

The Milton and Carroll Petrie **Department of Urology**

Prostate Cancer Program at Mount Sinai

Mount Sinai Doctors 625 Madison Avenue 2nd Floor New York, NY 10022

212-241-9955 www.mountsinai.org/roboticprostate



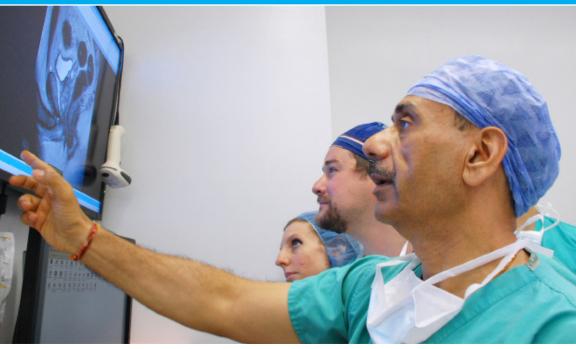
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The Milton and Carroll Petrie **Department of Urology**

Prostate Cancer Program at Mount Sinai

- Robot-Assisted Surgery
- Active Surveillance
- Genomic Marker Analysis
- Immunotherapy
- MRI Fusion Targeted Biopsy



Ash Tewari MBBS, MCh, FRCS (Hon.) System Chair, Milton and Carroll Petrie Department of Urology Director of Robotic Prostatectomy, Precision Urology[™] and Men's Health, Mount Sinai Health System Director, Prostate Cancer Program, The Barbara and Maurice A. Deane Prostate Health and Research Center Professor of Urology, Department of Urology at the Icahn School of Medicine at Mount Sinai

Overview

Our robotic prostate surgery program is led by Ashutosh (Ash) K. Tewari, MBBS, MCh, FRCS (Hon.), System Chair of the Department of Urology and one of the world's foremost researchers and surgeons in the field of prostate cancer. A pioneer of da Vinci[®] robotic surgery for prostate cancer, Dr. Tewari has performed more than 7,000 robotic prostatectomies (surgery to remove the entire prostate), making him one of the most skilled and experienced robotic surgeons in the world – expertise that is especially important if you are considering robotic prostatectomy where successful surgery depends more on the skill and experience of the surgeon than on the technology. He has been performing robot-assisted surgery since 2000.

Dr. Tewari performs this surgery with precision and ensures that all patients receive the best possible care. Our Precision Urology[™] approach involves integration

of clinical, genomic, molecular, and pathological imaging data for diagnosis and treatment decision-making so that men with prostate cancer can be assured of our commitment to diagnosis and achieving excellent outcomes while minimizing the side effects of treatment. Dr. Tewari also has one of the largest active surveillance ("watchful waiting") programs so men at lower risk for aggressive cancer can be monitored until intervention is warranted.

Currently Dr. Tewari is leading a number of critical, ongoing clinical trials. For patients who do not like the discomfort of a standard MRI, we have a trial testing an upright MRI to screen for prostate cancer. Another is an open-label trial of sipuleucel-T (Provenge®) administered to active surveillance patients for newly diagnosed prostate cancer.

We offer all treatment modalities for prostate cancer, including focal and targeted therapy, and we partner with radiation therapy and medical oncology experts to provide every currently available treatment. In collaboration with the Tisch Cancer Institute at Mount Sinai, a National Cancer Institute-designated center, we oversee clinical trials that provide access to the latest innovations in cancer care.



About Dr. Tewari

Ash Tewari, MBBS, MCh, FRCS (Hon.), is an innovator in the fields of robot-assisted prostate cancer surgery and prostate cancer treatment. He was a pioneer in the performance of a completely athermal technique (no use of cautery or heat energy) during robotic prostatectomy in order to minimize the damage to the nerves responsible for erectile function. Dr. Tewari developed the total reconstruction technique, where the support structures of the urinary mechanism are restored following prostate removal, for faster continence recovery. In addition, he was the first to publish a catheter-less robotic prostatectomy where a urethral catheter is avoided in order to minimize pain and discomfort after surgery.

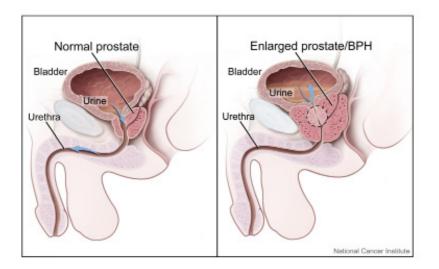
Dr. Tewari was the first to identify the nerves responsible for erectile function as a neural hammock. He also described various grades of nerve-sparing that utilize information from MRIs and allow for incremental nerve-sparing – even in cases that would not have qualified for nerve-sparing without this graded approach. This increased understanding of the prostate anatomy aids in nerve-sparing prostate surgery techniques. Using a multiparametric magnetic resonance imaging (mpMRI)-based nomogram allows Dr. Tewari to use the right nerve-sparing technique based on a particular patient's biology.

He has described traction free and athermal nerve-sparing techniques, and has also developed a novel Detrusor wrap technique for early urinary continence. Working with genitourinary pathologists and scientists from the University of Hamburg, he helped advance the role of MRI-guided NeuroSAFE® and sphincter safe approaches in expanding opportunities for nerve-sparing.

As an active researcher, and surgeon scientist, Dr. Tewari is one of only a few robotic surgeons to be awarded a NIH R01 and Department of Defense (DOD) cancer grant. This funding is for the investigation of real-time tissue identification during prostate cancer surgery and immunotherapy.

Prostate Cancer Types, Risks, and Symptoms

The prostate, an organ found only in males, produces a fluid that becomes part of semen, the male reproductive fluid. Prostates, which are normally the size of a walnut, surround the urethra, which removes urine through the penis. Unfortunately, the prostate is prone to becoming cancerous, and more than 30,000 men die from prostate cancer in the United States every year.



Almost all prostate cancers are **adenocarcinomas**, which develop in the gland cells. Men with prostate cancer usually have no noticeable symptoms, and the first sign of the disease is found during a routine screening exam. Symptoms of adenocarcinoma of the prostate include blood in the semen, frequent urge to urinate, and painful urination and ejaculation.

In rarer cases, prostate cancer originates in other tissues of the prostate. This type of cancer is called **sarcoma**. Other types of prostate cancers include **small cell carcinomas, neuroendocrine tumors** (other than small cell carcinomas), and **transitional cell carcinomas**.

Inherited gene mutations cause prostate cancer. We know that African-American men are at higher risk to get prostate cancer than Caucasian men are. In addition, if a close relative, such as your father or brother, has had prostate cancer, your risk is higher than average. Acquired gene mutations might also contribute to prostate cancer risk in some men. Male hormones such as testosterone promote prostate cell growth. When too much testosterone causes cells to grow and divide too quickly, mutations can occur.

Men over the age of 50 have the greatest risk of developing prostate cancer. More than 60 percent of prostate tumors occur in men age 65 or older. Starting at age 50, men should have an annual prostate-specific antigen (PSA) test. This test measures the amount of PSA, a protein that at an elevated level may be a sign of prostate cancer. A high



Avinash Reddy, MD, Assistant Professor, Urology

PSA reading also may indicate noncancerous conditions such as inflammation of the prostate (prostatitis) and enlargement of the prostate (benign prostatic hyperplasia).

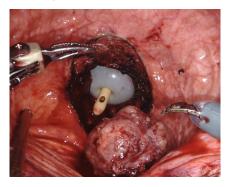
In addition to detecting prostate cancer, it is important to understand how aggressively the cancer may grow. Urologists use the Gleason Score grading system to determine appropriate treatment options based on the behavior of a prostate cancer. The higher the score, the quicker the cancer will grow and spread in the body.

The following symptoms usually indicate the presence of prostate cancer:

- Need to urinate frequently
- Difficulty starting or holding back urination
- Weak, dribbling, or interrupted flow of urine
- Painful or burning urination
- Blood in the urine or semen

- · Difficulty having an erection
- A decrease in the amount of fluid ejaculated
- · Painful ejaculation
- Pressure or pain in the rectum
- Pain or stiffness in the lower back, hips, pelvis, or thighs

Simple Prostatectomy for Benign Prostatic Hyperplasia (BPH)



Benign Prostatic Hyperplasia (BPH) is when a patient has an enlarged prostate (usually 100 grams or larger), which causes the flow of urine to be blocked. One of the best options to treat BPH is to perform a robot-assisted simple prostatectomy, which reduces the size of the patient's prostate. The procedure takes approximately 25-30 minutes, and usually involves minimal or no bleeding. A simple prostatectomy may involve an overnight stay or even same day discharge from the hospital.

Precision Urology™

At Mount Sinai, our Precision Urology[™] approach involves integration of multiple variables and imaging data in a decision support system. This is key in assuring men with prostate cancer of our commitment to a patient-centric, personalized diagnostic approach and excellent outcome while minimizing the side effects of treatment. Precision Urology[™] reflects our utilization of advanced technologies and incorporation of molecular and genomic analysis to identify markers of aggressive disease. This allows us to rigorously stage disease to determine if intervention is needed and if so, tailor the treatment accordingly.

Robotic Prostate Surgery Technique: ART™

The robotic prostate surgery approach used by Dr. Tewari is known as ART[™] (Advanced Robotic Technique) prostatectomy. It is a highly successful approach to curing prostate cancer while minimizing side effects in select patients. Dr. Tewari and his team have developed and refined ART[™] over the past decade based on the thousands of surgeries they have performed, their discoveries in prostate anatomy, and other leading-edge research.

ART[™] is highly individualized, reflecting a patient's unique anatomy, cancer location and neural structure. Indeed, for Dr. Tewari, ART[™] is truly an art. He routinely makes anatomical drawings of prostates on which he operates in order to map out a cancer's spatial relationships to the fascia, muscles and nerves that surround the prostate. By drawing the anatomy of individual cases, he continues to fine tune ART[™] and improve cancer control while sparing nerves. He also uses the drawings as a teaching tool for students as well as his peers worldwide who are eager to learn his technique.

The crux of the ART[™] technique is the delicate removal of the prostate from the top of the nerve hammock with maximal clearance for preserving sexual and urinary function. Not only are nerves not handled, but oxygenation of the nerves is monitored during this phase of the technique so these preserved nerves are greater in number and also healthy and vascular.

The ART[™] approach consists of not just one technique but a group of techniques, including those for diagnosis. We use a new state-of-the-art technique known as targeted biopsy, to precisely diagnose prostate cancer. This technique fuses highly detailed MRI (magnetic resonance imaging) with real-time ultrasound using the Artemis device. The procedure typically takes 15 to 20 minutes and is done in our office under local anesthesia. It provides highly accurate information about the location of cancer and its relation to nerves and sphincters. Mount Sinai is one of a few medical facilities in New York City with the Artemis device.

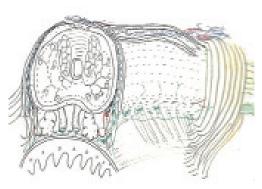
Outcomes

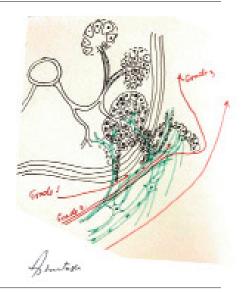
Cancer control – ART[™] has proven to provide low margin rates (less residual cancer). As a consequence, there is less need for radiation and hormone therapy post surgery and men have less reason to feel anxious about future rises in their PSA.

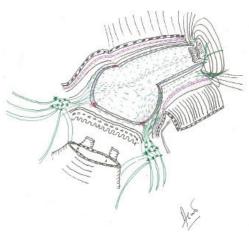
High rates of erectile function

recovery – The aim of ART[™] is to preserve every nerve fiber responsible for the fine balance between erection, orgasm, and bladder function. The benefits of the ART[™] technique for sexual function are significant. ART[™] allows for stronger erections and orgasms, a reduction in penile shrinkage and a reduction in the risk of climacturia (involuntary release of urine at the moment of orgasm).

In order to protect the delicate nerves involved, which do not handle heat, traction, or manipulation very well, we use a nerve-sparing, completely athermal and "traction free" technique (no use of cautery or heat energy) during robotic prostatectomy - a technique pioneered by Dr. Tewari and his team. A majority of our patients who experience normal sexual functioning and are candidates for nerve-sparing, return to normal sexual function after ART[™] surgical treatment. Our best case scenario is when patients are young, cancer is early and organ-confined, and baseline sexual functions are very high. Dr. Tewari can perform Grade I nerve-sparing that can achieve excellent potency (ability to have intercourse) with or without use of oral medications.





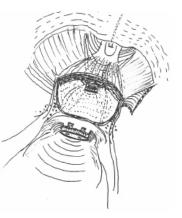


Faster return to urinary continence

ART[™] incorporates a novel surgical technique to minimize or prevent urinary leakage, even with exertion, and provide a strong urinary stream. It involves reconstruction of the supporting structures responsible for urinary continence that are typically either removed or disorganized during removal of the prostate. Dr. Tewari developed a detrusor wrap procedure that creates an additional wrap that serves as a sphincter and sling to provide enhanced and accelerated return to continence. Most of our patients who are continent before the surgery are continent 18 months after surgery.

Hood technique

Dr. Tewari performs approximately 400 robot-assisted radical prostatectomies every year. The procedure takes around 30-40 minutes, with an additional 30 minutes for real-time pathology. When removing the prostate, we want to leave as much of the prostate's surrounding tissue intact as possible, as this will minimize the disruption of urinary mechanisms. Our surgical technique allows for careful separation of the detrusor apron from the anterior prostate. The detrusor apron allows the bladder to store urine, and contracts during urination to release urine. It overlies the prostate and extends from the bladder neck to the pelvis. Because the detrusor apron covers this important area, we call this area, and the procedure we do to protect it, the "Hood".



In addition, with the ART[™] technique, patients and their families have been able to benefit from faster convalescence, shorter hospital stays, small incisions with less scarring, significantly less blood loss during surgery, and less pain following surgery. The majority of our patients are discharged and return home within 24 hours of their robotic surgery.

Outcomes and Implications

Less than 10 percent of men experience complications after prostatectomy, and these are usually treatable or short-term. The two most common post-surgery problems are urinary incontinence and erectile dysfunction. Less than 5 percent of men younger than age 50, and less than 15 percent of men age 70 or older, are incontinent after radical prostatectomy. Most men are able to have sex after prostatectomy while using ED medicines (such as Viagra or Cialis), an external pump, or injectable medications. The younger the man, the higher the chance of maintaining potency after prostatectomy. A period of penile rehabilitation is often necessary.

Sparing the nerves that can cause urinary incontinence or erectile dysfunction is the hallmark of a skilled surgeon. A patient who has a radical prostatectomy by a surgeon at an advanced prostate cancer center has a better chance of maintaining sexual and urinary function.

Active Surveillance

Active surveillance is an option for men whose prostate cancer is considered low risk. Active surveillance means that instead of treatment such as surgery or radiation, patients will be monitored on a regular basis for signs of more aggressive disease. Active surveillance is sometimes referred to as "watchful waiting" or "expectant management," but active surveillance is the favored term for this approach, because it is a proactive, rather than a passive regimen. At Mount Sinai, Dr. Ash Tewari has a large active surveillance study group.

Patients under active surveillance at Mount Sinai generally have a PSA blood test and a digital rectal exam (DRE) every three months, an MRI yearly, and a biopsy every three years. However, the order can change if the results warrant it. We also have all of our surveillance patients meet with Jillian Capodice, LAC, Director of Integrative Urology and Wellness. She creates a specialized program for each patient that suits his needs. She will also evaluate for psychosocial needs and support. Most surveillance patients do not need a psychological evaluation but if requested, we arrange for this.



Dr. Tewari and Nihal Mohamed, PhD, Director of Behavioral and Social Research, Department of Urology, are currently leading two studies funded by the Department of Defense to inform patients and their loved ones about active surveillance and some of the challenges that men and their loved ones face on long-term health care such as the need for information about follow-up screening tests and learning strategies to manage stress and worries. The Department of Defense program will help patients and their families prepare for active surveillance, stay on track regarding follow-up care, and maintain better emotional well-being.

Technologies

Artemis

Artemis is an imaging device that allows 3-D prostate visualization and tracking. By fusing multi-parametric MRI with real-time ultrasound, abnormal or suspicious areas seen on the MRI can be tracked and targeted during a prostate biopsy. Artemis offers sophisticated recording of actual biopsy sites sampled so sites can be reviewed at any time.

The technique is done in two steps. First an MRI is done and the studies are loaded onto a software where the radiologist marks the prostate gland and the regions of interest for biopsy. This is known as segmentation. This information is then loaded onto Artemis for a targeted biopsy. This can be done in an outpatient setting under local anesthesia within a few minutes.

We perform about 300-350 MRI-targeted biopsies every year through the rectum. In the future, we expect to conduct MRI-targeted biopsies via the transperineal approach (a thin needle is inserted through the skin of the perineum and into the prostate). There are no head-to head studies comparing the different MRI-targeted approaches, however, there is some evidence that shows the transperineal approach has excellent detection rates and none of the septic complications that occur after going through the rectum.

Biopsy and Cystoscopy under "Twilight Anesthesia" (Conscious Sedation)

Conscious sedation is a service offered to our patients for their comfort. Both systematic and MRI fusion guided prostate biopsies can be performed in the office at 625 Madison Avenue with the assistance of an anesthesiologist, who is able to give intravenous medications to gently and mildly sedate patients so that they can better tolerate potential discomfort of the biopsy. This sedation is considered moderate, but it can be mild or moderate based on the needs of the patient or dosages determined appropriate by the anesthesiologist. Patients can respond to commands, but will likely fall asleep through most of the procedure. Since they are not unconscious, there is no need for external breathing support.

While patients can choose if they would like IV sedation, all patients receive local anesthesia (usually injectable lidocaine) at the site of biopsy. It takes approximately



30 minutes for sedation to wear off. A team member monitors the patient after the procedure to make sure they are walking comfortably and discharged from our office in stable condition. We ensure that all patients urinate on their own at least once prior to leaving our clinic post-biopsy.

da Vinci Robot

The da Vinci surgical system is a sophisticated robotic platform designed to expand the surgeon's capabilities and offer a state-of-the-art minimally invasive option for prostate surgery. With da Vinci, small incisions are used to insert miniaturized instruments and a high-definition 3-D camera. Seated comfortably at the da Vinci console, Dr. Tewari views a magnified, high-resolution 3-D image of the surgical site inside your body.

At the same time, the latest robotic and computer technologies scale, filter, and seamlessly translate Dr. Tewari's hand movements into precise micro-movements of the *da Vinci* instruments. Although it is often called a "robot", the *da Vinci* surgical system cannot move or operate on its own; Dr. Tewari is 100 percent in control.



da Vinci console

High-Intensity Focused Ultrasound (HIFU)

High-Intensity Focused Ultrasound (HIFU) is a minimally invasive treatment for localized prostate cancer that uses high-frequency sound waves directed at the cancerous tissue through an ultrasound probe inserted into the rectum. The high intensity sound waves heat up and ablate the targeted tissue, causing cancer cell death.

Using HIFU Focal One[®] technology, the world's most advanced high intensity focused ultrasound, high resolution images are fused with biopsy data and realtime ultrasound imaging which allows the urologist to view cancerous tissue images in 3D. With this clear view, our surgeons can draw precise contours around the diseased tissue, ablate only that portion of the prostate, and minimize damage to the surrounding structure which include nerves, blood vessels, and muscle tissue. HIFU is customized for each patient and reduces the risk of side effects including urinary incontinence and erectile dysfunction preserving quality of life.

For men diagnosed with localized prostate cancer, HIFU and Focal One[®] provides another alternative between active surveillance, and radical surgery and radiation. HIFU is a minimally invasive, outpatient procedure and no incisions are made during treatment.







Genetics and Genomics

Genomic testing allows Dr. Tewari and his team to get a clearer understanding of a cancer's aggressiveness than PSA alone can provide, and tailor screening and treatment to each patient's unique risk profile.



Natasha Kyprianou, MBBS, PhD Vice-Chair, Basic Science Research



Suiit Nair, PhD Assistant Professor, Urology



Dimple Chakravarty, PhD Assistant Professor, Urology



Boris Reva, PhD Associate Professor Genetics and **Genomic Sciences**



Nihal Mohamed, PhD Director of Behavioral and Social Sciences



Eric Schadt, PhD Dean For Precision Medicine



Goutam Chakraborty, PhD Assistant Professor



Genetics and Genomic Sciences



Krunal Pandav, MD Associate Researcher



Kristin Beaumont, PhD Assistant Professor Genetics and Genomic Sciences



Xiangfu Zhang Associate Researcher



Avi Ma'ayan, PhD Professor Pharmacological Sciences



Stanislaw Sobotka, PhD. DSc Biostatistician

The 4KScore[®] is a tool that incorporates simple blood test results to estimate the risk of finding aggressive/clinically significant prostate cancer on a prostate biopsy. In combination with PSA and one's medical and family history, the tool helps assess the need for an initial biopsy.

Physicians use the Prolaris[®], Oncotype Dx[®], Decipher[®] and Precise MD tests for men with localized prostate cancer to add precision to their clinical risk assessment. These tests assess prostate biopsy tissue. The information provided about the aggressiveness of a tumor helps identify patients who can safely choose active surveillance. Decipher® and Precise MD can also be done after prostatectomy to give more detailed information on aggressiveness post-operatively.



Genomic screening of tumor tissue

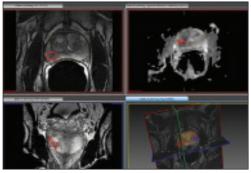
The ConfirmMDx[®] for Prostate Cancer testing solution addresses false-negative biopsy concerns. It can "rule out" otherwise cancer-free men from undergoing unnecessary repeat biopsies and screening procedures and "rule-in" high-risk men with a previous negative biopsy result who may be harboring undetected cancer (false-negative biopsy result) and therefore may benefit from a repeat biopsy and potentially treatment. The Progensa[®] PCA3 assay measures the concentration of prostate cancer gene 3 (PCA3) and prostate-specific antigen (PSA) RNA molecules in post-digital rectal exam (DRE) male urine specimens. The resulting PCA3 score predicts the results of repeat biopsies for men who have had one or more previous negative prostate biopsies.

In the laboratory, our researchers are working to unravel the genetic factors linked to prostate cancer. Two studies underway – single-cell genomics profiling and racial disparity profiling – are expected to advance the goal of truly personalized prostate care. Researchers, including computational biologists, are also working to identify therapeutics that can accurately target the root cause of the cancer, in the hopes of minimizing side effects and resistance development.

3 Tesla Multiparametric MRI

3 Tesla Multiparametric Magnetic Resonance Imaging is a state of the art, non-invasive imaging modality that facilitates diagnosing, staging and pre-operative

planning for prostate cancer. Magnetic waves create images of the prostate and surrounding tissue. Using advanced computer algorithms, these images can be processed to predict where prostate cancer lesions are located.



MRI guided fusion biopsy planning targets

Bachir Taouli, MD Director, Cancer Imaging





Sara Lewis, MD Assistant Professor, Radiology

Ivan Jambor, MD, PhD Radiologist

Intraoperative real time pathology – NeuroSAFE™

NeuroSAFE[™] allows the assessment of surgical margin for absence or presence of cancer intra-operatively.

Our program is one of the few in the world in which pathologists are on stand-by to provide real time rapid interpretation of the entire prostate margin rather than of small pieces of tissue when they are taken for a frozen tissue biopsy. This rapid pathology provides an additional element of security that cancer has not been left behind while we are working to preserve nerves.

Using a multiparametric magnetic resonance imaging (mpMRI)-based nomogram allows Dr. Tewari to use the right nerve-sparing technique based on a particular patient's biology.



MRI guided Neuro-SAFE[™] technique of intraoperative frozen section showing the prostate with cut off left margin and the inked false margin



Carlos Cordon-Cardo, MD, PhD Chair, Pathology



Ken Haines, MD Senior Faculty Pathology

Post-Surgery Rehabilitation Program

The Department of Urology is staffed with qualified medical professionals who provide expert in-office guidance on sexual function, continence, nutrition,



Neil Grafstein, MD



Rajveer Purohit, MD



Steven Kaplan, MD



Sovrin Shah, MD



Vannita Simma-Chiang, MD

exercise, stress management, and alternative medicine options for post-surgical recovery and rehabilitation.

Continence

Almost half of men who undergo radical prostatectomy experience incontinence immediately after surgery. For most men this condition resolves quickly (within six months). But for others, voiding dysfunction persists beyond a year resulting in both physical discomfort and emotional upheaval due to forced lifestyle changes. Fortunately, multiple treatment options are available, and in the hands of continence experts, can be tailored to a patient's medical history and physical condition as well as personal preference.

Neil Grafstein, MD, is the Director of Reconstructive Surgery, Female Urology and Voiding Dysfunction at Mount Sinai and oversees continence rehabilitation for our prostatectomy patients. Dr. Rajveer Purohit, MD, is the Director of Voiding Dysfunction and Reconstructive Urology at Mount Sinai. He performs complex reconstructive surgical procedures including urethroplasty for urethral strictures with grafts and flaps, surgery for complications of radiation therapy, treatment of mesh complications and complications of pelvic surgery such as incontinence. Steven Kaplan, MD, and Sovrin Shah, MD, are also specialists who treat post-prostatectomy patients. Vannita Simma-Chiang, MD, specializes in the medical and surgical care of male and female voiding dysfunction patients.

Behavioral training is a helpful first step for stress incontinence and patients are advised to start shortly after surgery. Pelvic floor exercises (referred to as Kegels or PEMs), timed voiding, double voiding and reduced fluid intake are all behavioral strategies that can significantly facilitate urinary control.

Men whose incontinence does not respond to behavioral training or resolve within six months to a year can consider minimally invasive surgical options that are highly successful, specifically the male urethral sling and the artificial sphincter. Dr. Grafstein was one of the first urologic surgeons to perform Advance[™] sling implantation and is one of the most experienced surgeons in the country doing sling procedures. At Mount Sinai this minimally invasive surgery is often done on an outpatient basis.

Other Program Centers in Urology Department at Mount Sinai

The Department of Urology's surgeons and scientists have pioneered the adoption of novel diagnostic techniques and minimally invasive treatments for a wide range of other urologic disorders. The program centers and procedures include:

Minimally Invasive Surgery and Advanced Procedures:

Dr. Michael A. Palese, Chair of Mount Sinai Downtown and Beth Israel Hospital leads the Minimally Invasive Surgery team for the Mount Sinai System. Dr. Palese and his group develop and perform the newest cutting edge minimally invasive techniques for robotic, laparoscopic and endoscopic procedures. The MIS team specializes in performing advanced procedures for complex conditions involving the kidney, prostate, bladder, ureter and adrenal gland.

Bladder Cancer Program:

Dr. Peter Wiklund MD, PhD, a world renowned physician-scientist, is the director of our bladder cancer program. His innovations include the entirely robotic removal of a bladder and creation of a new bladder and he has performed the highest number of these surgeries worldwide. Along with Dr. Mehrazin and Dr. Sfakianos, he has expanded the scope of robotic surgery, immunotherapy and research to provide a patient centered, personalized treatment approach to bladder cancer.

Comprehensive Kidney Cancer Center and Reconstructive Surgery Program:

Dr. Ketan K. Badani, MD, system Vice Chair of Urology, leads the Comprehensive Kidney Cancer Center and Robotic Kidney Surgery Program. Dr. Badani has the most experience performing robotic kidney surgery of any surgeon in the United States. He is also highly skilled in complex urinary tract reconstructive surgery. The Comprehensive Kidney Cancer Center at Mount Sinai offers all treatment modalities for kidney cancer including radical and partial nephrectomy, ablation, and active surveillance.

Kidney Stone Center:

The Kidney Stone Center at Mount Sinai, led by Mantu Gupta, MD, FRCS (Glasg.), provides a comprehensive approach to the treatment of kidney stones. He has brought to the Mount Sinai Department of Urology the latest technological advances for the treatment of kidney stones, including state-of-the-art lasers, best-in-class shock wave lithotripsy machines, and flexible miniature endoscopes that improve patient comfort and outcomes.



Sexual Function

Penile rehabilitation can play an important role in speeding the ability to resume sexual functioning. The goal of penile rehabilitation is to keep the penile tissue and muscles oxygenated and stretched to preserve erectile function while the nerves in the penis fully recover. At Mount Sinai, we encourage our patients to start working on penile rehabilitation even before surgery.

Pre-operative visits could include early evaluation, penile Doppler studies (a test of blood flow into and out of the penis), and testosterone level estimations if our experts Robert Valenzuela, MD, Susan Marshall, MD, and Barbara Chubak, MD, determine that your particular case could benefit from these evaluations. Occasionally we start penile rehabilitation using medications a few weeks before surgery.







Susan Marshall, MD



Barbara Chubak, MD

Post-operative rehabilitation usually starts a few weeks later and may include using intra-urethral suppositories, oral medications and vacuum device therapies as well as other approaches to maximize your chances of recovery. We are committed to finding the best option for you.

We also offer low intensity shockwave therapy (LIST) of the penis. LIST is an important and exciting new office-based therapy that uses sonic energy to improve penile function, blood flow, and ultimately sexual satisfaction. As we increase the use of this novel technology, we have been very encouraged by the positive impact of LIST in many patients' post-operative treatment plans.



Holistic Medicine, Nutrition and Diet, Exercise and Lifestyle Changes

It is important to achieve the best outcomes and offer comprehensive care for all of our patients. Dr. Tewari strongly believes that lifestyle factors significantly impact outcomes and, as such, the Integrative Urology Program, run by Jillian Capodice, LAC, Assistant Professor in the Department of Urology, plays an important role for our patients.

Program highlights include:

- Nutritional strategies and weight loss for patient health optimization prior to radical robotic prostatectomy
- Lifestyle recommendations for patients to facilitate post-surgery recovery, optimize healing and keep patients at low risk for potential recurrence
- Mind-body strategies and/or acupuncture to help patients cope with stress or anxiety pre-surgery
- Active Surveillance program: full individualized assessment and health optimization for patients on active surveillance to assist in risk reduction
- · Other holistic approaches for overall health and wellness



Jillian Capodice, LAC

Men's Health

The Men's Health Program at the Department of Urology provides men of all ages with a comprehensive, holistic assessment and approach to the diagnosis, treatment and management for some of the most common disease states affecting men, including disorders of the prostate and urination (prostatitis, benign prostatic hyperplasia (BPH) and urinary incontinence) and issues related to sexual function (erectile dysfunction, low testosterone, and sexually transmitted diseases).

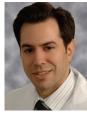


We also perform risk profiling for men wishing to understand the likelihood of their developing prostate, kidney and bladder cancer. Our mission is to provide a compassionate, focused and efficient program that encompasses medicine, nutrition, exercise and stress reduction in achieving a balanced and prolonged health span.

Our multidisciplinary program is directed by Dr. Tewari and Dr. Steven Kaplan. When appropriate, timely and priority access to expert specialists within the Mount Sinai Health System is arranged for our patients.

Advanced Prostate Cancer

Advanced prostate cancer is a disease that has spread beyond the prostate gland to the lymph nodes, bones or other areas and is referred to as metastatic. At the Mount Sinai Health System, our multidisciplinary team of outstanding physicians offers the latest research-backed services for the diagnosis and treatment of metastatic disease. We are utilizing all standard and newly approved chemotherapy and anti-androgen (hormone) treatments to help our patients with metastatic and castrate-resistant metastatic cancer. The Department of Urology, in collaboration with The Tisch Cancer Institute at Mount Sinai, is actively researching new treatments for advanced cancer.



Matt Galsky, MD Director of Genitourinary Medical Oncology



Bobby Liaw, MD Assistant Professor, Medicine, Hematology and Medical Oncology



William Oh, MD Associate Director, Tisch Cancer Institute

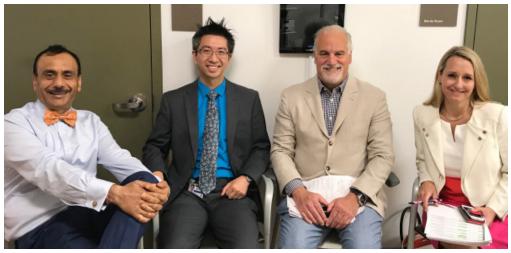


Che-Kai Tsao, MD Associate Professor, Medicine, Hematology and Medical Oncology

Multidisciplinary High-Risk Prostate Cancer Treatment Program in Midtown

Dr. Tewari has introduced a same-day multidisciplinary clinic for patients with advanced and high-risk prostate cancer at our midtown office. This team-based approach enables the optimal management of patients who have or are at risk for cancer metastasis. Patients are scheduled to meet with a senior medical oncologist, a renowned radiation oncologist, and experts in holistic and integrative medicine, sexual medicine, and urinary function at the same time as their appointment with Dr. Tewari.

The team then develops a plan which may include radiation or hormone treatment (if hormone injections are recommended, they can begin on the same day at the office). Our holistic medicine expert can advise on diet, exercise and supplements. Patients can also get perspectives about sexual recovery, urinary issues, novel therapies, comparative outcomes, side effect profiles and various newer treatments that are under study.



From left, **Ash Tewari, MBBS, MCh, FRCS (Hon.), Bobby Liaw, MD,** Clinical Director of Genitourinary Medical Oncology, **Richard Stock, MD,** Radiation Oncology and **Philippa Cheetham, MD,** Urologic Oncology.

High Intensity Focused Ultrasound (HIFU)

HIFU is a new, minimally invasive and highly targeted treatment option for localized prostate cancer that was recently approved by the FDA. A leader in diagnostic imaging for prostate cancer, Mount Sinai has acquired the HIFU device and will be making it available to select patients in the near future.

Clinical Trials and Innovations Team

We have recently expanded our Clinical Trials and Innovations team. Leading the group is Dara Lundon, MD, PhD, MBA, who has focused on clinical research work that has helped reduce the number of unnecessary prostate biopsies in men. Dr. Lundon has validated and developed risk tools for assessing men referred for assessment for prostate cancer that were adopted by the National Cancer Control Program and integrated into clinical practice. He has also discovered and characterized SRF

(serum response factor) in advanced and metastatic prostate cancer, demonstrating that SRF expression in such prostate tumors predicts clinical outcomes including metastasis and survival. Dr. Lundon demonstrated for the first time that SRF and other transcription factors could be manipulated using a variety of therapeutic modalities, and that prostate cancer's resistance to existing therapies could be reversed. Joining Dr. Lundon on the Clinical Trials and Innovations team are two Clinical Research Nurses Cristina Pasat-Karasik, RN and Lily Davenport, RN, and two Clinical Research Coordinators: Monali Fatterpekar, PhD and David Musheyev, BS.



Dara Lundon MD, PhD, MBA, Director, Clinical Trials and Innovations Team

Monali Fatterpekar PhD. Clinical Research Coordinator

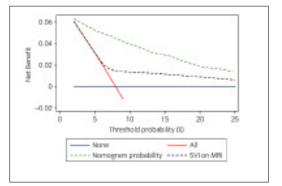
Karasik RN. Clinical **Research Nurse**

Cristina Pasat- Lily Davenport David RN. Clinical Research Nurse

Musheyev BS. Clinical Research Coordinator

Nomograms

Alberto Martini, MD, working with Dr. Tewari, has developed nomograms (predictive models based on mathematical functions) that minimize unnecessary nerve removal while minimizing the risk of positive surgical margins (the resection through the tumor). When published, these nomograms were the first that



integrated clinical data, such as PSA, biopsy information and MRI data, in a side-specific manner. These nomograms have provided Dr. Tewari with the best surgical strategy for nerve preservation on the right and left side of the prostate.

Radiogenomics

A patient sometimes needs a biopsy to analyze the genetic features of his cancerous prostate tissue. We use biopsies to remove tiny samples of prostate tissue through the rectum, which can be uncomfortable. This is the only way to diagnosis prostate cancer.

Radiogenomics is a promising new concept that aims to gain genomic insights from clinical images. For prostate cancer patients, we hope to minimize the amount of tissue we need to take for biopsy by combining prostate MRI (mpMRI) with real-time ultrasound imaging.

We are working to develop new procedures so that we would not need to conduct any biopsies. Current MRI technology cannot predict genetic features by itself; the best it can do is target the cancerous lesion during biopsy. As we evolve mpMRI and ultrasound imaging, we may get to the point where we do not need to do biopsies at all.

Open Radical Prostatectomy

Open radical prostatectomy is another way to treat prostate cancer surgically.

The primary advantages of modern, open radical prostatectomy include using only one small lower abdominal incision; minimal blood loss; transfusion rates under five percent; greater access to lymph node removal; the ability to do the surgery without entering the abdominal cavity; and comparable cancer, continence, and potency results to robotic prostatectomy. The open approach is appropriate for all patients with prostate cancer, but especially relevant for those patients who have had extensive, prior intra-abdominal surgery; radiation to the abdomen for other cancers; or have a high grade/stage/risk disease (as more lymph nodes can be removed).

Open radical prostatectomy usually takes 90 to 120 minutes to perform, and patients stay in the hospital for one night and go home the next day. Regular food can be eaten immediately after surgery because the abdominal cavity has not been entered. It is very important (and very feasible) for patients to walk within hours of the surgery so that they can go home the next day, as well as prevent blood clots, pneumonia, and abdominal bloating.

Prostate Cancer Racial Disparity

Prostate cancer affects one in nine men in the United States. However, one in five African-American (AA) men are diagnosed with the disease, and have a mortality rate 2.4 times higher than that of European-American (EA) men. AA men have 70 percent higher rates of high-risk prostate cancer than EA men do. In addition, AA men are more than twice as likely as EA men to die of prostate cancer, and often death occurs at significantly younger ages.



The following factors have been shown via research to contribute to the racial disparity:

- **Biological differences,** such as genetic predisposition, age, and family history of disease, affect AA men more than EA men do. Men who have a first-degree relative with a history of prostate cancer are two to three times more likely to develop prostate cancer.
- AA patients have a **lower socioeconomic status (SES)** than EA patients do. A patient's SES level contributes significantly to prostate cancer progression in AA patients due to poor adherence to follow-up care protocol, and increases in risky behavior (e.g., greater use of alcohol and tobacco, lack of physical activity, and a deficient diet).
- A patient's **social network and social support** can have a negative impact on cancer morbidity and mortality. Social networks with low SES may limit patient access to health resources, critical information, and positive emotional support while coping with a life-threatening disease.
- AA men have a **lack of medical insurance**, which is very detrimental to prostate cancer care. When AA and EA patients have equal access to care, survival rates are comparable after adjusting for prostate cancer stage and grade.

Advancing Clinical Practice: Early Detection

We are working on developing a platform to ensure that every AA man can receive personalized screening, decision support, and treatment for prostate cancer. By identifying specific biomarkers for each patient, we can drive precision management and treatment of the disease.

Key things we will do:

- Determine the **genetic and genomic** factors that underlie prostate cancer development and progression in AA men. In addition, we will use genetic counselors to help AA men with genetic susceptibility to prostate cancer and recommend appropriate treatment.
- Develop a guide for urologists to **detect cancer by leveraging use of molecular diagnostic tools** like Oncotype Dx, Decipher, Polaris, and hereditary and somatic gene targeted sequencing panels for risk stratification and decision support.
- Create a **new predictive model** for cancer in prostate tissue based on a range of imaging technologies and artificial intelligence.
- **Improve screening by utilizing a novel blood-based tool** that evaluates levels of five blood plasma proteins and more than 100 genetic markers and clinical data to determine risk of significant prostate cancer.
- Test the effectiveness of using a **stand-up MRI** versus a traditional MRI to screen for prostate cancer. Due to the claustrophobic nature of standard MRIs, AA men are less likely to get an MRI.
- Increase **participation in clinical trials.** AA men have been underrepresented in these trials, and they may respond differently than other segments of the population.
- Provide **access to lifestyle and health programs** such as smoking cessation and diet and nutrition programs.
- Raise **awareness about screening** and provide access to free screenings for those in need.

Advancing Clinical Practice: Prevention

Besides detecting cancer as early as possible, we must also provide medical intervention and prevention of prostate cancer in AA men. The following strategies are already underway:

- Develop a **catalog of DNA and RNA sequencing** for AA men in order to determine where alterations in the genes occur.
- Identify potential **drug candidates during a biopsy that can shrink tumors** based on specific genomic information.
- Understand what triggers AA men to have a **different immune and inflammatory response** to a prostate tumor than EA men do.
- Create various **immunotherapy clinical trials** to hone in on targeted, personalized responses that help AA men with their unique genetic predispositions.
- Test a **vaccine** that activates multiple elements of innate and adaptive immunity in a prostate tumor.

Our Team

Our office is dedicated to serving men with prostate and men's health issues. Dr. Tewari is assisted by a full time board-certified urologist and our medical team includes certified physician assistants, a registered nurse, and a nurse practitioner. Darren Deoraj, System Director of Operations, with our practice manager, surgical schedulers, and patient-care coordinators are dedicated to making your office visit with us easy and stress free.

Patients are seen at our spacious office at 625 Madison Avenue (between 58th and 59th Streets) in Manhattan. Our office is convenient to subways, buses, and parking garages.

Please feel free to ask us questions at any time. We can be contacted at 212-241-9955 or to speak to Dr. Tewari directly, call 347-271-1644 or email ash.tewari@mountsinai.org.

For more information about Dr. Tewari, ART[™] and services of the Mount Sinai Health System, please visit www.mountsinai.org/roboticprostate.



Our team includes:



Anastasia Karpenko assists Dr. Tewari in all areas of his surgical and patient practice, as well as role and responsibilities his as System Chair of the Department of Urology for the Mount Sinai Health System. She manages his calendar, coordinates the execution of strategic initiatives, and ensures the installation of appropriate systems and tools for the overall success of the department.

Shashank Mishra is the administrative and practice manager for Dr. Tewari. He is responsible for the overall management of Dr. Tewari's clinical practice. He ensures the highest standards of patient service and develops new practice initiatives to optimize patient communications, safety, and satisfaction.



Darren Deoraj is the System Director of Operations. He is responsible for fine-tuning all of our processes in our clinical offices. He develops and executes new initiatives across all clinical practice sites and insures that the sites have the tools and resources they need for success. She will implement protocols to maximize a stellar patient experience



Kacie Schlussel, PA-C, is the Clinical Director, Chair's Practice. She will focus on ensuring Dr. Tewari's team is committed to continuous development and growth while never compromising our high standards of care and best practices.



Adriana M. Pedraza, MD, has been working closely with Dr. Tewari for the past few years as a clinical fellow. Dr. Pedraza plays an active role in assisting with inpatient care and closely following-up once a patient is discharged from the hospital.



Mae Gerenia, NP, is a certified urologic nurse practitioner who helps manage pre-operative and post-operative clinical care. She sees patients for acute urologic concerns and manages patients on active surveillance. She orders and interprets lab and genomic test and imaging. She is also responsible for medication management.



Yohaira Rojas is the Director of Community Outreach. She is responsible for organizing outreach programs including the Prostate Screening Mobile Unit, and the coordination of patients, staff, and volunteers involved in community programs to bring prostate cancer screening and awareness to the surrounding communities.











Marla Gabriele, PA, Ian Hass, PA, Roy Berryhill, PA, Olivia Kyi, PA-C, Shilmi Patel, PA-C and Nicole Eisbrouch, PA-C and are board certified physician assistants. Joseph Kiper, RA is a clinical nurse. They play an active role in interpreting diagnostic imaging results and formulating treatment plans. They manage patients pre- and post- operatively and are responsible for medication management.





Fatou Lowe, Remelin Bellara, Emily Madera and Alin a Cardi are clinical assistants, working with physician assistants to provide pre- and post-operative care and medication management.



Katrina Cruz is the clinical supervisor. She makes sure that medical assistants properly support Dr. Tewari as he performs procedures in the exam room.



Anisa Eyssallenne and Antonnette Hewitt are medical assistants who take vitals, draw blood, and document all results. They assist Dr. Tewari in the exam room with procedures.





Jean Jean-Gilles, Daisy Castro, and Ageliki Pettas obtain and review the necessary administrative clearance for a surgery to proceed, and they work with our patients' insurance companies to obtain authorization. They also work directly with patients to answer questions and confirm schedules.



Kushmawattie Ramgopal is a patient coordinator. She checks patients in and out of the office, and is also a patient phone representative and appointment scheduler.



Milagros Giribaldi is the front desk supervisor. She manages a team that ensures proper patient check in, scheduling of future appointments, and collection of payments.



Lawrence Breedlove is a medical administrative assistant. He is a phone representative, confirming patient appointments, and conferring with referring physicians.



Justin Chang, project coordinator, helps manage insurance credentialing, which helps expand the insurance offerings that Dr. Tewari accepts in his practice. He also manages Dr. Tewari's patient access profiles, especially Zocdoc, so that patients can schedule appointments with Dr. Tewari.





Regina Bangiyev, Satish Maharaj and **Juan Mercado** are surgical coordinators responsible for coordination of all OR surgeries and procedures. They obtain preauthorizations for procedures and diagnostic tests as requested by the physician.

Frequently Asked Questions

Q: Is it true that patients go to "boot camp" before surgery?

Not literally. Dr. Tewari encourages patients to begin exercising and working toward getting into better shape before surgery. Sometimes that means weight loss and for others, building up cardiovascular endurance or muscle mass. At the very least, he wants patients to begin to walk on a regular basis, aiming for three miles a day if at all possible. In his experience, patients who are in good physical condition make a faster recovery and return to their pre-surgery quality of life quicker. He also believes that staying in shape is important for maintaining good health after surgery and for years to come.

Q: What are the most common outcomes and complications from surgery?

The two most common outcomes and complications are urinary incontinence and erectile dysfunction. Less than 5 percent of men younger than age 50, and less than 15 percent of men age 70 or older, are incontinent after radical prostatectomy. Most men are able to have sex after prostatectomy while using ED medicines (such as Viagra or Cialis), an external pump, or injectable medications. The younger the man, the higher the chance of maintaining potency after prostatectomy. A period of penile rehabilitation is often necessary.

Q: Will I be able to have erections after robotic prostate surgery?

A number of factors are involved in regaining erectile function, including the stage of your cancer and the strength of erections you had prior to surgery. The ART[™] surgery, pioneered by Dr. Tewari, is designed to eradicate the cancer while minimizing damage to the nerves responsible for erectile function. Most of Dr. Tewari's patients do regain the ability to have erections, but it is a gradual process – one that can take up to a year (or more), with erections usually improving with time.

Q: Will I have normal urinary control after this procedure?

Some men have normal urinary control immediately following ART[™] prostate surgery. However, most men leak some urine immediately following the surgery and then gradually regain control in the weeks following the removal of the catheter. Most of Dr. Tewari's patients who had normal urinary control prior to surgery achieve it again within 3-18 months of surgery. Some patients regain control following injections or penile implants.

Q. Do you treat patients from outside the United States?

Yes. Care for patients traveling from abroad will be coordinated by the Department of Urology and Mount Sinai's International Patient Services. We will coordinate transfer of relevant medical records, schedule additional exams with our vast network of complementary physicians, arrange for your hotel stay, and ensure your trip to The Mount Sinai Hospital is comfortable and satisfactory. We also offer translation services.