of the art in fusion technology.
223. IMPACT OF AGE AT DIAGNOSIS ON CAUSE OF DEATH IN PATIENTS WITH PROSTATE CANCER
Ankur Choksi, Alexander Henry, Shu Wang, Michael Naslund, Mohummad Minhaj Siddiqui
University of Maryland School of Medicine
Presented By: Ankur Choksi

Introduction: It is presumed that older patients are more likely to die from other causes of death than the cancer itself and hence the age at which a patient is diagnosed with cancer is a key determinant in the treatment modalities offered to a patient. The relationship between age at diagnosis and cause of death has not been well described for genitourinary cancers. The objective of this study is to examine the variation in causes of death with respect to age at diagnosis for patients diagnosed with non-metastatic prostate cancer.

Methods: We retrospectively analyzed the records of patients diagnosed with localized (N0M0) prostate cancer (ICD-O-3 8140) between the ages of 45 and 74 in the US Surveillance, Epidemiology and End Results Program (SEER) from 1975 to 2015. Patients with multiple primary tumors and unknown details regarding cause of death were excluded. Univariate and multivariate Cox proportional hazards regression was performed to investigate mortality and cause of death. Kaplan – Meier survival estimates were obtained for prostate cancer – specific and all cause of death at 10 and 15 years from diagnosis to calculate attributable cause of death to prostate cancer by age at diagnosis.

Results: We identified 687,795 patients diagnosed with localized prostate adenocarcinoma between 1975 and 2015. Treating age as a continuous variable, prostate cancer-specific hazards ratio is 1.058 (95% CI: 1.056 – 1.061, p < 0.001) and all-cause hazards ratio is 1.092 (95% CI: 1.090 – 1.093, p < 0.001) at 10 years after diagnosis while prostate cancer-specific hazards ratio is 1.057 (95% CI: 1.055 – 1.060, p < 0.001) and all-cause hazards ratio is 1.097 (95% CI: 1.095 – 1.098, p < 0.001) at 15 years after diagnosis. On multivariate analysis, patients diagnosed between the ages of 70 – 74 had a prostate cancer-specific hazards ratio of 3.78 (95% CI: 3.32 – 4.31, p < 0.001) with an all-cause hazards ratio of 7.09 (95% CI: 6.57 – 7.64, p < 0.001) 10 years after diagnosis when compared to patients diagnosed between the ages of 45 – 49 after controlling for race and marital status. At 15 years after prostate cancer diagnosis, patients diagnosed between the ages of 70 – 74 had a prostate cancer-specific hazards ratio of 3.46 (95% CI: 3.04 – 3.93, p < 0.001) with an all-cause hazards ratio of 7.09 (95% CI: 5.88 – 8.60, p < 0.001) when compared to patients diagnosed between the ages of 45 – 49.Kaplan Meier Survival Estimates showing prostate cancer-specific vs other causes of death at 10 years (top) and 15 years (bottom) from diagnosisAttributable cause of death to prostate cancer at 10 years (top) and 15 years(bottom) from diagnosis

Conclusion: Patients diagnosed with prostate cancer at a younger age are more likely to die from prostate cancer than other causes of death when compared to patients diagnosed at an older age.
224. INTERSECTION OF CONFIRM MDX HYPERMETHYLATION AND MULTIPARAMETRIC MRI IN MEN WITH PRIOR NEGATIVE PROSTATE BIOPSY

Daniel Artenstein1, Rex Parker2, Aaron Krug2, David Finley2, Margo Sidell3
1 Kaiser Permanente Los Angeles Medical Center, 2 Kaiser Permanente Los Angeles, 3 Kaiser Permanente Dept. of Biostatistics

Presented By: Daniel Artenstein

Introduction: Confirm MDx (MDx) is an epigenetic tissue test that analyzes benign prostate cores for tumor associated DNA promoter hypermethylation to geographically localize occult tumor. Multiparametric MRI (MRI) is useful for the detection of large or high-grade tumors. The purpose of our study was to evaluate the intersection of MRI and MDx in patients with a negative prostate biopsy.

Methods: After IRB approval, patients referred on January 2017-December 2017 with elevated PSA and negative prostate biopsy prospectively underwent MDx and 1.5T MRI. MRI was centrally re-reviewed and PIRADS V2 score was assigned. Geographical concordance was defined as MDx and MRI abnormality in the same or neighboring sextant of the prostate.

Results: A total of 202 patients were assessed. 111 patients (55%) had a positive MDx and 91 (47%) had a negative MDx. Of the patients with a positive MDx, 59 (53%) had a positive MRI. In this cohort, patients with PIRADS 3 lesions had a 65% geographical concordance with MDx. Of patients with PIRADS 4 and 5 lesions with + MDx, 89% were geographically concordant. All geographically discordant PIRADS 4 or 5 lesions in the + MDx group were in the anterior prostate. Biopsy results in patients with + MDx and PIRADS 3 lesions were found to have atypia (HGPIN or ASAP) in 56% and prostate cancer in 35.3% of cases. Patients with PIRADS 4 or 5 lesions had atypia in 22.7% and cancer in 63% when geographically concordant and 40.0% and 60.0% when lesion was discordant. Of the 91 patients with - MRI, 16 (17%) had a PIRADS 4 or 5 lesions. The lesion was in the anterior prostate in 80% of these patients. Predictors of PIRADS 4-5 lesions on MRI in patients with negative MDx are increased PSA and large prostate volume (all p values <0.05).

Conclusion: Routine anterior sampling during systematic biopsy should be done to enhance the detection ability of MDx. In patients with negative MDx, an MRI should be considered if PSA>10, PSAD >0.15 and/or the gland is large. Atypia may explain MDx false positives.
225. IDENTIFYING THE OPTIMUM DIAGNOSTIC PATHWAY IN MEN WITH SUSPECTED PROSTATE CANCER IN A US-BASED HEALTHCARE SYSTEM: A COST-EFFECTIVENESS ANALYSIS
Thomas Stonier1, Andrew Briggs2, Andrew Vickers3, Sigrid V. Carlsson4, James Eastham5
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Presented By: Sigrid Carlsson

Introduction: In the past, almost all men with an elevated prostate-specific antigen (PSA) level would be recommended a transrectal ultrasound-guided biopsy (TRUS-Bx). The introduction of pre-biopsy multiparametric (mp)MRI and biomarkers as reflex tests to PSA has been shown to increase the detection of clinically significant cancer and reduce overdiagnosis. We sought to compare the cost-effectiveness of alternative pathways for prostate cancer detection in a US-based healthcare system.

Methods: We set as the base case scenario a middle-age man with an elevated PSA (3-10 ng/mL) to construct a clinical decision tree and compare 5 different diagnostic pathways: (1) standard TRUS-Bx for all (reference), (2) mpMRI followed by systematic/targeted biopsy if positive mpMRI (PI-RADS score 3-5), (3) Biomarker (here: exemplified by 4Kscore) followed by standard TRUS-Bx if positive test (=7.5% risk score), and two combined strategies with either; (4) mpMRI first or (5) biomarker first. The mean cost (USD) per patient and clinically significant cancer (csPCa) detected was calculated for a hypothetical cohort of 1,000 men, with an underlying prevalence of clinically significant prostate cancer (csPCa; Gleason grade group >2) of 30%. The following assumptions (sensitivity/specificity/cost) were made based on up-to-date evidence and Medicare data: mpMRI (0.9/0.37/$964); 4Kscore biomarker (0.9/0.45/$500); TRUS-Bx (0.63/0.9/$3000); systematic/target biopsy (0.85/0.9/$3000). Analyses were conducted using TreeAge Pro 2019, R2. TreeAge Software, Williamstown, MA; software available at http://www.treeage.com.

Results: For every 1,000 men, all strategies were superior to standard TRUS-Bx (189 csPCa detected) as they yielded more csPCa detected with fewer biopsies, except a Biomarker only strategy (170 csPCa detected), as shown in Table 1. A mixed pathway with mpMRI as the initial reflex test and a biomarker performed in negative cases yielded the highest detection of csPCa (247 csPCa) however also at the highest cost $4,188 and with the most biopsies (880) (other than the reference test of standard TRUS-Bx for all), as shown in Figure 1. An mpMRI only strategy was comparable in cost and pick-up rate to a ‘mixed biomarker-first’ pathway (in which a biomarker was used as the initial screening test, with positive cases receiving an mpMRI to allow targeting of the biopsy if possible, while negative biomarker cases were put on surveillance). The ‘mpMRI-only’ strategy detected 216 cases at a cost of $3,493, while a ‘mixed biomarker-first’ detected 194 cases at a cost of $3,289. However, the biomarker-first strategy required 59 fewer biopsies (714 mpMRI vs 655 mixed strategy with biomarker first).

Conclusion: Our analysis suggests that a diagnostic pathway in which patients with an elevated PSA have a reflex biomarker test, and if test-positive, undergo an mpMRI, to allow biopsies to be targeted if possible, yields more csPCa detected, with fewer biopsies and at a lower cost than a standard TRUS-Bx pathway. This pathway would allow the initial screening test with both PSA and the reflex blood biomarker to be performed in primary care, yielding further cost savings. Strategies involving an mpMRI as the first screening test yielded marginally more csPCa cancer detection, but at greater cost and with more biopsies performed.

Table 1. Costs and cancer detection rate by strategy

<table>
<thead>
<tr>
<th>Strategy (1,000 men with elevated PSA – prevalence 0.3)</th>
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<tbody>
<tr>
<td>(1) Standard (TRUS-Bx)</td>
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<tr>
<td>------------------------</td>
</tr>
<tr>
<td>Cost</td>
</tr>
<tr>
<td>N Biopsies</td>
</tr>
<tr>
<td>TP (csPCa correctly identified)</td>
</tr>
<tr>
<td>FN (csPCa missed)</td>
</tr>
<tr>
<td>TN (No cancer/ insignificant cancer found)</td>
</tr>
<tr>
<td>FP (Insignificant cancer or no cancer wrongly identified)</td>
</tr>
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*TP= True Positives, FN=False Negatives, TN=True Negatives; TP=False Positives*
226. PRIMARY CARE PHYSICIANS’ PERCEPTIONS OF AN ELECTRONIC MEDICAL RECORD-EMBEDDED DECISION SUPPORT TOOL FOR PROSTATE CANCER SCREENING: A FOCUS GROUP STUDY
Sigrid Carlsson¹, Tiffany Le¹, Andrew Vickers¹, Behfar Eshdaie¹, Junaid Nabi², Mark Preston², Michael Healey², Adam Kibel², Deepak Malhotra³
¹ Memorial Sloan Kettering Cancer Center, ² Brigham and Women’s Hospital, Harvard Medical School, ³ Harvard Business School
Presented By: Sigrid Carlsson

Introduction: When used properly, prostate-specific antigen (PSA) screening can reduce prostate cancer mortality. However, screening remains relatively underused in younger, healthy men, and overused in the older less healthy population. We hypothesized that the widespread failure to follow well-accepted PSA-screening guidelines is because the recommended algorithms are relatively complex and primary care physicians (PCPs) lack tools to efficiently employ shared decision-making procedures in their busy practices. As a part of a larger project to develop and implement a digital clinical decision-support tool for PSA-screening for PCPs, we conducted a focus group to assess PCPs’ attitudes toward PSA-screening algorithms, perceptions of using decision support tools, and assessing the feasibility of implementing such a tool in clinic.

Methods: We assembled a multidisciplinary research team comprising experts in: primary care and urology, behavioral sciences, and bioinformatics and developed a version 1 of the decision support tool. The algorithm followed the National Comprehensive Cancer Network (NCCN) guidelines and narratives were developed using principles from behavioral economics, prompting PCPs to follow guideline-recommended directions. A provider-facing tool for shared decision making was also incorporated into the tool. The decision support tool was presented to a focus group of 10 PCPs from Brigham and Women’s Hospital (BWH) Primary Care, Boston. The focus group followed standard procedures. Open-ended questions were asked, and a survey was distributed to obtain qualitative and quantitative feedback. Notes were taken during the focus group, which was also audio-recorded, and transcribed verbatim through an independent service. Transcriptions were coded by two independent researchers, one of which was not involved in the conception and design of the study. Notes and transcripts were analyzed inductively to develop codes and themes using thematic content analysis.

Results: The sample was representative of the demographic distribution of physicians in terms of age, gender, ethnicity, and years in practice. Three major themes arose from the data: (1) Confirmatory reactions regarding the importance, innovation, and unmet need for a decision support tool embedded in the EHR (“That is the power of computers actually”, “Having this guideline makes me feel more comfortable with ordering the initial PSA”); (2) Issues around implementation and application of tool in clinic workflow (“How many minutes do you have on average for your visits? Negative five”) and physicians own clinical bias coloring conversations (“My grandfather and father had prostate cancer, they both had really awful side-effects from treatment…and I try to get rid of that bias.”); (3) Attitudes/reflections regarding discrepant recommendations from various guideline groups that cause confusion (“The guidelines all over the place”). Physicians appreciated that the tool would allow documentation that shared decision making has taken place. An important feature of the tool was to allow for flexibility and leeway for clinical judgment (“The clinician’s judgment should be able to override or ignore whatever the tool tells”). Most clinicians agreed with the guideline-recommended ages to start and stop screening but described that family history and African-American race push clinicians toward starting screening earlier. There was a 50:50 split between whether or not clinicians also included digital rectal examination as a primary screening test in conjunction with the PSA-test.

Conclusion: There was overwhelmingly positive support for the need of a provider-facing decision support tool to assist with PSA screening decisions in primary care. Incorporation of the suggestions from the PCPs from this focus group into a version 2 of the decision support tool will be used in subsequent pilot testing in clinic.

Funding: Prevent Cancer Foundation, NIH/NCI P30-CA008748, David Koch research fund
228. GENOMIC HETEROGENEITY IN TISSUE-BASED PROGNOSTIC SIGNATURES FROM PROSTATE BIOPSIES; RESULTS FROM TWO PROSPECTIVE TRIALS
Venkatasai Atluri1, Nachiketh Soodana-Prakash1, Chad Ritch1, Bruno Nahar1, Mark Gonzalgo1, Bruce Kava1, Dipen Parekh1, Sanoj Punnen1, Radka Stoyanova2, Alan Pollack2
1 Department of Urology, University of Miami, 2 Department of Radiation Oncology, University of Miami
Presented By: Venkatasai Atluri

Introduction: Tissue based prognostic signatures have been used in various stages of prostate cancer, including biopsy tissue from men who are deciding between active surveillance versus treatment. Recent studies have suggested that these tests may be affected by tumor heterogeneity impacting their performance for appropriate risk stratification. We evaluated the performance of tissue based prognostic signatures on biopsy tissue from two ongoing prospective trials in men with prostate cancer at the University of Miami.

Methods: The Miami Active Surveillance Trial (MAST) enrolls low–intermediate risk men who undergo an MRI and annual biopsy for three years, with positive cancers cores sent for genomic sequencing. The BlastEM trial includes intermediate-high-risk men who undergo targeted biopsy at the time of fiducial marker placement to assess for dose escalation during radiotherapy, in which both diagnostic and targeted biopsies are sent for genomic sequencing. This study reports on preliminary results from both trials on men whose biopsy cores were sequenced at GenomeDx, and evaluated for three commercially available gene signatures (Genome Dx Decipher Genomic Classifier, Oncotype DX Genomic Prostate Score, and Myriad Prolaris Cell Cycle Progression score). The biopsy cores from both trials represent either the diagnostic biopsy or a subsequent biopsy done within 12 months of diagnosis.

Results: The current cohort consists of 78 men from the MAST (n=46) and BlastEM (n=32) trials whose 231 biopsy cores were sent to GenomeDx for genomic sequencing. Among the 78 patients, 40 had Grade Group 1, 15 had grade Group 2, 10 had Grade Group 3 and 13 had Grade group 4 and 5 prostate cancer. We found that for each signature there was a trend toward higher scores with higher grade groups, however each signature displayed a significant degree of variation within each grade group (p<0.001). (Figure 1). When assessing genomic scores from different cores we found significant variability (Figure 2), with the level of genomic risk within each biopsy session changing by 25-62% depending on which core was sequenced and which signature was used. When restricting to MAST, which includes active surveillance patients whose biopsy tissue these tests are currently being used, we found that level of genomic risk changed in 10-57% of cases depending on which core was sequenced and which signature was used.

Conclusion: We assessed the performance of three commercially available genomic prognostic markers in men enrolled on two ongoing prospective trials whose biopsy tissue was sequenced at GenomeDx and found a significant degree of genomic heterogeneity between biopsy cores. This may have implications when considering the reliability of these signatures in biopsy tissue.
229. METABOLOMIC PROFILING OF PROSTATE CANCER UPGRADING DURING ACTIVE SURVEILLANCE

Bruce Trock¹, Mufaddal Mamawala¹, Sacha Wolfe¹, Patricia Landis¹, H. Ballentine Carter¹, Edward Karoly²
¹ Johns Hopkins School of Medicine, Department of Urology, ² Metabolon, Inc.

Presented By: Bruce Trock

Introduction: Active surveillance (AS) is the preferred management option for men with very low risk and low risk prostate cancer. Although biopsy pathology correctly identifies appropriate candidates for AS, approximately 25-40% of men eligible for AS are undergraded at biopsy. The objective of this study is to determine if metabolomic profiling of serum from men in AS can augment clinical variables to identify men likely to be upgraded to Gleason grade group 2 (GG2) or higher during surveillance.

Methods: Baseline serum samples were collected from 100 men in the Johns Hopkins AS program without biopsy upgrading for at least 5 years, and 100 who experienced biopsy upgrading within 3 years. Samples were analyzed by Metabolon Inc. using a Waters ACQUITY ultra-performance liquid chromatography (UPLC) and Thermo Scientific Q-Exactive high resolution/accurate mass spectrometer. Median scaled, log-transformed metabolite levels were filtered by Wilcoxon test at p<0.01, and fold-increase or decrease >75th percentile, and a model was developed using regularized logistic regression with elastic net penalty to control for overfitting.

Results: Median age was 66, median PSA density was 0.10, and median number of positive biopsy cores was 1. There were 850 metabolites identified in all serum samples, but 256 were significantly correlated with sample storage time and were excluded from analysis, leaving an analysis set of 594 metabolites. Only 6 metabolites passed both dimension reduction filters, and all 6 remained significant in regularized logistic regression. When these 6 metabolites were added to a model containing age, maximum percent of tumor in biopsy, number of positive cores, and ln(PSA density) only 2 remained significant – see TABLE. Adding these 2 metabolites to a logistic regression model of clinical variables increased the AUC from 0.809 to 0.835.

Conclusion: This is the first study to evaluate metabolomic profiling to classify risk of upgrading in AS. Metabolomic analysis of serum from AS patients identified 2 metabolites that were independently associated with upgrading to GG>2 even after adjusted for established strong prognostic factors. Consideration of potential pathways involving these 2 metabolites could suggest new hypotheses. For example, lower levels of gamma-glutamyl amino acids in upgraded patients could result if more aggressive tumors utilized more glutathione to maintain redox balance.

Funding: Department of Defense

<table>
<thead>
<tr>
<th>Variable</th>
<th>Odds ratio (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, per year</td>
<td>1.16 (1.06, 1.26)</td>
<td>0.0008</td>
</tr>
<tr>
<td>Maximum % of biopsy involved with tumor</td>
<td>1.04 (1.003, 1.07)</td>
<td>0.030</td>
</tr>
<tr>
<td>Number of positive biopsies</td>
<td>2.68 (1.46, 4.94)</td>
<td>0.0015</td>
</tr>
<tr>
<td>Ln(PSA density)</td>
<td>2.35 (1.17, 4.70)</td>
<td>0.016</td>
</tr>
<tr>
<td>Gamma-glutamyl epsilon-lysine</td>
<td>0.31 (0.12, 0.73)</td>
<td>0.010</td>
</tr>
<tr>
<td>N-oleoyltaurine</td>
<td>1.95 (1.16, 3.28)</td>
<td>0.012</td>
</tr>
</tbody>
</table>
230. WIDESPREAD USE OF MULTIPARAMETRIC MRI IN AN ACTIVE SURVEILLANCE COHORT RESULTS IN EARLIER IDENTIFICATION AND TREATMENT OF CLINICALLY SIGNIFICANT PROSTATE CANCER

Alice Yu, Eduouard Nicaise, Andrew Gusev, Timothy Baloda, Amirkasra Mojtahed, Mukesh Harisinghani, Douglas Dahl, Matthew Wszolek, Anthony Zietman, Adam Feldman
Massachusetts General Hospital

Presented By: Alice Yu

Introduction: Multiparametric MRI (mpMRI) has led to improved detection of clinically significant prostate cancer and is now increasingly used in active surveillance (AS) patients. However, most AS cohorts in the literature were described prior to widespread use of mpMRI. Our study compares AS outcomes in the MRI and pre-MRI era at our institution.

Methods: We used an institutional database of 1291 men enrolled in AS between September 1996 and December 2016. The cohort was divided into pre- and post-MRI era with the cut-off in July 2014, when mpMRI-US fusion biopsy was routinely incorporated into our AS protocol. Treatment-free survival was compared using the log-rank test and multivariable Cox regression.

Results: In total, 276 were from the MRI era and 1015 were from the pre-MRI era. Freedom from treatment at 2 and 5 years were 82% vs 90% and 63% vs 77% in the MRI and pre-MRI eras respectively. Men in the MRI era were more likely to undergo treatment even after controlling for baseline characteristics (P=0.003). Median time between diagnosis and treatment was 2.5 years (interquartile range, IQR 1.7-3.4) in the MRI era versus 5.9 years (IQR 2.8-8.9) in the pre-MRI era.

Conclusion: In the MRI-era, men on active surveillance experienced earlier disease reclassification. However, further follow up will be needed to see if this earlier identification and treatment of clinically significant disease ultimately results in a plateau in long-term treatment free survival.
231. RISK FACTORS WHICH PREDICT BIOPSY_UPGRADING OVER TIME IN ACTIVE SURVEILLANCE FOR PROSTATE CANCER
Peter Lonergan, Samuel Washington, Shoujun Zhao, Janet Cowan, Hao Nguyen, Katsuto Shinoara, Matthew Cooperberg, Peter Carroll
University of California, San Francisco
Presented By: Peter Lonergan

Introduction: Active surveillance (AS) is generally recognised as the preferred treatment option for men with low risk prostate cancer (PCa). No validated clinical tools currently exist to standardize the frequency of an individual patient’s biopsies and laboratory assessments and clinicians often tailor surveillance intensity based on tumor characteristics and patient factors such as age and comorbidities. Multi-parametric MRI (mp-MRI) and genomic testing have been proposed to aid in tailoring surveillance intensity for individual patients on AS, however this remains to be determined. We aimed to determine predictors of biopsy upgrading at specific time points in a contemporary cohort of patients on AS to understand which patients could be safely monitored with a less intensive surveillance strategy.

Methods: Men with clinically low risk PCa prospectively enrolled on AS at UCSF between 2000-2016 and who had at least one surveillance biopsy were included. mp-MRI was performed on a 3T magnet and imaging read by dedicated uroradiologists. The genomic tests used in this cohort were the Oncotype DX® Genomic Prostate Score®, Decipher® and Prolaris®. Men with a genomic score greater than the mean plus 1 standard deviation of the cohort were classified as “high” genomic risk and a score less than or equal to the mean plus 1 standard deviation were classified as “low” genomic risk. Biopsy upgrading was defined as an increase to ISUP grade group 2 or higher on subsequent biopsy. Multivariable Cox proportional hazards regression models were utilized to identify factors associated with risk of upgrade on follow-up at first surveillance biopsy and at 3, 5 and 10 years. Models were adjusted for characteristics at diagnosis (age, race, history of prior negative biopsy (yes/no), Gleason score (3+4 vs 3+3), percentage of biopsy cores positive, PSA density based on ultrasound measurements, MRI PI-RADS score (4-5 vs 1-3) and PSA kinetics. PSA kinetics was calculated using a linear mixed-effects model for log of PSA, adjusted for clinical characteristics.

Results: In total 1,303 patients were included with a median age of 62 years (IQR 57-67). Median PSA density was 0.13 ng/ml2 (IQR 0.09 - 0.18). 1,169 (90%) men were ISUP grade group 1. The median percentage of positive biopsy cores was 13 (IQR 8-21). 257 (62%) had a PI-RADS 4-5 lesion on mp-MRI. 70 (13%) of men stratified as “high” risk” on genomic testing. Upgrade-free survival at 3, 5 and 10 years were 73%, 53% and 27% respectively. The median follow-up for the cohort was 2.2 years (IQR 1.1 -4.2). The median time between the diagnostic biopsy and the first surveillance biopsy was 13 months (IQR 9-16) with the risk of upgrade at first surveillance biopsy associated with PSA density (hazard ratio [HR] 2.761, 95% confidence interval [CI] 1.895 -4.023), and “high” risk genomic score (HR 1.867, 95% CI 1.025 -3.401) on multivariable analysis after adjustments. Independent variables significantly associated with risk of upgrade at first surveillance biopsy and at 3, 5 and 10 years on multivariable analysis after adjustments are shown in Table 1.

Conclusion: Our findings suggest that genomic scores and PSA density are risk factors for biopsy upgrading within 3 years of commencing AS, however, PSA kinetics is associated with longer-term risk of upgrade at 5 and 10 years. When used in tandem, genomic scores may identify a subset of men eligible for AS who could potentially adopt a less intensive surveillance regimen.

Table 1. Independent variables significantly associated with risk of upgrade at follow-up biopsy

<table>
<thead>
<tr>
<th>Independent variables</th>
<th>Upgrade at first surveillance biopsy HR (95% CI)</th>
<th>Upgrade at 3 Years HR (95% CI)</th>
<th>Upgrade at 5 Years HR (95% CI)</th>
<th>Upgrade at 10 Years HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>% biopsy cores positive</td>
<td>1.18 (1.04-1.36)</td>
<td>1.13 (1.02-1.26)</td>
<td>1.17 (1.01-1.35)</td>
<td>NS</td>
</tr>
<tr>
<td>PSA density [log]</td>
<td>2.75 (1.90-4.02)</td>
<td>2.03 (1.46-2.82)</td>
<td>2.29 (1.48-3.53)</td>
<td>NS</td>
</tr>
<tr>
<td>Gleason 3+4 vs 3+3</td>
<td>0.45 (0.24-0.87)</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>“High” risk genomic score</td>
<td>1.87 (1.03-3.40)</td>
<td>2.10 (1.22-3.61)</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>PSA kinetics</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
<td>1.40 (1.15-1.70)</td>
</tr>
</tbody>
</table>

PSA prostate specific antigen, HR hazard ratio, CI confidence interval, NS not significant.
232. DOES TIME SPENT ON ACTIVE SURVEILLANCE ADVERSELY AFFECT THE PATHOLOGIC AND ONCOLOGIC OUTCOMES IN PATIENTS UNDERGOING DELAYED RADICAL PROSTATECTOMY?

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Presented By: Ardalan Ahmad

Introduction: Pathologic and oncologic outcomes of men undergoing radical prostatectomy (RP) for grade reclassification/progression following active surveillance (AS) for favorable-risk prostate cancer (PCa) are not well established. To assess pathologic and oncologic outcomes of favorable risk PCAs managed with AS and progressing to RP for clinically significant (CS) PCa (Grade Group (GG) = 2).

Methods: Prospectively maintained AS database at Princess Margaret Cancer Centre was queried for patients progressing to RP for CS PCa between 1992-2015 (ASRP) (n=170). We compared pathologic and oncologic outcomes of the ASRP cohort with those of a matched cohort of men treated with upfront RP (n=405). BCR free survival was compared using the Log-rank test and Cox proportional hazards model.

Results: The median time spent on AS before RP was 31.0 months (Interquartile range (IQR) 30.0-44.0). At RP, the rate of pT3 (extraprostatic extension, seminal vesicle invasion), positive surgical margin and pN1 were comparable. Median follow-up after RP was 5.6 years. BCR occurred in 26 (15%) and 77 (19%) of ASRP and matched-controls, respectively (p=0.28). Five-year BCR-free survival rate, overall and cancer-specific survival in ASRP cohort were 85.8%, 98.1% and 100% compared with 82.4%, 99.7% and 99.7% in upfront RP cohort (p> 0.05). On Cox regression analysis, delayed RP was not associated with BCR-free survival. Limitations are non-randomized, retrospective and single-center study design.

Conclusion: Curative-intent RP after a period of AS results in excellent pathologic and oncologic outcomes at 5 years. A period of AS does not result in inferior oncologic outcomes compared to patients with similar risk characteristics undergoing upfront RP.

Figure 1. Kaplan-Meier curves for biochemical recurrence (BCR) free survival rate in ASRP and upfront RP cohorts (controls).
233. PREOPERATIVE PROSTATE MAGNETIC RESONANCE IMAGING IMPROVES SURGICAL OUTCOME FOLLOWING RADICAL PROSTATECTOMY
Amir Lebastchi, Samuel Gold, Michael Ahdoth, Sherif Mehralivand, Jonathan Bloom, Sandeep Gurram, Patrick Gomella, Joannah Shih, Peter Pinto, Minhaj Siddiqui, Baris Turkbey

Presented By: Amir Lebastchi

Introduction: Prostate multiparametric magnetic resonance imaging can precisely depict prostate cancer location and adverse pathologic features. The ability of mpMRI to improve radical prostatectomy outcomes has not been established. The objective of this study was to see if a pre-operative mpMRI can facilitate preservation of the neurovascular bundles while reducing the risk of positive surgical margins during radical prostatectomy.

Methods: This prospective consecutive cohort study in 532 men with localized prostate cancer was conducted at the U.S. National Cancer Institute from 2007 to 2017. All patients had an mpMRI evaluated by a dedicated genitourinary radiologist and imaging margin risk factors for adverse pathology were communicated to the surgeon preoperatively. Patients underwent prostate MRI to identify margin risk factors, defined as frank extraprostatic extension, possible frank extraprostatic extension and prostate capsule irregularity. A robot-assisted radical prostatectomy was then performed with or without surgical modifications based on the imaging findings. We aimed to explore if a surgical adjustment based on preoperative mpMRI findings can result in reduction of PSMs while simultaneously increasing the opportunity for preservation of neurovascular tissue.

Results: Preoperative mpMRI identified 1041 prostate lesions in 532 patients who underwent robot-assisted laparoscopic radical prostatectomy. Imaging margin risk factors for extraprostatic extension and risk for positive surgical margin (PSM) were seen in 54.3% (289/532 patients) of patients. Nineteen percent (55/289) of men with versus 8.6% (21/243) of men without margin risk factors (p=0.0007) had PSMs on final pathology. Adjustment of surgical technique from bilateral full nerve-sparing to MRI-guided wider resection decreased the rate of PSM in the cohort with margin risk factors on imaging from 29.3% PSM (27/92) with full nerve-sparing to 14.2% PSM (28/197) with wider resection (p=0.004). By contrast, adjustment of surgical approach in the absence of margin risk factors on imaging had no impact on the PSM rate within that group (p=0.897). MRI-guided surgical adjustments based on preoperative imaging decreased the risk for PSM by 74.7% in patients with pT2 and 54.3% in patients with = pT3 disease on final pathology, respectively. On multivariable analysis controlling for PSA and surgical adjustments, margin risk factors on preoperative imaging remained significantly associated with PSM (OR 2.83 (95% CI 1.51-5.3); p = 0.001).

Conclusion: Preoperative mpMRI of the prostate effectively identifies men at high risk for PSM and may guide selection of men most likely to benefit from wider resection of the prostate to decrease PSM rates.
**234. HIGHER PREVALENCE OF BENIGN TUMORS IN MEN WITH TESTICULAR TUMORS AND HISTORY OF UNTREATED CRYPTORCHIDISM**

Rachel Davis, Mahir Maruf, Joseph Cheaib, Phillip Pierorazio, Heather Di Carlo  
Johns Hopkins University School of Medicine

**Presented By:** Joseph Cheaib

**Introduction:** Cryptorchidism or undescended testis (UDT) is a known risk factor for testicular cancer, increasing the risk for testicular cancer almost 6-fold if untreated and almost 2-3-fold if surgically corrected before puberty. Historically, it has been shown that patients with testicular cancer with a history of UDT have a greater rate of seminoma than patients with descended testes. However, in these studies, patients with a benign tumor on pathology were excluded from analysis. At this time, there are few contemporary studies that examine the effect of orchidopexy on testicular tumor pathology, inclusive of patients who have a benign testicular tumor. This study aimed to identify if surgically treated cryptorchidism correlated with testicular tumor pathology at presentation and overall survival.

**Methods:** An institutional database of patients treated for testicular cancer was reviewed from 2003 until 2018. Inclusion criteria included testis tumor patients who had undergone an orchiectomy. Exclusion criteria included unknown cryptorchidism history, unknown pathology, or laterality of orchiectomy. Data collection included demographics, surgical history, tumor marker status, testicular cancer staging, and survival. Chi-Square and Fisher Exact tests were used to evaluate the association between history of UDT and categorical variables, and the t-test was performed to compare differences in continuous variables. The Kaplan-Meier method and the log-rank test were used to assess and compare overall survival in those with and without a history of UDT.

**Results:** A total of 435 patients who met inclusion criteria were identified; 33 (7.6%) of these patients had a history of UDT. There was no statistical difference in age at orchiectomy, laterality of orchiectomy, or lymphovascular invasion in regards to UDT history. There was a statistical difference in the pathology of testis after orchiectomy, \( p = 0.03 \) (Table 1). On further analysis using a 2-sample test of proportions, there was a statistically significant difference in the rate of benign pathology in patients with a history of UDT (15.2%) compared to those without a history of UDT (4.7%), \( p = 0.01 \). There was also a statistically significant difference in the proportion of patients with mixed GCT in patients with a history of UDT (18.2%) compared those without a history of UDT (37.3%), \( p = 0.03 \). There were no statistically significant differences in other pathology (Figure 1). There was no difference in overall survival in patients with or without a history of an UDT.

**Conclusion:** Previous studies have shown that there is a greater rate of seminoma in patients with testicular cancer in an undescended testis. This study shows that in patients with a history of UDT compared to those without a history of UDT, there is a greater percentage of patients with benign testicular tumors after orchiectomy. It may be beneficial to consider screening these patients frequently with ultrasound or performing testis sparing surgery rather than proceeding immediately to radical orchiectomy.
235. PRIMARY ROBOTIC-ASSISTED RETROPERITONEAL LYMPH NODE DISSECTION FOR NON-SEMINOMATOUS GERM CELL TUMOR: EXPERIENCE FROM A MULTI-INSTITUTIONAL SERIES

Jacob Taylor1, Ezzequiél Becher2, James Wysock3, William C. Huang4, Andrew T. Lenis5, Mark S. Litwin6, Jacob Jipp7, Peter Langenstroer5, Marc A. Bjurlin5, Hung-Jui Tan5

1 New York University Langone Health, 2 Department of Urology, New York University Langone Health, 3 Institute of Urologic Oncology, Department of Urology, University of California Los Angeles, 4 Department of Urology, Medical College of Wisconsin, 5 Department of Urology, University of North Carolina Chapel Hill

Presented By: Jacob Taylor

Introduction: Primary robotic-assisted retroperitoneal lymph node dissection (RA-RPLND) is an alternative to open RPLND for stage I, IIA, and carefully selected IIB patients at high risk for metastatic non-seminomatous germ cell tumor (NSGCT). While a minimally-invasive robotic approach to RPLND provides faster recovery and lower morbidity, complications and oncologic control have been incompletely evaluated. Our study objective was to report complication rates and early oncologic outcomes from a multi-institutional series of patients undergoing primary RA-RPLND.

Methods: Between December 2014 and June 2019 patients undergoing primary RA-RPLND at four institutions for clinical stage IA–IIB NSGCT were retrospectively reviewed. Demographics, clinical information, operative parameters, rates of oncologic recurrence, sexual recovery, and hospital length of stay information were collected. Intra-operative and post-operative complications were assessed according to the Clavien grading system. Data are presented as median [interquartile range], or frequency and percentage, as appropriate.

Results: Forty-one patients who underwent primary RA-RPLND were analyzed with a median follow-up of 10.9 [5–27 months]. Median age was 29 [25–35 years]. Other demographic and baseline oncologic characteristics are presented in Table 1. Sixty-one percent of patients underwent modified unilateral templates, while 39% of patients underwent a full bilateral template dissection. The median operative time was 287 [234–374 minutes], estimate blood loss 100 [50–150 ml], and lymph node yield 32 [16–46 nodes]. There was one intra-operative ureteral thermal injury (Clavien grade 1). There were no intra-operative or post-operative blood transfusions, and no conversions to open. Median length of stay was 1 day, and there were 3 readmissions. There were a total of nine post-operative complications in 20% of patients, with only two Clavien grade > 3. Out of 17 patients with positive nodes, 71% had metastatic GCT and 29% had teratoma. Six patients received adjuvant chemotherapy for viable disease. There were no in-field recurrences. Two patients received salvage chemotherapy for out-of-field recurrent disease after RA-RPLND, including one patient who had received adjuvant chemotherapy. Of the 63% (26/41) of patients with documented post-operative ejaculatory function, 73% (19/26) had return of antegrade ejaculations at median 150 days.

Conclusion: Primary RA-RPLND for NSGCT can be safely performed with low rates of complications and acceptable early oncologic outcomes. Similar to improvements seen in other major urologic operations with robotic-assisted surgery, the minimally-invasive robotic approach RPLND has decreased lengths of stay and reduced post-operative morbidity. Importantly, this multi-institutional series corroborates prior work that suggests acceptable early oncologic outcomes for patients managed with primary RA-RPLND. In an era when compliance to surveillance is challenging and lapses in follow-up can lead to worsened survival, RA-RPLND may bridge the gap and improve overall outcomes for patients with NSGCT. Longer prospective data needs to be gathered to ensure these findings endure over time.
236. PREDICTIVE CAPACITY OF MI-RNA-375 IN IDENTIFYING TERATOMA ON POST-CHEMOTHERAPY RETROPERITONEAL LYMPH NODE DISSECTION (PC-RPLND)

Alexander Kenigsberg, John Lakin, Xiaosong Meng, Dreaux Abe, Anna Savalyeva, Nirmish Singla, Solomon Woldu, Yair Lotan, Payal Kapur, Vitaly Margulis, James Amatruda, Aditya Bagrodia

UT Southwestern

Presented By: Alexander Kenigsberg

Introduction: Traditional tumor markers for testicular germ cell tumor (TGCT), lactate dehydrogenase (LDH), beta-human chorionic gonadotropin (hCG), and alpha-fetoprotein (AFP), have limited sensitivity in detecting residual tumor on PC-RPLND. Micro-RNAs (miRNA) have emerged as a promising serum markers to predict residual TGCT on RPLND. Previous reports have suggested high levels of miRNA-375 in teratoma. The purpose of this study was to evaluate serum miRNA-375 as a tumor marker for PC-RPLND teratoma.

Methods: We prospectively collected pre-surgical serum samples from consecutive GCT patients undergoing PC-RPLND. Serum miRNA-375-3p and -5p expression was validated and quantified by qPCR. Receiver operating characteristic (ROC) analysis and logistic regression were utilized to evaluate test characteristics and predictors of teratoma.

Results: 40 patients underwent PC-RPLND. 18 had benign pathology, 2 viable TGCT, and 1 embryonal rhabdomyosarcoma. 3 miRNA specimens were excluded as outliers. miRNA-375-5p was undetectable in all samples examined. ROC analysis of miRNA-375-3p revealed an area under the curve of 0.503. Of 19 patients with teratoma, 16 had elevated miRNA-375-3p (84.2% sensitivity). 6/17 with benign pathology had normal miRNA-375-3p (35.3% specificity). 16/27 with positive tests harbored teratoma (59.3% positive predictive value). Logistic regression showed that yolk sac tumor on orchiectomy, pre-RPLND LDH, AFP, hCG, N/L ratio, largest recurrence size, and miRNA-375 were not significant predictors of teratoma.

Conclusion: miRNA-375 does not predict teratoma on PC-RPLND. Tissue expression of miRNA-375 did not translate to serum expression in our study. Reliable predictors of teratoma on PC-RPLND remain elusive.

Funding: Crit rp170152; Dedman family scholarship in clinical care

237. EXPRESSION OF CIRCULATING MIR375 TO DETECT TERATOMA IN PATIENTS WITH GERM CELL TUMOR

Lucia Nappi1, Bernhard Eigl1, Kim Chi1, Christian Kollmannsberger1, Marisa Thi2, Martin Gleave2, Alan So2, Peter Black2, Robert Hamilton2, Siamak Daneshmand3, Craig Nichols5

1 British Columbia Cancer, 2 Vancouver Prostate Centre, 3 Princess Margaret Cancer Centre, 4 USC/Norris Comprehensive Cancer Center Institute of Urology, 5 South West Oncology Group

Presented By: Lucia Nappi

Introduction: micro-RNAs 371-373 and 302a-d clusters have demonstrated to be detectable in the blood of patients with active germ cell malignancy (GCM) but they are not expressed by teratoma. The identification of a teratoma-specific biomarker is an unmet clinical need, especially to characterize the residual disease post-chemotherapy in patients with nonseminoma. A recent multi-omics study has showed that miR375 is over-expressed in the teratoma tissue from primary testicular germ cell tumors. However, the detectability in the blood and the operating characteristics of this microRNA to detect teratoma remain unexplored.

Methods: miR375 expression was evaluated by RT-PCR and quantified by qRTCT method in the plasma of patients with residual post-chemotherapy non -seminoma, no evidence of disease post-chemotherapy or post-orchiectomy and metastatic pure seminoma enrolled in the GU biobank at the British Columbia Cancer centre in Vancouver. miR-39-3p, miR-451 and miR-30b-5p were used as quality and internal controls. Sensitivity, specificity, and AUC of the ROC of miR375 in detecting teratoma were analyzed.

Results: 40 patients underwent PC-RPLND. 18 had benign pathology, 2 viable TGCT, 19 teratoma, and 1 embryonal rhabdomyosarcoma. 3 miRNA specimens were excluded as outliers. miRNA-375-3p and -5p expression was validated and quantified by qPCR. Receiver operating characteristic (ROC) analysis and logistic regression were utilized to evaluate test characteristics and predictors of teratoma.

Conclusion: miR375 does not predict teratoma on PC-RPLND. Tissue expression of miRNA-375 did not translate to serum expression in our study. Reliable predictors of teratoma on PC-RPLND remain elusive.

Funding: Crit rp170152; Dedman family scholarship in clinical care
238. MANAGEMENT OF TESTICULAR GERM CELL TUMOR WITH SECONDARY SOMATIC MALIGNANCY
Nathan Wong¹, Timothy Clinton¹, Sumit Isharwal¹, Mark Donoghue¹, Sujata Patil¹, Liwei Jia¹, William Tap¹, Gabriella Joseph¹, Samuel Funt¹, Deaglan McHugh¹, Hikmat Al-Ahmadi¹, Victor Reuter¹, Robert Motzer¹, George Bosl¹, Joel Sheinfeld¹, David Solit¹, Darren Feldman¹, Shawn Dason², Lucas Dean³
¹ Memorial Sloan Kettering Cancer Center, ² The Ohio State University, ³ University of Alberta
Presented By: Nathan Wong

Introduction: Testicular germ cell tumors (GCT) will rarely contain teratoma with secondary somatic malignancy (SSM). Little is known about the clinical implications of this finding in the primary testicular specimen. For this reason, we report the Memorial Sloan Kettering Cancer Center (MSKCC) experience with testicular SSM.

Methods: Institutional databases were reviewed to identify patients with testicular SSM assessed from 1985 to 2018 at MSKCC. The diagnosis of SSM was confirmed in all cases by an experienced genitourinary pathologist and clinical data was reviewed retrospectively. The Kaplan-Meier method was used to estimate overall survival.

Results: Fifty-nine patients with testicular SSM were identified, of which 15 patients were assessed for a pathology review only with limited clinical information. Patients had a median age at presentation of 27 years (range 17-69) and median follow-up for survivors of 3.9 years (range 0.4-23.3 years). Patients were evenly distributed by clinical stage (CS) [CS1 (32%), CS2 (34%), and CS3 (34%)]. The most common SSM histologies were sarcoma (63%) and primitive neuroectodermal tumor (22%). Of CS1 patients, 12 patients underwent primary retroperitoneal lymph node dissection (RPLND) with long term survival while the 1 patient who underwent surveillance relapsed in the retroperitoneum and eventually died of disease. For patients with CS 2/3 disease, 79% had elevated markers and 94% had retroperitoneal disease. Similar to those with metastatic GCT without SSM, patients with elevated markers were generally treated with GCT-directed chemotherapy regimens followed by RPLND and resection of any other residual disease. Histology-directed therapy was generally reserved for adjuvant therapy and unresectable disease lacking evidence of residual GCT. 8-year overall survival was: CS1 83% (1 death of disease as above), CS2 92% (1 death of disease), and CS3 31% (6 deaths, 5 from disease). [Log rank p=0.01 CS3 vs. CS1/2].

Conclusion: Patients with clinical stage 1 testicular SSM have an excellent prognosis when managed with orchiectomy and primary RPLND. Clinical stage 2/3 SSM are managed similarly to patients without SSM, with an emphasis on PC-RPLND and resection of extra-retroperitoneal post-chemotherapy masses.

Funding: This research was supported by the Sidney Kimmel Center for Prostate and Urologic Cancers and funded in part through the NIH/NCI Cancer Center Support Grant P30 CA008748.
**239. OUTCOMES FOLLOWING RETROPERITONEAL LYMPH NODE DISSECTION FOR CLINICAL STAGE II PATIENTS EXPERIENCING A LATE RELAPSE FOLLOWING UPFRONT PLATINUM BASED CHEMOTHERAPY**

**Ryan Speir, Sean Kern, Timothy Masterson, Richard Foster, Clint Cary**

*Indiana University School of Medicine*

**Presented By:** Ryan Speir

**Introduction:** Late Relapse following complete response to upfront radiation or chemotherapy for clinical stage II germ cell tumor is rare occurring in only 1-5% of cases. It is characterized by its resistance to additional chemotherapy and poor prognosis. We sought out to evaluate the histopathologic, intraoperative and survival outcomes in clinical stage II germ cell tumor patients requiring retroperitoneal lymph node dissection (RPLND) for late relapse (LR) after upfront radiation or chemotherapy.

**Methods:** The Indiana University Testis Cancer Database was queried from 2012-2018 to identify all patients who presented with clinical stage II GCT, received radiation or chemotherapy following orchietomy, relapsed >2 years after initial diagnosis, and underwent their first RPLND in treatment of the LR. Clinical, operative, pathologic, and treatment characteristics were reviewed.

**Results:** Twenty-three patients met inclusion criteria. The mean age at RPLND was 38.8 years. Testicular primary was pure seminoma in 2, nonseminomatous GCT in 17, and unknown in 4 patients. The median time from diagnosis to relapse was 127.5 months (IQR 92-157 months). At relapse, serum tumor markers were elevated in 13 patients (56.5%). Ten patients (43.5%) were given cisplatin-based chemotherapy at LR while RPLND was initial management of LR in 13 (56.6%). A bilateral template RPLND was performed in 7/23 (30.4%) patients, while the remaining 16 patients underwent modified template surgery. At RPLND, 4 (17.4%), 4 (17.4%), and 15 (65.2%) patients demonstrated fibrosis, teratoma, and viable malignancy, respectively. The most common malignancy identified was yolk sac tumor (n=11/15, 73.3%). On the last follow-up, 6 patients (26.1%) recurred: 3 in the chest, 1 in the spine and 2 in the retroperitoneal surgical field. 5 patients (21.7%) died of disease. Of the 10 patients who received chemotherapy at the time of the late relapse, 70% had elevated STM. 60% had cancer in the specimen, while the other 40% had necrosis. 4/10 (40%) had a recurrence with all 4 dying of disease. Of the 13 patients who did not receive chemo, 38.5% had elevated STM, 8/13 (61.5%) had cancer in their specimen with 4/13 (31%) having teratoma and the other 1 patient (7.7%) having necrosis. 2/13 (15.4%) had a recurrence, with ½ dying of their disease. The remaining patient is NED following surgical resection of pulmonary and supraclavicular disease.

**Conclusion:** While clinical stage II patients experiencing a LR have a high rate of active malignancy, appropriate surgical management is imperative and must be complete. The high rate of recurrence and death in this patient population stresses the need for multidisciplinary management from the outset to optimize patient outcomes.

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**240. ASSOCIATIONS OF PRE-ORCHIECTOMY HORMONE LEVELS TO TESTICULAR GERM CELL TUMOR PATHOLOGY, CLINICAL STAGE, AND SIZE**

**Kevin Pineault**, **Joseph Cheaib**, **Amin Herati**, **Phillip Pierorazio**

*Brady Urological Institute at Johns Hopkins Hospital, Brady Urological Institute*

**Presented By:** Kevin Pineault

**Introduction:** Despite the substantial body of evidence describing the alternations in and impact of hormones after treatment of testicular germ cell tumors (GCTs), only a few studies have examined hormones before orchietomy. This study investigates the relationship between pre-orchietomy hormones and pathology, clinical stage, and tumor size among patients with GCTs.

**Methods:** An institutional testicular cancer database was reviewed for all patients from 2013 to 2018 older than 18 years that had an orchietomy performed. Per routine at our institution, testosterone panel, luteinizing hormone (LH), follicle-stimulating hormone (FSH) and estradiol are ordered at index visit for presence of hypogonadism symptoms.

**Results:** 52 patients (median age 31 years (IQR 27-36)), 80.4% white, 48.1% pure seminoma tumor pathology) met study criteria. High estradiol (>50 pg/mL) was significantly associated with non-seminomatous tumor pathology (p=0.01). Patients with elevated pre-orchietomy levels of FSH (>7.6mIU/mL) and LH (>11.2mIU/mL) were associated with significantly larger mean tumor size (p=0.02 and p=0.05, respectively). The odds of having a non-seminoma were 16 times higher in patients with elevated pre-orchietomy estradiol levels compared to those with normal levels (OR=16, p=0.02, 95% CI 1.6, 55.8).

**Conclusion:** These data suggest high pre-orchietomy estradiol levels were associated with and may predict non-seminomatous tumor pathology. Furthermore, LH and FSH were associated with tumor size. Therefore, knowing the associations between hormone levels before orchietomy and GCT pathology and size may better personalize management strategies. Future research will evaluate the role of pre-orchietomy hormone levels and subsequent development of hypogonadism.
241. CLINICOPATHOLOGIC PREDICTORS OF OUTCOMES IN CHILDREN WITH STAGE I GERM CELL TUMORS: A POOLED POST HOC ANALYSIS OF TRIALS FROM THE CHILDREN'S ONCOLOGY GROUP

Shyamli Singla, Justin Wong, James Amatruda, Aditya Bagrodia, Mark Krailo, Li Huang, Furqan Shaikh, Deborah Billmire, Frederick Ressler, Jonathan Ross, Bryan Dicken, A. Lindsay Frazier

1 University of Texas Southwestern Medical Center, 2 University of Southern California, 3 Children's Oncology Group, 4 The Hospital for Sick Children, 5 Indiana University, 6 Rainbow Babies and Childrens Hospital, 7 University of Alberta, 8 Dana-Farber Cancer Institute

Presented By: Nirmish Singla

Introduction: Patients with clinical stage I (CS I: cN0M0) germ cell tumors (GCT) exhibit favorable oncologic outcomes. While prognostic features can help inform treatment in adults with CS I GCT, we lack reliable means to predict relapse among pediatric patients. We sought to identify predictors of relapse in children with CS I GCT.

Methods: We performed a pooled post hoc analysis on pediatric CS I GCT patients enrolled in 3 prospective trials: INT-0097 (phase II), INT-0106 (phase III), and AGCT0132 (phase III). Pathology was centrally reviewed. Patient demographics, pT stage, serum tumor markers, margin status, histology, relapse, and survival were compiled. Cox regression analyses were used to identify predictors of outcomes.

Results: 88 patients were identified with histologic data available. Most patients were pT1-2 stage. Yolk sac tumor was present in 75%, while 16% had embryonal carcinoma, and 9% had choriocarcinoma. When evaluable, lymphovascular invasion (LVI) was present in 36/66 (55%) of patients. Over a median follow-up of 5.0 years, no patients died and 24 patients (27%) relapsed (median relapse-free survival not reached). Predictors of relapse included presence of choriocarcinoma (HR 4.3, p=0.004), embryonal carcinoma (HR 3.8, p=0.002), pT3 stage (HR 6.9, p=0.027), and age >12 years (HR 3.1, p=0.011). LVI (HR 2.4, p=0.072), serum tumor markers, and dominant tumor size did not reach significance.

Conclusion: Using combined data from multiple prospective trials, our study identifies clinicopathologic features that predict relapse and potentially inform personalized treatment for children with CS I GCT.
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</table>
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www.massgeneral.org/urology
suonet.org/fellowships/Combined%20Harvard%20Urologic%20Oncology%20Fellowship%20Overview.pdf

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urology.surgery.duke.edu/education-and-training/fellowship-programs/urologic-oncology

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www.fccc.edu/healthProfessionals/fellowships/urologic.html

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my.clevelandclinic.org/services/urology-kidney/for-medical-professionals/education-opportunities/urology-fellowships

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urology.iupui.edu/education/fellowships/uro Onc_program.php

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www.mc.vanderbilt.edu/root/vumc.php?site=urologicssurgery&doc=24704

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The Society of Urologic Oncology (SUO) was created in 1984 to include members interested in the care of patients with malignant genitourinary disease. The SUO develops educational and research initiatives, studies in urologic oncology, and provides physician statements representing state-of-the-art assessments of these issues to other organizations.

For more information, visit www.suonet.org.

The National Cancer Institute (NCI) is the government’s primary agency for conducting and supporting research in cancer causes, diagnosis, prevention, and treatment. In support of the entire community of cancer researchers, NCI employs its funding mechanisms, organizations, and networks to support basic, translational, and clinical research, and to invest in extraordinary opportunities to further progress made possible by previous discoveries.

For more information, visit www.cancer.gov.
## 2021 MATCH TIMELINE

### Match Schedule

<table>
<thead>
<tr>
<th>Date Range</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 20, 2020:</td>
<td>Registration deadline for both applicants and programs.</td>
</tr>
<tr>
<td>April 24, 2020:</td>
<td>Preference list phase begins.</td>
</tr>
<tr>
<td>May 25, 2020:</td>
<td>Deadline for receipt of all online preference lists.</td>
</tr>
<tr>
<td></td>
<td>(You will receive e-mail instructions on how to submit your list.)</td>
</tr>
<tr>
<td>May 26 - June 12, 2020:</td>
<td>The Match is performed, using all possible safeguards to ensure accuracy and confidentiality.</td>
</tr>
<tr>
<td>June 15, 2020:</td>
<td>Match results sent out via e-mail link.</td>
</tr>
</tbody>
</table>
SPRING 2020 MEETINGS

2020 SUO/SBUR Joint Meeting
May 16, 2020
Marriot Marquis
Washington, DC

2020 SUO Spring Meeting at the AUA
May 16, 2020
Marriot Marquis
Washington, DC

ANNUAL MEETINGS

21st Annual Meeting of the SUO
December 2 - 4, 2020
Sheraton Dallas
Dallas, Texas

22nd Annual Meeting of the SUO
December 1 - 3, 2021
Washington Marriott Wardman Park Hotel
Washington, DC

23rd Annual Meeting of the SUO
November 29 - December 2, 2022
Hilton San Diego Bayfront
San Diego, CA