



Transforming

POSTGRADUATE
MEDICAL EDUCATION

Multidisciplinary

PATIENT-FOCUSED
CARE

10+

SUBSPECIALTIES

3

FELLOWSHIP
PROGRAMS

MRI-Guided

PROSTATE
BIOPSY

Urology

2015

YEAR IN REVIEW

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Dear Colleagues and Friends:

As chair of the Department of Urology at NYU Langone, I am committed to fostering a commitment to excellence and to furthering the vision and values of our academic medical center.

Over the past 22 years, I have been fortunate to recruit and retain a faculty of physicians and scientists who share my commitment to advance urological healthcare delivery, research, and education. Every day, our team of dedicated healthcare professionals, scientists, and educators strives to achieve excellence one patient, one experiment, and one lecture at a time. Together, our urology team achieved extraordinary advances for patients in 2015.

In these pages you will read about exceptional clinicians who are at the cutting edge of treatments for prostate cancer and diseases of the bladder and urinary system, as well as about the latest minimally invasive surgical options offered by experienced surgeons working in our Robotic Surgery Center. Our clinicians partner with radiologists, pathologists, medical oncologists, and health policy experts to improve screening, detection, and treatment techniques, leading to better patient outcomes.

We attract significant National Institutes of Health funding, and 2015 has been another exceptional year for our researchers. Of particular note: Our Goldstein Family Bladder Cancer Research Group is continuing to study the molecular tumorigenesis of bladder cancer, funded by an \$8.3 million program project grant from the National Cancer Institute.

Many of our faculty members have achieved national stature through their research, leadership roles in national societies, and seats on the editorial boards of major peer-reviewed journals. I invite you to read on to learn more about our work and accomplishments over the past year and our vision for moving forward.



A handwritten signature in black ink that reads "Herbert Lepor". The signature is fluid and cursive, with the first name and last name clearly distinguishable.

HERBERT LEPOR, MD

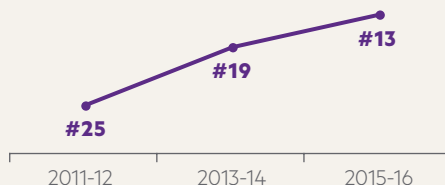
Professor of Urology and Biochemistry and
Molecular Pharmacology

Martin Spatz Chair of the Department of Urology
Urologist-in-Chief

Urology

#13
in the U.S.

for Urology in U.S. News & World Report's 2015–16 "Best Hospitals"



2 P01

**NCI program
project grants**

with a focus on molecular
tumorigenesis of bladder cancer
and urothelial biology

4

Urology CME courses

to be offered at NYU Langone in 2016

10+

subspecialties

1 in 8
**practicing
U.S. urologists**

have come to NYU Langone for
postgraduate education

160+
publications

produced by urology faculty in FY15

47
abstracts

presented at the AUA 2015 meeting

Prioritizing Detection
**of clinically significant
prostate cancer**

while helping to preserve men's quality of life

NYU Langone Medical Center



#1

overall patient safety
& quality for
three years in a row

AND

ambulatory care quality
& accountability

among leading academic medical centers
across the nation that were included in the
University HealthSystem Consortium 2015
Quality and Accountability Study

Top 15

in U.S. News & World Report



#12

**BEST HOSPITALS
HONOR ROLL**



#14

**BEST MEDICAL
SCHOOLS FOR
RESEARCH**

and nationally ranked in 12 specialties,
including top 10 rankings in
Orthopedics (#5), Geriatrics (#6),
Neurology & Neurosurgery (#9),
Rheumatology (#9),
and Rehabilitation (#10)

NYU Langone
MEDICAL CENTER

**Tisch
Hospital**

The University Hospital
of NYU

GROWTH AND MOMENTUM



Samir S. Taneja, MD, and
Herbert Lepor, MD

International Leadership in Focal Ablation Therapy

NYU Langone urologists are recognized international experts in the evaluation of focal therapy for treating prostate cancer. Herbert Lepor, MD, professor of urology and the Martin Spatz Chair of the Department of Urology, has been invited, along with seven other international experts, to prepare a collaborative review for *European Urology* on new and established technologies in focal ablation of the prostate.

Although interest in focal ablation of prostate tumors is growing internationally, building the evidence base for the procedure will require careful clinical trial design, says Samir S. Taneja, MD, the James M. Neissa and Janet Riha Neissa Professor of Urologic Oncology, and professor of urology and radiology. As part of a national conversation on this issue, Dr. Taneja led an FDA advisory panel discussion in May 2015 at the American Urological Association meeting on how to evaluate efficacy and endpoints with focal therapy. “We really don’t have proper long-term data, so clinical trial design is going to be important in the next decade,” he says. The study was also reported on in *Urology* in November 2015.

Repeat MRI Not Needed for Benign Prostate Lesions

Low-suspicion prostate lesions rarely progress over baseline within one year, making repeat imaging unnecessary, according to a new clinical study led by Dr. Lepor. Investigators evaluated 330 men who underwent magnetic resonance imaging/ultrasound (MRI/US) fusion target biopsy. Thirty-four of these men who had no evidence of cancer on initial target biopsy underwent a follow-up MRI one year later. None of the suspicious areas showed clinically significant changes in size or suspicion score. The authors concluded, in November 2015 in the *Journal of Urology*, that routine one-year follow-up MRI should be discouraged in men with pathologically benign cancer-suspicious regions.

Innovation

Lee C. Zhao, MD, and Michael D. Stifelman, MD, conducted a multi-institutional study on buccal mucosa graft and published their preliminary results in *Urology* in September 2015. Their article, “Robot-Assisted Ureteral Reconstruction Using Buccal Mucosa,” was named Best Laparoscopy and Robotics Paper by the Endourological Society at the 2015 World Congress of Endourology in London.

Appointments

Victor W. Nitti, MD, was appointed chair of the American Urological Association’s Office of Education by the AUA Board of Directors. Dr. Nitti is also a member of the International Continence Society’s Underactive Bladder Working Group.

Leading Education and Training in Prostate Cancer Imaging and Treatment

- In 2011, Dr. Lepor organized the first continuing medical education course in the United States on advances in prostate imaging and ablative treatment of prostate cancer. A forum for experts in the field, participants to discuss and debate how to improve the management of prostate cancer. The now annual course has attracted more than 700 urologists over the past five years.
- Dr. Taneja created an online module for the AUA and oversees a series of five hands-on MRI–fusion biopsy courses to accompany the postgraduate MRI course he has led for the past three years at the AUA’s annual meeting. The course is on proper interpretation of radiological images and biopsy technique.



Continuing medical education course

Editorial Leadership

- David S. Goldfarb, MD, holds several leadership positions in the field of nephrology, including associate editor of the *Clinical Journal of the American Society of Nephrology* and president of the Research on Calculus Kinetics (R.O.C.K.) Society.
- Herbert Lepor, MD, has served on the editorial boards of four major urology journals. He is the co-founder and current editor of *Reviews in Urology*.
- Stacy Loeb, MD, is on the editorial boards of *BJU International*, *European Urology*, *Urology Practice*, and *Reviews in Urology*. Dr. Loeb also hosts the Men’s Health Show on Sirius XM 81 satellite radio. And she is chair of the Urology Care Foundation’s Technology & Publications Committee.
- Danil V. Makarov, MD, is a member of the Society for Medical Decision Making, a Diplomate of the American Board of Urology, and chair of the White Paper Committee on Implementation of Shared Decision Making in Urology of the American Urological Association. He is also a consultant for the FDA’s Center for Devices and Radiological Health.
- Samir S. Taneja, MD, is the Consulting Editor for the *Urologic Clinics of North America* and is on the editorial board of *European Urology*.

NYU LANGONE MEDICAL CENTER NEWS

Groundbreaking Face Transplant Exemplifies Expertise and Multidisciplinary Collaboration

In August 2015, surgeons at NYU Langone Medical Center performed the most complex face transplant to date. The patient, former firefighter Patrick Hardison, had lost all of the skin around his entire face, scalp, and neck, including his eyelids, ears, lips, and nose, while trapped in a burning building. Led by Eduardo Rodriguez, MD, DDS, the Helen L. Kimmel Professor of Reconstructive Plastic Surgery and chair of the Hansjörg Wyss Department of Plastic Surgery, the successful 26-hour operation—the first to include transplantation of eyelids capable of blinking as well as functional ears, among other milestones—involved more than 100 physicians, nurses, and technical and support staff. More than a dozen departments contributed to the planning and execution of the procedure, or to postoperative care.

IMPROVING PATIENT CARE AND OUTCOMES



We offer a comprehensive team of urologists, each with a specific subspecialty. Patients whose needs go beyond a single specialty benefit from seeing other team experts, including nephrologists, urogynecologists, and radiologists.

Better Screening, Diagnosis, and Treatment for Men with Prostate Cancer

NYU Langone urologists are partnering across medical specialties to make detection of clinically significant prostate cancer a priority while helping to preserve patients' quality of life.

Since the advent of prostate-specific antigen (PSA) screening in the late 1980s, the rate of death from prostate cancer has decreased by 40 percent. Although the lives saved represent a triumph of modern medicine, the victory has come at the expense of millions of men who may have undergone unnecessary biopsies and treatment primarily because of the limitations of PSA screening and random biopsy of the prostate.

"For the past five years at NYU Langone, we have been asking the question: 'How can we do even better than a 40 percent decrease in mortality while reducing the morbidity associated with unnecessary biopsies and treatment?'" says Herbert Lepor, MD, professor of urology, and biochemistry and molecular pharmacology, and the Martin Spatz Chair of the Department of Urology.

NYU Langone urologists, radiologists, pathologists, and medical oncologists, along with health policy experts, are partnering to change the paradigm. The keys to making these gains for prostate cancer patients are "screening smarter, detecting smarter, and, ultimately, treating smarter," Dr. Lepor says.

LEADING THE CHARGE FOR ACTIVE SURVEILLANCE

Over their lifetimes, one in seven (14 percent) men will develop prostate cancer, but only 3 percent will die from the disease. Given this long-term survival rate, when men are diagnosed with low-grade prostate cancer, active surveillance is a safe and increasingly viable approach, says Stacy Loeb, MD, assistant professor of urology and population health.

"The era of active surveillance has arrived, and it should no longer be considered experimental," Dr. Loeb said in May 2015 in a session she was leading on active surveillance at the American Urological Association annual meeting.

Working with the public health service and cancer registries in Sweden, where active surveillance has become the default option for men diagnosed with low-grade prostate cancer, Dr. Loeb is tracking the outcomes for patients under surveillance.

"The challenge is that we don't have a consensus on the best way to follow patients on active surveillance yet," Dr. Loeb says. A 2011 National Institutes of Health (NIH) consensus statement made the identification of the optimal protocol for conservative management of prostate cancer a priority.

Dr. Loeb and her colleagues are entering year three of a five-year NIH grant aimed at improving active surveillance protocols. The researchers are developing a mathematical model to determine the need for and timing of invasive repeat prostate biopsies and to evaluate how new developments, such as the use of magnetic resonance imaging (MRI) in surveillance, affect outcomes. In addition, Dr. Loeb is exploring the design of a web-based educational tool to provide information on the benefits and risks of an active surveillance approach. "Active surveillance is increasingly being chosen by low-risk prostate cancer patients, and there are few educational resources to which physicians can refer patients," Dr. Loeb says.

Better Screening, Diagnosis, and Treatment for Men with Prostate Cancer (CONT'D)

NYU Langone is leading the nation in the use of advanced imaging modalities such as MRI in combination with active surveillance.

PIONEERING MRI IN COMBINATION WITH ACTIVE SURVEILLANCE

NYU Langone urologists pioneered three-dimensional co-registration of MRI and real-time transrectal ultrasound (TRUS) to detect only actionable prostate cancer. In support of the routine use of this technique in men considering surveillance and those without known cancer, in 2015 Samir S. Taneja, MD, the James M. Neissa and Janet Riha Neissa Professor of Urologic Oncology, professor of urology and radiology, and director of Urologic Oncology, and colleagues published the first research data showing that very few men with low suspicion scores on MRI have aggressive prostate cancer and many may be spared treatment and future biopsies. This finding, published online in June 2015 in *European Urology*, is based on a retrospective study of 600 men who received prebiopsy MRI and underwent both systematic biopsy and MRI-guided biopsy. The study also showed that MRI-targeted biopsy detects more high-grade cancers than systematic biopsy, so the technique can be used for more accurately selecting men in need of treatment and those most appropriate for active surveillance. At the Smilow Comprehensive Prostate Cancer Center, the team has already implemented the routine use of MRI in selecting men for surveillance, monitoring men on surveillance, and determining in select cases that biopsy may not be necessary.



▲ William C. Huang, MD, Samir S. Taneja, MD, and Herbert Lepor, MD

“There is heavy criticism of the use of MRI to decide who does or doesn’t need a biopsy, because of fear that you might miss high-grade cancers in men with low suspicion or normal MRIs,” says Dr. Taneja. “But our data show that that risk is very, very low.”

TARGETED MRI-GUIDED BIOPSY HITS THE MARK

For men whose suspicious lesions do require biopsy, NYU Langone radiologists and urologists employ advanced MRI techniques, including dynamic contrast enhancement and diffusion-weighted imaging, to identify the site of significant cancers. The fusion biopsy technique, performed on more than 1,500 men at the Smilow Comprehensive Prostate Cancer Center, has been shown to be more effective in accurately assessing cancers than conventional biopsy.

The clinical research team compared the use of targeted biopsy with standard 12-core systematic biopsy in 452 consecutive men who received their first prostate biopsy at NYU Langone between 2012 and 2015. The results, reported in the *Journal of Urology* in December 2015, showed that the targeted approach identified more potentially harmful high-grade cancers and fewer low-grade cancers unlikely to cause harm. Cancers identified by systematic biopsy but not by targeted biopsy were nearly all (82 percent) classified as low grade, or clinically insignificant, by the Epstein criteria and the University of California, San Francisco Cancer of the Prostate Risk Assessment Score (UCSF CAPRA).

USING GENOMICS TO SEPARATE AGGRESSIVE FROM NONAGGRESSIVE PROSTATE CANCERS

Since men diagnosed with low-risk disease after surgical sampling rarely develop metastasis, active surveillance makes sense for that group, according to a study by Dr. Lepor and colleagues, published in 2013 in *Urology*. However, Dr. Lepor’s team had reported in 2010 that more than half of men identified as having low-risk disease on prostate biopsy were subsequently shown to have aggressive disease in the surgical specimen. In an effort to more accurately stratify risk at the time of the biopsy, Dr. Lepor is collaborating with investigators at Cold Spring Harbor Laboratory in a Department of Defense-funded project. They are evaluating whether single-cell genetic profiling can improve risk stratification by identifying genetic deletions and amplifications associated with aggressive disease.

MOVING MRI IMAGING FROM DIAGNOSIS TO TREATMENT

NYU Langone's pioneering use of MRI-ultrasound (MRI-US) co-registration imaging to identify high-suspicion prostate lesions for targeted biopsy is now moving toward targeted treatment.

"We think that there are a lot of supportive data that most metastasis occurs from one dominant lesion within the prostate, and if you can identify that dominant lesion, then treating that lesion would probably remove the lethal potential of the disease," says Dr. Taneja. "That is a hypothesis that needs to be proven," he adds.

In a critical step in that direction, NYU Langone experts reported in December 2015 in *European Urology* that 96 percent of men undergoing targeted biopsy of the laser ablation zone within six months of treatment showed no cancer in the treatment zone. The clinical trial result represents one of the earliest published reports investigating focal laser ablation of prostate cancer. None of the 25 consecutive men who underwent focal laser ablation developed urinary incontinence or a change in their sexual function, and the median time to return to work, normal physical activity, and sexual activity was 1.0, 3.5, and 7.5 days, respectively. This study provides compelling evidence that short-term oncological control can be achieved with virtually no adverse consequences. Dr. Lepor cautions, however, that long-term control has not yet been established.

Similarly, a surgical team led by Dr. Taneja just completed the first-ever phase II clinical trial of MRI-US fusion biopsy-guided focal bipolar radiofrequency ablation in 21 men with localized prostate cancer (FUSAbate Trial). Six-month follow-up data are still being assessed; however, Dr. Taneja says that immediate results of using the technique indicate no negative urinary or sexual side effects.

NYU Langone was one of the first institutions

to publish clinical results using focal
ablation therapy for prostate cancer.

Targeted ablative treatment for prostate cancer can be performed with many energy sources, including laser, cryoablation, radiofrequency, and high-intensity focused ultrasound (HIFU). Unlike with radiofrequency and cryoablation, focal ablation using HIFU can be performed using MRI-US co-registration. William C. Huang, MD, associate professor of urology, recently led a multicenter FDA trial evaluating HIFU for recurrent disease following radiation therapy. On the basis of the positive results with HIFU/MRI-US, in October 2014 Dr. Lepor led a team of urology experts who made the case to the FDA for the treatment of recurrent disease following radiation therapy with HIFU. In October 2015, the FDA cleared HIFU for clinical use for prostate ablation. NYU Langone is one of just a few institutions with the Sonablate® HIFU surgical ablation system, and it is already among the first academic centers in the United States to perform a HIFU procedure.

"We must be mindful that the goal is to control the disease long term," says Dr. Lepor. "With our focal therapy studies, we are applying the same level of scientific rigor that we have applied to our large database of prostate surgery outcomes. We are going to help tell a more complete story of focal therapy, and it's exciting that NYU Langone's Department of Urology is once again at the forefront."

"We tend to find very few high-grade cancers in men with low MRI suspicion scores."

— SAMIR S. TANEJA, MD

Genomics, Animal Modeling Help Identify Bladder Cancer Subtypes

The first telltale sign of bladder cancer is usually blood in the urine and perhaps pain on urination. Here, the parallels among bladder tumors quickly diverge.

Once cancer cells are detected, it can become difficult to differentiate noninvasive tumors from high-grade invasive ones that have the potential to metastasize. It has been known for some decades that bladder cancers can be divided into two major pathways: low-grade and high-grade. The devil is in the details, says Xue-Ru Wu, MD, the Bruce and Cynthia Sherman Professor in Urological Research and Innovation, professor of pathology, and vice chair of Urologic Research, and director of the Goldstein Family Bladder Cancer Research Group. Even among the low-grade and/or noninvasive tumors, a subpopulation will harbor the potential to develop into the much more aggressive and lethal muscle-invasive bladder cancer. “Recent advances in whole-genome sequencing and molecular subtyping have shown that invasive cancers are molecularly quite different from one another. I am still surprised at the complexity of the molecular signatures we are seeing,” says Dr. Wu, who is leading an interdisciplinary NCI Program Project (P01) team tackling this emerging problem.

Bladder cancer is the
4th most commonly diagnosed
cancer in men and the

5th most common overall

1 in every 26 men

will develop bladder cancer
in his lifetime

NYU Langone has the nation's only interdisciplinary
NCI Program Project (P01) grant in bladder cancer

▼ Xue-Ru Wu, MD (left), and Arjun V. Balar, MD (right)

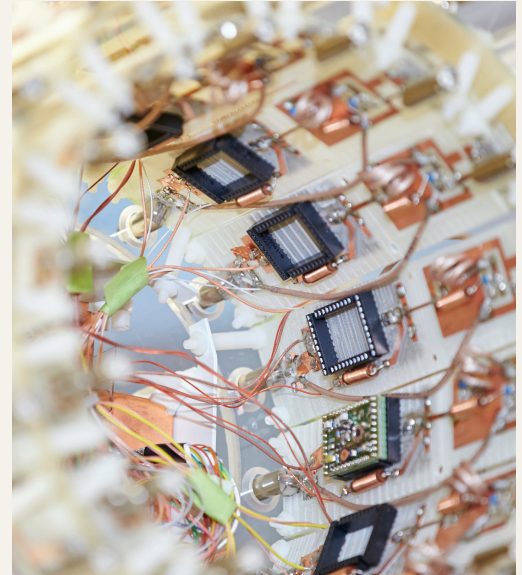


RISK STRATIFICATION IS KEY

Improving patient outcomes will depend on improved risk stratification, indicates Dr. Wu. Whole genome sequencing is good at identifying molecular alterations, but it does not indicate what is driving the most aggressive tumors. Animal modeling helps researchers pin down the molecular drivers that are potential therapeutic targets. “One of our current efforts is to apply genomics to understand why some patients respond better than others to chemotherapy,” says Arjun V. Balar, MD, assistant professor of medicine and co-leader of the genitourinary cancer program at the Perlmutter Cancer Center. For example, NYU Langone is participating in a three-center trial looking at the effect of dose-dense gemcitabine and cisplatin as neo-adjuvant chemotherapy prior to surgery for invasive bladder cancer. The study is investigating whether more intense neoadjuvant treatment improves patient response to treatment and whether the more intense treatment regimen is well tolerated. Early results, presented in January at the 2016 Genitourinary Cancers Symposium (ASCO GU) suggest that dose-dense chemotherapy does improve pathological response. But not all patients respond equally well. To help sort out which patients will benefit most from cisplatin therapy, the investigators will sequence more than 400 genes known to be involved in bladder cancer to try to correlate genetic mutations with response to chemotherapy. In particular, says Dr. Balar, the research team will zero in on alterations in DNA-damage repair genes that may correlate with better patient responses to the standard chemotherapy agent cisplatin.

Simultaneous PET/MRI Improves Fusion Accuracy for Bladder Cancer

In the first-ever published study of simultaneous MRI and PET image acquisition in patients with bladder cancer, researchers in NYU Langone's Departments of Radiology and Urology have shown that this novel technology, which simultaneously acquires FDG-PET and MRI imaging, can greatly improve co-registration accuracy of PET and MRI images. The small investigational study of six patients, published in *Clinical Nuclear Medicine* in August 2015, demonstrated that simultaneous imaging improved the accuracy of co-registration of bladder tumors and pelvic lymph nodes. The findings suggest potential utility of PET/MRI for assisting in the diagnostic evaluation of bladder cancer patients. Conventional PET/CT scan imaging, in comparison, performs fusion of PET images acquired in a sequential, rather than a truly simultaneous, fashion. Led by Andrew B. Rosenkrantz, MD, associate professor of radiology and urology, and Arjun V. Balar, MD, assistant professor of medicine and co-leader of the genitourinary cancer program at the Perlmutter Cancer Center, the research team is investigating whether the use of hybrid PET/MRI in a larger series can improve staging of complex bladder cancer, as well as assist in treatment decision making through the development of predictive imaging biomarkers.



▲ Close-up of components for novel MRI hardware designed at NYU Langone

USING THE IMMUNE SYSTEM TO FIGHT BLADDER CANCER

More than a decade ago, NYU Langone radiology researchers pioneered the use of low-dose radiation to prime the immune system against tumors. The abscopal effect is now well established in many radiation treatment regimens for immune sensitive tumors, such as melanoma. Taking immune therapy to the next level, NYU Langone investigators are testing this treatment approach in bladder cancer. Specifically, therapeutic antibodies to the programmed cell death pathway (PD)-1 protein and one of its ligands, PD-L1, have shown impressive responses against bladder cancer. Pembrolizumab is among the first of this anti-PD-1 pathway family of checkpoint inhibitors to gain accelerated approval from the FDA. It is currently being used for treatment of melanoma in cases that have become refractory to standard treatment.

Dr. Balar and his colleagues are among the first in the nation to test the effectiveness of anti-PD-1 treatment in augmenting treatment for muscle-invasive bladder cancer. They are leading a phase II trial that adds anti-PD-1 treatment (pembrolizumab) to the standard bladder-

sparing treatment (radiation given with low-dose chemotherapy, which acts as a radiation sensitizer). “We chose gemcitabine because it is very safe in older people and also because it has been shown to possibly augment the immune system sensitivity of the tumor by depleting certain immune-suppressive cells,” says Dr. Balar. “We are adding pembrolizumab with the idea that it may serve as a further immune system stimulant.”

Another study, planned for the coming year, innovatively combines an anti-PD-L1 monoclonal antibody (atezolizumab) with the anti-VEGF antibody bevacizumab. The randomized phase II trial in metastatic bladder cancer is being led by Dr. Balar at NYU Langone and Jonathan E. Rosenberg, MD, at Memorial Sloan Kettering Cancer Center. The research team is testing the hypothesis that bevacizumab can promote the maturation and function of dendritic cells and also inhibit the growth of tumor-promoting blood vessels, thereby facilitating a robust immune response boosted by atezolizumab. “A recent phase I trial in advanced melanoma showed promising results with a similar trial design,” says Dr. Balar.

Studies Shed Light on Pelvic Sling Use and Underactive Bladder

PELVIC SLING USE DECLINES FOLLOWING FDA ADVISORY

Of the thousands of women who undergo surgical treatment for pelvic organ prolapse each year, about a quarter also receive a midurethral sling to treat or prevent stress urinary incontinence (SUI). Studies suggest that the sling can improve outcomes for some women undergoing prolapse repair, but concerns about safety have risen since the FDA issued a public health advisory in 2011 warning of potentially serious complications with transvaginal surgical mesh. The FDA received numerous complaints of adverse events associated with use of transvaginal surgical mesh, including mesh erosion through the vagina, pain, infection, bleeding, pain during sexual intercourse, organ perforation, and urinary problems.

Physicians often recommend that a surgical mesh sling, which repairs weakened or damaged tissue surrounding the pelvic organs, be implanted at the time of prolapse surgery for women who show evidence of SUI on examination, urodynamic testing, or a home pessary trial. Although the FDA warning did not specifically address midurethral slings for stress incontinence, many patients subsequently became reluctant to undergo procedures involving transvaginal mesh.

In an effort to assess the impact of the FDA advisory, researchers reviewed the cases of more than 500 patients who underwent prolapse surgery at NYU Langone between June 2010 and October 2014. The researchers observed a trend after 2011 of 2 percent to 5 percent of patients per year refusing assessment or treatment for SUI, as well as a drop in the rate of sling placement from 42 percent to 36 percent. At the same time, the rates of subjective SUI and demonstrable SUI during preoperative evaluation remained stable. These findings were presented at the 2015 American Urological Association annual meeting.

The decline in sling procedures appears to have been triggered by the FDA advisory as opposed to physician counseling, notes urology resident Erin L. Ohmann, MD, the study's lead author. "Our counseling and shared decision-making model have been consistent with the exception of the additional discussion of the FDA warning," Dr. Ohmann says. "Thus, we believe that it is patient preferences and perceptions that have led to the decrease in a concomitant sling procedure, not that doctors are recommending against it."



▲ Nirit Rosenblum, MD, and Herbert Lepor, MD

▼ Victor W. Nitti, MD



DEFINING UNDERACTIVE BLADDER

Underactive bladder (UAB), a frequent cause of lower urinary tract symptoms, is poorly understood and lacks effective treatments. To address the issue, an expert panel met to create a working definition to help clinicians with diagnosis and facilitate future research.

UAB is characterized by prolonged bladder emptying and/or failure to achieve complete voiding within a normal time span. According to estimates, almost half of older men and women undergoing evaluation for lower urinary tract symptoms show evidence of UAB and may require catheterization to facilitate drainage.

An international panel that included Victor W. Nitti, MD, professor of urology, and obstetrics and gynecology, director of the Female Pelvic Medicine and Reconstructive Surgery Program, and vice chair of the Department of Urology, met at the International Consultation on Incontinence—Research Society and the International Continence Society (ICS) annual meetings in 2014 to review the available evidence on UAB and create a definition based on common symptoms. The panel, known as the ICS Underactive Bladder Working Group, published its findings in the September 2015 issue of *European Urology*.

Because there are no widely accepted diagnostic criteria for UAB, patients are often required to undergo invasive urodynamic testing in order to distinguish it from bladder outlet obstruction. The ICS working group identified a complex of symptoms that may help clinicians identify affected patients on the basis of clinical presentation and potentially avoid unnecessary invasive testing.

In their article, the group proposes the following definition: “The underactive bladder is a symptom complex suggestive of detrusor underactivity and is usually characterized by prolonged urination time with or without a sensation of incomplete bladder emptying, usually with hesitancy, reduced sensation on filling, and a slow stream.”

The group notes that associated factors, such as age, sex, and known neurological diseases, should also be considered. They also emphasize that detrusor underactivity must be confirmed by urodynamic testing.

Whereas other lower urinary tract dysfunctions, such as detrusor overactivity, are well represented in the scientific literature, further research is needed on all aspects of detrusor underactivity, the article’s authors note.

“It must be emphasized that the proposed definition has been developed on the basis of expert opinion and discussion rather than the results of prospective studies,” the authors write. “Nevertheless ... the development of the definition presented in this paper represents a significant step in the right direction and will help raise the profile of this much-neglected problem.”

The ICS Underactive Bladder Working Group met again at the 2015 ICS annual meeting to continue their work on defining the condition. It is their hope that this work will lead to effective UAB treatments.

Dispelling Concerns About ED Drugs, Hormone Therapy

STUDY FINDS NO LINK BETWEEN ERECTILE DYSFUNCTION DRUGS AND MALIGNANT MELANOMA

Researchers have observed that men who take medications for erectile dysfunction (ED) are at higher risk for malignant melanoma, raising the concern that the drugs may promote development of the disease. However, a recent study led by researchers at the Laura and Isaac Perlmutter Cancer Center suggests that the association more likely reflects socioeconomic and lifestyle factors.

The researchers examined more than 20,000 medical records from Swedish databases, including 4,065 cases of melanoma, and found that patients with diagnoses of melanoma were more likely than a control group to fill prescriptions for phosphodiesterase type 5 (PDE5) inhibitors (11 percent versus 8 percent), such as sildenafil (Viagra), vardenafil (Levitra), and tadalafil (Cialis). They calculated a 21 percent elevated risk of diagnosis with malignant melanoma among users of the ED drugs.

However, the researchers found no difference in melanoma risk according to number of prescriptions filled, type of drug, or stage of disease. As a result, they concluded that the relationship between ED drug use and melanoma is unlikely to be causal. Instead, they hypothesized that the association is due to lifestyle factors tied to both drug use and low-stage melanoma.

“What our study results show is that groups of men who are more likely to get malignant melanoma include those

with higher disposable incomes and education—men who likely can also afford more vacations in the sun—and who also have the means to buy ED medications, which are very expensive,” says lead author Stacy Loeb, MD, assistant professor of urology and population health.

The study, published in June 2015 in the *Journal of the American Medical Association*, was prompted by a highly cited 2014 analysis in 14 men who had taken Viagra and were later diagnosed with melanoma. The possibility of a causal connection arose because PDE5, the target of oral ED drugs, is part of the same signaling pathway implicated in the development of malignant melanoma caused by BRAF gene mutations, in which PDE5 is down-regulated. However, in the current study, use of PDE5 inhibitors was also associated with increased risk for basal cell carcinoma, which involves a different biological pathway.

“Physicians should still screen men for melanoma risk, but they do not need to add use of erectile dysfunction drugs to their list of screening criteria,” says Dr. Loeb. “When used appropriately, erectile dysfunction medications are very effective and improve the quality of life for many men; so, they should know it is doubtful that taking these medications puts them at greater risk of getting skin cancer.”

▼ Joseph P. Alukal, MD (right), and medical assistant Jonathan Olmo



TESTOSTERONE THERAPY SAFE IF PRESCRIBED AND MONITORED CORRECTLY

The number of testosterone prescriptions among men aged 40 and older in the United States has more than tripled since 2001, an increase bolstered by studies showing that the therapy can lead to improved sexual function and overall well-being. However, despite the known benefits of the therapy, it has also been associated with potential cardiovascular risks, triggering concern over its widespread use.

Although data from large randomized trials are lacking, current evidence suggests that testosterone therapy can be safely prescribed if patients meet clinical criteria and if their treatment is appropriately monitored, Joseph P. Alukal, MD, assistant professor of urology, and obstetrics and gynecology, and director of Male Reproductive Health, and colleagues note in their article published in March 2015 in *Current Atherosclerosis Reports*.

Dr. Alukal and his colleagues found that more than 25 percent of men who received prescriptions between 2001 and 2011 in the United States had not had a testosterone level measurement in the prior 12 months and many did not meet the indications for therapy. They therefore attributed the sharp increase in use of the medications largely to marketing aimed at older men to treat “low T” syndrome and to improve sexual function and reduce fatigue.

Thus, the increase in adverse events noted by some researchers may be partly explained by insufficient screening and safety monitoring, Dr. Alukal and colleagues say. For example, in addition to measuring patients’ testosterone levels, practitioners must screen for obstructive sleep apnea, which is a known risk factor for atherosclerosis and can be aggravated by testosterone therapy. In addition, testosterone levels must be monitored as therapy progresses to prevent adverse outcomes caused by over- or under-treatment.

“In many patients at increased cardiovascular risk, testosterone therapy to address clinical androgen deficiency can be safely considered,” the authors conclude. However, it should be prescribed only “in accordance with guideline recommendations in men with clinical symptoms of testosterone deficiency and unequivocally low testosterone levels, and with safety monitoring to avoid potential adverse effects.”

Leader in Fertility

PERSONALIZED TREATMENT FOR INFERTILITY

NYU Langone is a leader in treating both male and female infertility. Experts in male infertility, such as Joseph P. Alukal, MD, assistant professor of urology, and obstetrics and gynecology, and director of Male Reproductive Health, guide patients through tests and treatments that can identify and correct the problem; these include microsurgical techniques for testicular sperm extraction, vasectomy reversal, and varicocele repair. Urologists also collaborate closely with the NYU Langone Fertility Center, which provides comprehensive evaluation and care for couples dealing with infertility.

NEW FELLOWSHIP

NYU School of Medicine has launched a clinical fellowship in male infertility, male sexual function, and urologic reconstruction. Under the mentorship of Joseph P. Alukal, MD, assistant professor of urology, and obstetrics and gynecology, and director of Male Reproductive Health, and Lee C. Zhao, MD, assistant professor of urology, fellows will spend a year working at NYU Langone in the Department of Urology. They will also work at NYU Langone’s Fertility Center, as well as at the Manhattan campus of the VA NY Harbor Healthcare System and at Bellevue Hospital Center. The primary area of concentration is male infertility, followed by urethral reconstruction and male sexual dysfunction.

Pediatric Team Successfully Repairs Birth Defect

Omphalocele-Exstrophy-Imperforate Anus-Spinal Defects, or OEIS complex, is a rare combination of birth defects that occurs in approximately one of every 200,000 live births.

Most children born with OEIS complex do not survive, and those who do require numerous complex surgeries to correct malformations of the bowel, bladder, anus, and spine.

Last year, a team of pediatric specialists at NYU Langone successfully treated a child born with multiple serious manifestations of OEIS complex. At birth, the newborn's abdominal wall had not closed, leaving her intestines visible through a sac. Other anomalies included:

- Imperforate anus, meaning the opening was missing and the ends of the colon and rectum were atretic, or very narrow
- Bladder that was open, flattened, and exposed below the intestines and that was flanked by muscle and overlying skin
- Two uteri and two vaginas that opened into the back of the bladder
- Abnormal formation of the lower sacral vertebrae, with an associated lipomeningocele
- Pubic diastasis, causing the pelvic bones to be widely separated
- Duplicated inferior vena cava

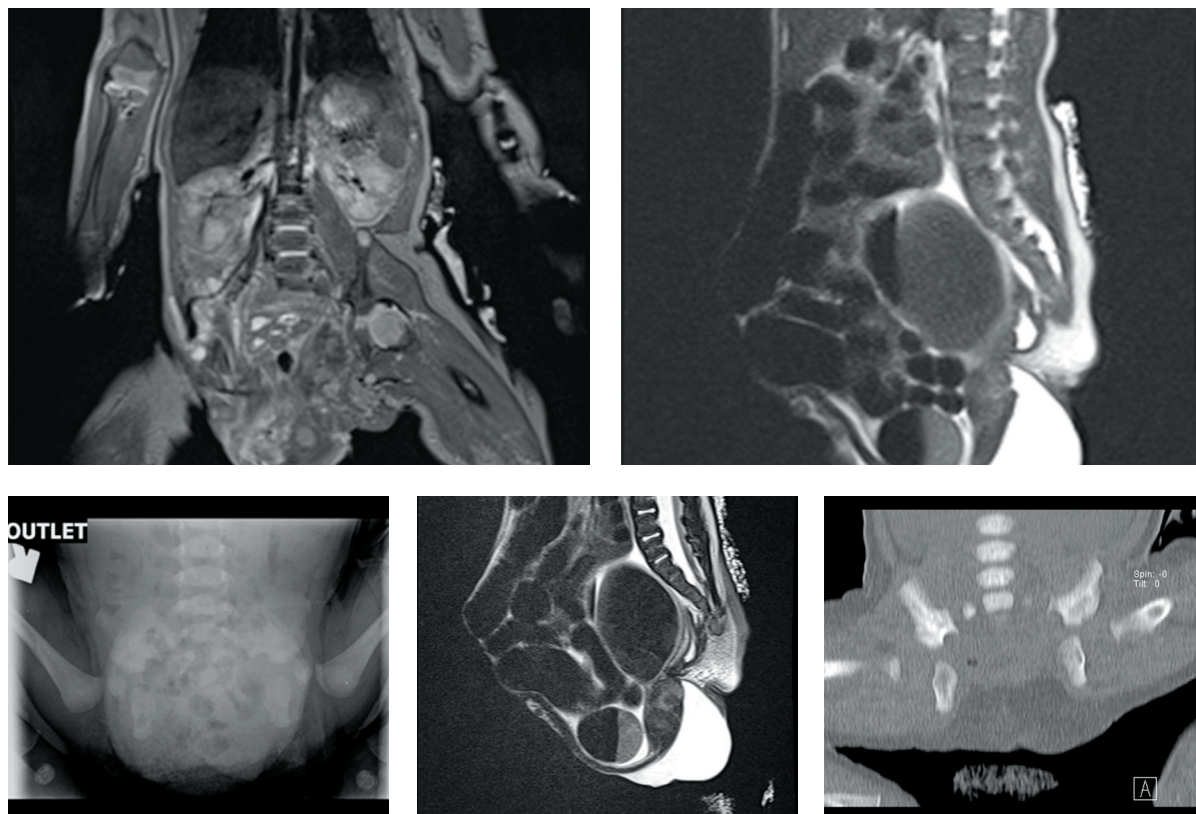
▼ Ellen Shapiro, MD



MULTIDISCIPLINARY TEAM PERFORMS A MAJOR RECONSTRUCTION

Surgeons first replaced the patient's visible bowel back into her abdomen and performed a colostomy to divert its contents. Six weeks later, NYU Langone pediatric urologist, professor of urology, and director of Pediatric Urology Ellen Shapiro, MD, who had trained at Johns Hopkins Hospital under renowned expert in exstrophy and its variants Robert D. Jeffs, MD, assembled a multidisciplinary team, including two orthopaedic surgeons and a pediatric anesthesiologist, to undertake a major reconstruction of the patient's organs. Says Dr. Shapiro, "After speaking to many of my colleagues and reviewing the literature, it is clear that this is a very unusual variant of a rare condition and one that has most likely never been seen before."

The most challenging aspect of the reconstruction was closing the lower end of the bladder, because the lower edge was attached posteriorly along the spine. Below this was a shelf of leathery tissue where the pelvic floor muscles should have been but were not, making it impossible for a urethra to be formed and therefore necessitating the performance of a vesicostomy.



▲ MRI and plain films of an infant born with OEIS


During the challenging, daylong operation, the team successfully closed the patient's bladder, abdominal wall, and pelvic bones. Although physicians were optimistic about a favorable outcome, the patient remained at high risk for complications over the next month. Any tension on the abdominal wall and/or the pelvic bone could have broken down the abdominal wall closure and pushed the bladder back out of the pelvis.

Fortunately, the patient made steady progress. After transfer to the intensive care unit, she remained asleep and on a ventilator for a week, after which she continued

recovering in the hospital for about a month, until she was discharged with no complications. "The patient has since undergone successful spinal surgery with our pediatric neurosurgeons," says Dr. Shapiro. "She is a delightful, engaging toddler, passing all of her developmental milestones appropriately."

In a few years, Dr. Shapiro says, the patient likely will require surgery to achieve urinary continence and to reposition her lower reproductive tract. Otherwise, she is embarking on a normal childhood."

A NEW GENERATION OF PHYSICIAN-SCIENTISTS



Applicants for urology residency training are drawn to NYU Langone by the stellar reputation of its faculty, attractive post-training opportunities, and diverse patient population.

Broad Base of Training

The outstanding reputation of our faculty, attractive post-training opportunities, and opportunity to work with diverse patient populations draw many urology residents to train at NYU Langone. In addition to NYU Langone's own care settings, there are opportunities to train at New York City Health and Hospital Corporation's member institutions Bellevue Hospital Center and Gouverneur Health and at the Veterans Affairs Department's VA NY Harbor Healthcare System. A fully accredited five-year program, the residency provides training in:

- General urology
- Urologic oncology
- Endourology and kidney stone disease
- Pediatric urology
- Female pelvic medicine and reconstructive surgery
- Urinary tract reconstruction
- Erectile dysfunction, male infertility and microsurgery

High Standards

Of 250 applicants to NYU School of Medicine's urology residency program in 2014, 40 were interviewed and 3 were accepted—a rate of approximately 1 percent. The residents typically match into the top choices of fellowship training programs. In 2015, graduating residents pursued fellowship training in endourology, urologic oncology, and female pelvic medicine and reconstructive surgery at Hackensack University Medical Center, UCLA Health, and Virginia Mason Medical Center.

NYU Langone offers three urology fellowships:

- Female pelvic medicine and reconstructive surgery (ACGME-accredited)
- Andrology/male reproductive health
- Urologic oncology

International Education

With support from the Allergan Foundation, Sidhartha Kalra, MD, is engaged in a one-year clinical and research residency with experts in female pelvic medicine and functional urology at NYU Langone. Dr. Kalra recently completed postgraduate work at India's Jawaharlal Institute of Postgraduate Medical Education & Research.

CME Postgraduate Courses Offered in 2016

→ **Second Annual Advanced Multispecialty Robotic Surgery: A Team Approach**

June 10-11

→ **Advances in Prostate Imaging, Detection and Ablative Treatment of Prostate Cancer**

June 17-18

→ **Advances in Female Pelvic Medicine and Reconstructive Surgery**

September 23-24

→ **Surgical, Pharmacological, and Technological Advances in Urology**

December 8-10



▲ Michael D. Stifelman, MD

Select Publications

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COLLABORATING PHYSICIANS ON SITE

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Assistant Professor of Medicine

Daniel C. Cho, MD

Assistant Professor of Medicine

David S. Goldfarb, MD

Professor of Medicine and Neuroscience and Physiology

Locations

As of December 2015

1

Smilow Comprehensive Prostate Cancer Center
135 East 31st Street
2nd Floor
New York, NY

2

Joan H. Tisch Center for Women's Health
207 East 84th Street
New York, NY

3

NYU Langone Urology Associates
150 East 32nd Street
2nd Floor
New York, NY

4

Preston Robert Tisch Center for Men's Health
555 Madison Avenue
2nd Floor
New York, NY

5

NYU Langone Fertility Center
660 1st Avenue
New York, NY

6

Perlmutter Cancer Center
160 East 34th Street
New York, NY

7

NYU Langone Multiple Sclerosis Comprehensive Care Center
240 East 38th Street
18th Floor
New York, NY

8

NYU Langone at Columbus Medical
97-85 Queens Boulevard
Rego Park, NY

9

NYU Langone Levit Medical
1220 Avenue P
Brooklyn, NY

10

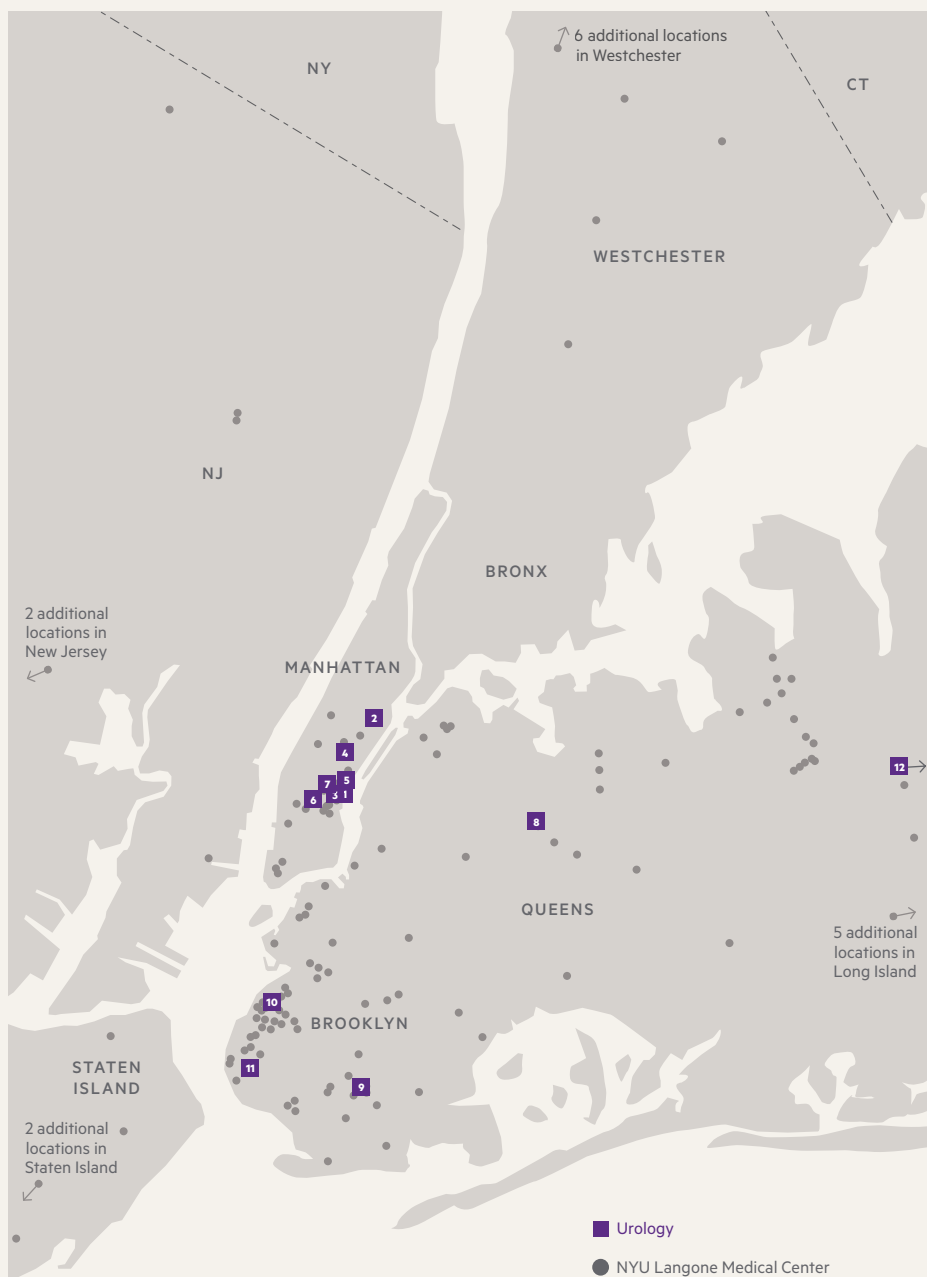
NYU Lutheran Associates
150 55th Street
Brooklyn, NY

11

NYU Lutheran Associates—Medical Arts Pavilion
8714 Fifth Avenue
Brooklyn, NY

12

NYU Langone Huntington Medical Group
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Chief of Hospital Operations

Nancy Sanchez

Senior Vice President and Vice Dean
for Human Resources and Organizational
Development and Learning

By the Numbers*

NYU LANGONE MEDICAL CENTER

*Numbers represent FY15 (Sept 2014–Aug 2015)

1,069

Total Number of Beds

1,469

Full-Time Faculty

611

MD Candidates

3,800

Publications

77

Operating Rooms

1,392

Part-Time Faculty

79

MD/PhD Candidates

550,000

Square Feet of Research Space

38,554

Patient Discharges

2,627

Voluntary Faculty

272

PhD Candidates

\$178,000,000

NIH Funding

1,216,428

Hospital-Based Outpatient Visits

128

Endowed Professorships

400

Postdoctoral Fellows

\$295,000,000

Total Grant Funding

5,766

Births

2,740

Physicians

1,063

Residents and Fellows

2,900,000

Faculty Group Practice
Office Visits

3,465

Registered and Advanced
Practice Nurses

730

Allied Health Professionals



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