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Needs

There is a need to increase communication among urologic oncology researchers and forge a strong relationship between the National Cancer Institute and the Society of Urologic Oncology, as well as the Society’s members and others interested in Bladder, Prostate, Kidney and Testis Cancers. This relationship will provide a community of urologic oncologists with the most up-to-date research that will provide optimal patient care.

Bladder cancer is the second most common genitourinary cancer in males and the fourth most common in females. There will be an estimated 71,000 new cases and 14,000 deaths from bladder cancer in 2009. Approximately 70% of the time, patients present with superficial disease. Of those, 70% are Ta lesions, 20% T1, and 10% carcinoma in situ (CIS).

Treatment of superficial bladder cancer consists of eradicating existing tumor(s) and preventing recurrence and progression, while preserving bladder function. Currently available agents meet these criteria to some degree, but their efficacy and tolerability are not ideal. There are new agents and device-assisted therapies currently being investigated to improve outcomes for patients with superficial bladder cancer.

Management of the small renal mass has become controversial and, to some extent, current practices are inconsistent with the supporting literature. In particular, we now recognize that these masses are very heterogeneous: 20% are benign and only about 20% to 25% exhibit potentially aggressive features.

In spite of this, even in this era, most of these patients are managed with radical nephrectomy. This is essentially over-treatment for many of these patients. Radical nephrectomy predisposes patients to chronic kidney disease and there’s strong evidence in the literature showing a correlation between chronic kidney disease and morbid cardiovascular events and death. It is important for urologists to be knowledgeable about all treatment options and the current literature about small renal masses, their natural history, and their biological aggressiveness. It is also important to try to make individualized decisions based on the patient’s health, the size of the tumor, and a number of other important considerations. Beyond that, ideally, urologists either need to be able to provide the full spectrum of treatment options ranging from laparoscopic radical nephrectomy to thermal ablation, to work in a team environment where these options can be provided, or to develop referral patterns for patients who need treatment options that they might not provide.

Prostate cancer is the most common noncutaneous cancer in men in the US, and the second leading cause of male cancer mortality, accounting for an expected 28,660 deaths in 2008. The natural history of this disease is remarkably heterogeneous and, at this time, is not clearly and consistently understood. An analysis of autopsy studies has shown that approximately one in three men over the age of 50 years had histologic evidence of prostate cancer, with up to 80% of these tumors being limited in size and grade and, therefore, clinically insignificant. A recent study of incidental prostate cancer diagnosed in organ donors found prostate cancer in 1 in 3 men age 60-69, and this increased to 46% in men over age 70. Fortunately, the lifetime risk of prostate cancer death is only about 3%.

Some studies have found that a large proportion of patients diagnosed with clinically localized prostate cancer who did not receive early aggressive treatment still had favorable clinical outcomes and normal life expectancies. Most of these studies included an older population of men as well as a larger proportion of men with low-grade tumors. Although outcomes can be worse with extended follow up, the general disparity between the high prevalence of prostate cancer and the relatively low lifetime risk of prostate cancer death highlights the importance of distinguishing those cancers that are destined to cause significant illness and premature death from those that are not. The use of PSA testing for the early detection of prostate cancer remains controversial, however, owing to its biological variability, high prevalence, and the strong evidence for over diagnosis and overtreatment.

Objectives

Following participation in this program, attendees will be able to:

- Describe recent advances in robotic and minimally invasive therapies for prostate, kidney and bladder cancer
- Recognize new methods for active surveillance and focal therapy for patients with localized prostate cancer
- Report recent advances in targeted systemic therapy of advanced kidney cancer
- Assess new biomarkers for screening and other predictive markers for bladder cancer
- Use recent advances in proton beam and brachytherapy for localized prostate cancer
- Apply current thinking about the role of the urologic surgeon in the management of patients with kidney cancer who present with metastatic kidney cancer with their kidney in place
- Recognize recent advances in surgical treatment of patients with localized bladder cancer
- Describe new approaches for advances adjuvant therapy of advanced kidney cancer
- Describe new approaches in the role of finasteride in prevention of prostate cancer
- Recognize new strategies to enhance the role of intravesical chemotherapy in superficial bladder cancer
- Apply recent advances in management of complications in female cystectomy
Evaluation of Quality of Activity
The educational quality of the meeting will be assessed with evaluation questionnaires to be filled out by the participants.

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CME Accreditation Statement
This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of the University of Oklahoma College of Medicine and the Society of Urologic Oncology. The University of Oklahoma College of Medicine is accredited by the ACCME to provide continuing medical education for physicians.

The University of Oklahoma College of Medicine designates this educational activity for a maximum of 13.00 AMA PRA Category 1 Credits™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Conflict Resolution Statement
The University of Oklahoma College of Medicine, Office of Continuing Medical Education has reviewed this activity’s speaker and planner disclosures and resolved all identified conflicts of interest, if applicable.

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.

Meals
A continental breakfast, lunch and mid-morning snack on both days of the meeting are included in the registration fee.

Young Urologic Oncologist Dinner
Date: Wednesday, December 2, 2009
Time: 6:00 p.m. – 9:30 p.m.
Location: Hyatt Regency Bethesda, Lalique Room
Attire: Business Casual
Membership in the YUO Section of the Society of Urologic Oncology consists of fellows, scientists, and board certified or eligible physicians who are members of the SUO and have some post-residency training in urologic oncology. Membership is limited to the first 7 years after completion of fellowship.

SUO Dinner at the Hyatt Regency Bethesda
Date: Thursday, December 3, 2009
Time: 7:00 p.m. – 10:00 p.m.
Attire: Business casual attire is appropriate
Enjoy dinner with friends and colleagues at the Hyatt Regency Bethesda.

Industry Sponsored Breakfast Symposium
Date: Friday, December 4, 2009
Time: 6:30 a.m. – 7:30 a.m.
Location: Hyatt Regency Bethesda, Cabinet/Judiciary Room
Estrogen Deficiency Side Effects of Androgen Deprivation Therapy
Evan Yu, MD
University of Washington School of Medicine
Assistant Professor Oncology
10th Annual SUO Meeting to Discuss Current Topics and Strategies
Co-Sponsored by the Society of Urologic Oncology and the National Cancer Institute
December 2 – 4, 2009
Natcher Conference Center
National Institutes of Health
Bethesda, Maryland

All sessions located at the Natcher Center, unless otherwise noted.

Wednesday, December 2, 2009
6:00 p.m. – 9:00 p.m. Board of Directors Meeting
Location: Hyatt Regency Bethesda, Diplomat/Ambassador Room

6:00 p.m. – 9:30 p.m. Young Urologic Oncologist Dinner
Location: Hyatt Regency Bethesda, Lalique Room

7:30 p.m. #Y1 SERUM-SOLUBLE B7X IS ELEVATED IN PATIENTS WITH PROSTATE CANCER
Preston Sprenkle, R. Thompson, Xingxing Zang, Caroline Savage, Hikmat Alahamadie, Victor Reuter, James Eastham, Peter Scardino and James Allison
Memorial Sloan-Kettering Cancer Center, NY, NY
(Presented By: Preston Sprenkle)

7:40 p.m. #Y2 IN VIVO DETECTION AND TREATMENT OF PROSTATE CANCER CELLS IN A LOCAL RECURRENCE MODEL BY A PSA-PROMOTER DEPENDENT ADENOVIRUS
Frederic Pouliot¹, Makoto Sato², Mai Johnson², Jeremy Burton², Steve Huyn² and Lily Wu²
¹Institute of Urologic Oncology, UCLA, Los Angeles, CA; ²Dept. of Pharmacology, UCLA, Los Angeles, CA
(Presented By: Frederic Pouliot)

7:50 p.m. #Y3 COMPARATIVE RISK-ADJUSTED MORTALITY OUTCOMES FOLLOWING PRIMARY SURGERY, RADIATION THERAPY, AND ANDROGEN DEPRIVATION THERAPY FOR PROSTATE CANCER
Matthew Cooperberg¹, Andrew Vickers², Jeanette Broering¹ and Peter Carroll¹
¹UCSF, San Francisco, CA; ²Memorial Sloan-Kettering, New York, NY
(Presented By: Matthew Cooperberg)
Thursday, December 3, 2009

6:30 a.m. – 5:00 p.m.  Registration/Information Desk Open
   Location: NIH Natcher Conference Center

7:00 a.m. – 8:00 a.m.  Continental Breakfast

8:00 a.m. – 8:05 a.m.  Introduction
Eric Klein, MD
   Cleveland Clinic
   President, Society of Urologic Oncology
   Program Co-Director
W. Marston Linehan
   National Cancer Institute
   Program Co-Director
Laurence Klotz, MD
   Sunnybrook Medical Science Center
   Program Co-Director/WUOF Liaison

8:05 a.m. – 9:05 a.m.  Bladder Cancer I: Emerging Technology – How Will This Affect Decision Making or Outcome?
   Moderator: Harry Herr, MD
   Memorial Sloan-Kettering Cancer Center

   8:05 a.m. – 8:10 a.m.  Overview: Quality Measures of Endoscopic Staging and NBI
   Harry Herr, MD
   Memorial Sloan-Kettering Cancer Center, Novel Imaging Technology

   8:10 a.m. – 8:20 a.m.  Fluorescence Cystoscopy
   Yves Fradet, MD
   Laval University Cancer Research Center

   8:20 a.m. – 8:30 a.m.  Optical Coherence Tomography
   Seth Lerner, MD
   Baylor College of Medicine

   8:30 a.m. – 8:40 a.m.  Confocal Microscopy
   Joseph Liao, MD
   Stanford University

   8:40 a.m. – 8:50 a.m.  Discussant
   Michael Droller, MD
   Mount Sinai Medical Center

   8:50 a.m. – 9:05 a.m.  Panel Discussion
   Moderator: Harry Herr, MD
   Memorial Sloan-Kettering Cancer Center
   Panelists: Yves Fradet, MD
   Laval University Cancer Research Center
   Seth Lerner, MD
   Baylor College of Medicine
   Joseph Liao, MD
   Stanford University
   Michael Droller, MD
   Mount Sinai Medical Center
9:05 a.m. – 10:05 a.m.  Prostate Cancer I: Chemoprevention
Moderator: Eric Klein, MD
Cleveland Clinic
President, Society of Urologic Oncology
Program Co-Director

9:05 a.m. – 9:20 a.m.  Can Future Risk of Prostate Cancer Be Predicted?
Neil Fleshner, MD
United Health Network

9:20 a.m. – 9:35 a.m.  Do 5ARIs Improve the Sensitivity of PSA for Detecting Prostate Cancer?
Gerald Andriole, MD
Washington University Medical Center

9:35 a.m. – 9:50 a.m.  Do 5ARIs Increase the Risk of High-Grade Prostate Cancer?
Peter Scardino, MD
Memorial Sloan-Kettering Cancer Center

9:50 a.m. – 10:05 a.m. Panel Discussion:
Who is a Candidate for Chemoprevention of Prostate Cancer?
Moderator: Eric Klein, MD
Cleveland Clinic
President, Society of Urologic Oncology
Program Co-Director
Panelists: Neil Fleshner, MD
United Health Network
Gerald Andriole, MD
Washington University Medical Center
Peter Scardino, MD
Memorial Sloan-Kettering Cancer Center

10:05 a.m. – 10:15 a.m.  Break

10:15 a.m. – 10:35 a.m.  State-of-the-Art: In Vivo Lymphatic Real Time Imaging
Eva Sevik, MD
UT Health Science Center Houston

10:35 a.m. – 11:00 a.m.  Testis Cancer Update
Darren R. Feldman, MD
Memorial Sloan-Kettering Cancer Center

11:00 a.m. – 12:00 p.m. Kidney Cancer I:
Ramaprasad Srinivasan, MD, PhD
Urologic Oncology Branch, NCI

11:00 a.m. – 11:15 a.m.  The Role of Systemic Therapy in Patients Who Present with Metastatic
Kidney Cancer With Their Primary Kidney Cancer in Place
Surena F. Matin, MD
MD Anderson Cancer Center
<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Speaker(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>11:15 a.m.</td>
<td>Recent Advances in the Management of Metastatic Clear Cell RCC</td>
<td>Michael Atkins, MD&lt;br&gt;Beth Israel Deaconess Medical Center</td>
</tr>
<tr>
<td>11:30 a.m.</td>
<td>Systemic Therapy of Non-Clear Cell RCC – What Can We Learn From Familial Kidney Cancer Syndromes?</td>
<td>Ramaprasad Srinivasan, MD, PhD&lt;br&gt;Urologic Oncology Branch, NCI</td>
</tr>
<tr>
<td>11:45 a.m.</td>
<td>Panel Discussion</td>
<td>Moderator: Ramaprasad Srinivasan, MD, PhD&lt;br&gt;Urologic Oncology Branch, NCI&lt;br&gt;Michael Atkins, MD&lt;br&gt;Beth Israel Deaconess Medical Center&lt;br&gt;Surena F. Matin, MD&lt;br&gt;MD Anderson Cancer Center&lt;br&gt;Ramaprasad Srinivasan, MD, PhD&lt;br&gt;Urologic Oncology Branch, NCI</td>
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<td>12:00 p.m.</td>
<td>Lunch</td>
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<td>1:30 p.m.</td>
<td>SUO Huggins Medal Presentation</td>
<td>Eric Klein, MD&lt;br&gt;Cleveland Clinic&lt;br&gt;President, SUO</td>
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<tr>
<td>1:40 p.m.</td>
<td>Huggins Medal Lecture</td>
<td>W. Marston Linehan, MD&lt;br&gt;National Cancer Institute</td>
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<tr>
<td>2:00 p.m.</td>
<td>Prostate Cancer II: Fundamental Processes in Prostate Cancer</td>
<td>Moderator: Adam Kibel, MD&lt;br&gt;Washington University</td>
</tr>
<tr>
<td>2:00 p.m.</td>
<td>Characterization of XMRV in Prostate Cancer</td>
<td>Eric Klein, MD&lt;br&gt;Cleveland Clinic</td>
</tr>
<tr>
<td>2:15 p.m.</td>
<td>TRMPSS – ETS Gene Fusions</td>
<td>Himisha Beltran, MD&lt;br&gt;Weill Cornell Medical College</td>
</tr>
<tr>
<td>2:30 p.m.</td>
<td>Androgen Receptor</td>
<td>Martin Gleave, MD&lt;br&gt;University of British Columbia</td>
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<tr>
<td>2:45 p.m.</td>
<td>Panel Discussion: Progress in Molecular Targeting for Diagnosis, Prognosis, and Therapy</td>
<td>Moderator: Adam Kibel, MD&lt;br&gt;Washington University Medical School&lt;br&gt;Panel: Himisha Beltran, MD&lt;br&gt;Weill Cornell Medical College&lt;br&gt;Martin Gleave, MD&lt;br&gt;University of British Columbia</td>
</tr>
</tbody>
</table>
3:00 p.m. – 4:00 p.m.  
**Bladder Cancer II: Biomarkers**  
Moderator: Seth Lerner, MD  
Baylor College of Medicine

3:00 p.m. – 3:20 p.m.  
Utility (or Lack of) of FDA Approved Voided Urine Biomarkers

3:00 p.m. – 3:10 p.m.  
Pro  
Badrinath Konety, MD  
University of California, San Francisco

3:10 p.m. – 3:20 p.m.  
Con  
Yair Lotan, MD  
University of Texas Southwest

3:20 p.m. – 3:30 p.m.  
DNA Methylation  
Mark Gonzalgo, MD  
Stanford University

3:30 p.m. – 3:50 p.m.  
MSA Trial  
Mark Schoenberg, MD  
Johns Hopkins University

3:50 p.m. – 4:00 p.m.  
Panel Discussion  
Moderator: Seth Lerner, MD  
Baylor College of Medicine  
Panelists: Badrinath Konety, MD  
University of California, San Francisco  
Yair Lotan  
University of Texas Southwest  
Mark Gonzalgo, MD  
Stanford University  
Mark Schoenberg, MD  
Johns Hopkins University

4:00 p.m. – 6:00 p.m.  
Poster Session I / Reception  
Posters 1 – 100.5

7:00 p.m. – 7:30 p.m.  
SUO Reception  
*Location: Hyatt Regency Bethesda, Waterford Foyer*

7:30 p.m.  
SUO Dinner  
*Location: Hyatt Regency Bethesda, Waterford/Lalique Room*

**Friday, December 4, 2009**

**6:30 a.m. – 7:30 a.m.**  
Industry Sponsored Breakfast Symposium  
*Location: Hyatt Regency Bethesda, Cabinet/Judiciary Room*

**6:30 a.m. – 5:00 p.m.**  
Registration/Information Desk Open  
*Location: NIH Natcher Conference Center*

**7:00 a.m. – 8:00 a.m.**  
Continental Breakfast
<table>
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<tr>
<th>Time</th>
<th>Event</th>
<th>Presenter(s)</th>
<th>Institution(s)</th>
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<tbody>
<tr>
<td>8:00 a.m.</td>
<td>#1 THE ASSOCIATION BETWEEN OXIDATIVE STRESS AND PROSTATE CANCER RISK IN MEN UNDERGOING PROSTATE BIOPSY</td>
<td>Daniel A. Barocas, Saudara Motley, Qi Dai, Ginger Milne, Jason Morrow, Michael S. Cookson, Joseph A. Smith, Jr. and Jay H. Fowke</td>
<td>Vanderbilt University Medical Center, Nashville, TN</td>
</tr>
<tr>
<td>8:10 a.m.</td>
<td>#2 HER2 EXPRESSION STATUS PROVIDES INDEPENDENT PROGNOSTIC INFORMATION IN PATIENTS WITH UROTHELIAL CARCINOMA OF THE BLADDER</td>
<td>Shahrokh Shariat¹, Christian Bolenz², Daher Chade¹, Raheela Ashfaq², Richard Ho², Arthur Sagalowsky² and Yair Lotan²</td>
<td>¹Memorial Sloan-Kettering Cancer Center, New York, NY; ²UT Southwestern, Dallas, TX</td>
</tr>
<tr>
<td>8:20 a.m.</td>
<td>#3 MOLECULAR SUB-CLASSIFICATION OF RENAL EPITHELIAL NEOPLASMS</td>
<td>Thomas Sanford, Ariel Reinish, Paul Chung, Ramaprasad Srinivasan, W. Marston Linehan and Gennady Bratslavsky</td>
<td>Urologic Oncology Branch, National Cancer Institute, Bethesda, MD</td>
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<tr>
<td>8:30 a.m.</td>
<td>Kidney Cancer II: Management of Localized Disease</td>
<td>Robert Uzzo, MD</td>
<td>Fox Chase Cancer Center</td>
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<tr>
<td>8:30 a.m.</td>
<td>Case Presentation #1: T1A: Observe/Ablate/Remove</td>
<td>Robert Uzzo, MD</td>
<td>Fox Chase Cancer Center</td>
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<tr>
<td>8:35 a.m.</td>
<td>Observation of Renal Cancer</td>
<td>Michael Jewett, MD</td>
<td>Princess Margaret Hospital</td>
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<td>8:40 a.m.</td>
<td>Ablation</td>
<td>Jeffrey A. Cadeddu, MD</td>
<td>Southwestern Medical School</td>
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<tr>
<td>8:45 a.m.</td>
<td>Discussion With Panel</td>
<td>Robert Uzzo, MD</td>
<td>Fox Chase Cancer Center</td>
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<td>Panelists: Paul Russo, MD</td>
<td>- Memorial Sloan- Kettering Cancer Center</td>
<td>- Princess Margaret Hospital</td>
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<td>- Michael Jewett, MD</td>
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<td>- Jeffrey A. Cadeddu, MD</td>
<td>- Peter A. Pinto, MD</td>
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<td>- National Cancer Institute</td>
<td>- Arthur Sagalowsky, MD</td>
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<td>- UT Southwestern Medical Center</td>
<td>- Gennady Bratslavsky, MD</td>
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*MODERATOR: Robert Uzzo, MD  
MEMORIAL SLOAN- KETTERING CANCER CENTER*
8:55 a.m. – 9:00 a.m.  Case Presentation #2: T1B: Partial Versus Nephrectomy
Robert Uzzo, MD
Fox Chase Cancer Center

9:00 a.m. – 9:05 a.m.  Partial Nephrectomy Open
Paul Russo, MD
Memorial Sloan-Kettering Cancer Center

9:05 a.m. – 9:10 a.m.  Partial Nephrectomy (MIS)
Gennady Bratslavsky, MD
National Cancer Institute

9:10 a.m. – 9:15 a.m.  Radical Nephrectomy
Arthur Sagalowsky, MD
UT Southwestern Medical Center

9:15 a.m. – 9:30 a.m.  Discussion with Panel
Moderator: Robert Uzzo, MD
Fox Chase Cancer Center
Panelists:  Paul Russo, MD
Memorial Sloan-Kettering Cancer Center
Michael Jewett, MD
Princess Margaret Hospital
Jeffrey A. Cadeddu, MD
Southwestern Medical School
Peter A. Pinto, MD
National Cancer Institute
Arthur Sagalowsky, MD
UT Southwestern Medical Center
Gennady Bratslavsky, MD
National Cancer Institute

9:30 a.m. – 10:30 a.m.  Penile Cancer
Moderator: Curtis Pettaway, MD
UT MD Anderson Cancer Center

9:30 a.m. – 9:35 a.m.  Introduction
Moderator: Curtis Pettaway, MD
UT MD Anderson Cancer Center

9:35 a.m. – 9:55 a.m.  New Developments in Penile Preservation
Surgical Techniques and Outcomes of Penile Preservation
Suks Minhas, MD, FRCS
Institute of Urology,
University College Hospital, London

Radiation Based Strategies for Penile Preservation
Juanita Crook, MD, FRCPC
University of British Columbia

9:55 a.m. – 10:25 a.m.  Management of the Inguinal Region Indications and Techniques for Inguinal Staging
Curtis Pettaway, MD
UT MD Anderson Cancer Center
Program Schedule

Integration of Chemotherapy and Surgery for Locally Advanced Penile Cancer: Where Do We Stand?
Lance Pagliaro MD
UT MD Anderson Cancer Center

10:25 a.m. – 10:30 a.m. Question and Answer

10:30 a.m. – 11:30 a.m. Recent Advances: Prostate
Moderator: Edward Messing, MD
University of Rochester Medical Center

10:30 a.m. #4 SHORT-TERM ENDOCRINE THERAPY PRIOR TO AND DURING RADIATION THERAPY IMPROVES OVERALL SURVIVAL IN PATIENTS WITH T1b-T2b ADENOCARCINOMA OF THE PROSTATE AND PSA ≤20: INITIAL RESULTS OF RTOG 94-08
David G. McGowan¹, MD; Daniel Hunt², PhD; Christopher U. Jones³, MD; Mahul Amin⁴, MD; Mark H. Leibenhaut⁵, MD; Siraj M. Husian⁶, MD; Marvin Rotman⁷, MD; Luis Souhami⁸, MD; Howard Sandler⁹, MD; William U. Shipley¹⁰, MD
¹Cross Cancer Institute, Edmonton, AB, Canada; ²American College of Radiology, Philadelphia, PA; ³Radiological Associates of Sacramento, Sacramento, CA; ⁴Cedars-Sinai Medical Center, Los Angeles, CA; ⁵Tom Baker Cancer Centre, Calgary, AB, Canada; ⁶State University of New York Health Science Center at Brooklyn, Brooklyn, NY; ⁷McGill University, Montreal, QC, Canada; ⁸Massachusetts General Hospital, Boston, MA
(Presented By: Howard Sandler)

10:45 a.m. #5 ANTITUMOR ACTIVITY OF MDV3100 IN A PHASE 1-2 TRIAL IN CASTRATION RESISTANT PROSTATE CANCER CONDUCTED BY THE PROSTATE CANCER CLINICAL TRIALS CONSORTIUM
Howard Scher¹, Thomaz Beer², Celestia Higano³, Daniel Danila⁴, Bruce Montgomery³, Julia Shelkey⁵, Mohammad Hirmand⁶, David Hung⁶, Aseem Anand⁷, Martin Fleisher¹ and Charles Sawyers¹
¹Memorial Sloan-Kettering Cancer Center; ²Oregon Health Sciences University, Portland, OR; ³University of Washington, Seattle, WA; ⁴Memorial Sloan-Kettering Cancer Center, NY, NY; ⁵Memorial Sloan-Kettering Cancer Center, NY, NY; ⁶Medivation, San Francisco, CA
(Presented By: Howard Scher)

11:00 a.m. #6 A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTI-CENTER, PHASE III TRIAL OF SIPULEUCEL-T IN MEN WITH METASTATIC, CASTRATE RESISTANT PROSTATIC ADENOCARCINOMA
Leonard Gomella¹, Celestia Higano², David Penson³, Simon Hall⁴, Joseph Chin⁵, David McLeod⁶, Ron Israeli⁷, Robert Flanagan⁸, Chris Teigland⁹, Gerald Chodak¹⁰, Brian Miles¹¹, Mark Frohlich¹² and Paul Schellhammer¹³
¹Kimmel Cancer Center at Jefferson, Philadelphia, PA; ²Seattle Cancer Care Alliance, Seattle, WA; ³Vanderbilt Department of Urologic Surgery, Nashville, TN; ⁴Mount Sinai School of Medicine, New York, NY; ⁵London Health Sciences Centre, London, ON, Canada; ⁶Walter Reed Army Medical Center, Washington, DC; ⁷State Island Urological Res., PC, Staten Island, NY; ⁸Loyola University, Maywood, IL; ⁹McKay Department of Urology at Carolinas Medical Center, Charlotte, NC; ¹⁰Midwest Prostate and Urological Healthcare Center, Chicago, IL; ¹¹The Houston Prostate Institute, Houston, TX; ¹²Dendreon Corporation, Seattle, WA; ¹³Department of Urology, Eastern Virginia Medical School, Norfolk, VA
(Presented By: Leonard Gomella)
11:15 a.m.  #7 TOREMIFENE IMPROVES PSA PROGRESSION FREE SURVIVAL IN CASTRATE MEN WITH DETECTABLE BASELINE PSA LEVELS
Dan Lin¹, Michael Brawer², Mitchell Steiner², Ronald Morton², Domingo Rodriguez², Gary Barnette², Michael Hancock² and Evan Yu¹
¹University of Washington Medical Center, Seattle, Washington; ²GTx, Inc., Memphis, Tennessee
(Presented By: Evan Yu)

11:30 a.m. – 12:30 p.m.  Lunch

12:30 p.m. – 1:15 p.m.  WUOF: International Perspective on Genitourinary Cancer
Moderator: Laurence Klotz, MD
Sunnybrook & Women’s College Health Science Center

12:30 p.m. – 12:45 p.m.  ADT and Cancer Stem Cell: Novel Findings with Clinical Implications
George Thalmann, MD
University Hospital of Bern

12:45 p.m. – 1:00 p.m.  Prostate Cancer Epidemiology in Asia
Christopher Cheng, MD
Singapore General Hospital

1:00 p.m. – 1:15 p.m.  Renal Cell Carcinoma in China: Clinical Characteristics and Treatment Options
Ming Li, MD
Beijing Cancer Hospital & Institute, Peking University

1:15 p.m. – 1:45 p.m.  Recent Advances: Kidney
Moderator: Arie Belldegrun, MD
UCLA School of Medicine

1:15 p.m.  #8 NEPHRECTOMY INDUCED CHRONIC RENAL INSUFFICIENCY IS ASSOCIATED WITH INCREASED RISK OF CARDIOVASCULAR DEATH AND DEATH FROM ANY CAUSE IN PATIENTS WITH LOCALIZED RENAL MASSES
Christopher Weight, Benjamin Larson, Amr Fergany, Tianming Gao, Brian Lane, Steven Campbell, Jihad Kaouk and Eric Klein
Cleveland Clinic, Cleveland, OH
(Presented By: Christopher Weight)

1:30 p.m.  #9 FACTORS ASSOCIATED WITH MANAGEMENT OF SMALL RENAL MASSES: A SURVEY OF THE AMERICAL UROLOGICAL ASSOCIATION
Rodney Breau¹, Paul Crispens², R. Houston Thompson¹, Michael Blute¹ and Bradley Leibovich¹
¹Mayo Clinic, Rochester, MN; ²University of Kentucky, Lexington, KY
(Presented By: Rodney Breau)

1:45 p.m. – 2:45 p.m.  Recent Advances: Bladder
Moderator: Badrinath Konety, MD
University of California, San Francisco

1:45 p.m. – 2:00 p.m.  Pros and Cons of Adjuvant Versus Neoadjuvant Therapy
Dean Bajorin, MD
Memorial Sloan-Kettering Cancer Center
2:00 p.m.  #10  EFFICACY AND SAFETY OF INTRAVESICAL VALRUBICIN IN PATIENTS WITH CARCINOMA IN SITU OF THE BLADDER REFRACTORY TO BACILLUS CALMETTE-GUÉRIN: A PHASE III OPEN-LABEL, MULTICENTER STUDY
Gary Steinberg
The University of Chicago
(Presented By: Gary Steinberg)

2:15 p.m.  #11  ASSESSING THE CLINICAL BENEFIT OF NMP22 IN THE SURVEILLANCE OF PATIENTS WITH NON-MUSCLE-INVASIVE BLADDER CANCER: A DECISION-CURVE ANALYSIS
Shahrokh Shariat, Caroline Savage, Pierre Karakiewicz, Daher Chade, Guilherme Godoy, KianTai Chong and Andrew Vickers
Memorial Sloan-Kettering Cancer Center, New York, NY
(Presented By: Shahrokh Shariat)

2:30 p.m. – 2:45 p.m.  Bladder Cancer Targeted Therapeutics
Matthew Milowsky, MD
Memorial Sloan-Kettering Cancer Center

2:45 p.m. – 4:00 p.m.  SUO Clinical Trials Consortium
Leading Urologic Oncology Clinical Research
Colin P.N. Dinney, MD
President, SUO-CTC
UT MD Anderson Cancer Center

4:00 p.m. – 6:00 p.m.  Poster Session II / Reception
Posters 101 – 200
SERUM-SOLUBLE B7X IS ELEVATED IN PATIENTS WITH PROSTATE CANCER
Preston Sprenkle, R. Thompson, Xingxing Zang, Caroline Savage, Hikmat Alahamadie, Victor Reuter, James Eastham, Peter Scardino and James Allison
Memorial Sloan-Kettering Cancer Center, NY, NY
Presented By: Preston Sprenkle

Introduction: B7x, the newest member of the B7-CD28 family of co-stimulatory molecules, negatively regulates CD4+ and CD8+ T-cell proliferation, cell-cycle progression, IL-2 production, and can render tumor cells refractory to apoptosis. Using immunohistochemical (IHC) techniques, tumor expression of B7x was recently described in patients with prostate cancer and was associated with adverse pathologic features and diminished survival. A soluble form of B7x (sB7x) has been identified in patients with ovarian, breast, and kidney cancer, and was previously observed to not be present in patients with prostate cancer. Using an alternative ELISA assay, we sought to directly evaluate the presence of sB7x in prostate cancer patients compared with controls.

Methods: 92 patients with a preoperative serum sample and pathology proven adenocarcinoma of the prostate treated surgically at the Memorial Sloan-Kettering Cancer Center between 1999 and 2008 were identified. A sandwich ELISA for the detection of sB7x was performed on the sera of patients with prostate cancer, volunteer male blood donors and men with an elevated prostate specific antigen (PSA) but biopsy-proven absence of prostate cancer. A positive serum B7x value was defined as any measurement 0.1ng/ml or greater. B7x IHC was categorized as none/moderate vs. strong and was available for 52 patients with prostate cancer.

Results: 214 patients were included in the analysis, 66 (31%) were normal controls, 56 (26%) had an elevated PSA with a negative prostate biopsy and 92 (43%) had prostate cancer. Positive (pre-surgery) sB7x levels predicted group: 15% (n=10) of controls had positive B7x levels compared to 46% (n=26) of patients with elevated PSA and 79% (n=73) of patients with prostate cancer (p <0.001). Among cancer patients, everyone with seminal vesicle invasion (n=4) or lymph node involvement (n=1) had positive B7x levels, although these associations were not statistically significant. Among the 52 patients with IHC data, preoperative sB7x did not predict B7x IHC intensity (p=0.3).

Conclusions: Contrary to prior reports, a soluble form of B7x is detectable in patients with prostate cancer, and is more likely to be detected in the sera of prostate cancer patients than healthy control patients or patients with an elevated PSA (p<0.001). These results suggest that further investigation of B7x in prostate cancer patients is warranted for diagnostic, prognostic, and potential therapeutic purposes.

IN VIVO DETECTION AND TREATMENT OF PROSTATE CANCER CELLS IN A LOCAL RECURRENCE MODEL BY A PSA-PROMOTER DEPENDENT ADENOVIRUS
Frederic Pouliot¹, Makoto Sato², Mai Johnson², Jeremy Burton², Steve Huyn² and Lily Wu²
¹Institute of Urologic Oncology, UCLA, Los Angeles, CA; ²Dept. of Pharmacology, UCLA, Los Angeles, CA
Presented By: Frederic Pouliot

Introduction and Objectives: PSA recurrence after radical prostatectomy might be secondary to pelvic recurrence or distant metastasis. Currently, there is no way to ascertain the localization of PSA-recurrence, which renders the choice of treatment difficult. We studied the ability of an adenovirus expressing a reporter and/or a suicide gene under an androgen-dependent modified PSA-promoter to detect and prevent prostate cancer local recurrence.

Methods: LAPC-9 prostate cancer cell line was stably infected with a lentivirus expressing constitutively Renilla luciferase to generate the LAPC-9-RL cell line. LAPC-9-RL cells were then implanted in the peritoneum (instead of retroperitoneum for technical purpose) of scid/beige mice and tumor growth was monitored in vivo using bioluminescence. Adenovirus expressing firefly luciferase or the cytotoxic gene sr39tk under the control of a modified PSA promoter and the Two-Step-Amplification-Transcription system (Ad-PSA-TSTA-fl) was constructed as previously described (Sato et al. 2008).
Results: LAPC-9-RL cells were grown i.p. in mice for three weeks and in vivo Renilla luciferase activity confirmed the tumor growth and its location (Figure, left panel). Instillation of PSA-TSTA-fl i.p. was able to detect tumor and normal prostate cells in vivo at the expected locations (Figure left and right middle panels). Specificity of the signals were confirmed ex-vivo (Figure right panel). Also, we show that neoadjuvant intratumoral injection of PSA-TSTA-sr39tk (sr39tk is a cytotoxic gene when cells are exposed to gancyclovir) into xenograft tumors before resection followed by treatment with gancyclovir could prevent local recurrence in a prostate cancer resection model.

Conclusion: We show that adenovirus mediated PSA-specific expression of reporter or cytotoxic genes can detect and prevent local recurrence in a local recurrence mouse prostate cancer model.

#Y3

COMPARATIVE RISK-ADJUSTED MORTALITY OUTCOMES FOLLOWING PRIMARY SURGERY, RADIATION THERAPY, AND ANDROGEN DEPRIVATION THERAPY FOR PROSTATE CANCER
Matthew Cooperberg¹, Andrew Vickers², Jeanette Broering¹ and Peter Carroll¹
¹UCSF, San Francisco, CA; ²Memorial Sloan-Kettering, New York, NY
Presented By: Matthew Cooperberg

Background: No adequate randomized trials comparing active treatment modalities for localized prostate cancer have been reported. We analyzed risk-adjusted cancer-specific mortality outcomes among men undergoing radical prostatectomy, external-beam radiation therapy, or primary androgen deprivation therapy.

Methods: The CaPSURE registry comprises men from 40 urologic practice sites followed prospectively under a uniform protocol, regardless of treatment. 7402 men with localized disease were analyzed. Prostate cancer risk was assessed using the Kattan preoperative nomogram and the Cancer of the Prostate Risk Assessment (CAPRA) score, both well-validated instruments calculated from clinical data at the time of diagnosis. A parametric survival model was constructed to compare outcomes across treatments, adjusting for risk and age.

Results: 219 men died of prostate cancer during follow-up. Adjusting for age and risk, the hazard ratio for cancer-specific mortality relative to prostatectomy was 2.3 (1.5-3.3) for radiation therapy, and 3.3 (2.2-5.0) for androgen deprivation therapy. Absolute differences between prostatectomy and radiation therapy were small for men at low risk, but increased substantially for men at intermediate and high risk. These results were robust to sensitivity analyses adjusting for neoadjuvant therapy, risk adjustment with the CAPRA score rather than Kattan nomogram, and examination of overall survival as the endpoint.

Conclusions: Surgery for localized prostate cancer was associated with a significant and substantial reduction in mortality relative to radiation or androgen deprivation monotherapy. Although not a randomized study, this analysis was adjusted for clinical risk and age, and it is unlikely that unmeasured confounders would account for the large observed differences in survival.
THE ASSOCIATION BETWEEN OXIDATIVE STRESS AND PROSTATE CANCER RISK IN MEN UNDERGOING PROSTATE BIOPSY
Daniel A. Barocas, Saundra Motley, Qi Dai, Ginger Milne, Jason Morrow, Michael S. Cookson, Joseph A. Smith, Jr. and Jay H. Fowke
Vanderbilt University Medical Center, Nashville, TN
Presented By: Daniel A. Barocas

Introduction and Objectives: Oxidative stress is implicated in prostate cancer (PCa) by the association of PCa with inflammation in the prostate. F2-Isoprostanes (F2IP), a COX-independent product of arachidonic acid peroxidation, is a validated marker of oxidative stress. We studied the relationship between F2IP levels and PCa and high-grade prostatic intraepithelial neoplasia (HGPIN).

Methods: This case-control analysis within the Nashville Men’s Health Study included men recruited at prostate biopsy. Body morphometrics, health history and urine were collected prior to biopsy. Of over 2000 participants, this study included all 140 patients with HGPIN and a random sample of 160 biopsy-negative controls and 200 PCa cases (100 Gleason 6; 100 Gleason 7-10). Urine F2IP was measured by gas chromatography/mass spectrometry and normalized to creatinine. F2IP levels and other characteristics were compared across diagnostic groups using Kruskal-Wallis and Fisher’s exact tests. Associations between F2IP level and HGPIN and PCa were tested with multinomial logistic regression, controlling for factors associated with PCa risk.

Results: Mean age was 66.9 (SD 7.2) and 10.1% were non-white. Patients differed across diagnostic groups (benign, HGPIN, PCa) with respect to PSA (median 5.0, 5.7, 6.2 ng/mL, p<0.01), positive DRE (3.1%, 0.7%, 8.7%, p<0.01) and prostate volume (median 47, 47, 40 cc, p<0.01), but were similar in terms of family history of PCa, NSAID use and BMI. F2IP levels were significantly higher in white men (median 1.76 vs. 1.43 ng/mg of creatinine, p=.03), but were not associated with age, family history, clinical stage, NSAID use, waist-to-hip ratio (WHR) or prostate volume. There were non-linear associations between F2IP levels and BMI (median 2.08, 1.62, 1.77 for BMI<25, 25 to <30, >30, p<.01) and PSA (median 1.82, 1.67, 1.85 for PSA<4, 4 to <10, >10, p=.08). On univariate analysis, F2IP levels were higher in patients with PCa (median 1.89) or HGPIN (1.83) than in those with benign biopsies (1.54), p=.03, but was similar across Gleason scores. After adjusting for age, race, WHR, BMI, NSAID use, prostate volume and PSA, F2IP level was significantly associated with HGPIN (OR 1.62, 95% CI [1.02-2.57], p=.04) and PCa (all cases: OR 1.65 [1.06-2.57], p=.03).

Conclusion: Pre-diagnosis urine F2-Isoprostane level is elevated in men with HGPIN or PCa, suggesting a role for oxidative stress in prostate carcinogenesis.

HER2 EXPRESSION STATUS PROVIDES INDEPENDENT PROGNOSTIC INFORMATION IN PATIENTS WITH UROTHELIAL CARCINOMA OF THE BLADDER
Shahrokh Shariat¹, Christian Bolenz², Daher Chade¹, Raheela Ashfaq², Richard Ho², Arthur Sagalowsky² and Yair Lotan²
¹Memorial Sloan-Kettering Cancer Center, New York, NY; ²UT Southwestern, Dallas, TX
Presented By: Shahrokh Shariat

Introduction: HER2 plays a fundamental role in cell growth, survival, and migration, and abnormal activation of HER2 has been proposed to lead to oncogenic transformation. HER2 is expressed in a proportion of urothelial cell carcinoma (UCB), making it a potential target for UCB therapy. However, the rates of HER2 positivity and the prognostic value of HER2 expression vary significantly between studies. The aim of the current study was to evaluate HER2 expression and its association with outcomes in a contemporary cohort of patients with UCB treated with radical cystectomy (RC).

Methods: Tissue microarrays of 198 patients were constructed and immunohistochemical staining was performed on the primary tumors and on lymphatic nodal metastases. All patients were treated with RC and regional lymphadenectomy for UCB. HER2 expression was assessed using continuous HER2 expression scores (ranging from 0.1 to 3.9) generated using an automated cellular imaging system. Scores ≥1.0 in at least 10% of tumor cells were regarded HER2 positive. We correlated HER2 scores with pathological and clinical parameters, including disease recurrence and cancer-specific mortality.
Results: Of 198 patients undergoing RC with lymphadenectomy, HER2 positivity was found in 55 primary tumors (27.8%) compared with 44.2% of the evaluable positive lymph nodes (p<0.001). HER2 positivity was significantly associated with the presence of lymphovascular invasion (LVI; p=0.026). With a median follow-up of 35.4 (range 1.3-176.1) months, 101 patients (51.0%) experienced UCB recurrence and 82 patients (41.4%) died from the disease. In multivariable analyses that adjusted for the effects of pathologic tumor stage, grade, LVI and lymph node metastasis, HER2 positive patients were at increased risk for both UCB recurrence (Hazard Ratio 1.681, p=0.048) and UCB-specific mortality (Hazard Ratio 1.513, p=0.049) compared to patients with negative HER2 expression.

Conclusion: A positive HER2 status is associated with aggressive bladder UCB and provides independent prognostic information for UCB recurrence and mortality. Assessment of HER2 status can be used to identify patients at high risk of disease progression who may benefit from adjuvant HER2-targeted mono- or combination therapy following RC.

Podium #3

MOLECULAR SUB-CLASSIFICATION OF RENAL EPITHELIAL NEOPLASMS
Thomas Sanford, Ariel Reinish, Paul Chung, Ramaprasad Srinivasan, W. Marston Linehan and Gennady Bratslavsky
Urologic Oncology Branch, National Cancer Institute, Bethesda, MD
Presented By: Thomas Sanford

Introduction and Objectives: Sub-classification of renal epithelial neoplasms poses a challenge to both pathologists and treating physicians. Despite the use of immunohistochemistry to distinguish the sub-classes of renal neoplasms, diagnostic accuracy is still suboptimal and frequently yields confusing results. In this study, we sought to improve the accuracy of sub-classification of renal cell carcinoma using molecular signatures.

Methods: We searched the Gene Expression Omnibus (GEO) database for publically available gene expression microarray datasets with multiple histologic sub-types of renal cortical neoplasms. The data were normalized and filtered using BRB array-tools (http://linus.nci.nih.gov/BRB-ArrayTools.html). Meta-analysis was performed to identify differentially expressed genes for each histologic subtype. The list of genes obtained from the meta-analysis was used to create 50-gene predictive signatures through a pair-based method. These predictive signatures were organized into an algorithm to sub-classify renal neoplasms based on molecular characteristics. The signatures were then validated on independent datasets identified in GEO. The training and validation datasets were obtained from different sources.

Results: We identified three GEO datasets that fit our criteria to develop a training set. The training set included 149 samples and consisted of 69 clear cell RCC, 41 papillary type 1 RCC, 16 chromophobe RCC, and 23 oncocytomas. From these samples, we created predictive signatures that were applied in sequential fashion according to our algorithm. We evaluated the performance of these signatures on a validation set comprised of data from five separate GEO datasets. We were able to correctly classify 68 of the 72 samples (94%) in our validation set. The correct classification by subtype was: 19/20 (95%) for clear cell, 14/14 (100%) for papillary, 17/19 (89%) for chromophobe, 18/19 (95%) for oncocytomas.

Conclusions: Through the use of meta-analytic techniques, we were able to create an algorithm that sub-classified renal neoplasms on a molecular level with 94% accuracy across multiple independent datasets. This algorithm may improve the accuracy of sub-classification of renal neoplasms, aid in selection of molecular therapies, and potentially allow for increased diagnostic yield by decreasing the number of “unclassified” or “indeterminate” renal tumors and biopsies.
Podium #4

SHORT-TERM ENDOCRINE THERAPY PRIOR TO AND DURING RADIATION THERAPY IMPROVES OVERALL SURVIVAL IN PATIENTS WITH T1b-T2b ADENOCARCINOMA OF THE PROSTATE AND PSA ≤20: INITIAL RESULTS OF RTOG 94-08

David G. McGowan1, MD; Daniel Hunt2, PhD; Christopher U. Jones3, MD; Mahul Amin4, MD; Mark H. Leibenhaut3, MD; Siraj M. Husian5, MD; Marvin Rotman6, MD; Luis Souhami7, MD; Howard Sandler4, MD; William U. Shipley8, MD

1Cross Cancer Institute, Edmonton, AB, Canada, 2American College of Radiology, Philadelphia, PA, 3Radiological Associates of Sacramento, Sacramento, CA, 4Cedars-Sinai Medical Center, Los Angeles, CA, 5Tom Baker Cancer Centre, Calgary, AB, Canada, 6State University of New York Health Science Center at Brooklyn, Brooklyn, NY, 7McGill University, Montreal, QC, Canada, 8Massachusetts General Hospital, Boston, MA

(Presented By: Howard Sandler)

Purpose & Objectives: To test if short-term endocrine therapy prior to and during radiation therapy will improve overall survival in patients with good prognosis, locally confined, adenocarcinoma of the prostate.

Materials & Methods: Patients with biopsy-proven T1b-T2b prostate cancer and PSA ≤20 were randomized to radiation therapy alone (RT) or to radiation and four months of total androgen suppression (H+RT) starting two months prior to RT, consisting of flutamide 250 mg PO tid with either monthly goserelin 3.6 mg SQ or leuprolide 7.5 mg IM. 46.8 Gy were delivered to the regional lymphatics followed by a 19.8 Gy prostate boost to 66.6 Gy. If surgical stage N0 or Gleason Score (G.S.) ≤5 with PSA ≤10, 68.4 Gy were delivered to the prostate only. All doses were prescribed to isocenter. Patients were to have prostate biopsies two years after completion of radiation. The primary endpoint was overall survival. Secondary endpoints included disease-free survival, local progression, distant metastases, biochemical failure, clinical relapse, second biochemical failure and disease-specific survival.

Results: From October 1994 to April 2001, 2028 patients were enrolled. 1979 eligible patients were randomized to H+RT (n=987) or RT (n=992). Pretreatment characteristics were balanced. Median age was 71 years. 964 patients (49%) had T1 tumors, 1015 (51%) had T2. 209 patients (11%) had PSA <4, 1770 (89%) had PSA 4-20. The G.S. was 2-6 in 1215 patients (61%), 7 in 538 (27%), 8-10 in 180 (9%) and unknown in 46 (2%). 1501 patients (76%) were white, 395 (20%) were black and 83 (4%) were of other race.

Median follow up time of all eligible patients was 8.4 years in the H+RT arm and 8.1 years in the RT arm. Estimated overall survival at 12 years was 51% in the H+RT arm and 46% in the RT arm. (p=0.03) Negative prognostic factors by Cox regression analysis included older age, G.S. ≥7 and non-white race. Re-biopsy was done in 439 of 987 patients in the H+RT arm; 344 (78%) of these were negative. In the RT arm, 404 of 992 patients had re-biopsy; 241 (60%) were negative. Acute radiation toxicity was similar in both arms (4%-5% Grade III, 1% Grade IV) as was late radiation toxicity (10%-13% Grade III, 1%-3% Grade IV, <1% Grade V). Hormonal toxicity was mainly liver and was Grade III in 4% and Grade IV in <1% of patients. Hormonal cardiovascular toxicity was Grade 1 in 12 patients (1%) and Grade 2 in one patient.

Conclusions: The addition of only four months of total androgen suppression given prior to and during radiation therapy significantly improved overall survival in patients with T1b-T2b adenocarcinoma of the prostate with PSA ≤20. Analysis of secondary endpoints and risk-stratified subsets continues and will help identify those patients most likely to benefit.

Funding: Supported by RTOG U10 CA21661, CCOP U10 CA3742 2 and Stat U10 CA32115 grants from the NCI.
Podium #5

ANTITUMOR ACTIVITY OF MDV3100 IN A PHASE 1-2 TRIAL IN CASTRATION RESISTANT PROSTATE CANCER CONDUCTED BY THE PROSTATE CANCER CLINICAL TRIALS CONSORTIUM

Howard Scher¹, Thomaz Beer², Celestia Higano³, Daniel Danila⁴, Bruce Montgomery³, Julia Shelkey⁵, Mohammad Hirmand⁶, David Hung⁶, Aseem Anand⁴, Martin Fleisher¹ and Charles Sawyers¹
¹Memorial Sloan-Kettering Cancer Center; ²Oregon Health Sciences University, Portland, OR; ³University of Washington, Seattle, WA; ⁴Memorial Sloan-Kettering Cancer Center, NY, NY; ⁵Memorial Sloan-Kettering Cancer Center, NY, NY; ⁶Medivation, San Francisco, CA
Presented By: Howard Scher

Background: MDV3100 is a novel oral androgen receptor (AR) antagonist that binds the AR with greater affinity than bicalutamide, and prevents nuclear translocation. Unlike bicalutamide, MDV3100 blocks DNA binding of AR, causing tumor cell apoptosis, and has no known agonist activity when AR is overexpressed. Antitumor activity of MDV3100 in a Phase 1-2 trial of castration-resistant prostate cancer (CRPC) was assessed by PSA, soft tissue and osseous disease, and circulating tumor cells (CTC).

Material and methods: Patients (pts) with progressive CRPC were enrolled in sequential cohorts of 3-6 pts at 30, 60, 150, 240, 360, 480, and 600 mg/day. Once the safety of a dose was established, enrollment was expanded at doses > 60 mg/day to include approximately 24 additional pts per cohort.

Results: 140 pts were enrolled. PSA declines (>50% from baseline) occurred in 62% (40/65) of chemotherapy-naïve (naïve) and 51% (38/75) of post-chemotherapy pts. 25 naive and 34 post-chemo pts had evaluable soft tissue disease at baseline. Partial responses were seen in 36% (9/25) of naïve and 12% (4/34) of post-chemo pts. Stable disease was observed in 44% (11/25) of naïve and 53% (18/34) of post-chemo pts. For pts with baseline bone lesions, there was evidence of radiographic stabilization in 63% (26/41) of naïve and 51% (35/68) of post-chemo pts. Median time to PSA progression was not reached in naïve pts and was 186 days for post-chemo pts. Median time to radiographic progression was not reached in naïve pts and 201 days in post-chemo pts. CTC counts on 60 of 65 naïve pts showed 91% (40/44) with favorable (<5) counts pretreatment were maintained post-treatment, while 75% (12/16) converted from unfavorable to favorable post-treatment. CTC counts on 68 of 75 post-chemo pts showed favorable retention in 91% (30/33) and unfavorable to favorable conversion for 37% (13/35). MDV3100 was generally well-tolerated with fatigue the most frequently reported adverse event. Only 1 subject discontinued treatment for fatigue, which coincided with disease progression. There were 2 witnessed seizures (1 each at 600 and 360 mg/day); both pts were taking concomitant medications that could cause seizures. The maximum tolerated dose was 240 mg/day.

Conclusions: MDV3100 is a promising candidate for both pre and post chemotherapy treated CRPC as assessed by PSA, imaging, and CTC in this Phase 1-2 study. A Phase 3 placebo-controlled survival trial in post-docetaxel CRPC pts is beginning this year.

Podium #6

A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTI-CENTER, PHASE III TRIAL OF SIPULEUCEL-T IN MEN WITH METASTATIC, CASTRATE RESISTANT PROSTATIC ADENOCARCINOMA

Leonard Gomella¹, Celestia Higano², David Penson³, Simon Hall⁴, Joseph Chin⁵, David McLeod⁶, Ron Israeli⁷, Robert Flanigan⁸, Chris Teigland⁹, Gerald Chodak¹°, Brian Miles¹¹, Mark Frohlich¹² and Paul Schellhammer¹³
¹Kimmel Cancer Center at Jefferson, Philadelphia, PA; ²Seattle Cancer Care Alliance, Seattle, WA; ³Vanderbilt Department of Urologic Surgery, Nashville, TN; ⁴Mount Sinai School of Medicine, New York, NY; ⁵London Health Sciences Centre, London, ON, Canada; ⁶Walter Reed Army Medical Center, Washington, DC; ⁷State University of New York, Stony Brook, NY; ⁸Loyola University, Chicago, IL; ⁹McKee Department of Urology at Carolinas Medical Center, Charlotte, NC; ¹°Midwest Prostate and Urological Healthcare Center, Chicago, IL; ¹¹The Houston Prostate Institute, Houston, TX; ¹²Dendreon Corporation, Seattle, WA; ¹³Department of Urology, Eastern Virginia Medical School, Norfolk, VA
Presented By: Leonard Gomella

Introduction and Objectives: Sipuleucel-T (APC8015, Provenge®) is a patient specific autologous cell product consisting of antigen presenting cells loaded with a recombinant fusion protein composed of prostatic acid phosphatase linked to GM-CSF. Reported here is final overall survival (OS) data from the randomized Phase III trial, D9902B (IMPACT). The primary objective was to assess the safety and efficacy of sipuleucel-T in prolonging survival of men with metastatic castrate resistant prostate cancer.
**Methods:** 512 patients with asymptomatic or minimally symptomatic, metastatic, castrate resistant prostate cancer were randomized (2:1) to receive sipuleucel-T (N=341) or placebo (N=171) intravenously every 2 weeks x 3. The primary endpoint was overall survival. The primary analysis used a stratified Cox regression model adjusted for PSA and LDH.

**Results:** Patient demographics and baseline characteristics were well balanced between treatment arms. Patients on the sipuleucel-T arm experienced a 22.5% reduction in the risk of death (HR=0.775; 95% CI: 0.614, 0.979; p=0.032). Median survival in the sipuleucel-T arm was 25.8 months vs. 21.7 for placebo arm, a 4.1 month difference. The survival probability at 36 months following treatment was 31.7% for the sipuleucel-T arm vs. 23.0% for placebo. The treatment effect was consistent across multiple patient subsets; it remained consistent using the log rank test and an unadjusted Cox model (HR=0.766, p=0.023) and after adjustment for docetaxel use following investigational therapy (HR=0.763; p=0.036). The adverse events seen more commonly in sipuleucel-T treated patients included chills (54.1%), pyrexia (29.3%), and headache (16.0%). Only 1.2% of patients withdrew from therapy due to an adverse event.

**Conclusions:** Sipuleucel-T is the first active cellular immunotherapy to demonstrate a statistically significant and clinically meaningful improvement in overall survival for cancer and demonstrates a favorable benefit to risk profile for men with metastatic, castrate resistant prostate cancer. It has the potential to create a new paradigm for the treatment of advanced prostate cancer.

**Funding:** This study was funded by Dendreon Corporation

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**Podium #7**

**TOREMIFENE IMPROVES PSA PROGRESSION FREE SURVIVAL IN CASTRATE MEN WITH DETECTABLE BASELINE PSA LEVELS**

Dan Lin¹, Michael Brawer², Mitchell Steiner², Ronald Morton², Domingo Rodriguez², Gary Barnette², Michael Hancock² and Evan Yu¹

¹University of Washington Medical Center, Seattle, Washington; ²GTx, Inc., Memphis, Tennessee

Presented By: Evan Yu

**Purpose:** We conducted a double blind, randomized, placebo controlled trial to determine if toremifene 80 mg could prevent fractures in men on ADT. We also assessed the effect of toremifene on PSA progression free survival in a subset of men at the highest risk for progression.

**Patients and Methods:** 1,389 men were randomized at 150 sites in the US and Mexico to placebo or toremifene 80 mg oral once daily for 2 years. All subjects had histologic documentation of prostate cancer, were on ADT for ≥ 6 months, had a serum PSA ≤4 ng/mL, Zubrod PS ≤1 and were either >70 years of age or were at or below WHO thresholds for spine or hip (BMD). In the modified intent to treat analysis, 970 subjects received at least one dose of study drug and had at least one on-treatment radiograph. To evaluate the population at greatest risk for progression, only subjects with a detectable PSA of ≥0.1 ng/mL at the time of randomization were analyzed for PSA progression free survival. PSA progression was defined by a rise in PSA level of ≥25% increase over baseline and to >2 ng/mL.

**Results:** Four hundred nineteen (419) subjects were eligible for this analysis (204 toremifene and 215 placebo). Median progression free survival was not reached in either arm. The exact duration of ADT is known for 391. Subjects and additional statistical analysis was performed using this population. After 2 years of treatment, 51 of 187 (27.2%) developed PSA progression in the toremifene arm and 76 of 204 (37.3%) developed PSA progression in the placebo arm (p=0.043, log rank test). Among the 391 patients, there were no significant differences between the two arms in regards to age (p=0.88), race (p=0.33), years on ADT at baseline (p=0.38), baseline serum testosterone levels (p=0.61), and serum PSA level at baseline (p=0.18).

**Conclusions:** In addition to a demonstrated fracture benefit, toremifene may also offer antitumor activity for men receiving ADT for prostate cancer and who have a detectable PSA at baseline, as measured by 2-year PSA progression-free survival. Additional studies in a population of men with higher risk of prostate cancer progression should be considered.
Podium #8

NEPHRECTOMY INDUCED CHRONIC RENAL INSUFFICIENCY IS ASSOCIATED WITH INCREASED RISK OF CARDIOVASCULAR DEATH AND DEATH FROM ANY CAUSE IN PATIENTS WITH LOCALIZED RENAL MASSES

Christopher Weight, Benjamin Larson, Amr Fergany, Tianming Gao, Brian Lane, Steven Campbell, Jihad Kaouk and Eric Klein
Cleveland Clinic, Cleveland, OH
Presented By: Christopher Weight

Background: Radical nephrectomy (RN) has traditionally been preferred to partial nephrectomy (PN) in patients with localized renal cell cancer (RCC) because of its simplicity and established cancer control. Recent data suggest that these patients have significant competing risks of death, some of which may be escalated by chronic renal insufficiency. We therefore compared overall survival (OS), cancer specific survival (CSS) and cardiac specific survival in patients undergoing PN or RN for cT1b tumors.

Methods: From 1999-06, 1004 patients with renal masses between 4 and 7 centimeters underwent extirpative surgery, PN (n=524) or RN (n=480). We generated a propensity model based on pre-operative patient characteristics and then modeled survival with the additional variables of pathologic stage and new baseline renal function.

Results: CSS was equivalent for those treated with PN or RN on multivariate analysis. Those undergoing RN lost significantly more renal function than those undergoing PN. The average excess loss of renal function observed with RN was associated with a 25% (95% CI: 3-73) increased risk of cardiac death and 17% (95% CI: 12-27) increased risk of death from any cause on multivariate analysis.

Conclusions: PN offers equivalent CSS to RN and is technically feasible in the majority of patients with cT1b tumors. Preservation of renal function was significantly better in patients treated by PN. Postoperative renal insufficiency was a significant independent predictor of overall and cardiovascular specific survival and efforts should be made to limit the renal function loss associated with surgery for localized renal masses.

Podium #9

FACTORS ASSOCIATED WITH MANAGEMENT OF SMALL RENAL MASSES: A SURVEY OF THE AMERICAN UROLOGICAL ASSOCIATION

Rodney Breau¹, Paul Crispen², R. Houston Thompson¹, Michael Blute¹ and Bradley Leibovich¹
¹Mayo Clinic, Rochester, MN; ²University of Kentucky, Lexington, KY
Presented By: Rodney Breau

Introduction: The benefits and harm of nephron sparing surgery (NSS) have been extensively investigated. Despite overwhelming evidence in favor of NSS, most patients with a small renal mass are treated with radical nephrectomy (RN).

Methods: In May 2009, AUA members were solicited to complete an online survey. Respondents were asked to rate the importance of several patient and tumor characteristics and were asked their preferred choice of treatment of a healthy 68 year-old patient with a normally functioning contralateral kidney with a solitary, sporadic T1a renal mass of varied size and location. In each case, computed tomographic axial and schematic coronal images were provided.

Results: 772 active urologists with varied training background and clinical practice setting completed the survey. Many respondents (476; 62%) evaluate over 10 newly diagnosed small renal masses per year and most perform or refer patients for radical nephrectomy (728; 94%), partial nephrectomy (681; 88%), tumor ablation (568; 74%) and active surveillance (683; 88%) When asked which factors are important contributors to the decision for radical nephrectomy versus NSS (partial nephrectomy or ablation), most believed tumor size (591; 77.2%), location (676; 88.1%) and pre-operative renal function (669; 87.1%) were important, while fewer cited age (347; 45%) and medical comorbidities (481; 62%). When asked about factors associated with the decision to actively survey patients, almost all urologists believed size (655; 85%), age (661; 86%), comorbidities (691; 90%), solitary kidney (565; 74%) and growth pattern (585 (78%) were important considerations, but there were varied opinions regarding the importance of location, pre-operative renal function, legal ramifications, prior surgery and tumor biopsy results. The respective proportions of urologists who chose radical nephrectomy for a 2 or 4 cm tumor were: 79 (10%) and 603 (78%) if endophytic mid-pole, 26 (3%) and 77 (10%) if exophytic mid-pole, 223 (29%) and 523 (68%) if hilar and 30 (4%) and 24 (3%) if exophytic lower pole.

Conclusions: Most urologists offer a variety of management options for patients with small renal masses and there appears to be some consensus about the importance of several factors when counseling patients. Tumor size and location appear to strongly influence the decision to perform NSS and RN remains a preferred treatment option in select patients.
Podium #10

EFFICACY AND SAFETY OF INTRA VESICAL VALRUBICIN IN PATIENTS WITH CARCINOMA IN SITU OF THE BLADDER REFRACTORY TO BACILLUS CALMETTE-GUÉRIN: A PHASE III OPEN-LABEL, MULTICENTER STUDY

Gary Steinberg
The University of Chicago
Presented By: Gary Steinberg

Introduction and Objectives: Carcinoma in situ of the bladder (CIS-B) is a frequently aggressive form of bladder cancer. Invasive disease develops in 40% to 60% patients (pts) within 5 years of diagnosis. Limited medical therapy is available for bacillus Calmette-Guérin (BCG) refractory CIS-B pts. Valrubicin, a lipid-soluble doxorubicin analogue was recently reintroduced as a treatment option for BCG refractory CIS-B. Phase III study results previously published of 90 IVe valrubicin treated pts are discussed.

Methods: Pts had ≥2 prior IVe therapies for CIS-B including at least one course of BCG with pathologic confirmation of non-muscle invasive bladder cancer recurrence. Each pt received 800 mg valrubicin instillations once weekly for 6 weeks, with primary disease evaluation (PDE) 6 weeks after last dose and then every 3 months until recurrence.

Results: Of the 90 evaluable patients most were male (88%), white (98%), mean age 68 years, and 80% had history of smoking. Mean bladder cancer duration at baseline was 5 years; 28% had 3 or more prior IVe therapy courses (70% ≥2 BCG courses) and 82% had 4 or more TURBTs; 16/90 pts (18%) had documented complete response and 10 pts without complete response showed a reduction in tumor grade. The number of patients who derived clinical benefit with valrubicin treatment in this refractory study population was 26/90 pts (29%). 10/90 pts (11%) developed muscle invasive and/or metastatic bladder cancer during follow-up. Local bladder symptoms (LBS) were present in 45% pts at enrollment and 88% during therapy, most commonly urinary frequency (61%), urgency (57%), and dysuria (56%). 2% of pts did not complete therapy because of LBS. Systemic adverse events other than LBS were mild in nature, self-limited, and not life-threatening.

Conclusions: In this difficult to treat study population IVe valrubicin provided an effective and tolerable alternative to cystectomy for some heavily pretreated patients with BCG refractory CIS-B.

Funding: This study was conducted by the Valrubicin Study Group, funded by Anthra Pharmaceuticals. Further analysis is now supported by ENDO Pharmaceuticals.

Podium #11

ASSESSING THE CLINICAL BENEFIT OF NMP22 IN THE SURVEILLANCE OF PATIENTS WITH NON-MUSCLE-INVASIVE BLADDER CANCER: A DECISION-CURVE ANALYSIS

Shahrokh Shariat, Caroline Savage, Pierre Karakiewicz, Daher Chade, Guilherme Godoy, KianTai Chong and Andrew Vickers
Memorial Sloan-Kettering Cancer Center, New York, NY
Presented By: Shahrokh Shariat

Purpose: The expense of cystoscopy and inadequate sensitivity of cytology have led to a search for non-invasive urinary markers. Several studies have shown that abnormal NMP22 is associated with bladder cancer leading to its approval by the FDA. Nonetheless, although statistically significant, the clinical significance of NMP22 remains unclear. We applied decision-curve analysis to determine whether NMP22 improves medical decision-making during monitoring of patients with a history of bladder cancer.

Methods: The study comprised 2,222 patients from 11 institutions who presented with history of non-muscle invasive bladder cancer and a current negative cytology result. We created statistical models to predict cancer recurrence and progression (muscle-invasive stage) using NMP22 levels, age and gender. Clinical net benefit was calculated by summing the benefits (true positives) and subtracting the harms (false positives), weighting these by the threshold probability of a disease at which a patient or clinician would opt for cystoscopy.
**Results:** 581 (26%) patients were found to have cancer after cystoscopy. NMP22 level was significantly associated with bladder cancer recurrence and progression (p<0.001 for both). For cancer recurrence, NMP22 offered a superior net benefit over the strategy of performing cystoscopy on everyone at threshold probabilities above 15%. For cancer progression (figure; grey line: cystoscopy for all), NMP22 (dashed line) offered a clinical net benefit over the strategy of performing cystoscopy on everyone at threshold probabilities above 2%.

**Conclusions:** Decision-curve analysis is a simple, novel method of evaluating alternative diagnostic and prognostic strategies that provides clear data on clinical value. For very risk-averse clinicians, who would perform a cystoscopy at a threshold of 10% for recurrence or 1% for progression, NMP22 will not aid clinical decision-making. For less clinicians who would only perform a cystoscopy at a threshold probability >15% for recurrence or >2% for progression, NMP22 can help determine which patients require immediate cystoscopy and which can be spared this procedure.
Poster# 1

**A PHASE II STUDY OF CEDIRANIB (AZD2171) IN POST-DOCETAXEL, CASTRATION-RESISTANT PROSTATE CANCER (CRPC)**

David Adelberg¹, Joyson Karakunnel¹, James Gulley¹, Philip Arlen¹, Howard Parnes², David Kohler³, Peter Choyke⁴, Douglas Price⁵, John Wright⁶, Ramaprasad Srinivasan⁷, Marcia Mulquin¹, Seth Steinberg⁸, William Figg⁹, William Dahut¹

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Presented By: David Adelberg

**Introduction:**
Currently, there is no agent that prolongs survival in CRPC patients once the disease progresses on docetaxel. Thus, alternative and novel treatments are needed. Angiogenesis mediated through vascular endothelial growth factor-A (VEGF) signaling plays an important role in prostate cancer progression. Cediranib (AZD-2171) is an orally bioavailable small molecule inhibitor of the pro-angiogenic VEGF receptor tyrosine kinases Flt-1 (VEGFR-1) and KDR (VEGFR-2).

**Methods:**
Primary objective is 30% progression free survival at 6 months by radiographic and clinical assessment, excluding PSA criteria. Secondary objectives include assessment of vascular flow via DCE-MRI, PSA response rate and overall response rate. Eligibility requires CRPC disease progression on prior docetaxel but does not limit number of prior chemotherapy regimens. Simon two-stage trial design requires at least 2 of 12 patients in first cohort be progression-free at 6 months. Enrollment then proceeds to a total of 35 evaluable patients, all of who receive cediranib monotherapy, 20 mg daily over a 28-day cycle. Once two-stage design completed, an additional 23 patients receive prednisone 10 mg daily over a 28-day cycle. Once two-stage design completed, an additional 23 patients receive prednisone 10 mg daily in combination with cediranib.

**Results:**
Fifty-three of a planned 58 patients have been enrolled with six patients currently on active treatment (2 weeks –7 months). In the first cohort, 13 of 24 patients with measurable soft tissue disease had evidence of tumor regression, with four of these patients meeting criteria for partial response. In the second cohort, 6 of 10 patients with evaluable disease had tumor shrinkage with two patients qualifying for partial response. Decreases in metastatic disease were seen in lymph nodes, lung, liver and bone in both cohorts. PSA levels have increased dramatically in some patients with tumor responses. Adverse events have been similar to other drugs in this class and include hypertension, dysphonia and fatigue. Most common grade 3 toxicities have included fatigue (8), dehydration (5), muscle weakness (5) hyponatremia (6), lymphopenia (6), anemia (4), anorexia (3) transaminitis (3), and elevated alkaline phosphatase (8). Addition of prednisone did not significantly alter the constitutional toxicities.

**Conclusion:**
The safety profile and activity makes cediranib a promising drug in highly pretreated patients with CRPC that progressed despite docetaxel. Data suggests that cediranib may have direct effects on the microcirculation and vasculature.

**Poster# 2**

**A PHASE I CLINICAL STUDY OF HIGH-DOSE KETOCONAZOLE PLUS WEEKLY DOCETAXEL IN METASTATIC CASTRATION-RESISTANT PROSTATE CANCER**

Wenhui Zhu¹, Sukyung Woo², Xiaohong Chen², Atinuke Ajiboye³, Seth Steinberg⁴, Douglas Price⁵, John Wright⁶, Howard Parnes⁶, Philip Arlen⁴, James Gulley⁴, William Figg⁹, William Dahut⁷ and William Figg⁹

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Presented By: Wenhui Zhu

**Introduction & Objectives:**
High-dose ketoconazole and docetaxel have shown activity as single agents against castration-resistant prostate cancer (CRPC). The goal of this phase I study was to determine the maximum tolerated doses, side effects, and pharmacokinetic interaction of coadministered docetaxel and ketoconazole.
Methods: Patients with metastatic CRPC received weekly docetaxel for 3 of every 4 weeks, plus daily ketoconazole. Pharmacokinetic studies were performed on day 1 (docetaxel alone) and day 16 (after ketoconazole).

Results: The study enrolled 42 patients at 9 different dose levels. The combination regimens investigated included docetaxel weekly for three weeks out of four escalating from 5 to 43 mg/m², with starting doses of ketoconazole of 600, 800, or 1200 mg/day. Declines in prostate-specific antigen of ≥ 50% were seen in 62% of patients. Of 25 patients with soft tissue disease, 7 (28%) had partial response. Median overall survival was 22.8 months, and was significantly greater in docetaxel-naïve patients than in patients pretreated with docetaxel (36.8 vs. 10.3 months; P = 0.0001). The most frequently observed adverse events were anemia, edema, fatigue, diarrhea, nausea, sensory neuropathy, and elevated liver function tests. The fractional change in docetaxel clearance correlated significantly with ketoconazole exposure (P < 0.01). Concomitant ketoconazole increased docetaxel exposure 2.6-fold with 1200 mg/day, 1.6-fold with 800 mg/day, and 1.3- to 1.5-fold with 600 mg/day.

Conclusions: Results suggest that the combination of weekly docetaxel and ketoconazole has significant antitumor activity in CRPC with manageable toxicities. The extremely long survival in the docetaxel-naïve cohort (36.8 months) warrants additional larger trials of docetaxel with ketoconazole or possibly CYP17A1 inhibitors such as abiraterone.

# Poster# 3

THE ECONOMIC BURDEN OF PROSTATE CANCER SURVIVORSHIP CARE
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Presented By: Ted Skolarus

Introduction: Most men live with rather than die from prostate cancer. As a result, survivors have a protracted course harboring considerable clinical and economic implications. For this reason, we investigated the extent to which health services utilization and expenditures varied during continuing care for prostate cancer.

Methods: We identified 105,918 patients diagnosed with prostate cancer between 1992 and 2005 using SEER-Medicare data. All Medicare payments for prostate cancer-related care following diagnosis were assigned to a phase of care (initial, continuing care, end-of-life), adjusted and summed in 2005 dollars. Overall and annual per-capita expenditures by phase of care were measured. Next, patients were sorted into five equally sized groups according to their average annual per-capita continuing care survivorship expenditures. Health services utilization during the continuing phase of care was examined for each quintile.

Results: In absolute terms, initial phase prostate cancer care comprised the greatest expenditure burden over the study period at $843,632,376 (59%), followed by continuing care, $441,289,205 (31%), and end-of-life care, $142,921,738 (10%). However, continuing care represented the longest phase of care both individually and collectively during the study period. The average estimated annual per capita continuing care phase expenditures were $1,435. Thus, after eight years of survival following diagnosis (i.e., seven in the continuing care phase), per-capita continuing care expenditures of $10,045 exceeded those of initial care at $8,796, on average. The most common prostate cancer-related services across all expenditure groups were office visits, followed by urinary and PSA testing and androgen deprivation therapy injections. Each of these services increased across the expenditure groups. (Table 1)

Conclusions: Wide variation exists in health services utilization and expenditures for prostate cancer survivors with continuing care representing over 30% of total spending. Better understanding the drivers of prostate cancer care during this protracted phase of survivorship may reveal opportunities to decrease the cost and improve the quality of care for survivors.
THE EFFECT OF RACE ON THE DISCRIMINATORY ACCURACY OF MODELS TO PREDICT BIOCHEMICAL RECURRENCE AFTER RADICAL PROSTATECTOMY: RESULTS FROM THE SEARCH AND DPC DATABASES

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Presented By: Daniel Moreira

Introduction: African American men (AAM) bear a disproportional burden of prostate cancer. Given the significant racial disparities between AAM and Caucasian men (CM), it is not clear whether the currently available models to predict biochemical recurrence (BCR) after radical prostatectomy, which were developed from datasets composed predominantly of CM, are as accurate among AAM as in CM. Therefore, we sought to evaluate whether race modifies the accuracy of nomograms to predict BCR after radical prostatectomy among subjects from the Shared Equal Access Regional Cancer Hospital (SEARCH) and Duke Prostate Cancer (DPC) databases.

Materials and Methods: Retrospective analysis of 1,721 and 4,511 subjects from the SEARCH and DPC cohorts, respectively. Comparison of baseline patients’ and disease characteristics between AAM and CM was performed using chi-square for categorical data and rank-sum for continuous variables. The univariable association between race and BCR-free survival was analyzed using Kaplan-Meier plots and log-rank test. The discrimination accuracy for BCR of 7 previously published predictive models was assessed using concordance index and compared between AAM and CM.

Results: AAM represented 44% of SEARCH and 14% of DPC. In both cohorts, AAM were younger, had a higher preoperative PSA and were more likely to experience BCR than CM (all P<0.01). In SEARCH, the mean concordance index across all 7 models was lower in AAM (0.683) than CM (0.714), though the mean difference between CM and AAM was modest (0.031; range 0.015-0.059). In DPC the overall mean concordance index for BCR across all 7 nomograms was 0.692. In contrast to SEARCH, the mean concordance index in DPC was higher in AAM (0.728) than CM (0.686), though the mean difference between CM and AAM was also modest (-0.042; range -0.078 to -0.025).

Conclusion: Across all 7 models for predicting BCR, the discriminatory accuracy was better among CM in SEARCH and better among AAM in DPC. The mean difference in discriminatory accuracy of all 7 nomograms between AAM and CM was approximately 3-4%. This indicates that currently used predictive models have similar performances among CM and AAM. Therefore, the currently available nomograms predicting BCR after radical prostatectomy represent a valid and accurate method to predict recurrence regardless of race.
Poster Session I

Poster# 5

COMPARATIVE EFFECTIVENESS OF SURGICAL TREATMENTS FOR PROSTATE CANCER: A POPULATION-BASED ANALYSIS OF POSTOPERATIVE OUTCOMES
William Lowrance, James Eastham, Lindsay Jacks, David Yee, Thomas Jang, Vincent Laudone, Bertrand Guillonneau, Peter Scardino and Elena Elkin
Memorial Sloan-Kettering Cancer Center, New York, NY
Presented By: William Lowrance

Introduction and Objectives: Enthusiasm for laparoscopic surgical approaches to prostate cancer treatment has grown, despite limited evidence of improved outcomes compared with open radical prostatectomy. We compared laparoscopic (with or without robotic assistance) versus open radical prostatectomy in terms of postoperative outcomes and subsequent cancer-directed therapy.

Methods: Using a population-based cancer registry linked with Medicare claims, we identified men age 66 or older with localized prostate cancer who received a radical prostatectomy from 2003-2005. Outcome measures were general medical/surgical complications and mortality within 90 days following surgery; genitourinary/bowel complications within 365 days; receipt of radiation therapy, androgen deprivation therapy or both within 365 days; length of hospital stay.

Results: Of the 5,923 men, 18% received a laparoscopic radical prostatectomy. Adjusting for patient and tumor characteristics, there were no differences in rates of general medical/surgical complications (OR 0.93; 95% CI: 0.77-1.14) or genitourinary/bowel complications (OR 0.96; 95% CI: 0.76-1.22) or in the use of postoperative radiation, androgen deprivation or both (OR 0.80; 95% CI: 0.60-1.08). Laparoscopic prostatectomy was associated with a 35% shorter hospital stay (p<0.0001) and a lower rate of bladder neck/urethral obstruction (OR 0.74; 95% CI 0.58-0.94). In laparoscopic patients, surgeon volume was inversely associated with length of hospital stay and the odds of any genitourinary/bowel complication.

Conclusions: Laparoscopic and open radical prostatectomy have similar rates of postoperative morbidity and use of additional treatment. Men considering prostate cancer surgery should understand the expected benefits and risks of each technique to facilitate decision-making and to set realistic expectations.

Funding: This work was supported in part by funds from the National Institutes of Health [T32-CA82088 to P.S. and W.L.]; the National Cancer Institute [P50-CA92629 SPORE to P.S., CA118189-01A2 to E.E]; Sidney Kimmel Center for Prostate and Urologic Cancers; and David H. Koch provided through the Prostate Cancer Foundation.

Poster# 6

ETHNIC VARIATION IN PELVIMETRIC MEASURES AND ITS IMPACT ON APICAL POSITIVE SURGICAL MARGINS AT RADICAL PROSTATECTOMY
Christian von Bodman¹, Mika Matikainen², Luis Herran Yunis³, Fernando Secin³, Kinjal Vora³, Bertrand Guillonneau³, Vincent Laudone³, James A. Eastham³, Peter T. Scardino³, Oguz Akin⁴ and Farhang Rabban³
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Presented By: Christian von Bodman

Background: Previous reports have reported that African-American (AA) men have a higher apical positive surgical margin (PSM) rate at radical prostatectomy (RP). It remains unclear whether an anatomically smaller pelvis in AA men might present more of a technical challenge for the apical dissection and thereby be a significant factor predicting apical PSM.

Objective: Evaluation of the ethnic variation in pelvimeterity and its impact as a predictor of apical PSM.

Materials and Methods: We identified 482 consecutive Caucasian men in our prospective database with preoperative prostate MRI imaging undergoing RP (open (RRP) or laparoscopic (LRP)) without prior treatment between July 2003 and January 2005 by one of five dedicated prostate surgeons and 103 consecutive AA men with preoperative MRI undergoing RP between November 2001 and June 2007. Using T1- and T2- weighted MRI images we measured various bony and soft tissue dimensions to evaluate the pelvic inlet and midplane as well as prostate size and apical depth. Analysis of covariance was performed with ethnicity as a fixed factor, surgeon and prostatectomy approach as random factors and age and body mass index (BMI) as covariates to determine the effect on the midpelvic area. Multivariate logistic regression analysis for prediction of apical PSM was performed using preoperative variables alone including pelvimetric measures as well as a model including postoperative variables as well.
Results: The midpelvic area was significantly less in AA than Caucasian men: 78.5 (IQR 72.4, 86.7) cm² versus 83.9 (IQR 77.3, 90.7) cm², respectively (p=0.004). African-American men had a significantly steeper symphysis pubis angle as well as smaller anteroposterior diameter at the pelvic inlet and narrower transverse diameter at the midpelvis and consequently a smaller midpelvic area. Ethnicity and BMI were found to have a significant effect on the midpelvic area. Apical depth of the prostate was identified as a significant independent predictor of apical PSM with a more pronounced effect in AA men.

Conclusion: African-American men have a significantly smaller midpelvic area. The adverse impact of a deep pelvis, as measured by the apical prostatic depth, on apical PSM was found to be greater in AA men. Evaluation of pelvic dimensions and prostate parameters in preoperative MRI imaging might influence surgical planning.

Poster# 7

EXTERNAL BEAM RADIOTHERAPY FOR PROSTATE CANCER DOES NOT INCREASE THE RISK OF HIP FRACTURE
Shaheen Alanee¹, Sean Elliott², Stephanie Jarosek³ and Beth Virnig³
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Presented By: Shaheen Alanee

Background: Hip fracture results in high morbidity and mortality. Treatment of prostate cancer with androgen suppression therapy (AST) is associated with osteoporotic hip fractures. External beam radiotherapy (EBRT) is associated with hip fractures in women. EBRT is frequently combined with AST in the treatment of prostate cancer. We tested the hypothesis that EBRT is a risk factor for hip fractures but not generalized fractures in men with prostate cancer. To do this we sought to compare the cumulative incidence of hip and generalized fractures in men treated with EBRT either alone or in combination with AST to men not treated with EBRT.

Methods: 35,027 men ≥66 years, diagnosed with prostate cancer 1999-2001 were identified from the SEER-Medicare database. The primary outcome of hip fracture risk was compared among men in the following treatment groups: (1) AST, (2) EBRT, (3) AST+EBRT or (4) neither. A secondary outcome was generalized fractures. A pre-planned subset analysis of hip and generalized fracture risk in men with locally advanced prostate cancer was done.

Results: EBRT use does not increase the risk of fractures and combination therapy carries no additional risk beyond AST alone. As previously reported, AST doubles the risk of hip and generalized fractures. We found no change in the risk of fractures between men with low risk and high-risk cancer. Age and comorbidities did not change this association.

Conclusion: EBRT, either alone or in combination with AST, is not a risk factor for hip fractures. In particular, in locally advanced prostate cancer for which EBRT+AST is standard of care, adding EBRT to AST does not increase the risk of hip fracture above that of AST alone.

Poster# 8

COMPARATIVE RISK-ADJUSTED MORTALITY OUTCOMES FOLLOWING PRIMARY SURGERY, RADIATION THERAPY, AND ANDROGEN DEPRIVATION THERAPY FOR PROSTATE CANCER
Matthew Cooperberg¹, Andrew Vickers², Jeanette Broering¹ and Peter Carroll¹
¹UCSF, San Francisco, CA; ²Memorial Sloan-Kettering, New York NY
Presented By: Matthew Cooperberg

Background: No adequate randomized trials comparing active treatment modalities for localized prostate cancer have been reported. We analyzed risk-adjusted cancer-specific mortality outcomes among men undergoing radical prostatectomy, external-beam radiation therapy, or primary androgen deprivation therapy.
**Methods:** The CaPSURE registry comprises men from 40 urologic practice sites followed prospectively under a uniform protocol, regardless of treatment. 7402 men with localized disease were analyzed. Prostate cancer risk was assessed using the Kattan preoperative nomogram and the Cancer of the Prostate Risk Assessment (CAPRA) score, both well-validated instruments calculated from clinical data at the time of diagnosis. A parametric survival model was constructed to compare outcomes across treatments, adjusting for risk and age.

**Results:** 219 men died of prostate cancer during follow-up. Adjusting for age and risk, the hazard ratio for cancer-specific mortality relative to prostatectomy was 2.3 (1.5-3.3) for radiation therapy, and 3.3 (2.2-5.0) for androgen deprivation therapy. Absolute differences between prostatectomy and radiation therapy were small for men at low risk, but increased substantially for men at intermediate and high risk. These results were robust to sensitivity analyses adjusting for neoadjuvant therapy, risk adjustment with the CAPRA score rather than Kattan nomogram, and examination of overall survival as the endpoint.

**Conclusions:** Surgery for localized prostate cancer was associated with a significant and substantial reduction in mortality relative to radiation or androgen deprivation monotherapy. Although not a randomized study, this analysis was adjusted for clinical risk and age, and it is unlikely that unmeasured confounders would account for the large observed differences in survival.

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**Poster Session I**

**Poster# 9

IS THE CANCER OF THE PROSTATE RISK ASSESSMENT (CAPRA) SCORE READY FOR THE PRIME TIME AS A PROSTATE CANCER STAGING TOOL?**

Stacy Loeb¹, Gustavo Carvalhal², Donghui Kan², Angel Desai² and William Catalona²

¹Johns Hopkins, Baltimore, MD; ²Northwestern University, Chicago, IL

Presented By: Stacy Loeb

**Purpose:** The University of California San Francisco Cancer of the Prostate Risk Assessment (UCSF CAPRA) is a staging system that uses clinical variables to generate a score ranging from 0 to 10. Our objective was to perform an external validation of the CAPRA score as a predictor of 5-year recurrence-free survival in a single surgeon radical retropubic prostatectomy (RRP) series.

**Materials and Methods:** From 2003 to 2009, we examined the association between preoperative CAPRA score (0-10) and biochemical progression-free survival (PFS) in 990 men who underwent RRP by a single surgeon.

**Results:** CAPRA scores were significantly associated with the risk of early biochemical progression in our series. For example, 5-year PFS was markedly different for scores at the extremes of 0 to 1 versus ≥7 (95% vs. 40%, respectively). The concordance index was 0.764 for the prediction of biochemical progression using CAPRA scores in this cohort, which compares favorably with the concordance index of 0.66 in the original CaPSURE dataset.

**Conclusions:** Our results validate the UCSF-CAPRA score as a significant predictor of 5-year PFS in a single surgeon series. The CAPRA score is a simple preoperative tool that can be readily applied in clinical practice to help risk-stratify prostate cancer patients.
**Poster# 10**

**POSITIVE SURGICAL MARGINS AT RADICAL PROSTATECTOMY PREDICT PROSTATE CANCER-SPECIFIC MORTALITY: SUPPORT FOR OPTIMIZING SURGICAL TECHNIQUE AND PATHOLOGICAL EVALUATION AT RADICAL PROSTATECTOMY**

Jonathan L. Wright¹, Bruce L. Dalkin², Lawrence D. True², William J. Ellis², Janel L. Stanford², Paul H. Lange² and Daniel W. Lin²

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Presented By: Jonathan L. Wright

**Purpose:** Positive surgical margins (PSM) in men undergoing radical prostatectomy (RP) for prostate cancer (PCa) are associated with an increased risk of biochemical recurrence. Little data have evaluated the role of PSM in PCa-specific mortality (PCSM). Using a large, population-based national cancer registry, we evaluate the risk of PCSM associated with margin status.

**Methods:** The SEER cancer registry data for patients diagnosed in 1998–2002 were used to identify men undergoing RP for PCa. Margin status, pathologic stage, Gleason grade and post-operative radiation therapy were recorded along with demographic data. Multivariate Cox regression analysis was used to estimate the risk of PCSM associated with PSMs.

**Results:** A total of 66,463 patients comprised the cohort in which 343 (0.52%) PCa-specific deaths occurred over an average follow-up of 50 months. PSMs were reported in 21.5% and were more common in pT3a than pT2 tumors (45% vs. 18%, p<0.001) and higher-grade tumors (28% vs. 18%, p<0.001). The 7-year disease-specific survival rates for those at highest risk of PCSM (higher grade pT3a) were 96.5% for cases with negative surgical margins and 90.8% for those with PSMs. PSMs were associated with a 2.9-fold increased risk of PCSM (HR 2.87, 95% CI 2.32–3.55). PSM remained an independent predictor of PCSM in the multivariate analysis (HR 1.69, 95% CI 1.34–2.13).

**Conclusion:** These data demonstrate the independent role of positive surgical margin in PCSM. These finding support the importance of optimizing surgical technique to achieve a sound oncologic surgical outcome with negative surgical margins when possible.

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**Poster# 11**

**CUSUM’S AS A QUALITY CONTROL MEASURE IN ROBOT-ASSISTED RADICAL PROSTATECTOMY**

Andrew K. Williams¹, Venu Chalasani¹, Carlos Martinez¹, Erica Osbourne¹, Linda Nott¹, Larry Stitt², Jonathan I. Izawa¹ and Stephen E. Pautler¹

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Presented By: Andrew K. Williams

**Introduction:** Cumulative summation (CUSUM) is a technique used within industry to monitor production lines and detect possible changes in production quality. By assessing the proportion of negative outcomes in a continuous data set, underperforming production lines or techniques can be distinguished from those due to random variation alone. CUSUM has been applied to surgical outcomes such as mortality in cardiac bypass and complications associated with bladder cancer. This was a feasibility study to pilot the use of CUSUM quality control monitoring of positive surgical margin (PSM) outcomes with the introduction of robotic assisted radical prostatectomy (RARP).

**Methods:** Patient data was prospectively collected from patients undergoing RARP by a single surgeon (SP) following institutional ethics review and approval. All patients included were either low or moderate risk under the D’Amico classification system. Preoperative, intraoperative and postoperative features were recorded. Retrospectively, a CUSUM graph was performed to analyze the PSM rate in patients undergoing RARP for pT2 disease. Maximum and minimum acceptable levels were set by the 95% CI for PSM rates in T2 disease previously presented by Cancer Care Ontario (CCO).

**Results:** From the entire cohort of 226 patients, there were 158 patients with pathologic T2 disease (pT2), who formed the cohort for this study. Mean Patient age was 59.2 Years (39-73), Median Gleason Score was 6 (4-9), Mean PSA was 6.43 ng/ml (0.52-17.5) and mean prostate volume was 44cc (18cc-120cc). Of these 158 pT2 patients, 21 had PSM (13%). CUSUM graphs were produced both using continuous data and with resetting of the graph to allow for ongoing monitoring of changes in PSM rates.

**Conclusions:** CUSUM’s can be used as a continuous quality control measure for a surgeon to monitor their results and identify a possible need for review of their technique at any stage throughout their career. We have used this to show graphically the well described learning curve associated with robotically assisted radical prostatectomy however this was still within the 95% confidence interval of PSM rates presented by CCO.
**Poster Session I**

**Poster# 12**

**EXTERNAL VALIDATION OF THE SEARCH MODEL FOR PREDICTING AGGRESSIVE RECURRENCE AFTER RADICAL PROSTATECTOMY: RESULTS FROM THE DUKE PROSTATE CENTER DATABASE**

Anna Teeter¹, Leon Sun², Judd Moul³ and Stephen Freedland²

¹Duke University School of Medicine, Durham, NC; ²Duke University Medical Center, Durham, NC

Presented By: Anna Teeter

**Introduction:** A short PSA doubling time (PSADT) following biochemical recurrence after radical prostatectomy (RP) portends a poor prognosis. Using the SEARCH database, we previously developed tables to predict risk of aggressive recurrence after surgery (defined as PSADT <9 months) using pathologic stage, pre-operative PSA, and pathologic Gleason sum. These tables had an AUC of 0.79. We sought to validate this prediction model with a cohort of men from the Duke Prostate Center (DPC).

**Methods:** Data on 1989 men from the DPC database who underwent RP for node-negative prostate cancer between 1987 and 2003 were included. Of these men, 100 recurred with a PSADT <9 months, while 1889 either did not recur but had at least 36 months of follow-up or recurred with a PSADT >/=9 months. We examined the ability of the SEARCH model to predict aggressive recurrence within DPC and the correlation between the predicted risk of aggressive recurrence and the actual outcome within DPC.

**Results:** The SEARCH model predicted aggressive recurrence within DPC with an AUC of 0.85. There was a strong and significant correlation between the predicted risk of aggressive recurrence based on the SEARCH tables, and the actual outcomes within DPC (r=0.68, p<0.0001), though the model predictions tended to be slightly higher than actual risk.

**Conclusions:** The SEARCH model to predict aggressive recurrence after RP predicts aggressive recurrence in an external dataset with a high degree of accuracy. These tables, now validated, can be used to help select men for adjuvant therapy and clinical trials.

**Poster# 13**

**A COMPARISON OF ROBOT-ASSISTED RADICAL PROSTATECTOMY AND RADICAL RETROPUBIC PROSTATECTOMY IN MEN WITH HIGH-RISK, CLINICALLY LOCALIZED PROSTATE CANCER (CAP)**

Jin Yeoh, Nicholas Hellenthal, James Mohler and Khurshid Guru

Roswell Park Cancer Institute, Buffalo, NY

Presented By: Jin Yeoh

**Introduction:** Robot-assisted surgery is increasingly employed for treatment of prostate cancer patients. We sought to compare surgical margin status and cancer outcomes for patients with high-risk prostate cancer who underwent either robot-assisted radical prostatectomy (RARP) or radical retropubic prostatectomy (RRP).

**Methods:** Using a single-institution retrospective database, we identified 123 with high-risk CaP (PSA≥20 or Gleason grade ≥ 8 or clinical tumor state ≥T2c) who underwent either RARP or RRP from 1996-2008. Of these men, 107 (64 underwent RARP and 43 underwent RRP) had complete clinical and pathologic date, and were studied. The RARP and RRP groups were stratified by preoperative PSA, clinical grade, and stage; and differences were sought in rates of positive surgical margins and biochemical recurrence. Average time of follow-up was 1.7 years. Biochemical recurrence was defined as a post-operative PSA of ≥0.2ng/ml that increased in subsequent measurements.

**Results:** Twenty-three of the 107 patients (22%) had a positive surgical margin and the rate of positive surgical margins was similar (p=1.00) after undergoing RARP (22%) and RRP (21%). The rate of biochemical recurrence differed between the groups (p=0.024), with recurrence in 21 RRP patients (49%) and 17 RARP patients (27%). Time to recurrence did not differ between the groups; an average time to biochemical recurrence of 0.73 years after RARP and 1.48 years after RRP (p=0.093).

**Conclusions:** Positive surgical margin rates in men with high-risk prostate cancer are similar after RARP or RRP. The risk of biochemical recurrence is lower in patients with high-risk disease who undergo RARP compared to RRP.


Poster# 14

PELVIC LYMPH NODE DISSECTION DURING ROBOTIC RETROPUBIC PROSTATECTOMY: A SINGLE SURGEON EXPERIENCE
Dhiren Dave and James Porter
Swedish Medical Center, Seattle, WA
Presented By: Dhiren Dave

Introduction: Pelvic lymph node dissection (PLND) at the time of radical retropubic prostatectomy (RRP) provides staging information and a potential therapeutic advantage. The value and extent of PLND remains controversial with little data evaluating outcomes of PLND during robotic RRP. We present the results of PLND performed during robotic RRP by a single surgeon.

Methods: 596 patients underwent robotic RRP between July 2005 and January 2009 by a single surgeon (JRP). Patients underwent extended PLND if they were considered to be intermediate or high risk by D’Amico criteria. Boundaries of PLND included Cooper’s ligament caudally, bifurcation of the common iliac artery cranially, external iliac vein laterally, bladder wall medially and internal iliac vessels posteriorly. Rate of PLND was assessed. In addition, age, pre-op PSA, biopsy Gleason score, clinical stage, and length of surgery were compared between patients who did and did not undergo PLND. The rate of positive nodes was determined, and patients with and without lymph node invasion were compared for age, PSA, RRP Gleason score, and pathologic stage. Complications of PLND were also assessed.

Results: Of 596 patients undergoing robotic RRP, 213 (35.7%) underwent extended PLND. Those undergoing PLND were slightly older (62.3 yrs vs. 60 yrs; p<0.05) with a higher PSA (8.5 ± 10.2 vs. 5.5 ± 2.9; p<0.05), higher biopsy Gleason score (7.1 ± 0.7 vs. 6.2 ± 0.4; p<0.05), and higher average clinical stage (T2a vs. T1c; p<0.05). In addition, those undergoing PLND had a longer length of surgery (204 ± 41 min. vs. 185 ± 36 min.; p<0.05). Of those undergoing PLND, 22 patients (10.6%) had positive nodes. Patients with positive nodes had higher RRP Gleason scores (7.6 ± 0.8 vs. 6.8 ± 1.2; p<0.05) and higher average pathologic stage (T3 vs. T2c with 20 of 22 pts with positive nodes having T3 or higher disease) compared to those patients with negative nodes. Although approaching statistical significance, patients with positive nodes had a higher pre-op PSA compared to those with negative nodes (16.1 ± 20.3 vs. 7.8 ± 8.1; p=0.07). Complications included pelvic lymphoceles in three patients.

Conclusions: Extended pelvic lymph node dissection can be performed robotically when indicated with minimal complications. Rates of positive nodes appear to be similar to that seen with open RRP, and risk of lymph node invasion increases with Gleason score, pathologic stage, and pre-op PSA (this approaches significance).

Poster# 15

NEOADJUVANT DOCETAXEL / ESTRAMUSTINE PRIOR TO RADICAL PROSTATECTOMY OR EXTERNAL BEAM RADIOTHERAPY IN HIGH RISK LOCALIZED PROSTATE CANCER: A PHASE II TRIAL
Stephen McKim, Eugene Simopoulos, William Kim, Paul Godley, Young Whang, Kim Rathmell, Matthew Nielsen, Eric Wallen and Raj Pruthi
The University of North Carolina at Chapel Hill, Chapel Hill, NC
Presented By: Stephen McKim

Background: Patients with high-risk prostate cancer are at significant risk of having disease recurrence despite definitive local therapy. We evaluated the two-year progression-free survival of subjects treated with chemotherapy administered prior to definitive therapy with surgery (RP) or radiation (XRT).

Methods: Patients (n=24) with locally advanced and high-risk localized prostate cancer were treated with neoadjuvant docetaxel (36 mg/m2 IV weekly for 3 weeks) and estramustine (140 mg orally tid for three consecutive days every 28 days) prior to definitive treatment with RP or XRT. The primary objective of the study was to determine the biochemical (PSA) progression rate 2 years after the completion of treatment.

Results: All evaluable patients, except one, completed the proposed cycles of neoadjuvant chemotherapy with minimal dose reductions or delays. Of the 22 evaluable patients, 12 underwent RP and 10 underwent XRT. No patient who underwent RP was found to pT0 disease. Of RP patients, 6 of 12 (50%) had organ-confined disease on pathology. Of the entire cohort, 21/22 (95%) patients achieved a PSA reduction > 25%. All patients had a minimum follow up of 24 months, and the two-year progression free survival was 55%. The table shows the characteristics of those who progressed versus those who did not.
Conclusions: Our findings support the safety, tolerability, and efficacy of neoadjuvant chemotherapy in patients with men with high-risk prostate cancer. The effectiveness of neoadjuvant chemotherapy in preventing prostate cancer relapses should be studied in a randomized trial.

Poster# 16

RECALIBRATION AND EXTERNAL VALIDATION OF AN EXISTING NOMOGRAM TO PREDICT AGGRESSIVE RECURRENCES AFTER RADICAL PROSTATECTOMY (RP)
Florian Schroeck¹, Michael Kattan², Judd Moul¹, William Aronson³, Joseph Presti⁴, Martha Terris⁵, Christopher Kane⁶, Christopher Amling⁷, Leon Sun¹ and Stephen Freedland¹
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Presented By: Florian Schroeck

Introduction and Objective: Previous studies have found that nomograms developed to predict biochemical recurrence (BCR) after RP are also very accurate at predicting aggressive recurrences (i.e. a BCR with a postoperative PSA doubling time (PSADT) of <9 months). Therefore, the objective for this study was to recalibrate the previously published Duke Prostate Center (DPC) nomogram for the prediction of BCR after radical prostatectomy to not only predict overall BCR but also the clinically more relevant endpoint of an aggressive recurrence.

Methods: Using the established point scale system based upon the previously published DPC nomogram, we recalibrated this point system to predict not just BCR, but also aggressive BCR within 2,599 men treated with radical prostatectomy from the DPC database. PSADT was computed on all patients meeting the recurrence definition who had a minimum of 2 PSA values, separated by at least 3 months, and within 2 years after recurrence. External validation was performed using data from 1,695 men treated with radical prostatectomy within the SEARCH database by calculating the concordance index c and by plotting calibration curves.

Results: Median follow-up for patients without BCR was 56 and 47 months for DPC and SEARCH, respectively. In the DPC modeling cohort and the SEARCH validation cohort, 645 (25%) and 557 (33%) men had BCR, while 83 (3.2%) and 71 (4.2%) patients had an aggressive recurrence. In external validation, predictive accuracy for an aggressive BCR was high (c=0.83) and the nomogram showed good calibration.

Conclusions: We have recalibrated an existing nomogram to not only predict overall BCR after RP but also aggressive recurrence after RP. Our new tool can provide valuable information for patient counseling and patient selection for adjuvant therapy trials. Note: The corresponding manuscript is currently in press in BJU Int.
PERFORMANCE OF PELVIC LYMPH NODE DISSECTION DURING RADICAL PROSTATECTOMY: ROLE OF DISEASE PATHOLOGY, SURGEON VOLUME AND SURGICAL APPROACH

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Presented By: Sandip Prasad

Objectives: We assessed the likelihood and extent of pelvic lymph node dissection during radical prostatectomy, in light of potential confounders such as tumor characteristics, surgical approach (open vs. minimally invasive), and surgeon volume.

Methods: We used Surveillance, Epidemiology, and End Results (SEER) Medicare linked data to identify 5,448 men aged 65 years and older undergoing either minimally invasive (MIRP) or open retropubic radical prostatectomy (RRP) from 2003 to 2006. Multivariable logistic regression was used to assess whether surgical approach, surgeon volume, age, co-morbidity, and geographic region were associated with performing PLND.

Results: Overall, PLND was performed less than half as often during MIRP vs. ORP (38.3% vs. 87.6, p<0.001). In adjusted analyses, men undergoing RRP vs. MIRP (odds ratio [OR] 16.7; 95% confidence interval [CI], 11.1-25.0), men with intermediate (OR 1.87; 95% CI 1.48-2.37) or high (OR 2.77; 95% CI 2.02-3.78) vs. low-risk disease were more likely to undergo PLND. Greater surgeon volume, as a continuous variable, was also associated with greater use of PLND (OR 1.008, 95% CI 1.004-1.011). The odds of performing PLND and number of nodes retrieved increased with increasing MIRP surgeon volume; however, RRP surgeon volume did not affect use of or extent of PLND. Additionally, the median lymph node yield from MIRP was less than that for RRP (3 vs. 5 lymph nodes retrieved, p<0.001), while positive lymph nodes were recovered half as often (1.2% for MIRP vs. 2.5% for RRP, p=0.057).

Conclusions: Independent of tumor pathology, men undergoing MIRP vs. ORP are less likely to undergo PLND although higher volume MIRP surgeons were more likely to perform PLND. Moreover, the number of lymph nodes removed and the likelihood of removing a positive lymph node were lower with MIRP. This may arise from the greater lead-time in use of RRP vs. MIRP or variations in technique by surgical approach.

DIFFERENCES IN PRESENTATION AND OUTCOMES FOR DUCTAL VERSUS ADENOCARCINOMA OF THE PROSTATE

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Presented By: Todd Morgan

Introduction and Objectives: The clinical significance of the ductal subtype of prostatic carcinoma has not been well defined. Given its rarity, most analyses have been small, single institution series. We utilized a population-based cancer registry to identify a larger group of patients with ductal carcinoma and better characterize the impact of the ductal subtype on the presentation and survival of men with prostate cancer.

Methods: The Surveillance, Epidemiology, and End Results cancer registry was used to identify incident cases of both adenocarcinoma (adeno) and ductal carcinoma of the prostate for the years 1996 –2006. Clinicopathologic variables were compared with Chi-squared tests. Cox multivariate survival analysis was performed. There was evidence of effect modification by stage (likelihood test p-value = 0.01) so the survival analysis was stratified by stage (localized/regional vs. distant). PSA values were available for the years 2004 –2006. Differences in PSA between ductal and adeno was determined with 2 models: a multivariate linear regression model and a 2nd model predicting the likelihood of having a PSA < 4.0 ng/ml.
Results: A total of 442,881 adeno cases and 371 ductal cases were identified. Ductal cases were more likely to present with distant disease than adeno cases (13% vs. 4%, p<0.001), and more likely to be poorly differentiated (61% vs. 32%; p<0.001). Ductal histology was associated with a 30% reduction in the geometric mean PSA (adjusted coeff. = 0.7, 95% CI 0.6 –0.8) and a more than two-fold increased odds of having a PSA < 4.0 ng/ml (adjusted OR 2.4, 95% CI 1.4 –4.0). For patients with localized disease, those with ductal tumors had worse disease specific survival than those with adeno tumors (adjusted HR 2.4, CI 1.5-3.8). No difference in survival was seen for those with distant disease.

Conclusions: To our knowledge, this is the largest analysis of the ductal variant of prostate cancer. We found that ductal cancers are more likely to present with advanced stage cancer and a lower PSA, making timely detection of the disease a significant challenge. In addition, those with locoregional disease were more likely to die of their disease. These findings could have important implications for the counseling and initial therapy of men with ductal prostate cancer.

Poster# 19

THE INFLUENCE OF OBESITY ON PERIOPERATIVE PARAMETERS IN ROBOTIC VERSUS OPEN PROSTATECTOMY CASES AT A SINGLE CENTER THAT SPECIALIZES IN BOTH TECHNIQUES

Suzanne Biehn Stewart¹, Matvey Tsivian¹, Lionel Bañez¹, ², Tong Gan³, Cary Robertson¹, Philip Walther¹, ², Thomas Polascik¹, Vladimir Mouraviev¹, David Albala¹ and Judd Moul⁴

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Presented By: Suzanne Biehn Stewart

Introduction and Objectives: Public competition between robotic and open prostatectomy remains prominent in the current era. Prior comparisons between the two modalities have been criticized for their lack of analyses in centers that specialize in both techniques and that apply similar clinical pathways. Additionally, obesity in the United States continues to grow as a national health dilemma. Investigation of an optimal prostatectomy approach for specific body mass index (BMI) subgroups has yet to be explored. We sought to compare differences in perioperative parameters between robotic and open prostatectomy approaches using a center that specializes in both modalities, at a time point that minimizes the learning curve, and to investigate the influence of BMI on these outcomes.

Methods: We retrospectively analyzed 576 robotic assisted laparoscopic (RALP) and 513 radical retropubic prostatectomy (RRP) cases from 2005 to 2009 at Duke University. Patients were stratified into BMI subgroups of normal: <25kg/m², overweight: 25-29kg/m², obese ≥ 30kg/m². Associations between surgical modality and perioperative variables were assessed using the Student's T-test, Mann-Whitney and Chi-squared tests. Comparisons of variables across BMI subgroups, for each surgical modality, were evaluated using the Kruskal-Wallis and Chi-squared tests.

Results: We found operative and anesthesia times were shorter with RRP and post-anesthesia care (PACU) stays were shorter with RALP (p < 0.001). Maximum and minimum PACU pain scores were significantly lower for RALP compared with RRP (p < 0.001). Stratification by BMI did not influence surgical times, PACU stay or pain scores. RRP patients were 4.7 times more likely to receive blood products compared with RALP (95% CI 2.95-7.53, p < 0.001). Obese men were less likely to receive blood products compared to all other BMI subgroups in both RRP (p = 0.025) and RALP (p = 0.017) groups.

Conclusions: RALP patients had shorter PACU stays, lower pain scores and risk of blood product transfusions compared with RRP cases, which may be an indicator of overall decreased procedure morbidity for RALP. Obesity was not found to influence these perioperative parameters between RRP and RALP. Further investigation is required to examine the influence of obesity on local disease control between RRP and RALP and explore more completely whether an optimal prostatectomy approach exists for certain BMI subgroups.
A PHASE III EFFICACY AND SAFETY CLINICAL STUDY OF A NEW SUSTAINED-RELEASE LEUPROLIDE ACETATE 3.75 MG DEPOT FORMULATION IN PROSTATE CANCER

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Presented By: Neal Shore

Introduction and Objectives: This phase III, open-label, international, multicenter clinical trial was conducted to investigate the efficacy and safety profile of a new one-month formulation of leuprolide acetate 3.75 mg depot, namely Lutrate 3.75 mg, in suppressing testosterone levels in prostate cancer patients.

Methods: 160 prostate cancer patients who could benefit from androgen suppression therapy received six doses of Lutrate 3.75 mg depot every 28 days as single intramuscular injections. Plasma testosterone was determined at specific times throughout the study. The primary endpoint was the proportion of successful patients over the total number of evaluable patients. Patients’ success was defined as testosterone suppression (<0.5 ng/ml) at day 28 and continuance of castration at all the monthly assessments until study completion (day 168). An exact two-sided binomial test at 5% significance level with a two-sided 95% confidence interval (CI), estimated with the exact method, was performed to verify study success.

Results: Leuprolide pharmacokinetic profile during the first three months of treatment evaluated on a subset of the study population (n=12) confirmed sustained release of leuprolide from the formulation. At day 28, 151 out of the 156 evaluable patients (96.8%) achieved testosterone suppression and 114/156 (73.1%) achieved testosterone levels ≤ 0.2 ng/ml. At study completion, 100% of the patients (152/152) maintained castration, with the 92.8% of them (114/152) presenting testosterone levels ≤ 0.2 ng/ml. Overall the proportion of successful patients over the total number of evaluable patients was 96.8% (152/157) and study success was confirmed (exact binomial test p-value=0.000094, 95% CI: 92.7–99.0%). The most common treatment-related adverse events were hot flashes (45%), typically associated with testosterone suppression. Fatigue, hyperhidrosis, night sweats and headache occurred in ≤ 6.3% of patients. Pain at the injection site was the most frequent local adverse reaction and was reported by 8.1% of patients.

Conclusions: Lutrate 3.75 mg depot was well tolerated and effective in establishing and maintaining testosterone concentration below castration levels in prostate cancer patients.

Funding: GP-Pharm S.A., Spain, funded the study

DEGARELIX VERSUS LEUPROLIDE IN PATIENTS WITH ADVANCED PROSTATE CANCER (PCA): FURTHER ANALYSES FROM A PHASE III TRIAL (CS21)

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Presented By: Neal Shore

Introduction and Objectives: Androgen deprivation with gonadotropin-releasing hormone (GnRH) agonists is standard therapy for advanced PCa. Here we report results from a phase III randomized one-year trial comparing degarelix, a new GnRH blocker, with the GnRH agonist leuprolide, in the treatment of PCa.

Methods: Patients with histologically confirmed PCa (all stages) were randomized to: degarelix s.c. 240 mg for one month and thereafter, monthly maintenance doses of 80 mg (n=207) or 160 mg (n=202), or leuprolide 7.5 mg/month (n=201). Bicalutamide could be given as flare protection in the leuprolide group. Data for degarelix 240/80 mg (FDA-approved dose) vs. leuprolide are reported here.

Results: Overall, 610 patients (mean age 72 years; median testosterone (T) 3.93 ng/mL; median prostate-specific antigen [PSA] 19.0 ng/mL) were treated. 31.3% of patients had localized, 29.2% had locally advanced and 20.5% had metastatic PCa. Median PSA reductions on Days 14 (64% vs 18%) and 28 (85% vs 68%) were significantly greater with degarelix (p<0.001). PSA failure (2 consecutive increases in PSA of 50% and ≥5 ng/mL compared with nadir) occurred in 8.9% vs 14.1% of patients receiving degarelix and leuprolide. A statistically lower (p=0.0495; log-rank test) risk of PSA failure or death was found for patients randomized to degarelix compared with patients randomized to leuprolide (ITT population; Figure). PSA failure occurred more often in patients with metastatic disease and exclusively in patients with baseline PSA ≥20 ng/mL across both treatment groups.
Conclusions: Degarelix achieved fast suppression of PSA. A statistically lower risk of PSA failures was experienced by patients receiving degarelix 240/80 mg versus leuprolide (ITT population). PSA failure occurred more often in patients with metastatic disease and only in patients with baseline PSA ≥20 ng/mL—the latter group experienced significantly longer time to PSA failure with degarelix compared with leuprolide.

Funding: The phase III CS21 trial was sponsored by Ferring Pharmaceuticals.

Figure: PSA progression-free survival (time to PSA failure/death: ITT population)

Poster# 22

ALCOHOL INTAKE AND THE RISK FOR PROSTATE CANCER IN A MULTI-ETHNIC POPULATION OF UNITED STATES VETERANS: IS RACE AN IMPORTANT FACTOR?

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Presented By: Lionel L. Bañez

Introduction and Objectives: Alcohol intake is a known risk factor for several types of cancers including laryngeal, esophageal and liver cancers. However, reports on the effect of alcohol consumption on prostate cancer risk have been largely inconsistent. Most studies, from predominantly Caucasian populations, show no association between alcohol intake and prostate cancer risk. Though previous studies have found that certain polymorphisms of the alcohol dehydrogenase gene specific to African- and Native-Americans may lead to bodily accumulation of the chemical carcinogen acetaldehyde in men with these ethnic backgrounds, the effect of alcohol intake on prostate cancer risk in African-American populations is poorly understood. We sought to determine whether alcohol consumption is associated with increased risk for being diagnosed with prostate cancer in a multi-racial cohort of men undergoing prostate biopsy in an equal-access hospital and whether this association varies by race.

Methods: Clinical information was prospectively collected from 333 men undergoing prostate biopsy at the Durham Veterans Affairs Medical Center from 2007 to 2009 including alcohol intake data. Logistic regression models were used to determine the relationship between alcohol intake and risk for a positive prostate biopsy independent of demographic, anthropometric and clinical covariates.

Results: Overall, there was a statistically significant association between alcohol intake and risk for prostate cancer (odds ratio [OR]=2.46; 95% confidence interval [CI]=1.06-5.69; p=0.04). When stratified according to race, alcohol intake was associated with increased prostate cancer risk among African-American men (OR=5.14; 95% CI=1.20-21.9; p=0.03) but not among Caucasian men (OR=1.85; 95% CI=0.56-6.07; p=0.31).

Conclusions: In a multi-ethnic prospective cohort of men undergoing prostate biopsy, alcohol consumption was associated with increased risk for prostate cancer in African-Americans but not in Caucasians. If confirmed in other populations, steps to increase public awareness of the potential negative effects of alcohol intake on prostate cancer, specifically in African-Americans, must be taken. Furthermore, investigations aimed at elucidating the underlying biological mechanism for this apparent race-specific prostate cancer risk factor are, likewise, warranted.
ADOPTION OF LAPAROSCOPIC RADICAL PROSTATECTOMY IN NEW YORK STATE
David Yee, William Lowrance, Kian Tai Chong, Caroline Savage, Angel Cronin and Farhang Rabbani
Memorial Sloan-Kettering Cancer Center, New York, NY
Presented By: David Yee

Introduction and Objectives: Recent literature suggests increased use of laparoscopy for prostate cancer in the academic and community setting, however, precise characterization of the diffusion of laparoscopic radical prostatectomy (with or without robotic assistance) remains unknown. We therefore describe temporal trends and predictive factors in the adoption of laparoscopic radical prostatectomy in New York State.

Methods: Data from the Statewide Planning and Research Cooperative System (SPARCS) of New York State were abstracted for 2000 through 2006. International Classification of Diseases-Ninth Revision, Clinical Modification 9 codes were used to identify patients undergoing open (ICD9 60.5) or laparoscopic radical prostatectomy (ICD9 60.5 plus 54.21 or 54.51) for prostate cancer. A multi-level mixed-effects logistic regression model was used to identify patient and hospital characteristics associated with the use of laparoscopic technique.

Results: Of the 28,183 patients who received a radical prostatectomy in New York State between 2000 and 2006, 2,048 (7.3%) were performed laparoscopically. We observed a dramatic increase in the use of laparoscopic technique over time: the proportion of cases performed laparoscopically increased from 0.2% to 17.1% from 2000 to 2006. These increases were seen almost exclusively in urban and teaching hospitals (Figure 1). 162 (90%) hospitals were classified as urban and 109 (60%) were classified as teaching; 103 (57%) were classified as both urban and teaching Greater surgeon and hospital volumes were both significantly associated with an increased likelihood for a laparoscopic technique (OR per 10 surgeon cases: 1.13; 95% CI: 1.08, 1.18; p<0.001 and OR per 100 hospital cases: 1.82; 95% CI: 1.65; 2.02; p<0.001). We found no evidence that patient age, race, payment type or Charlson comorbidity scores were significantly associated with laparoscopic technique (all p>0.5).

Conclusions: Although the use of laparoscopic RP has increased dramatically over the last few years, the majority of RP were not performed laparoscopically in New York State. The choice of technique appears to be strongly associated with hospital characteristics.
ROBOTIC-ASSISTED LAPAROSCOPIC PROSTATECTOMY FOR LOCALLY ADVANCED PROSTATE CANCER
Keith Kowalczyk, Anup Vora, Keith Christiansen, John Lynch, Reza Ghasemian, Mohan Verghese and Jonathan Hwang
Georgetown University Hospital/Washington Hospital Center, Washington, DC
Presented By: Keith Kowalczyk

Introduction and Objective: Robotic Assisted Laparoscopic Prostatectomy (RALP) offers minimally invasive treatment with comparable oncologic outcomes for localized disease compared with Open Radical Prostatectomy. However, the oncologic efficacy of RALP in locally advanced prostate cancer (CaP) is less clear. We report our experience with RALP in men with locally advanced CaP.

Methods: Data was collected prospectively as part of an IRB approved database. Patients with locally advanced CaP (stage T3 or greater) were identified. Clinicopathologic features including age, clinical stage, pre- and post-operative PSA values, surgical margin status, Gleason score, and tumor multifocality were reviewed. We further examined the incidence of positive surgical margins in these patients, the effect of the surgical learning curve on margin status, and the need for adjuvant therapy.

Results: From 2003 to 2008, 661 patients underwent RALP at our institution. Seventy-six of these patients had locally advanced disease with a median follow-up of 22 months. The mean age was 62 ± 7 and mean preoperative PSA level was 6.3 ± 1.9 ng/ml. Forty-three patients (57%) had palpable disease on preoperative DRE. The median total Gleason score was 7 ± 0.9. Forty-three (57%) patients had positive surgical margins. The margin positive rate on patients with advanced CaP was 67% within the first 300 cases and 49% within the latter 361 cases. Fourteen patients (18%) had evidence of biochemical recurrence within 2 years of follow-up. Sixteen patients (21%) received adjuvant treatment in the form of radiotherapy (12) and/or androgen deprivation (4).

Conclusions: In our series, up to 2 out of 3 men with locally advanced CaP had evidence of a positive margin after RALP. Although not clinically significant, there was a trend towards lower positive margin rates with increasing surgeon experience (67% vs. 49% after 300 cases). More studies are needed before RALP is routinely offered to patients with high risk of locally advanced disease.

PROSTATE CANCER BIOCHEMICAL RECURRENCE RATES AFTER ROBOTIC-ASSISTED LAPAROSCOPIC RADICAL PROSTATECTOMY
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Presented By: Serge Ginzburg

Introduction and Objectives: To determine prostate cancer biochemical recurrence rates with respect to surgical margin (SM) status for patients undergoing robotic-assisted laparoscopic radical prostatectomy (RALP).

Methods: A retrospective review of a prospectively maintained, Internal Review Board (IRB) approved radical prostatectomy database was performed. Using preoperative data, patients were stratified as low, intermediate, and high risk according to D’Amico’s risk classification. Pathologic specimens were categorized by Gleason score, TNM stage (2002 AJCC Cancer Staging), and SM status. Postoperative PSA values were routinely obtained at 1, 3, 6, 9, 12, 18 and 24 months and annually thereafter. PSA recurrence was defined as greater than or equal to 0.2 ng/ml. Patients receiving adjuvant or salvage treatment were included in the analyses. Kaplan-Meier curves of biochemical recurrence-free survival (BRFS) as a function of SM were generated with SPSS v 14. Multivariate Cox regression using forward stepwise entry of pre-operative PSA, Gleason score, pathologic stage and SM status was performed.

Results: One thousand four hundred and thirty eight patients underwent RALP between January 1, 2004 and January 1, 2009 at our institution. One thousand one hundred and sixty patients had sufficient clinical, pathologic and follow-up data and were included in the analyses. Figure 1 demonstrates Kaplan-Meier curves of BRFS for D’Amico’s risk groups and the overall cohort by SM status. Overall BRFS at 1 and 5 years were 93.3% and 71.9%, respectively. Pre-operative PSA, Gleason score, pathologic stage and SM status were found to be significant on multivariate analysis.
Conclusions: Biochemical recurrence-free survival for our RALP series compares favorably with other open radical retropubic prostatectomy and RALP series. Documenting biochemical recurrence rates for RALP in a multi-institutional fashion is important as this treatment for localized prostate cancer is validated.

Poster# 26

EXTENSIVE MULTIFOcal PROSTATIC ADENOCARCINOMAS (GREATER THAN 20) IN RADICAL PROSTATEctomy SPECIMENS OF YOUNG MEn
Bungo Furusato¹, Patrick Parker², Timothy Nydam², Kevin Rice², Shiv Srivastava¹, Stephen Brassell³, David McLeod² and Isabell Sesterhenn¹
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Presented By: Bungo Furusato

Introduction and Objectives: Although the majority of prostatectomy specimens contain 3 to 4 tumors on average, it is rare to encounter greater than 20 tumors in prostatectomy specimens. The aim of this study is to characterize patients in the latter group.

Methods: Radical prostatectomy specimens of 1400 consecutive patients obtained from a single institution between 1993 and 2008 were analyzed retrospectively. For each specimen, the entire prostate was sectioned and embedded as whole-mounts. Each tumor was circled and characterized separately. The presence of prostatic intraepithelial neoplasia, atypical glands, atrophy etc., were recorded. Biochemical recurrence was defined as two consecutive values of serum PSA levels ≥ 0.2 ng/mL.

Results: Among the 1400 consecutive radical prostatectomy specimens, 5 patients (0.36%) had more than 20 tumors. The median age was 42 years, and the median time of follow-up was 52 months. In 4 patients all tumors were well differentiated corresponding to a Gleason score of 6 (3+3). In one case, one of the tumors had a Gleason score of 7 (3+4, well and poorly differentiated). A number of tumors clustered in a specific region suggesting confluence to a single tumor and were measured as a single tumor. The median total tumor volume was 1.2 cc; all tumors were organ confined, surgical margin negative. Most of the tumors were located in the peripheral zone of the mid and apical thirds and were associated with prostatic intraepithelial neoplasia. In all of the patients, atypical glands were also seen. The median preoperative PSA was 2.8 ng/ml. To date, none of the patients has exhibited PSA recurrence.

Conclusions: The large number of individual microscopic tumors and the focal confluence may indicate an early stage in the development of carcinoma and could explain the heterogeneity of a large tumor. The tumor with 40% poorly differentiated component did not cause PSA recurrence at this point.
THE EFFECT OF STATIN USE ON BIOCHEMICAL RECURRENCE FOLLOWING RADICAL PROSTATECTOMY
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Presented By: Chad Ritch

Introduction: Statin use has significantly increased in recent years and they are among the most widely prescribed medications in the US. Studies suggest that statins may significantly lower PSA levels and statin users may have a reduced risk of prostate cancer, particularly advanced disease. Few studies have addressed the influence of statins on outcomes following local therapy. We therefore sought to determine the association between statin use and biochemical recurrence (BCR) following radical prostatectomy.

Materials and Methods: A retrospective analysis was performed on 4171 patients who underwent radical prostatectomy from 1988-2008. Patients were excluded if they had insufficient PSA data and undergone neoadjuvant or adjuvant therapy (hormones or radiation). Data on statin use was determined from the patient’s discharge record. BCR was defined as PSA > 0.2 ng/mL after a previously undetectable post-surgery PSA. Clinical and pathological variables were compared between statin users and non-users. Kaplan Meier and multivariate Cox-regression analyses were performed to determine the effect of statin use on BCR.

Results: 1261 patients were identified who met the inclusion criteria and of these, 281 were taking a statin at the time of surgery. Mean age was 59 years and median follow-up was 35 months (mean 43 months). Median pre-operative PSA was 5.6, median clinical T stage was T1c and median Gleason sum (GS) was 6. The median pathological T stage was T2c, N0, and pathological GS was 7. Comparing statin users to non-users, the mean pre-operative PSA was lower: 6.4 vs 7.2 respectively (p<0.05) and there was a trend toward higher biopsy GS: 7 vs 6 respectively (p=0.076). There was a higher proportion of statin users with pathological GS ≥ 7 compared to non-users (p<0.05). On multivariate analysis, statin use was an independent predictor of BCR (HR 1.64, p=0.009). On Kaplan Meier analysis overall five-year BCR free survival was 78% for all patients. Statin users demonstrated a significantly decreased five-year BCR free survival compared to non-users (72% vs. 80%, p<0.05).

Conclusions: Statin users have lower pre-operative PSA levels than non-users. The effect of statin use on PSA may mask aggressive disease and delay diagnosis possibly leading to an increased risk of biochemical recurrence after surgery. Further studies are needed to determine the association between statin use and PSA and to evaluate the outcomes of prostate cancer therapy in statin users.

RADICAL PROSTATECTOMY FOR PROSTATE CANCER FOLLOWING ILEAL POUCH-ANAL ANASTOMOSIS OFFERS ONCOLOGIC CONTROL AND SUSTAINS QUALITY OF LIFE
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Presented By: Eric Umbreit

Background: We evaluated the feasibility and oncologic durability of performing prostate biopsy and open radical retropubic prostatectomy (RRP) in patients who have previously undergone proctocolectomy and ileal pouch-anal anastomosis (PC-IPAA).

Study Design: We performed a retrospective review of all patients at our institution that underwent a RRP following a PC-IPAA between June 1992 and February 2009. Variables evaluated included demographic characteristics, biopsy technique, tumor pathology, surgical technique, complications, and functional and oncologic outcomes.

Results: Sixteen patients were identified. Mean PSA was 9.3 (median 5.9, range 4.3-26.8). Prostatic biopsy was performed without complication by a variety of radiographic techniques. Successful RRP was achieved in all patients without pouch violation or pouch-related postoperative complications. The most common intraoperative finding was pelvic adhesions between the posterior prostate/semenal vesicles and the IPAA. Neurovascular bundle preservation was not altered by pelvic adhesions in any patient in which this was the goal of surgery. Urinary continence was restored by 3 months in 94% of patients and erectile function returned without the use of medication in 73% who had neurovascular bundle preservation. Overall pouch function was subjectively unchanged postoperatively. Biochemical recurrence (BCR) occurred in 3 patients and local recurrence in 2 patients. Only 1 recurrence occurred within 5 years of RRP during a mean follow-up of 5.7 years (median 3.8 years, range 0.3-14.5).

Conclusions: Despite altered pelvic anatomy from previous PC-IPAA, prostate biopsy and RRP can be done safely and effectively. Previous PC-IPAA should not be a contraindication to RRP in men with clinically localized prostate cancer.
Poster# 29 – WITHDRAWN

PREDICTORS FOR LYMPHOCELE FORMATION AFTER PELVIC LYMPHADENECTOMY DURING ROBOT-ASSISTED RADICAL PROSTATECTOMY

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Presented By: Marcelo Orvieto

Introduction and Objectives: The frequency of lymphocele formation after pelvic lymphadenectomy (PLND) during robot-assisted radical prostatectomy (RARP) is unclear and likely underestimated. We sought to determine the incidence and predictive factors of lymphocele formation in patients undergoing PLND during RARP.

Methods: Between April and December 2008, 76 patients underwent PLND during RARP for ≥cT2c, PSA≥10, Gl≥7 prostate cancer. All patients were prospectively followed with pelvic CT at 6-12 weeks after the procedure. All patients received subcutaneous heparin preoperatively and postoperatively. PLND was limited to zones 1 & 2 as defined by Studer. Plasma-kinetic (PK) bipolar forceps were used for hemostasis during PLND.

Results: Median lymph node yield was 6 nodes per side (range 2-12). At a mean follow up of 10.8 weeks, 51% (39/76) of pts had developed a lymphocele on CT. Of these, 32/39 (82%) were unilateral, while 7 pts (18%) developed bilateral lymphoceles. Mean size was 4.3 x 3.2cm (range 1.5-12.3cm) with 41% lymphoceles <4cm, 53.9% 4-10cm, and 5.1% >10cm in diameter. Of the patients with radiologically apparent lymphoceles, 15.4% (6/39) were clinically symptomatic (pelvic pressure (5/6), abdominal distension with ileus (3/6), leg pain/weakness (1/6), and costovertebral tenderness (1/6). 2/39 (5.1%) required drainage for persistence of symptoms. On the logistic regression model the presence of nodal metastases, tumor volume in the prostate, seminal vesicles involvement and extracapsular extension were independent risk factors for the development of a lymphocele. There was no correlation between EBL, BMI, pathologic Gleason score and number nodes retrieved with the development of lymphocele.

Poster# 30 – WITHDRAWN

SALVAGE ROBOTIC-ASSISTED LAPAROSCOPIC PROSTATECTOMY FOR RADIORECURRENT PROSTATE CANCER: MULTI-INSTITUTIONAL OUTCOMES

Sanket Chauhan¹, Manoj Patel¹, Rafael Coelho¹, Marcelo Orvieto¹, Kenneth Palmer¹, Michael Liss², Robert Ferrigni³, Jean Joseph⁴, Erik Castle³, Thomas Ahlering² and Vipul Patel¹
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Presented By: Rafael Coelho

Introduction: An estimated 10-60% of men who undergo definitive radiation therapy (RT) for prostate cancer (PCa) may experience biochemical recurrence. Salvage treatment options for local recurrences have historically been limited to cryotherapy, HT or salvage radical prostatectomy (RP), with the latter being associated with significant morbidity. The recent introduction of advanced robotic devices to the field of minimally invasive urologic surgery has added new hopes of reducing complications and improving outcomes following salvage RP. We report here a multi-institutional experience with performing Salvage Robotic-Assisted Laparoscopic Prostatectomy (sRALP) in patients with recurrent PCa after definitive radiotherapy.

Methods: Between March 2007 and December 2008, 15 men underwent sRALP, in 4 different institutions, for treatment of locally recurrent PCa. Radiation treatment consisted of external beam radiation in 4 cases, brachytherapy in 6 cases, proton beam therapy in 2 cases, and external beam radiation followed by brachytherapy in 3 cases. Perioperative, oncologic and functional outcomes were evaluated. Continence was defined as the use of no pads; Potency was defined as erections sufficient for sexual intercourse with or without the assistance of oral medications; Biochemical recurrence after sRALP was defined as PSA>0.2

Results: The mean estimated blood loss was of 76.67 ml, operative time of 125.25 min and hospital length of stay of 1.3 days. At a mean follow-up period of 7.1 months, 3 patients (20%) presented with biochemical progression, defined as PSA>0.2; all 3 had negative surgical margins and underwent bilateral PLND, which revealed no evidence of malignancy. When stratified by age, all (8/8) patients younger than 64 years were continent, defined as 0 pads; 40% of men aged 64-70 (2/5) were continent; and no men older than 70 years were continent after surgery. None of the patients in our series were potent after salvage RALP; however, all the patients did report mild-moderate erectile dysfunction (defined as SHIM<17) after RT and before salvage surgery. There were no rectal injuries, blood transfusions, or conversion to open surgery.
**Poster Session I**

**Poster# 31 – WITHDRAWN**

**PREDICTORS FOR POSITIVE SURGICAL MARGINS AND ITS LOCATION AFTER ROBOTIC-ASSISTED LAPAROSCOPIC RADICAL PROSTATECTOMY**

Rafael Coelho, Marcelo Orvieto, Sanket Chauhan, Kenneth Palmer, Bernardo Rocco, Bobby Ardila and Vipul Patel  
Global Robotics Institute, Florida Hospital Celebration Health, University of Central Florida School of Medicine, Celebration, FL  
Presented By: Rafael Coelho

**Introduction:** Positive surgical margin (PSM) after radical prostatectomy (RP) has been shown to be an independent predictive factor for cancer recurrence. Several investigations have correlated preoperative variables, surgical experience and technical modifications with the margin status after open RP. However, few studies have addressed the predictive factors for PSM after RARP. Herein, we sought to identify predictive factors for PSMs and its location after RARP.

**Methods:** We analyzed prospectively 876 consecutive patients who underwent RARP performed by a single surgeon. Logistic regression was used to identify potential predictive factors for PSM. Three models were built: (1) one model using preoperative variables only (age, BMI, PSA, clinical stage, number of positive cores, percentage of positive cores and AUASS); (2) another model using pre-operative, intra-operative and post-operative variables combined (type of nerve-sparing, presence of median lobe, percentage of tumor in the surgical specimen, gland size, pathological stage and pathological Gleason grade); and, finally, (3) one model was created to identify potential predictive factors for PSM location.

**Results:** In the multivariate analysis including pre-operative variables (model 1), clinical stage was the only independent predictive factor for PSM, with a higher PSM rate for T3 vs. T1c (OR 10.7, 2.6–.8) and for T2 vs. T1c (OR 2.9, 1.9–.6). Considering pre, intra and post-operative variables combined (model 2), percentage of tumor, presence of EPE, pathological stage and pathological gleason score were associated with increased risk of PSM in the univariable analysis (P<0.001 for all variables). However, in the multivariate analysis, pathological stage (p<0.0001) and percentage of tumor in the surgical specimen (p=0.0022) were the only independent predictive factors for PSM. Finally, in the multivariate analysis of predictive factors for PSM locations (model 3), BMI was shown to be an independent predictive factor (p=0.0119) for apical PSMs, with increasing BMI predicting higher incidence of apex location.

**Conclusions:** Clinical stage was the only pre-operative variable independently associated with PSM after RARP. Pathological stage and percentage of tumor in the surgical specimen were identified as independent predictive factors for PSMs when analyzing pre, intra and post-operative variables combined. Regarding PSM location, BMI was shown to be an independent predictive factor for apical PSMs.

**Poster# 32**

**ONCOLOGIC OUTCOMES OF ROBOTIC ASSISTED RADICAL PROSTATECTOMY (RARP) IN D’AMICO HIGH RISK PATIENTS**

Sanjeev Kaul¹, Mireya Diaz¹, Piyush Agarwal¹, Craig Rogers, James Peabody¹ and Mani Menon¹  
¹Vattikuti Urology Institute  
Presented By: Sanjeev Kaul

**Objective:** We evaluated the biochemical recurrence (BCR) in patients with D’Amico high risk who underwent RARP at a single institution. A cox hazard proportion analysis was performed to determine variables predicting biochemical failure in this group.

**Methods:** Between January 2001 and December 2008, 4,116 patients underwent RARP. BCR was defined as one post-operative PSA of ≥0.2ng/ml followed by a consecutive PSA of >0.2ng/ml or A single PSA≥0.4 ng/ml or any adjuvant or salvage treatment. A step-wise Cox-proportional hazard regression model was built to determine pre-operative, pathological and post-operative clinical characteristics that best predicted the occurrence of BCR in this group.
**Results:** Of 4,116 patients, 625 belonged to D’Amico high-risk group. Of these 24% experienced Gleason downgrading and 4.3% Gleason upgrading. The D’Amico high-risk group is a heterogeneous group in which individuals with fewer risk factors exhibit better prognosis, particularly if the risk factor satisfying the condition is clinical stage. Organ confined disease was predominant among those with 1 risk factor, extraprostatic extension among those with 2, and seminal vesicle invasion among those with 3 risk factors. 135 patients experienced BCRs (21.6%). Unadjusted and adjusted hazard ratios for each of the predictors examined are shown in Table 1. Only D’Amico sub-stratification and pathology features (Gleason, stage and angiolymphatic invasion) remained clinically and statistically significant.

**Conclusion:** D’Amico high-risk group is a heterogeneous prognostic group, in which the presence of additional factors satisfying the threshold for inclusion increases the likelihood of BCR. In multivariable analysis, pathology stage, Gleason and angiolymphatic invasion in addition to the sub-stratification of the D’Amico high risk by number of factors were independent predictors of BCR.

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**ANALYSIS OF FACTORS AFFECTING EARLY RECOVERY OF CONTINENCE AFTER ROBOT-ASSISTED LAPAROSCOPIC RADICAL PROSTATECTOMY**

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Presented By: Jeongyun Jeong

**Introduction and Objectives:** Urinary incontinence after radical prostatectomy remains one of the most troublesome surgical complications that can profoundly worsen quality of life of the patient. We have investigated the independent factors affecting early recovery of continence following robot-assisted laparoscopic radical prostatectomy (RALRP).

**Methods:** Retrospective chart review identified 131 men who underwent RALRP for localized prostate cancer. Patients were divided into two groups according to the recovery of continence: patients who became continent within 3 months after urinary catheter removal (Group I) and patients who gained continence after 3 months following catheter removal (Group II). We defined continence as being pad free. Using univariate and multivariate analyses, we evaluated the influence of several different factors related to the operation.

**Results:** There were 106 patients (80.9%) in Group I and 25 (19.1%) in Group II. In Group I, there were 34 men (26.0%) who achieved continence within one week after catheter removal. Preoperative PSA level and clinical stage were associated with early recovery of continence in univariate analysis, and PSA level was the only factor showing a significant association in multivariate analysis. Given this result, we divided the patients again according to the D’Amico risk group classification. There were 81 men (81/123, 65.9%) in low risk group (Group L) and 42 (42/123, 34.1%) in intermediate and high risk group (Group H). After adjusting body mass index factor, we found that lower risk group had better chance of early recovery of continence significantly (Odds Ratio 2.70, 95% confidence interval 1.07–6.82).
**Poster Session I**

**Conclusions:** Among several pre- and perioperative risk factors, preoperative PSA level was strongly associated with early recovery of continence in the patients who underwent RALRP. Also, patients in the lower risk group using D’Amico classification had better chance of early regaining of continence. There is a possibility of applying more aggressive surgical technique for the purpose of better oncologic control in the intermediate and high-risk group, which results in delayed recovery of continence.

**Poster# 34**

**IMPACT OF PRIOR PROSTATE RADIATION ON COMPLICATIONS AFTER RADICAL PROSTATECTOMY**

Geoffrey Gotto, Luis Herran Yuis, Kinjal Vora, James Eastham, Peter Scardino and Farhang Rabbani  
MSKCC, New York, NY  
Presented By: Geoffrey Gotto

**Introduction:** While salvage radical prostatectomy (SP) is known to have more complications than radical prostatectomy (RP) without prior radiation, the magnitude of the increase is not well delineated.

**Objectives:** To compare quality-of-care measures and medical and surgical complications of SP to RP using a standardized reporting methodology.

**Methods:** From 01-1999 to 06-2007, 3458 (97.1%) consecutive patients underwent open RP, while 103 (2.9%) underwent open SP. Data was collected from prospective surgical and institutional morbidity databases as well as retrospectively from billing records, medical records, operative notes, discharge summaries, nursing notes and correspondence with local physicians. Medical and surgical complications were captured and graded according to the modified Clavien classification and classified by timing of onset.

**Results:** Median follow-up for the SP and RP groups was 35.7 and 45.5 months, respectively. The SP group had higher median patient ages (65.6 vs. 59.4 years, p<0.001), American Society of Anesthesiologists Physical Status classification (ASA) scores, and Charlson comorbidity scores. They had significantly higher preoperative prostate specific antigen (PSA), and clinical and pathologic stage and Gleason scores. They were less likely to be pN0 (79.6 vs. 93.3%, p<0.001), less likely to have organ-confined disease (43.7 vs. 69.3%, p<0.001), and more likely to have seminal vesicle invasion (33.0 vs. 7.5%, p<0.001). Median operative time was significantly longer for the SP group (222 vs. 202 minutes, p=0.030) but there was no difference in blood loss or transfusion rates. There were more emergency room visits by SP patients (33.0 vs. 13.1%, p<0.001). There were 5 (0.1%) mortalities versus none in the RP versus SP group. The SP group had higher rates of medical (26.0 vs. 8.8%, p<0.001) and surgical (52.9 vs. 18.7%, p<0.001) complications. The SP group had higher rates of UTI (20.4 vs. 2.8%, p<0.001), bladder neck contracture (42.7 vs. 5.5%, p<0.001), urinary retention (23.3 vs. 3.6%, p<0.001), urinary fistula (3.9 vs. 0.0%, p<0.001), abscess (4.9 vs. 0.7%, p<0.001), and rectal injury (9.7 vs. 0.7%, p<0.001).

**Conclusions:** Medical and surgical complications are significantly increased in patients with prior prostate radiation. The magnitude of this increased risk is important in initial patient counseling regarding treatment choice in the event of need for salvage therapy.

**Poster# 35**

**HYPOFRACTIONATED ROBOTIC RADIOSURGERY FOR THE TREATMENT OF PROSTATE CANCER: ACUTE TOXICITY AND EARLY BIOCHEMICAL RESULTS**

Eric Oermann, Heather Hanscom, Sue Lei, Simeng Suy, Brian Collins, Gerald Batipps, Edward Dunne, Nicholas Constantinople, Stephen Dejter, James Regan, Kevin McGeagh, John Pahira, Nancy Dawson, Anatoly Dritschilo, Sean Collins and John Lynch  
Georgetown University Hospital, Washington, DC  
Presented By: Sean Collins

**Introduction:** Clinical data suggest that fewer large fractions are radio-biologically favorable to smaller fraction sizes in prostate cancer radiotherapy. The CyberKnife is the ideal delivery system for hypofractionated radiosurgery due to its ability to deliver highly conformal radiation and to track and adjust for prostate motion in real-time. We report our early experience using the CyberKnife system to deliver hypofractionated radiotherapy to localized prostate cancer.

**Methods:** 23 patients were treated with hypofractionated robotic radiosurgery with or without supplemental external radiation therapy. Patients receiving androgen deprivation therapy were excluded from analysis. Four gold fiducials were placed within the prostate, either transrectally or transperitoneally, for X-ray guided prostate localization and beam adjustment. Fused CT and MRI scans were used for treatment planning. Sixteen patients were treated with radiosurgery alone (3625 cGy in five fractions). Seven patients were treated with radiosurgery (1950 cGy in three fractions) followed by IMRT (5040 cGy in 28 fractions). Quality of life data, including EPIC and IPSS questionnaires, was collected before and after treatment. The early PSA responses and acute urinary and rectal toxicities are reported here.
Results: There were no complications associated with fiducial placement. All 23 patients completed the proposed course of treatment without unplanned breaks. The mean pretreatment PSA was 7.28 ng/ml. PSA levels steadily decreased in all patients. The mean six-month post-treatment PSA was 1.24 ng/ml. Acute side effects associated with treatment included grade 2 urinary and gastrointestinal toxicity. No patient experienced acute grade 3 or greater toxicity. IPSS scores returned to baseline by six months after treatment.

Conclusion: Hypofractionated robotic radiosurgery using the CyberKnife system appears to be a well-tolerated treatment alternative for older men with prostate cancer. Early PSA results suggest a biochemical response similar to or better than the other standard radiation therapy options.

Poster# 36

PELVIC LYMPH NODE DISSECTION IS ASSOCIATED WITH VENOUS THROMBOEMBOLISM RISK DURING LAPAROSCOPIC RADICAL PROSTATECTOMY

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Presented By: John Eifler

Introduction: Venous thrombo-embolism (VTE) is a source of serious morbidity and mortality after radical prostatectomy (RP). It is unknown whether pelvic lymph node dissection (PLND) is related to the development of VTE. Given that PLND may not be necessary in most contemporary surgical patients, we wondered whether omitting PLND might decrease the incidence of VTE.

Materials and Methods: The records of 778 consecutive patients who underwent laparoscopic radical prostatectomy (LRP) by a single surgeon from 2001-2007 were reviewed for postoperative VTE. All patients underwent transperitoneal or extraperitoneal LRP +/- PLND and had at least 3 months of follow-up. Only patients at increased risk for lymph node metastasis by Partin nomogram and patients who requested PLND received it.

Results: 469 patients (60.4%) underwent LRP+PLND; 309 underwent LRP only (39.6%). VTE occurred in 7/472 LRP+PLND patients (1.5%), and in 0/309 LRP only patients (0%) (p =0.046). Patients who underwent LRP+PLND and developed VTE had greater BMI (30.8 vs. 27.1, p=0.006) and a trend toward longer operative times (3.7 vs. 3.2 hrs, p=0.15), but similar lymph node counts (5.9 vs. 5.7) than those who underwent LRP+PLND and did not develop VTE. Surgical approach (extra- or trans-peritoneal) was not a risk factor for VTE. Only 4/469 (0.9%) men had positive lymph nodes.

Conclusions: PLND during RP may increase the risk of VTE without providing cancer control benefit in most patients with clinically localized prostate cancer. Our data argue that PLND should be judiciously rather than routinely performed for patients at low risk for LN metastasis.

Poster# 37

PROSTATE SIZE INVERSELY CORRELATES WITH POSITIVE SURGICAL MARGINS IN RADICAL RETROPUBIC PROSTATECTOMY AND ROBOT ASSISTED LAPAROSCOPIC PROSTATECTOMY

Adeep B Thumar, Thenu Chandrasekar, Franklin C Lee, Stephanie Lappe, Peter A McCue, Costas D Lallas, Leonard G Gomella and Edouard J Trabulsi
Thomas Jefferson University Department of Urology Philadelphia, PA
Presented By: Adeep B Thumar

Introduction and Objectives: RALP has been compared to RRP in terms of oncological outcomes. We hypothesized that prostate size may be an inverse predictor of positive surgical margins (PSM).

Methods: We retrospectively examined our departmental, IRB approved, database of radical prostatectomy procedures performed by several surgeons from 2001-2009. A total of 600 RALP and 397 RRP patients were reviewed. Pathological reports yielding prostatic weight in grams was identified in 565 RALP patients and 355 RRP patients. A standard whole mount, step sectioned pathologic evaluation was used for all patients. Statistical analysis was conducted using the Student’s t-test and chi-square statistical models.
Results: The mean and median prostate weight for RALP was 41.0g and 37.0g, and for RRP was 44.2g and 39.0g, respectively (p=0.15). For the RALP cohort, PSM rate was lower for prostate weights >40g than <40g, 17.6% (43/245) vs. 29.0% (93/320), respectively (p=0.002). When examining higher prostate weights, this inverse association was maintained with PSM rate for glands >50g vs. <50g: 11.5% (15/130) vs. 27.9% (121/435), respectively (p=0.0001); and for prostate sizes >60g vs. <60g: 13.1% (8/61) vs. 25% (128/504), respectively (p=0.03). When examining organ confined disease (pT2), the PSM for larger prostates (>40g) were lower than prostates <40g: 9.3% (18/193) vs. 24.0% (63/263), respectively (p=<0.0001); for even larger prostates (>50g), the PSM rate was similarly improved: 6.6% (7/106) vs. 27.9% (121/435), respectively (p=0.0001). Conversely, for pT3/T4 disease prostate weight had no association with PSM in RALP patients. For the RRP cohort, larger prostate size (>40g) was similarly associated with a significantly lower PSM: 10.7% (18/167) vs. 22.4% (42/145), respectively (p=0.003). Examining pathologic stage for RRP, prostate size >40g in pT2 patients had lower PSM than prostates <40g: 6.4% (9/140) vs. 14.5% (20/138), respectively (p=0.03). Similarly for RRP, pT3/4 had no association between prostate size and margin status.

Conclusions: Prostate size is inversely associated with PSM for both RALP and RRP. Prostates size greater than 40g are at a lower risk of PSM with either technique. The benefit for PSM for each technique appears to be present only for organ confined disease (pT2), with no significant association between prostate size and PSM for pT3/4 patients with either technique.

ZIBOTENTAN (ZD4054): A SPECIFIC ENDOTHELIN-A RECEPTOR ANTAGONIST WITH POTENTIAL FOR THE TREATMENT OF CASTRATE-RESISTANT PROSTATE CANCER
Nancy A. Dawson¹, James W. Growcott², Thomas Morris², De H. Phung² and Nicholas D. James³
¹Washington, DC; ²Macclesfield, UK; ³Birmingham, UK
Presented By: Nancy A. Dawson

Introduction and Objective: Endothelin-1 (ET-1), acting through the endothelin-A receptor, is implicated in the development of prostate cancer through activation of pathways involved in proliferation, invasion, osteogenesis, and angiogenesis. In contrast, the endothelin-B receptor may counter tumor progression by promoting apoptosis and clearing ET-1. Zibotentan (ZD4054) is a small-molecule and a specific antagonist of the endothelin-A receptor in clinical development for the treatment of castrate-resistant prostate cancer (CRPC).

Methods: A review of both preclinical and clinical zibotentan data was conducted and the findings summarized.

Results: In vitro, zibotentan inhibited ET-1-induced proliferation and invasion, and counteracted ET-1-induced escape from apoptosis after serum starvation. In vivo, zibotentan inhibited xenograft tumor growth in prostate, ovarian, and breast cancer models, and inhibited metastasis and tumor blood vessel formation in dedicated murine models of metastasis and angiogenesis. In the clinical setting, zibotentan has been assessed in a randomized placebo-controlled phase II trial in patients with CRPC and bone metastases who were pain free or mildly symptomatic (n=312). Although no significant difference was observed between zibotentan and placebo for the primary endpoint, progression-free survival, zibotentan was associated with an increase in overall survival (OS).

Conclusions: Zibotentan showed promising anticancer activity in preclinical studies, and phase II clinical trial results support potential effects on OS. The ENTHUSE phase III trial program, which is currently recruiting, will evaluate whether zibotentan 10 mg once daily can prolong OS in patients with CRPC as monotherapy (M0, M1 disease) or in combination with docetaxel (M1 disease).

Funding: Supported by funding from AstraZeneca Pharmaceuticals, LP.
Poster# 39

THE INCIDENCE AND CONTEMPORARY MANAGEMENT OF LYMPHOCELES AFTER ROBOTIC-ASSISTED EXTRAPERITONEAL LAPAROSCOPIC RADICAL PROSTATECTOMY AND PELVIC LYMPH NODE DISSECTION

Thomas Hoang, Rodney Taylor and Ingolf Tuerk
Caritas St Elizabeth’s Medical Center, Tufts University School of Medicine, Brighton, MA
Presented By: Thomas Hoang

Introduction and Objectives: The most common method of performing the robotic-assisted laparoscopic prostatectomy is transperitoneal but recently the extraperitoneal technique is becoming more popular. The many advantages of robotic-assisted extraperitoneal laparoscopic radical prostatectomy (RAELP) have been elucidated and most are derived from the fact that the peritoneum is not entered. However, the disadvantages of RAELP are relevant and include post-operative lymphoceles. These can be large enough to cause significant ipsilateral leg edema or pain due to the obstruction of other lymph channels or nerves by a mass effect. It can also cause bladder symptoms by compression of the bladder wall. We present a review of the incidence and contemporary management of post-operative lymphoceles after robotic-assisted extraperitoneal laparoscopic radical prostatectomy with either unilateral or bilateral pelvic lymph node dissections performed by a single surgeon. We also discuss the contemporary management of these lymphoceles at our institution.

Methods: We retrospectively reviewed all RAELP by a single surgeon from November 2008 to August 2009. We identified the surgeries where a pelvic lymph node dissection was done either unilaterally or bilaterally. We then identified the number of post-operative lymphoceles as diagnosed by a CT scan of the pelvis.

Results: 205 RAELP were performed by a single surgeon. 102 (49.8%) of these surgeries involved unilateral or bilateral pelvic lymph node dissections. 55 (53.9%) of these were bilateral dissections. 16 (15.7%) were left sided pelvic lymph node dissections. 31 (30.4%) were right sided pelvic lymph node dissections. Overall 10 (9.8%) lymphoceles were diagnosed out of 102 lymph node dissections. 5 (50%) of these were managed conservatively with observation and repeat CT scans. 4 (40%) required percutaneous drainage by interventional radiology. 1 (10%) elected to undergo robotic-assisted laparoscopic bilateral lymphocelectomy.

Conclusions: The many advantages of the extraperitoneal approach to robotic-assisted laparoscopic radical prostatectomy have been elucidated. The disadvantages of this technique have not been thoroughly examined, including post-operative lymphoceles. We have demonstrated that there is a significant incidence when performed in large numbers and we discuss the contemporary management in our series.

Poster# 40

EVALUATION OF PRE AND POST TREATMENT PSA VALUES AND PROSTATE BIOPSIES IN PATIENTS FAILING EXTERNAL BEAM RADIATION THERAPY IN THE MODERN ERA: THE COLUMBIA EXPERIENCE

Ethan Fedida, Matthew Truesdale, Philippa Cheetham, Gregory Hruby and Aaron Katz
Columbia Medical Center, New York, NY
Presented By: Matthew Truesdale

Introduction and Objectives: External beam radiation therapy (EBRT) is an effective treatment for localized prostate cancer. Following EBRT, close PSA surveillance and if necessary, repeat prostate biopsy, is imperative for early detection of men with recurrent disease. The objective of this study was to evaluate baseline and follow-up PSA values, as well as repeat biopsy Gleason scores to determine the incidence and timing of recurrent disease following primary EBRT.

Methods: A retrospective analysis of the IRB-approved Columbia University Urologic Oncology Database identified 106 men post EBRT (from 2000-2008) for prostate cancer who subsequently underwent a TRUS guided prostate biopsy for a rising PSA from nadir values. PSA values and TRUS prostate biopsy Gleason scores pre and post EBRT were evaluated using Wilcoxon signed rank tests.

Results: 106 men were evaluated. Mean age of 72.5±7.1 years. Mean baseline PSA 15.6±25.9ng/mL, with 25-75th percentiles of 5.8-16.0ng/mL. Pre-EBRT biopsy Gleason score range 2-9 with 28%, 30% and 14% having grades 6, 7 and 8, respectively. Mean PSA at time of post-EBRT prostate biopsy 7.3±11.3ng/mL, with 25-75th percentiles of 2.7-7.4ng/mL. 63.3% of men who underwent a prostate biopsy for suspected recurrent disease had evidence of carcinoma; Gleason score range 5-9 with 33.3%, 23.8% and 36.5% having grades 7, 8, and 9, respectively. Of those with biopsy-proven recurrent cancer, 69.4% had an upgrade in Gleason grade (p<0.001) with 30.6% increasing by 1 grade, 21.0% increasing by 2 grades, and 21.0% showing no change. When compared to pre-treatment values, 74.6% of men had a decrease in post-radiation therapy PSA, (p<0.001). No significant association was seen between change in Gleason grade and PSA values following radiation.
**Conclusions:** Continued surveillance is required following radiation therapy for prostate cancer, in order to detect recurrent disease. However, PSA may not be an ideal marker for recurrent malignancy. In this study, men who failed radiation therapy had a much higher Gleason grade (and presumably are at increased risk of metastatic disease) than those who did not. Development of serum molecular markers in this patient population prior to radiation therapy may help identify those men at increased risk of recurrent disease, so that effective intervention can be promptly initiated.

**Poster# 41**

**IS MORE NECESSARILY BETTER?: STANDARD VERSUS EXTENDED PELVIC LYMPH NODE DISSECTION DURING ROBOTIC-ASSISTED RADICAL PROSTATECTOMY**

Jay Shah, Huong Truong and John Davis  
MD Anderson Cancer Center, Houston, TX  
Presented By: Jay Shah

**Introduction:** For men undergoing open radical prostatectomy, recent literature suggests that extended pelvic lymph node dissection (PLND) is better than standard PLND for detecting lymph node-positive prostate cancer. In keeping with this, the most recent National Comprehensive Cancer Network (NCCN) guidelines recommend that an extended template be used in those cases where PLND is performed. In contrast to this trend, PLND is often omitted during robotic-assisted laparoscopic prostatectomy (RALP) due to the technical difficulty of reaching the lymph node fields and to the low-risk nature of the disease in most men undergoing RALP. We sought to evaluate the utility of extended PLND in men undergoing RALP.

**Methods:** We retrospectively reviewed the experience of a single surgeon (JWD) performing RALP over three years. From May 2006 to October 2007, all robotic PLND were performed using a standard template (obturator nodes only). From November 2007 to May 2009, the technique was modified and all robotic PLND were performed using an extended template (external iliac, internal iliac, obturator, and hypogastric nodes). These two cohorts of men were well matched with regards to pre-operative PSA, Gleason sum, and clinical stage. We compared lymph node yields in men undergoing standard versus extended PLND during RALP and we used the Fisher’s exact test to determine differences in rates of LN positivity.

**Results:** Of 612 patients that underwent RALP between May 2006 and May 2009, 118 had standard PLND and 150 had extended PLND. The average number of LNs removed was 8.0 for standard PLND and 17.4 for extended PLND. The rate of LN positive disease was 6.8% for standard PLND versus 20% for extended PLND (p = 0.0024). The average time commitment was 20 minutes for standard PLND and 40 minutes for extended PLND.

**Conclusions:** Routine use of extended PLND as part of RALP provides higher LN yield and greater detection of LN positive disease. In keeping with current NCCN guidelines and similar to the trend for open radical prostatectomy, an extended template should be considered for all men undergoing RALP in whom a PLND is to be performed.
Poster# 42

DO MEN WITH PROSTATE CANCER YOUNGER THAN 50-YEARS-OLD HAVE BETTER CLINICOPATHOLOGIC OUTCOMES COMPARED TO OLDER PATIENTS UNDERGOING RADICAL PROSTATECTOMY?

Fangmin Chen, Gerald Tan, Abhishek Srivastava, Sonal Grover, Kumaran Mudaliar, David Peters, Robert Leung, Majnu John and Ashutosh Tewari
Weill Cornell Medical College-New York-Presbyterian Hospital
Presented By: Fangmin Chen

Objective: Widespread PSA screening has resulted in downstage migration of prostate cancer at diagnosis. We evaluated the effect of age on pathologic and biochemical progression-free outcomes in a contemporary cohort of men undergoing robotic-assisted radical prostatectomy (RARP).

Methods: Of 1490 men undergoing RARP between January 2005 and December 2008, 162 men were less than 50 years of age. We compared their preoperative and postoperative clinicopathologic profiles against those aged over 50 years (Group 2), the latter group being further sub-stratified into 51-60 years, 61-70 years, >70 years respectively (Groups 2a, 2b, 2c).

Results: Mean BMI, core positivity, maximum % cancer core biopsy, preoperative clinical stage and Gleason sum were not significantly different between Groups 1 and 2. Surgical margin status and lymph node positivity were also not significantly different across the groups. However, Group 1 patients had significantly lower mean preoperative PSA (p<0.001) and prostate volume (p<0.001), but significantly higher cancer density compared to older patients in Group 2 (p=0.024). Final Gleason sum ≤ 7 (p<0.001) and pT2 status was significantly more common in Group 1 patients. Conversely, older patients in Group 2 had significantly higher incidence of extracapsular cancer extension (p=0.003), and final pT3/T4 status (p=0.031). Group 1 patients also had a lower incidence of biochemical failure following surgery, but this observation was not statistically significant (1.4% versus 3.8%, p=0.098).

Conclusions: Men less than 50 years of age undergoing RARP have significantly smaller prostates, with better characteristics on final pathology compared to older patients.

Poster# 43

IMPACT OF POSTERIOR BLADDER NECK PLICATION ON CONTINENCE OUTCOMES IN PATIENTS RECEIVING ANATOMIC RESTORATION OF VESICOURETHRAL JUNCTION DURING ROBOTIC PROSTATECTOMY: A PROSPECTIVE RANDOMIZED TRIAL

David Peters, Abhishek Srivastava, Gerald Tan, Sonal Grover, Kumaran Mudaliar, Robert Leung, Majnu John, Fangmin Chen and Ashutosh Tewari
Weill Cornell Medical College, New York-Presbyterian Hospital, New York, NY
Presented By: David Peters

Objective: Posterior bladder neck plication (PBNP) has been reported to improve early continence recovery after radical prostatectomy. We report our experience with this technique in men undergoing received total anatomic restoration (ART) of the vesicourethral junction (VUJ) during robotic-assisted radical prostatectomy.

Methods: Between October 2008 and April 2009, 215 patients underwent total anatomic restoration during RARP by a single surgeon either with (Group 1) or without PBNP (Group 2) in a prospective randomized fashion. Outcomes data were collected using standardized health-related quality-of-life measures, including Expanded Prostate Cancer Index Composite survey, and then re-verified by telephone and email correspondence with a standardized questionnaire at regular intervals up to 24 weeks. Continence was defined as no pad usage or one small liner used for security purposes only. Univariate analyses was performed with student t and chi-square tests, and continence outcomes compared using Kaplan-Meier adjusted survival curves at all follow-up intervals.

Results: Preoperative clinicopathologic characteristics of age, body mass index, prostate volume, pre-operative PSA, biopsy Gleason sum, and clinical stage were comparable between patients in both groups. Urinary continence rates were high in both Groups 1 and 2 (95% vs. 91% continence at 24 weeks follow-up, p=0.284). Median time to continence was not significantly different between Groups 1 and 2 (5.0 vs. 4.0 weeks, p=0.126).

Conclusion: Posterior bladder neck plication does not appear to contribute significantly to earlier continence for patients receiving total anatomic restoration during RARP.
RETRO-APICAL DISSECTION OF THE PROSTATO-URETHRAL JUNCTION FOR LOWERING POSITIVE SURGICAL MARGINS DURING ROBOT-ASSISTED RADICAL PROSTATECTOMY
Ashutosh Tewari, Kumaran Mudaliar, Sonal Grover, David Peters, Abhishek Srivastava, Robert Leung, Gerald Tan, Fangmin Chen and Majnu John
Weill Cornell Medical College, New York-Presbyterian Hospital, New York, NY
Presented By: Kumaran Mudaliar

Purpose: After robot-assisted radical prostatectomy (RARP), the apex is the most common site of positive margin involvement. We introduce a new surgical approach of retro-apical dissection of the prostato-urethral junction. Our technique consists of approaching and transecting the junction from the posterior aspect. We compared positive surgical margin rates in patients who underwent retro-apical dissection of the prostate against those who underwent conventional apical dissection of the prostate.

Methods: From April 2009 to August 2009, 151 consecutive patients underwent RARP with retro-apical dissection of the prostate performed by a single surgeon at a single institution. We compared positive surgical margin rates in these patients to 1665 patients who underwent RARP with conventional apical dissection via an antegrade approach (control group) from August 2005 to April 2009 performed by the same surgeon.

Results: Preoperative parameters (age, BMI, maximum biopsy cancer %, core positivity %, Gleason biopsy characteristics, clinical stage) were not statistically different between the two groups except for preoperative PSA which was slightly higher in the control group versus the retro-apical group (5.9 vs. 5.2, p=.011). While statistically insignificant, the incidence of pathological T3 was higher in the control group versus the retro-apical group (16% vs. 10% respectively, p=.1187). After introduction of retro-apical dissection of the prostato-urethral junction, total positive margin rates decreased from 9.8% in the control group to 5.3% in retro-apical group. Positive apical margin rates decreased from 4.4% in the control group to 1.3% in the retro-apical group.

Conclusions: Retro-apical dissection is a novel approach to dissection of the prostato-urethral junction during RARP. It allows for better visualization of the prostatic apex and leads to both decreased total positive margin rates and decreased apical margin rates.

RADICAL PROSTATECTOMY FOR CLINICALLY LOCALIZED, HIGH RISK PROSTATE CANCER: IMPACT OF THE DEFINITION AND SURGICAL APPROACH ON OUTCOME.
Karim Touijer, Darren Katz, Caroline Savage, Andrew Vickers, Victor Reuter, James Eastham, Peter Scardino and Bertrand Guillonneau
Memorial Sloan-Kettering Cancer Center
Presented By: Karim Touijer

Objective: Our aim was to compare the probability of freedom from recurrence following radical prostatectomy for open and laparoscopic surgery in high-risk patients.

Methods: 3917 patients underwent radical prostatectomy between January 1998 and December 2007. Patients who received neoadjuvant hormones (n=210) or were missing clinical (n=275) or follow up information (n=183) were excluded, leaving 3249 patients for analysis. Six different definitions of high-risk were pre-specified: 1) biopsy Gleason score 8+, 2) preoperative PSA 20+, 3) TNM stage T3+, 4) PSA>=20 or clinical stage T2c+ or biopsy Gleason score 8+, 5) 5-year preoperative predicted probability of survival < 70%, and 6) PSA >=20 or clinical stage T3+ or Gleason score 8+. Each definition identified a subgroup of patients in which the probability of recurrence was estimated using Kaplan-Meier methods.
Results: Of the 3249 patients available for analysis, only a small number were classified as high-risk patients using any of the definitions (Table 1). The most inclusive definition was PSA $\geq$ 20 or clinical stage T2C+ or biopsy Gleason grade 8+ (n=492), whereas the least inclusive was TNM stage T3 or greater (n=91). The overall probability of recurrence at two years differed according to the definition of high-risk used (Table 2). There was an association between the inclusiveness of the definition of high-risk status and the predicted probability of being recurrence free: the more inclusive definitions tended to have better freedom from recurrence than the less inclusive definitions. The probability of freedom from BCR ranged from 57% to 66% and from 38% to 66% for patients treated by LRP and ORP, respectively.

Conclusion: the wide variability of the most commonly used definition of high risk prostate cancer will affect the eligibility and sample size when designing surgical clinical trials. The surgical approach should not be a discriminating factor in such trials.

<table>
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<tr>
<th>Definition</th>
<th>Total Number Patients</th>
<th>LRP</th>
<th>ORP</th>
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<tbody>
<tr>
<td>Definition 1: Biopsy Gleason score 8+</td>
<td>230</td>
<td>68 (30%)</td>
<td>162 (70%)</td>
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<td>Definition 2: PSA $\geq$ 20</td>
<td>106</td>
<td>43 (41%)</td>
<td>63 (59%)</td>
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<td>Definition 3: TNM stage T3+</td>
<td>91</td>
<td>29 (32%)</td>
<td>62 (68%)</td>
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<tr>
<td>Definition 4: PSA $\geq$ 20 or clinical stage T2C+ or biopsy Gleason grade 8+</td>
<td>492</td>
<td>158 (32%)</td>
<td>334 (68%)</td>
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<td>Definition 5: 5-year preoperative predicted probability of survival &lt; 70%</td>
<td>115</td>
<td>39 (34%)</td>
<td>76 (66%)</td>
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<td>Definition 6: PSA $\geq$ 20 or $\geq$ clinical stage T3+ or biopsy Gleason grade 8+</td>
<td>389</td>
<td>127 (34%)</td>
<td>242 (66%)</td>
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<table>
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<tr>
<th>Definition of High Risk</th>
<th>Probability of freedom from progression (95% CI)</th>
<th>LRP</th>
<th>ORP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition 1: Biopsy Gleason score 8+</td>
<td>60% (45%, 72%)</td>
<td>55% (46%, 63%)</td>
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<tr>
<td>Definition 2: PSA $\geq$ 20</td>
<td>61% (43%, 75%)</td>
<td>51% (34%, 64%)</td>
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<td>Definition 3: TNM stage T3+</td>
<td>66% (44%, 81%)</td>
<td>44% (30%, 58%)</td>
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<tr>
<td>Definition 4: PSA $\geq$ 20, clinical stage T2C+ or biopsy Gleason grade 8+</td>
<td>65% (56%, 73%)</td>
<td>66% (60%, 71%)</td>
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<tr>
<td>Definition 5: 5-year preoperative predicted probability of survival &lt; 70%</td>
<td>57% (40%, 71%)</td>
<td>38% (26%, 51%)</td>
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<tr>
<td>Definition 6: PSA $\geq$ 20, clinical stage T3+ or biopsy Gleason grade 8+</td>
<td>64% (54%, 73%)</td>
<td>58% (50%, 55%)</td>
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Pastor Session I

Poster# 46

SURVIVAL RATES AND RELATED FACTORS IN MEN WITH HORMONE-REFRACTORY PROSTATE CANCER
Hong Koo Ha, Seung Soo Lee, Tae Nam Kim and Wan Lee
Pusan National Univ. Hospital, Busan
Presented By: Seung Soo Lee

Introduction and Objectives: We evaluated survival rate in patients with hormone-refractory prostate cancer (HRPC) and clinical factors, which influenced survival rate and time.

Methods: Medical records of 96 patients who had HRPC and were not treated with chemotherapy from 2000 to 2008 were reviewed. We evaluated the survival rates at 1st, 3rd and 5th year using Kaplan-Meier survival curve. And we also evaluated survival differences according to clinical variables (clinical T stage, Gleason score, nadir prostate-specific antigen (PSA), PSA doubling time and PSA velocity) using log-rank test and relations between survival rates and these variables using Cox proportional hazards model.

Results: Mean age of patients was 67.8±7.5 years and mean follow up period was 23.3±13.7 months. Cancer-specific survival rates at 1st, 3rd and 5th year were 57.8%, 16.8% and 10.1% and survival differences significantly related to nadir PSA (p=0.002) and PSA velocity (p=0.019). At univariate analysis, nadir PSA (p=0.004) and PSA velocity (p=0.024) were related to survival rate, but only nadir PSA remained as a significant variable for survival rate in patients with HRPC at multivariate analysis (p=0.044).

Conclusions: Cancer-specific survival rates in patients with HRPC at 1st, 3rd and 5th year were 57.8%, 16.8% and 10.1% and they were related to nadir PSA. These results may benefit in determining therapeutic method in patients with HRPC.

Poster# 47

ONCOLOGICAL OUTCOME FOR LOCALLY ADVANCED (PT3A) PROSTATE CANCER FOLLOWING RADICAL PROSTATECTOMY ALONE WITH AT LEAST FIVE YEARS FOLLOW-UP
Amit Mevcha, Edward Rowe and David Gillatt
Presented By: Amit Mevcha

Introduction: This study looked at the oncological outcome of the patients who underwent radical prostatectomy (RP) with histologically confirmed T3a prostate cancer and have had a minimum follow up of 5 years.

Methods and Materials: We retrospectively reviewed the data for pathological T3a prostate cancer patients who had RP from January 1997 to August 2004.

Results: Total of 67 patients had pathological T3a disease. The biochemical recurrence was defined as PSA >/= 0.2. 32 (48%) patients had biochemical recurrence. These patients had salvage treatment at PSA relapse rather than adjuvant. 18 out of 32 patients received radiotherapy before their PSA reached 2 and 1 patient had subcapsular orchidectomy. Overall 3 out of 37 patients had progressive disease (1 lymph node, 2 bone metastases) requiring hormonal treatment. Hence in our study 96% had progression free survival and 100% disease specific survival. Five-year biochemical recurrence free survival was 67%. The overall survival was 94%.

Conclusions: Surgery alone can be sufficient for pT3a prostate cancer in selected cases. Salvage radiotherapy offers additional advantage to the patients without compromising oncological outcome. Hence, we may offer surgery as a first line of multimodality therapy to all suspected pT3a patients over radiotherapy +/- hormones.

Poster# 48

A RETROSPECTIVE ANALYSIS OF INTRAMURAL NCI PROSTATE CANCER TRIALS WITH COMBINATION CHEMOTHERAPY: PROGRESS MADE AND LESSONS LEARNED
Paul Kluetz, Wilfred Stein, William Figg, James Gulley, Philip Arlen, Yang-min Ning, Ravi Madan, Doug Price, Susan Bates, Tito Fojo and William Dahut
Medical Oncology Branch, NCI, NIH, Bethesda, MD
Presented By: Paul Kluetz
Background: In solid tumors such as prostate cancer, better surrogate endpoints for survival are needed to assess therapeutic efficacy. We developed a method for estimating PSA growth and regression rate constants from serial PSA measurements. We assessed the method's potential in patients with metastatic castrate-resistant prostate cancer (CRPC) by comparing results obtained across four studies of differing chemotherapy protocols conducted over more than a decade.

Methods: Patients with CRPC enrolled in four phase II studies were retrospectively evaluated. PSA measurements obtained prior to, and during, therapy were used. Data analysis using a two-phase mathematical equation yielded concomitant tumor (PSA) regression and growth rate constants.

Results: Incremental reductions in tumor growth rate constants were recorded in successive trials enrolling similar patients. Growth rate constants correlated with survival. In combination chemotherapy trials, the analysis suggests that prolonging drug exposure beyond arbitrary cutoffs could result in increased survival. In the most recent trial of Avastin, Taxotere, Thalidomide and Prednisone (ATTP), a substantial fraction of patients achieved a complete response. Upon relapse, the clone that emerged after a variable delay was insensitive to therapy, growing at a pre-treatment rate despite drug administration.

Conclusion: A progressive increased efficacy in successive trials is suggested by incremental reductions in tumor growth rate constants. Because the derived growth rate constant correlates with survival, it may be a valid surrogate to predict a survival benefit and to modify treatment regimes to improve survival. Confirmation of the growth rate constant as a surrogate for survival is warranted.

Poster# 49

ADVANCED PATIENT AGE IS ASSOCIATED WITH INFERIOR CANCER-SPECIFIC SURVIVAL AFTER RADICAL NEPHROURETERECTOMY

Shahrokh Shariat¹, Guilherme Godoy², Yair Lotan³, Michael Droller⁴, Pierre Karakiewicz⁴, Jay Raman⁵, Hendrik Isbarn⁶, Alon Weizer⁷, Mesut Remzi⁸, Marco Roscigno⁹, Eiji Kikuchi¹⁰, Christian Bolenz¹¹, Karim Bensalah¹², Theresa Koppie¹³, Wassim Kassouf¹⁴, Umberto Capitanio¹⁵, Mario Fernandez¹⁶, Francesco Montorsi¹⁷, Philipp Stroebel¹⁸, Jeffrey Wheat¹⁹, Richard Zigeuner²⁰, Casey Ng²¹, Christopher Wood²², Cord Langner²³ and Vitaly Margulis²⁴

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Presented By: Shahrokh Shariat

Purpose: To assess the impact of patient age on outcomes following radical nephroureterectomy (RNU) for upper tract urothelial carcinoma (UTUC).

Patients and Methods: Data were collected on 1453 patients treated with RNU at 13 centers. Pathologic slides were reviewed by dedicated genitourinary pathologists according to standardized criteria. Age at RNU was analyzed both as a continuous and categorical variable (<50, n=85; 50–9, n=229; 60–9, n=416; 70–79.9, n=523; >80 years old, n=200).

Results: Patients younger than 50 years old were less likely to have undergone previous ureteroscopy and to have a history of bladder cancer (p-values≤0.026). Advanced age was associated with infiltrative architecture and female gender (p-values≤0.003). Patients older than 70-years-old were less likely to undergo lymphadenectomy and to receive adjuvant chemotherapy (p-values≤0.026). In multivariate analyses, higher age was associated with decreased all-cause (>60 years old) and cancer-specific survival (>80 years old) after controlling for the effects of standard pathologic features (p values≤0.006). Addition of age, however, did not improve the predictive accuracy of a base model that included standard pathologic features for prediction of either disease recurrence, all-cause, or cancer-specific survival.

Conclusions: Greater patient age at the time of RNU is associated with decreased survival. This finding could be due to a change in the biologic potential of the tumor cell, a decrease in the host's defense mechanisms, or differences in care patterns. Further work is needed to improve our understanding of UTUC outcomes in this growing segment of the population and to develop strategies to improve cancer control in the elderly.
Poster Session I

Poster# 50

LONG-TERM OUTCOMES OF NEPHROURETERECTOMY VERSUS ENDOSCOPIC MANAGEMENT FOR UPPER TRACT UROTHELIAL CARCINOMA
University of Michigan, Ann Arbor, MI
Presented By: J. Stuart Wolf, Jr.

Purpose: To compare outcomes for patients treated with immediate nephroureterectomy versus nephron-sparing endoscopic surgery for upper tract urothelial carcinoma.

Materials and Methods: We studied patients treated at our institution from 1996 to 2004 for upper tract urothelial carcinoma. Patients were monitored for upper tract and bladder recurrence, metastases, and cancer-specific and overall survival. Outcomes were compared between treatment groups with univariate and multivariate analyses based on pertinent pathological and demographic variables.

Results: Of 96 renal units, 62 underwent immediate nephroureterectomy and 34 were managed endoscopically. Median follow-up among all living patients was 77 months. Overall complication rates for nephroureterectomy and endoscopy were 29% and 9.3%, respectively. In patients with low grade tumors, the 5-year metastasis-free survivals of patients undergoing nephroureterectomy or endoscopy were 88% and 94% respectively; the corresponding 5-year cancer-specific and overall survivals were 89% versus 100% and 72% versus 75%, respectively. In patients with high grade tumors, the 5-year metastasis-free survivals of patients undergoing nephroureterectomy or endoscopy were 64% and 86% respectively; the corresponding 5-year cancer-specific and overall survivals were 72% versus 86% and 48% versus 25%, respectively. Multivariate analysis revealed that only tumor grade significantly correlated with metastasis-free survival, body mass index and grade correlated with cancer-specific survival, and Charlson Comorbidity index and grade correlated with overall survival. Treatment group did not impact any survival outcome.

Conclusions: Endoscopic management appears equivalent to immediate nephroureterectomy in patients with low-grade upper tract urothelial carcinoma, in terms of cancer-related and overall survival, such that treatment decisions can be based on other factors. Although nephroureterectomy should still be considered standard treatment of high-grade cancer in the setting of a normal contralateral kidney, endoscopy is a viable option when there are imperative indications for nephron-sparing.
**Poster# 51**

SINGLE INSTITUTION EXPERIENCE OF FLUORESCENCE IN SITU HYBRIDIZATION (FISH) IN THE DIAGNOSIS OF BLADDER CANCER AND UPPER TRACT TCC

Adeep B. Thumar, James R. Johannes, Ryan C. Cleary, Timothy B. Brown, Murat Arslan, Peter A. McCue, Demetrius H. Bagley, Costas D. Lallas, Edouard J. Trabulsi and Leonard G. Gomella

Thomas Jefferson University Department of Urology Philadelphia, PA

Presented By: Adeep B. Thumar

**Introduction and Objectives:** FISH has become an adjunct test for the detection of TCC. We review a 4-year single institution experience to evaluate the value of FISH for the detection of de novo and recurrent TCC.

**Methods:** We performed a retrospective review of consecutive patients from January 2004 to September 2008 who submitted outpatient voided urine specimens upon which FISH testing and cytology was performed. When clinically indicated, patients had an endoscopic evaluation in the OR. Only evaluations performed within 6 months of a FISH test were used in our analysis. Patients were considered to have TCC of the bladder (BTCC) with a positive biopsy; upper tract TCC (UTTCC) was determined by positive biopsy, positive or highly suspicious upper tract cytology, or visual confirmation of tumor. A total of 907 FISH tests from 415 patients were collected. 345 patients underwent a total of 1202 endoscopic evaluations. Of these patients, 152 had no evidence of TCC, 110 had BTCC only, 41 had UTTCC only, and 42 had both BTCC and UTTCC.

**Results:** The overall sensitivity for FISH to detect TCC was significantly higher than cytology: 55.3% (73/132) vs. 42.2% (182/431), respectively (p<0.05). The specificity for TCC detection was higher for cytology than for FISH: 93.3% (720/772) vs. 71.7% (109/152), respectively (p<0.05). For patients with BTCC only, the sensitivity and specificity for FISH was 51.1% (24/47) and 71.9% (109/152), respectively compared with 34.4% (66/192) and 93.3% (720/772), respectively for voided cytology (p<0.05). Of the patients with UTTCC only, FISH was not more sensitive or specific than cytology: sensitivity of 51.9% (28/54) and specificity of 80.8% (21/26), compared to 43.2% (63/146) and 91.6% (98/107), respectively for voided cytology (p>0.05). FISH was equally sensitive in patients with concurrent UTTCC and BTCC: 67.7% (21/31) vs. 67.5% (52/77) (P>0.05); however was less specific, 71.9% (109/152) vs. 93.3% (720/772) (P<0.05).

**Conclusions:** Outpatient voided urine FISH testing does offer a higher detection of TCC, specifically for BTCC compared to voided cytology; however the specificity was significantly worse. In a secondary analysis, FISH does not appear to improve detection of TCC in patients with either UTTCC only or both BTCC and UTTCC. Therefore, FISH does not appear to offer clinical improvement over voided cytology in the detection of TCC. The poor specificity of FISH may lead to unnecessary testing and operative evaluations.

**Poster# 52**

A “TRIPLE SCREEN” OF IPSILATERAL HYDRONEPHROSIS, URETEROSCOPIC BIOPSY GRADE, AND URINARY CYTOLOGY CAN IMPROVE PREOPERATIVE PREDICTION OF INV ASIVE UPPER-TRACT UROTHELIAL CARCINOMA

James Brien¹, ², Shahroksh Shariat³, Michael Herman⁴, Casey Ng⁴, Douglas Scherr⁴, Benjamin Scoll⁴, Robert Uzzo⁵, Mark Wille⁶, Scott Eggener⁶, John Terrell⁷, Steven Lucas⁷, Yair Lotan⁷, Stephen Boorjian⁸ and Jay Raman⁸

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Presented By: James Brien

**Purpose:** We evaluated if a combination of ipsilateral hydronephrosis, ureteroscopic (URS) biopsy grade, and urinary cytology could improve preoperative prediction of upper-tract urothelial carcinoma (UTUC) stage.

**Methods:** Charts from 469 patients with localized UTUC treated with radical nephroureterectomy (RNU) or segmental ureterectomy (SU) were reviewed. Complete data on ipsilateral hydronephrosis (present vs. absent), URS grade (high vs. low), and urinary cytology (positive or atypical vs. negative) was available in 172 patients. Chi square analysis and Cox proportional hazard modeling were used to determine predictors for advanced UTUC.
**Poster Session I**

**Results:** Preoperatively, 92 patients (54%) had hydronephrosis, 74 (43%) had high-grade disease on URS biopsy, and 137 (80%) had positive cytology. On univariate analysis, the presence of hydronephrosis (p<0.001), high URS grade (p<0.001), and positive cytology (p=0.03) were associated with muscle-invasive and non-organ confined UTUC. On multivariate analysis, hydronephrosis and high grade URS biopsy were independent predictors of muscle invasive UTUC (HR 12.0 and 4.5 respectively, p<0.001 for both), while cytology was not (HR 2.3, p=0.17). All three, however, were predictors of non-organ confined UTUC (HR 5.1 p<0.001, HR 3.9 p<0.001, and HR 3.1 p=0.035, respectively). Combination of all three features stratified patients into distinct risk groups for prediction of UTUC stage (p<0.001). An abnormality with all three features had a positive predictive value of 89% for muscle-invasive and 73% for non-organ confined UTUC. Conversely, normality of all three variables had a negative predictive value of 100% for > pT2 and non-organ confined disease.

**Conclusion:** Ipsilateral hydronephrosis, URS grade, and cytology can be used in conjunction to create a “triple screen” model with high accuracy for prediction of advanced UTUC. Such a tool may facilitate improved preoperative stratification to guide clinical decision-making regarding treatment options.

**Poster# 53**

**COMPARISON OF 2004 WORLD HEALTH ORGANIZATION (WHO) AND 1973 WHO GRADING SYSTEMS FOR PREDICTING LONG-TERM PROGNOSIS IN UROTHELIAL CARCINOMA (UC) PATIENTS.**

Samay Jain¹, Dengfeng Cao¹, Robin Vollmer², Jason Luly¹, Timur Roytman¹, Charles Ferris¹ and M’Liss Hudson¹

¹Washington University, Saint Louis, MO; ²Durham VAMC, Durham, NC; ³Missouri Baptist Medical Center, Saint Louis, MO

Presented By: Samay Jain

**Introduction and Objectives:** We compared the 1973 and 2004 WHO grading systems for correlation to time to tumor recurrence (TR), tumor progression (TP), and overall survival (OS) in a cohort of UC subjects using the previous and more recent interpretations of the term “invasive” (pT1 versus > pT2).

**Methods:** 269 tumors were graded using the 1973 WHO system between 1994-98 under an IRB-approved protocol. Another blinded urologic pathologist re-graded them using the 2004 system. Kaplan-Meier plots, the log-rank test, Chi square, and the Cox proportional hazard model were used to relate clinical and histological variables.

**Results:** Mean follow-up was 12.5 years (10.7 –14.5). 102 subjects had TR, and 41 subjects had TP. 184 subjects died. Initially tumors were stratified using the superficial (pTa + pT1) and muscle invasive (>pT2) groupings. In univariate analysis, > pT2 stage was significantly associated with TR (p=0.0035), TP (p=2.6 X 10-7), and OS (p=6.3 X 10-7). We compared clinical outcomes between high grade (HG) pTa and pT1 UC. Recurrence-free survival and progression-free survival were similar in both. However, OS was significantly longer for HG pTa than HG pT1 UC subjects (p=0.05 by log-rank test). No significant difference in OS was observed between subjects with HG pT1 UC and > pT2 UC (p=0.069, log-rank test. The data was stratified with respect to tumor grade. HG was strongly associated with > pT1 stage (Chi square, 1973 WHO p= 0.0026, 2004 WHO p<0). Grade was only important for subjects with pTa UC, with significant differences observed between LG and HG with respect to TR-free and TP-free survival (p=0.05 and p=0.01, respectively). Cox model analyses that included tumor stage as a co-variate to grade showed the 2004 WHO grade was more closely associated with TR (p=0.025) and TP (p=0.012) than was the 1973 WHO grade (p=0.47, and p=0.046, respectively). OS was similar and significant for both (2004 grade p=0.034, 1973 grade p=0.026).

**Conclusions:** Our study confirms that muscle invasion is the strongest predictor of TR, TP, and OS for UC subjects. We confirmed a poorer prognosis for subjects with pT1 compared to pTa tumors. Subjects with HG pT1 tumors showed an expected OS that was similar to those with > pT2 tumors, confirming the suggestion that HG pT1 tumors are an early form of invasive disease. The 2004 WHO system is superior to the 1973 WHO system for predicting TR and TP, while the two are equivalent for predicting OS for subjects with UC.
TOPICAL TREATMENT OF UPPER TRACT UROTHELIAL CARCINOMA
Kenneth Nepple and Michael O’Donnell
University of Iowa, Iowa City, Iowa
Presented By: Kenneth Nepple

Introduction: Clinical experience with topical treatment of upper tract urothelial carcinoma (UTUC) is limited. We reviewed our experience with immunotherapy or chemotherapy topical treatment of UTUC (2003-2008).

Methods: Topical treatment of UTUC was offered to selected patients as an alternative to nephroureterectomy. Patients received 6 weekly office treatments, either antegrade by nephrostomy tube or retrograde by externalized ureteral catheter. Agents used included BCG/interferon, mitomycin, gemcitabine, adriamycin, or docetaxel based on prior intravesical treatment and investigator preference. Patients were restaged by cystoscopy with bladder and upper tract cytologies.

Results: 21 patients (median age 68 years, range: 40-86) with 28 renal units were treated. Presentation was gross hematuria in 3 and bladder cancer surveillance in 18. Indications were abnormal upper tract cytology consistent with CIS (16) or adjunct treatment after endoscopic resection (5). 18 patients were treated with ureteral catheter and 3 via nephrostomy tube. Treatments were well tolerated and no patient developed BCG sepsis. One patient developed ureteral stricture during follow-up. Eight of 21 (38%) had no ureteral recurrence during mean follow-up of 2.1 years (range: 0.8-5.8 years). All 13 recurrences occurred within 13 months (see Figure). Four patients underwent nephroureterectomy and four were not surgical candidates or refused further treatment. Of the non-responders, salvage therapy was attempted in eight and successful in four. Thus, at last follow-up upper tract treatment was successful in 13 of 21 (62%). One patient developed contralateral UTUC and required nephroureterectomy. Thirteen of 20 (65%) patients had recurrent urothelial carcinoma in the bladder and three patients developed metastatic disease.

Conclusions: We report moderate success using topical treatment of UTUC, but patients are at risk of recurrence in the upper tracts, bladder, or with metastatic disease. Topical treatment of UTUC is feasible and can be considered in selected patients with CIS, low-grade non-invasive disease after ureteroscopic ablation, or when renal preservation is necessary.
Poster# 55

CARCINOMA-IN-SITU OF THE TESTIS: WORLD LITERATURE REVIEW
Wassim Bazzi¹, Ithaar Derweesh², Christopher Kane² and Tracy Downs²
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Presented By: Wassim Bazzi

Background: In 2009, 8,400 new cases of testicular cancer will be diagnosed and 380 men will die of testicular cancer in the United States. Carcinoma-in-situ (CIS) is thought to be the predecessor for testicular carcinoma.

Methods: A PubMed (www.pubmed.gov) literature search was performed in the English language using terms: TIN and Testicular CIS and Partial Orchiectomy with 8 articles return. Those 8 articles were critically evaluated and their references were reviewed to a total of 19 articles and case reports on human experience.

Results: CIS pathology was first described by Sakkebaek 1972 in two patients referred for infertility after testicular biopsying; one of the two patients subsequently developed carcinoma. CIS is found concurrently in 80% of ipsilateral testicular carcinomas, 5% in contralateral testicle, which is equal to the incidence of developing contralateral testicular carcinoma in patients with a prior history of testicular carcinoma, cryptorchidism (2% to 4%), infertility (0% to 1%), ambiguous genitalia (25%) and <1% in the general population again similar to the risk of developing testicular carcinoma. The estimated risk of CIS progressing to invasive growth is 40%, 50% and 70% with 3, 5 and 7 years respectively. The biopsying of contralateral testicle at time of orchiectomy is debated between the German and United States literature. German literature proposes biopsying because it decreases necessary follow up from 25 to 5 yrs. In general CIS is radiosensitive although there are a few reports of radioresistance. Recommended radiation dose is 18-20 Gy in multiple sessions, this seems to preserve androgen production and provide good oncologic control. Chemotherapy for CIS has been investigated and overall CIS shows chemo-resistance although that is hard to predict because the majority of patients do receive chemotherapy for initial contralateral testicular carcinoma.

Conclusions: Literature reviewing reveals that CIS is thought to be a predecessor to the development of testicular carcinoma because its incidence parallels the incidence of testicular carcinoma including those at risk for developing carcinoma. It is radiosensitive yet chemoresistant. Biopsying to look for this entity is more common in Europe than the United States. Patients with history of cryptoorchidism, infertility, ambiguous genitalia and contralateral carcinoma need to be followed closely with routine physical examination and/or imaging studies.

Poster# 56 - WITHDRAWN

Poster# 57

THE INDICATIONS AND FEASIBILITY OF PARTIAL ORCHIECTOMY: WORLD LITERATURE REVIEW
Wassim Bazzi¹, Ithaar Derweesh², Christopher Kane² and Tracy Downs²
¹University of California San Diego, San Diego, CA; ²University of California, San Diego John and Rebecca Moores Comprehensive Cancer Center, La Jolla, CA
Presented By: Wassim Bazzi

Background: In 2009, 8,400 new cases of testicular cancer will be diagnosed and about 380 men will die of testicular cancer in the United States. Since the introduction of platinum based chemotherapy, the mortality from testicular cancer has decreased. There are cases in which a radical orchiectomy is not desirable; patients with a solitary testicle, bilateral concurrent malignancies, desire for paternity and being independent from androgen supplementation.

Methods: A PubMed (www.pubmed.gov) literature search was performed for articles written in the English language. Search terms were: partial orchiectomy with 322 articles return. Most of the world literature is from Germany, Denmark and The Netherlands. There are few case reports from Australia (1), France (1), Turkey (1) and Spain (1). A critical review of selected articles was done.
Poster Session I

Results: First partial orchiectomy was performed by Richie 1984. Patients who are candidates for this procedure have a solitary testicle with malignancy, concurrent bilateral testicular malignancies, desire for paternity, improved cosmesis and independence from androgen supplementation. Weissbach et al. series (1997) was successful in 10 of 14 patients; none of his patients did demonstrate any local recurrence. In Heidenreich et al. series (2001) 72 of 73 patients did not have any recurrence after 91 months of follow up. Local irradiation with 18-20 Gy was given after partial orchiectomy for cases with concomitant carcinoma in situ. Partial orchiectomy is feasible however it represents a surgical challenge; maintaining cold ischemia, tumor size less than 2cm, protecting testicular vasculature and performing multiple biopsies of adjacent areas to tumor bed to rule out concurrent CIS. Radiotherapy to a total dose of 18-20 Gy divided in multiple sessions is efficacious at eradicating residual CIS as well as maintaining Leydig Cell function however patients will lose sperm production. Majority bilateral testicular tumors are of similar histologies, seminomas most common, and metachronous.

Conclusions: Patients with a history of testicular carcinoma have a 5% chance of developing another one contralaterally. With the excellent response to platinum based chemotherapy with improved survival, patients will live longer to develop contralateral tumors and hence the number of candidates for this procedure is expected to rise. Partial orchiectomy is technically challenging and requires close post-operative follow up.

Poster# 58

CLINICAL AND PATHOLOGIC FEATURES PREDICTIVE OF NEPHRECTOMY AT POST-CHEMOTHERAPY RETROPERITONEAL LYMPH NODE DISSECTION (PCRPLND)
Kelly Cary, Stephen Beck, Richard Bihlre and Richard Foster
Indiana University Department of Urology, Indianapolis, IN
Presented By: Kelly Cary

Introduction and Objectives: To determine clinical and pathologic features associated with nephrectomy at PCRPLND.
Material and Methods: The testis cancer database was retrospectively reviewed from 1980 to 2007 to identify all patients undergoing PCRPLND. Patients with pure seminoma and non-germ cell histology were excluded. 1807 patients were identified. 17 patients without recorded mass size were excluded from further analysis. Variables analyzed included retroperitoneal histology, year of surgery, and tumor size.
Results: The incidence of nephrectomy at PCRPLND was 14.8% (265 of 1790). Nephrectomy rate was 17.0%, 18.9%, 13.6%, and 8.0% for years 1980-1988, 1989-1997, 1998-2002, and 2002-2007, respectively (p = 0.0001). Nephrectomy for tumor size < 2 cm, 2-5 cm, 5-10 cm, and > 10 cm was 6.0%, 5.8%, 13.9%, and 31.9%, respectively (p = 0.0001). The incidence of nephrectomy based on retroperitoneal histology was 10.3% for fibrosis, 14.5% for teratoma, and 20.4% for cancer (p = 0.0001)
Conclusion: The incidence of nephrectomy at PCRPLND has decreased over the last three decades. A higher incidence is observed in patients with larger volume tumors and teratoma or cancer in the retroperitoneum.

Poster# 59

LYMPH NODE COUNT IN PRIMARY RETROPERITONEAL LYMPH NODE DISSECTION: A BENCHMARK FOR GERM CELL TUMORS
R. Houston Thompson¹, Brett Carver², George Bosl³, Dean Bajorin², Robert Motzer², Darren Feldman², Victor Reuter² and Joel Sheinfeld²
¹Mayo Clinic, Rochester, MN; ²Memorial Sloan-Kettering Cancer Center, New York, NY
Presented By: R. Houston Thompson

Purpose: Lymph node counts are a measure of quality assurance and are associated with prognosis for numerous malignancies. To date, investigations of lymph node counts in testis cancer are lacking.
Methods: Using the Memorial Sloan-Kettering Testis Cancer Database, we identified 255 patients treated with primary retroperitoneal lymph node dissection (RPLND) for nonseminomatous germ cell tumors (NSGCT) between 1999 and 2008. Features associated with node counts, positive nodes, number of positive nodes, and risk of positive contralateral nodes were evaluated with regression models.
**Poster Session I**

**Poster# 60**

**MARITAL STATUS INDEPENDENTLY PREDICTS SURVIVAL IN ADULT MEN WITH TESTIS CANCER**

Michael Abern and Christopher Coogan
Rush University Medical Center Chicago, IL
Presented By: Michael Abern

**Objectives:** Previous reports have shown that married men with malignancies have improved survival over unmarried men. We seek to investigate the effect of marital status on survival in a U.S. population based cohort of men with testis cancer.

**Methods and Materials:** We examined 30,789 cases of testis cancer reported to the Surveillance, Epidemiology and End Results (SEER 17) database between 1975 and 2005. All staging was converted to the 1997 AJCC TNM system. Patients less than 18 years of age at time of diagnosis were excluded. A subgroup analysis of patients with stage I or II non-seminomatous germ cell tumors (NSGCT) was performed. Univariate analysis compared characteristics of patients separated by marital status. Multivariate analysis was performed using a Cox proportional hazard model with 10-year overall survival as the primary endpoint, to generate Kaplan-Meier survival curves.

**Results:** 20,487 cases met the inclusion criteria. Married men were more likely to be older (39.5 vs. 32.0 years), Caucasian (94.6% vs. 92.3%), stage I (72.9% vs. 61.0%), and have seminoma as the tumor histology (59.2% vs. 46.1%). On multivariate analysis, married status (HR 0.58, p < 0.01) and Caucasian race (HR 0.65, p < 0.01) independently predicted improved survival, while increased age (HR 1.05, p < 0.01), increased stage (HR 2.6, p < 0.01), and lymphoid (HR 3.9, p < 0.01) or NSGCT (HR 1.8, p < 0.01) histology independently predicted death. The subgroup of men with stage I or II NSGCT had similar characteristics as the overall cohort, although retroperitoneal lymph node dissection (RPLND) was an additional independent predictor of survival (HR 0.55, p < 0.01), despite equal rates of the treatment between married and unmarried men (32.54% vs. 32.47%, p = 0.95).

**Conclusions:** Marital status is an independent predictor of improved overall 10-year survival in men with testis cancer. This relationship also applies to men with stage I or II NSGCT, and RPLND also predicts improved survival in this cohort. Marital status does not appear to influence the rate of men who undergo RPLND.

**Poster# 61**

**TREATMENT OF CHEMOTHERAPY-REFRACTORY ADVANCED PENILE SQUAMOUS CELL CARCINOMA WITH SORAFENIB AND SUKITINIB**

Ding-Wei Ye, Shi-Lin Zhang, Hai-Liang Zhang and Guo-Hai Shi
Fudan University Shanghai Cancer Center
Presented By: Ding-Wei Ye

**Background:** Penile cancer is a substantial health problem in developing countries. Despite continued advanced in the optimal management of early disease, encouraging therapeutic improvement in advanced disease remains lacking. Sorafenib and sunitinib are orally bioavailable, small-molecule tyrosine kinase inhibitors that target the vascular endothelial growth factor receptor. We describe our experience with sorafenib and sunitinib in the treatment of chemotherapy-refractory advanced penile squamous cell carcinoma.
**Methods:** Between May 2008 and Jun 2009, six advanced penile cancer patients were treated with sorafenib or sunitinib in our center. All of them previously received at least two chemotherapy regimens. Sorafenib was administered at 400 mg twice daily on a continuous basis, while sunitinib dose at 37.5 mg once daily on a continuous basis. Tumor responses were evaluated by radiologic assessment and serum squamous cell carcinoma antigen (SCCa) change. The immunohistochemical staining of Ki-67 and CD31 were performed in paired tumor tissue before and after treatment. Toxicities were assessed using the Common Terminology Criteria for Adverse Events version 3.0.

**Results:** Of the six patients, one partial response and four stable diseases were observed. Three patients had pain response and quality of life improvement. After molecular targeted therapies, reduction in microvessel density and Ki-67 LI was observed in paired specimen. Serum SCCAg levels decreased in five patients after medication. The percentage of decrease seems to correlate with outcome. The patient achieved partial response had an SCCAg reduction of nearly 95% after treatment with sunitinib. The toxicity of sorafenib and sunitinib was moderate, including grade one hand-foot skin reaction and grade two neutropenia. However, the risk of fatal infection and femoral vessel rupture was high in these patients with ulcerated tumor lesions. After progression under sunitinib, one patient started on erlotinib at a dosage of 150 mg per day. Disease control was found at week four and continued at last visit.

**Conclusion:** The efficacy of sorafenib and sunitinib in our series suggests that this approach may be a promising alternative in chemotherapy-refractory advanced penile SCC. The findings and response seen in this report need to be confirmed in further studies.

**Poster# 62**

**IS THE MORBIDITY OF POST-CHEMOTHERAPY RETROPERITONEAL LYMPH NODE DISECTION FOR TESTICULAR CANCER RELATED TO THE SIZE OF THE RESIDUAL MASS OR TO THE INTERNATIONAL GERM CELL CONSENSUS CLASSIFICATION?**

Moffitt Cancer Center, Tampa, FL
Presented By: Jose Correa

**Introduction and Objectives:** To evaluate whether surgical morbidity or perioperative complications following post-chemotherapy retroperitoneal lymph node dissection (PCRPLND) are related to tumor bulk or to the International Germ Cell Consensus Classification (IGCCC).

**Methods:** A retrospective review was performed to identify patients who underwent PCRPLND from December 1992 through July 2009. Patients were divided into groups based on the size of the residual mass (group 1 ≤ 5cms; group 2 > 5cms). The IGCCC status was determined to assign risk categories. Clavien’s system was utilized to classify the severity of perioperative complications.

**Results:** 86 patients underwent PCRPLND. Groups 1 and 2 included 38 and 48 patients, respectively. The IGCCC status was determined for 71 of the 86 patients (83%); good risk=28, intermediate risk=19 and poor risk=24. The mean EBL, the mean operative time, and the mean LOS was higher in group 2 compared to group 1; 2103 ml vs. 922 ml, 511 min vs. 429 min, and 9.5 days vs. 7.1 days. Intraoperative and post-operative complications occurred in 12 (13.9%) and 37 (43%) patients, respectively. However, complications deemed significant and requiring intervention according to the Clavien classification (i.e. Clavien’s III or higher) occurred in only 10 (11.6%) patients. A univariate analysis revealed that a residual mass > 5 cm (group 2) was significantly associated with EBL (p=0.0048) and vascular/adjacent organ resection (i.e. nephrectomy, adrenalectomy, major vessel resection, bowel resection) (p=0.012). Poor-risk IGCCC status was significantly associated with EBL (p=0.010), longer OR time (p=0.049), and transfusion requirements (p=0.03). However, neither the size of the residual mass nor the IGCCC status predicted the occurrence of perioperative complications on multivariate analysis.

**Conclusions:** Although PCRPLND is often associated with extensive surgery, significant complications (Clavien III-V) are limited to a minority of patients. The EBL, operative time, LOS and number of organ and vascular resections is increased in patients with bulky retroperitoneal disease. The IGCCC status or the largest residual mass size did not predict post-operative morbidity.
**Poster Session I**

**Poster# 63**

15-HYDROXYPROSTAGLANDIN DEHYDROGENASE IS A POTENTIAL THERAPEUTIC TARGET IN HUMAN BLADDER CANCER
Monica Liebert, Stephanie Tseng-Rogenski, Lakshmi Kunju, Kathleen Woods-Ignatoski and Cheryl Lee
University of Michigan, Ann Arbor, MI
Presented By: Monica Liebert

Introduction and Objective: Increased levels of prostaglandin E2 (PGE2) contribute to cancer progression. PGE2 is inactivated by the catabolic enzyme, 15-hydroxyprostaglandin dehydrogenase (PGDH). PGDH is reported to be an important tumor-suppressor in lung, colon, and breast cancers but has not been studied in detail in bladder cancer. The objective is to study the expression and function of PGDH in bladder cancer.

Methods: Formalin-fixed, paraffin-embedded tissue sections were stained by immunohistochemistry after deparaffinization and antigen retrieval using a rabbit anti-PGDH antibody and the avidin-biotin peroxidase complex (ABC) method (Vectastain). Cells were cultured in Dulbecco’s Modified Eagle Medium containing 10% fetal calf serum and antibiotics. Levels of PGDH were modified using siRNA or infection with lentivirus with shRNA or PGDH expression constructs. Protein expression in cellular extracts was evaluated by western blotting. Cell migration was evaluated using the scratch/wound-healing assay. Anchorage-independent growth was evaluated using the soft agar clonogenic assay.

Results: Tissue staining revealed that PGDH is highly expressed by normal urothelial cells in 18/19 specimens, but in only half of superficial bladder cancers (25/49) and lost in the majority of higher stage bladder cancers (only 8% strongly positive, 6/73). Only relatively well-differentiated bladder cancer cell lines, RT4 and UC9, expressed readily detectable levels of PGDH. In RT4 cells, reduction of PGDH expression resulted in increased cell migration and anchorage-independent growth. Forced expression of PGDH in UC3, a poorly differentiated human bladder cancer cell line that does not routinely express PGDH, caused morphological changes and growth retardation. PGDH expression was shown to be regulated by DNA methylation in UC3 and histone deacetylation in UC9 bladder cancer cells.

Conclusions: The loss of PGDH expression is associated with a more aggressive bladder cancer phenotype and may be necessary for bladder cancer development and progression. Restoration of PGDH expression may be a therapeutic target for bladder cancer.

**Poster# 64**

URETEROILEAL ANASTOMOTIC STRICTURES AFTER A BRICKER ILEAL CONDUIT: ASSESSMENT OF THE IMPACT OF CONVERSION FROM A SLIT INCISION TO A “SHIELD-SHAPED” ILEOTOMY
Marina Cheng and James Brown
Medical College of Georgia, Augusta, GA
Presented By: Marina Cheng

Introduction and Objectives: Ileal conduit remains the most frequent urinary diversion after radical cystectomy. Ureteroileal anastomotic stricture is a well-known late complication of ileal conduits. We hypothesize that utilizing a “shield-shaped” rather than a standard slit ileotomy will reduce the incidence of anastomotic strictures. This hypothesis originates from the observation that the “shield-shaped” ileotomy closely mimics the opening of the spatulated ureter, potentially minimizing suture line tension and gapping. Furthermore, a small segment of ileum is excised, potentially inhibiting fusion of the ileal edges of the anastomosis. We retrospectively reviewed the outcomes of one surgeon’s (JAB) experience at a medium size tertiary state hospital performing initially a standard incision (24 patients, 2001 -2005, cohort 1) and subsequently a “shield-shaped” incision (24 patients, 2006-2009, cohort 2).

Methods: A retrospective review of patient’s records (who survived beyond 90 days after surgery) was performed. Each patient’s electronic medical record was reviewed and age, date of surgery, type of ileotomy, development of postoperative ureteroileal anastomotic stricture, date of diagnosis of stricture, method (imaging modality) used to diagnose stricture, stricture treatment, and length of follow-up was recorded. All patients had a Bricker ileal conduit procedure performed using similar surgical technique other than variance in the ileotomy incision. Two patients who died within 90 days of surgery were excluded.
Results: A total of 6 (12.5%) ureteroileal anastomotic strictures were identified—4 (16.7%) in cohort 1 and 2 (8.3%) in cohort 2. Mean follow-up was 21.5 (1-79) months and 8 (1-23) months for each cohort, respectively. Stricture diagnosis occurred at 4, 4, 14 and 42 months in cohort 1. The cohort 2 strictures were diagnosed at 6 and 10 months after surgery. Radiologic detection techniques used to identify/confirm strictures included intravenous pyelogram (IVP), Mag-3 renogram, loopogram, and abdominopelvic CT scan. No cases of postoperative anastomotic leakage were identified.

Conclusion: Modifying the ileotomy from a standard slit to “shield-shaped” incision does not eliminate postoperative anastomotic strictures. A possible decrease in stricture rate will need confirmation with longer follow-up. This surgical modification did not result in anastomotic extravasation and we believe it is technically easier to perform.

Poster# 65

PROSPECTIVE VALIDATION OF MULTIPLE BIOMARKERS FOR IMPROVED CLINICAL DECISION-MAKING IN PATIENTS WITH UROTHELIAL CARCINOMA OF THE BLADDER
Ramy Youssef¹, Shahrokh Shariat², Feras Alhalbi¹, Christian Bolenz¹, Raheela Ashfaq³, Yull Arriaga⁴, Ganesh Raj¹, Arthur Sagalowsky¹ and Yair Lotan¹
¹Department of Urology, University of Texas Southwestern Medical Center, Dallas, TX; ²Memorial Sloan-Kettering Cancer Center, New York, NY; ³Departments of Pathology, University of Texas Southwestern Medical Center, Dallas, TX; ⁴Departments of Oncology, University of Texas Southwestern Medical Center, Dallas, TX
Presented By: Ramy Youssef

Objectives: To prospectively assess the predictive value of a panel of biomarkers (cyclin E1, p53, p21, p27 and pRB/Ki-67) for staging of patients with urothelial carcinoma of the bladder (UCB).
Methods: 174 consecutive patients treated with transurethral resection (TUR) and/or radical cystectomy (RC) for UCB were prospectively included in the study starting in January 2007. Standardized, automated immunohistochemical staining and scoring was performed. A prognostic score (PS; ≤2 altered biomarkers=Favorable; >2 altered biomarkers=Unfavorable) was defined and correlated with clinical and pathological data.
Results: The study comprised of 102 RC patients and 72 TURBT cases. Unfavorable PS was noted in 36.3 % of RC cases and 16.6 % of TURBT cases matching the more advanced pathological stages of RC patients. In RC group; an unfavorable PS was significantly associated with advanced tumor stage (p=0.02), the presence of LVI (p=0.017), recurrence (p=0.02) and survival (p=0.048). In the subgroup of patients who had biomarker evaluation at TUR and then underwent RC (n=24), 75 % and 37.5 % of the cases with unfavorable PS showed upstaging and LN involvement at RC versus 29 % and 12.5 % in cases with favorable PS. Unfavorable PS at TUR was associated with the presence of LVI (p=0.001) and LN metastasis (p=0.026).
Conclusions: The preliminary analysis of our ongoing prospective trial strongly suggests that a panel of five biomarkers not only predicts poor outcome after RC but also improves the identification of patients at risk of upstaging at RC. An unfavorable PS may identify patients who are most likely to benefit from neo-adjuvant and adjuvant chemotherapy combined with RC.

Poster# 66

THE SONIC HEDGEHOG TRANSCRIPTION FACTOR GLI-2 CORRELATES WITH INVASION IN HUMAN TRANSITIONAL CELL CARCINOMA CELL LINES
Clay Mechlin¹, Matt Tanner², Badar Mian³ and Ralph Buttyan²
¹Division of Urology, Albany Medical College, Albany, NY; ²The Ordway Research Institute, Inc., and the Albany College of Pharmacy, Albany, NY; ³Division of Urology, Albany Medical College, Albany, New York, Stratton Veterans Affairs Medical Center, Albany, NY
Presented By: Clay Mechlin

Purpose: Hedgehog (Hh) is a signaling pathway that regulates Gli transcription factors. Aberrant Hh signaling portends an invasive and metastatic phenotype. Here, we tested whether Hh signaling might be involved in proliferative or invasive behavior of human bladder transitional cell carcinoma (TCC).
**Materials and Methods:** Human bladder TCC lines of variable growth and invasive capacity, RT4, 253JP, 253BV, UMUC6 and UMUC3, were stratified for their growth rate and for in vitro invasiveness using a Matrigel invasion assay. Cells were tested for growth inhibition by the Hh blocking drug, cyclopamine or the inactive mimic, tomatadine. RNAs from the cells were characterized for expression of Hh signaling components, including ligands, receptors and signaling mediators, by quantitative RT-PCR. RT4 cells were stably transduced with active Gli2 to assess effects on proliferation or invasiveness.

**Results:** The relative growth rates and invasiveness of the cells were stratified into an equivalent order (RT4<243JP<253BV<UMUC6<UMUC3). All cells were specifically growth inhibited by cyclopamine though the effect was weak. Gli2 was the only Hh signaling molecule whose expression correlated with the stratification. Overexpression of active Gli2 increased invasiveness of poorly invasive RT4 cells but not their growth rate.

**Conclusions:** Weak growth suppression by cyclopamine suggests that Hh is not significantly involved in bladder cancer cell proliferation. However, Gli2 expression, a downstream element of Hh, strongly correlated with invasive behavior and active Gli2 increased invasiveness of poorly invasive (RT4) cells. The results suggest that Gli2 expression through non-canonical signaling contributes to bladder cancer cell invasiveness.

**Funding:** This material is based upon work supported in part by the Equinox Foundation and the Medical Research Foundation of Albany, New York and the Stratton Veterans Affairs Medical Center, Albany, New York.

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**COMBINING TYROSINE KINASE AND MAMMALIAN TARGET OF RAPAMYCIN INHIBITORS WITH TRAIL: EFFECT ON TRANSITIONAL CELL CARCINOMA OF THE BLADDER (TCCB)**

Jacob Moibi, Allan Mak, Jimmy Xiao and Ronald Moore
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Presented By: Jacob Moibi

**Introduction and Objectives:** High-risk superficial TCCB is commonly treated with intravesical bacillus Calmette-Guerin (BCG), but with side effects. We have shown that direct application of tumor necrosis factor-related apoptosis-inducing ligand (TRAIL) is highly effective against TCCB with no toxicity to normal cells. However TCCB, like other cancer cells become refractory to TRAIL during monotherapy. Combinatorial approaches for concurrent inhibition of multiple oncogenic pathways are therefore needed to improve efficacy and abrogate resistance. This study investigated interactions between tyrosine kinase inhibitors (TKIs), mammalian target of rapamycin inhibitor mTORi) and TRAIL in TCCB cells.

**Methods:** Sorafenib, Sunitinib, Temsirolimus and TRAIL/Apo2L were each prepared as aliquots stored at -80°C and dilutions made before each experiment. TCCB cell panel (HT1376, UMUC14, T24, RT112, 253J and MGHU3) in logarithmic phase were tested under standard conditions. Cells were pre-sensitized with varying concentrations of sorafenib, sunitinib or temsirolimus for 20-24 h followed by TRAIL or growth medium for additional 20 h after which the proportion of viable cells was determined by MTT assay. Expression of apoptotic proteins was determined by SDS-PAGE and Western blot analysis of whole-cell lysates from cells presensitized for 20 h with sublethal concentrations of TKI or mTORi, followed by 4-hr TRAIL incubation.

**Results:** Sorafenib inhibited the proliferation of TCCB cells irrespective of TRAIL-sensitivity. Cells pretreated with sorafenib followed by TRAIL showed extensive lethality that correlated with apoptosis induction. Sorafenib induction or augmentation of TRAIL-apoptosis in TCCB cells was accompanied by mixed effect on apoptotic proteins (XIAP, p53, procaspases 9, 8 and 3) with increased activation/cleavage of procaspase-9 in some cell lines but limited effect on others. Sorafenib/TRAIL had no effect on the expression of caspase-8. Sunitinib showed little effect at concentrations lower than 1 micromolar in all cell lines. However, at 10-µM sunitinib inhibited proliferation by 50% in all cells, except the HT-1376 (TRAIL) cell line. Sunitinib at clinical levels did not enhance the anticancer effect of TRAIL. Temsirolimus had limited direct effect and did not augment TRAIL.

**Conclusions:** The pan-TKI sorafenib, potentiated TRAIL in TCCB cells. More specific targeting of the Akt and mTOR survival pathway did not and warrants further investigation.
**Poster# 68**

**MULTI-ANALYTE DIAGNOSTIC READOUT (MADR): COMBINING PROTEIN AND DNA MARKERS TO MAXIMIZE CLINICAL PERFORMANCE**

Cecilia Fernandez¹, John Millholland¹, Ian Summerhayes², John Libertino², Jeffrey Karnes³ and Anthony Shuber¹

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Presented By: Anthony Shuber

**Introduction:** We have recently reported the development of a non-invasive diagnostic assay utilizing urinary Matrix Metalloproteinases (MMPs) as monitors of disease-free status and cancer in high-risk bladder cancer populations. Using a novel approach called Clinical Intervention Determining Diagnostic (CIDD), in a study comprised of 86 patients with bladder cancer and 341 cancer-free individuals, we were able to identify with high confidence, ~94% Negative Predictive Value (NPV), those patients who do not have bladder cancer (~38%).

**Methods:** In order to further increase NPV, we have now developed a Real Time PCR based assay for detecting FGFR3 mutations in urine samples. FGFR3 mutations have been identified in 30-50% of bladder cancer patients, and are particularly associated with low-stage non-invasive tumors (Ta) where sensitivity reaches 70-80%. In addition, FGFR3 mutations have been previously detected in the urine of bladder cancer patients, making this an attractive non-invasive DNA marker. We are currently analyzing the same sample cohort for the presence of the eight most prevalent FGFR3 mutations, and have modeled results to ultimately combine both the protein and DNA analyses into one assay.

**Results:** Given the inherent specificity of DNA mutations to cancer cells, the presence of an FGFR3 mutation in the urine of patients undergoing bladder recurrence monitoring would be limited to samples containing mutant DNA and not those from cancer-free individuals. This would effectively increase sensitivity and NPV, while retaining or potentially increasing the number of patients who could be excluded (i.e. Specificity) from receiving invasive procedures. Based on the percent of mutant FGFR3 detected in urine samples from bladder cancer patients in previous studies, a simulation was run on the sample cohort above resulting in 97% NPV while retaining 38% exclusion of patients who do not have bladder cancer.

**Conclusion:** In addition, using this Multi-Analyte approach, patients below a set MMP cutoff, would be excluded from unnecessary intervention while those patients who are positive for an FGFR3 mutation would receive accelerated intervention. All remaining patients would continue to receive the already existing standard of care procedure.

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**Poster# 69**

**VEGF165B, AN INHIBITORY SPLICE VARIANT OF VEGF165 IN TRANSITIONAL CELL CARCINOMA OF THE BLADDER: INVIVO EXPRESSION**

Shyamala S Gopi¹, ², Maryam A H-Zadeh¹, Chandan Sen², Steven J Harper², David O Bates² and David A Gillatt¹

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Presented By: David A Gillatt

**Introduction and Objective:** In the UK, bladder cancer is the fifth most common cancer and second commonest urological malignancy. Angiogenesis is essential for tumor growth, survival and metastasis. Vascular endothelial growth factor (VEGF-A) is a key factor in most solid tumors, including bladder cancer. The VEGF₁₆₅ᵇ family of splice isoforms is endogenous, anti-angiogenic and inhibits colorectal tumor growth. The objective of this study is to determine the invivo expression of VEGF₁₆₅ᵇ in bladder cancer.

**Materials and Methods:** The established human bladder cancer cell line EJ28 were transfected with pcDNA3, VEGF₁₆₅, VEGF₁₆₅ᵇ and both in tandem, and was instilled by intravesical injections in nude female mice, under general anaesthetic. The harvested tumor was fixed in 4% PFA. The tissue was stained using haematoxylin and eosin and viewed under light microscope to determine tumor uptake and infiltration. The subcutaneous tumor injections assessed tumor growth and volume over 28 days. The invitro growth of the transfected cells studied the growth of the cell number.

**Results:** The intravesical tumors showed that the mean tumor area was reduced in VEGF₁₆₅ᵇ expressing tumors compared with control, and inhibited growth of VEGF₁₆₅ expressing tumors. Tumor take was less in VEGF₁₆₅ᵇ expressing tumors than control, and VEGF₁₆₅ᵇ inhibited tumor take of VEGF₁₆₅ expressing tumors. The subcutaneous tumor growth demonstrated that VEGF₁₆₅ᵇ significantly increased the doubling time of the tumors (two way ANOVA). The invitro growth assay demonstrated that the VEGF₁₆₅ᵇ expressing cells grew at a faster rate.

**Conclusions:** The invivo models shows, VEGF₁₆₅ᵇ increases tumor growth compared to control. VEGF₁₆₅ᵇ has an inhibitory effect on angiogenesis in established human bladder cancer cell lines grown in invitro models.
**Poster# 70**

**E2F3A AND E2F3B ARE EXPRESSED IN BLADDER CANCER AND EXISTS AS A NOVEL PHOSPHORYLATED ISOFORM**
Kamal Pohar, Lubka Ilieva, Gustavo Leone and Hongtao Jia
Columbus, OH
Presented By: Kamal Pohar

**Introduction:** The mammalian E2F gene family consists of several members that are grouped based on structure and function into gene activators and repressors. A number of experimental studies support the role of E2Fs in regulating cell cycle progression and gene expression through sequential interactions between activator and repressor E2Fs with their target promoters. The transcription activator, E2F3, is commonly over expressed in bladder cancers of higher grade and stage and is often due to increased copy number of the gene associated with amplification of chromosomal region 6p22. Importantly the E2F3 locus is complex and encodes two protein products (E2F3a and E2F3b) through the use of alternative promoters and different 5′-coding exons. There is limited knowledge of the overlapping or independent roles of the E2F3 isoforms in cancer. The purpose of this study was to determine the expression of each of the E2F3 isoforms in bladder cancer and to explore non-cell cycle dependent functions of E2F3.

**Material and Methods:** Bladder cancer cell lines and human bladder cancer tissue were studied. Gene expression was measured by RT-PCR, immunohistochemistry (IHC) and protein immunoblot. Histologic characterization of human tumors was performed by H and E stain. Macrophage infiltration in human tumors was characterized by IHC for CD68 and MRP8.

**Results:** RT-PCR demonstrated that E2F3a and E2F3b are expressed in all bladder cancer cell lines, including cell lines without 6p22 amplification. A novel observation was the presence of both phosphorylated and non-phosphorylated form of E2F3a and E2F3b in all bladder cancer cell lines. Similar findings were confirmed in human bladder tumors that expressed E2F3. Knockdown experiments with siRNA demonstrated that both E2F3a and E2F3b contribute to cell proliferation in culture. Increased E2F3 expression was associated with the small cell cancer phenotype and with decreased macrophage infiltration of the tumor tissue.

**Conclusion:** Both E2F3 isoforms may have increased expression in bladder tumors. A novel phosphorylated form of E2F3 has been identified. Non-cell cycle dependent functions of E2F3 may exist and further study of E2F3 may lead to a novel therapeutic target.

**Poster# 71**

**HER2 EXPRESSION STATUS PROVIDES INDEPENDENT PROGNOSTIC INFORMATION IN PATIENTS WITH UROTHELIAL CARCINOMA OF THE BLADDER**
Shahrokh Shariat¹, Christian Bolenz², Daher Chade¹, Raheela Ashfaq², Richard Ho², Arthur Sagalowsky² and Yair Lotan²
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Presented By: Shahrokh Shariat

**Introduction:** HER2 plays a fundamental role in cell growth, survival, and migration, and abnormal activation of HER2 has been proposed to lead to oncogenic transformation. HER2 is expressed in a proportion of urothelial cell carcinoma (UCB), making it a potential target for UCB therapy. However, the rates of HER2 positivity and the prognostic value of HER2 expression vary significantly between studies. The aim of the current study was to evaluate HER2 expression and its association with outcomes in a contemporary cohort of patients with UCB treated with radical cystectomy (RC).

**Methods:** Tissue microarrays of 198 patients were constructed and immunohistochemical staining was performed on the primary tumors and on lymphatic nodal metastases. All patients were treated with RC and regional lymphadenectomy for UCB. HER2 expression was assessed using continuous HER2 expression scores (ranging from 0.1 to 3.9) generated using an automated cellular imaging system. Scores ≥1.0 in at least 10% of tumor cells were regarded HER2 positive. We correlated HER2 scores with pathological and clinical parameters, including disease recurrence and cancer-specific mortality.

**Results:** Of 198 patients undergoing RC with lymphadenectomy, HER2 positivity was found in 55 primary tumors (27.8%) compared with 44.2% of the evaluable positive lymph nodes (p<0.001). HER2 positivity was significantly associated with the presence of lymphovascular invasion (LVI; p=0.026). With a median follow-up of 35.4 (range 1.3-176.1) months, 101 patients (51.0%) experienced UCB recurrence and 82 patients (41.4%) died from the disease. In multivariable analyses that adjusted for the effects of pathologic tumor stage, grade, LVI and lymph node metastasis, HER2 positive patients were at increased risk for both UCB recurrence (Hazard Ratio 1.681, p=0.048) and UCB-specific mortality (Hazard Ratio 1.513, p=0.049) compared to patients with negative HER2 expression.

**Conclusion:** A positive HER2 status is associated with aggressive bladder UCB and provides independent prognostic information for UCB recurrence and mortality. Assessment of HER2 status can be used to identify patients at high risk of disease progression who may benefit from adjuvant HER2-targeted mono- or combination therapy following RC.
Poster# 72

INHIBITION OF PROLIFERATION, COLONY FORMATION, INVASION, AND MIGRATION OF PROSTATE CANCER CELLS BY DOWN-REGULATING ELONGATION FACTOR-1 ALPHA EXPRESSION

Gang Zhu, Wei Yan, Ben Wan and Jian-ye Wang
Beijing Hospital
Presented By: Gang Zhu

Objective: To investigate the influence of EF-1α on Du145, a high-grade metastatic PCa cell line, and demonstrate the role of EF-1α in cellular properties associated with tumor invasion and progression, namely cell proliferation, colony formation, invasion, and migration.

Methods: In this study, we set up the control, scramble control transfected with scramble siRNA and test group transfected with EF-1 alpha siRNA. Cancer cell migration and invasion capability of DU145 cells were studied by Transwell technique in these three groups of DU145 cells. Then, the cell proliferation and colony formation assays were carried on as well.

Results: We had archived the down-regulation of EF-1 alpha expression in DU145 cell line confirmed by immunoflorescent staining. Cell migration and invasion study showed that after seeding 20×10⁴ DU145 cells into the upper chamber of the transwlls for 12 hours, the cells collected in the lower chambers were 10.6±1.0×10⁴ in control group, 11.2±0.8×10⁴ in scramble control group and 3.9±0.6×10⁴ in test group. Compared with controls, the cancer cells' migration and invasion capability was significantly inhibited to only 37.1% (p<0.05). Compared with control group, after the down-regualtion of EF-1 alpha in DU145 cell line, the cell proliferation rate decreased from day four to day seven after transfection by 45.9%, 53.5%, 35.3% and 38.1%, respectively, p<0.05. By the meantime, colony formation number in test group decreased by 67%, p<0.01.

Conclusions: These findings support that EF-1α affects multiple processes involved in prostate cancer invasion and progression.

Poster# 73

GENE EXPRESSION SIGNATURE OF DYSREGULATED ANDROGEN RECEPTOR FUNCTION IN PROSTATE CANCER

Timothy Nydam, Suma Ravulapalli¹, Bungo Furusato¹, Yongmei Chen¹, Amina Ali¹, Isabell Sesterhenn², David McLeod¹, Gyorgy Petrovics¹, Shiv Srivastava¹ and Albert Dobi¹
¹CPDR Rockville, MD; ²AFIP Washington, DC
Presented By: Timothy Nydam

Introduction: Elucidation of chromosomal fusion events between the androgen regulated TMPRSS2 gene promoter and ERG gene, revealed an important link between androgen signaling and ERG overexpression. Our goal is to determine if linkage exists between androgen signaling, ERG overexpression, and aggressive prostate cancer.

Materials and Methods: The CPDR 80 GenChip database consists of a forty patient cohort split into two groups of 20 based on Gleason score being greater/equal than or less than 8 by whole mount pathologic score. Using a bioinformatic approach, approximately 3000 gene features were examined to determine those genes which are up- or downregulated with a greater than 3 fold magnitude between normal and matching tumor tissues isolated by laser-capture microdissection from whole-mount prostatectomy specimens. The pathologic and molecular features were then correlated with clinical parameters of PSA recurrence and PSA doubling time. Characteristic gene expression features were ranked by their prevalence within individual patients of the study cohort and were correlated with PSA doubling time using a stringent six-month cutoff. The gene expression signature of the cohort was also analyzed in relation to the expression of ERG oncogene and by the knowledge-based pathway analysis program BiblioSphere.

Results: Evaluating ERG in the context of androgen signaling, we found a strong relationship between quantitative expression of ERG and the downstream functions of androgen receptor. To define androgen receptor function by a cumulative index (ARFI) we measured the expression of AR regulated genes characteristic of differentiated prostate epithelium. Consistent with the androgen regulated expression of ERG in the TMPRSS2-ERG fusion context, strong positive association was found between the expression of ERG and other androgen regulated genes. Intriguingly, in a subset of clinically significant tumors we found compromised androgen receptor functions.

Conclusion: Incorporating ERG expression into ARFI is valid as well as consistent with the goal of precisely prognosing outcome at the time of prostate cancer surgery.
Introduction: The detection of shed tumor cells is receiving increasing attention for its prognostic ability. Prostate cancer (PCa) has a proclivity to metastasize to bone and therefore bone marrow (BM) aspirates are ideal sources for the detection, isolation and characterization of disseminated tumor cells (DTC). Currently a variety of epithelial markers and techniques are used for DTC detection. However, given the increasing importance placed on DTC detection and characterization, it is important to determine the differences in detection rates of DTC among the most commonly used epithelial markers. Using a biomarker that will detect the greatest number of DTC could improve the detection rate in patients with very few DTC as well as allowing a more comprehensive isolation and therefore characterization of DTC.

Methods: Patients were at varying stages of PCa disease progression: i.e., at radical prostatectomy (RRP, N=300) for localized disease, no evidence of disease (NED, N=45) post RRP, androgen dependent recurrence (AD, N=11), and castration resistant (CR, N=25). Patients, after signing informed consent, underwent BM aspirations from the iliac crest either at the time of surgery or during follow-up. Briefly, a 10mL BM aspirate was mixed 1:1 with citrate and centrifuged over Ficoll-Hypaque. The buffy coat initially underwent negative selection using CD-45/61 immunomagnetic beads (Miltenyi) followed by positive enrichment with anti-EpCam/HEA immunomagnetic beads. DTC were detected and quantified microscopically in the resulting enriched cell fraction using antibodies to BerEp4 (EpCam), pan-cytokeratin (CK) or PSA.

Results: Antibodies to EpCam detected DTC in a greater percentage of patients compared to those to CK or PSA. These DTC also had gene expression and genomic profiles consistent with tumor cells (See table).

Conclusion: An explanation for the differences in epithelial marker expression may be attributed to the process of epithelial-to-mesenchymal transition (EMT), which we have previously reported to occur in DTC. In EMT, certain epithelial markers are lost as the cells transition to a more plastic/mobile phenotype. The detection rate was not only higher by targeting EpCam, but also more durable during EMT. Characterization of these DTC may identify marker(s) that elucidate the cellular phenotype of cells that will later produce disease recurrence.

<table>
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Introduction: There is emerging interest in cytostasis, or disabling the proliferative capacity of cancer cells, as a less toxic alternative to cytotoxic treatment strategies. Cellular senescence is a distinct response to non-lethal stress that results in a persistent cytostatic phenotype. The development of senescence as therapy has been limited by a lack of effective agents and identified molecular mechanisms.

Methods: We recently identified diaziquone (AZQ) as a potential therapeutic agent using a novel high-throughput screen for compounds that induce senescence in prostate cancer (JMS, 2009). We utilized AZQ in vitro and xenograft tumors in vivo examining cell/tumor growth, viability, senescence-associated β-galactosidase (SA-β-gal) staining and the expression and regulation of cyclin-dependent kinase (CDK) inhibitor proteins.
Results: Exposure to 250nM AZQ for 3 days induces SA-β-gal, increases side-scatter and persistently arrests viable cells in G2/M consistent with senescence induction. Screening a panel of CDK inhibitors identified p27kip1 induction by AZQ occurs independent of androgen-dependence and p53 status. Moreover, AZQ decreased expression of the p27kip1-regulating ubiquinase Skp2 in DU145 and PC3 cells suggesting a regulatory role for Skp2 in senescence induction. Extending these observations to other senescence-inducing agents including low-dose doxorubicin indicates their uniform occurrence in drug-treated senescent cells. Knockdown of Skp2 by siRNA in DU145 and PC3 cells increases p27kip1 expression and decreases proliferation after 72 hours. Enforced expression of Skp2 disrupts the growth-inhibitory effects of AZQ. In vivo, a single injection (4mg AZQ/kg) in tumor-bearing mice increases SA-β-gal and p27kip1 i in tumors harvested 7 days later. Furthermore, AZQ qod for three weeks significantly limits xenograft tumor growth and prolongs survival. Compared to vehicle controls, decreased proliferation (Ki-67) occurs with no increase in apoptosis. No toxicity was demonstrated.

Conclusions: Skp2-regulated induction of p27kip1, a gene commonly downregulated in prostate cancer, is required for drug-induced senescence. AZQ is a novel FDA-approved agent that induces a potent senescence growth arrest and represents a lead compound for the development of senescence as therapy. Drug-induced senescence in cancer may provide an effective therapeutic alternative to cytotoxic treatment while reducing patient side effects.

Funding: DODPCRP

Poster# 76

METABOLOMIC PROFILE OF EXPRESSED PROSTATE SECRETIONS IN PROSTATE CANCER
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Presented By: James Nederostek

Introduction and Objectives: While prostate cancer is the most commonly diagnosed cancer in men over 50, discriminating between indolent and aggressive disease at the point of diagnosis remains difficult. Biomarkers that distinguish indolent from aggressive disease have the potential to reduce overtreatment. An exploratory investigation was performed to identify metabolite markers of prostate cancer aggressiveness in expressed prostate secretions (EPS) following an attentive digital rectal examination (DRE).

Methods. Post-DRE urine specimens were obtained from 153 patients who had presented for prostate biopsy or who were on active surveillance from March 2007 through February 2009. Of those, 106 patients were diagnosed with prostate cancer and 47 had either normal prostates or high grade PIN by prostate biopsy. The EPS samples were analyzed using a unique global metabolomics platform. This non-targeted metabolomics analysis was performed using an LC/MS/MS and GC/MS-based technology platform. Analysis of over 270 metabolites was performed comparing specimens from patients with D’Amico low and high-risk groups.

Results: The results identified 63 compounds significantly altered between the groups (p<0.05). Potential biomarkers of aggressiveness included polyamines, glycerol-3-phosphate, and acetylated aromatic amino acids. Levels of polyamines decreased in post-DRE urine as a function of cancer risk category. Spermine was observed to have a more significant decrease as compared with spermidine and putrescine for low risk disease. To test whether the spermine was derived from the prostate following DRE, pre- and post-DRE urine specimens were collected from a subset of patients at the same office visit and analyzed for polyamines. The levels of polyamines were higher in the post-DRE urine as compared with the pre-DRE urines indicating an effectiveness of DRE for recovery of this metabolite.

Conclusions: Towards the goal of developing relatively non-invasive tests for prostate cancer aggressiveness, polyamines in post-DRE urine, specifically spermine in combination with additional biomarkers, may be a useful addition in helping to distinguish indolent from more aggressive prostate cancers at the DRE stage.
IN VIVO DETECTION AND TREATMENT OF PROSTATE CANCER CELLS IN A LOCAL RECURRENCE MODEL BY A PSA-PROMOTER DEPENDENT ADENOVIRUS.

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Presented By: Frederic Pouliot

Introduction and Objectives: PSA recurrence after radical prostatectomy might be secondary to pelvic recurrence or distant metastasis. Currently, there is no way to ascertain the localization of PSA-recurrence, which renders the choice of treatment difficult. We studied the ability of an adenovirus expressing a reporter and/or a suicide gene under an androgen-dependent modified PSA-promoter to detect and prevent prostate cancer local recurrence.

Methods: LAPC-9 prostate cancer cell line was stably infected with a lentivirus expressing constitutively Renilla luciferase to generate the LAPC-9-RL cell line. LAPC-9-RL cells were then implanted in the peritoneum (instead of retroperitoneum for technical purpose) of scid/beige mice and tumor growth was monitored in vivo using bioluminescence. Adenovirus expressing firefly luciferase or the cytotoxic gene sr39tk under the control of a modified PSA promoter and the Two-Step-Amplification-Transcription system (Ad-PSA-TSTA-fl) was constructed as previously described (Sato et al. 2008).

Results: LAPC-9-RL cells were grown i.p. in mice for three weeks and in vivo Renilla luciferase activity confirmed the tumor growth and its location (Figure, left panel). Instillation of PSA-TSTA-fl i.p. was able to detect tumor and normal prostate cells in vivo at the expected locations (Figure left and right middle panels). Specificity of the signals were confirmed ex-vivo (Figure right panel). Also, we show that neoadjuvant intratumoral injection of PSA-TSTA-sr39tk (sr39tk is a cytotoxic gene when cells are exposed to gancyclovir) into xenograft tumors before resection followed by treatment with gancyclovir could prevent local recurrence in a prostate cancer resection model.

Conclusion: We show that adenovirus mediated PSA-specific expression of reporter or cytotoxic genes can detect and prevent local recurrence in a local recurrence mouse prostate cancer model.
COPY NUMBER VARIATION OF SEX-STEROID METABOLIZING GENES AS BIOMARKERS OF PROSTATE CANCER RECURRENCE AFTER PROSTATECTOMY: LOOKING AT THE END OF THE ANDROGENIC SIGNAL

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Presented By: Genevieve Nadeau

Purpose: Inherited variations in hormone-related genes have been investigated for a possible association with prostate cancer risk, but their prognostic value has not been well studied. The glucuronidation pathway catalyzed by UDP-glucuronosyltransferases (UGT) leads to inactivation of sex-steroids, thus influencing the intracellular levels of these hormones in target cells. Our aim was to determine if genomic variations in five candidate UGT genes are associated with an elevated risk of biochemical recurrence of prostate cancer after prostatectomy.

Methods: The study included 526 French-Canadian men who underwent radical prostatectomy for clinically localized (cT2/T3) prostate cancer between 1999 and 2002. The genotypes for common variations in UGT2B7, UGT2B15, UGT2B17, UGT2B28, and UGT1A1 and their relationship with biochemical recurrence-free survival (bRFS) were assessed using Cox proportional hazard models.

Results: At a median follow-up of 7.4 years, 130 patients (24.7%) experienced prostate-specific antigen (PSA) failure. Polymorphic deletions of UGT2B17 and UGT2B28 were both associated with an increased likelihood of PSA failure (hazard ratio (HR) 1.43, 95% CI [1.01; 2.01] and HR 1.57, 95% CI [1.10; 2.25], respectively). The deletion of two or more copies of these genes resulted in an HR of 2.12 (95% CI [1.34; 3.37]) for biochemical recurrence. No significant association was observed for other UGT variants.

Conclusion: Copy number variations of UGT2B17 and UGT2B28 are prognostic molecular biomarkers of early biochemical recurrence after prostatectomy. This study is the first to recognize copy number variation in genes at the end of the androgenic signal as independent predictors of prostate cancer recurrence.

CIRCULATING STEM CELLS ARE PREDICTIVE OF THE PRESENCE AND CLINICAL CHARACTERISTICS OF PROSTATE CANCER

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Presented By: Armine Smith

Introduction and Objectives: Progenitor cells that possess self-renewal and differentiation capacity serve as tumor initiating cells, aided by recruited hematopoietic stem cells. Circulating tumor cells correlate with the patient survival in advanced prostate cancer. Therefore, there may be a role in correlating the profile of circulating progenitor and hematopoietic stem cells with the presence and severity of prostate cancer, and using this profile for creation of minimally invasive testing for detection and surveillance of prostate cancer. We investigated whether circulating prostate progenitor and hematopoietic stem cells could be used as a prognostic tool for the presence and severity of prostate cancer.

Methods: Sixty-four patients with biopsy-proven prostate cancer awaiting prostatectomy were enrolled in the study. Whole blood samples were collected preoperatively, 1 week postoperatively, and 3-6 months thereafter. Seven patients underwent collection of dorsal venous complex (DVC) blood during prostatectomy. Lymphocytes were isolated and stained for the presence of CD133, CXCR4/CD184, CD34 and c-kit/CD117 surface proteins. The samples were then analyzed by fluorescence-activated cell sorting, and the resulting data for each patient was correlated with the clinical characteristics of their disease. The clinical and pathological parameters included preoperative PSA, grade, stage, and volume of cancer in the final prostatectomy specimen.

Results: For the duration of follow-up, only one patient experienced biochemical failure, described as a rise in PSA above 0.5 ng/mL. High levels of circulating CD133+ and CD133+/c-kit+ cells were indicative of presence of prostate cancer. This number was reduced immediately after the surgery and remained low on postoperative collections. There was a correlation between increased CD133 expression and tumor pathological T-stage and volume. Increased CD133/c-kit expression also correlated with stage and grade of the disease. Increased expression of CD34+ cells was detected in all of the DVC samples.

Conclusions: CD133+/c-kit+ cells likely represent neoplastic prostate progenitors. There was a strong correlation between the levels of circulating CD133+ and CD133+/c-kit+ cells and clinical extent and aggressiveness of the cancer. The role of CD34+ hematopoietic stem cell in the establishment and growth of prostate cancer remains to be established.
THE ASSOCIATION BETWEEN OXIDATIVE STRESS AND PROSTATE CANCER RISK IN MEN UNDERGOING PROSTATE BIOPSY

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Presented By: Daniel A. Barocas

Introduction and Objectives: Oxidative stress is implicated in prostate cancer (PCa) by the association of PCa with inflammation in the prostate. F2-Isoprostanes (F2IP), a COX-independent product of arachidonic acid peroxidation, is a validated marker of oxidative stress. We studied the relationship between F2IP levels and PCa and high-grade prostatic intraepithelial neoplasia (HGPIN).

Methods: This case-control analysis within the Nashville Men’s Health Study included men recruited at prostate biopsy. Body morphometrics, health history and urine were collected prior to biopsy. Of over 2000 participants, this study included all 140 patients with HGPIN and a random sample of 160 biopsy-negative controls and 200 PCa cases (100 Gleason 6; 100 Gleason 7-10). Urine F2IP was measured by gas chromatography/mass spectrometry and normalized to creatinine. F2IP levels and other characteristics were compared across diagnostic groups using Kruskal-Wallis and Fisher’s exact tests. Associations between F2IP level and HGPIN and PCa were tested with multinomial logistic regression, controlling for factors associated with PCa risk.

Results: Mean age was 66.9 (SD 7.2) and 10.1% were non-white. Patients differed across diagnostic groups (benign, HGPIN, PCa) with respect to PSA (median 5.0, 5.7, 6.2 ng/mL, p<0.01), positive DRE (3.1%, 0.7%, 8.7%, p<0.01) and prostate volume (median 47, 47, 40 cc, p<0.01), but were similar in terms of family history of PCa, NSAID use and BMI. F2IP levels were significantly higher in white men (median 1.76 vs. 1.43 ng/mg of creatinine, p=.03), but were not associated with age, family history, clinical stage, NSAID use, waist-to-hip ratio (WHR) or prostate volume. There were non-linear associations between F2IP levels and BMI (median 2.08, 1.62, 1.77 for BMI<25, 25 to <30, >30, p<. 01) and PSA (median 1.82, 1.67, 1.85 for PSA<4, 4 to <10, >10, p=.08). On univariate analysis, F2IP levels were higher in patients with PCa (median 1.89) or HGPIN (1.83) than in those with benign biopsies (1.54), p=.03, but was similar across Gleason scores. After adjusting for age, race, WHR, BMI, NSAID use, prostate volume and PSA, F2IP level was significantly associated with HGPIN (OR 1.62, 95% CI [1.02-2.57], p=.04) and PCa (all cases: OR 1.65 [1.06-2.57], p=.03).

Conclusion: Pre-diagnosis urine F2-Isoprostane level is elevated in men with HGPIN or PCa, suggesting a role for oxidative stress in prostate carcinogenesis.

DIFFERENTIAL EFFECTS OF CALORIC AND CARBOHYDRATE RESTRICTION UPON PROSTATE CANCER TUMOR GROWTH IN A MOUSE MODEL

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Presented By: Jean Thomas, II

Background: Caloric restriction (CR) has been shown to be anti-cancer. However, whether these effects are the result of generalized reduction in overall caloric intake or reduced intake of macronutrients (i.e. carbohydrates) are unknown. We sought to investigate the differential effects of caloric and carbohydrate restriction upon prostate cancer tumor growth in a xenograft model.

Materials and Methods: A total of 100 male SCID mice were injected subcutaneously with the LAPC-4 cell line. Mice were randomized to 1 of 4 diets: ad libitum Western diet (WD, 49% carbohydrates, 35% fat, and 16% protein), pair-fed No Carbohydrate Ketogenic Diet (NCKD; 1% carbohydrates, 83% fat, 16% protein), Western diet calorically restricted (WD-CR), and NCKD calorically restricted (NCKD-CR). Calorically restricted arms were fed 75% of the calories of their reference diet group. Tumor volumes and bodyweights were measured twice weekly. Mice were sacrificed when tumor volumes reached 1,000 mm3.
Results: Relative to WD, there was a suggestion of smaller body weights in both NCKD-CR and WD-CR arms (rank-sum, p≤0.06). There was trend for heavier mice in the NCKD group (rank-sum, p=0.09). By day 50, median tumor volumes for NCKD, WD-CR, and NCKD-CR were 45, 51, and 62% smaller than WD (rank-sum, all p≤0.001). At any time point, there were no significant differences in tumor volume among the NCKD, NCKD-CR, and WD-CR arms. However, there was a suggestion of smaller tumors in the NCKD-CR arm by day 42 relative to NCKD and WD-CR (p<0.11). Diet was significantly associated with mouse survival (log-rank, p=0.004). In 2-way comparisons, NCKD, NCKD-CR, and WD-CR had significantly prolonged survival relative to WD (log-rank, all p≤0.02). However, no difference in survival was seen among any calorically or carbohydrate restricted arms (log rank, p≥0.16). A total of 34 mice died due to infection prior to their tumors reaching 1,000mm^3 and therefore were not included in the survival analyses (WD-CR, n=14; NCKD, n=5; NCKD-CR, n=15).

Conclusions: Both CR and carbohydrate restriction without weight loss are effective in delaying tumor growth and improving mouse survival. We found no differences between caloric and carbohydrate restricted arms, though this may relate to loss of study power due to mouse infections. CR may further weaken the immune system of immunocompromised mice subjecting them to increased risk of infections. A confirmatory study is underway in a high-level barrier facility.

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LOW-CARBOHYDRATE DIETS AND PROSTATE CANCER GROWTH: HOW LOW IS “LOW ENOUGH”?
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Presented By: Elizabeth M. Masko

Introduction: Previous dietary studies indicate that carbohydrate intake may influence prostate cancer biology, as LAPC-4 and LNCaP xenograft mice fed a no-carbohydrate ketogenic diet (NCKD; 84% fat-0% carbohydrate-16% protein kcal) had significantly smaller tumors and longer survival times compared to mice fed a Western diet (40% fat-44% carbohydrate-16% protein kcal). The NCKD mice were also found to have higher levels of circulating IGFBP-3 and the lowest levels of insulin, IGF-1, and IGF-1:IGFBP-3 ratio despite consuming more calories than the Western group. As it is nearly impossible for a human to consume and maintain a no-carbohydrate diet similar to that in the previous xenograft studies, we sought to determine whether diets containing 10% or 20% kcal from carbohydrates could slow tumor growth in a similar manner to the NCKD in a xenograft model.

Methods: A total of 150 male SCID mice were injected with LAPC-4 cells and placed on a Western diet (35% fat-49% carbohydrate-16% protein kcal) ad libitum. Two weeks after injection, all mice were randomized to three arms: NCKD, 10% carbohydrate, or 20% carbohydrate. Ten mice not injected with tumor were fed an ad libitum low-fat diet (12% fat–% carbohydrate–% protein kcal) and served as the reference group in a modified-paired feeding protocol for the other three diet groups. Calorie intake and body weights were measured thrice weekly and tumor volumes twice per week. Mice were sacrificed when tumors reached 1,000mm^3.

Results: Despite consuming 5-10% extra calories on average, all mice receiving low-carbohydrate diets were significantly lighter than the mice consuming the low-fat diet (p<0.04). Overall, the mice fed a 20% carbohydrate diet were significantly lighter than the other two arms (p<0.05). By Day 39, there was a suggestion of smaller tumors in the NCKD and 20% carbohydrate arms relative to the 10% carbohydrate group, but did not reach significance (p=0.06). Dietary treatment did not impact overall survival (p=0.34). NCKD mice had significantly higher glucose levels at sacrifice compared to the mice fed 10% and 20% carbohydrates (p=0.001), but similar levels of urinary ketones (p=0.37).

Conclusions: From this study, we conclude that LAPC-4 xenograft mice fed a low-carbohydrate diet (10-20% carbohydrate kcal) had similar survival to as mice consuming a NCKD (0% carbohydrate kcal). The survival benefit of a NCKD may be achievable with less restrictive low-carbohydrate diets.
TISSUE AMINO ACID LEVELS ARE SIGNIFICANTLY DECREASED IN MICE FED A NO-CARBOHYDRATE KETOCGENIC DIET COMPARED TO WESTERN DIET
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Presented By: Brian Whitley

Introduction: We previously showed mice injected with subcutaneous prostate cancer cells (LAPC-4 or LNCaP) and fed a no-carbohydrate ketogenic diet (NCKD, 84% fat-0% carbohydrate-16% protein kcal) have significantly decreased tumor volume and significantly prolonged survival when compared to mice fed a western diet (WD, 40% fat-44% carbohydrate-16% protein kcal). We sought to evaluate differences in the metabolome of mice injected from the LNCaP study.

Methods: A total of 130 male SCID mice were randomized to one of three diets; WD, NCKD, or Low-Fat diet (LF, 12% fat-72% carbohydrate-16% protein kcal). Mice receiving LF diet were fed ad libitum and served as the reference group in paired-feeding protocols for the other two groups. After 34 days, mice were injected subcutaneously with LNCaP cells and sacrificed when tumor volumes reached 1000mm³. Serum and tumor tissue from time of sacrifice were submitted for metabolomic evaluation using gas chromatography-mass spectroscopy. Metabolites, including amino acids, acyl carnitines, and organic acids, were identified and quantified. Tissue and serum concentrations of metabolites were compared among mice fed WD, NCKD, and LF using Kruskal-Wallis one-way analysis of variance.

Results: Tissue from mice fed NCKD showed significantly decreased concentrations of multiple amino acids compared to mice fed WD or LF. These amino acids included Ala (p=0.039), Ser (p=0.012), Pro (p=0.012), Val (p=0.007), Leu/Ile (p=0.01), Met (p=0.031), His (p=0.024), Phe (p=0.014), Tyr (p=0.012), Asn/Asp/Asp acid (p=0.024), Orn (p=0.021), and Arg (p=0.01). Tissue concentrations of Gly, Gln/Glu/Glu acid, and Cit were also decreased in mice fed NCKD, but did not reach statistical significance. There were no significant differences in tissue amino acid concentrations between mice fed WD and LF. In serum analysis, mice fed WD had significantly increased levels of the branched chain amino acids Ile/Leu (p=0.042) and Val (p=0.004) compared to mice fed LF and NCKD.

Conclusions: Mice fed NCKD demonstrate decreased tumor volume and prolonged survival compared to WD-fed mice. The metabolome of mice on NCKD revealed significantly decreased amino acid levels in tissue tumor, and significantly decreased serum levels of branched chain amino acids Ile/Leu and Val. The NCKD may deprive prostate tumors of components necessary for tumor proliferation. Conversely, WD may increase the availability of a metabolite that contributes to prostate tumor growth.

EVALUATION OF THE ETS RELATED GENE (ERG) mRNA IN URINE FOR DETECTION OF PROSTATE CANCER
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Presented By: Kevin Rice

Introduction and Objective: Prevalent gene fusions in prostate cancer involve androgen regulated gene promoters (primarily TMPRSS2) and ETS transcription factors (predominantly ERG) which result in tumor selective overexpression of ERG in two thirds of patients. Objective is to evaluate the potential of a urine assay measuring the ERG mRNA expression levels for improving prostate cancer detection.
Methods: Patients scheduled to undergo transrectal ultrasound-guided needle biopsy of the prostate were prospectively enrolled. On the day of biopsy patients provided urine samples following a digital rectal exam. Urine ERG mRNA was measured and normalized to urine PSA mRNA using a DTS® 400 system. Demographic traits, clinical characteristics, ERG score, and biopsy results were examined. This study was funded by GenProbe Inc. (CRADA to Shiv Srivastava, David G McLeod and Gyorgy Petrovics), and by Center for Prostate Disease Research through an ongoing grant from the US Army Medical Research and Materiel Command.

Results: The study was conducted on 237 patients. Adenocarcinoma of the prostate was demonstrated on biopsy in 40.9% of study subjects. A higher urine ERG score correlated significantly with malignancy on biopsy (p=0.0145), but not with clinical stage or Gleason score. Urine ERG score performed best in Caucasians and in men with a PSA of < 4 ng/mL (AUC=0.8).

Conclusions: A higher urine ERG score in post-DRE urine is associated with diagnosis of adenocarcinoma of the prostate on biopsy. Urine ERG score performed particularly well in men with a PSA of <4.0 ng/mL, a segment of the screening population where further diagnostic markers are needed to determine in whom biopsy should be performed.

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SERUM-SOLUBLE B7X IS ELEVATED IN PATIENTS WITH PROSTATE CANCER
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Presented By: Preston Sprenkle

Introduction: B7x, the newest member of the B7-CD28 family of co-stimulatory molecules, negatively regulates cd4+ and CD8+ T-cell proliferation, cell-cycle progression, IL-2 production, and can render tumor cells refractory to apoptosis. Using immunohistochemical (IHC) techniques, tumor expression of B7x was recently described in patients with prostate cancer and was associated with adverse pathologic features and diminished survival. A soluble form of B7x (sB7x) has been identified in patients with ovarian, breast, and kidney cancer, and was previously observed to not be present in patients with prostate cancer. Using an alternative ELISA assay, we sought to directly evaluate the presence of sB7x in prostate cancer patients compared with controls.

Methods: 92 patients with a preoperative serum sample and pathology proven adenocarcinoma of the prostate treated surgically at the Memorial Sloan-Kettering Cancer Center between 1999 and 2008 were identified. A sandwich ELISA for the detection of sB7x was performed on the sera of patients with prostate cancer, volunteer male blood donors, and men with an elevated prostate specific antigen (PSA) but biopsy-proven absence of prostate cancer. A positive serum B7x value was defined as any measurement 0.1ng/ml or greater. B7x IHC was categorized as none/moderate vs. strong and was available for 52 patients with prostate cancer.

Results: 214 patients were included in the analysis, 66 (31%) were normal controls, 56 (26%) had an elevated PSA with a negative prostate biopsy and 92 (43%) had prostate cancer. Positive (pre-surgery) sB7x levels predicted group: 15% (n=10) of controls had positive B7x levels compared to 46% (n=26) of patients with elevated PSA and 79% (n=73) of patients with prostate cancer (p <0.001). Among cancer patients, everyone with seminal vesicle invasion (n=4) or lymph node involvement (n=1) had positive B7x levels, although these associations were not statistically significant. Among the 52 patients with IHC data, preoperative sB7x did not predict B7x IHC intensity (p=0.3).

Conclusions: Contrary to prior reports, a soluble form of B7x is detectable in patients with prostate cancer, and is more likely to be detected in the sera of prostate cancer patients than healthy control patients or patients with an elevated PSA (p<0.001). These results suggest that further investigation of B7x in prostate cancer patients is warranted for diagnostic, prognostic, and potential therapeutic purposes.
ANDROGEN TRANSPORT GENE POLYMORPHISMS AND PROSTATE CANCER RISK AND OUTCOMES
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Presented By: Jonathan L Wright

Purpose: Cellular uptake of steroid hormones may be facilitated by organic anion transport polypeptides. The genes SLCO2B1 and SLCO1B3 are two members of this super-family and are involved in the transport of androgens. Variations in these genes may alter the risk of prostate cancer (PCa) and affect outcomes through altered androgen uptake. To examine this, we investigate PCa risk and outcomes associated with single nucleotide polymorphisms (SNPs) in SLCO2B1 and SLCO1B3.

Methods: Participants in two population-based case-control studies were included. SNPs in SLCO2B1 and SLCO1B3 were selected from the Genome Variation Server. The relative risk of PCa was estimated with multivariate logistic and polytomous regression for dominant and codominant genetic models adjusting for age, family history of PCa (FH) and PSA testing history. Mortality and cause of death were determined from the SEER registry. Risk of prostate cancer-specific mortality (PCSM) was determined with multivariate Cox proportional hazards analysis adjusting for age, FH, PSA, Gleason score, stage, primary treatment, BMI and smoking status.

Results: Five SNPs in SLCO2B1 and 4 SNPs in SLCO1B3 were genotyped in 1,309 cases and 1,266 controls. Carriers of either one copy (OR 0.90, 95% CI 0.75 –1.07) or two copies (OR 0.67, 95% CI 0.43 –1.03) of the variant A allele for SNP rs949069 in SLCO2B1 had a reduction in risk of PCa compared to homozygotes for the wild-type allele (p-trend = 0.05). The median follow-up for cases was 7.0 years (range 0.77 –16.4 years), with 64 deaths due to PCa. Carriers of the variant A allele in the SLCO2B1 SNP rs12422149 (coding, non-synonymous SNP) had a more than 2-fold increased risk of PCSM (HR 2.07, 95% CI 1.15 –3.71). No associations with risk or PCSM were seen with SLCO1B3 gene variants.

Conclusions: These data suggest that polymorphisms in the androgen transporter gene SLCO2B1 are associated with a modest reduction in the risk of PCa (rs949069) and an increased risk of PCSM (rs12422149). These findings underscore the complexity of the androgen pathway in relation to PCa and warrant further investigation.

ANDROGEN INDEPENDENT BONE METASTASIS CELL LINE AND ANGIogenEsIS PROTEIN ENDOGLIN EXPRESSION
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Presented By: Kenneth S. Koeneman

Introduction: Endoglin can be upregulated in “in situ” prostate cancer, and in the serum prior to surgery. C4-2B is androgen independent and exhibit osteoblastic characteristics. To better study the function of endoglin, a permanently overexpressed C4-2B line was established.

Materials and Methods: Human L-Endoglin was engineered into pCDNA3.1 vector and transfected into C4-2B cell, after G418 selection, cells stained endoglin positive by IHC; to purify and enrich, the highly and uniformed endoglin overexpression C4-2B cells were sorted out by FACS to obtain a >90% overexpression. C4-2, C4-2B-pcDNA vector control and C4-2B-Endo cells were subjected to cell proliferation assay, anchorage independent soft agar assay and migration assay. Cell cycle analysis was performed by DNA content assay at different time points. Subcutaneous Growth pattern was performed in Nude mice, and tissue subjected to IHC for endoglin.

Results: Endoglin overexpressed C4-2B cells showed high level both cell surface and cytosol expression by IHC. Western blot on reducing gel has shown both glycosylated and non- glycosylated form. The growth of endoglin-overexpressed cells in vitro was slower than the original and vector control cells. Softagar assay revealed endoglin overexpressed cell formed 6 fold more colonies than the original and vector control cells (P<0.01). In the cell migration assay, overexpressed cC4-2B showed 50-60% less migrated cell than vector control cells in plain medium
T Media and NIH3T3 condition medium. Cell cycle analysis using FACS to analyze cell DNA content, after cells have been synchronized, showed that C4-2B-endoglin has more cells reenter the G1 phase than C 4-2B parental and vector control cell at 2 and 4 hours after Nocodazol removal. At 8 hours, they reached the similar population and there is an S phase peak at 24 hours for control cell, but at 48 hour for endoglin transfectant. Mice xenograft Sq tumors revealed endoglin expression at 30 -40% by IHC, but mainly only around blood vessels in control cell lines.

**Conclusion:** C4-2B is a very good model currently used in androgen independent prostate cancer research. Endoglin is a neovascularature marker mostly used in tumor angiogenesis studies. Establishing Endoglin overexpressed C4-2B line facilitates future understanding of the biological function of endoglin in prostate cancer. Clinical studies have shown endoglin in the serum to be potentially important in discerning metastasis.

**Poster# 88**

**CHARACTERIZATION OF A C-TERMINAL HEAT SHOCK PROTEIN 90 INHIBITOR IN PROSTATE CANCER CELLS**

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Presented By: Heidi A. Penn

**Objective:** Heat shock protein 90 (Hsp90) is a molecular chaperone involved in the folding and activation of nascent polypeptides. It has been shown to be over-expressed and constitutively active in tumors. The cytotoxic effects of Hsp90 inhibitors are hypothesized to be more active in cancer cells and represent a viable drug target in several cancers, including prostate. The antibiotic novobiocin has been demonstrated to bind the C-terminal ATP-binding pocket of Hsp90, interfering with its role as a molecular chaperone. We present in vitro efficacy data of a novobiocin analogue, KU-174, that appears to be more selective against the hormone dependent (LNCaP-LN3) and independent (PC-3-MM2) prostate cancer cell lines compared to normal renal proximal tubule epithelial cells (RPTEC).

**Methods:** LNCaP-LN3, PC3-MM2, and RPTEC cells were treated with KU-174 in modified trichrome stain (MTS) anti-proliferation assays, measuring the cell’s ability to convert tetrazolium dye to a formazan by-product using dehydrogenase enzymes. Spectrometry was used to assess the cell’s metabolism by assessing the color change in cells with enzyme present. Western blot experiments to determine the effect on Hsp90, Hsp70 and client protein expression were performed. KU-174 was analyzed in flow cytometry for the induction of apoptosis and arrest of cell cycle.

**Results:** KU-174 demonstrated anti-proliferative activity, induced the degradation of client proteins, and stimulated the induction of apoptosis in both cancer cell lines with less effect on RPTEC cells. In cell cycle experiments, KU-174 induced significant G2/M and S-phase arrest with the LNCaP-LN3 cell line demonstrating an increasing percentage of cells in the sub-G0/apoptotic fraction. In both cancer cell lines, the KU-174 induction of apoptosis and cell cycle arrest increased over time in a dose-dependent manner with less of an effect on RPTEC cells.

**Conclusion:** KU-174 represents a putative C-terminal Hsp90 inhibitor with selective activity against prostate cancer cells. It has a different mechanism of action from N-terminal Hsp90 inhibitors. KU-174 represents a new class of Hsp90 inhibitors that may prove to be selective for tumor cells and superior to N-terminal inhibitors for the treatment of prostate cancer.
Poster# 89

GENOMIC STUDY ON PROSTATE CANCER DISPARITIES REVEALS THE DIFFERENTIAL TRANSCRIPTOMES, ALTERNATIVE SPLICING VARIANTS AND COPY NUMBER ABERRATIONS BETWEEN CAUCASIAN AND AFRICAN AMERICAN POPULATIONS

Bi-Dar Wang¹, Ramez Andrawis², Fernando Bianco³, Thomas Jarrett³, Harold Frazier³, James Tall³, Steven Patierno¹ and Norman Lee¹

¹GWU Cancer Institute, Washington, DC; ²Washington, DC; ³GWU, Washington, DC

Presented By: Ramez Andrawis

Introduction: African Americans (AA) have higher risks of developing prostate cancer (PCa) with aggressive disease compared to Caucasian Americans (CA). After adjustment of the socioeconomic factors, the death and recurrence rates are still higher in AAs, suggesting additional biological components may be associated with the observed PCa disparities.

Objectives: In order to identify ‘predisposition’ and ‘oncogenetic’ networks responsible for the PCa disparities, genomic technologies were applied to determine the genetic alterations in PCa.

Methods: PCa and adjacent benign biopsy cores were collected from 13 AA and 7 CA patients for RNA and DNA isolations. The purified RNA and DNA samples were processed and hybridized onto Affymetrix Exon and SNP 6.0 arrays to examine the RNA expression profiles, alternative splicing and DNA copy number variation (CNVs).

Results: 95 genes were differentially expressed in benign prostatic tissues from normal AAs and CAs. These genes were selected for further clustering analysis and functional classification. These genes could be functionally classified into four major networks involving in ERK, NF-kB, insulin/INS1 signaling and androgen metabolism. Comparisons of the expression profiles from PCa with adjacent benign tissues revealed that 289 differentially expressed genes were involved in the regulation of several oncogenic and inflammatory pathways in AA patients. STAT1 and RHOA genes were highly expressed in AA patients, suggesting the more aggressive tumor. Exon and SNP array data analyses have revealed hundreds of alternative splicing variants and dozens of CNVs between AA and CA PCa patients, respectively. Together with pathway analysis, our results have further identified several important cancer signaling pathways with alterations in gene expressions, alternative splicing patterns and CNVs between AA and CA patients.

Conclusions: The Exon and SNP profiling reveals differential transcriptomes, alternative splices and CNVs in AAs and CAs. This suggests that differences of gene expressions, alternative splicing, and CNVs in inflammatory responses, oncogenic pathways, and insulin and androgen metabolisms may account for the disparities between AA and CA populations.

Poster# 90

RADICAL RETROPUBIC PROSTATECTOMY VERSUS ROBOTIC ASSISTED LAPAROSCOPIC PROSTATECTOMY IN HIGH-RISK PROSTATE CANCER

Eugene Lee, Janet Baack, Kevin Art, J. Brantley Thrasher and David Duchene

University of Kansas Department of Urology

Presented By: Eugene Lee

Purpose: According to the da Vinci website, robotic-assisted laparoscopic prostatectomy (RALP) is the most common surgical procedure for localized prostate cancer. Many urologists still feel an oncologic difference may exist between the two procedures, especially in high-risk disease. Recent studies have shown the feasibility of robotics in high-risk prostate cancer as well as the possibility of extensive lymph node dissections. However, no studies directly compare the radical retropubic prostatectomy (RRP) to the RALP in a high-risk population.

Materials/Methods: This is a retrospective review of our prostate cancer database. High-risk patients were identified from each surgical approach. High risk was defined as any patient with Gleason grade 8-10 or T3 pathologic disease on final pathology. Only those patients within the time frame of our robotic experience were included in our study. We compared our two cohorts for margin status, lymph node status, and rate of biochemical recurrence.
Results: There were 50 patients in the robotic group including 18 (36%) with T2 disease and 32 (64%) with T3 disease. There were 32 patients in the RRP group including 10 (31.3%) patients with T2 disease and 22 (68.8%) patients with T3 disease. The average PSA in the RALP group was 10.7 and 14.5 in the RRP group. The Average Gleason sum was 7.84 in the RALP group and 8.41 in the RRP group. The percent of cancer in the prostate was 26.84% in the RALP group and 34.2% in the RRP group. 15 (30%) patients had a positive margin in the RALP group while 18 (56.3%) in the RRP group. 9 (18%) in the RALP group had a biochemical recurrence compared to 2 (6.25%) patients in the RRP group. Eleven patients in the RALP group and 4 patients in the RRP group had adjuvant therapy.

Conclusion: In our cohort of patients with high-risk prostate cancer, we found that patients who underwent an RRP were more likely to have a positive margin than those who underwent a robotic procedure. This may have been explained by the higher average Gleason score, higher pre-operative PSA, and larger amount of cancer in the prostate specimen in the RRP group. RALP appears to be a reasonable approach for high-risk prostate cancer patients with similar short-term results as RRP. However, longer follow-up will be needed to ensure oncologic results are similar between the two groups.

Poster# 91

LONGITUDINAL CHANGES IN PROSTATE SPECIFIC ANTIGEN AND PROSTATE VOLUME IN MEN WHO DEVELOP PROSTATE CANCER
Rodney Breau, R. Jeffrey Karnes, Debra Jacobson, Michaela McGree and Jennifer St.Sauver
Mayo Clinic, Rochester, MN
Presented By: Rodney Breau

Introduction: We evaluated the rate of prostate growth and the rate of change in PSA for men in a large population-based cohort.

Methods: In 1990, 616 men between 40 and 79 years of age without prostate disease were randomly selected from Olmsted County, Minnesota. Patients participated in biennial examinations for 14 years, which included PSA and transrectal ultrasonographic prostate volume measurements. The ratios of longitudinal change in PSA and prostate volume were compared between groups.

Results: Of 616 men, 58 (9.4%) were diagnosed with prostate cancer. The median PSA velocity in patients with and without a prostate cancer diagnosis was 6.0%/year and 3.3%/year, respectively. In both groups of patients, median prostate volume increase was 2.2% per year. For patients who developed prostate cancer, the rate of PSA increase was 2.5 (IQR: 2.0-3.3) times the rate of prostate volume increase, compared to a rate of 1.5 (IQR:0.8-2.2) for those who did not develop prostate cancer (p<0.001).

Conclusions: In a large population based cohort, men who developed prostate cancer had a similar rate of prostate growth but a disproportionate rise in PSA compared to men who did not develop prostate cancer. These results suggest that the disproportionate rise in PSA in men who develop prostate cancer is not due solely to concomitant prostatic enlargement.

Poster# 92

PROSTATE BIOPSIES FROM AFRICAN-AMERICAN MEN EXPRESS HIGHER LEVELS OF AGGRESSIVE DISEASE BIOMARKERS THAN PROSTATE BIOPSIES FROM CAUCASIAN MEN
Howard Kim¹, Daniel M. Moreira¹, Jayakrishnan Jayachandran¹, Leah Gerber¹, Lionel L. Bañez¹, Robin Vollmer², Amy Lark², Michael J. Donovan³, Douglas Powell³, Faisal M. Khan⁴ and Stephen J. Freedland⁴
¹Division of Urologic Surgery, Department of Surgery, and the Duke Prostate Center, Duke University School of Medicine, Durham, NC; ²Department of Pathology, Duke University School of Medicine, Durham, NC; ³Aureon Laboratories, Yonkers, NY; ⁴Division of Urologic Surgery, Department of Surgery and Department of Pathology, Duke University School of Medicine and Urology Section, Veterans Affairs Medical Center, Durham, NC
Presented By: Howard Kim

Objective: A wide array of putative biomarkers, including androgen receptor (AR), α-methylacyl CoA racemase (AMACR) and Ki-67 are being investigated as predictors of prostate cancer (PCa) diagnosis and recurrence. Given that African-American men (AAM) are at increased risk for PCa progression compared to Caucasian men (CM), we compared the expression of these biomarkers as a function of race among men undergoing radical prostatectomy (RP).
**Methods**: Formalin-fixed, paraffin-embedded prostate needle biopsy specimens from 131 patients treated with RP at the Durham Veterans Affairs Medical Center were H&E stained and immunofluorescent (IF) assayed for AMACR, AR, and Ki67. Proprietary image analysis was used to identify significant IF markers of progression: relative area AR- and AMACR-positive tumor nuclei (AR & AMACR), relative area AR- and AMACR-positive tumor nuclei/lumen area (AR & AMACR/lum), normalized AR intensity in Gleason 1-3 tumor nuclei (norm AR), dynamic AR intensity (dyn AR), relative area Ki67-positive tumor nuclei (Ki67) and relative area Ki67-positive tumor nuclei/lumen area (Ki67/lum). Analysis of baseline characteristics of the study population, stratified by race, was performed using t-test, rank-sum, and x². The effect of race on expression of IF markers was accomplished using multivariate linear regression, adjusting for age, PSA, year, and biopsy Gleason score.

**Results**: Of the 131 patients we identified, 67 (51%) were AAM and 64 (49%) were CM. On analysis of baseline characteristics, all but one IF marker (Ki67/lum, rank-sum, AAM=0.81, CM=0.83, P=0.18) were expressed at higher levels in AAM than CM, with Norm AR (rank-sum, AAM=1.39, CM=1.23, P=0.006) and Ki67 (rank-sum, AAM=0.06, CM=0.05, P=0.02) attaining statistical significance. On multivariate analysis, all IF markers were expressed more in AAM, with Norm AR (AAM=1.100, CM=0.715, P=0.001), Ki67 (AAM=0.051, CM=0.035, P=0.007), and Ki67/lum (AAM=0.589, CM=0.400, P=0.022) being statistically significant.

**Conclusion**: Prostate biopsies from AAM were more likely than those from CM to have higher expression of all adverse biomarkers studied, with Norm AR and the tumor proliferation markers of Ki67 and Ki67/lum reaching statistical significance. These data support the hypothesis that PCa is biologically more aggressive among AAM.
IS THE LOW PROSTATE SPECIFIC ANTIGEN CUTOFF POINT APPLICABLE TO CHINESE MEN?

Ming Li
Department of Urology, Peking University, School of Oncology, Beijing Cancer Hospital & Institute
Presented By: Ming Li

Introduction and Objective: More recently, studies demonstrated that there was about 1/4 prostate cancer with prostate specific antigen (PSA) less than 4ng/ml. Some of the urologists in the USA and European countries suggested a lower PSA cutoff point of 2.5ng/ml, in order to find more curable prostate cancers. There are dramatic differences of prostate cancer incidence between different races. Chinese is one of the races, which have the lowest incidence of prostate cancer. Is the low PSA cutoff point applicable to Chinese men? The aim of the present study was to evaluate the effects of different PSA values on the percentage of positive prostate biopsies in Chinese men.

Methods: Between Jan 2000 and June 2005 a total of 1144 men underwent transrectal ultrasound guided prostate biopsy due to elevated total PSA (tPSA) values or abnormal DRE in the Institute of Urology, Peking University. All biopsies were taken transrectally using an 18-gauge biopsy needle. The prostate cancer detection rates in the tPSA ranges of <4ng/ml, 4-10ng/ml, 10.1-20ng/ml, >20ng/ml, as well as Gleason scores in men with prostate cancer were assessed.

Results: The mean prostate cancer detection rate from initial biopsy was 39.4% (451/1144). The cancer detection rates in different groups of PSA values and the distribution of Gleason score in different groups was shown in table. The present data show that a significant low number of prostate cancer was detected in the low PSA range (only 11.6% positive biopsies in group of PSA 4-10ng/ml with fPSA/tPSA>0.16). Men with a PSA<4ng/ml had a slightly higher detection rate (18.1%) only with positive DRE. Men with lower PSA value are apparently to have lower Gleason score.

Conclusion: Based on our results, the low PSA cutoff point may not be applicable to Chinese men, unless they have abnormal DRE or PSA 4-10ng/ml with fPSA/tPSA<0.16.

<table>
<thead>
<tr>
<th>PSA value</th>
<th>Number</th>
<th>Positive (%)</th>
<th>GS&lt;7 (%)</th>
<th>GS&gt;8 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;4ng/ml</td>
<td>72</td>
<td>13 (18.1)</td>
<td>11 (84.6)</td>
<td>2 (15.4)</td>
</tr>
<tr>
<td>4.10ng/ml fPSA &gt; 0.16</td>
<td>86</td>
<td>10 (11.6%)</td>
<td>9 (90)</td>
<td>1 (10)</td>
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<tr>
<td>4.10ng/ml fPSA &lt; 0.16</td>
<td>228</td>
<td>40 (17.5)</td>
<td>31 (77.5)</td>
<td>9 (22.5)</td>
</tr>
<tr>
<td>10.1-20ng/ml</td>
<td>402</td>
<td>126 (31.3)</td>
<td>78 (61.9)</td>
<td>48 (38.1)</td>
</tr>
<tr>
<td>&gt;20ng/ml</td>
<td>356</td>
<td>262 (73.6)</td>
<td>133 (50.8)</td>
<td>129 (49.2)</td>
</tr>
<tr>
<td>total</td>
<td>1144</td>
<td>451 (39.4)</td>
<td>262 (58.1)</td>
<td>189 (41.9)</td>
</tr>
</tbody>
</table>
THE SIGNIFICANCE OF PROSTATE VOLUME TO BIOPSY CORESAMPLE RATIO ON CANCER DETECTION RATES STATE UNIVERSITY OF NEW YORK DOWNSTATE MEDICAL SCHOOL NEW YORK HARBOR VETERANS ADMINISTRATION HOSPITAL SYSTEM

John Sfakianos¹, Ostap Dovirak¹, Richard Long², Jeffrey P. Weiss¹, Ivan Colon¹, Richard J. Macchia¹ and Nicholas T. Karanikolas¹

¹Brooklyn, NY; ²Malaysia

Presented By: John Sfakianos

Introduction and Objective: There have been many long debates over the number of cores to perform during a prostate biopsy. Prostate biopsies are currently performed using a standardized number of cores mostly based on physician preference. We argue in favor of varying the number of cores taken for prostate biopsies based on the TRUS size. This method will transfer the homogeneous number from cores taken to amount of tissue examined per core.

Methods: A retrospective review of a prospectively registered prostate biopsy database identified 2224 consecutive patients undergoing prostate biopsy at a Veterans Administration Hospital between 1994 and 2008. Of these 2224 patients 663(30%) were found to have cancer and 1561 (70%) had negative biopsies. We eliminated all patients with findings of high grade PIN (HGPIN) and atypical small acinar proliferation (ASAP). Prostate volume to biopsy core ratios (volume / number of cores) was derived and a comparative analysis was performed to determine its impact on cancer detection rates.

Results: The mean prostate volume was significantly smaller for those patients diagnosed with prostate cancer as compared to those with negative biopsies (38.3 grams as compared to 50.7 grams p=0.00). The median number of cores was the same for both groups of patients (median 12, p=0.66). The ratio of TRUS volume to number of cores differed significantly between these two cohorts of patients. The median TRUS / core volume ration was 3.5 (iqr 2.5) for patients with identified cancer as compared to 4.7 (iqr 3.9) for those with negative biopsies (p=0.000). On multivariable logistic regression analysis TRUS / core ratio significantly impacted cancer detection with a relative risk ratio of 1.29 (95% CI 1.1 to 1.5, p=0.001) even when controlled for age, race, prostate volume, dre and PSA.

Conclusions: Prostate cancer detection can be enhanced by individualizing the number of cores to real-time prostate volume sampling. Our study emphasizes that optimal cancer detection rates were observed when a ratio of 3.5 grams per tissue core was achieved. Proper prospectively designed studies must be performed to further validate our findings.

OPERATOR IS AN INDEPENDENT PREDICTOR OF DETECTING PROSTATE CANCER AT TRANSRECTAL ULTRASOUND GUIDED PROSTATE BIOPSY

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Presented By: Nathan Lawrentschuk

Purpose: We sought to investigate whether inter-operator differences exist in the setting of prostate cancer (PCa) detection for transrectal ultrasound-guided prostate biopsy (TRUS-BX). Our secondary aim was to investigate if a learning curve exists for PCa detection.

Materials and Methods: A prospective database from 2000-2008 of 9,072 TRUS BX at our institution was limited to TRUS BX on initial presentation (n=4724). Biopsies are performed by 4 uro-radiologists. The odds ratio (OR) for detecting cancer in TRUS BX was calculated for likely independent prognostic variables including operator. We also examined rates of biopsy positivity in increments comparing first and last cohorts. The senior radiologist (AT) with most biopsies (75%) was considered the referent for PCa detection. Univariate and multivariate logistic regression modeling was used to determine significant covariates with p<0.05 deemed relevant.
Results: PCa was detected among 2,331 men (49.3%). Operators had a median number of TRUS-BX of 514 (187-3509) with PCa detection rates of 43.8-52.4% (p=0.001). Other significant covariates included prostate-specific antigen level, ultrasonographically suspicious lesions, nodule on digital rectal exam, smaller prostate volume and increasing patient age. Operator was a significant multivariate predictor of cancer detection (OR 0.67-0.89; p=0.003) [Table 1]. No learning curve was detected with biopsy rates consistent throughout the series.

Conclusions: Significant differences for PCa detection exist between various operators performing TRUS-BX even in the same setting. Volume of previously performed TRUS-BX does not appear to influence positive PCa detection rate, nor could a learning curve be identified. The PCa detection differences between operators are likely related to unknown differences in expertise or technique and further research is needed.

Poster# 97

THE INVESTIGATIONAL PROCAM™ ASSAY CORRELATES WITH THE Probability OF A POSITIVE BIOPSY128568
Jonathan Baden, Jennifer Painter, Jadwiga Markiewicz, Kathleen Curtin, Jennifer Jones, Tara Astacio, Susan Canning, Trust Carrie, Yixin Wang and George Green Veridex, LLC Raritan, NJ
Presented By: Jonathan Baden

Purpose: Early detection of cancer is important to improve patient outcome. Current guidelines for prostate cancer screening suggest that in addition to the measure of PSA and DRE a physician should consider additional risk factors. The rationale for these guidelines rests in large part on the lack of accuracy of PSA in predicting which men are at risk of prostate cancer. Previous studies have demonstrated that the ProCaM™ assay had a sensitivity of 60% and specificity of 81% in men with PSA 2.0 –10.0 ng/mL. In this report we describe a large multicenter study conducted to verify the performance of the ProCaM Assay.

Materials and Methods: The assay detects CpG island methylation within the promoter regions of 3 markers (GSTP1, RARβ2 & APC), which is indicative of the presence of prostate cancer and an endogenous control (β-ACTIN). The assay was run on post-DRE urine samples collected at 18 clinical sites from 515 consenting subjects with no previous history of prostate cancer, 40 - 75 years old, with PSA test results 2.0 –10.0 ng/mL and a scheduled prostate biopsy. Assay results were compared to histologic findings of biopsy (≥10 cores). Results of the assay were not used for patient management.

Results: Biopsy results found 232 cancer positive cases and 283 cases with negative biopsies. Informative assay results were obtained from 499 of 515 samples. The AUC for the 4 markers (AUC = 0.73) was higher than individual factors for age, DRE, family history, PSA, history of previous biopsy, and race (0.54, 0.57, 0.53, 0.52, 0.56, 0.55, respectively) p < 0.001. With both univariate and multivariate analyses the ProCaM™ assay was the best predictor of positive biopsy (p < 0.001). Addition of the ProCaM™ Assay statistically improves both the PCPT (Prostate Cancer Prevention Trial) risk calculator and the Prostate Risk Indicator compared with independent use of these algorithms, (p < 0.001).
**Conclusion:** These data demonstrate that the selected DNA methylation markers correlate with biopsy results for prostate cancer. This investigational assay has the potential to add value to the biopsy decision-making process by increasing accuracy over clinical risk factors alone.

### COMPARATIVE ANALYSIS BETWEEN WHOLE MOUNT PROCESSING AND SYSTEMATIC SAMPLING OF RADICAL PROSTATECTOMY SPECIMENS: PATHOLOGICAL OUTCOMES AND RISK OF BIOCHEMICAL RECURRENCE

Shady Salem¹, Sam Chang¹, Peter Clark¹, Rodney Davis¹, S. Duke Herrell¹, Yakup Kordan¹, Roxelyn Baumgartner¹, Sharon Phillips², Marcia Wills³, Scott Shappell³, Ian Thompson, III¹, Joseph Smith, Jr.¹, Michael Cookson¹ and Daniel Barocas¹

¹Department of Urologic Surgery Vanderbilt University Medical Center Nashville, TN; ²Department of Statistics Vanderbilt University Medical Center Nashville, TN; ³Department of Pathology Vanderbilt University Medical Center Nashville, TN; ⁴Avero Diagnostic, Dallas, TX

Presented By: Shady Salem

**Introduction and Objectives:** Whole mount (WM) processing is more time intensive and resource consuming than the more commonly practiced systematic sampling (SS) of radical prostatectomy specimens. Thus, we compared WM and SS processing techniques for detection of pathological outcomes, and the risk of biochemical recurrence (BCR).

**Methods:** The cohort consisted of men who underwent retropubic radical prostatectomy between January 2000 and June 2008. Patients with prior treatment, or missing data were excluded. Univariate and multivariate analyses were used to assess the difference in detection of pathological outcomes between the two methods. Univariate Kaplan-Meier curves and log rank tests and multivariate Cox proportional hazards models were used to determine the impact of pathologic method on BCR while stratifying by or controlling for pathologic outcomes associated with BCR.

**Results:** There were 1133 patients, 608 in WM and 525 in SS group. Age was higher in SS group 61.4 vs. 59.7 in WM group, but patients were similar with respect to preoperative PSA, clinical stage, and biopsy Gleason score. WM and SS were similar in detection of extra prostatic extension (EPE, 25% vs. 30%), positive surgical margin (SM, 31% vs. 31%), pathologic Gleason score (PGS) >7 (49% vs. 43%), PGS 7 (39% vs. 43%), PGS >7 (12% vs. 13%), seminal vesicle invasion (SVI, 8% vs. 10%) and lymph node involvement (LNI, 3% vs. 5%). On multivariate analyses, pathologic method was not a predictor of EPE, SM, PGS, SVI or LNI. Tumor volume was significantly higher in the SS group (median 4.38 vs. 1.8cc, p<.001). There were no differences between pathologic processing methods in BCR when the cohort was stratified by pathological outcomes such as EPE (p=.78 for + EPE, p=.73 for -EPE), SM (p=.58 for +SM, p=.21 for ), PGS (p=.76 for PGS<7, p=.38 for PGS=7, p=.64 for PGS>7), SVI (p=.94 for +SVI, p=.52 for ), or LNI (p=.75 for +LNI, p=.07 for ). On multivariate analysis, PSA, EPE, SVI, LNI, SM, PGS and year of surgery, were predictors of BCR, while pathologic method was not (HR 0.83 95% CI [0.48, 1.42], p=0.50 for SS vs. WM).

**Conclusion:** WM and SS yield similar detection rates of pathological outcomes in radical prostatectomy specimens, except for tumor volume. Pathologic method does not modify the effect of pathological outcomes on BCR, suggesting that these methods provide comparable key pathologic information.
Poster# 99

ABILITY OF PERCENT POSITIVE BIOPSY CORES AND POSITIVE BIOPSY CORE DENSITY TO PREDICT LOW VOLUME LOW GRADE PROSTATE CANCER
James Nederostek¹, Bethany Barone² and Raymond Lance²
¹Dept. of Urology, Eastern Virginia Medical School, Norfolk, VA; ²EVMS Dept. of Urology - Norfolk, VA
Presented By: James Nederostek

Introduction and Objectives: We investigated the prognostic value of percent positive biopsy cores (PPBC) and positive biopsy core density (CD) to predict low volume low-grade (LVLG) prostate cancer.

Methods: A cohort of 529 patients who underwent radical retropubic prostatectomy from January 2007 through July 2009 with available biopsy information on number of cores, number of positive cores, and prostate volume was retrospectively reviewed. Patients missing the appropriate biopsy information or any of the parameters needed to determine LVLG disease were excluded (n=123), the final sample size was 406 patients. Patients were divided into significant and LVLG prostate cancer groups from the same cohort and evaluated for an association with two variables: PPBC (the number of positive biopsy cores divided by the total number of cores - %), and CD (PPBC divided by the prostate volume - %/g). These variables were further stratified by race and prostate volume. Patients with strictly Gleason 6 (3+3) and Gleason 7 (3+4) disease were also evaluated by correlating individual numbers of positive cores with significant or LVLG prostate cancer. All continuous variables were checked for normality and nonparametric methods were used when necessary.

Results: Overall, 23% of the cohort had LVLG prostate cancer, with 24% being African American. Patients with LVLG prostate cancer had significantly lower PPBC and CD (p<0.001). This trend remained significant when stratified by race and prostate size, but the difference in PPBC and CD comparing LVLG and significant prostate cancer was greater in whites and in men with smaller prostates. Lower number of positive biopsy cores was significantly association with LVLG disease in men with biopsy Gleason 6 (3+3), and this trend was not observed in the group with biopsy Gleason 7(3+4). Age and race did not differ between patients with significant and LVLG prostate cancer. Prostate volume was significantly larger in patients with LVLG disease.

Conclusions: Patients with lower PPBC and CD have a higher association with LVLG prostate cancer.

Poster# 100

COMPARISON OF TERTIARY CENTER AND REFERRED PROSTATE BIOPSIY: IMPACT OF REVIEW ON GLEASON SCORE ACCURACY
Michael A. Feuerstein¹, Tipu Nazeer², Michael Hong¹, Hugh Fisher¹, Ronald Kaufman, Jr.¹ and Badar M. Mian¹
¹Division of Urology, Albany Medical College and Stratton Veterans Affairs Medical Center, Albany NY; ²Department of Pathology, Albany Medical College and Stratton Veterans Affairs Medical Center, Albany NY
Presented By: Michael A. Feuerstein

Introduction: It has been reported that referred prostate biopsies are often less accurate than tertiary center biopsies in predicting prostatectomy Gleason score (pGS). Therefore, a review of referred biopsies by pathologists at the tertiary center is recommended for improved risk stratification before treatment. We sought to determine the differences in diagnostic accuracy of referred biopsies and tertiary center biopsies by comparing biopsy Gleason score (bGS) to pGS. We also sought to determine whether review of outside biopsies by our tertiary center pathologists could improve the correlation between bGS and pGS.

Methods: We identified 360 consecutive patients with detailed biopsy and prostatectomy data, including primary and secondary Gleason grades, biopsy scheme, number of positive cores, percent of cores involved, age, PSA and clinical stage. Gleason scores were divided into 3 risk categories: ≤ 6, 7, and ≥ 8. Patients were divided into three groups based on their biopsy location and review: 1) biopsy by outside urologist - not reviewed; 2) biopsy by outside urologist - reviewed by our tertiary center pathologist; and 3) biopsy performed at our center. Outside biopsies were reviewed based on the surgeon’s discretion. All patients underwent radical prostatectomy at our center.
Results: Of 360 patients, 243 (68%) had a biopsy performed at our tertiary center. Of the remaining 116 patients, 54 (47%) patients had the biopsy slides reviewed by a tertiary center pathologist. The outside biopsy report was in agreement with the tertiary center biopsy review in 46/54 cases (85%, k=0.69). Correlation between tertiary center bGS and pGS was noted in 172/243 (71%) men, upgrading in 36/243 (15%), and downgrading in 35/243 (14%). Outside biopsies that were not reviewed correlated with pGS in 39/62 (63%), upgrading in 21/62 (34%), and downgrading in 2/62 (3%). Pathology review of outside biopsies correlated with pGS in 27/54 (50%), upgrading in 23/54 (43%), and downgrading in 4/54 (4%). Even after a review of outside biopsies, tertiary center biopsies resulted in better correlation with pGS (p<0.005) and fewer patients upgraded (p<0.005).

Conclusions: Tertiary center biopsies were superior to outside biopsies in predicting pGS despite pathology review. The data suggest that urologists performing the biopsy may represent an important variable in predicting final Gleason score, possibly due to improved targeting and sampling.

Poster# 100.5

COMPARISON OF BODY IMAGE AND URINARY FUNCTION BETWEEN ILEAL CONDUIT AND ORTHOTOPIC NEOBLADDER PATIENTS AFTER RADICAL CYSTECTOMY FOR BLADDER CANCER
Ryan Hedgepeth¹, Chang He¹, Gilbert Scott², James Montie¹, John Wei¹, Cheryl Lee¹ and David Wood¹
¹University of Michigan, Ann Arbor, MI; ²University of Florida, Gainesville, FL
Presented By: Ryan Hedgepeth

Introduction and Objective: Patients undergoing a radical cystectomy and ileal conduit often have better functional urinary outcomes than those with a neobladder, but the urinary bother is the same in both groups. It has been hypothesized that neobladder patients tolerate worse function because of improved body image. The purpose of this study is to compare changes in urinary outcomes and body image between the two diversion types.

Methods: The Bladder Cancer Index (BCI) and EORTC Body Image Scale were used to assess urinary outcomes and body image. Patients who underwent a radical cystectomy at the University of Michigan from November 1999 onwards and completed follow-up between July 2007 and August 2008 were enrolled. A third cohort of patients who had cystoscopy for bladder cancer was enrolled as a reference group. Analysis of variance was used to compare mean scores and for pair-wise comparison at baseline, 1 month, 6 months, and 1, 2, 4, 6, and 8 years after treatment. A generalized estimated equation model was used to account for repeated measures and non-normal score distribution.

Results: A total of 336 patients were enrolled. Of the radical cystectomy patients, 139 had a neobladder and 85 had a conduit. The remaining 112 patients were the cystoscopy reference group. No difference in baseline body image scores between the three groups was observed. After radical cystectomy, both conduit and neobladder groups had worse body image scores that improved over time, although the neobladder group did not return to baseline. Comparison between diversion groups showed no significant difference at any time point. A linear effect of time on body scores was observed but there was no difference between diversion groups. Age was associated with score but gender was not. Urinary function was better in conduit patients but urinary bother was the same in both diversion types.

Conclusions: Radical cystectomy has a significant impact on body image that improves slowly over time. However, there was no difference in the patient’s body image between those with an ileal conduit and neobladder. Factors other than body image are involved in the patient’s acceptance of worse urinary function associated with a neobladder.
Poster# 101

PREDICTORS OF FAVORABLE PSA AFTER PROSTATE CRYOABLATION
David Levy and Stephen Jones
Cleveland Clinic Health System Department of Urology
Presented By: David Levy

Purpose: To identify prognostic factors for favorable biochemical disease free survival following primary whole gland prostate cryoablation based upon initial post cryoablation PSA < 0.6 ng/ml.

Materials and Methods: The charts from 122 patients who underwent prostate cryoablation at the Cleveland Clinic from 2004 through May 2009 were reviewed. Patient age, race, PSA at diagnosis, Gleason score, risk category, prostate gland volume, clinical T stage, number of cores positive, percent of core involved with disease, ratios of: number of cores positive to total cores biopsied and number of cores positive to prostate gland volume, and initial PSA results were studied. An initial PSA of < 0.6 was employed as the criterion for favorable outcome based on previously published data.

Results: 16.4% of patients had unfavorable PSA levels. On univariate analysis, number of cores positive (p= 0.0312) and maximum percent core positive (0.0236) were prognostic of PSA outcome. On multivariate analysis, number of cores positive (p=0.0097), maximum percent core positive (p = 0.0337) and ratio of number of positive cores to prostate gland volume (p=0.0225) were prognostic for favorable PSA outcomes based on an initial PSA < 0.6 ng/ml.

Conclusion: This is the initial report of prognostic factors for favorable PSA outcomes following primary prostate cryoablation. The number of and percent core positive, and the ratio of number of cores positive to prostate gland volume are highly prognostic for initial post cryoablation PSA < 0.6 ng/ml which is associated with favorable long term biochemical disease free survival regardless of risk stratification.

Poster# 102

SALVAGE CRYOABLATION OF THE PROSTATE AFTER PRIMARY RADIOTHERAPY: A SINGLE INSTITUTION ANALYSIS OF PREDICTIVE FACTORS FOR RECURRENCE AFTER SALVAGE THERAPY IN A PREDOMINANTLY PROTON THERAPY POPULATION
Christopher Tenggardjaja, Amanjot Rangi, Ryan Bowman, Walter Yuen, Kamyar Ebrahimi, Kristin Sanderson and Herbert Ruckle
Loma Linda University Medical Center, Loma Linda, CA
Presented By: Christopher Tenggardjaja

Introduction: Since the inception of modern cryoablative techniques for prostate cancer in the 1990s, the modality’s application in the salvage setting has been investigated. Prior studies in the literature suggest that prostate specific antigen (PSA) and Gleason score prior to cryoablation are risk factors for biochemical recurrence following salvage therapy after radiation. Our primary goal is to analyze our experience with salvage cryoablation after predominantly primary proton radiotherapy and assess predictive factors that lead to recurrence after salvage therapy.

Materials and Methods: We performed a retrospective review of all cryoablation cases from February 2004 to September 2008. Only salvage cryoablation cases that had recurrence after initial radiotherapy were included for analysis. All cases included were curative in intent. Patient demographics were recorded as well as disease specific factors such as PSA and Gleason score prior to radiotherapy, PSA and Gleason score prior to cryoablation, number of positive cores prior to cryoablation, time to recurrence after radiotherapy and after cryoablation. Recurrence after salvage cryoablation was defined by initiation of androgen deprivation therapy or a PSA of 0.4 or greater. Statistics were analyzed with Student’s T-test, Chi-square or Mann-Whitney when appropriate with a p value < 0.05 considered significant.

Results: 33 patients underwent salvage cryoablation for recurrence after primary radiotherapy. 75% of the patients had undergone proton therapy. Median follow up after cryoablation was 24 months. 15 patients (45%) failed salvage cryoablation therapy. Mean time to failure was 4.3 months. There was no significant association observed between modality of primary therapy and recurrence after salvage therapy. Analysis revealed that only PSA prior to cryoablation was significantly related to recurrence after salvage therapy (p < .016).

Conclusion: To our knowledge, these findings are the first to be reported in a cohort of patients with predominantly post proton therapy prostate cancer recurrence. Our institution’s findings are similar to the PSA biochemical free survival rates reported in the literature with other radiotherapy groups. An elevated PSA prior to cryoablation was associated with biochemical failure after salvage therapy. More studies to evaluate the efficacy of earlier salvage cryoablation in regards to biochemical recurrence after radiotherapy are needed.
Poster Session 2

Poster# 103

LONG TERM CANCER-SPECIFIC SURVIVAL FOR MEN FOLLOWED MORE THAN 10 YEARS AFTER PROSTATE CRYOABLATION
Philippa Cheetham, Matthew Truesdale and Aaron Katz
Columbia Medical Center, New York, New York
Presented By: Philippa Cheetham

Introduction: Albertsen reported 10-year disease-specific survival for clinically localized prostate cancer after radical radiotherapy; 93%, 88%, 80% for low, medium, high-risk groups respectively. We report long-term cancer survival rates for men who had prostate cryotherapy over 10 years ago.

Methods: 49 men stratified according to low, moderate and high-risk groups underwent prostate cryotherapy (primary or salvage) before 11.1.98. Data retrieved pre-, intra- and post treatment included; patient age, presenting PSA, Gleason grade, primary or salvage treatment, biochemical failure (ASTRO definition) and need for adjuvant hormones. Primary endpoints were overall mortality and prostate cancer-specific death.

Results: Mean age 69 yrs, preoperative PSA 14.91, median follow up 11.3 years; mean Gleason score was 7 (range 4-9). 8 primary cases; 39 post-radiation; 2 unspecified; 33 received hormones post ablation. At 10 years 29 men were still alive (59.2%). Only 3 (6.1%) had died of prostate cancer and 9 (18.4%) had died of non-cancer causes.

Conclusions: The long-term results of prostate cryotherapy in our series are extremely good, with 94% 10-year prostate cancer-specific survival despite early cryotherapy technology. Our findings suggest that patients undergoing cryotherapy may have a cancer specific survival advantage compared to those electing for radiation or hormones alone.

Poster# 104

IS SELECTION FOR FOCAL THERAPY FOR PROSTATE CANCER ONCOLOGICALLY SAFE BASED ON CONTEMPORARY NEEDLE BIOPSY PROTOCOL? PREDICTORS OF CONTRALATERAL INVOLVEMENT FROM RADICAL PROSTATECTOMY SPECIMENS.
Sonal Grover, Kumaran M. Mudaliar¹ ², Abhishek Srivastava¹ ², David L. Peters¹ ², Fangmin Chen¹ ², Gerald Tan¹ ², Robert Leung¹ ², Majnu John¹ ² and Ashutosh Tewari¹ ²
¹New York Presbyterian Hospital, New York, NY; ²Weill Cornell Medical College, New York, NY
Presented By: Sonal Grover

Objective: Focal/hemiablated treatment for unilateral low risk prostate cancer has been advocated as definitive treatment for patient with unilateral low risk prostate cancer. We present the prevalence and predictors of contralateral disease in this patient cohort who eventually underwent radical robotic prostatectomy.

Patients and Methods: Between June 2005 and July 2009, 1113 patients who underwent radical robotic prostatectomy at our institution had unilateral disease on preoperative biopsy. We reviewed biopsy, operative and clinical data to record age, BMI, preoperative prostate specific antigen (PSA), clinical stage, Gleason score, high grade intraepithelial neoplasm (HGPIN), perineural invasion (PNI), prostate volume, number of positive cores and maximum percentage of positive cores. These clinical and biopsy variables were correlated with final surgical pathology. Logistic regression and Backward Wald analysis were performed to identify the predictors of cancer in contralateral lobe. Odd ratios (OR) were also determined.

Results: Of the 1113 patients with unilateral disease on biopsy, 867 (77.89%) had bilateral disease and 246 (22.10%) had unilateral disease on final surgical pathology. Logistic regression analysis identified biopsy regimen of more than 12 cores (P=0.043; OR= 0.736) and presence of HGPIN on biopsy (P=0.020; OR= 1.791) as significant predictors of contralateral involvement, but HGPIN (P=0.036; OR= 1.743) was the only significant predictor on Backward Wald analysis. Age (P=0.708; OR= 0.996), BMI (P=0.425; OR= 1.015), preoperative PSA (P=0.696; OR= 0.696), total positive cores (P=0.287; OR= 1.054), maximum percentage of positive cores (P=0.583; OR= 1.002), PNI (P=0.251; OR=2.342), Prostate volume (P=0.558; OR= 0.998) were not significant predictors of contralateral involvement.
Conclusion: There is little correlation between biopsy and the final surgical pathology, which makes patient selection for focal/ hemiablative therapy challenging. Only 22.10% of patients with unilateral disease on biopsy had unilateral cancer on final pathology. Among various clinic-pathological variables, HGPIN was the significant predictor for contralateral involvement. However additional methods are still needed to improve predictability of cancer laterality and to identify men appropriate for focal therapy.

Poster# 105

PRIMARY FOCAL CRYOTHERAPY FOR LOCALIZED PROSTATE CANCER: EARLY OUTCOME DATA AND DISEASE-FREE SURVIVAL
Matthew Truesdale, Philippa Cheetham, Gregory Hruby and Aaron Katz
Columbia Medical Center, New York, NY
Presented By: Matthew Truesdale

Introduction and Objective: Cryotherapy, an effective treatment for prostate cancer, has traditionally been targeted to ablate the entire gland. While efficacious, this may be associated with significant side effects, particularly permanent loss of sexual function. Partial gland cryoablation targets unilateral disease, sparing healthy tissue and the ipsilateral neurovascular bundle with the aim of preserving quality of life. The objective of this study is to report our early focal cryoablation outcome data.

Methods: Retrospective patient chart review from IRB-approved on-line cryotherapy database. Inclusion criteria: unilateral prostate cancer treated with primary focal cryotherapy. Patients stratified using D’Amico risk criteria. Exclusion criteria: men who had received radiation or hormones. Disease-free survival using combined ASTRO and Phoenix criteria (biochemical failure = nadir+2ng/mL followed by 3 consecutive PSA rises) was calculated, Kaplan-Meier curves and Cox regression analyses constructed comparing outcomes across risk groups.

Results: From 2004-2009, 69 men underwent primary focal cryosurgery at a single institution: mean age 69.8±7.2yr; mean follow-up time 1.71 yrs; overall mean pre-cryosurgical PSA 6.48±5.2ng/mL; median Gleason score 6 (range 5-9). 75.7% had clinical stage T1c disease. Mean pre-treatment AUA score 7.1±4.7 (n=17). 38, 27 and 5 men had low, intermediate and high-risk disease, respectively. All patients discharged home same day. No reported cases of postoperative urinary incontinence. 5/69 (7.2%) men met criteria for biochemical failure; 2/38 low (5.3%), 1/26 intermediate (3.8%) and 2/5 high (40%). 4/5 underwent prostate biopsy; 2/4 had recurrent ipsilateral disease and 2/4 had contralateral disease. Overall mean post-treatment PSA nadir was 1.48±1.62ng/mL. Biochemical failure associated with age>75 (p=0.02) and high-risk disease (p<0.001). Race, cancer side and post-treatment PSA nadir had no significant effect on survival. No disease progression, nor attributable deaths seen during study period.

Conclusions: Primary focal cryoablation is associated with extremely low rates of morbidity. Early efficacy data is supported by encouraging disease-free survival rates in patients with low and intermediate risk prostate cancer. Focal cryotherapy is a promising option for carefully selected patients, though further follow-up and long-term disease control will determine its role in prostate cancer treatment.

Poster# 106

MRI GUIDED TRANSCUTANEOUS ULTRASOUND THERAPY WITH REAL TIME THERMAL MAPPING FOR LOCALIZED PROSTATE CANCER: INITIAL STUDIES
Kashif Siddiqui, Rajiv Chopra, Michael Bronskill and Laurence Klotz
Sunnybrook Health Sciences Center, Toronto ON
Presented By: Kashif Siddiqui

Introduction and Objective: MRI guided transurethral ultrasound therapy is a novel minimally invasive treatment developed at our Centre. The system uses MR derived temperature mapping to target and modulate transurethral ultrasound power and frequency enabling thermal ablation of the prostate with speed and precise control. We report the correlation between initial planning, thermal injury as determined by MR, and subsequent histologic evidence of tissue injury and necrosis.

Methods: Experiments were performed in a clinical 1.5T MRI using an MRI compatible prototype treatment system. Seven experiments were performed in acute model and four to assess the delayed effects. Transurethral planar ultrasound heating applicators mounted on a rigid urethral device were inserted through perineal urethrostomy and positioned in prostatic urethra. A target boundary was defined within the prostate gland, based on MR images. A rectal device was placed for cooling. A single transducer (9.1MHz) was used to distribute energy. The spatial temperature distribution was measured continuously with MRI using the proton-resonant frequency shift method producing a temperature
resolution of ±1°C updated at five-second intervals. A feedback control algorithm was used to achieve a spatial precision of 1-2mm in heating to a minimum of 55°C. After the treatment, prostates were harvested, formalin fixed, sectioned and stained with H&E in whole-mount fashion. These sections were compared to the MR images using image-registration techniques.

**Results:** A targeted region of thermal damage was generated within the prostate gland by transurethral ultrasound. Comparison between thermal mapping, post treatment MRI and histology demonstrated that temperature information was highly predictive of thermal damage. The greatest distance between the tissue targeted for ablation and histologic injury was 3 mm. Treatment time was less than 30 minutes for all animals. There was no evidence of thermal damage to rectal tissue.

**Conclusions:** MRI guided transurethral ultrasound therapy using real-time thermal mapping to adjust the energy delivered and regulate the extent and degree of ablation, enables precise and rapid thermal ablation of the canine prostate. The deviation between targeted tissue and thermally ablated tissue was 0-3 mm. This approach has obvious applications in human prostate cancer management.

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**Poster# 107**
**ONANCE IMAGING FINDINGS AS A MARKER FOR MEN AT RISK OF PROSTATE CANCER A PROSPECTIVE TRIAL OF THE ROLE OF MAGNETIC RES PROGRESSION WITH LOW RISK DISEASE OTHERWISE SUITABLE FOR ACTIVE SURVEILLANCE**

Nathan Lawrentschuk¹, Masoom Haider², Anthony Finelli³, Alexandre Zlotta³, Michael Jewett³ and Neil Fleshner⁴

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Presented By: Nathan Lawrentschuk

**Introduction:** AS is now an acceptable option for the management of localized prostate cancer (PC) but optimal patient selection criteria, currently based on biopsy results and clinical stage, are yet to be developed. MRI may add to the ability of clinicians to select patients with low risk disease who are at risk of progression and thus may not be suitable for AS. The aim of our prospective study is to evaluate the performance of MRI in AS patients to assist in identifying patients with more extensive disease that require radical treatment, including anterior evasive tumors.

**Patients and Methods:** Men with PC and suitable for AS (Gleason score ≤ 7; PSA<15ng/ml, Stage T1c- T2a) were enrolled as part of an ethics-approved trial. MRI with multiple sequences is conducted ≥12 weeks after biopsy using endorectal coil. The radiologists are blinded to the biopsy findings. If the MRI results revealed an anterior tumor or were regarded as extensive, repeat biopsy was ordered and suitability for remaining on AS discussed.

**Results:** Currently, 40 men have been enrolled. MRI has identified 23 tumors definitely, 2 equivocally and 15 were not visible. Four biopsies have been requested with one patient refusing. Of the 4 biopsies 3 were positive for higher grade and/or more extensive PC and one was negative. Two tumors were anteriorly located and missed on initial biopsy with the thirds at the apex. Two patients have proceeded to radical treatment based on MRI findings prompting re-biopsy and/or clinical suspicion of far greater disease burden confirmed on MRI.

**Conclusions:** MRI had acceptable PC detection rates in men with low risk, low volume PC. Early results indicate that MRI may change management in a significant proportion of men suitable for AS by helping to identify patients who stand to benefit from radical treatment. As such, MRI may be a prudent investigation to conduct in men prior to committing them to AS and we await further recruitment in this study.

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**Poster# 108**
**CONCORDANCE OF PREOPERATIVE PROSTATE ENDORECTAL MRI WITH RADICAL RETROPUBIC PROSTATECTOMY SPECIMENS**

Kenneth Nepple and Richard Williams

University of Iowa, Iowa City, IA

Presented By: Kenneth Nepple

**Introduction and Objective:** Endorectal MRI can identify areas suspicious for prostate cancer but the accuracy is not yet fully known. Since 2003, we have routinely obtained MRI in patients with factors suspicious for local extension (Gleason grade ≥ 4+3, PSA ≥ 10, abnormal exam, or extensive biopsy core involvement.) The objective of the study was to evaluate the accuracy of MRI compared to subsequent surgical specimen.
Methods: We reviewed 309 open RRP cases performed from 2003 to 2008 to identify men with a preoperative MRI. Findings on MRI of extracapsular extension (ECE), seminal vesicle involvement (SV), and lymphadenopathy (LAD) were compared to subsequent findings on RRP pathology specimens.

Results: 94 men (median age: 61 years, range 48 to 72) with a mean PSA of 9.3 ng/mL (range 1.3 to 35) had a preoperative endorectal MRI. Indication for MRI included: Gleason grade ≥ 4+3 in 34%, PSA >10 in 18%, exam in 13%, extensive core involvement in 14%, or combination of factors in 21%. No tumor was seen on MRI in 9 men (10%). When compared to surgical specimen, MRI was accurate for ECE in 74% and SV in 93%. Lymph nodes were positive in 10 men, none of which had LAD on MRI.

Conclusions: Endorectal MRI in the evaluation of prostate cancer was moderately accurate for ECE and SV involvement, but insensitive for metastatic lymph node involvement.

Poster# 109

OVERUSE AND UNDERUSE OF IMAGING TO STAGE NEWLY DIAGNOSED PROSTATE CANCER PATIENTS IN THE MEDICARE POPULATION

Danil Makarov¹, Richa Sharma¹, James Yu¹, Nitya Abraham², Rani Desai¹, Peter Albertsen³, David Penson⁴ and Cary Gross¹
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Presented By: Danil Makarov

Purpose: The National Comprehensive Cancer Network (NCCN) has issued consensus guidelines on when men with newly diagnosed CaP should be imaged. Until recently, population-based data allowing classification of patients into NCCN risk groups were unavailable. We sought to determine the correlates of imaging overuse and underuse, and their regional variation, among men newly diagnosed with CaP.

Methods: We used data from SEER-Medicare, including men with CaP diagnosed in 2004-5, aged 66-85, and missing <3 of the following: PSA, clinical stage (CS) and Gleason score (GS). Patients were divided into low risk (LR) (imaging not recommended) and high risk (HR) (imaging recommended). LR had no high-risk features: PSA>10ng/mL, GS≥8, or CS>T2. We used logistic regression to model receipt of any staging imaging among LR after diagnosis and before treatment (within 9 months). We used logistic regression to model receipt of at least a bone scan and axial pelvic imaging in HR. We calculated the predicted probabilities of imaging overuse in LR (pOv) and imaging underuse among HR (pUn) in each SEER region and used linear regression to determine their correlation at this level.

Results: We identified 19,785 LR, and 11,383 HR. 48.9% of LR received staging imaging (overuse), while 52.7% of HR did not receive the minimum NCCN recommended imaging (underuse). Among LR, logistic regression demonstrated higher odds of imaging overuse as age, income, CS, GS, and comorbidity increased. Imaging underuse in HR was associated with increased age and black race, as well as decreasing income, CS, GS, and PSA. In a registry-level scatterplot of pOv as a function of pUn, we fit a line with R2 of 0.67 and slope of 0.67. Regions with higher pOv tended to have lower pUn.

Conclusions: We found poor compliance with the NCCN recommended imaging staging evaluation for men newly diagnosed with CaP, with approximately half of patients receiving guideline inappropriate care. Imaging use appears to be determined strongly by regional practice patterns and affinity for imaging. These behaviors must be considered prior to instituting policy-level solutions, as addressing overuse in LR may potentially have an adverse affect on access to imaging for HR.
ENDORECTAL T2-WEIGHTED MRI DOES NOT DIFFERENTIATE BETWEEN FAVORABLE AND ADVERSE PATHOLOGIC FEATURES IN MEN WITH PROSTATE CANCER WHO WOULD QUALIFY FOR EXPECTANT MANAGEMENT

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Presented By: Matthew Resnick

Purpose: With the increased diagnosis of low grade, low volume, potentially non-lethal disease, active surveillance has become an increasingly popular alternative for select men with low-risk prostate cancer. The absence of precise clinical staging modalities currently makes it difficult to predict which patients are most appropriate for active surveillance. The goal of our study was to evaluate the ability of endorectal MRI (eMRI) to predict adverse pathologic features in patients who would otherwise qualify for an active surveillance program.

Materials and Methods: We retrospectively reviewed our institution’s radical prostatectomy (RP) database from 1991-2007 and identified 172 patients who would have qualified for active surveillance and underwent pre-operative staging eMRI with T2-weighted (T2W) sequences. MRI findings were correlated to final pathology in order to assess the ability of staging eMRI to predict adverse pathologic features in patients suitable for active surveillance.

Results: The mean age of our cohort was 59.8±6.2 years. The mean PSA at the time of diagnosis was 5.2±2.2 ng/ml. In fifty-one percent of patients, no discrete tumor was visualized on eMRI and in 49% of patients’ discrete tumor was detected. At the time of RP, Gleason score upgrading, extracapsular extension and a positive surgical margin occurred in 17%, 6%, and 5% of cases respectively. Patients with documented tumor on eMRI did not have an increased incidence of adverse pathologic findings with regard to tumor volume (p=0.31), extracapsular extension (p=0.82), Gleason upgrading (p=0.92), seminal vesicle invasion (p=0.97) or positive margin rate (p=0.95) compared to those in which no tumor was seen.

Conclusion: Discrete tumor identification on T2W-eMRI is not predictive of adverse pathologic features in patients who would otherwise qualify for active surveillance. T2W-eMRI likely does not provide additional information when prospectively evaluating patients for active surveillance protocols.

PREDICTIVE VALUE OF ENDORECTAL MAGNETIC RESONANCE IMAGING IN SHOWING EXTRACAPSULAR EXTENSION OF PROSTATE CANCER IN PATIENTS UNDERGOING ROBOTIC ASSISTED RADICAL PROSTATECTOMY: HOW HAS IT HELPED US?

Abhishek Srivastava, David Peters, Kumaran Mudaliar, Sonal Grover, Gerald Tan, Robert Leung, Fangmen Chen, Majnu John and Ashutosh Tewari

Weill Cornell Medical College-New York Presbyterian Hospital

Presented By: Abhishek Srivastava

Introduction and Objective: Endorectal MRI (eMRI) of Prostate Cancer allows surgeons visual appreciation of cancer architecture, but its predictive value for final extracapsular extension (ECE) on histopathology has been controversial. We report our experience with 656 patients receiving 1.5/3.0 Tesla MRI prior to Robotic Assisted Radical Prostatectomy (RARP).

Materials and Methods: We retrospectively analyzed the eMRI reports and final pathological findings of radical prostatectomy specimens of 656 patients who underwent RARP from August 2005 to August 2009. We compared ECE on eMRI with the final histopathological ECE status and calculated sensitivity, specificity, Positive predictive value (PPV), Negative predictive value (NPV) and accuracy of eMRI.
**Results:** Out of the 656 patients receiving eMRI for prostate cancer prior to RARP, 79 patients had positive ECE on eMRI. Of these 79 patients, 24 had positive ECE status and 55 had organ confined disease on final histopathology. MRI accurately predicted 500 patients with negative ECE but it failed to detect 77 patients with positive ECE on final histopathology. Sensitivity=23.76%, Specificity=90.09%, PPV=30.38%, NPV=86.66%, Accuracy=79.88%.

**Conclusion:** The results of present study suggest that eMRI is an accurate test for predicting organ confined disease but less accurate for predicting positive ECE.

**Poster# 112**

**DIFFERENTIAL MICROTERMOMERTRY REVEALS THAT NEOPLASTIC CELLS ACTIVELY MODULATE MICROENVIRONMENT TEMPERATURE: A NOVEL STUDY OF TISSUE THERMODYNAMICS**

Steven Mercereau¹, Moustafa Sadek¹, Nikhil Wainganker¹, Louis Kavoussi¹ and Manish Vira²

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Presented By: Manish Vira

**Introduction:** Thermodynamics is the study of the energy state of an isolated object and its conversion to work and heat as a known external force is applied. The measurement of thermodynamic phenomena includes temperature, pressure, volume, internal energy and entropy that are related to each other by complex formulae. This study is based on the hypothesis that thermodynamic laws also can be applied to groups of cells (tissue) within an organ. The study of thermodynamic phenomena within cellular systems has the potential to provide novel insight into the structure, function, operation and health of cells and tissue.

**Methods:** Hybridoma cells, commonly used for commercial antibody production, were grown in standard media suspension. Temperature measurements were obtained using the IT-18 T-type thermocouple calibrated to 0.1°C, range of -20 to 150°C (time constant 0.1 seconds, Physitemp Instruments, Inc.). Cells were placed in suspension media in 10 mL culture tubes. Microthermometry of suspension of live cells (96% viable) was compared to suspension of dead cells (6% viable). Measurements were made both in 37°C water bath and then allowed to cool to ambient temperature.

**Results:** Initial measurements were performed simultaneously in the same environment to verify precision of the thermocouple sensors. At 37°C, suspension of viable hybridoma cells maintained temperature 0.3°C greater than suspension of non-viable cells. When both suspensions were allowed to cool to ambient temperature (~24°C), although temperature of the suspensions decreased at a different rate, the suspension of viable cells again equilibrated to a temperature 0.3°C higher than suspension of non-viable cells. The culture tubes were placed back into the 37°C water bath and after a short period of equilibration, the viable cells again maintained a temperature 0.3°C higher than non-viable cells. Results are described in Graph 1.

**Conclusions:** This report is the first description of differential microthermometry in cell culture showing differences in microenvironment temperature between viable and non-viable neoplastic cells.
Introduction and Objectives: According to recommendations from the U.S. Preventive Service Task Force (USPSTF), men aged 75 and older should not be screened for prostate cancer. This study identifies the prevalence of high-grade prostate cancer in men 75 and older undergoing prostate biopsy.

Methods: A retrospective review of a prospectively registered prostate biopsy database from a single Veterans Administration hospital identified 200 men aged 75 or older who underwent prostate biopsies between 1994 and 2006.

Results: Of the 200 men 77 (38.5%) had a previous prostate biopsy and 64 men (32%) had a PSA prior to their biopsy. At the time of biopsy, 54% of the 200 patients had a screening PSA less than or equal to 10, 26% between 10 and 20, and 20% greater than 20. 116 of the 200 patients (58%) had biopsies that were positive for cancer. Of the 116 diagnosed with prostate cancer, 48 (41.4%) had Gleason scores of 6 or less, 39 (34%) had Gleason 7 disease, and the remaining 29 (25%) had a Gleason 8 or greater cancer. Neither an abnormal DRE (p=.109), ethnicity (p=.880) or history of prior biopsy (p=.191) characterized patients with high grade cancer (Gleason 8 or higher). Patients with high-grade cancer were less likely to have undergone prior PSA screening (p=0.014) and had significantly higher PSA levels at time of biopsy (p=0.00).

Conclusions: Nearly 60% of men 75 and older who underwent prostate biopsy following an abnormal screening examination were found to have cancer with roughly 34% of men having Gleason 7 prostate cancer and 25% with Gleason 8 or greater disease. These findings are very worrisome in view of the present recommendations that advocate discontinuing prostate cancer screening after age 75.

Introduction: With increasing use of prostate specific antigen (PSA) screening more and more patients are diagnosed with small volume prostate cancer. We aimed to look at histological characteristics of tumor on radical prostatectomy specimen in patients who had only one positive core on prostate biopsy.

Methods: We retrospectively reviewed all radical prostatectomy (RP) performed during January 2007 and December 2008 and their pre operative prostate biopsy. All the patients who had only one positive core on biopsy and underwent RP were included in the study.

Results: Total of 255 RP were performed during study period. 33 (13%) patients underwent RP for prostate cancer diagnosed by single positive core on biopsy and had less than 10% of tumor. Median age was 62 years (range 50-73). 29 patients had Gleason Score 6 prostate cancer and others four had 7 (3+4). Majority of patients had PSA <= 10 (25/33) and clinically T1c (28/33) disease. On RP specimen, 19 (58%) patients had tumor volume less than 1 ml. No tumor (pT0) was identified in 2 prostate. Number of pT2 a, b and c was 6, 0 and 20 respectively. The rest (5) had pT3a disease. All the patients with pT3a disease had either Gleason Score of above 10 or cT2b disease. None of these patients had any evidence of biochemical recurrence during follow up from 10 to 31 months.

Conclusion: In PSA screening era, more patients undergo surgery to cure low volume, low grade prostate cancer who may be eligible for initial period of observation. Patients particularly with single positive core on biopsy, PSA value less than 10, clinically impalpable disease and Gleason Score of 6 or 7 (3+4) are suitable for deferred treatment or active surveillance. Hence avoiding potential complications of surgery.
THE PATHOLOGIC AND CLINICAL OUTCOMES OF MEN WITH MICROFOCAL PROSTATE CANCER UNDERGOING RADICAL PROSTATECTOMY
LaMont Barlow, Michael Whalen, Melissa Laudano, Alexa Meyer, Michael Rothberg, Gregory Hruby, Mitchell Benson and James McKiernan
Columbia University Medical Center, New York, NY
Presented By: LaMont Barlow

Introduction and Objectives: Over the last decade, there has been an increase in the diagnosis of low-volume and low-grade prostate cancer from transrectal ultrasound-guided biopsy (TRUS Bx) attributed to an increase in the average number of biopsy cores taken. However, this finding does not always correlate with less indolent cancer. This study examines the pathological and clinical outcomes of patients with Gleason score (GS) 6 microfocal (MF) prostate cancer diagnosed from TRUS Bx and treated with radical prostatectomy (RP).

Methods: A retrospective analysis of patients treated with RP at a single institution from 1988 to 2009 was conducted. All patients with GS 6 prostate cancer diagnosed from TRUS Bx were included in the study. MF disease was defined as a single positive core with ≤ 5% cancer involvement. Preoperative characteristics and TRUS Bx pathology results were evaluated as risk factors for bilateral disease and GS upgrading on RP pathology among MF patients. Comparisons were made between MF and non-MF patients to determine pathological outcomes and biochemical failure (BCF).

Results: 550 patients with GS 6 were analyzed, including 80 patients with MF disease. 76.6% of MF patients had bilateral disease on RP pathology. High-grade prostatic intraepithelial neoplasia (HG-PIN) on TRUS Bx was a risk factor for bilateral disease (OR 7.23 [1.52-34.26]) and GS upgrade (OR 2.97 [1.16-7.64]). Positive surgical margins were seen in 10.0% and 27.0% of MF and non-MF patients, respectively (p=0.001), and perineural invasion was seen in 41.3% and 59.8% of MF and non-MF patients, respectively (p=0.008). There was no difference in other pathological outcomes analyzed, including GS, extracapsular extension, seminal vesicle involvement, vascular space invasion, tumor multicentricity, or HG-PIN. There was no difference in the risk of BCF between the two groups (p=0.53).

Conclusions: Although there were decreased positive surgical margin rates and perineural invasion in MF patients, most surgical outcomes as well as BCF did not differ from other GS 6 non-MF patients. A majority of MF patients actually had bilateral disease at the time of RP, and the presence of HG-PIN on TRUS-Bx was predictive of both bilaterality and higher GS in subsequent RP pathology. These findings suggest that low-grade MF prostate cancer behaves similarly to higher-volume disease and should not be considered as a unique entity, particularly when HG-PIN is present.

PATHOLOGIC UPGRADING IN PATIENTS ELIGIBLE FOR ACTIVE SURVEILLANCE IN A VETERAN POPULATION
Eugene Lee, Janet Baack, Kevin Art, Cecil Bromfield, J. Brantley Thrasher and Jeffrey Holzbeierlein
University of Kansas Department of Urology
Presented By: Eugene Lee

Purpose: Active surveillance for prostate cancer is a therapeutic option which is gaining more favor. This is likely a result of the substantial stage migration to lower risk cancer with the advent of PSA. The decision to begin a patient on active surveillance is typically based on biopsy results and PSA. There are several protocols in existence but most agree that patients qualify with a Gleason Sum of 6, PSA less than 20, and a low volume of cancer in the biopsy specimen. Studies have shown upgrading or upstaging rates on repeat biopsy to be around 27% to 37%. We review our series with our veteran population.

Materials/Methods: We conducted a retrospective review of patients from the KCVA who met the requirements for active surveillance between January 2004 and December 2008. Our criteria for active surveillance includes: Gleason sum 6 or less, percent of cancer in the specimen less than 20%, and PSA less than 20 ng/dl. Final pathology of patients who underwent immediate prostatectomy were examined for stage, Gleason grade, percent of tissue involved with cancer, margin status, nodal status, and rate of biochemical recurrence.

Results: 180 patients met the requirements for active surveillance. Among them, 61 patients chose to undergo immediate radical prostatectomy at the KCVA. The average age was 62.1 years, the average PSA was 6.4, and the average percentage of biopsy involved with cancer was 6.5%. All men had a Gleason sum of 6. Upon radical prostatectomy, 59/61 (96.7%) had T2 disease while two patients had T3 disease. 40 of 61 (65.6%) patients had upgrading of Gleason score including 12 patients with Gleason 8 to 10 disease. 8/61 (13.1%) patients had positive margins. 0/53 patients had positive lymph nodes. 2 patients have had biochemical recurrence on follow-up.

Conclusions: Active surveillance is a viable option for patients with low risk disease. However, this study raises concerns about the significant rate of under-grading that may occur in this population. This emphasizes the need for better predictors of indolent disease.
Poster# 117

COST COMPARISON BETWEEN WATCHFUL WAITING WITH ACTIVE SURVEILLANCE AND ACTIVE TREATMENT OF CLINICALLY LOCALIZED PROSTATE CANCER
Anthony Corcoran¹, Pamela Peele² and Ronald Benoit¹
¹University of Pittsburgh School of Medicine, Department of Urology; ²University of Pittsburgh School of Public Health, Department of Health Policy & Management
Presented By: Anthony Corcoran

Introduction and Objectives: In part due to the concern of overtreatment in men with prostate cancer, watchful waiting with active surveillance (WWAS) has been increasingly utilized in men diagnosed with low risk prostate cancer. The present study investigates the difference in costs between men with low risk prostate cancer treated with up front radical prostatectomy (RP) and men who undergo WWAS.

Methods: A cost model was constructed using data from centers that have published their results in men who were followed with WWAS. Two WWAS arms were created in which the follow up protocol and conversion rate to active treatment were varied. The two WWAS arms were further stratified by the length of time men were assumed to undergo serial prostate biopsies with the potential to convert to active treatment. The costs of WWAS in these scenarios were compared to the cost of up front RP. Costs were calculated for 15 years from the time of diagnosis in all arms of the model. No financial funding was required for this study.

Results: The cost of up front RP including costs of surgery, complications, and follow up for 15 years was $15,235 per person. Costs of WWAS were estimated using annual conversion rates from WWAS to RP of both 5% and 7%. Costs per person in the WWAS arms ranged from $6,558 to $11,992 in the scenarios created which represent a 21.3% - 57.0% reduction in costs when compared to men undergoing up front RP.

Conclusions: Watchful waiting with active surveillance is being increasingly utilized in hopes of decreasing the potential overtreatment of prostate cancer in men with low risk disease. The present study suggests that WWAS is likely to markedly decrease costs when compared to active treatment with RP.

Poster# 118

LIFELONG YEARLY PSA SURVEILLANCE IS NOT NECESSARY IN LOW- RISK PROSTATE CANCER TREATED BY RADICAL PROSTATECTOMY
Matthew Tollefson, Michael Blute, Laureano Rangel, Jeffrey Karnes, Erik Bergstralh and Igor Frank
Mayo Clinic, Rochester, MN
Presented By: Matthew Tollefson

Introduction and Objective: Many patients undergoing radical prostatectomy in the PSA era have a low risk for recurrence. Aggressive PSA surveillance is costly and anxiety-provoking. This study investigates the need for yearly PSA measurements in patients with surgically treated low-risk prostate cancer.

Methods: We identified 2321 patients who underwent a radical prostatectomy (RP) between 1994 and 2004 for low risk localized prostate cancer. Low-risk was defined as PSA <10 ng/ml, pathologic stage pT2c or less, Gleason score of 6 or less, negative lymph nodes, and negative surgical margins. Patient who underwent neoadjuvant or adjuvant therapy were excluded. Biochemical recurrence (BCR) was defined as PSA>0.4 ng/ml and PSA values of <0.15 ng/ml were considered undetectable. Biochemical recurrence rates were calculated according to the duration of the PSA-free period following RP.

Results: 380 (16.4%) patients experienced BCR during the course of the study. The risk of BCF decreased with increasing duration of the PSA-free interval. For example, 1-, 3-, 5-year BCR rates calculated at the time of surgery were 1.8%, 4.2%, and 6.3%, respectively. For patients with undetectable PSA measurements five years after surgery, 1-, 3-, 5-year BCR rates were 0.0%, 0.7%, and 1.3%, respectively. Additionally, 1-year BCR rates were 0.2%, 0.4%, 0.0%, and 0.0% after a PSA-free period of 1, 3, 5, and 10 years, respectively.
**Conclusions:** The risk of BCR is inversely proportional to the duration of the PSA-free interval after RP in low-risk patients. Biochemical recurrence 1 year after an undetectable PSA is very uncommon especially after a PSA-free period of 3 years. These data suggest that yearly PSA measurements are unnecessary, especially after a PSA-free interval of 3 years and that PSA measurements every two years captures the majority of progressors.

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**Poster# 119**

**OUTCOME OF CLINICALLY LOCALISED PROSTATE CANCER MANAGED WITH ACTIVE SURVEILLANCE**

Amit Mevcha, Edward Rowe and David Gillatt

Presented By: Amit Mevcha

**Introduction and Objective:** We aimed to look at the outcome of patients who have been on active monitoring for low grade localized prostate cancer at our institute.

**Method:** We retrospectively reviewed all the patients (age ≤ 75 years) who have opted for the option of active surveillance for localized prostate cancer from January 2003 to February 2008.

**Results:** Total of 101 patients was under active surveillance during study period. The median age was 67 years (range 50 to 75). Patients with PSA value of ≥ 20 and cancer volume of ≥ 40% or clinical T2 disease had bone scan and MRI scan respectively to rule out distal metastases and locally advanced disease. Only 6 (6%) had TURP diagnosed prostate cancer. All 101 patients had Gleason Score of 7 or less prostate cancer and were followed up with regular PSA and digital rectal examination. 18 patients had a radical treatment (1 radiotherapy, 17 surgery) during the follow up time. Mean follow up was 42 (18 to 77) months. Only 1 patient had disease progression and developed metastatic disease. The overall and disease specific survival was 98%.

**Conclusion:** Active surveillance can be offered to low grade localized prostate cancer patients without compromising oncological outcome. It can defer or prevent potential complications of definitive treatment in patients with indolent disease. However, long-term follow up is required to validate our results.
Objective: As the purpose of the present study, we detected the expressions of BNIP3, HIF1a and VEGF in renal clear cell carcinoma and in normal renal tissues by immunohistochemical method, analyzing their correlations, to try to explore the role of BNIP3, HIF1a and VEGF in the resistance to hypoxia-mediated apoptosis among renal clear cell carcinoma.

Methods: The expressions of BNIP3 HIF1a and VEGF were examined by immunohistochemistry S-P method in 67 cases of RCC and in 35 cases of normal renal tissues. Results were compared with clinical pathologic parameters, and the associations between BNIP3 HIF1a and VEGF were statistically studied. SPSS 13.0 software was used to analyze the data. P<0.05 was considered as the level of significance.

Result: (1) The positive rate of BNIP3 in RCC was 13.5%, but the positive expression of BNIP3 was not found in the normal tissues. BNIP3 expression in RCC was significantly higher than those in normal renal tissues. There was significant difference. But BNIP3 expression had not significant differences in the tumor grading and in the tumor staging. (2) The positive rates of the HIF1a and VEGF in RCC were 68% and 76.5%. The positive expressions of them in the normal renal tissues were 0% and 18%. The expressions of them in RCC were significantly higher than those in normal renal tissues. There were significant differences. The expressions of HIF1a and VEGF had significant differences in the tumor grading and in the tumor staging. (3) There was significant correlation between HIF1a and VEGF, but there were not statistically significant correlations between BNIP3 vs. HIF1a and BNIP3 vs. VEGF.

Conclusion: As a hypoxia-inducible pro-apoptotic member of the BCL-2 family that induces cell death by associating with the mitochondria, the expressions of the BNIP3 in RCC were significantly higher than those in normal renal tissues, but it had not significant differences in the tumor grading and in the tumor staging. As the downstream reactive protein target gene of HIF, there was not statistically significant correlation between BNIP3 and HIF1a. RCC cells often show resistance to hypoxia-mediated apoptosis, the low expression of BNIP3 which results in evading apoptosis caused by hypoxia maybe is one of the most important reasons in the course of the occurrence and development of renal cell carcinoma. The more study on the causes of low expression of BNIP3 possibly can provide new clues and theoretical basis for the treatment of renal cell carcinoma.
Poster# 122

ACTIVATION OF MTOR/P70S6 PATHWAY IN PRIMARY TUMOR AND MATCHED METASTASES OF PATIENTS WITH METASTATIC NON-CLEAR CELL RENAL CELL CARCINOMA (RCC)
Alexander Kutikov, Brian Egleston, Zachary Piotrowski, Min Huang, Tahseen Al-Saleem and Robert Uzzo
Fox Chase Cancer Center, Philadelphia, PA
Presented By: Alexander Kutikov

Introduction and Objective: The mTOR/p70S6 kinase pathway regulates cell growth, proliferation, motility, and survival. Here we assess and compare its activation in primary non-clear cell-RCC and matched metastases (n=10).

Methods: Tissue from primary renal tumors and from resected/biopsied metastatic deposits was obtained from our institutional biosample repository. Tissue microarray (TMA) slides were constructed and included normal kidney controls. TMAs were incubated with rabbit polyclonal antibodies against Ser2448 of p-mTOR and Ser235/236 of p-ribosomal protein S6. Semiquantitative assessments of immunohistochemical staining were made, and Spearman rank correlation coefficients were used to assess associations between variables.

Results: Both primary tumors and metastatic deposits exhibited heterogeneous levels of staining for p-mTOR and for p-S6. Statistically significant association was seen between level of p-mTOR expression and p-S6 both in primary tumors (p<0.001) and within metastatic lesions (p<0.001). We observed a strong relationship between phosphorylation of m-TOR in primary tumors and that of matched metastases (p=0.0001); however we did not identify statistically significant relationships between staining for p-S6 in the primary tumors and that of matched metastatic deposits (p=0.904). The exact opposite relationship was noted in primary tumors and matched metastases in patients with clear cell carcinoma that we have reported in abstract form elsewhere.

Conclusions: Our data suggest that mTOR/p70S6 kinase pathway activation is common, but not ubiquitous in patients with metastatic non-clear cell RCC. We document a strong relationship between phosphorilation of m-TOR in primary tumors and their matched metastatic deposits. In contrast, we have observed that such a relationship does not exist in clear cell RCC patients. Instead, a strong correlation between staining for p-S6 is noted in clear cell tumors. These findings are provocative and deserve further study.

Poster# 123

ONCOLOGIC OUTCOMES OF PARTIAL NEPHRECTOMY FOR MULTIFOCAL RENAL CELL CARCINOMA WITH LARGEST TUMOR GREATER THAN 4CM
Gopal Gupta, James Peterson, Kailash Daryanani, Peter Pinto, W. Marston Linehan and Gennady Bratslavsky
NIH/NCI, Urologic Oncology Branch, Bethesda, MD
Presented By: Gopal Gupta

Introduction and Objectives: Despite aggressive screening, patients with hereditary renal cancers can present with large, multifocal tumors. We present the oncologic outcomes in hereditary renal cell carcinoma patients who underwent partial nephrectomy for solid tumors greater than 4 cm in the setting of bilateral multifocal tumors.

Methods: Between 1995 and 2008, we identified hereditary patients treated at our institution with partial nephrectomy for solid tumors greater than 4cm. The data collected included demographic parameters and tumor characteristics. Oncologic outcomes were assessed by overall and metastasis-free survival based on the information from the most recent follow up.

Results: The cohort included 58 patients that underwent a total of 60 partial nephrectomies and consisted of 41 patients with VHL (72%), 10 patients with BHD syndrome (17%), and 7 with HPRC (11%). Fifty-two partial nephrectomies were performed for clinical stage T1b, while the other 8 surgeries were done for clinical stage T2 tumors. The mean age was 43.7 years (range 18-63). The mean largest tumor size was 5.5 cm (range 4-13), while the mean number of kidney tumors resected was 6.4 (range 1-44). The most common pathology was clear cell RCC (73%) followed by papillary type I histology (11.7%). Nuclear grade 2 was present in 51 of 60 largest tumors (85%) Overall survival of the cohort was 94% and metastasis-free survival was 96% at the median follow up of 3.5 years (range 0.25-12.6).

Conclusions: Patients with multifocal RCC and tumors greater than 4cm have similar metastasis-free and overall survival when compared to their sporadic counterparts with solitary renal lesions reported in the literature. Presence of tumors greater than 4 cm in the setting of hereditary syndromes or multifocality should not dissuade surgeons from offering nephron sparing surgery to these patients.
Poster# 124

A NEOADJUVANT CLINICAL TRIAL WITH SORAFENIB FOR PATIENTS WITH STAGE II OR GREATER RENAL CELL CARCINOMA
Eugene Simopoulos, Stephen McKim, Kim Rathmell, William Kim, Paul Godley, Young Whang, Matthew Nielsen, Eric Wallen and Raj Pruthi
The University of North Carolina at Chapel Hill, Chapel Hill, NC
Presented By: Eugene Simopoulos

Purpose: The multitargeted tyrosine kinase inhibitor sorafenib is used for the treatment of advanced stage renal cell carcinoma, but its safety and efficacy has not been evaluated in the preoperative setting -- a setting offers several potential advantages such as tumor downstaging. This prospective trial evaluates the safety and feasibility of the tyrosine kinase inhibitor, sorafenib, in the preoperative setting.

Methods: Thirty patients with clinical Stage II or greater renal masses, selected based on their candidacy for nephrectomy, underwent preoperative treatment with sorafenib. Toxicities, surgical complications, and tumor responses were evaluated.

Results: Of the 30 patients enrolled, 17 patients had localized disease and 13 had metastatic disease (3% Stage I, 33% Stage II, 13% Stage III, 50% Stage IV). The majority proved to be clear cell cancers (70%), followed by papillary (13%), mixed (7%), chromophobe (3%), and other (7%). After a course of sorafenib therapy (median duration of therapy, 33 days), a decrease in primary tumor size (mean shrinkage 9%) and radiographic evidence of loss of intratumoral enhancement (mean decrease 14%) was seen in most patients. According to RECIST guidelines, of the 28 patients evaluable for response, 2 patients had a partial response and 26 had stable disease, with no patients progressing on therapy. Toxicities were similar to that expected with this class of medication. All patients were able to proceed with nephrectomy (mean time off therapy before nephrectomy = 3 days) and no surgical complications believed to be related to sorafenib administration were observed, including no delay in wound healing or dehiscence.

Conclusion: Preoperative sorafenib therapy can impact the primary tumor and appears safe and feasible to administer. Further studies are required to determine if preoperative systemic therapy improves survival outcomes in patients undergoing nephrectomy for high-risk renal cell carcinoma.

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Poster# 125

CLINICAL ANALYSIS OF PROGNOSIS OF ADRENOCORTICAL CARCINOMA (REPORT OF 40 CASES)
Dexin Dong, Hanzhong Li and Weigang Yan
Beijing Xiehe Hospital
Presented By: Hanzhong Li

Objective: Study clinical impact factors affecting the prognosis of adrenocortical carcinoma (ACC) in order to guide the diagnosis and treatment of adrenocortical carcinoma.

Methods: Analyze retrospectively the clinical data of 40 cases of ACC treated in our hospital. The 40 patients have been diagnosed as ACC by histopathological examination after operation or biopsy, including 19 cases of nonfunctional ACC and 21 cases of functional ACC. The functional ACC included 14 cases of Cushing’s syndrome, 4 cases of sexual abnormality (3 cases of androphany and one case of male sexual precocity) and 3 cases of primary aldosteronism. The clinical stage included 3 cases in stage I, 10 cases in stage II, 7 cases in stage III, and 21...
cases in stage IV. 18 cases underwent complete excision, 10 cases underwent palliative excision, 12 cases underwent expectant treatment (2 cases underwent arterial embolism). All the patients were followed up from 2 months to 121 months. Calculate the total life span and survival rate, and compare the dependability between life span and certain indexes (tumor size, function, clinical stage and surgical treatment, et al). Analyze statistically the results by utilizing the SPSS 11.5 software. Rank-sum test is used for the two independent samples, one-factor analysis of variance is used for multiple samples and Pearson correlation analysis is used for the correlation of two variances. (P<0.05 is considered to be significantly different)

Results: There were no statistical correlation between gender, age, sides and survival time (P>0.05). The survival time of nonfunctional 19 cases of ACC patients was 37.0 months, of which 11 dead cases survived 11.0 months and 8 survival cases survived 73.5 months. The survival time of nonfunctional 21 cases of ACC patients was 11.5 months, of which 19 dead cases survived 12.2 months and 2 survival cases survived 4.8 months. The survival time of nonfunctional ACC was statistically longer than that of functional ACC (P<0.05). The actual survival time was 66 months and 120 months in stage I, of which all survived. The actual survival time was 44.9 months in stage II, of which 4 survival cases survived 59.0 months. The actual survival time was 34.5 months in stage III, of which 2 survival cases survived 42.0 months. The actual survival time was 7.1 months in stage IV, of which 2 survival cases survived 8 months. There was statistical correlation between clinical stage and survival time (F=11.078, P<0.05). There was no statistical correlation between operation methods and survival time in Stage III (54.3 and 19.6 months, P>0.05). There was no statistical correlation between treatment methods and survival time (10.0 and 4.5 months, P>0.05; 5.3 and 3.6 months, P>0.05).

Conclusions: The most important influencing factors are function and clinical stage. For ACC in stage I and II, tumor resection is the most effective treatment, and second surgical operation is recommended for local recurrence. For ACC in stage III, radical or extensive surgical operation is recommended, and for ACC in stage IV, surgical operation has no effect on the prognosis.

Poster# 126

THE CLINICAL ANALYSIS OF NEPHRON SPARING SURGERY FOR UNILATERAL SPORADIC RENAL CELL CARCINOMA OF T1B STAGE (REPORTS OF 54 CASES)
ZhouJun Shen
Ruijin Hospital, Shanghai Jiao Tong University School of Medicine
Presented By: ZhouJun Shen

Objective: To discuss the clinical efficacy and feasibility of nephron sparing surgery (NSS) for the treatment of unilateral sporadic renal cell carcinoma(RCC) of T1b stage.

Method: Clinical data of 54 patients (34 males and 20 females, whose mean age is 49 years old) with unilateral sporadic RCC of T1b stage who received NSS were reviewed retrospective. Unilateral tumors are distributed, no local lymph nodes and distant metastases. The tumor mean diameter was 4.7 cm and 41 cases were the patients with polar RCC. The pathological stage was T1b in all patients. Of the 54 cases, 45 cases were clear cell renal carcinoma, 7 cases were renal granular cell carcinoma, and 2 cases were cystic renal cell carcinoma. There were 35 cases of renal tumor enucleation, 7 cases of wedge nephrectomy, 12 cases of partial nephrectomy. The follow-up time was from 6 month to 3 years. After operation all the patients underwent abdominal CT, ultrasound, urine test and chest X-ray. And the operative time, intraoperative renal interrupted time, blood loss, operative complications and prognosis.

Result: The operations were successful in all patients with the mean operative time of 110 minutes and the mean intraoperative renal interrupted time of 15 minutes. The mean volume of blood loss was 250 ml. After operation 4 cases of urine leakage and 3 cases of bleeding occurred, who recovered after placed with the double-J catheter and interventional therapy. No patient progressed to acute renal failure. Two cases relapsed again one year after NSS and underwent radical nephrectomy(RN) later.

Conclusion: In the patients with unilateral sporadic RCC of T1b stage, NSS whose incidence of complication is relatively low is effective and provides oncological outcomes equivalent to patients managed with RN. We recommend NSS to patients with 4 to 7 cm RCC with intensive follow-up.
Poster# 127

**ROBOTIC ASSISTED PARTIAL NEPHRECTOMY FOR HEREDITARY RENAL CANCERS: THE NCI EXPERIENCE**
Brian Stisser, Deborah Kaye, Juan Proano, Peter A. Pinto, W. Marston Linehan and Gennady Bratslavsky
Urologic Oncology Branch, National Cancer Institute, Bethesda, MD
Presented By: Brian Stisser

**Introduction:** Patients with hereditary renal cancers often present with bilateral multifocal renal tumors. We describe our early experience using a robotic assisted partial nephrectomy approach in this patient population.

**Methods:** We retrospectively reviewed the records of all patients with hereditary renal cancers who underwent attempted robotic assisted partial nephrectomy at our institution in the past 30 months. We identified 31 patients who underwent a surgery on a total of 37 renal units. Demographic information, type of hereditary renal cancer syndrome, tumor characteristics, and peri-operative outcomes were evaluated. Renal functional outcomes were assessed prior to and at least 3 months postoperatively.

**Results:** The cohort was comprised of the following hereditary syndromes: von Hippel-Lindau (42%), Birt-Hogg-Dube (29%), Succinate Dehydrogenase B Deficiency (7%), Hereditary Papillary Renal Carcinoma (3%), Lymphangioleiomyomatosis (3%), Tuberous Sclerosis (3%), and Bilateral Multifocal Carcinoma with unknown genetic mutation (13%). Six of the 37 procedures (16%) were converted to open nephron sparing surgery. One more case was completed laparoscopically. All cases in this cohort were completed without loss of a renal unit. Overall, 30 procedures (81%) were completed using robotic assistance with a resection of a total of 50 tumors (1.7 tumors per procedure). We removed 1 to 4 tumors per patient in a single setting. Six patients required staged bilateral procedures. The average size of the largest lesion resected was 3.8 cm (2.5-8) with the average EBL of 635 ml (median 425 ml), (range 100-2,700). The median warm ischemia time was 25.6 minutes (range 0-61). Perioperative complications occurred in 3 cases. There was one postoperative pancreatic leak, which resolved within 2 weeks, one ureteral obstruction and one urine leak both of which required ureteral stenting. There was no statistically significant increase in the preoperative and postoperative renal function (mean serum creatinine 0.89 mg/dl versus 0.93 mg/dl (p=0.23).

**Conclusion:** Robotic assisted partial nephrectomy is a feasible approach for patients with complex bilateral multifocal renal masses of hereditary patients. This procedure has acceptable perioperative morbidity, while long-term oncologic and functional outcomes will need to be assessed further.

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Poster# 128

**LAPAROSCOPIC PARTIAL NEPHRECTOMY VERSUS RENAL CRYOABLATION: A MULTICENTER COMPARISON OF INTERMEDIATE ONCOLOGIC OUTCOMES**
Sean Stroup¹, Jon Silberstein¹, Reza Mehrazin², John Malcolm³, James L’Esperance⁴, Kerrin Palazzi-Churas¹, Matthew Christman⁴, Robert Wake², Robert Gold², Christopher Kane¹, Brian Auge⁴, Tracy Downs¹, Michael Fabrizio³ and Ithaar Derweesh¹
¹University of California, San Diego, CA; ²University of Tennessee Health Science Center, Memphis TN; ³Eastern Virginia University School of Medicine, VA; ⁴Naval Medical Center, San Diego, CA
Presented By: Sean Stroup

**Introduction:** The surgical paradigm for small renal masses (SRMs) has evolved towards less invasive nephron sparing intervention. While partial nephrectomy remains the gold standard for the management of most SRMs increasing experience with renal cryoablation has suggested a viable alternative with a favorable morbidity profile and good efficacy. We compared our intermediate-term oncologic outcomes following laparoscopic partial nephrectomy (LPN) and renal cryoablation (RC).
Methods: Multicenter retrospective review of LPN and RC between 9/1998-9/2008. LPN was performed via retro- or transperitoneal approach. RC was performed via percutaneous or laparoscopic approach. Follow-up consisted of imaging at regular intervals. Persistent enhancement was considered a treatment failure following RC, and repeat biopsy and retreatment were recommended. Residual enhancing tumor was evidence of treatment failure following LPN.

Results: 119 patients (60% male, 39% black, mean BMI: 29.3) underwent RC with mean follow-up of 39.5 months. 116 patients (41% male, 34% black, mean BMI: 27.5) underwent LPN with mean follow-up of 33.8 months. Mean age was 58 for LPN and 68 for RC (p<0.001). Overall, comorbid conditions were prevalent with 20% DM, 61% HTN, and 68% smoking history in the LPN cohort and 24% DM (p=0.40), 78% HTN (p<0.05), and 53% smoking history (p=0.05) in the RC cohort. Mean tumor size was 2.7 cm for LPN and 2.6 cm for RC (p=0.84). 70% of LPN specimens were RCC while 48% of RC were biopsy-confirmed RCC (p=0.001). 5 positive margins were reported in the LPN cohort. Local failures after primary RC were retreated in 8 patients, 3 of whom ultimately progressed. Disease free survival was 99% in the LPN cohort with only 1 local recurrence and no metastatic recurrences. Disease free survival in the RC cohort was 94.1% with 8 patients having evidence of disease at last follow-up (p=0.027). Overall survival was 99% and 97% in the LPN and RC cohorts, respectively (p=0.71).

Conclusions: In this multi-center study of well-matched LPN and RC cohorts with intermediate follow up, RC had higher primary treatment failure rates than LPN, and with retreatment able to salvage some but not all patients. Disease free survival was significantly higher with LPN, though overall survival, at this point did not demonstrate a significant difference. While further follow up is needed, caution should be exercised in offering cryoablation as a primary treatment modality to younger, healthy patients.

Poster# 129

NEOADJUVANT SUNITINIB PRIOR TO CONSOLIDATIVE RENAL SURGERY FOR RENAL CELL CARCINOMA
Jonathan Silberstein¹, Wassim Bazzi¹, Tracy Downs¹, Sephir Nowfar¹, Reza Mehrzain², Anthony Lynn Patterson², Robert Wake², Fred Millard¹, Christopher Kane¹ and Ithaar Derweesh¹
¹University of California at San Diego, CA; ²University of Tennessee Health Science Center, Memphis, TN
Presented By: Jonathan Silberstein

Introduction: Sunitinib (SUTENT; Pfizer, New York, NY) is a Tyrosine Kinase Inhibitor (TKI), which improves progression-free survival in patients with metastatic Renal Cell Carcinoma (RCC). Sparse data is available on impact of TKI therapy with primary tumor in situ. Herein we report our experience with use of neoadjuvant sunitinib (n-TKI).

Methods: Multicenter retrospective review of all patients receiving n-TKI for 8 weeks prior to intended resection of the primary renal lesion from 2/2006-5/2009. Patients underwent percutaneous biopsy confirming clear cell RCC and then received TKI prior to intended surgical resection for bulky metastatic disease burden or imperative nephron sparing surgery (NSS) with a large or central located renal tumor in the setting of advanced disease. Demographics, tumor characteristics, outcomes and complications were recorded and reviewed.

Results: 22 patients (11 Male, mean age 55.9 years, ECOG performance status 0-1, 24 tumors) received n-TKI. None had a complete response. Twenty patients (90.9%, 22 renal units) demonstrated decrease in size of primary lesion (average 20.9%, 1.65 cm) and went on to surgery after a two-week washout period. Two patients (9.1%) with rapid disease progression did not undergo surgery; both died within four months of initiation of therapy. All patients (20 patients, 22 tumors) who underwent surgical resection had negative margins. In addition to reduction of the primary lesion, 12/14 patients (85.7%) with metastatic disease had metastatic tumor reduction, 4/4 patients with vascular tumor thrombi had partial regression, prior to surgery. With average follow-up of 18 months, 18 (82%) patients remain alive, including 10/14 (71.4%) of patients with metastatic disease, all of whom are disease free. Postoperative complications were noted in 5/20 (25%) patients: 1 bowel leak after duodenal resection, 3 urinary leaks following NSS, and 1 post-operative pneumonia.

Conclusion: n-TKI therapy potentially induces reduction of primary and metastatic tumor and may allow further insight into the natural history of disease, obviating unnecessary surgical intervention in those with rapid disease progression. Additionally n-TKI may more readily facilitate complete metastectomy and challenging NSS for imperative indications in locally advanced and metastatic disease. Further study is needed.
ADVERSE HISTOLOGY AND THE SMALL RENAL MASS: A CASE FOR ACTIVE SURVEILLANCE
Gino Vricella, Nicholas Boncher and Hui Zhu
Case Western Reserve University Urology, Cleveland, OH
Presented By: Gino Vricella

Introduction and Objectives: Currently, the majority of kidney cancers are diagnosed incidentally on imaging for unrelated medical reasons. As a result, more patients are now found to have asymptomatic small renal masses (SRM) (<4-cm). This stage migration has led to a paradigm shift of kidney cancer management for SRMs from aggressive surgical extirpation towards active surveillance (AS). Despite likely decreasing surgical morbidity, this management schema raises the concern that the potential curative window could be missed. In this retrospective study of a modern day nephrectomy series, we assessed the incidence of aggressive kidney cancers. We defined aggressive as those with sarcomatoid or Fuhrman nuclear grade 4 features. This information was used to further define the risk of clinical progression of SRMs while being managed with AS.

Methods: We retrospectively reviewed the kidney cancer database from one single institution (The Cleveland VA Medical Center) from 1999-2009. The radiologic and pathologic records were reviewed for all nephrectomies and partial nephrectomies performed during this period. We also associated the patient’s initial presentation with both the size and pathological features of the kidney cancers.

Results: In 108 patients, the mean age was 61.4 with a mean tumor size of 6.1cm. Over a mean follow up of 43 months, disease free survival was 70.4%, cancer-specific survival was 92.6% and overall survival was 78.7%. Histological characteristics were 15.7% papillary, 0.9% TCC, 0.9% simple cyst, 4.6% chromophobe, and 77.7% clear cell. Tumor size with and without adverse histology (sarcomatoid or Fuhrman Grade 4) was 5.99 cm and 9.5cm, respectively (p=0.03). No tumors with adverse histology were less than 4cm in size. All sarcomatoid kidney cancer patients presented with symptoms prior to diagnosis.

Conclusions: In our series, the majority of kidney cancers with adverse histology were both symptomatic and greater than 4-cm at presentation. Additionally, the incidence of adverse pathology is rare in SRMs. These findings would suggest that AS of SRMs without definitive biopsy is oncologically sound. This study supports managing incidentally discovered, asymptomatic SRMs with serial cross-sectional imaging to assess for tumor growth and use this criterion as a basis for selective intervention. Further study with a larger cohort is needed to confirm these findings. We have no financial disclosures to report.

CONCORDANCE OF ONCOCYTOMA OR ONCOCYTIC TUMOR WITH CONTRALATERAL RENAL MASS IN PATIENTS WITH BILATERAL RENAL NEOPLASMS: 25-YEAR REVIEW FROM THE NATIONAL INSTITUTES OF HEALTH (NIH)
Ronald Boris¹, Thomas Sanford¹, Maria Merino², Peter Pinto¹, W. Marston Linehan¹ and Gennady Bratslavsky¹
¹NIH/NCI Urologic Oncology Branch, Bethesda, MD; ²NIH/NCI Department of Pathology, Bethesda, MD
Presented By: Ronald Boris

Introduction: Renal oncocytomas account for 3 to 5% of renal neoplasms, are usually single but may be multifocal and bilateral. Although some oncocytomas and oncocytic neoplasms are seen with certain hereditary renal syndromes, others occur in the sporadic form. To our knowledge, there are no studies that evaluated pathologic concordance of oncocytoma or oncocyctic neoplasm in one kidney with tumors in contralateral kidney in patients with bilateral renal masses. These patients present a difficult diagnostic and therapeutic dilemma. We review our 25-year experience on pathologic concordance in patients with oncocytoma or oncocyctic neoplasm on one side and contralateral renal masses.

Methods: We identified 35 patients seen at the NIH between 1983 and 2008 that met the following inclusion criteria: 1) presence of bilateral renal masses; 2) oncocytoma or oncocyctic neoplasm pathologically confirmed in at least one of the kidneys; 3) the pathology from the contralateral renal mass(es) was available. The final cohort was comprised of 35 patients and included 14 patients with known hereditary Birt-Hogg-Dube (BHD) syndrome, one patient with von Hippel-Lindau (VHL), and 20 patients without known hereditary mutation. A total of 105 procedures were performed on these 35 patients. The presence of oncocytoma or oncocyctic neoplasm in the contralateral kidney was considered concordant.
Results: 66 percent of our cohorts were males and 91% were Caucasian. Although only 42% of all procedures were performed at NIH, 83% of all pathology reports were reviewed at NIH. Concordance rates for known hereditary syndromes and all other patients, as well as overall cohort are listed in table 1.

Conclusions: Our results demonstrate a concordance rate of only 53% in patients with hereditary renal disease, which is explained by propensity of BHD patients to form tumors of various histological subtypes. These patients, therefore, should undergo intervention for contralateral masses. Conversely, patients without known hereditary mutations or typical BHD manifestations who have oncocytoma on one side demonstrate high contralateral concordance rates of 90%. These patients may be counseled towards a more conservative course of management.

<table>
<thead>
<tr>
<th>Table 1.</th>
<th>Oncocytoma/Oncocytic Neoplasm in Patients with Bilateral Renal Masses</th>
<th>Bilateral Disease Concordance (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with known hereditary syndrome (15)</td>
<td>8/15 (53)</td>
<td></td>
</tr>
<tr>
<td>Patients without known hereditary syndrome (20)</td>
<td>18/20 (90)</td>
<td></td>
</tr>
<tr>
<td>Overall Cohort (35)</td>
<td>27/35 (77)</td>
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Poster# 132

LAPAROSCOPIC PARTIAL NEPHRECTOMY: PREOPERATIVE AND INTRAOPERATIVE PARAMETERS CAN DRIVE SELECTIVE USE OF SUTURELESS TECHNIQUE

Sean Stroup¹, James L’Esperance², Chong Choe², Matthew Christman², Brian Auge², Audrey L’Esperance² and Ithaar Derweesh¹

¹University of California, San Diego, CA; ²Naval Medical Center, San Diego, CA

Presented By: Sean Stroup

Purpose: A standard technique for laparoscopic partial nephrectomy (LPN) has not been widely accepted. We introduce a multi-institutional study showing that LPN can be performed, in select cases, without sutured reconstruction of parenchymal defects. We also propose preoperative and intraoperative parameters to predict the ideal type of closure required following laparoscopic excision of a renal tumor.

Materials and Methods: We performed a retrospective review of all LPN performed at one of two institutions between August 2003 and January 2009. Cases were divided into 3 groups: Group A (entirely sutureless), Group B (bolstered cortical closure only), and Group C (deep collecting system/medullary sutured repair + bolstered cortical closure). We evaluated the techniques used at each institution, the indications for sutureless technique, and the preoperative/intraoperative tumor parameters.

Results: A total of 95 laparoscopic partial nephrectomies were performed with a mean follow-up of 16.8 months. The groups were similar with respect to age, laterality of the lesion, and calyceal involvement on preoperative imaging. Significant differences between groups were found for tumor size and location, with Group 3 trending towards larger, more centrally located lesions. Collecting system entry was higher in Group 3. Blood loss, warm ischemia time, and post-operative renal function at 6 and 12 months significantly favored the sutureless technique over the sutured approach. The complication rate was 17.9 overall, and was similar between groups. Two patients were converted to radical nephrectomy intraoperatively. Disease free survival was 98.8% and negative margins were achieved in 96.6%.

Conclusions: A sutureless technique can be employed for repair of defects following LPN. This is true, even in the setting of small to moderate collecting system injury or significant hemorrhage. The potential effectiveness of a suture-less approach can be predicted based upon preoperative imaging and intraoperative findings, prior to tumor excision. In addition, when sutured repair is needed, a bolstered repair with a hemostatic agent is often sufficient, without any specific suture ligation of bleeders, or sutured repair of the collecting system.
RETROSPECTIVE COMPARISON OF METASTATIC TUMOR VOLUME TO PRIMARY TUMOR VOLUME IN PATIENTS UNDERGOING CYTOREDUCTIVE NEPHRECTOMY FOR METASTATIC RENAL CELL CARCINOMA
Michelle Lerner¹, Michael Risk², Christopher King¹, Theodore Logan¹ and Thomas Gardner¹
¹Indiana University, Indianapolis, IN; ²Dept of Urology, Indiana University

Presented By: Michael Risk

Introduction: Cytoreductive nephrectomy (CN) remains a controversial step in the management of advanced renal cell carcinoma (RCC). Urologic oncologists and surgeons are divided on the benefits of this aggressive approach in the management of metastatic RCC. The objective of this study was to examine if the volume of metastatic disease compared to the volume of the primary tumor could be used as a predictor of which patients might benefit from a CN.

Methods: A retrospective chart review was performed on all patients that had a CN between the years 1999-2008 (N=136). All patients had radiographic or pathologic evidence of metastatic RCC pre-operatively. Spherical data measurements were taken on metastatic sites as well as the primary tumor. Factors such as the ratio of metastatic tumor volume to primary tumor volume (RMP) the tumor histology, Fuhrman grade, tumor size and overall survival were compared using univariate analysis.

Results: 136 patients underwent CN between 1999 and 2008. Overall survival was compared between patients with clear cell vs. non-clear cell RCC and the presence vs. absence of sarcomatoid elements. Mean overall survival was 31.8±2.7 vs. 8.3±2.7 months (p<0.0007) and 34.6±4.1 vs. 11.1±2.6 (p<0.0001), respectively. Mean overall survival was 65.9±9.9, 30.6±4.3, 10.0±1.8 for grades 2, 3 and 4 (p<0.0001). Patients with tumor size 4-7cm had better overall mean survival compared to patients with tumor size >7cm (50.5±9.4 vs. 23.9±3.1, p=0.004). When comparing the volumes of metastatic disease to the primary tumor, the groups were divided into patients with metastatic volume less than the primary tumor volume (RMP<1.0) and patients with metastatic volume greater than the primary tumor volume (RMP>1.0). Median overall survival for RMP< 1.0 and RMP>1.0 was 27.9±3.6 and 29.6±3.8 (p=0.04).

Conclusion: Known poor prognostic variables such as non-clear cell RCC, presence of sarcomatoid elements and increasing Fuhrman grade associated with poorer overall survival in this series. Intuitively, we hypothesized that patients with low metastatic volume and higher primary tumor volume would do better after CN than patients in which the metastatic tumor volume exceeded the primary tumor volume. The analysis did not show this hypothesis to be true, as patients with an RMP>1.0 had statistically significant longer median overall survival.

PERIOPERATIVE OUTCOMES OF THE MANAGEMENT OF RENAL TUMORS IN THE ELDERLY
Amin Herati, Arvin George, Sandeep Saluja, Arun Srinivasan and Manish Vira
Smith Institute for Urology

Presented By: Arvin George

Objective: Improved life expectancy combined with an aging population has led to an increase in operative interventions in patients traditionally managed conservatively. However, very little is known about the complications of surgical extirpation versus minimally invasive cryoablative and radiofrequency therapies.

Methods: Retrospective analysis was conducted to identify patients over the age of 75 that presented to a single institution for the surgical management of renal mass. Demographic, clinicopathologic, and perioperative factors of patients undergoing open resection (N=30), laparoscopic resection (N=46) and percutaneous ablation (N=24) were analyzed.

Results: The mean age of patients in the open, laparoscopic, and ablative groups were 78.27, 80.57, and 85 years respectively. No significant differences existed in the demographics, ASA, or BMI. Those patients undergoing percutaneous treatment had the lowest intra-operative and post-operative transfusion rate 0% (0/24), followed by laparoscopic 17.3% (8/46) and open resection 50% (15/30). Patients in the laparoscopic arm had the lowest post-operative transfusion rate at 15.2% (7/46) when compared to the percutaneous and open group, although the difference was not significant. The postoperative complication rates of the open, laparoscopic, and percutaneous groups were 60% (18/30), 19.5% (9/46), and 37.5% (9/24) respectively. Complications in the three groups included altered mental status, decompensated CHF, bleeding, hematoma, urinoma, and acute renal failure. No mortalities were noted.

Conclusion: Patients undergoing open resection, laparoscopic resection, and percutaneous ablation of renal tumors are comparable in morbidity and mortality in the octogenarian population. Long-term studies are needed to determine what impact these surgeries have on the expected survival.
ACTIVE SURVEILLANCE OF AN INCIDENTAL RENAL MASS IN THE SETTING OF AN ACTIVE OR RECENTLY TREATED NON-RENAL MALIGNANCY
Frances Alba¹, Chaan Ng², Christopher Wood² and Surena Matin²
¹UT Houston School of Medicine, UT M.D. Anderson Cancer Center, Houston, TX; ²UT MD Anderson Cancer Center, Houston, TX
Presented By: Frances Alba

Background: We evaluated the results of observation of a renal mass in patients with a separate active or recently treated non-renal malignancy, reporting on tumor growth kinetics, biopsy results, interventions, and survival.

Methods: A prospective, IRB approved study enrolling patients on a renal tumor active surveillance (AS) protocol was reviewed. Patients were enrolled based on age, comorbidities, or presence of an active or recently treated non-renal malignancy. Patients were followed semiannually with axial abdominal imaging. Patients were divided into 2 groups: Group 1 patients had an enhancing renal mass and a separate non-renal malignancy. Group 2 patients did not have a separate cancer. We performed an analysis of the available information including demographics, treatment data, imaging data, survival and pathologic data. Patients with less than 2 imaging studies were excluded. Tumors were measured in 3 dimensions by one of two radiologists, and all tumor measurements within each patient were measured by a single radiologist.

Results: A total of 175 patients were enrolled in the AS protocol. There were 168 renal tumors and 153 patients meeting inclusion criteria who were analyzed. Mean tumor size on enrollment was 2.3 cm. The mean clinical follow up was 10 months (median 6 months) and the mean radiographic follow up was 24 months (median 18.5 months). There were 57 patients in Group 1 and 96 patients in Group 2. The most common non-renal malignancies were breast cancer (23% of Group 1 patients) and prostate cancer (14%). Biopsy of the renal mass was performed in 43 (28%) patients, showing RCC in 32 (58%). Fifteen (10%) patients had delayed intervention and of these 53% had RCC. No patients had a renal biopsy or excision showing metastasis of a non-renal cancer. Tumor growth was 0.22 cm/yr (volume 2.4 cm^3/yr) in Group 1 patients and did not differ from patients in Group 2, 0.18 cm/yr (2.7 cm^3/yr) (p=0.39). No patient in either group developed metastatic RCC or died from progression of the renal mass.

Conclusion: AS of the incidental small renal mass in patients with a non-renal malignancy is a reasonable strategy. A core biopsy can confirm absence of metastatic disease to the kidney, and confirmation of RCC can aid in devising a follow up imaging strategy. Aggressive treatment of the renal mass in these patients is unlikely to alter their survival.

THE UTILITY OF CONTEMPORARY ULTRASOUND IMAGING IN THE EVALUATION OF SMALL RENAL MASSES
Matthew Kaag¹, Yulia Lakhman², Ariadne Bach², Patrick Telokin², Akshay Sood², R. Houston Thompson², Angel Cronin², Melanie Bernstein² and Paul Russo²
¹Memorial Sloan-Kettering Cancer Center, New York, NY; ²Memorial Sloan-Kettering Cancer Center
Presented By: Matthew Kaag

Introduction and Objective: The indolent nature of many small renal masses has prompted the urologic community to explore surveillance protocols for tumors unlikely to prove fatal over a patient’s lifetime. CT imaging provides the principle means of following such lesions, but is associated with cumulative radiation exposure and significant cost. We assess the accuracy with which ultrasound (US), a possible alternative imaging modality, evaluates the diameter of small renal masses.

Methods: We identified patients with small (<4cm on CT) renal lesions who had undergone US, CT, and pathologic assessment of lesion diameter at MSKCC between 2000 and 2008, with imaging available for review. All measurements (US, CT, and pathologic) were performed within a maximum 120-day span. Scans were reviewed by one of two radiologists (YL or AB). We compared measurements obtained by US with those obtained from pathology and CT imaging, assessing the agreement between methods using Bland-Altman limits of agreement (LOA).
Results: We identified 189 patients (109 male, 80 female) who met our criteria. The mean pathologic size was 2.44 cm; US (mean 2.71 cm) tended to overestimate pathologic size by about 3 mm with 95% LOA of -1.00 to 1.55 cm. When stratifying by pathologic size, the agreement between US and pathologic size deteriorates. In tumors with pathologic size <2 cm US could overestimate pathologic size by as much as 30% of the true diameter on average. The measurements generated by US and CT were highly correlated (concordance correlation coefficient 0.86). US measurements tended to be lower than CT measurements (mean difference -0.04 cm). However, matched US and CT-based estimates of size differed by as much as 1 cm (95% LOA -0.86 to 0.79 cm). This difference remained consistent across tumor sizes when stratifying by pathologic diameter. Tumor location did not affect the agreement between matched US and CT-based size estimates.

Conclusions: Contemporary US imaging overestimates the pathologic (true) tumor size by approximately 3 mm in the evaluation of small renal masses. The variation is not likely to be clinically important in lesions >1 cm, and we conclude that US is an effective means of assessing and following small renal masses. However, CT and US imaging of the same small renal mass may yield measurements that differ by nearly ±1 cm. Caution is required when using these two modalities interchangeably during surveillance.

Poster# 137

GALLBLADDER METASTASIS OF RENAL CELL CARCINOMA: OUTCOMES OF PATIENTS TREATED AT THE NCI AND REVIEW OF LITERATURE
Paul Chung, W. Marston Linehan and Gennady Bratslavsky
Urologic Oncology Branch, Center for Cancer Research, National Cancer Institute, Bethesda, MD
Presented By: Paul Chung

Introduction: Although as many as 30% of patients with renal cell carcinoma (RCC) will develop distant disease, little is known about metastasis to the gallbladder. This study reviews four new cases from the National Cancer Institute and the world literature on presentation and outcomes of patients with RCC to the gallbladder.

Methods: We performed a query of the RCC database in the Urologic Oncology Branch at the NCI and identified 4 patients with metastatic RCC to the gallbladder. A PubMed search was performed for articles describing patients with metastatic RCC to the gallbladder. When available, the data was extracted to focus on demographics, histology of primary renal tumor, timing and clinical presentation of metastasis to the gallbladder, concomitant metastasis, and outcomes of these patients.

Results: The final cohort included a total of 30 patients consisting of 4 new cases from the NCI and 26 patients from previously published cases. The average age at presentation of gallbladder metastasis was 61.5 years (39-80). Most commonly, the metastatic disease was detected incidentally on imaging (n=12), followed by complaints of biliary colic or cholecystitis (n=4). All cases of metastasis were Clear Cell RCC (n=21). All gallbladder masses were intraluminal and did not extend beyond the gallbladder wall. Eight cases presented synchronously with RCC, while the majority (n=22) presented metachronously. Five cases showed additional metastasis on presentation to pancreas (n=2), lung (n=2), and contralateral kidney (n=2). Three more patients subsequently developed additional metastasis to the pancreas. The average time to metachronous metastasis was 6 years (range 1-27) after nephrectomy. The average follow-up for all patients following cholecystectomy was 2.8 years (range 0.1-11). Out of 19 patients with available follow up after cholecystectomy for metastatic RCC, 14 (74%) were alive at an average follow up of 2.3 years (0.1-7).

Conclusion: Gallbladder metastasis from RCC is a rare event occurring both synchronously and metachronously. Although metastatic events to the gallbladder are a rare event, the asymptomatic presentation of most patients with gallbladder metastasis adds to the need of periodic surveillance with cross-sectional imaging for patients with high-risk RCC. Additionally, those with gallbladder metastasis should have a close long-term surveillance for pancreatic metastasis.
**COMPARISON IN RENAL FUNCTIONAL OUTCOMES AFTER RADICAL NEPHRECTOMY, PARTIAL NEPHRECTOMY, AND CRYOABLATION OF RENAL MASSES**

Mary Henderson, James Brien, Joshua Logan, David Staneck, John Malcolm, Michael Fabrizio and Stephen Riggs
Eastern Virginia Medical School, Norfolk VA

Presented By: Mary Henderson

**Introduction and Objective:** Chronic kidney disease is associated with cardiovascular disease and death; therefore, nephron sparing approaches such as partial nephrectomy (PN) is considered the standard of care for small renal masses. Additionally, cryoablation (CA) has emerged as a nephron sparing approach. Renal functional outcomes following RN and PN are documented; however, direct comparison to CA is limited. We report renal functional outcomes from a single-center experience on patients treated with RN, PN and CA.

**Methods:** We performed a retrospective review of our experience since 2003 with CA (laparoscopic or percutaneous (PCT) and compared this with RN and PN cases over the last 2 years. A total of 256 patients were identified with 178 meeting inclusion criteria. The eGFR was assessed preoperatively and at ≥ 6 months post-treatment using the modification of diet in renal disease formula (MDRD equation). Chronic kidney disease (CKD) was defined as eGFR < 60 ml/min/1.73m².

**Results:** 83, 44, and 51 patients underwent RN, PN and CA (16 PCT; 28 laparoscopic) respectively. Average patient age was highest for CA (68.6) as compared to RN (57.0) and PN (57; p=0.0002). Mean tumor size was largest for RN patients (7.60 cm; range: 2-20cm) followed by PN (3.1cm; range: 1-9cm) and smallest in the CA group (2.3cm; range: 1-3.8cm). Comorbid condition(s) were present in at least 25% of all patients. The percent change in eGFR was 16 % for CA, 13% for RN and 6% for PN. This reached statistical significance only when comparing CA to PN cohorts (p=0.03). Pre-existing CKD was present in 34%, 25% and 27% of patients undergoing RN, PN and CA, respectively. Postoperative CKD was seen 54 of 83 (64%) patients who underwent RN, 13 of 44 (30%) of patients who underwent PN and 21 of 51 (41%) of patients who underwent CA. De novo CKD was noted in 29 of 83 (35%) who underwent RN, 4 of 44 (9%) of patients who underwent PN and 8 of 51 (16%) of patients who underwent CA.

**Conclusion:** Nephron sparing approaches to the treatment of small renal masses with PN or CA are more likely to preserve renal function compared to RN. Interestingly, in our study patients who underwent CA suffered a significantly greater percent change in eGFR when compared to PN. Additional studies with larger cohorts are needed to confirm this finding.

**OUTCOMES OF RADIOFREQUENCY ABLATION OF HEREDITARY RENAL CELL CARCINOMA IN PATIENTS WITH A SOLITARY KIDNEY**

Jennifer Robles¹, Gopal Gupta¹, Brad Wood², W. Marston Linehan¹ and Gennady Bratslavsky¹
¹NIH/NCI, Urologic Oncology Branch, Bethesda, MD; ²NIH/NCI, Department of Radiology, Bethesda, MD

Presented By: Jennifer Robles

**Introduction:** Patients with hereditary renal cell carcinoma (RCC) are prone to develop bilateral multifocal disease at an early age. While open nephron sparing surgery is established as the standard of care in a solitary kidney, it has inherent risks and morbidity. Recently, laparoscopic and percutaneous radiofrequency ablations (RFA) have emerged as less invasive options in the treatment of RCC. However, its efficacy and safety in the treatment of RCC in solitary kidneys has not been established. This study evaluates the outcomes of RFA on the solitary kidney in the setting of multifocal recurrent tumors.

**Methods:** We reviewed the records of all patients with hereditary RCC who underwent laparoscopic or percutaneous RFA on a solitary kidney at our institution. We collected data on demographics and perioperative outcomes. Renal functional outcomes were assessed by comparing pre-treatment and post-treatment creatinine, while oncologic outcomes were evaluated by the need for subsequent intervention.
Results: We identified 13 patients with hereditary syndromes and solitary kidneys who underwent a total of 17 RFA sessions (8 laparoscopic and 9 percutaneous) for 25 lesions at the NCI. The cohort consisted of 7 patients with von Hippel-Lindau, 2 with Birt-Hogg-Dube, 2 patients with Hereditary Papillary Renal Carcinoma, and 2 with familial RCC of unknown genetic cause. The mean age was 46 years (28-54) and 77% were female. There were a total of 1.9 lesions treated per patient with mean lesion size of 2.4 ± 0.63 cm. The most common location was endophytic (69%), followed by exophytic (19%) and mesophytic (12%). There were two minor complications: urinary retention and a skin burn. There was a 32% and 25% decrease in renal function at 3 and 12 months respectively with rise in pre-op creatinine of 1.19 ± 0.32 mg/dl, to 1.57 ± 1.02 at 1-3 months post-operative, and 1.49 ± 0.79 at 1 year. Six of 13 patients (46%) required subsequent intervention for de novo tumors either via repeat RFA or subsequent nephrectomy at a median follow up of 33 months (range 9-67).

Conclusions: Both percutaneous and laparoscopic radiofrequency ablation appear to be safe for treatment of hereditary RCC in patients with solitary kidneys. Although there was a low rate of periprocedural complications, there was a concerning decline in renal function post-RFA. Further work is needed to assess the long-term effects of RFA on renal function and for selection of appropriate RFA candidates.

Poster# 140

RENAL CELL CARCINOMA IN RENAL TRANSPLANT RECIPIENTS
Michael Leveridge, Mireia Musquera, Michael Jewett, Michael Robinette, Carl Cardella, York Pei and Antonio Finelli
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Presented By: Michael Leveridge

Introduction: The prevalence of renal cell carcinoma (RCC) in the native kidneys of renal transplant recipients has been estimated at 30 or more times higher than in the general population. This study was undertaken to assess the prevalence of RCC in a large single-center recipient population, and to determine the histologic class and outcomes of these tumors and patients.

Methods: We examined the outcomes of patients undergoing renal transplantation at our center between 1975 and 2003 to determine the prevalence of renal masses occurring in both the native kidneys and the allograft. Tumor histology was determined, and the follow up and outcomes of the patients were assessed.

Results: The records of 2,626 patients who received a cadaveric (n=1866) or living-related (n=769) renal allograft at our institution between 1975 and 2003 were reviewed. Among these patients, 42 renal masses were diagnosed in 35 patients (1.3%). 37 tumors were found in native kidneys and five in transplanted kidneys. All tumors were discovered on routine surveillance imaging. Mean age at tumor diagnosis was 48.9 years. Mean duration of dialysis prior to transplantation in these patients was 4.3 years, and mean interval between transplantation and RCC diagnosis was 9.3 years. Mean diameter of the masses was 2.87 cm. Conventional clear cell carcinoma was the most common tumor histology (n=21). Papillary RCC was diagnosed in 14 cases, while one tumor was chromophobe RCC and one was urothelial carcinoma. Three masses were benign and histology was indeterminate in 2 cases. Native kidney tumors were managed with radical nephrectomy by an open (n=18) or laparoscopic (n=15) approach, except for one patient who opted for active surveillance. Allograft tumors were managed by nephrectomy (n=1), partial nephrectomy (n=2) or radiofrequency ablation (n=2). At a mean follow-up of 5.1 years, 27 patients are alive, one of whom has metastatic RCC. Two patients have died from non-cancer causes and 6 patients have been lost to follow up.

Conclusions: Renal cell carcinoma is more prevalent in patients with end-stage renal dysfunction and renal transplantation. Routine screening imaging can identify suspicious masses, which most commonly represent RCC, though the pattern of subtype differs from the general population. Survival rates are good at 5 years following diagnosis and management.
**Poster# 141**

**PREDICTIVE FACTORS FOR KIDNEY-RELATED COMPLICATIONS IN PARTIAL NEPHRECTOMY PATIENTS**
Scott Delacroix Jr., Stephen Culp, Sooyeon Choi, Pheroze Tamboli, Surena Matin and Christopher Wood
The University of Texas MD Anderson Cancer Center Houston, TX
Presented By: Scott Delacroix Jr.

**Introduction:** Our objective was to review a contemporary cohort of patients undergoing open and minimally invasive partial nephrectomy to determine pre and intra-operative factors predictive of kidney-related complications within thirty days of surgery.

**Methods:** This is a retrospective study identifying patients undergoing unilateral partial nephrectomy for a suspicious kidney mass or multiple masses within the same kidney. Clinical, pre-operative laboratory, perioperative, and post-operative variables were collected for each patient. Patients were considered to have a kidney-specific post-operative complication (KSPC) if they exhibited retroperitoneal bleeding, gross hematuria, pseudo-aneurysm, arterio-venous fistula, acute renal failure, urine leak, and/or peri-nephric abscess within 30 days of surgery. Chi-square (x2) and linear regression analyses were used to identify categorical and continuous variables, respectively, that were significantly different between those patients that did or did not have a kidney-specific post-operative complication. Univariate and multivariate logistic regression analyses were then used to calculate an odds ratio corresponding to the odds of having a KSPC based on each variable significant on x2 or linear regression analysis. For all analyses, Stata 10.1 (Stata corp, College Station, TX) was used.

**Results:** We identified 420 patients undergoing unilateral partial nephrectomy for a solitary or multifocal renal mass between 2007 and 2009. A total of 45 patients (10.7%) had a KSPC. On multivariate analysis, factors predicting a KSPC included pre-operative WBC count (OR 1.13; 95% CI 1.01, 1.25; p=0.027), pre-operative hemoglobin level (OR 0.74, 95% CI 0.58, 0.94; p=0.015), history of chronic renal insufficiency (CRI) (OR 4.46, 95% CI 1.36, 14.66; p=0.014), blood transfusion during surgery (OR 12.45, 95% CI 1.00, 154.74; p=0.05), and peri-renal fat involvement by tumor on pathology (OR 3.20, 95% CI 1.16, 8.81; p=0.024). Of interest, surgical clamp time, total surgical time, urine output or fluids during surgery did not have a significant association with KSPC.

**Conclusions:** We have identified factors predictive of post-operative kidney specific complication in patients undergoing unilateral partial nephrectomy. These include pre-operative WBC count, pre-operative hemoglobin level, a history of CRI, blood transfusion during surgery, and peri-renal fat involvement by tumor.

**Poster# 142**

**OBESITY IS NOT ASSOCIATED WITH PATHOLOGIC FEATURES OF RENAL CELL CARCINOMA**
Joshua E. Logan, David A. Staneck, Mary F. Henderson, Jack W. Lambert and Stephen B. Riggs
Eastern Virginia Medical School, Norfolk, VA

**Introduction & Objective:** The incidence of renal cell carcinoma (RCC) is increasing, as is the incidence of obesity. Obesity is a well-established risk factor for RCC. Studies have demonstrated that there is a negative association between obesity as it relates to stage and grade of RCC. This suggests that obesity, aside from being a risk factor for RCC, protects from a progressive and aggressive disease state. We analyzed our database to determine if these same negative associations were consistent in our community-based population. In addition, we explored other clinical and pathological factors to identify trends in this population.

**Methods:** We performed a retrospective analysis of 198 patients with RCC to determine how body mass index (BMI) was associated with gender, race, stage, grade, tumor size, histologic subtype and presence of sarcomatoid features. Patients were divided into 3 groups (normal, overweight, and obese) based on standard BMI cutoffs. The relationship between BMI and pathologic, as well as clinical features was investigated using a test for trend across increasing BMI groups.

**Results:** There were 41 patients in the normal BMI group (<25.0 kg/m2), 54 in the overweight group (25.0 kg/m2 –29.9 kg/m2), and 103 in the obese group (≥30.0 kg/m2). The average ages in the respective groups were 59, 60, and 58 (p=0.93). Gender distribution among the groups, male/female, were 21/20, 45/9, and 59/44 respectively (p=0.83). Race distribution among groups (Caucasian, African American, Asian) was 20/16/1, 31/15/0, and 60/36/0 respectively (p=0.69). Finally, pathologic features, including stage (p=0.43), nuclear grade (p=0.30), tumor size (p=0.18), histologic subtype (p=0.84), and presence of sarcomatoid features (p=0.55) demonstrated no significant associations between the three different BMI groups.

**Conclusion:** Our results demonstrate that obesity is not associated with lower pathologic stage, or grade of RCC. This is inconsistent with previously reported data, which may be secondary to lack of statistical power. However, it may also be due to the heterogeneity of our population that this protective effect does not exist. Further investigation is warranted given the conflicting results.
Introduction and Objective: Hereditary papillary renal carcinoma (HPRC) is an autosomal dominant hereditary cancer syndrome characterized by the development of bilateral multifocal papillary type 1 renal carcinomas. Due to the multiplicity of the tumors in each kidney and the tendency for continued de novo formation of these masses it has been our practice to monitor the growth of these lesions until they reach 3 cm in the largest dimension. With recent interest in surveillance of small renal masses this cohort of patients allows the evaluation of the natural history and growth rates of papillary type 1 RCC.

Methods:
We reviewed records of patients with a mutation proven HPRC seen at the National Cancer Institute within the last two years. All evaluable lesions at the time of the last follow up were identified and the images of these lesions were retrospectively reviewed and measured in two dimensions by a single urologic surgeon. The volume of each lesion was calculated. The median changes in the largest dimension of the tumor and in the tumor volume per year were determined.

Results:
We identified 15 patients who had 42 measurable lesions in 21 renal units. There were total of 226 tumor measurements performed. The median size of the lesion at the last follow up was 1.72cm (range 0.81 to 3.51). Median follow up was 3.5 years (range 1.2 to 8.8). The median increase in the largest tumor dimension per year was 0.16cm (range -0.1 to 1.35). The median increase in the tumor volume per year was 0.35cc (range -0.2 to 14.31). None of the patients in this cohort developed metastatic disease during the follow up period.

Conclusions:
Renal papillary type 1 carcinomas have a slower growth rate when compared to conventional clear cell carcinomas in recent published series. It is important to recognize that slow growing renal masses on active surveillance may represent papillary type 1 carcinomas. Additionally, our findings support expectant management of papillary type 1 lesions in selected cohort of patients until they reach approximately 3 cm in the largest dimension.

Poster# 144
MULTICENTER EXPERIENCE WITH NON-ISCHEMIC LAPAROSCOPIC NEPHRON SPARING SURGERY UTILIZING HABIB 4X™ BIPOLAR RADIOFREQUENCY ABLATION
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Presented By: Wassim Bazzi

Introduction: Laparoscopic nephron sparing surgery (L-NSS) has gained increasing acceptance with emerging data demonstrating equivalence of oncologic outcomes with open NSS. Concerns continue regarding prolonged warm ischemic times and longer-term renal functional outcomes. We report our initial experience utilizing the Habib 4x™ laparoscopic radiofrequency ablation coagulator (Angiodynamics, Queensbury, NY) for non-ischemic L-NSS.

Methods: 50 cases were performed by transperitoneal or retroperitoneal laparoscopy. L-NSS involved renal dissection and hilar control; prior to specimen excision and renorrhaphy. Non-ischemic tumor excision and hemostasis were achieved utilizing the Habib 4X. We analyzed patient demographics, tumor/perioperative characteristics, and short term outcomes.

Results: Multicenter retrospective review of 50 patients (51 tumors) undergoing L-NSS between 4/2006-5/2009. Mean follow up was 8.0 months. All successfully underwent non-ischemic resection. Average age was 57.5 years (54% M/47% F). Average tumor size was 2.46 cm. Mean operative time was 160.42 minutes and mean estimated blood loss was 133.5 mL. Collecting system entry was made in 12 (24%). Preoperative and postoperative creatinine (mg/dL) were 1.03 and 1.08 (p=0.573). Preoperative and postoperative eGFR (mL/min/1.73 m2) were 81.0 and 78.1 (p=0.613). Final pathology was Renal Cell Carcinoma-35, and benign-16. All had negative margins. Eleven (22%) patients developed complications. Two (4%) developed urine leaks which resolved with conservative measures. At last follow-up, all patients with RCC were alive and cancer free.

Conclusion: Initial experience demonstrates that non-ischemic L-NSS utilizing Habib 4x is safe and efficacious, with excellent short-term preservation of renal function. Long-term data are needed to confirm oncological efficacy of this technique.
Poster# 145

TUMOR SIZE AND ENDOPHYTIC GROWTH PATTERN AFFECT RECURRENCE RATES AFTER LAPAROSCOPIC RENAL CRYOABLATION
Matvey Tsivian¹, Jorge Caso², Christopher Lyne³, Vladimir Mouraviev¹, Masaki Kimura¹ and Thomas Polascik¹
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Presented By: Jorge Caso

Introduction: Laparoscopic cryoablation (LCA) has gained popularity in the treatment of small renal tumors but local tumor control remains a concern. In this study we analyze factors that may contribute to local relapse after LCA of renal tumors.

Methods: We analyzed 165 patients who underwent LCA between October 2001 and June 2008 at either Allegheny General Hospital or Duke University Medical Center with at least 6 months of post-surgical follow-up. Demographics, perioperative variables, tumor characteristics (size, pattern of growth, biopsy results) and follow-up were recorded. Growth pattern was categorized as exophytic, mesophytic or endophytic. Regression analyses were performed to evaluate risk factors for local relapse after LCA.

Results: Median patient age was 66 (range: 33-90) with males comprising 60.6% of the cohort. Median tumor size was 2.3 cm (range: 0.5-5.0). Pathology was distributed as follows: renal cell carcinoma in 118 (71.5%), oncocytoma in 13 (7.9%), angiomyolipoma in 8 (4.8%) and other in 26 (15.8%) patients. Patients were treated for a single lesion in 94.5% of cases and multiple tumors in 5.5%. Endophytic growth pattern was present in 22.4%. We observed 7 (4.2%) local recurrences over a median follow up of 60 (range: 6-79) months. Median time to recurrence was 15 (range: 6-48) months. On proportional hazards regression, tumor size and endophytic growth pattern were significantly associated with local recurrence (p=0.008 and p=0.001, OR=4.1 and OR=1.15, respectively).

Conclusions: LCA demonstrated good short-term tumor control with an acceptable recurrence rate. Larger tumors and those with endophytic growth pattern may be at increased risk of relapse after LCA.

Poster# 146

RATIONALE FOR A LESS AGGRESSIVE THERAPY FOR SMALL RENAL TUMORS
Matvey Tsivian¹, Jorge Caso², Vladimir Mouraviev¹, M. Kimura¹, David Albala¹, Cary Robertson¹, Philip Walther¹ and Thomas Polascik¹
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Presented By: Jorge Caso

Introduction: Currently, most renal masses are detected incidentally on imaging for unrelated problems. Small renal masses, amenable to nephron-sparing procedures are frequently encountered. We evaluated the influence of tumor size on pathological characteristics of the lesion to determine whether less aggressive treatment may be appropriate for smaller renal lesions.

Methods: We retrospectively reviewed medical records of patients who underwent a partial nephrectomy for a solitary enhancing lesion suspected to be renal cell carcinoma (RCC) between 2000-2008. Cases of known von Hippel Lindau syndrome were excluded from the analysis. Pathological features were analyzed and correlated to radiologically measured tumor size.

Results: We identified 243 records matching the criteria. Mean tumor size was 2.93 (±1.60) cm. Pathology reports showed RCC in 179 (73.7%) specimens, benign tumors in 45 (18.5%) and no tumor in 19 (7.8%). Benign tumors were found in 25.5% of lesions <2cm and 16.5% of larger lesions. No tumor was found in 14.5% of <2cm lesions and 5.9% of larger lesions (p=0.021). RCC was pathologically confirmed in only 60% of smaller kidney lesions. Moreover, pathologically confirmed RCC lesions <2cm by imaging had a significantly lower mean Fuhrman grade (1.09 vs 1.4, p=0.037). There were no grade 3 and 1 grade 4 RCC among tumors <2cm.

Conclusions: Among patients treated with partial nephrectomy, our experience reveals that solitary kidney lesions <2cm suspected to be RCC are malignant by final pathology in only 60% of cases. Additionally, small sized RCC lesions are mostly low (1-2) grade. These findings suggest possible overtreatment of small suspicious lesions that may be adequately treated with less invasive modalities or even carefully followed.
PARTIAL NEPHRECTOMY IN PATIENTS WITH RENAL VEIN TUMOR THROMBUS.
Cesar Ercole, Jose Correa, Luke Wieand, Philippe Spiess, Julio Pow-Sang and Wade Sexton
Moffitt Cancer Center, Tampa, FL
Presented By: Jose Correa

Objectives: Renal cell carcinoma (RCC) has a propensity to invade vascular structures. While pre-operative radiographic studies usually detect tumor thrombus if present, a small percentage of patients with suspected RCC have thrombus found incidentally during partial nephrectomy (PN) or with CT/MRI imaging prior to PN. We determined the frequency of muscle containing renal vein or venous branch thrombus in patients undergoing PN, and the success of nephron preservation determined by renal function, margin status, complications, and local recurrence.

Methods: Since October 2004, 305 patients underwent PN at a single institution. A retrospective review of an IRB approved dataset identified 7 men (~2%) who underwent open PN for pT3b tumors (2002 TNM staging).

Results: All 7 patients had centrally located endophytic tumors (4 left-sided, 3 right-sided). Absolute indications for nephron preservation were present in 6 (solitary kidney [5], renal insufficiency [1]). The clinical stage was T1a (5) and T3b (2). In the 5 cT1a patients, thrombus was first identified with intraoperative ultrasound in 1 and by palpation of the renal vein or during the performance of the PN in the remaining 4. Renal surface hypothermia was applied in 4 cases (avg. 76 min clamp) and warm ischemia only utilized in 3 (avg. 38 min clamp). Mean tumor size was 4.7 cm and 100% of the tumors were clear cell RCC. All surgical margins were negative (aside from the interface with the thrombus). Renal function as measured by serum Cr (pre-op and ≥ 30 days post-op) increased an average of 0.38 gm/dl (range 0.0 to 0.9 gm/dl). No patient required dialysis. Complications were limited to one delayed, post-operative urine leak successfully managed with a JJ stent and percutaneous drainage. One patient developed a local recurrence associated with level III IVC tumor thrombus 9 months following PN. He was managed with radical excision and IVC thrombectomy followed by post-operative dialysis. Mean follow-up in the remaining 6 patients is 20 months (range 1 to 36 months) and none have experienced local or distant recurrences.

Conclusions: In candidate patients for PN, pre-operative radiographic studies should be scrutinized carefully to exclude tumor associated venous thrombus—especially for centrally located renal tumors. However, when thrombus is encountered incidentally during the course of PN, our findings suggest that most patients can be managed successfully with PN.

Funding: None

ROBOTIC PARTIAL NEPHRECTOMY IN THE SETTING OF PRIOR ABDOMINAL SURGERY
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Presented By: Emil Kheterpal

Introduction and Objectives: Transperitoneal minimally invasive partial nephrectomy may be challenging in patients with previous abdominal surgery. We evaluate feasibility and perioperative outcomes of robotic kidney surgery in patients with previous abdominal surgery. We also described a novel technique for intraperitoneal access for patients with prior abdominal surgery utilizing the 8 mm robotic camera for direct vision trocar placement.

Methods: A total of 94 patients underwent robotic partial nephrectomy from 2004 to 2009, 41 of which had a history of prior abdominal surgery. Patients without prior abdominal surgery were compared to patients with major and minor prior abdominal surgery. Minor abdominal surgery was defined as contralateral, lower abdominal or minimally invasive surgery. Major abdominal surgery was defined as ipsilateral, upper quadrant and upper midline abdominal surgery. Access was obtained using a Veress needle or Hassan technique. We utilized a technique of direct vision placement of the initial trocar on our 10 most recent cases, using an 8 mm robotic camera placed through the obturator of 12 mm trocar. Lysis of adhesions was performed as needed to allow for placement of additional robotic ports.

Results: A total of 41 patients with prior abdominal surgery underwent robotic kidney surgery (minorá”‘20, majorá”‘10). There was no statistically significant difference between groups in operative time, blood loss, transfusion rates, and complication rates. An enterotomy during laparoscopic lysis of adhesion occurred in one patient in the major surgery group, which was repaired robotically without sequelae. There were no access related injuries in the cases in which the robotic 8 mm camera was used for initial trocar placement.

Conclusions: Robotic partial nephrectomy is a feasible in the setting of prior abdominal surgery. We described a novel technique of an 8 mm robotic camera for direct vision placement of the initial 12 mm trocar, which may be beneficial in patients with prior abdominal surgery.
Poster# 149

RADICAL NEPHRECTOMY AND INFERIOR VENA CAVA THROMBECTOMY: ASSESSMENT OF OUTCOMES IN A LOWER VOLUME PRACTICE

John Calhoun and James Brown
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Presented By: James Brown

Introduction and Objectives: Surgical volume correlates with improved outcomes for some complex urologic procedures (e.g. radical prostatectomy). Our objective, therefore, was to review the outcomes of a lower volume (1-2 cases/year) experience of radical nephrectomy with infra/retrohepatic vena caval thrombectomy (RNCT) in patients with renal cell carcinoma (RCC) at a state university.

Methods: A retrospective review was conducted for 9 patients who underwent RNCT performed by a single surgeon at a single state institution over a 7-year period from 2002 to 2009. We examined patient demographics, presenting symptoms, preoperative imaging, intraoperative factors, final pathology, hospital course, and postoperative outcomes. Level of caval involvement, renal artery embolization, liver mobilization, blood loss, transfusion requirements and postoperative follow-up times were also evaluated.

Results: The most common presenting symptom was weight loss (n=5, 56%), followed by abdominal pain (n=4, 44%) and hematuria (n=3, 33%). Median patient BMI (n=7) was 25.5 (18.3 - 31.9). Three patients had metastasis at diagnosis: pulmonary and hepatic (n=1), bilateral adrenal (n=1), and renal hilar lymph nodes (n=1). Seven patients underwent renal artery embolization prior to RNCT. A chevron incision was used and the operation performed with the assistance of a vascular or liver surgeon in all cases. Six thrombi were infrahepatic and 3 were low retrohepatic requiring liver mobilization. No intraoperative deaths occurred. The median operative time was 5.5 hours (3.5 - 8) with a median vena cava clamp time of 17.2 minutes (11 - 22). Seven (78%) patients required intraoperative transfusion. Median pathologic tumor size was 12.7cm (6 - 21). Median hospital stay was 9 days (5 - 15) with a median ICU stay of 4 days (1 - 6). Four patients had complications included descending colon mesenteric rent (n=2), postoperative abscess (n=1), retroperitoneal hematoma (n=1), distal pancreatic injury (n=1), and splenic capsular tear (n=1). Two patients died from postoperative metastasis after 5 months and 11 months, respectively.

Conclusions: RNCT can be performed, with the assistance of a vascular/liver transplant surgeon, for an infrahepatic or retrohepatic thrombus satisfactorily in a lower volume practice (1.3 cases/year) with mean operative times, vena cava clamp times, estimated blood loss, transfusion rates, and hospital stay comparable to higher volume tertiary centers.

Poster# 150

NATURAL HISTORY OF RECURRENCE IN RENAL CELL CARCINOMA AFTER 2,350 PARTIAL OR RADICAL NEPHRECTOMIES

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Presented By: Kian Tai Chong

Introduction and Objectives: To analyze patterns of disease recurrence and oncological outcome after surgical resection of renal cell carcinoma.

Methods: We reviewed all patients who underwent any nephrectomies in our institution though our prospective renal cell carcinoma database between Jan 2000 to Dec 2008. Patients with renal cell carcinoma who did not have clinical or pathological lymph node disease, loco-regional or distant metastases were included in this study. Study exclusions were metastasis at presentation, prior renal cancer surgery, unresectable or incompletely resected primary, clinical or pathological regional renal hilar lymphadenopathy, benign or non-renal cell carcinoma pathology, or unilateral nephrectomies in the presence of bilateral renal masses. Patient demographics, clinico-pathological characteristics and imaging studies were assessed to determine local or distant disease recurrence.
Results: Out of 3066 patients with 3219 nephrectomies, only 2327 patients with 2350 operations were eligible. At median follow-up of 41 months (IQR 15.4-83.3), 177 (7.6%) of 2327 patients developed recurrence, of which 14 (7.9%) were local and 163 (92.1%) were distant metastases. Median progression-free survival was 23.4 months (IQR 8.5-49.8). Ninety-one patients (51.4%) recurred within 2 years after nephrectomies. The most frequent recurrence in the first 3 years occurred in lung, bone and regional lymphadenopathy. After 3 years, lung, non-regional lymphadenopathy and non-traditional distant sites (e.g. nose, axilla, pancreas, salivary glands, etc) dominated recurrence sites. After recurrence, univariate factors for worsened cancer-specific and overall survival were collecting duct, clear cell pathology and pT4 disease. Multivariate analyses showed primary renal cancer pathology (p=0.002) and time to recurrence (p=0.01) were significant prognostic factors for survival.

Conclusions: Understanding patterns of recurrence after surgical management of renal cell carcinoma will improve our follow-up management, especially after 3 years post-nephrectomy.

Poster# 151

COMPARISON OF OPERATIVE AND FUNCTIONAL RESULTS IN ROBOTIC, LAPAROSCOPIC AND OPEN PARTIAL NEPHRECTOMY
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Presented By: Hugo Davila

Objectives: Laparoscopic partial nephrectomy (LPN) has technical challenges because it requires intracorporeal suturing skills during shortened warm renal ischemia times. Robotic assisted PN (RAPN) may have a clear indication based on these challenges. Our aim is to compare the operative results of our initial cases of RAPN, with our last cases of LPN, hand assisted PN (HAPN) and open PN (OPN).

Patients and Methods: Our initial 30 patients that underwent RAPN for renal tumors were divided in group A) RAPN (initial 15) and group B) RAPN (last 15) and these were compared retrospectively with the last 15 patients each that underwent LPN, HAPN and OPN. Operative measures evaluated included operative time, estimated blood loss (EBL), and warm ischemia time (WIT). Outcomes measured included serum creatinine before surgery and at hospital discharge, length of hospital stay and surgical margin status.

Results: There were no differences between the groups in patient characteristics (age, body mass index, gender, tumor side). However, there was a significant difference (p<0.05) in the EBL when comparing A) RAPN (367cc) vs. B) RAPN (104cc) and LPN (90cc), HAPN (105cc) and OPN (303cc). WIT was; A) RAPN (34 min) vs. B) RAPN (24 min), LPN (36 min), HAPN (25 min) and OPN (27 min), (p>0.05). As expected patients undergoing OPN had larger tumors (4.4 cm) vs. A/B RAPN: 2.9 cm, LPN: 2.1 cm and HAPN: 2.4 cm (p<0.5). Functional outcomes (creatinine before surgery/discharge) were comparable among groups and there were no differences in surgical margins. One RAPN case required conversion to standard OPN in each group A/B for failure to progress and bleeding, respectively.

Conclusion: Most measured outcomes for our 30 RAPN cases were similar to the last 15 patients undergoing LPN, HAPN and OPN. The EBL and WIT was lower in Group B) RAPN as compared to group A) RAPN reflective of a continued learning curve. The conversion rate was similar in both groups of RAPN. We believe EBL, WIT and functional/oncologic outcomes are the limiting factors in the learning curve of RAPN –likely abbreviated in the group B) of RAPN owing to our previous laparoscopic and OPN experience.
Poster# 152

ELDERLY PATIENTS WITH MEDICAID AS THE PRIMARY PAYER ARE NO LESS LIKELY TO UNDERGO NEPHRON SPARING SURGERY (NSS) FOR RENAL CELL CARCINOMA (RCC) THAN THEIR PRIVATELY INSURED COUNTERPARTS
Alexander Kutikov and Robert Uzzo
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Presented By: Alexander Kutikov

Introduction and Objective: Partial nephrectomy is an established standard for treatment of localized RCC. Nevertheless, NSS remains widely underutilized except at high-volume academic centers. Previously we evaluated the potential impact of a patient’s primary insurance status as an independent variable predicting a patient’s likelihood of undergoing NSS using inpatient discharge data from New York (NY), New Jersey (NJ), and Pennsylvania (PA), and found that patients with Medicare were less likely to undergo partial nephrectomy. Here we report a similar analysis for patients whose primary payer was Medicaid.

Methods: A database generated from discharge claims data of individual state agencies of NJ, NY, and PA, was queried for all patients >=18 years of age who underwent radical or partial nephrectomy from 2000 to 2006. We used multiple linear regressions to investigate effects of insurance status on likelihood of undergoing partial nephrectomy.

Results: 39,836 radical or partial nephrectomies were included in the analysis. On univariate analysis, likelihood of undergoing NSS was associated with age, gender, hospital procedure volume, socioeconomic status, payer, and rurality. In the multivariate analysis, older patients (p<0.001), those with Medicare (p<0.001), the uninsured (p=0.017), those treated at lower volume hospitals (p<0.001), but not those patients with Medicaid, were less likely to undergo partial nephrectomy. In a secondary analysis of those patients >=65 (n= 20,137), individuals with Medicare as the primary payer (n=17,150, OR=0.87, p=0.016), but not those with Medicaid (n=309, OR=1.43, p=0.014), were less likely to undergo NSS than patients who had a private provider as the primary payer (n=2,512; OR=1.00).

Conclusions: By examining a large discharge claims database from NY, NJ, and PA, we were able to show that when compared to privately insured counterparts, patients with Medicaid coverage were no less likely to undergo partial nephrectomy. These findings contrast previously reported results from the same dataset that patients with Medicare coverage are more likely to forego NSS. We suspect that our findings are explained by the fact that a large proportion of patients with Medicaid coverage reside in close proximity to large tertiary referral centers; nevertheless, this hypothesis remains to be validated.

Poster# 153

FEASIBILITY AND OUTCOMES OF PARTIAL NEPHRECTOMY FOR RESECTION OF AT LEAST 20 TUMORS FROM A SINGLE RENAL UNIT
Amaka T. Fadahunsi, Thomas Sanford, W. Marston Linehan, Peter A. Pinto and Gennady Bratslavsky
NIH/NCI Bethesda, MD
Presented By: Amaka T. Fadahunsi

Purpose: Patients with hereditary renal cancer are at increased risk for formation of bilateral and multifocal renal tumors. Some patients present with an aggressive renal cancer phenotype and require prolonged and morbid nephron sparing surgery to prevent hemodialysis and renal transplantation. In this study we evaluate the feasibility, functional and oncologic outcomes of patients who underwent partial nephrectomy for at least 20 tumors removed during a single procedure.

Materials and Methods: We performed a chart review of patients who underwent partial nephrectomy at the NCI from 1993 to 2008. We included only those patients who had at least 20 tumors removed at the time of surgery. Operative reports and hospital records were reviewed for perioperative data, renal functional and oncologic outcomes. Comparison of preoperative and postoperative renal function was performed at least 3 month post-op using the 2-tailed T test.
Results: We identified 27 patients that underwent a total of 30 partial nephrectomies on 30 kidneys via an open approach. The median number of tumors removed was 26.5 (20-70), with the median number of solid tumors removed being 17 (9-43). The median size of solid tumors removed was 4cm (2-7). The median EBL was 3,500ml (800-19,500), and the median operative time was 9.5hrs (6.5-14.0). Perioperative complications occurred in 50% of cases; there were no mortalities, and no renal units were lost in this series. Ten patients had solitary renal units at the time of surgery. None of these patients required hemodialysis postoperatively. There was a statistically significant increase in postoperative serum creatinine (1.15 vs 1.37 mg/dl, p <0.01) and statistically significant decrease in the split renal function on nuclear scans obtained at least 3 months postoperatively. Median follow up of the entire cohort was 40 months (6-192). During this period, 6 of the 30 renal units involved required subsequent intervention for recurrences or de novo tumor development.

Conclusions: Aggressive partial nephrectomy with removal of at least 20 tumors is feasible. Although there was a significant decrease in postoperative renal function, all patients avoided hemodialysis and the majority remained free from subsequent oncologic interventions at intermediate follow up.

Poster# 154

BIOPSY OF METASTATIC SITES IN RENAL CELL CARCINOMA: COMPARISON OF PATHOLOGIC FINDINGS WITH NEPHRECTOMY SPECIMENS IN 240 PATIENTS
E. Jason Abel, Alonso Carrasco, Stephen H Culp, Surena F. Matin, Pheroze Tamboli, Nizar Tannir and Christopher G. Wood
University of Texas MD Anderson Cancer Center
Presented By: E. Jason Abel

Purpose: Patients with metastatic renal cell carcinoma (mRCC) often undergo biopsy of metastatic sites to obtain tissue diagnosis prior to treatment. The presence of poor prognostic features such as non-clear cell histologic subtype and sarcomatoid de-differentiation are often used to guide therapy, but it not known how reliably these features correlate with primary tumor pathology. We present a series of 240 patients who had a metastatic site biopsy and compare the results to pathologic findings in specimens from cytoreductive nephrectomy (CN.)

Materials and Methods: An institutional database was used to identify all patients from 1993 to 2007 who had a metastatic site biopsy prior to CN. Clinical and pathologic data was collected for each patient. Specimens obtained at outside institutions were reviewed by a dedicated genitourinary pathologist prior to inclusion in this study.

Results: A total 240 patients had metastatic site biopsy prior to CN. Mean primary tumor size was 8.9cm. Biopsied sites include: bone (89), lung (55), lymph node (39), brain (9), adrenal (6) and other (44). In 95 patients, a histologic subtype was assigned to the biopsy specimen. In 85/89 (95.5%) patients with clear cell subtype and 4/6 (66.6%) patients with papillary subtype from biopsy, the nephrectomy subtype correlated with the biopsy specimen. Compared with the nephrectomy specimen, the histologic subtype was able to be identified from the biopsy in 5/12 papillary, 0/2 chromophobe, and 0/3 collecting duct carcinomas. Of 43 patients with sarcomatoid de-differentiation in their nephrectomy specimen, only 5 (11.6%) had sarcomatoid features identified in their biopsy specimen.

Conclusions: Pathologic findings from biopsy of metastatic lesions in mRCC correlate poorly with nephrectomy specimens in non-clear cell subtypes and for identification of sarcomatoid features. The lack of correlation may represent a difference in the biology of metastatic lesions and/or technical limitations of biopsy. Physicians should use caution when making treatment decisions based on pathologic features from metastatic site biopsy.

Poster# 155

COST COMPARISON ANALYSIS OF TWO SURVEILLANCE STRATEGIES FOR RENAL CELL CARCINOMA AFTER RADICAL NEPHRECTOMY IN CANADA
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Presented By: Carlos H. Martinez

Objective: The costs of follow-up strategies in patients after radical nephrectomy for primary renal cell cancer (RCC) have not been evaluated. We compared the costs of two different surveillance strategies, the new Canadian Urological Association (CUA) Guidelines and the old strategy implemented in our institution.
Method: With institutional ethics review, 75 patients who underwent radical nephrectomy for primary non-metastatic renal cancer were retrospectively reviewed. Patients were scheduled for follow-up at 3, 6, 12 months and then yearly until recurrence was detected or the 60 months mark was reached. During each visit patients underwent history, physical exam, laboratory testing (CBC, electrolytes, renal and liver panels), urinalysis, and chest x-ray. At the 6 month visit CT chest/abdomen/pelvis was performed for all patients. After 12 months a stage based strategy of surveillance was implemented. For T1, no imaging was ordered unless symptoms were present. For T2/3, CT was considered at the 2 year mark, or if symptoms were present. The estimated costs following the CUA guidelines and our old institutional protocol were compared.

Results: The distribution of our patients stage by stage was T1 41, T2 15, and T3 19 patients. Our mean follow up was 31.1 (± 20.4 SD) months. The overall and disease free survival were 87.7% and 85.2%. Total medical costs were higher for our old Institutional surveillance strategy than the CUA guidelines ($181 861 vs. $135 054). For the complete follow-up of 75 patients a cost savings of $46 806 could have been achieved following the CUA guidelines (p=0.0019). Of recurrences 6 out of 7 were detected by routine screening, only one recurrence was identified by symptoms. The cost per recurrence detected in our old protocol was $9812.92. The increased cost of our institution analysis was due to more visits with basic testing, symptomatic investigation, and follow-up of imaging tests. The cost attributable to these extra tests was a median of 15% (range of 0-59%).

Conclusions: Based on our results we endorse the new CUA surveillance strategy for RCC follow-up. Significant cost savings would be achieved by changing from our older follow-up strategies used at our institution.

Poster# 156

LONG-TERM FOLLOW-UP OF PATIENTS INITIALLY MANAGED WITH ACTIVE SURVEILLANCE FOR SOLID RENAL MASSES

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Presented By: Eugene Simopoulos

Objectives: In recent years some institutions have reported on the relatively short-term follow-up of expectant management of small renal masses. This study sought to provide a long-term follow-up of our initial series of patients whose renal masses were managed expectantly to provide some insight into the feasibility and safety of this approach in the long term.

Methods: 43 patients with 46 renal masses underwent an expectant management strategy for enhancing renal masses initiated between 12/99 –1/05. Follow-up of this initial cohort are reported.

Results: Mean (median) follow-up of the entire cohort is 57.4 (64.9) months. The mean (median) initial tumor size was 2.9 cm (2.9 cm) and the mean (median) growth rate of the tumors was 0.6 cm/yr (0.2 cm/yr) with 12 (26%) of tumors having no growth. For the entire group, 6 patients were lost to follow-up (or refused follow-up) before intervention at a mean time 24.8 months. For the remaining 37 patients (40 tumors) the mean (median) follow up was 62.5 (65.5) months. Of these, 17 tumors in 15 patients have remained on surveillance and 23 tumors in 22 patients have undergone an intervention. Of the 15 patients (17 tumors) on surveillance, 8 patients (comprising 10 tumors) have died in their follow-up at a mean time from diagnosis of 45.7 months –all of other causes. No patient on surveillance has developed a metastasis or death secondary to renal carcinoma. 23 tumors (22 patients) have undergone an intervention with an overall mean (median) follow-up from diagnosis of 65.0 (68.0) months and with a mean (median) time from diagnosis to intervention of 25.1 (21.9) months. These patients have undergone surgery (19), cryotheraphy (2), and RFA (2), with 2 patients requiring second intervention (repeat partial nephrectomy, repeat RFA). No patient in the intervention subgroup has developed a known metastasis nor has died of renal carcinoma at a mean follow-up of 65.0 (68.0) months with 2 patients dying of other causes. (5 patients in the intervention group were eventually lost to follow-up at a mean time of 23.9 months after treatment.)

Conclusions: Active surveillance for renal masses remains an appropriate option for the carefully selected patients –especially those with competing co-morbidities. The long-term follow-up of such patients demonstrates the safety of this approach, and delayed intervention does not appear to adversely impact clinical outcomes.
PREDICTORS OF PERINEPHRIC DESMOPLASTIC REACTION IN PATIENTS UNDERGOING PARTIAL NEPHRECTOMY

Stephen Culp, Sooyeon Choi, Pheroze Tamboli, Surena Matin and Christopher Wood
The University of Texas MD Anderson Cancer Center, Houston, TX
Presented By: Stephen Culp

Introduction and Objectives: Nephron-sparing surgery is the standard of care for amenable kidney tumors based on size and anatomy. However, partial nephrectomy can be difficult and potential complications may arise when an unexpected desmoplastic reaction is present between the perinephric fat and renal capsule. Our objective was to perform a retrospective review to potentially identify clinical and pathological factors that were associated with the presence of a perinephric desmoplastic reaction.

Methods: Using an institutional database, we identified all patients undergoing partial nephrectomy between 1/2007 and 5/2009. All operative notes were meticulously reviewed as well as clinical and pathological data. Multivariable stepwise logistic regression analysis was used to calculate an odds ratio (OR) corresponding to the odds of the presence of a perinephric desmoplastic reaction at the time of surgery.

Results: We identified 419 patients undergoing partial nephrectomy for a suspicious lesion between 2007 and 2009. Of these, a perinephric desmoplastic reaction was noted in 94 (22.4%) patients. On multivariable analysis controlling for surgeon and open vs. laparoscopic approach, factors associated with an increased risk of a perinephric desmoplastic reaction included: Male gender (OR 4.06; 95% CI 2.07, 7.97, p<0.001), history of nephrolithiasis regardless of treatment (OR 3.81; 95% CI 1.83, 7.95, p<0.001), history of diabetes mellitus (OR 1.91; 95% CI 1.01, 3.61, p=0.047), left side (OR 1.77; 95% CI 1.02, 3.07, p=0.043), history of coronary artery disease (OR 2.62; 95% CI 1.26, 5.45, p=0.01), and prior renal biopsy (OR 4.41; 95% CI 1.93, 10.06, p<0.001). Surprisingly, the presence of multiple renal arteries was protective (OR 0.35; 95% CI 0.16, 0.80, p=0.012).

Conclusions: We have identified factors associated with the presence of a perinephric desmoplastic reaction at the time of surgery. Knowledge of these factors may help in pre-operative counseling of patients undergoing partial nephrectomy.

COMPARATIVE ANALYSIS OF ONCOLOGIC OUTCOMES SEVEN YEARS AFTER LAPAROSCOPIC AND OPEN PARTIAL NEPHRECTOMY

Brian Lane¹ and Inderbir Gill²
¹Cleveland Clinic; ²University of Southern California, Los Angeles, CA
Presented By: Brian Lane

Introduction and Objectives: Open partial nephrectomy (OPN) has proven long-term oncologic efficacy. Long-term outcomes of laparoscopic partial nephrectomy (LPN) are pending. Herein, we present comparative long-term outcomes of patients undergoing LPN or OPN for a single cT1 renal cortical tumor < 7 cm.

Methods: Of 2246 patients undergoing PN for a single cT1 tumor (1999-2008), minimum 7-year follow-up was available in 77 and 310 patients, and minimum 1 year follow-up in 672 and 944 patients, after LPN and OPN, respectively. Survival and recurrence data, obtained from medical records, radiographic reports, and patient contact, were analyzed retrospectively.

Results: Median follow-up after LPN and OPN was 4.0 and 5.7 years, respectively. In multivariable analysis, predictors of all-cause mortality included advancing age (p<0.0001), co-morbidity (p<0.0001), pre-operative renal dysfunction (p=0.0001), but not tumor size (p=0.6) or operative approach (LPN vs. OPN, p=0.07). Cancer recurred infrequently, and only rarely caused mortality, after either LPN or OPN. At 7 years, metastasis-free survival was 97.5% and 97.3% (p=0.47) after LPN and OPN (Figure). The unadjusted HRs for cancer-specific mortality at 7 years for patients with pT1a or >pT1b RCC were 0.98 (CI: 0.22–4.47, p=1.0) and 4.60 (CI: 0.86–24.6, p=0.12). In a Cox proportional hazards model accounting for nomogram-predicted recurrence-free survival (p=0.0001), surgical approach (LPN vs. OPN) was not significantly associated with cancer-specific survival (HR: 1.45, p=0.49). Propensity score analysis indicated that LPN and OPN were not evenly applied. After accounting for predicted recurrence-free survival (p=0.044) and propensity to undergo LPN (p=0.01), surgical approach was not associated with a significant difference in the odds of metastasis within 7 years (OR: 2.18, CI: 0.85, 5.89, p=0.11).
Conclusions: LPN and OPN appear to provide similar long-term overall and cancer-specific survival in patients undergoing partial nephrectomy for clinical stage T1 (≤7cm) renal cortical tumors. Oncologic outcomes at 7 years after LPN and OPN are excellent, with the vast majority (97%) of patients experiencing metastasis-free survival.

Poster# 159

TRENDS IN RENAL TUMOR SURGERY DELIVERY WITHIN THE UNITED STATES
Lori Dulabon¹, William Lowrance², Paul Russo² and William Huang¹
¹New York University School of Medicine, Department of Urology; ²Memorial Sloan-Kettering Cancer Center, Urology Service, Department of Surgery
Presented By: Lori Dulabon

Purpose: Most small renal tumors are amenable to partial nephrectomy (PN). Studies have documented the association of radical nephrectomy (RN) with increased risk of co-morbid conditions such as chronic kidney disease. Despite evidence of equivalent oncologic outcomes, PN remains underutilized within the United States (US). The aim of this study was to examine data from the most current Surveillance, Epidemiology and End Results (SEER) cancer registry (1999-2006), identify trends in kidney surgery for small renal tumors, and determine the factors associated with the utilization of PN versus RN within the US. No financial funding was provided in the creation of this study.

Materials and Methods: We analyzed a population-based cohort of patients using the SEER cancer registry. 18,330 patients, aged 40-90 years, who underwent a surgery for kidney tumors 4cm or less in the US from 1999-2006 were identified. Summary statistics were constructed and unadjusted associations between the type of renal surgery and patient characteristics were examined using either chi-square or Fischer’s exact test. Multivariable logistic regression was used to estimate the likelihood of receiving PN versus RN.

Results: A total of 11,870 (65%) patients underwent RN and 6,460 (35%) underwent PN from 1999-2006. The ratio of PN to RN increased (p <0.001) yearly representing 45% of small kidney tumor surgery in 2006. There were significant differences among patients undergoing PN versus RN including age, gender, location, marital status, year of treatment, and tumor size (per 1cm). When adjusting for these variables, males were more likely to undergo PN than women (odds ratio [OR] = 1.22, p<0.001); however, those older than 70 years of age and living in a rural location had significantly lower odds of undergoing PN. Additional predictors of PN included a more recent year of surgery as well as smaller tumor size (p<0.001). No differences were noted based on race. Although married status was predictive of PN, this was not significant on multivariable analysis (p=0.53).

Conclusions: Although the total number of PN has increased within the US from 1999 to 2006, there is still a significant underutilization of PN, particularly among certain cohorts of patients including women, the elderly, and those living in rural locations. Further investigation is required to determine the reasons for such disparities. Strategies to optimize access to PN in the US need to be developed.
Racial Differences in Histological Subtypes of Renal Cell Carcinoma

Jacob Cohen, Nicholas Karanikolas, Ivan Colon and Richard Macchia

SUNY Downstate, Brooklyn, NY

Presented By: Jacob Cohen

Introduction: Previous studies on racial differences in the incidence patterns and outcomes of renal cell carcinoma (RCC) have failed to account for the different histological subtypes of RCC. It is well known that the various RCC histologies differ in terms of genetics as well as prognosis. We sought to identify racial differences in the patterns of histological subtypes of RCC in a racially diverse, equal-access health care system.

Methods: We preformed a multi-institutional, retrospective review of patients with a diagnosis of RCC between January 1st, 2000 and Dec 31st, 2007. Benign histologies, such as oncocytoma, angiomyolipoma were excluded. All slides underwent centralized pathology review.

Results: We identified 154 cases of RCC in 77 white patients (50%) and 77 black patients (50%). Among white patients, there were 60 clear cell tumors (78%), 9 papillary tumors (12%), 8 chromophobe tumors (10%), and no medullary/collecting duct tumors. In contrast, papillary tumors comprised the majority for black patients, with 48 cases (62%), followed by 23 clear cell tumors (30%), 2 chromophobe tumors (3%), and 4 medullary/collecting duct tumors (5%).

Conclusions: This is the first study to document such a great racial disparity of the different RCC histologies. Papillary and medullary subtypes of RCC were far more common among black patients as compared to white patients. Given the genetic basis of RCC histology and its role in response to adjuvant therapy, race may be important when counseling patients regarding prognosis and adjuvant treatments.

Comparison of Warm Ischemia Versus No Ischemia During Partial Nephrectomy on Solitary Kidneys

R. Houston Thompson¹, Brian R. Lane², Christine M. Lohse¹, Bradley C. Leibovich¹, Amr Fergany², Igor Frank¹, Inderbir S. Gill³, Stephen C. Campbell² and Michael L. Blute¹

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Presented By: R. Houston Thompson

Purpose: We update our collaboration to evaluate the short and long-term renal effects of warm ischemia in patients with solitary kidneys.

Methods: Using the Cleveland Clinic and Mayo Clinic databases, we identified 458 patients who underwent open (n=411) or laparoscopic (n=47) partial nephrectomy for a renal mass in a solitary kidney. Patients treated with cold ischemia were excluded. Glomerular filtration rate (GFR) was estimated using the abbreviated MDRD equation. Associations of warm ischemia with pre-defined endpoints were evaluated using logistic or Cox regression models.

Results: No ischemia was utilized in 96 (21%) while 362 (79%) patients had a median of 21 (range 4-55) minutes of warm ischemia. There were no significant differences in age, gender, or histology; however, patients treated with warm ischemia had a significantly higher preoperative GFR (median 61 vs. 54 mL/min/1.73m², p<0.001) and larger tumors (median 3.4 vs. 2.5cm, p<0.001) compared with patients treated with no ischemia, respectively. Warm ischemia patients were significantly more likely to develop acute renal failure (Odds Ratio 2.1, p=0.044) and a GFR<15 mL/min/1.73m² in the postoperative period (Odds Ratio 4.2, p=0.007) compared with patients who did not have hilar clamping; similar results were obtained adjusting for tumor size and preoperative GFR in a multivariable analysis (p=0.017 and p=0.002, respectively). Among the 297 patients with a pre-operative GFR ≥30 mL/min/1.73m² and ≥30 days of follow-up, patients with warm ischemia were significantly more likely to develop new onset stage IV chronic kidney disease (Hazard Ratio 2.3, p=0.028) even after multivariable adjustment (p=0.024) during a mean follow-up of 3.3 years. For patients with no ischemia and warm ischemia, the incidence of intra-operative hemorrhage was 2% vs. 5% (p=0.38) and urine leak was 1% vs. 5% (p=0.14), respectively.

Conclusions: Warm ischemia during partial nephrectomy increases the risk of acute renal failure and chronic kidney disease. Partial nephrectomy with none or regional ischemia should be utilized when technically feasible in patients with solitary kidneys.
COMPLICATIONS AFTER RADICAL AND PARTIAL NEPHRECTOMY AS A FUNCTION OF AGE
William Lowrance, David Yee, Caroline Savage, Angel Cronin, Matthew O’Brien, Machele Donat, Andrew Vickers and Paul Russo
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Presented By: William Lowrance

Introduction and Objectives: Partial nephrectomy may be underutilized in elderly patients due to concerns of higher complication rates compared with radical nephrectomy. We sought to determine if the association between age and perioperative outcomes differed between types of nephrectomy.

Methods: We identified patients who underwent radical or partial nephrectomy between January 2000 and October 2008. Using multivariable methods, we determined whether the relationship between age and risk of postoperative complications, estimated blood loss, or operative time differed by type of nephrectomy.

Results: Obtained: Of 1,712 patients, 651 (38%) underwent radical nephrectomy and 1061 (62%) underwent partial nephrectomy. Patients treated with partial nephrectomy had higher complication rates than those treated with radical nephrectomy (20% vs. 14%). In a multivariable model, age was significantly associated with a small increased risk of having a complication (OR for 10-year age increase: 1.17; 95% CI, 1.04-1.32; p = 0.009). When including an interaction term between age and procedure type, the interaction term was not significant (p = 0.09), indicating there was no evidence the risk of complications associated with a partial versus a radical nephrectomy increased with advancing age. We found no evidence that age was significantly associated with estimated blood loss or operative time.

Conclusions: We found no evidence that elderly patients experience a proportionally higher rate of complications, longer operative times, or higher estimated blood loss from partial nephrectomy than do younger patients. Given the advantages of renal function preservation, we should expand the use of nephron-sparing treatment for renal cortical tumors in elderly patients.

Funding: This project was supported in part by NIH T32-CA82088 Urologic Oncology training grant and by the Sidney Kimmel Center for Prostate and Urologic Cancers. We are also indebted to the Stephen Hanson Family Fellowship for their support.

COMPARISON OF COMPLICATIONS OF LAPAROSCOPIC VERSUS OPEN PARTIAL NEPHRECTOMY USING THE MODIFIED CLAVIEN GRADING SYSTEM
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Presented By: Ranjith Ramasamy

Introduction and Objectives: Laparoscopic partial nephrectomy is increasingly performed as an alternative to open partial nephrectomy (OPN). Although benefits of laparoscopic surgery have been elucidated in several studies, few groups have performed a comprehensive analysis of complications following open or laparoscopic surgery. We compared post-operative complications in patients undergoing LPN versus OPN using a standardized complication reporting system.

Methods: We performed a retrospective analysis of patients who underwent elective partial nephrectomy for renal masses either by laparoscopic or open technique. Demographic, perioperative, and complication data were recorded retrospectively. Thirty-day and 90-day complication rates were compiled and graded using the modified-Clavien complication scale. Chi-squared test was used to analyze categorical data, and multinomial logistic regression was used to determine independent predictors of complications.

Results: In total, 364 patients entered the study after either LPN (173 patients) or OPN (191 patients). Surgical, hospitalization times, and estimated blood loss were shorter in the LPN group (p < 0.001). At 30 days, there was no difference in the overall complication rate between the OPN and LPN groups (13% vs. 10%, p > 0.05). Of the patients with complications, there was a higher major complication (Grade 3-5) rate in the LPN group (65% vs. 28%, p = 0.04). When subjected to logistic regression analysis, OPN was a predictor of fewer major complications at 30 days. Higher American Society of Anesthesiologists (ASA) score (3-4) was an independent predictor of both overall and major complications. There was no difference in the complication rates at 90 days.

Conclusions: LPN has the advantages of decreased operative time as well lower blood loss and a shorter hospital stay. These advantages however are associated with a statistically significant increase in post-operative major complications when compared to OPN, even in experienced hands.
TRENDS IN PRESENTATION AND TREATMENT OF RENAL TUMORS AT MAYO CLINIC
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Presented By: Rodney Breau

Introduction: Secular patterns of disease and treatment allow clinicians to evaluate their practice and prepare for future challenges. We reviewed trends in presentation and management of renal tumors at Mayo Clinic Rochester.

Methods: All patients from 1970 to 2006 treated at Mayo Clinic for primary localized renal masses were evaluated.

Results: 4598 patients were identified and reviewed. Over time, gender (~65% male), age (~63 years) and pre-operative renal function (GFR~62ml/min/m2) has not changed appreciably. While average tumor size has decreased slightly over time (6.8cm in 1970s to 5.3 cm since 2000), there has been a dramatic stage migration. In the 1970s, tumors were approximately uniformly distributed between T1a, T1b, T2 and T3. However, since 2000, 47% were T1a, 24% were T1b, 12% were T2 and 16% were T3. Over time there has been a dramatic shift away from radical nephrectomy in favor of nephron sparing techniques (Figure).

Conclusion: While some patient characteristics have remained stable over time, a significant stage migration has occurred and nephron sparing procedures now dominate treatment of renal masses at our institution.

ELIMINATION OF BOWEL PREPARATION IN PATIENTS UNDERGOING CYSTECTOMY AND URINARY DIVERSION
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Presented By: Eugene Simopoulos

Introduction: Current studies in the colorectal surgery literature have suggested no differences in perioperative outcomes with or without mechanical bowel preparation (MBP) prior to surgery. However, studies examining the role of MBP in urologic surgery are lacking. This study compared outcomes in patients who underwent cystectomy and ileal urinary diversion with or without MBP.

Methods: The study represents a consecutive case series of 70 patients who underwent cystectomy and ileal urinary diversion either with MBP or no bowel preparation (NO PREP). Patients excluded from both groups included those with history of pelvic XRT or with history of complex bowel surgery (e.g. prior colostomy). 37 patients (6/08 –12/08) underwent a MBP that included 1 bottle of Magnesium citrate, Fleets enema, clear liquid diet on day before surgery, and peri-operative antibiotics. The 33 patients in the NO PREP group (1/09 –7/09) had a regular diet until midnight before surgery, a Fleets enema the morning of surgery, and peri-operative antibiotics. Operative outcomes were assessed and postoperative complications were graded using the Clavien classification.
**Results:** There were no differences with recovery of bowel function, time to discharge, or complication rates. With regard to GI complications, the MDC group had 6 cases (16.2%) of ileus/emesis (all resolved with conservative management), 1 case of fascial dehiscence, and 1 case of new incarcerated inguinal hernia. In the NO PREP group, GI complications included 5 cases (15.2%) of ileus/emesis (all resolved with conservative management) and 1 case of fascial (port site) dehiscence. There were no cases of anastomotic leak, fistula, peritonitis, or abscess in either group.

**Conclusions:** MBP does not demonstrate any significant advantage in perioperative outcomes in patients who undergo cystectomy and ileal urinary diversion. These results suggest that MBP can be omitted in many patients undergoing urologic procedures involving use of small bowel. Non-prepped regimen may provide potential benefits of improved patient tolerability and hydration status. A prospective randomized study would help provide the high levels of clinical evidence to confirm these findings.

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**Poster# 166**

**SURVIVAL AND PREDICTORS OF DEATH IN A CONTEMPORARY SERIES OF A SINGLE SURGEON CYSTECTOMY EXPERIENCE**

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Presented By: Muben Mirza

**Introduction:** Radical cystectomy is the standard of care for muscle invasive bladder cancer. Outcomes have ranged depending on surgeon volume, stage, and time from diagnosis to cystectomy. The purpose of this study was to examine a single surgeon contemporary series of cystectomies from 2002-2009 to determine survival and predictors of death.

**Methods:** Retrospective review of a cystectomy database including patients who had undergone radical cystectomy by a single surgeon from Jan 2002 to Jun 2009 was performed. Survival outcomes were correlated with clinicopathologic factors including: age, smoking status, presence of carcinoma in situ (CIS), and pathologic stage. Survival was identified by database records and the social security index database. Statistical analysis of the parameters was performed to compare the group of patients who had died and the group of patients who are living.

**Results:** A total of 271 patients underwent cystectomy for bladder cancer between 2002 and 2009 and were available for analysis. Of these, 79 had died with a mean survival of 1.3 yrs. Mean follow-up for living patients was 2.9 yrs. Mean age in the death group was 70.4 vs. 64.7 yrs for the living group (p<0.001). 45% of patients in the death group were smokers compared to 57% in living group (p=0.08). High-grade disease was present in 92% of death group patients vs. 84% of living patients (p=0.16). CIS was present in 38% of death group vs. 45% of living patients (p=0.4). Residual pathological diagnosis of >T2 occurred in 63% of dead patients vs. 29% of living patients with higher stage predictive for death (p<0.0001). 53% of patients in the death group were upstaged compared to 35% in the living group (p<0.0001). Positive lymph nodes occurred in 31% of dead patients vs. 14% of living patients (p<0.01). 84% of patients in the death group had ileal conduit vs. 76% in the living group (p=0.24).

**Conclusion:** Overall survival in this study was 71% demonstrating the effectiveness of radical cystectomy. In univariate analysis, age, residual pathologic stage, upstaging, and lymph nodes status significantly predict death for patients who have undergone radical cystectomy. Smoking status, grade, CIS, and type of diversion did not show significant differences between the groups. Radical cystectomy offers excellent disease outcomes but is adversely affected by upstaging at time of cystectomy emphasizing the need for early referral to high volume centers.
DOES THE YIELD OF RANDOM BLADDER BIOPSIES JUSTIFY THEIR USE FOLLOWING BCG THERAPY FOR NONMUSCLE-INVASIVE UROTHELIAL CARCINOMA?
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Presented By: Matthew Resnick

Introduction and Objective: The utility and yield of bladder biopsies following intravesical BCG is poorly described. In this study we aimed to assess the yield of random bladder biopsies in the evaluation of treatment failure following BCG therapy for nonmuscle-invasive urothelial carcinoma (UC).

Methods: We reviewed our prospectively maintained database of patients with nonmuscle-invasive bladder cancer and isolated 245 patients with UC who were subject to intravesical BCG therapy and underwent either directed or random bladder biopsies performed between 8 and 12 weeks following intravesical BCG. The results of such biopsies were studied to assess the yield of random biopsies in the detection of treatment failure.

Results: Of those studied, 142 (58.0%) underwent directed biopsies secondary to suspicious findings on cystoscopy, with the remaining 103 (42.0%) patients undergoing random bladder biopsies. Of those who underwent directed biopsies, 50 (35.2%) were found to have UC compared to 8 (7.8%) patients with a normal cystoscopic examination resulting in a risk ratio for cancer diagnosis of 4.53 (95% CI 2.24, 9.14 p < 0.0001). The presence of positive urine cytology improved the yield of random biopsies, as 23.1% of patients with positive cytology manifested recurrent disease upon random biopsy as compared to 5.6% of patients with negative cytology. The overall sensitivity and specificity of cystoscopy were 86.2% and 50.1%, respectively, with the positive predictive value of suspicious cystoscopic findings of 35.2% and the negative predictive value of a normal cystoscopy 92.2%. The yield of random biopsies was found to be higher in those undergoing surveillance following induction BCG as compared to maintenance BCG (10.3% vs. 2.9%, respectively). Additionally, the yield of random biopsies was higher in patients following treatment for PUNLMP/Ta, T1, and CIS+/−T1 (4.3%, 8.7%, 14.3%, respectively).

Conclusions: Detection of UC following intravesical BCG is essential to ensure appropriate triage and management of BCG-failures. The yield of random bladder biopsies in was found to be 7.8%, improved with the incorporation of urine cytology data. The yield of random biopsies remains particularly low in those patients with antecedent PUNLMP or Ta disease and in those undergoing surveillance following a maintenance BCG. As such, one should strongly consider withholding biopsies in these patients to avoid the morbidity and cost associated with bladder biopsies.
Results: A total of 131 patients were available for analysis, including 110 males and 21 females. The mean age was 66.7 (range 41-89, SD 10.6) and the mean BMI was 27.6 (range 17.6-43.1, SD 4.8). A mean of 33.7 (SD 13.6; range 9-81) lymph nodes were reported on pathologic analysis. Extended PLND performed on patients with a BMI of 25 or greater had a higher likelihood of yielding an adequate lymph node count (≥25) than patients with a BMI less than 25 (OR 18.8, p<0.001). Age less than 65 was also significantly associated with an adequate lymph node count (OR 3.57, p=0.047). On multivariate analysis, BMI of 25 or greater was found to be an independent predictor of adequate lymph node count.

Conclusions: Extended PLND in overweight or obese patients can be expected to yield lymph node counts that provide precise disease staging and optimal locoregional cancer control. Careful attention to the anatomic extent of the PLND cannot be overlooked and may actually lead to a greater lymph node count in this subset of patients.

Poster# 169

MORTALITY OF PATIENTS WITH HIGH GRADE NON-MUSCLE INVASIVE UROTHELIAL BLADDER CANCER AFTER RADICAL CYSTECTOMY

Daniel Woodruff\(^1\), Sandra Koo\(^2\), Janet Baack\(^1\), Moben Mirza\(^1\) and Jeffrey Holzbeierlein\(^1\)
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Presented By: Sandra Koo

Objectives: Management of carcinoma in situ (CIS) and clinical stage Ta/T1 grade 3 urothelial carcinoma of the bladder is clinically challenging. Treatment after initial diagnosis includes intravesical BCG therapy; however, high recurrence rates (75%) and substantial risk of progression (over 20%) make the optimal management of these cancers controversial. Identifying significant prognostic markers will improve our ability to predict those who may have a durable response to BCG therapy versus those who should proceed to radical cystectomy (RC). While several studies have evaluated time from tumor resection to RC as a predictor of outcomes, none have specifically evaluated time from diagnosis (first transurethral resection of bladder tumor) to RC in patients with non-muscle invasive high-grade bladder cancer as a predictor of outcomes. Our objective was to assess the clinical outcomes of patients with CIS and high grade Ta and T1 urothelial bladder cancer treated with RC in relation to time from initial diagnosis to RC.

Methods: We performed a retrospective chart review of 359 consecutive patients from the University of Kansas Medical Center and the Kansas City Veteran’s Administration hospitals who underwent RC for bladder cancer from May 1997 to June 2009. Sixty-nine patients had CIS and/or Ta/T1G3 urothelial bladder cancer who ultimately went on to RC.

Results: To date, mean follow-up after RC was 24 months. Of the 69 patients with high-grade non-muscle invasive bladder cancer, 7 patients had CIS alone, 49 had Ta or T1 alone, 13 had Ta or T1 with CIS. Twenty-nine patients underwent intravesical BCG treatment—for CIS alone, 19 for Ta or T1 alone, 6 for Ta or T1 with CIS. Mean time to RC was 14.6 months; the median was 6.5 months. Patients were divided into two groups based off the median time to RC: group of patients who underwent RC in less than 6.5 months had a mean time to RC of 6.5 months. The group of patients who had RC over 6.5 months had a mean time to RC of 26.2 months. The early cystectomy group had 8 deaths versus 4 in the late cystectomy group (p=0.25).

Conclusions: Optimal management of high-grade non-muscle invasive urothelial carcinoma of the bladder is not clear. Published data appear to support improved survival with early cystectomy. Our experience to date has not shown a significant survival advantage.

Funding: None

Poster# 170

EARLY ONCOLOGIC OUTCOMES FOR ROBOTIC-ASSISTED RADICAL CYSTECTOMY IN UROTHELIAL CARCINOMA PATIENTS

Eric Kauffman, Casey Ng, Ming Ming Lee, Brandon Otto, Gerald Wang and Scherr Douglas
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Presented By: Eric Kauffman

Objectives: Robotic-assisted radical cystectomy (RRC) has emerged as an investigational alternative to open radical cystectomy, the gold-standard treatment for invasive urothelial carcinoma (UC) patients. However, survival outcomes data for RRC are not yet reported. Here we describe oncologic outcomes, including 1- and 2-year survival data, in among the largest reported cohorts of UC patients treated by RRC.
Methods: Clinicopathologic data were prospectively collected for 86 consecutive patients with preoperative UC diagnosis undergoing RRC with a single surgeon (DSS) between 2004-2008. Kaplan-Meier survival analyses were performed, including with subgroup stratification by tumor stage and lymph node (LN) positivity. Multivariate analysis was performed using a Cox proportional hazards model to identify independent predictors of survival.

Results: Patients were relatively old (median age 73.5 years). Most (60%) were overweight or obese, and close to half (40%) had undergone prior abdominal surgery or pelvic radiation. 20% had received neoadjuvant chemotherapy. Extended LN dissection was performed in 84/86 (98%) patients, with a mean of 19.3 nodes retrieved. On final pathology, 31/86 (36%) patients had extravesical disease. Positive surgical margins were observed in 5/86 (6%) patients and significantly correlated with extravesical tumor stage, LN positivity, lymphovascular invasion and perineural invasion. At a mean follow-up of 18.1 months, there were 16 recurrences leading to 9 deaths. In all, 74% of patients were alive without disease, 8% were alive with disease, 10% were dead of disease, and 7% were dead of other causes. Disease-free (DF), cancer-specific (CS) and overall (Ov) survival at 1- and 2-years were 80% and 74%, 89% and 85%, and 83% and 79%, respectively. Patients with either LN-positive or extravesical LN-negative disease had significantly worse DF, CS and Ov survival relative to lower-stage LN-negative patients (41%/57% vs. 96%, 71%/73% vs. 98%, 58%/69% vs. 94%, respectively, at 1 year; p<0.005 in all cases). Total LN count >15 nodes did not predict better survival. On multivariate analysis, lower tumor stage was the most important predictor of survival.

Conclusions: RRC achieves high lymph node yields with an acceptably low positive margin rate. Early oncologic outcomes suggest similar rates of recurrence and mortality after RRC compared to that reported after open radical cystectomy, but long-term follow-up data are needed.

Poster# 171

MUSCLE INVASIVE BLADDER CANCER IN THE ELDERLY: DOES RADICAL CYSTECTOMY IMPROVE CO-MORBIDITY ADJUSTED MORTALITY?

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Washington University, St. Louis, MO
Presented By: Alex Shteynshlyuger

Introduction and Objective: Radical cystectomy is a standard definitive treatment for muscle invasive bladder cancer. Elderly patients with muscle invasive disease often do not undergo cystectomy due to age and co-morbid conditions. Instead, these patients are often treated with less aggressive therapies such as transurethral resection, chemotherapy, and radiation therapy, which are known to be less effective. Herein, we compare the overall survival of elderly patients with muscle invasive bladder cancer who underwent radical cystectomy with similar patients who underwent alternative therapies.

Methods: We performed a retrospective review of patients ≥75 years with ≥cT2 non-metastatic bladder cancer diagnosed from 1986-2007 using the oncology database at Washington University. We recorded age, treatment modality, sex, race, clinical T stage, grade, and co-morbidity status. Overall survival (OS) was defined as the time from date of initial diagnosis to the date of death due to any cause, and survivors were censored at the date of last contact. Distribution of survival in the two treatment groups was described using the Kaplan-Meier product limit method and compared using the log-rank test. A multivariate proportional hazards model was also fitted to adjust for age, race, clinical stage and co-morbidity status. The study was self-funded.

Results: We identified 118 patients who met entry criteria. The median age was 81 years (range 75-94). 63 patients underwent radical cystectomy and 55 patients underwent alternative forms of therapy. The median follow-up was 15.9 months (range 1.2 - 177.3). In univariate analyses, radical cystectomy was associated with improved OS with a median OS of 48.7 months (95% CI 20.6 - 146.9) compared to 15.6 months (95% CI 11.1-24.3) for patients who received alternative therapies. On multivariate analyses controlling for age, clinical stage of tumor, race, and co-morbidity status, patients who underwent radical cystectomy had improved OS compared to patients who received alternative therapies, HR=0.47, 95% CI 0.25-0.89.

Conclusions: Radical cystectomy was associated with improved OS in elderly patients with muscle invasive bladder cancer compared to alternative therapies, when accounting for clinical stage of tumor, race, age, and co-morbidity status. While some of the difference may be due to unmeasured confounding variables, this suggests that elderly patients should be considered for aggressive surgical treatment.
INITIAL REPORT ON THE EFFICACY OF INTRAVESICAL BCG IN A COHORT OF PUERTO RICAN PATIENTS WITH NON-MUSCLE INVASIVE BLADDER CANCER
Ronald Cadillo and Ricardo Sanchez-Ortiz
University of Puerto Rico, San Juan, PR
Presented By: Ronald Cadillo

Introduction: Data from SEER have shown that racial disparities exist in bladder cancer incidence and mortality. The clinical response to intravesical BCG has never been evaluated in Puerto Rican patients, a community with a unique heritage of European, African, and Native American influences.

Methods: In 2005, a prospective database was developed to collect clinical, quality of life, and outcome data for all cancer patients treated at our institution. Herein we describe the characteristics of the patients referred for the management of non-muscle invasive bladder cancer.

Results: The cohort consisted of 58 patients with a mean age of 69 yrs. (range 36 to 95). Clinical stage was low-grade Ta in 9 patients, high-grade Ta in 8 patients, high-grade T1 in 25 patients, high-grade T1 and CIS in 5 patients, and CIS alone in 11 patients. Re-TUR was performed with high-grade Ta or T1 disease. Two patients upstaged to muscle invasion underwent cystectomy and were excluded. BCG was used in 93% (52/56) of patients using the SWOG regimen. The mean time from diagnosis to BCG was 2.8 months. All patients underwent re-biopsy after induction. Dose reduction was required in 5 (9.6%) patients. Of the 52 patients who received BCG, the overall recurrence rate was 28.8% (15/52), of which 40% (6/15) were small or low-grade. Five patients (9.6%) had recurrent CIS or high-grade non-T2 disease after 6 months of BCG; 3 went directly to cystectomy and 2 underwent cystectomy after failing salvage intravesical BCG-IFN. Four patients (7.7%) progressed to T2 disease; 2 underwent cystectomy and 2 chemoradiation due to comorbidities. After a median follow-up of 29 mo. (range 4.5 to 60), the 3-year actuarial progression-free survival was 85%. Of the 52 patients treated with BCG, all remained disease-free except for 1 patient died of metastatic disease after cystectomy, for a 5-year actuarial disease-specific survival of 96.7%.

Conclusions: In this cohort of Puerto Rican patients with non-T2 bladder cancer, BCG was well tolerated with a response rate of 83% (43/52). The progression rate was 7.7% and the rate of recurrence of high-grade non-T2 disease was 9.6%. With the integration of early cystectomy, all but one patient remained disease-free at last follow-up. These data constitute the first reported validation of the use of intravesical BCG in Puerto Rican patients with high-grade non-muscle invasive bladder cancer. Funding: none

ROBOTIC VERSUS OPEN RADICAL CYSTECTOMY IN THE ELDERLY
Casey Ng¹, Eleni Greenwood², Eric Kauffman¹, Ming Ming Lee², Brandon Otto¹, Josh Ehlrich² and Douglas Scherr¹
¹New York Presbyterian Hospital - Cornell Medical College; ²Weill Cornell Medical College, New York, NY
Presented By: Casey Ng

Objective: To compare perioperative outcomes, complication rates and survival data in patients age 80 and over undergoing RC by the open versus robotic approach.

Patients and Methods: Between July 2001 and June 2009, 231 consecutive patients underwent RC by a single surgeon (DSS) for bladder cancer. Of these, 37 patients (28 robotic, 9 open) were age 80 or older. Demographic, perioperative, complication and survival data were collected prospectively, and analyzed using the two-tailed student t-test, Fischer’s exact method and Kaplan-Meier survival algorithms.

Results and Limitations: Patients from both cohorts shared similar BMI, ASA score, history of previous surgery and clinical stage. Patients from the robotic cohort had a higher level of baseline comorbidity as measure by the Charlson index (p = 0.03). They experienced lower blood loss (300 vs 700 mL; p = 0.004), transfusion requirement (0.0 vs 2.0 units; p = 0.006) and shorter hospital stay (6 vs 10 days; p = 0.007). Operative time was similar (5.5 h robotic vs 5.0 h open; p = 0.17). Within 30 days, there was a trend toward a lower complication rate (50% vs 89%; p = 0.06) and a significantly lower complication count per patient (2.5 vs 1.0; p = 0.01) in the robotic cohort compared to the open group. 90-day complication rate was similar (57% robot vs 89% open; p = 0.12). Median number of lymph nodes removed was also similar (16 robot vs 18 open; p = 0.41). Pathologic staging and node status were similar between the two cohorts (p = 1.00). At a median followup of 14.8 and 39.7 months in the robotic and open cohort respectively, no difference was observed between overall survival (p = 0.12) and cancer-specific survival (p = 0.60). This study is limited by the small sample sizes and the non-randomized cohort assignment process.

Conclusions: The robotic approach may offer certain perioperative and post-operative benefits to elderly patients undergoing RC for invasive bladder cancer. Further follow-up in a larger set of patients randomly assigned to cohorts is necessary to evaluate these observations and discern long-term oncologic and survival outcomes.
**Poster Session 2**

**Poster# 174**

**DISCHARGE STATUS AFTER RADICAL CYSTECTOMY: WHAT DETERMINES WHERE OUR PATIENTS GO?**
Monty Aghazadeh, Daniel Barocas, Shady Salem, Peter Clark, Michael Cookson, Rodney Davis, Justin Gregg, CJ Stimson, Joseph Smith and Sam Chang
Vanderbilt University Department of Urologic Surgery, Nashville, TN
Presented By: Monty Aghazadeh

**Objectives:** To describe discharge status of patients after radical cystectomy for bladder cancer and to determine factors affecting discharge status.

**Methods:** The cohort consisted of 445 patients who underwent radical cystectomy for urothelial carcinoma with or without other histologic elements between January 2004 and December 2007. Five patients with incomplete data were excluded. Patients were grouped based on discharge status into: Home under self-care [Home alone]; Home with home health services [Home with services]; Subacute care facility/nursing home/rehabilitation facility/skilled nursing facility [Facility]; or Hospice/in-hospital mortality [Mortality]. The Home alone, Home with services, and Facility groups were compared with respect to clinical, perioperative and pathologic variables using Kruskal-Wallis tests and Fisher exact tests where appropriate. A multinomial logistic regression model was fit to identify variables associated with discharge status. We also tested the association between discharge status and readmission rate and 90 day mortality.

**Results:** 250 of 440 patients (56.8%) were discharged to Home alone; 145 (32.9%) were discharged home with services; 39 (8.9%) were discharged to a Facility; 6 (1.4%) were Mortalities. On univariate analysis, patients discharged to Home with services or to a Facility were older, more likely to live alone, be unmarried (single, divorced or widowed), have poor preoperative exercise tolerance (< 3 METs), have undergone a perioperative transfusion, have a positive surgical margin, have a longer hospital stay and have a higher rate of complications. Older age, lower preoperative albumin, being unmarried, and higher CCI were predictors of Home with services on multivariate analysis. Older age, poor preoperative exercise tolerance, positive surgical margins and longer hospital stay predicted discharge to a Facility. Patients who were discharged to a Facility were more likely to suffer mortality within 90 days of surgery than patients who went home independently or with services (20.5% vs. 4.0%, 4.8%, p<0.001). There was no difference in the likelihood of readmission.

**Conclusion:** Sociodemographic factors, preoperative performance status and comorbidities, and perioperative factors contribute to the discharge decision after radical cystectomy. Some subgroups can be predicted to have increased post-operative care needs and may be appropriate targets for disposition planning preoperatively.

**Poster# 175**

**EFFECTS OF PRE-OPERATIVE NUTRITIONAL DEFICIENCY ON 90-DAY MORTALITY AND OVERALL SURVIVAL IN PATIENTS UNDERGOING RADICAL CYSTECTOMY FOR BLADDER CANCER**
Justin Gregg, Shady Salem, Sam Chang, Peter Clark, Michael Cookson, Rodney Davis, C.J. Stimson, Monty Aghazadeh, Joseph Smith and Daniel Barocas
Vanderbilt University Medical Center, Department of Urologic Surgery, Nashville, TN
Presented By: Justin Gregg

**Introduction and Objectives:** Poor preoperative nutritional status may be a risk factor for peri-operative mortality and poor overall survival after radical cystectomy (RC) for bladder cancer. We evaluated the effect of preoperative nutritional deficiency (ND) on peri-operative mortality and overall survival.

**Methods:** 789 consecutive patients underwent RC for urothelial carcinoma (UC) between January 2000 and December 2007. Patients with preoperative albumin <3.5, BMI <18.5 or pre-surgical weight loss >5% of body weight were considered ND. 525/789 (66.5%) had all data points documented. Primary outcomes were 90-day mortality and overall survival. Survival rates were estimated using Kaplan-Meier analysis and compared using the log-rank test. Cox proportion hazards models were used for multivariate survival analysis.

**Results:** Mean age was 68.4 (SD 10.5), 79.4% were male and 4.3% were non-white. 105 of 525 patients (20%) met criteria for ND (71 [13.5%] weight loss; 17 [3.3%] low BMI; 32 [6.3%] low albumin). 90-day mortality was 7.1% overall (37 deaths); 15.4% in patients with ND and 5% in the others, p<0.01. Kaplan-Meier estimated 90-day survival was 83.3% (95% CI [74.1, 89.4]) for ND patients vs. 94.8% (92.1, 96.6) for others, p<0.01. ND was a strong predictor of death within 90 days on Cox proportional hazard model (HR 3.30, 95% CI [1.56, 6.95], p<0.01), controlling for age-adjusted Charlson comorbidity index (CC1), lymph node density, organ-confined vs. extravesical disease, peri-operative complications and peri-operative transfusion. Median follow-up of patients alive at last visit was 16.3 months and 181 (34.6%) patients had
died. Overall survival at 3 years was 35.6% (24.2, 47.2) for patients with ND and 57.7% (51.2, 63.7) for other patients, p<0.01. On multivariate analysis, patients with ND had significantly higher risk of death (HR 1.64, 95% CI [1.13, 2.38], p<0.01), after controlling for age, CCI, race, sex, smoking history, preoperative hematocrit, estimated blood loss, pathological grade, tumor stage, histology, lymph node density and transfusion.

**Conclusions:** Nutritional deficiency, as measured by preoperative weight loss, BMI and serum albumin, is a strong predictor of 90-day mortality and poor overall survival. Prospective studies are needed to demonstrate the most appropriate markers and indices of preoperative nutritional status and whether nutritional intervention can alter the poor prognosis for patients with nutritional deficiencies.

**Poster# 176**

**PERIOPERATIVE BLOOD TRANSFUSION INCREASES THE RISK OF OVERALL MORTALITY IN PATIENTS UNDERGOING RADICAL CYSTECTOMY FOR BLADDER**

Todd Morgan, Daniel Barocas, Sam Chang, Peter Clark, Shady Salem, Joseph Smith and Michael Cookson  
Vanderbilt University Department of Urologic Surgery, Nashville, TN

Presented By: Todd Morgan

**Introduction and Objectives:** Transfusion of blood products is known to have an immunosuppressive effect, and the use of perioperative blood transfusions (PBT) may impair the immune surveillance of cancer cells. In fact, PBT in patients undergoing surgery for colon cancer is known to carry a significant recurrence and mortality risk. We therefore sought to evaluate whether PBT has any effect on overall survival following radical cystectomy (RC) among patients with bladder cancer.

**Methods:** The medical records of 789 consecutive patients undergoing RC from 2000-2007 for urothelial carcinoma of the bladder with or without other histologic elements were reviewed. PBT was defined as transfusion of packed red blood cells during cystectomy or within the hospital stay following surgery, and the primary outcome measure was overall survival. Clinical and pathologic variables were compared using chi-squared tests, and Cox multivariate survival analysis was performed. Mortality rates were estimated using the Kaplan-Meier product limit method.

**Results:** A total of 321 patients (40.2%) underwent PBT of an average of 3.1 units of packed red blood cells. Median follow-up was 16.1 months (1-91.5 months), and there have been 310 deaths (39.3%). In the Kaplan-Meier analysis (Figure), PBT was associated with a significantly increased mortality rate (p<0.0001). Controlling for age-adjusted Charleson comorbidity index, node density, stage, grade, margin status, preoperative hematocrit, and blood loss, transfusion was associated with a significant mortality risk (HR 1.46, CI 1.06-2.00, p=0.02). The increased mortality risk associated with each transfused unit was 15% (HR 1.15, 1.06-1.24, p=0.04).

**Conclusions:** These data suggest that PBT carries significant mortality risk, independent of clinicopathologic factors. This effect occurred regardless of blood loss and in a dose-dependent fashion. The increased mortality risk shown here suggests that stringent requirements should be utilized for PBT in patients undergoing RC. Strategies to further reduce the need for transfusions should be actively pursued.
**Introduction and Objective:**
The advent of intravesical immunotherapy therapy has significantly improved outcome in high-risk bladder tumors, but the natural history of these tumors following immunotherapy failure has not been examined. We report our institution’s experience with bacillus Calmette-Guerin (BCG) alone and combined with interferon-α2B (INF) in regards to bladder cancer recurrence, disease progression, eventual cystectomy and survival for a cohort of patients receiving this treatment strategy following initial BCG failure.

**Methods:**
We identified a consecutive series of 139 patients undergoing intravesical instillations of BCG alone (n=114) or with interferon-α2B (n=25) performed at Brigham and Women’s Hospital, Boston between 2002 and 2007. All patients previously received an initial six-week course of BCG therapy and subsequently had BCG failure on follow-up cystoscopy. Time to cancer recurrence, progression of disease, eventual cystectomy and mortality were analyzed.

**Results:**
At a median follow-up of 64.7 months from initial BCG administration, 84% treated with BCG + INF had disease recurrence. The average time to recurrence was less than one year, and 63% of these patients had recurrence on the first post-treatment biopsy. Among patients with a positive first biopsy, 52% had disease progression on initial surveillance. Overall, disease progression was seen in 48% of patient receiving BCG + INF therapy, and 28% of all patients eventually underwent radical cystectomy. All outcomes occurred more frequently in patients undergoing combination intravesical therapy compared with BCG alone. Only one patient died during this period.

**Conclusions:**
Combination BCG + INF immunotherapy may have a short-term therapeutic benefit on cancer recurrence, but we did not find evidence that it significantly decreases disease progression. Patients undergoing salvage intravesical interferon at our institution have greater than a 50% chance of recurrence and progression, and over one-quarter eventually proceed to radical cystectomy. Randomized trials are needed to clarify the issues present in these findings and to determine the appropriate role for concomitant interferon therapy in BCG failure.
INTRA VESICAL BACILLUS CALMETTE-GUERIN (BCG) AND INTERFERON ALPHA-2B THERAPY FOR PATIENTS WITH NON-MUSCLE INVASIVE BLADDER CANCER (NMIBC) WHO HAVE PACEMAKERS OR ARTIFICIAL HEART VALVES (AHVS)

Henry M. Rosevear, Andrew J. Lightfoot and Michael A. O’Donnell
University of Iowa, Iowa City, IA
Presented By: Henry M. Rosevear

Introduction and Objectives: The presence of pacemakers or AHVS has been considered a contraindication for intravesical BCG treatment because of the risk of seeding the hardware or developing infective endocarditis (IE). Recently, the American Heart Association’s Taskforce on the Prevention of IE changed its recommendations to no longer recommend preoperative antibiotics for most procedures of the genitourinary tract, citing no published data linking IE and procedures of the genitourinary tract. A caveat remained that some patients, including those with pacemakers and AHVS, may be at increased risk. We reviewed the outcomes of NMIBC patients with pacemakers or AHVS undergoing combination BCG plus interferon alpha-2B therapy.

Methods: Over two years, 1106 post-resection NMIBC patients were enrolled in a national multicenter phase II trial of combination BCG plus interferon alpha-2B therapy. 93 patients had pacemakers and 13 had AHVS. Patients completed a daily questionnaire regarding side effects after each intravesical treatment, including cystitis, hematuria, flu-like symptoms, fever/chills, arthralgias, and any other concerns.

Results: No patient with a pacemaker or an AHVS developed IE. One patient with a pacemaker required cessation of treatment upon development of fever >102.5 after his sixth treatment, which resolved within 24 hours and no sequelae. Overall, 13 of 106 (12%) patients with pacemakers or AHVS stopped treatment compared to 127 of 1000 (13%) of the remaining cohort for other reasons including patient preference or non-life threatening treatment toxicity. Patients with pacemakers or AHVS had a similar overall toxicity profile compared to those patients without pacemakers or AHVS.

Conclusions: Patients with pacemakers or AHVS were no more likely to stop treatment due to side effects than the general population. Given this treatment toxicity profile, we recommend that patients with pacemakers and AHVS not be excluded from combination intravesical BCG plus interferon alpha-2B therapy for NMIBC.

Reference
Poster# 180

CANCER RECURRENCE DISPARITIES AMONG RACIAL AND GENDER GROUPS WITH NON-MUSCLE INVASIVE BLADDER CANCER (NMIBC) AFTER INTRAVESICAL BACILLUS CALMETTE-GUERIN (BCG) AND INTERFERON ALPHA-2B THERAPY

Henry M. Rosevear, Andrew J. Lightfoot and Michael A. O’Donnell
University of Iowa, Iowa City, IA
Presented By: Henry M. Rosevear

Introduction and Objectives: Variation in diagnosis, treatment and cancer outcomes between genders and between African-Americans (AA) and Caucasians has been well documented. Recent evidence has suggested that disparities in racial and gender bladder cancer survival are not fully explained by late stage presentation and undertreatment.1 We sought to identify differences in NMIBC recurrence rates based on race or gender in a population undergoing BCG plus interferon alpha-2B therapy.

Methods: Over 2 years, 1106 post-resection NMIBC patients were enrolled in a national multicenter phase II trial of BCG plus interferon alpha-2B therapy. 975 were either Caucasian or AA. Treatment induction was tailored according to prior BCG treatments. The endpoint of tumor recurrence was defined as visible tumor on cystoscopy (unless histologically confirmed as benign), definitive positive cytology, or biopsy proven disease even with a negative cystoscopy. Time to recurrence was indexed to the first intravesical treatment date.

Results: Of the 975 patients, 721 (74%) were Caucasian males, 230 (23%) were Caucasian females, 15 (2%) were AA males and 9 (1%) were AA females. Given that 1 of 7 Americans are AA and that Caucasians are 4 times as likely to develop NMIBC, our cohort roughly approximates the general NMIBC population. No differences were noted in NMIBC recurrence between either races or genders. AA females appeared more likely to develop NMIBC recurrences than any other group, with only 20% remaining recurrence-free after 35 months compared to 47% for Caucasian females, 48% for Caucasians males and 59% for AA males. There was no difference in group age, grade, stage, BCG failure status or tumor size, though AA women were more likely to present with multiple tumors.

Conclusions: AA women may be more likely to develop recurrences of NMIBC after BCG plus interferon alpha-2B treatments than Caucasians or AA males and may require more diligent monitoring to ensure early detection, though a larger study is required.

Reference


Poster# 181

POSTOPERATIVE ADMINISTRATION OF CHEMOTHERAPY FOLLOWING TRANSURETHRAL RESECTION OF BLADDER TUMOR (TURBT) FOR NON-MUSCLE INVASIVE BLADDER CANCER (NMIBC)

Andrew J. Lightfoot, Henry M. Rosevear and Michael A. O’Donnell
University of Iowa, Iowa City, IA
Presented By: Andrew J. Lightfoot

Introduction and Objectives: Current meta-analyses support the use of single-agent intravesical chemotherapy in the immediate postoperative period to decrease the risk of recurrence following an uncomplicated TURBT for NMIBC. Patients shown to benefit most have Ta, small volume, and low-grade disease. We investigated the practice patterns of urologists with regard to the use of post-TURBT chemotherapy administration.

Methods: Over a 2-year period, 1106 post-resection NMIBC patients were enrolled in a national multicenter phase II trial of combination BCG plus interferon alpha-2B therapy. Treatment induction was tailored according to prior BCG treatments. The endpoint of tumor recurrence was defined as visible tumor on surveillance cystoscopy (unless histologically confirmed as benign), definitive positive cytology, or biopsy proven disease even with a negative cystoscopy. Time to recurrence was indexed to the first intravesical treatment date.

Results: Of the 1106 enrolled, 983 (89%) had information about the use of post-TURBT instillation of chemotherapy. Of the 983, 40 (4%) received post-TURBT chemotherapy. There was no statistical significance between those who received chemotherapy and those who did not regarding age, gender, stage, grade, tumor size, or history of BCG failure. Interestingly, patients who received intravesical chemotherapy were significantly more likely to have multiple tumors (78% had >1) than the non-treated group (45% had >1) p<0.001. Of the group treated with intravesical chemotherapy, 27 of 33 (82%) had intermediate-high grade disease, 16 of 40 (40%) had >Ta disease, 21 of 32 (66%) had tumor burden >1cm, and 31 of 36 (86%) had >2 tumors.

Conclusions: Urologic practice patterns between 1999 and 2001 did not commonly involve administration of intravesical chemotherapy following TURBT for NMIBC. Patients who did receive therapy were typically not ideal candidates due to increased grade, tumor burden and multicentricity.
MULTI-INSTITUTIONAL ANALYSIS OF ROBOTIC RADICAL CYSTECTOMY FOR BLADDER CANCER: PERI-OPERATIVE OUTCOMES IN 227 PATIENTS
Matthew Raynor¹, Angela Smith¹, Christopher Amling², J. Erik Busby³, Erik Castle⁴, Rodney Davis⁵, Raju Thomas⁶, Matthew Nielsen¹, Eric Wallen¹ and Raj Pruthi¹
¹The University of North Carolina at Chapel Hill, Chapel Hill, NC; ²Oregon Health Sciences University; ³University of Alabama at Birmingham; ⁴Mayo Clinic Scottsdale; ⁵Vanderbilt University; ⁶Tulane University
Presented By: Matthew Raynor

Purpose: Radical cystectomy remains one of the most effective treatments for patients with localized, invasive bladder cancer. Recently, some surgeons have begun to describe single institution case series with less-invasive surgical approaches to this disease such as laparoscopic or robotic-assisted techniques. We report on a multi-institutional, multi-surgeon experience with robotic-assisted laparoscopic radical cystectomy with regard to operative and pathologic outcomes and complications to evaluate the feasibility and reproducibility of this technique in a large cohort of patients with bladder cancer.

Methods: 227 patients (178 males and 49 females) underwent a robotic cystectomy and urinary diversion at one of four institutions. Operative outcomes, pathological results, and complications of this combined case series are herein reported.

Results: Mean age of this cohort was 67.1 years (range 33-86 years) with a mean ASA score of 2.7 (range 2-4). 168 patients (74%) underwent ileal conduit diversion, 58 (26%) underwent an orthotopic ileal neobladder, and 1 patient (<1%) required no diversion (ESRD). The urinary diversion was performed extracorporeally in 97% cases with 7 patients (3%) undergoing an intracorporeal diversion. Mean OR time of all patients was 5.4 hours and mean surgical blood loss was 256 ml. On surgical pathology, 128 (56%) patients had <=pT2 disease, 46 (20%) pT3/T4 disease, and 53 (23%) N+ disease. The mean number of lymph nodes removed was 18 (range 3 to 52). There was a positive surgical margin in 4 cases (1.7%) –all with pT3-4 disease. Mean (median) time to discharge was 5.5 days (5.0 days) with 157 patients (69%) discharged on POD#5 or sooner. Sixty-eight patients (30%) experienced complications with 7% having Clavien grade 3 or higher.

Conclusions: A combined multi-institutional experience with robotic radical cystectomy, bilateral pelvic lymphadenectomy, and urinary diversion appears to demonstrate acceptable operative and pathologic outcomes thus helping to validate the previously reported single institution case series. Ultimately, oncologic follow-up these patients will remain as the most important measure of therapeutic success.

FAST TRACK PROGRAM IN PATIENTS UNDERGOING RADICAL CYSTECTOMY: EXPERIENCE IN 362 CONSECUTIVE CASES
Stephen McKim, Eugene Simopoulos, Matthew Nielsen, Eric Wallen and Raj Pruthi
The University of North Carolina at Chapel Hill, Chapel Hill, NC
Presented By: Stephen McKim

Purpose: This paper analyzes our current perioperative management of patients undergoing cystectomy and urinary diversion utilizing advancements in perioperative care to allow for early institution of an oral diet, early hospital discharge.

Methods: 362 consecutive patients underwent a radical cystectomy and urinary diversion with curative intent. Each underwent a peri-operative care plan (“fast track” program). Throughout our experience evidence-based modifications to this program were instituted. We analyzed the impact of these modifications and report the outcomes with the most recent 100 cases in which no further modification has been used.
Results: Mean age is 66.3 years with 44% of the patients being over the age of 70 and 12% over age 80. We have found no detrimental effects to immediate removal of the OG tube at the end of the procedure, but found a beneficial effect of empiric metoclopramide use with lower rates of nausea and vomiting (3% vs. 12%; p = 0.011). Peri-operative antibiotic coverage has been reduced to 24 hours as per AUA guidelines. Gum chewing has also been shown to be of benefit with regard to a more rapid recovery of bowel function (time to BM: 3.2 vs. 3.9 days; p < 0.001). The use of non-narcotic analgesics (e.g. ketrolac) has also been central in the pathway. Finally, the early institution of an oral diet has been an original and central component to our fast track program. The results in our most recent 100 patients are shown in the table.

Conclusions: A successful application of a fast track program has been applied to our patients undergoing radical cystectomy and urinary diversion with the potential to utilize evidence-based modifications to reduce morbidity and improve recovery.

Post# 184

USE AND OUTCOMES OF ADJUVANT CHEMOTHERAPY IN PT3-4 OR NODE POSITIVE BLADDER CANCER: ANALYSIS OF A MODERN SURGICAL COHORT
Stephen McKim, Eugene Simopoulos, ELizabeth Dray, Angela Smith, Matthew Nielsen, William Kim, Eric Wallen and Raj Pruthi
The University of North Carolina at Chapel Hill, Chapel Hill, NC
Presented By: Stephen McKim

Purpose: Some controversy exists as to the potential benefits of adjuvant chemotherapy for bladder cancer with regard to disease recurrence and survival. We sought to evaluate the short-term oncologic outcomes of adjuvant systemic chemotherapy in a modern cohort of patients undergoing radical cystectomy with high-risk features on surgical pathology

Methods: 286 consecutive patients underwent radical cystectomy and urinary diversion with curative intent (2005-2008). Of these patients, 84 had either pathologic stage T3-4 and/or N+ disease and did not receive any prior (neo-adjuvant) chemotherapy. Seventy-five patients had at least 1 year of complete clinical follow-up resulting in the study group. We analyzed the clinical and demographic features as well as 1-year recurrence rates of those patients who received versus did not receive adjuvant chemotherapy. Of note, all such patients with pT3-4 or N+ disease meet and are counseled by dedicated GU medical oncologists on the risks and potential benefits of adjuvant chemotherapy at 4 weeks post-operatively with the decision primarily based on pt preference, pathology, co-morbidities/performance status.

Results: Of the 75 patients, 43 underwent adjuvant chemo and 32 did not. Those undergoing adjuvant chemo were significantly younger (64.1 vs. 72.9 years; p = < 0.001) and were more often female (53% vs. 31%; p = 0.038), but were not otherwise different with regard to race, BMI, pre-op renal function, or with regard to peri-operative variables (EBL, LOS). The table shows the 1-year recurrence rates for each group and sub-stratified by surgical pathology. Note the significantly higher proportion of patients in the adjuvant chemo group who were N+ perhaps reflecting a treatment bias.

Conclusions: This retrospective analysis seems to show a potential short-term benefit of adjuvant chemotherapy for high-risk patients. However, significant selection biases are likely to account for some of the differences in recurrence rates.
Poster# 185

IMPACT OF SUB-STAGE ON THE CLINICAL OUTCOME OF PT1 BLADDER CANCER
Bas Van Rhijn¹, Theo van der Kwast², Rati Vajpeyi¹, David Kakiashvili¹, Sultan Alkhateeb¹, Madelon van der Aa³, Chris Bangma³, Neil Fleshner¹, Michael Jewett¹ and Alex Zlotta⁴
¹Urology, UHN, Toronto, Ontario, Canada; ²Pathology, UHN, Toronto, Ontario, Canada; ³Urology, Erasmus MC, Rotterdam, The Netherlands; ⁴Urology, UHN & Mount Sinai hospital, Toronto, Ontario, Canada
Presented By: Bas Van Rhijn

Objective: Management of pT1 bladder cancer is controversial. We evaluated the impact of sub-stage on the clinical outcome of a large series of primary pT1 bladder cancer patients treated with BCG.

Material and Methods: The slides of 134 primary (first diagnosis) bladder tumors from two university hospitals (Rotterdam, the Netherlands n=60 and Toronto, Canada n=74) were reviewed and the pT1 diagnosis was confirmed. Sub-staging was done in two separate rounds, using pT1 micro-invasive (pT1m) and pT1 extensive-invasive (pT1e) [1] and according to invasion of the muscularis mucosae (pT1a/pT1b/pT1c) [2]. If the muscularis mucosae was not present at the invasion front, the case was assigned to pT1a or pT1c based on the extent of invasion into the lamina propria. All 134 patients were initially managed conservatively (BCG). Grade review was done according the WHO 1973 and 2004 classifications systems. Multivariate analyses for progression and disease specific survival were performed with sub-stage, size, hospital, CIS, gender, age, grade-1973 and grade-2004 as variables.

Results: Mean follow-up was 6.8 years (median 6.4 yrs; range 0.3-21.6 yrs), 25/134 patients were female. Mean age was 68.5 years. CIS was found in 48 (36%) cases. Forty-two patients remained recurrence-free (31%). Progression to pT2 or metastasis was observed in 40 (30%) patients and 19 patients (14%) died of their disease. The muscularis mucosae was not present at the invasion front in 50 (37%) of tumors. The slides were sub-staged as follows: 40 pT1m and 94 pT1e; 81 pT1a, 18 pT1b and 35 pT1c. Grade review resulted in 56 G2 and 78 G3 lesions (WHO1973 system) and 26 low-grade and 108 high-grade lesions according to the WHO2004 system. In multivariate analyses, sub-staging using pT1m and pT1e was significant for progression (P=0.001) and disease specific survival (P=0.021), whereas sub-stage according to pT1a/b/c was not significant in any multivariate analysis. Female gender (P=0.006) and CIS (P=0.035) were also significant predictors for progression in multivariate analysis.

Conclusions: Sub-stage (pT1m and pT1e) was possible in all the cases and very predictive of pT1 bladder cancer behaviour. Future studies may lead to the incorporation of sub-stage in the TNM classification system for urinary bladder cancer.

References:

Poster# 186

THE IMPACT OF RADICAL CYSTECTOMY ON ELIGIBILITY TO RECEIVE PERIOPERATIVE CISPLATIN-BASED CHEMOTHERAPY BASED ON RENAL FUNCTION STATUS

Poster Session 2
Introduction and Objectives: Perioperative chemotherapy has been shown to confer a survival benefit in patients with high-risk invasive bladder cancer. One argument in favor of neoadjuvant treatment has been the potential for radical cystectomy to preclude receipt of chemotherapy postoperatively. Nevertheless, only a minority of patients receives systemic therapy before surgery. We evaluated the proportion of patients who would be eligible to receive cisplatin-based chemotherapy before and after cystectomy based on renal function.

Methods: We reviewed 451 consecutive patients who underwent radical cystectomy at our institution from 2000-2009 to identify 194 patients with cT2-T4 urothelial carcinoma. Serum creatinine immediately before and nadir serum creatinine 1-3 months after cystectomy were used to calculate creatinine clearance (CrCl) and glomerular filtration rate (GFR). A cutoff CrCl ≥ 60 mL/min or GFR ≥ 60 mL/min/1.73 m2 was used to determine eligibility for chemotherapy.

Results: Median age was 70.5 years (IQR 63,77) and median preoperative serum creatinine was 0.90 mg/dL (IQR 0.5,1.3). Of the overall cohort of patients, 41% and 33% had inadequate renal function to receive chemotherapy before surgery based on CrCl and GFR, respectively (Table). The frequency of inadequate baseline renal function increased significantly with patient age, from 12% in patients <65 to 54% in patients >65 (p<0.0001). Radical cystectomy did not adversely impact the proportion of patients eligible to receive chemotherapy based on renal function, regardless of patient age. In fact, after controlling for preoperative renal function, gender, race, and diversion, patients <65 were found to have a 14% increase in CrCl (p<0.001) and an 11% increase in GFR (p=0.004) after surgery.

Conclusions: Approximately 40% of patients who would be eligible for neoadjuvant chemotherapy based on pathologic criteria cannot receive cisplatin due to poor baseline renal function. Importantly, surgery does not adversely impact patients’ eligibility to receive chemotherapy based on renal function status. Development of effective non-cisplatin containing regimens is therefore required to improve survival, particularly in older patients.

Poster# 187

**DOES PRIOR ROBOT-ASSISTED PROSTATECTOMY EXPERIENCE AFFECT OUTCOMES AT ROBOT-ASSISTED RADICAL CYSTECTOMY? RESULTS FROM THE INTERNATIONAL ROBOTIC CYSTECTOMY CONSORTIUM**

Matthew Hayn¹, Nicholas Hellenthal², Abid Hussain², Paul Andrews³, Paul Carpentier³, Erik Castle³, Prokar Dasgupta³, Rodney Davis⁴, Shamim Khan⁵, Adam Kibe⁶, Hyung Kim⁷, Murugesan Manoharan⁸, Mani Menon⁹, Alex Mottrie⁴, David Ornstein¹⁰, James Peabody¹¹, Raj Pruthi¹¹, Joan Redorta¹², Lee Richstone¹³, Francis Schanne¹⁴, Hans Stricker¹⁵, Peter Wiklund¹⁶, Greg Wilding² and Khurshid Guru²

¹Roswell Park Cancer Institute, Buffalo, NY; ²Roswell Park Cancer Institute, Buffalo, NY; ³Mayo Clinic, Scottsdale, AZ; ⁴Onze-Lieve-Vrouw Ziekenhuis, Aalst, Belgium; ⁵Guy’s Hospital, London, England; ⁶Tulane University, New Orleans, LA; ⁷Washington University, St. Louis, MO; ⁸University of Miami, Miami, FL; ⁹Henry Ford Health System, Detroit, MI; ¹⁰Vanguard Urologic Institute, Houston, TX; ¹¹University of North Carolina, Chapel Hill, NC; ¹²Fundacio Puigvert, Barcelona, Spain; ¹³Arthur Smith Institute for Urology, Long Island, NY; ¹⁴Urologic Surgical Associates of Delaware, Wilmington, DE; ¹⁵Karolinska University, Stockholm, Sweden

Presented By: Matthew Hayn
Background: Little is known regarding the impact of prior robotic surgical experience on the implementation and execution of robot-assisted radical cystectomy (RARC). The purpose of this study was to evaluate the effect of prior robot-assisted radical prostatectomy (RARP) case volume on outcomes at the time of RARC.

Methods: Utilizing the International Robotic Cystectomy Consortium (IRCC) database, we identified 496 patients who underwent RARC by 21 surgeons at 14 institutions from 2003-2009. We divided the surgeons into 4 groups based on previous RARP experience (≤50 cases, 51-100 cases, 101-150 cases, and more than 150 cases). We then compared intraoperative time and blood loss, lymph node counts, and surgical margin status between the groups using chi-squared analysis.

Results: Mean intraoperative time was 386 minutes (range 65-827 minutes). Decreased operative time was significantly associated with prior RARP experience (p<0.001). Mean estimated blood loss was 408 milliliters (range 25-3500 mL). Decreased blood loss was significantly associated with prior RARP experience (p<0.001). Mean lymph node count was 17.8 nodes (range 0-68 nodes). Seven patients (0.1%) had 0 lymph nodes sampled. Increased lymph node count was significantly associated with prior RARP experience (p<0.001). Finally, 34 of the 482 patients (7.0%) had a positive surgical margin. Surgical margin status was not significantly associated with prior RARP experience (p=0.089).

Conclusions: Prior robot-assisted radical prostatectomy case volume significantly impacts operative time, blood loss, and lymph node counts at robot-assisted radical cystectomy. Prior RARP experience, however, does not impact surgical margin status.

Poster# 188

ROBOT ASSISTED LAPAROSCOPIC PELVIC LYMPHADENECTOMY AT THE TIME OF RADICAL CYSTECTOMY RIVALS THAT OF OPEN SURGERY: SINGLE INSTITUTION REPORT
Kyle Richards, Ashok Hemal, Karim Kader and Joseph Pettus
Wake Forest University Baptist Medical Center Department of Urology, Winston-Salem, NC
Presented By: Kyle Richards

Objective: Currently there is controversy whether robot assisted laparoscopic PLND (RALPLND) at radical cystectomy is technically feasible and oncologically equivalent to PLND at the time of open radical cystectomy (ORC). Until robust long-term survival data are available, oncologic efficacy may be estimated with surrogate markers such as margin status and lymph node yield. The purpose of this study is to analyze the PLND and margin status using a standard technique in the first 35 patients undergoing robot assisted radical cystectomy (RARC) at our institution while establishing a robotics program and compare the results to the past 35 ORC performed at our institution.

Materials and Methods: After obtaining Institutional Review Board approval, we reviewed the clinical and pathologic data from 70 consecutive patients with clinically localized bladder cancer that underwent radical cystectomy with PLND from April 2007- June 2009. Thirty-five operations were performed open and 35 utilized the da Vinci robotic systemTM. The PLND was performed in all patients using either a modified standard or extended PLND template.

Results: There was no significant difference between the ORC and RARC group in regards to patient demographics, American Society of Anesthesiologists class, prior abdominal surgery history, tumor stage (43% ORC and 40% RARC having pT3/pT4 disease), and node status (29% N+ in each group). The median total lymph node yield was similar with 15 (IQR 11, 22) in the ORC group and 16 (IQR 11, 24) in the RARC group (p-value 0.5). One patient that underwent RARC had a positive margin compared to three patients in the ORC group.

Conclusions: The initial 35 RARC with PLND performed at our institution compared to the last 35 ORC resulted in equivalent lymph node yield and similar rates of positive margins. RARC with PLND is feasible, safe, and effective when performed at a high volume center by an experienced team.
**Poster Session 2**

**Poster# 189**

**COMBINED SPINAL/EPIDURAL ANESTHESIA IN PULMONARY CRIPPLES DURING RADICAL CYSTOPROSTATECTOMY: PILOT STUDY**

Jennifer Linehan and Jonathan Walker  
University of Arizona, Tucson, AZ  
Presented By: Jennifer Linehan

**Introduction and Objective:** Cigarette smoking increases the risk of transitional cell carcinoma (TCC) fourfold and is associated with 50-66% of TCC in men and 25% in women. Smoking is also linked with development of chronic obstructive pulmonary disease (COPD). Often patients with TCC will often have COPD due to tobacco use. They are denied surgery due to the greater risk of general anesthesia, ventilator dependence, and mortality. Radical cystectomy alone can provide a 5-year overall survival rate ranging between 48% and 58%. If left untreated more than 85% of patients die within 2 years of diagnosis. Since postoperative pulmonary complications occur 9.5 times more frequently in patients with COPD, surgery under spinal/epidural anesthesia alone was pursued. This is a pilot study of three patients who each had radical cystoprostatectomy with pelvic lymph node dissection and urinary diversion with non-general anesthesia.

**Methods:** Average age was 70 (60 to 80) years old. All three had high-grade TCC. One patient with recurrent TCC was treated with external beam radiation therapy and chemotherapy secondary to his high peri-operative pulmonary risk. Another patient received neoadjuvant chemotherapy. All three patients had severe COPD and two were oxygen dependent. The average FEV1 was 29% (17% to 41%) of predicted value. Each patient was counseled on their high risk of ventilator dependence with general anesthesia. Indications for intervention were: high-grade TCC, recurrent gross hematuria, clot retention and anemia requiring transfusion and bilateral ureteral obstruction.

**Results:** Each of the patients tolerated the surgery well with no intra-operative discomfort. Average blood loss was 750cc and operative time was ~3.5 hours. None of the patients needed to be converted to general anesthesia during the procedure or re-intubated in the peri-operative period. Pulmonary complications included pneumonia in one patient. The three patients were discharged home without worsening in their pulmonary function.

**Conclusion:** This pilot study demonstrates the feasibility of combined spinal/epidural without the need for general anesthesia during radical cystectomy in patients with severe COPD. These patients would otherwise have been denied surgical therapy. To our knowledge this is the first series describing the use of non-general anesthesia during cystectomy for patient with severe COPD. No funding was used for this research.

**Poster# 190**

**LYMPHADENECTOMY AT THE TIME OF ROBOT-ASSISTED RADICAL CYSTECTOMY: RESULTS FROM THE INTERNATIONAL ROBOTIC CYSTECTOMY CONSORTIUM**

Nicholas Hellenthal¹, Abid Hussain¹, Paul Andrews², Paul Carpentier³, Erik Castle², Prokar Dasgupta³, Rodney Davis⁵, Shamim Khan⁴, Adam Kibel⁶, Hyung Kim³, Murugesan Manoharan⁷, Mani Menon⁸, Alex Mottrie³, David Ornstein⁹, James Peabody⁸, Raj Pruthi¹°, Joan Redorta¹¹, Lee Richstone¹², Francis Schanne¹³, Hans Stricker⁴, Peter Wiklund¹⁴, Greg Wilding¹ and Khurshid Guru¹  
¹Roswell Park Cancer Institute, Buffalo, NY; ²Mayo Clinic, Scottsdale, AZ; ³Onze-Lieve-Vrouw Ziekenhuis, Aalst, Belgium; ⁴Guy’s Hospital, London, England; ⁵Tulane University, New Orleans, LA; ⁶Washington University, St. Louis, MO; ⁷University of Miami, Miami, FL; ⁸Henry Ford Health System, Detroit, MI; ⁹Vanguard Urologic Institute, Houston, TX; ¹°University of North Carolina, Chapel Hill, NC; ¹¹Fundacio Puigvert, Barcelona, Spain; ¹²Arthur Smith Institute for Urology, Long Island, NY; ¹³Urologic Surgical Associates of Delaware, Wilmington, DE; ¹⁴Karolinska University, Stockholm, Sweden  
Presented By: Nicholas Hellenthal
Background: Studies suggest that a properly performed lymphadenectomy at the time of radical cystectomy not only proffers adequate staging but may also confer a survival benefit. The purpose of this study was to evaluate the incidence of and predictors for lymphadenectomy in patients undergoing robot assisted radical cystectomy (RARC) for bladder cancer.

Methods: Utilizing the International Robotic Cystectomy Consortium (IRCC) database, we identified 496 patients who underwent RARC at 14 institutions from 2003-2009. After stratification by age group, gender, pathologic T stage, nodal status, sequential case number, institutional volume, and surgeon volume we performed logistic regression to correlate variables to the likelihood of undergoing lymphadenectomy (defined as 10 or more nodes removed).

Results: Four hundred fourteen of the 496 patients (83.5%) underwent lymphadenectomy at the time of RARC. A mean of 17.8 lymph nodes were examined (range 0-68 nodes). Tumor stage, sequential case number, institution volume, and surgeon volume were significantly associated with the likelihood of undergoing lymphadenectomy. Surgeon volume was most significantly associated with lymphadenectomy on multivariate analysis. High volume surgeons (>20 cases) were almost 3 times more likely to perform lymphadenectomy than lower volume surgeons, all other variables being constant (OR: 2.90, 95% CI 1.61-5.22, p<0.001).

Conclusions: The rates of lymphadenectomy at RARC for advanced bladder cancer are similar or even superior to open cystectomy series using a large, multi-institutional, prospective cohort. There does, however, appear to be a learning curve associated with the performance of lymphadenectomy at RARC.

Poster# 191

STATUS OF SURGICAL MARGINS AFTER ROBOT-ASSISTED RADICAL CYSTECTOMY: RESULTS FROM THE INTERNATIONAL ROBOTIC CYSTECTOMY CONSORTIUM
Nicholas Hellenthal¹, Abid Hussain¹, Paul Andrews², Paul Carpentier³, Erik Castle², Prokar Dasgupta⁴, Rodney Davis⁵, Shamim Khan⁶, Adam Kibel⁷, Hyung Kim¹, Murugesan Manoharan⁷, Mani Menon⁸, Alex Mottrie³, David Ornstein⁹, Raj Pruthi¹⁰, Joan Redorta¹¹, Lee Richstone¹², Francis Schanne¹³, Hans Stricker⁴, Peter Wiklund⁴, Greg Wilding¹ and Khurshid Guru¹

¹Roswell Park Cancer Institute, Buffalo, NY; ²Mayo Clinic, Scottsdale, AZ; ³Onze-Lieve-Vrouwenziekenhuis, Aalst, Belgium; ⁴Guy’s Hospital, London, England; ⁵Tulane University, New Orleans, LA; ⁶Washington University, St. Louis, MO; ⁷University of Miami, Miami, FL; ⁸Henry Ford Health System, Detroit, MI; ⁹Vanguard Urologic Institute, Houston, TX; ¹⁰University of North Carolina, Chapel Hill, NC; ¹¹Fundacio Puigvert, Barcelona, Spain; ¹²Arthur Smith Institute for Urology, Long Island, NY; ¹³Urologic Surgical Associates of Delaware, Wilmington, DE; ¹⁴Karolinska University, Stockholm, Sweden

Presented By: Nicholas Hellenthal

Background: Positive surgical margins at the time of radical cystectomy confer a poor prognosis. The purpose of this study was to evaluate the incidence of and predictors for positive surgical margins in patients undergoing robot assisted radical cystectomy (RARC) for bladder cancer.

Methods: Utilizing the International Robotic Cystectomy Consortium (IRCC) database, we identified 482 patients who underwent RARC at 14 institutions from 2003-2009. After stratification by age group, gender, pathologic T stage, nodal status, sequential case number, and institutional volume, we performed logistic regression to correlate variables to the likelihood of obtaining a positive surgical margin.

Results: 34 of the 482 patients (7%) had a positive surgical margin at the time of RARC. Increasing ten-year age group, lymph node positivity, and higher pathologic T stage were significantly associated with an increased likelihood of a positive margin; while gender, sequential case number, and institutional volume were not significantly associated with margin positivity. The rates of margin positive disease at RARC were 1.6% for patients with ≤ pT2 disease, 8.6% for pT3 disease, and 40% for pT4 disease.

Conclusions: The positive surgical margin rates at RARC for advanced bladder cancer are similar to open cystectomy series using a large, multi-institutional, prospective cohort. Sequential case number, a surrogate for a learning curve, and institutional volume were not significantly associated with positive margins at RARC.

Poster# 192

PROGNOSIS OF T1G3 NON-MUSCLE INVASIVE BLADDER CANCER (NMIBC) TREATED WITH BACILLUS CALMETTE-GUERIN: DIFFERENCES BETWEEN PRIMARY AND NON-PRIMARY TUMORS
Sultan Alkhateeb, Bas van Rhijn, Theodorus van der Kwast, Sally Hanna, Rati Vajpeyi, Antonio Finelli, Neil Fleshner, Michael Jewett and Alexandre Zlotta

Toronto, ON

Presented By: Sultan Alkhateeb
Objectives: To compare the clinical outcome of primary versus non-primary (progressive) T1 High Grade Non-Muscle Invasive Bladder Cancer (NMIBC) treated with intravesical Bacillus Calmette-Guerin (BCG).

Materials and Methods: Between 1988 and 2008, patients with T1G3 NMIBC treated with intravesical BCG were identified from our database (BLISS) and stratified into primary versus non-primary. Their clinical outcomes were compared using univariate analysis, Kaplan-Meier survival analysis and multivariate Cox regression analysis adjusting for various clinical and pathological features including, age, gender, tumor size, multifocality, pathological grade and associated carcinoma-in-situ (CIS).

Results: A total of 191 patients were identified, 95 patients (49.7%) with primary and 96 patients (50.3%) with non-primary tumors. Both groups were similar with respect to gender distribution, mean age, median follow-up, percentage of multifocal tumors, distribution of pathological grade and percentage of associated CIS, while primary tumors had a higher percentage of larger (>3cm) tumors 53.7% versus 33.3% for non-primary tumors (p-value 0.006). With a median follow-up of 48 months, the overall progression rate for primary tumors was 24.2% compared to 39.6% for the non-primary ones (p=0.03, univariate analysis. Kaplan-Meier survival analysis (Logrank p-value 0.007) as well as multivariate Cox regression analysis adjusting for the other clinico-pathological features (Non-primary HR for progression 1.38, 95% CI 1.03-1.85, p-value 0.02) confirmed a significant improved progression-free rate for primary versus non-primary tumors. Recurrence-free survival and disease-specific survival were not statistically different in the two groups in both univariate and multivariate analysis.

Conclusion: Non-primary T1 HG NMIBC treated with BCG have a significantly higher rate of progression to muscle invasive disease compared to primary tumors and therefore they may require more aggressive treatment such as early cystectomy. This is the first study to show such a difference in T1 disease in particular which needs further confirmation in a larger cohort.

Poster# 193

ROLE OF FLUORESCENCE IN SITU HYBRIDIZATION IN BLADDER CANCER SURVEILLANCE OF PATIENTS WITH NEGATIVE CYTOLOGY

Ramy Youssef¹, Bruce Schlomer², Richard Ho², Arthur Sagalowsky², Raheela Ashfaq³ and Yair Lotan²

¹Department of Urology, University of Texas Southwestern Medical Center, Dallas, TX; ²Urology Department, UTSW, Dallas, TX; ³Pathology Department, UTSW, Dallas, TX

Presented By: Ramy Youssef

Purpose: The clinical utility of urine markers in urothelial cancer (UC) surveillance is not established. We previously evaluated use of fluorescence in situ hybridization (FISH) in managing patients with atypical cytology at risk for UC. This study evaluates its role in patients with negative cytology with history of UC.

Materials and Methods: Between June 2007 and Jan. 2009, 142 patients with history of UC who underwent cystoscopy and cytology with UroVysion test were identified. A comprehensive chart review was performed on each patient with negative cytology. Patients were grouped according to cystoscopic findings.

Results: The population comprised 123 patients undergoing cancer surveillance with average follow up of 19.3 months after exclusion of 19 patients with uninformative FISH assays. UroVysion detected the only UC in 95 patients with negative cytoscopic but the positive predictive value was 20%. In 16 patients with equivocal cystoscopy, it detected 2 tumors that would be missed by cytology but missed 4 high-grade cancers (3 Tis and 1 invasive). In 12 patients with obvious lesion on cystoscopy, there were 9 false negative results (sensitivity 10% and negative predictive value 18.2%).

Conclusions: Few patients with negative cystoscopy and negative cytology have cancer. Patients with equivocal and positive cystoscopy and negative cytology frequently have cancer and the Urovysion FISH assay was not helpful in these cases. The cost-effectiveness of the FISH assay needs to be assessed prior to widespread use in patients with negative cytology.

Poster# 194

THE UTILITY OF FISH AND CYTOLOGY IN A PROSPECTIVE SURVEILLANCE PROTOCOL

Jose Karam¹, Roosevelt Anderson¹, Colin Dinney¹, H. Barton Grossman¹, Ruth Katz² and Ashish Kamat¹

¹Department of Urology, UT MD Anderson Cancer Center, Houston, TX; ²Department of Pathology, UT MD Anderson Cancer Center, Houston, TX

Presented By: Jose Karam

Introduction: Bladder cancer is the 5th most common malignancy in the US with 60,000 new cases reported yearly. 70% of patients present with superficial disease; however, up to 60% experience recurrence. Current standard of care for surveillance includes cystoscopy and cytology. New methods to improve diagnosis of current and prediction of future recurrence are of utmost importance.
**Methods:** 200 patients with a history of bladder cancer were prospectively enrolled. Routine studies included cystoscopy, cytology, and FISH every 3-6 months. Operating characteristics of FISH and cytology were calculated. Cox-regression analyses were performed to evaluate the utility of positive cytology or FISH at study entry in predicting future recurrences.

**Results:** Median patient age was 66.9 years. 72.5% were males. Thirteen patients had cancer at study entry and were excluded from predictive analyses. Out of 187 patients, 33 recurred at a median of 11.0 months. Median follow-up in patients who did not recur was 24.5 months. Out of 28 patients with positive FISH at study entry (with concurrent negative cystoscopy), 11 later developed a recurrence at a median of 8.7 months. 5 had Ta, 5 had Tis; 1 Grade 1, 3 Grade 2, 7 Grade 3. Patients with positive FISH who did not recur (N=17) were followed for a median of 25.9 months. Out of 12 patients with positive cytology at study entry (with concurrent negative cytoscopy), 7 later developed a recurrence at a median of 7.7 months. 3 had Ta, 3 had Tis, 1 unknown; 0 Grade 1, 3 Grade 2, 4 Grade 3. Patients with positive cytology who did not recur (N=5) were followed for a median of 27.4 months. Sensitivity, specificity, positive predictive value, and negative predictive values were 50, 85.5, 18.9, 96.2% for FISH and 38.5, 94.6, 35.7, 95.2% for cytology, respectively. Using ROC analysis, the area under the curve was 69.2 (95% CI 53.6-84.9) for FISH and 63.5 (95% CI 46.8-80.2) for cytology, respectively. Using Cox regression, positive FISH or cytology at study entry (and negative cystoscopy) predicted a higher risk of recurrence on subsequent cystoscopy (HR=3.35 and HR=5.32, p<0.001), while history of BCG/interferon, intravesical chemotherapy, and high tumor grade prior to study entry did not.

**Conclusion:** FISH appears to be more sensitive but less specific than cytology. Both were able to predict future recurrences. Studies are currently being performed at our institution to find the most cost-effective method for bladder cancer surveillance.

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**Poster# 195**

**CIRCULATING TUMOR CELLS DO NOT PREDICT EXTRAVESICAL DISEASE IN BLADDER CANCER PATIENTS PRIOR TO RADICAL CYSTECTOMY**

Thomas Guzzo¹, Brian McNeil², Trinity Bivalacqua², Lori Sokoll² and Mark Schoenberg²

¹The Hospital of the University of Pennsylvania; ²The Johns Hopkins Medical Institutions

Presented By: Thomas Guzzo

**Purpose:** Due to imprecise clinical staging, the finding of extravesical and node positive disease at the time of radical cystectomy (RC) in patients with clinically localized bladder cancer is not uncommon. Circulating tumor cells (CTCs) have been shown to be present in the peripheral blood of patients with metastatic urothelial carcinoma. The object of this study was to evaluate the ability of CTCs to predict extravesical disease in bladder cancer patients prior to RC.

**Materials and Methods:** Peripheral blood samples from 43 patients with bladder cancer were evaluated using the CellSearch system prior to RC. The sensitivity, specificity and positive predictive value (PPV) of CTC status to predict extravesical disease was calculated. Receiver operating characteristic (ROC) curves were generated to quantify the ability of CTCs to predict extravesical and node positive disease.

**Results:** CTCs were detected in 9 (21%) patients prior to RC. The sensitivity, specificity and PPV of CTC status in predicting extravesical disease was 27%, 88% and 78% respectively. The accuracy of CTC status in predicting extravesical (>pT3 or node positive) disease for the entire cohort was 0.576. In a model incorporating preoperative hydronephrosis, CTC status did not improve the predictive accuracy for extravesical disease (0.576 vs. 0.585, p=0.915).

**Conclusion:** CTCs were detected in low numbers in a small percentage (21%) of patients prior to undergoing RC at our institution. CTC status was not a robust predictor of extravesical or node positive disease in this cohort. CTC status is not likely to be a clinically useful parameter for directing therapeutic decisions in patients with <cT2 bladder cancer.
**Poster Session 2**

**Poster# 196**

**PROGNOSTIC INFLUENCE OF THE NEUTROPHIL TO LYMPHOCYTE RATIO AFTER CYSTECTOMY FOR UROTHELIAL CARCINOMA OF THE BLADDER**

Christopher Deibert, Greg Hruby and James McKiernan
Columbia University Medical Center, Department of Urology
Presented By: Christopher Deibert

**Introduction:** The Neutrophil to Lymphocyte Ratio (NLR) is part of the white cell count differential of the typical complete blood count preformed on all patients. This inexpensive blood test has proven to be a marker of inflammation and can aid in the risk stratification and prognosis of patients in several disease states, including Acute Coronary Syndrome, Hepatocellular, and colon cancer. An increased NLR \( \geq 5 \) has been shown to be a strong independent predictor of disease-free survival and disease recurrence for these disease states. As such, we evaluated the effect of pre-operative NLR on disease specific (DSS) and overall survival (OS) in patients undergoing cystectomy for urothelial carcinoma of the bladder.

**Methods:** A retrospective analysis of the Columbia University Urologic Oncology Database found 275 patients meeting inclusion criteria among the 632 patients undergoing cystectomy for urothelial carcinoma of the bladder from 1988-2008. Inclusion criteria were limited to known preoperative NLR. Other variables included age, race, sex, neoadjuvant chemotherapy, margin status, cause of death, most recent follow up, pathologic stage and grade. A NLR cut of \( \geq 5 \) delineated groups as high and normal NLR. Chi-squared and Fisher’s Exact tests was used to analyze differences among high and normal NLR. Univariate log rank and multivariate Cox regression tests evaluated NLR as a predictor of overall and disease specific survival. As chemotherapy may cause neutropenia, a sub-group analysis excluding patients who received chemotherapy was performed.

**Results:** The high and normal NLR groups consisted of 55 (22%), and 220 (78%) patients. The 2 year OS for high and normal NLR was 48 and 71%, respectively. NLR was associated with OS \((0.0041)\), but was not an independent multivariate predictor of OS. The 2 year DSS for high and normal NLR was 82 and 87 months. NLR was not associated with DSS survival \((0.49)\). When excluding patients that received neoadjuvant chemotherapy \((n=22)\), the 2 year OS was 50 and 72% and the 2 year DSS was 85% and 88%. In this sub group of patients NLR was again associated with OS \((p=0.0097)\), but was not an independent predictor of OS. NLR was not associated with DSS \((p=0.7915)\).

**Conclusions:** NLR, an independent predictor of disease and survival in other malignancies, is not an independent predictor of DSS or OS after cystectomy. However, NLR \( \geq 5 \) was associated with OS in both the entire cohort and the subgroup excluding neoadjuvant chemotherapy patients.

**Poster# 197**

**NARROW-BAND IMAGING CYSTOSCOPY TO EVALUATE BLADDER TUMORS-INDIVIDUAL SURGEON VARIABILITY**

Jennifer Taylor¹, S. Machele Donat², Guido Dalbagni² and Harry Herr²
¹Memorial Sloan-Kettering Cancer Center; ²Memorial Sloan-Kettering Cancer Center, New York, NY
Presented By: Jennifer Taylor

**Introduction and Objectives:** Narrow-band imaging (NBI) cystoscopy uses technology which filters white light into bands absorbed uniquely by hemoglobin, to increase visibility of superficial and submucosal vasculature. Early reports suggest that NBI cystoscopy may enhance detection of papillary bladder tumors and carcinoma in situ over white-light imaging (WLI) cystoscopy alone. The objective is to assess variability among individual urologists using WLI and NBI cystoscopy to evaluate suspicious bladder lesions.

**Patients and Methods:** 50 patients with a history of non-muscle-invasive bladder cancer, including 18 previously treated with BCG, underwent white-light and narrow-band imaging cystoscopy to evaluate for recurrent tumors. In all patients, a lesion was biopsied for histologic evaluation. Without biopsy results, endoscopic images of the lesions from each patient were independently viewed by four urologic surgeons, three at senior faculty level and one a urologic oncology fellow, to assess for presence or absence of tumor. Their assessments were correlated with biopsy results. Correlative statistics were used to compare performance between the four surgeons.
Results: 26 patients had recurrent tumor and 24 had benign histology. With the combination of WLI and NBI cystoscopy, the sensitivity among the four urologists to correctly detect a malignant lesion ranged from 69-92%, and specificity was 67-79%. The positive predictive value was 69-83% and negative predictive value ranged from 67-90%. There was no significant difference among the four urologists in detecting recurrent tumor or in determining final pathology.

Conclusions: There does not appear to be a learning curve for utilizing NBI cystoscopy for surveillance in patients with urothelial cancer. As a readily accessible modification to standard cystoscopy, it may be a valuable supplement to white-light imaging to improve detection of recurrent tumor.

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Poster# 198

RESULTS OF BLADDER PRESERVATION AFTER “NEOADJUVANT” CHEMOTHERAPY IN PATIENTS WITH CLINICAL COMPLETE RESPONSE TO PLATINUM-BASED CHEMOTHERAPY FOR MUSCLE-INVASIVE BLADDER TCC
Matthew Wosnitzer, LaMont Barlow, Solomon Woldu, Gregory Hruby, Daniel Petrylak, Mitchell Benson and James McKiernan
Columbia University Medical Center, New York, NY
Presented By: Matthew Wosnitzer

Introduction and Objectives: SWOG 8710 trial results indicate that 38% of patients experience pathologic complete response following platinum-based chemotherapy. While systemic chemotherapy has been extensively described in the neoadjuvant setting, there is no established regimen for patients who show complete clinical response to chemotherapy and desire avoidance of morbidity from cystectomy. We are unaware of any prospective data regarding outcomes for patients who elect to defer cystectomy in this setting. We sought to describe the outcomes of patients with muscle-invasive or more advanced bladder transitional cell carcinoma (TCC) with clinical complete response to platinum-based “neoadjuvant” chemotherapy who refuse cystectomy.

Methods: Retrospective review of the institutional database from January 1988 through July 2009 identified 187 patients treated with systemic chemotherapy for muscle-invasive or more advanced bladder cancer. 76 of 187 patients received neoadjuvant chemotherapy for T2 N0 M0 or more advanced bladder cancer.

Results: 25 of 76 patients had clinical complete response following “neoadjuvant” chemotherapy without immediate cystectomy. Mean age of this cohort at chemotherapy start was 65 years, 21 of 25 patients were male, 22 of 25 patients were Caucasian. “Neoadjuvant” chemotherapy regimen was MVAC (n=18), gemcitabine/cisplatin (n=5) or gemcitabine/carboplatin (n=2). 14 of 25 patients had cystectomy at median 3 months following chemotherapy, revealing pT0 (n=5), pT1 or greater (n=9). Of patients not undergoing cystectomy, 5 received intravesical therapy (BCG and interferon-alfa (n=3) or BCG (n=2)). At median follow-up of 29 months (mean 54), overall survival was 78% and disease-specific survival was 100%. 1 patient died from bladder cancer (6 years after cystectomy). Of patients receiving intravesical therapy, all remain alive without disease progression, >60% without evidence of bladder cancer. Median interval between systemic and intravesical chemotherapy administration was 11 months (1-121 months). Mean number of BCG cycles was 11.4. No significant toxicity was reported following intravesical administration.

Conclusions: For patients with complete response to platinum-based “neoadjuvant” chemotherapy, bladder preservation appears to be associated with a durable disease-free survival. Further elucidation of this assertion will require additional prospective study and analysis of quality of life impact.
**EVALUATION OF URINARY FUNCTION OF FEMALE NEOBLADDER PATIENTS USING A VALIDATED HEALTH-RELATED QUALITY OF LIFE QUESTIONNAIRE**

Georg Bartsch, John Stein, Eila Skinner, Stuart Boyd, Anne Schuckman, Jie Cai, Gus Miranda, Donald Skinner and David Penson
University of Southern California, Los Angeles, CA
Presented By: Georg Bartsch

**Introduction:** The ratio between orthotopic and none orthotopic diversions in women is far lower than in male patients. Data on urinary function in female patients after radical cystectomy and orthotopic urinary diversion is therefore not profound. We investigated the urinary function of female neobladder patients utilizing the Bladder Cancer Index (BCI), a validated and reliable health-related quality of life (HRQOL) questionnaire.

**Methods:** All living female patients after radical cystectomy and neobladder formation (N=82) from the University of Southern California Bladder Cancer Database were sent a questionnaire including the University of Michigan Bladder Cancer Index, which is a HRQOL instrument based on the FACT-G. The FACT-G contains 44 questions in 6 domains: Physical Well-Being, Social/Family Well-Being, Emotional Well-Being, Functional Well-Being, Additional Concerns, and Demographics. Three additional disease-specific domains are included in the BCI: Urinary function (7 questions), Bowel Habits (6 questions), and Sexual Function (6 questions). Univariate analyses were performed using the Kruskal-Wallis Test followed by a multivariate stepwise regression model.

**Results:** 56 patients responded and were included in the analysis. 35 (62.5%) had to catheterize their neobladder. 71.43% of the patients that needed to catheterize were not able to void at all without using a catheter. In a univariate analyses the only variable that was associated with whether a patient had to catheterize or not was the patient’s age (younger or older than 65 years of age). Better urinary bother scores were associated with organ confined disease (p=0.038) and education level (p=0.01). However, these variables were not significant in a multivariate stepwise linear regression model.

**Conclusion:** Results from this study indicate that considerably more women require urinary catheterization to void than previously thought. Unfortunately, we were unable to identify any predictors of this outcome or urinary HRQOL in this cohort. This may be related to relatively small sample size.

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**A COMPARISON OF METHODS OF URINARY DIVERSION FOLLOWING CYSTECTOMY IN A SINGLE CENTRE**

Amit Mevcha, Angela Cottrell and David Gillatt
Bristol Urological Institute, Bristol, UK
Presented By: Amit Mevcha

**Introduction and Objectives:** Radical cystectomy confers overall survival benefit in patients with muscle invasive bladder cancer compared with radical radiotherapy. Ileal conduit still remains a standard method of urinary diversion following radical cystectomy however continent urinary diversions may have quality of life and body image advantages with comparable morbidity and mortality. A retrospective notes analysis was performed to compare the outcomes of patients undergoing ileal conduit, orthotopic neobladder formation and continent cutaneous urinary diversion (Mitrofanoff).

**Materials and Methods:** The part prospective and part retrospective study of patients undergoing radical cystectomy under a single surgical team between the years of 1990 and 2008 were reviewed.

**Results:** 563 patients underwent radical cystectomy. Where appropriate, patients were counselled regarding choice of diversion. Approximately 60% of patients offered choice of diversion chose orthotopic neobladder. Mean follow up was 52 months. 49% of patients underwent ileal conduit, 10% Mitrofanoff and 41% orthotopic neobladder. In total, 36% of patients experienced early complications, comprising 38% ileal conduit, 46% Mitrofanoff, 31% neobladder. Overall peri-operative mortality was 1.5%; all from ileal conduit group. Late complications were experienced by 18% of all patients: 42% of patients in the Mitrofanoff group, 16% of neobladder group and 15% patients undergoing ileal conduit. The most frequent late complication being stomal stenosis (15%) in Mitrofanoff group, bladder neck stenosis and ureteric anastomotic stricture (14% and 11% respectively) in neobladder and herniae (parastomal and incisional: 7%) in ileal conduit groups. 92% of patients in neobladder group and 96% undergoing Mitrofanoff achieved full daytime continence and 22% of neobladder and 4% of Mitrofanoff patients experienced occasional nocturnal incontinence. 72% of patients were found to be disease free at follow up.

**Conclusions:** Suitable patients should be offered a choice of method of urinary diversion following radical cystectomy. Early complication rates are comparable. When considering orthotopic neobladder or Mitrofanoff, although continence rates are similar, a considerable higher rate of late complications is seen in the Mitrofanoff group.
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SUO Fellowship Programs

**Division of Urologic Oncology, Fox Chase Cancer Center**  
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<td>Program Director: Arie Beldegrun, MD</td>
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<td>University of Washington</td>
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<td>Los Angeles, CA 90095</td>
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<tr>
<td>Phone 206-543-4740</td>
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<td><a href="mailto:dlin@u.washington.edu">dlin@u.washington.edu</a></td>
<td><a href="mailto:abeldegrun@mednet.ucla.edu">abeldegrun@mednet.ucla.edu</a></td>
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| Seattle, WA 98195                                         | | |
| (206) 543-3918                                            | | |
| lange@u.washington.edu                                    | | |

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<td>Program Director: Stephen Beck, MD</td>
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<td>3875 Taubman</td>
<td>535 N. Barnhill, Suite 420</td>
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<td>Ann Arbor, MI 48109</td>
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<td>(734) 763-9269</td>
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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.
Mark Your Calendars!

SUO 2010 Annual Meeting
May 29, 2010
San Francisco, California

SUO 2010 Annual Meeting
December 8-10, 2010
Marriott Bethesda North Hotel & Conference Center
and
NIH Natcher Conference Center
Bethesda, Maryland