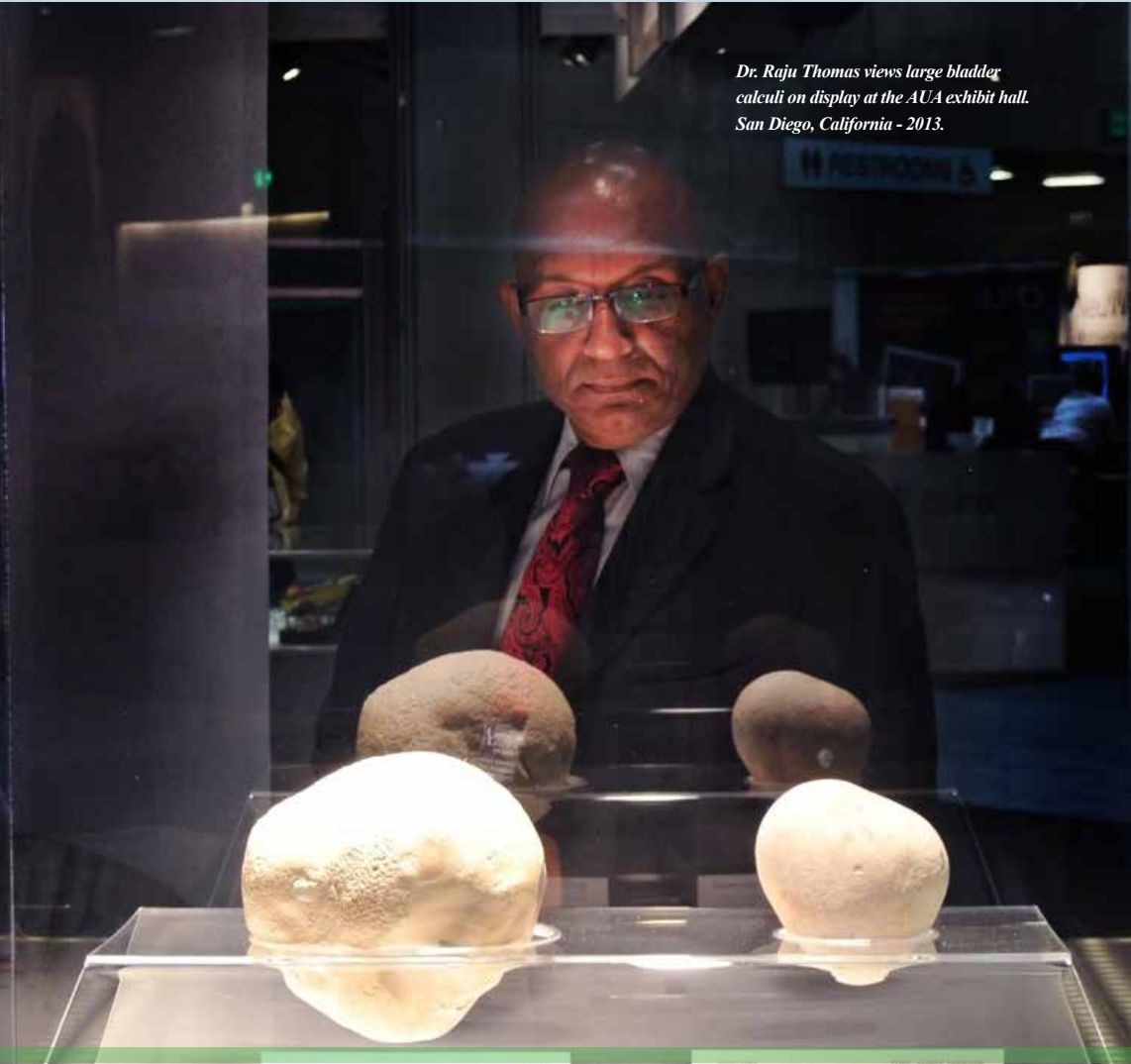




Research Focused **2014** Urologic Care.™

Dr. Raju Thomas views large bladder calculi on display at the AUA exhibit hall. San Diego, California - 2013.



NOTE FROM THE CHAIRMAN

As another calendar year goes by, I wanted to take a moment and reflect on a memorable 2013. Our faculty have worked tirelessly on research studies and clinical trials, in addition to attending seminars and symposia around the world to both learn and educate. We have the unique responsibility and privilege to teach locally, regionally, nationally, and internationally while providing exceptional care for our patients - be it Andrology, male sexual function, promoting and teaching new laparoscopic and robotic techniques, or conducting clinical and basic science trials, Tulane Urology, along with our many visiting professors throughout the year, are dedicated to improving the knowledge and skills of our faculty, colleagues, residents, fellows, and medical students.

In October Dr. Benjamin Lee (as Organizing Secretary) and I (as President) hosted the 31st World Congress of Endourology here in New Orleans. The WCE 2013 had a record number of attendees from 93 countries around the world. Dr. Lee performed a very difficult hilar renal mass robotic partial nephrectomy, which was broadcast live at the conference. The accolades our department received from around the world has been truly humbling, and give us renewed energy and dedication to continue our mission of practical education throughout the world.

As the funds from the NIH and other related agencies have decreased, we have been fortunate and privileged to have Dr Asim-Abdel Mageed, our molecular cell biologist bring in a multi-year, multi-million dollar research project to the department. Dr Mageed's research team is dedicated to discovering the various factors of prostate cancer that can promote early diagnosis and more effective treatment by unraveling the genetic link. The research activities sections of this report lists the work our outstanding research team has undertaken.

With a rejuvenated clinical trials department, we are conducting research on HIFU in post radiation failures in prostate cancer as well as the Argos trial for patients with metastatic kidney cancer. Dr. Wayne Hellstrom's clinical research includes an exploratory study for the treatment of premature ejaculation, an injectable treatment for Peyronie's

Disease, as well as multiple studies for the treatment of erectile dysfunction. You can read an overview on a select number of studies, eligibility requirements, and contact information in the Clinical Research section inside this report.

All in all this has been a memorable year. In 2014, the Affordable Care Act, issues such as the SGR, decreasing reimbursements, and other quality improvement initiatives promise to present a unique set of challenges for all of us. However, we believe that consistency and high quality patient care will continue to drive our residency training program, as well as our clinical and research activities.

We wish you continued success in your endeavors and here's to a successful and prosperous 2014.

Raju Thomas, MD, FACS, MHA
Chairman, Department of Urology
Tulane University School of Medicine



TULANE UROLOGY RECEIVES PROSTATE SURGERY EXCELLENCE AWARD 5-STAR RATING FOR PROSTATE REMOVAL SURGERY

The 2014 Prostate Surgery Excellence Award recognizes hospitals for superior outcomes in the surgical removal of part or the entire prostate to treat prostate cancer or an enlarged prostate (benign prostatic hyperplasia, or BPH). Men who have prostate surgery at one of these top 10% hospitals have a lower risk of experiencing complications. (healthgrades®)



ONGOING CLINICAL RESEARCH STUDIES

1. ADAPT STUDY FOR KIDNEY CANCER

Tulane Urology is participating in an International Phase 3 study for metastatic renal cell carcinoma sponsored by Argos Therapeutics called the ADAPT (Autologous Dendritic Cell Immunotherapy Plus Standard Treatment)

This study will investigate the combination of an autologous dendritic cell based immunotherapy, AGS-003, plus standard treatment (Sunitinib). The primary objective in this study is to determine the median overall survival achieved by this combination compared to overall survival of standard treatment alone, in a population of adults with advanced renal cell carcinoma with nephrectomy indicated, and with remaining measurable metastatic disease.

Patient enrollment criteria:

- 18 years of age or older
- Newly diagnosed with metastatic kidney cancer and no brain metastases
- No underlying autoimmune disorders
- Good candidates for standard surgery (nephrectomy)
- Good candidates to receive standard targeted drug therapy (initiating with Sunitinib)

Please visit the study website for more information: adaptkidneycancer.com.

Contact Dr. Benjamin Lee (brlee@tulane.edu) or Dr. Sree Harsha Mandava - (504) 988-0897

2. STUDY OF VIBERECT® AND CAVERJECT®

Objective: The objective is to compare the effectiveness of a new vibratory device with currently prevalent intracavernosal injection of a vasoactive agent in inducing penile blood flow for diagnostic purposes.

Penile blood flow measurements will be done using Doppler Ultrasound technology in patients attending Tulane Urology/Fertility Clinic for erectile dysfunction and/or Peyronie's disease.

Patient enrollment criteria:

- adult male at least 18 years of age
- erectile dysfunction and/or Peyronie's disease
- International Index of Erectile Function (IIEF) score between 12-20

Open to enrollment

Contact (504) 988-6233 for more information.



3. RENO-PROTECTIVE AGENTS STUDY

Comparative evaluation of renal protective agents to reduce reperfusion injury during robotic nephrectomy

Currently, the standard surgical practice is to administer Lasix and Mannitol also known as Furosemide 15 minutes before the renal artery is clamped. We will investigate administration of Allopurinol and N-acetylcysteine and assess their reno-protective effect.

Enrollment criteria:

- Patients diagnosed with a condition that would require undergoing robotic partial nephrectomy

Enrollment begins March 2014.

Contact Dr. Benjamin Lee (brlee@tulane.edu) or Dr. Sree Harsha Mandava - (504) 988-0897

4. PROSTATE CANCER HIFU CLINICAL TRIAL

Dr. Benjamin Lee

STAR Trial - Multicenter clinical study, Treatment of locally recurrent prostate cancer with HIFU (High Intensity Focused Ultrasound)

Patients enrollment criteria:

- Previous primary treatment with External Beam Radiation for Prostate Cancer
- Re-emergence of localized Prostate Cancer within last two years
- No evidence of metastatic disease
- No prostatic calcifications
- Salvage option for Recurrent Prostate cancer

Open to enrollment.

Contact Dr. Benjamin Lee (brlee@tulane.edu) or Dr. Sree Harsha Mandava - (504) 988-0897

5. EXPLORATORY STUDY - BOTOX® FOR TREATMENT OF PE

An Exploratory Study of the Safety and Efficacy of BOTOX® for the Treatment of Premature Ejaculation

Clinical Hypotheses: BOTOX injected bilaterally into the bulbospongiosus muscle has an acceptable safety profile and shows an efficacy signal in comparison to placebo, as demonstrated by an increased intravaginal ejaculatory latency time (IELT).

Men aged between 18 and 50 years in a stable monogamous sexual relationship with a female partner, who have PE as defined by the 2008 ISSM guidelines and who meet the eligibility criteria.

- ejaculation which always or nearly always occurs prior to or within 1 minute of vaginal penetration
- inability to delay ejaculation on all or nearly all vaginal penetrations
- negative personal consequences, such as distress, bother, frustration and/or the avoidance of sexual intimacy

Open to enrollment.

Contact (504) 988-6233 for more information.

DR OLIVER SARTOR'S CLINICAL TRIALS FOR PROSTATE CANCER - OPEN FOR RECRUITMENT

A Phase 2, Open-label, Multicenter Study of PSMA ADC in subjects with Castration-resistant Metastatic Prostate Cancer (CRMPC)

(Sponsor: PSMA Development Company)
Who to consider for eligibility: Chemotherapy naïve patients who received and progressed on abiraterone and/or enzalutimide

A 2 Part, Phase 2 Trial of Galeterone in the Treatment of Castration Resistant Prostate Cancer

(Sponsor: Tokai Pharmaceuticals)
Who to consider for eligibility: M0 patients, Abiraterone refractory M1 patients, Enzalutamide refractory M1 patients (without prior abiraterone exposure)

A Re-treatment Safety Study of Radium-223 Dichloride in Castration-Resistant Prostate Cancer with Bone Metastases who Received Initial Course or Six Doses of Radium-223 Dichloride 50 kBq/kg Every Four Weeks

(Sponsor: Bayer HealthCare AG)
Who to consider for eligibility: Patients that received 6 prior doses of radium 223 dichloride

A randomized open-label phase IIa study evaluating the efficacy and safety of radium-223 dichloride in combination with abiraterone acetate or enzalutamide in subjects with castration-resistant prostate cancer (CRPC) who have bone metastases

(Sponsor: Bayer HealthCare AG)
Who to consider for eligibility: Abiraterone and enzalutamide naïve patients with bone metastases

A Phase III Trial of Short Term Androgen Deprivation with Pelvic Lymph Node or Prostate Bed Only Radiotherapy (SPPORT) in Prostate Cancer Patients with a Rising PSA after Radical Prostatectomy

Who to consider for eligibility: Patients with a rising PSA (≥ 0.1 and < 2 ng/ml) after radical prostatectomy

A Phase III Prospective Randomized Trial of Dose-Escalated Radiotherapy with or without Short-Term Androgen Deprivation Therapy for Patients with Intermediate-Risk Prostate Cancer

Who to consider for eligibility: Patients with an intermediate risk of recurrence (AJCC) that are considering radiation as their initial treatment

Androgen Deprivation Therapy and High Dose Radiotherapy with or Without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High Risk Prostate Cancer: A Phase III Randomized Trial

Who to consider for eligibility: Patients with an intermediate to high risk of recurrence (AJCC) that are considering radiation as their initial treatment

Phase III Trial of Dose Escalated Radiation Therapy and Standard Androgen Deprivation Therapy (ADT) with a GNRH Agonist vs. Dose Escalated Radiation Therapy and Enhanced ADT with a GNRH Agonist and TAK-700 For Men with High Risk Prostate Cancer

Who to consider for eligibility: Patients with a high risk of recurrence (AJCC) that are considering radiation as their initial treatment

Docetaxel (Taxotere®) plus 6-Month Androgen Suppression and Radiation Therapy vs. 6-Month Androgen Suppression and Radiation Therapy for Patients with High-Risk Localized or Locally Advanced Prostate Cancer: A Randomized Controlled Trial

(Sponsor: Dana-Farber Cancer Institute)
Who to consider for eligibility: Patients with a high risk of recurrence (AJCC) that are considering radiation as their initial treatment

Please contact Patrick Cotogno for more information.
Phone: 504-988-6542
E-mail: pcotogno@tulane.edu



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NEW FACES AT TULANE UROLOGY

DR. JONATHAN SILBERSTEIN, MD DIRECTOR, SECTION OF UROLOGIC ONCOLOGY

Jonathan Silberstein earned his medical degree at SUNY Upstate Medical University in Syracuse. He completed his general surgery internship and his urology residency at the University of California in San Diego.

Following his residency, Dr. Silberstein completed a fellowship in urologic oncology at

FOR REFERRALS, PLEASE CALL OUR PATIENT REFERRAL HOTLINE: (504) 988-2536

Memorial Sloan Kettering Cancer Center. He spent one year at MSK designing and performing clinical trials, including a randomized study of robotic versus open radical cystectomy. Dr. Silberstein spent the remainder of his time at MSK on active clinical rotations. He is the author of more than 40 peer-reviewed publications and several book chapters. He is also the winner of numerous

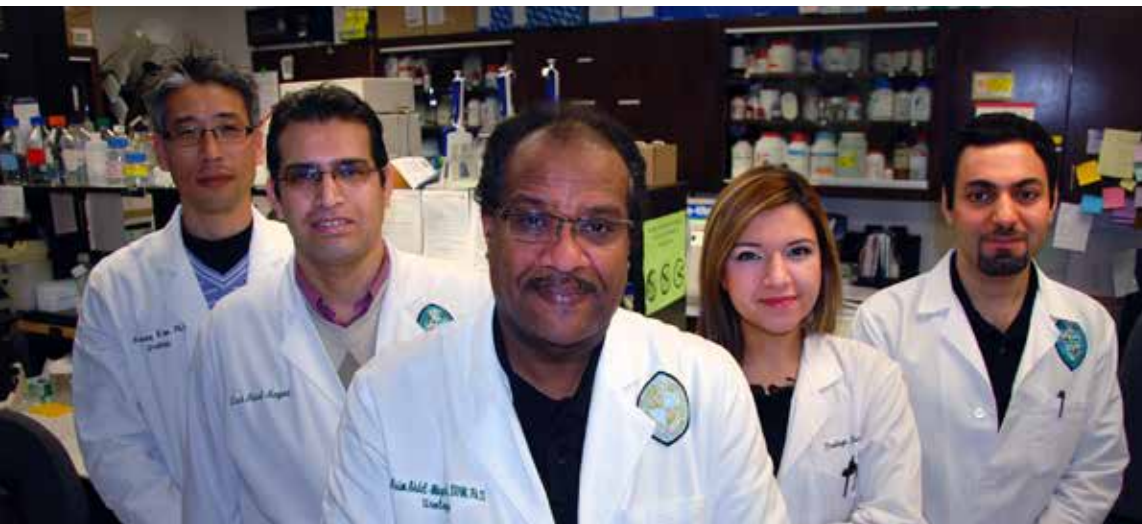
awards from national and international meetings and is a reviewer for several prominent urologic journals.

We are delighted to have Dr Silberstein join us and bring his robotic, laparoscopic, and open surgical skills to our cancer care center.



RESEARCH PROJECTS

1. **"Targeting Tumor-Derived exRNA-Containing Microvesicles by High Throughput Screening"**
PI: Asim Abdel-Mageed, PhD - NIH/NCATS
2. **"Estrogen-ER Axis in Disparity of Prostate Cancer"**
PI: Asim Abdel-Mageed, PhD - NIH-NCI
3. **"Adipose Stem Cell-Based Therapeutic Targeting of Residual Androgens in African Americans with Metastatic Prostate Cancer"**
PI: Asim Abdel-Mageed, PhD - Synergistic Idea Award-Department of Defense
4. **"Nuclear Matrix Proteins in Disparity of Prostate Cancer"**
PI: Asim Abdel-Mageed, PhD
5. **Genetic Studies of Prostate Cancer**
PI: Oliver Sartor, MD
The purpose of this research study is to confirm current and find new prostate cancer genes that may increase the risk of prostate cancer in certain families. Finding the genes that cause prostate cancer will help improve the detection and diagnosis of this cancer when combined with modern screening procedures.
6. **The Association Between Prenatal Testosterone and Prostate Cancer Risk Using an Anthropometric Marker Derived From Measuring the Lengths of the Fingers, the Ratio of the Index-Finger Length to Ring-Finger Length Ratio (2D:4D)**
PI: Oliver Sartor, MD
The purpose of this study is to compare values determined from the ratio of the index-to-ring-finger length, between men with and without prostate cancer. This ratio has been postulated to reflect hormonal levels at birth, which may influence the risk of prostate cancer.
Please contact Elisa Ledet for more information
E-mail: eledet@tulane.edu



UROLOGIC ONCOLOGY RESEARCH STUDIES

1. A multiphase, prospective, non-randomized, longitudinal review of men diagnosed with localized, low-risk prostate cancer who choose to undergo **Active Surveillance (AS)**, a therapeutic strategy that involves active monitoring of the patient's disease with the expectation to intervene with intent to cure if the cancer progresses. The study aims to avoid over treatment of prostate cancer, and identify predictors of progression and outcomes of these patients. Patients receive confirmatory MRI fusion biopsies with visual co-registration, and are seen every six months for physical exam, lab work and quality of life surveys. Of particular interest is the role of AS in African Americans, as this is currently controversial.
2. **Fusion Urine Assays for Men at Risk for or with Biopsy-Proven Prostate Cancer**

Who's eligible?

Men diagnosed with low-risk prostate cancer, as defined by the National Comprehensive Cancer Network (NCCN), which includes Gleason score of 6 or less, with a PSA less than 10 ng/mL.

A non-randomized, prospective study involving the collection of urine specimens from patients at risk for prostate cancer electing prostate biopsy, or patients with biopsy proven prostate cancer electing active surveillance or radical prostatectomy. The goal of the study is to assess whether the combination of PCA3 and TMPRSS2:ERG gene fusion urinary assays improve the performance of PSA for detection of prostate cancer and prediction of clinically significant prostate cancer in the Tulane patient population.

Who's eligible?

Men at risk for prostate cancer with pending prostate biopsy or men diagnosed with prostate cancer electing to undergo active surveillance or radical prostatectomy.

Questions?

Contact Allison Feibus
Clinical Research Coordinator
(504) 988-1205
afeibus@tulane.edu

CARING FOR OUR COMMUNITY

Tulane Urology is engaged in many community outreach programs educate the public about prostate cancer. Beyond our commitment to providing free prostate cancer screenings monthly at Tulane Medical Center, our support team conducts a Prostate Cancer Support Group every other month to inform patients diagnosed with prostate cancer of the available treatment options for their specific condition.

In addition, Tulane Urology is a member of the AUA & NFL Players Association Screening Event to screen former NFL Players annually for prostate cancer.

For more information on this and other programs offered at Tulane Urology please visit our website tulaneurology.com.

Why TULANE UROLOGY ?

MOST EXPERIENCED & LEADERS IN

UROLOGIC ROBOTIC SURGERY . DIFFICULT AND COMPLEX CASES OF KIDNEY STONES . MANAGING COMPLEX RETROPERITONEAL TUMORS
COMPLEX RECONSTRUCTIVE PROCEDURES . UROLOGIC PROSTHETIC SURGERY . MANAGEMENT OF COMPLEX ERECTILE DYSFUNCTION



Raju Thomas, MD, FACS, MHA
*Robotic Surgery, Prostate Cancer,
Bladder Cancer, Kidney Stones*



Wayne Hellstrom, MD, FACS
*Andrology, Male Sexual
Dysfunction & Infertility*



Oliver Sartor, MD
*Medical Oncology,
Prostate Cancer*



Suresh Sikka, PhD
*Andrology, Male Sexual
Dysfunction & Infertility*



Benjamin Lee, MD, FACS
*Robotic Surgery, Kidney Cancer,
Prostate Cancer, Kidney Stones*



Jonathan Silberstein, MD
Urologic Oncology



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Asim-Abdel Mageed, PhD, DVM
Urologic Oncology



Margie Kahn, MD
*Female Urology,
Incontinence*

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Krishnarao Moparty, MD
General Urology



Ryan Krlin, MD
*Female Urology,
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Michael Maddox, MD
*Clinical Instructor,
Robotic Surgery*

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