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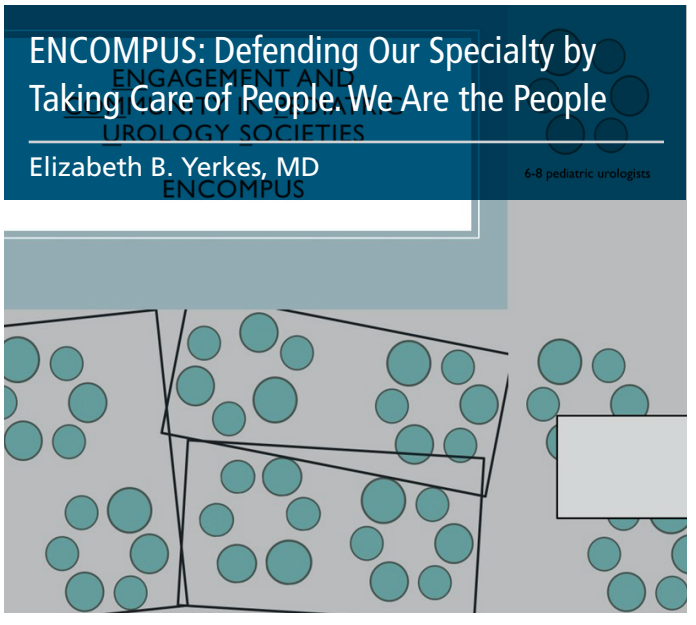

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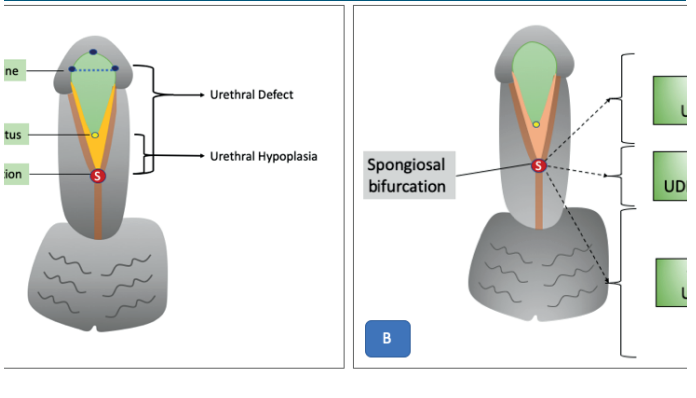

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Bridging the Gap Between Health Policy Research and Impact: Mark Cuban Visits Vanderbilt University

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Figure 1. Dr Dusetzina, Mr Cuban, and Dr Talwar.

At its core, health policy research aims to influence tangible sociopolitical landscape as it relates to medicine, with the ultimate goal of improving the overall health of the population. An analysis published in *The Journal of Urology*® exploring the potential cost savings for the federal government if Medicare urological drugs had been purchased via Mark Cuban's Cost Plus Drug Pharmacy (MCCPDC)[1] recently caught the attention of the billionaire entrepreneur himself. The analysis demonstrated that purchasing urological drugs via MCCPDC alone, Medicare would have cut costs by nearly $1.29 billion. After connecting several times with the article's senior author, Dr Ruchika Talwar, to explore dissemination strategies given the staggering research findings, Mr Cuban visited the Vanderbilt University Medical Center campus for an in-person panel on MCCPDC on March 23, 2023. The panel was moderated by Dr Talwar and included Dr Stacie Dusetzina, a national leader in drug pricing research and professor of health policy at Vanderbilt University.

At the start of the panel, Dr Dusetzina provided an information overview of the current state of prescription pricing. She explained that part of the reason for rising drug costs is inherent to the Medicare Part D program design. Prior to 2006, most Medicare beneficiaries actually paid cash to obtain prescriptions, as the price was generally low and affordable. After prescription drug benefits were implemented, this provided an incentive for companies to increase prices. Outside of Medicare, she outlined that Americans face 2 major issues: being uninsured or underinsured. She stated, "There are too many entities in it who are making a lot of money. Everyone in the system will have to make less money if you want to fix this for patients." That's where Mark Cuban comes in.

> "There are too many entities in it who are making a lot of money. Everyone in the system will have to make less money if you want to fix this for patients."

Mr Cuban next shared the genesis of his journey as a pharmaceutical industry disrupter. In response to a cold email by Dr Alex Oshmyansky, a physician who was looking to provide a solution to sky-high prescription drug prices, Cuban asked himself, "If the Pharma Bro [Martin Shkreli] can raise prices by 500%, can't we cut prices by 500%?" He launched MCCPDC as a public benefit corporation to give patients access to low-cost drugs by providing price transparency and cutting out intermediaries such as pharmacy benefit managers. Each drug price is set using the following formula: cost of manufacturing the drug + 15% markup + a low, standard shipping/dispensing fee.

Launched in January 2022, the company now has over 2 million accounts, growth that far outpaced Mr Cuban's expectations. This has created some challenges for the small company, which has approximately

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BRIDGING THE GAP BETWEEN HEALTH POLICY RESEARCH AND IMPACT

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Figure 2. Dr Dusetzina, Mr Cuban, and Dr Talwar at a live panel discussing *The Journal of Urology*® article, "Urological Drug Price Stewardship: Potential Cost Savings Based on the Mark Cuban Cost Plus Drug Company Model,"[1] on March 23, 2023.

40 employees, to keep up with demand. However, he shared with Dr Talwar that he hopes to continue to find new ways to shake things up in the industry. MCCPDC is building a manufacturing plant in Texas, plans to begin offering select brand name medications, and hopes to partner with local pharmacies to fill certain medications that may be difficult to ship due to temperature or packaging requirements, while still supporting community-based small pharmacy businesses.

As it relates to urological drugs, MCCPDC currently offers several, including abiraterone, alfuzosin, oxybutynin, solifenacin, tamsulosin, tolterodine, vaginal estrogen cream/tablet, sildenafil, vardenafil, and tadalafil. In fact, Cuban shared that MCCPDC now supplies over 5% of the tadalafil market. A 30-count supply costs $4.80. He encouraged the audience to reach out to him directly via social media or email (and shared his address with those watching in person, via live stream, and on YouTube) with any drug requests. He emphasized the foundation of his business model is based on transparency, and thereby, trust, hence the reason MCCPDC is the only company that he has put his name on. Mr Cuban left the audience with his primary motivation: "I want to do something that my kids will be proud of."

Miss the live stream? Watch the event video at https://www.youtube.com/watch?v=AHHiW-fQTk5w or access through the QR code. ■

1. Cortese BD, Chang SS, Talwar R. Urological drug price stewardship: potential cost savings based on the Mark Cuban Cost Plus Drug Company model. *J Urol.* 2023;209(2):309-311.

Conversation With Dr Patricia Turner Regarding the American College of Surgeons

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The American College of Surgeons (ACS) is often referred to as the House of Surgery because it represents all surgical specialties. The ACS and the AUA have a long history of collaboration and working together through its members. Dr Patricia Turner has been with the ACS for over 11 years, initially serving as the Director of Member Services. She began to lead the College as Executive Director and Chief Executive Officer in January 2022. We asked Dr Turner to highlight the ACS and some of its activities, particularly those of interest to urological surgeons.

Dr Turner, can you please tell us about the ACS?

Dr Turner: With more than 87,000 members, the ACS is the largest organization of surgeons in the world. The ACS is uniquely positioned to serve surgeons of all specialties in the areas of optimal patient care, surgical research, health policy, continuing education, and networking opportunities. The ACS has much to offer surgeons at any point in their careers. Urology is the second largest specialty in the ACS, with over 4,500 members.

Would you describe the levels of membership available?

Dr Turner: ACS offers membership across the career spectrum, from medical students to practicing surgeons and into retirement.

ACS Intern and Resident membership is currently free as we explore a pilot recruitment program. Group membership is available for residency programs to enroll and manage applications and membership for all trainees.

Associate Fellows are a class of membership for physicians who have completed residency training and are in the process of meeting the requirements to apply for Fellowship. Depending on your specialty, you may be early in practice or may be between written and oral board examinations.

Once Associate Fellows are Board Certified and have completed a year of independent practice, they may apply for Fellowship. Applications for all membership categories are available online at www.facs.org and are accepted year-round. Generally speaking, there is less than a year between the completion of an application and induction at the Convocation ceremony at Clinical Congress.

Could you please share the process for becoming a fellow of the ACS?

Dr Turner: Fellowship applicants must meet the requirements for Associate Fellow status and, in addition, be Board certified, have hospital or institution privileges, and have 12 consecutive months of practice in the same location with a case list reflecting their current surgical practice that establishes the applicant as a specialist in surgery. Finally, successful applicants will be interviewed by Fellows in their area to verify their application and practice. Upon completion of

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CONVERSATION WITH DR PATRICIA TURNER REGARDING THE AMERICAN COLLEGE OF SURGEONS

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the requirements, the applicant is named an Initiate and will be inducted into the Fellowship of the College at the following October Clinical Congress.

Once inducted, the physician can add the letters FACS (Fellow, American College of Surgeons) after their name, ie, Jane Doe, MD, FACS. The FACS designation signifies that the surgeon's education and training, professional qualifications, surgical competence, and ethical conduct have passed a rigorous evaluation and have been found to be consistent with the high standards established and demanded by the College. Patients often seek surgeons with the FACS designation.

Could you describe how urologist members contribute to ACS committees and programs?

Dr Turner: Absolutely; the ACS represents the House of Surgery and eagerly looks for diversity of specialty across all our committees, workgroups, and in leadership roles. You are a terrific example, Dr Atala, serving not only as a member of the Board of Regents, but as its vice chair this year.

There are many opportunities for engagement starting in residency and continuing through Fellowship. Resident members are automatically part of the Resident and Associate Society, and Fellows under the age of 45 are members of the Young Fellows Association. Both groups are focused on member engagement and the creation of meaningful programming. They have liaison positions to many of the committees of the College and serve as a springboard to engagement for those who want to be involved. Multispecialty committees, such as the Commission on Cancer, History of Surgery, Program Committee, Committee on Informatics, Women in Surgery, Committee on Diversity Issues, and the Committee on Trauma, include representation from all surgical specialties. In addition, each surgical specialty has its own Advisory Council comprising representatives from subspecialty societies and other leaders. The Urology Advisory Council participates in programming recommendations for Clinical Congress and supports the work of the Central Judicial Council and other efforts.

> "The American College of Surgeons (ACS) is often referred to as the House of Surgery because it represents all surgical specialties. The ACS and the AUA have a long history of collaboration and working together through its members."

ACS urologists are, of course, participants on panel sessions and courses presented at the annual Clinical Congress, Quality and Safety Conference, Committee on Trauma, and Commission on Cancer meetings, and are also eligible for nomination as a member of the American Board of Urology, or a member of the Residency Review Committee for Urology, both of which have ACS member representation.

ACS offers several research scholarships, fellowships, and awards for all levels of membership, from residents to FACS. These awards are for academic and private practice surgeons, in rural and urban areas, both domestically and abroad. Some are travel awards for meetings, and some are supplements to research awards.

Another way to contribute and become involved in the ACS is to be an active member of your local chapter. The chapters are a great way to become involved and participate in a meaningful way with other members of the College in your area. We encourage all specialties to be involved in chapter leadership.

How does the ACS advocate for surgeons?

Dr Turner: The College advocates for positions and issues that benefit all surgical specialties at the state and national levels. The annual Leadership and Advocacy Summit provides an opportunity for members to attend sessions on effective leadership and to attend congressional visits to establish relationships with their members of Congress.

In addition to the leadership sessions offered at the Leadership and Advocacy Summit, the ACS offers courses for all members, including Surgeons as Leaders, Surgeons as Educators, and Residents as Teachers and Leaders.

The AUA is an active participant in the ACS Surgical Coalition, which advocates for access to quality surgical care for all Americans. The Surgical Coalition works to promote sound policy solutions to the U.S. Congress and federal regulatory agencies to solve the biggest challenges in health care.

The ACS, with the AUA and other surgical specialties, has been leading the effort to prevent Medicare physician payment cuts and to reform the overall Medicare physician payment program.

How does the ACS help educate patients?

Dr Turner: The ACS offers a wide variety of patient education products, including safe pain control information, wound home skills kits, and patient education materials written by surgeons for surgical patients. The patient education programs at the ACS also include hands-on training materials for adult and pediatric urostomy care. These home skills programs are available to members to enhance their patient's ability to master caring for their urostomy through guided training using actual supplies. Mindful of all elements of health literacy, patients benefit significantly from these educational materials.

Could you explain the resources the ACS offers that may benefit the practicing urologist?

Dr Turner: The ACS has a range of practice management offerings on the website. In an effort to provide meaningful information to all members, the site has areas focused on the information for the employed surgeon as well as the private/small business practice surgeon. Resources include markedly discounted access to productivity benchmarking information from the Medical Group Management Association, American Medical Group Association, and the Association of American Medical Colleges; discounts with a national legal firm specializing in physician contract review; and numerous educational primers and videos designed to support your success, regardless of your specialty or practice setting.

How does the AUA collaborate with the ACS?

Dr Turner: Collaboration with the AUA is strong. There is representation from the AUA on the ACS Board of Governors and the Advisory Council for Urology. The ACS offers a jointly sponsored annual ACS/AUA Health Policy Scholarship for the Executive Leadership Program in Health Policy and Management at Brandeis University. The College's annual Clinical Congress begins with the Martin Memorial Lecture, which is sponsored by the AUA.

Membership in the ACS complements your membership in the AUA. The ACS is focused on bringing together all surgical specialties to support each other and provide opportunities for networking across our profession. The motto of the ACS is to Heal All With Skill and Trust. With all specialties, we truly can heal all as the House of Surgery. ■

ENCOMPUS: Defending Our Specialty by Taking Care of People. We Are the People

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The practice of medicine is an honor and privilege and should bring us joy as a return on the investment of energy and time.

For various systemic and personal reasons, the joy may be eclipsed by burden. Medicine has always been a demanding field with great responsibility. The needs of others always come first. That has not changed, but the metrics with which we are publicly measured by the hospital and government and the lens with which we are viewed by the public are quite different. In many parts of the country, the doctor not only needs to prove expertise, but they must appear to bring their best every day. Patient satisfaction scores and web-based grades do not comprehensively sample our work or represent our worth. Comparing oneself to others on social media or ranking systems is exhausting and may be misguided. The weight of imperfect outcomes, expectations to see more patients, messages and requests coming via numerous mechanisms, incomplete charts, looming deadlines, family stressors, or medical issues can be heavy.

> "In many parts of the country, the doctor not only needs to prove expertise, but they must appear to bring their best every day. Patient satisfaction scores and web-based grades do not comprehensively sample our work or represent our worth."

Despite all the conversation and statistics about physician burnout and physician suicide, it does not appear that a real solution is imminent. Talking about it without actionable and achievable steps is insulting. Raising awareness and taking the stigma and barriers away from getting help for mental health issues is a very positive step that is being pursued at the national and state level by the Dr Lorna Breen Heroes' Foundation.[1] Removing barriers to seeking treatment will save lives, and it will likely allow many others the capacity to continue serving children and families.

Although surrounded by people daily, relationships may not exist wherein we can safely share the things that only other surgeons understand. Perhaps showing doubt or "weakness" within one's practice or health system is feared too risky. Reputation and livelihood are at risk.

What if we could create a space where people can come together and share about pressure points, personal and professional challenges, difficult cases, and complications? What if we could reveal vulnerability and find resolutions without fear of exposure of perceived weakness?

Last summer a group of pediatric urologists answered a call to step forward and build a different model for mentorship and support. Our small field had just lost a talented colleague to suicide. The responses to this call clearly recognized a deep preexisting need to reinvent support and community among pediatric urologists of all ages. One may not perceive this need for themself and may be completely unaware of the neighbor in need.

The group brainstormed about what size communities might function best and what needs they would serve. How would confidentiality be addressed? Should members span the career cycle or be comprised of similar age? Connection with those outside the local area was deemed important to allow sharing without exposure, and it would also expand the personal and professional networks. Virtual connections across time zones were noted to present challenges as well. The ENCOMPUS (ENgagement and COMmunity in Pediatric Urology Societies) initiative was presented at the Pediatric Urology Fall Congress in October 2022, along with plans for an annual wellness event or topic to be identified by a Wellness (Task) Force.

Approximately 175 pediatric urologists and fellows from the private, managed care, and academic arenas submitted information about their practice and interests, and disclosed what they can give and hope to receive within these small groups.

The process of forming the groups based upon these preferences proved challenging, but it was time for ENCOMPUS to launch. The groups are in the early stages of getting to know each other, acknowledging some awkwardness, but creating a nonjudgmental space. Questions were offered to learn more about shared experiences and memorable challenges without full exposure. Each group will set a schedule of virtual meetings to suit their needs and will establish a check-in chain or other regular communication. Groups with similar interests but more distant time zones will be paired to meet up at the Fall Congress and future meetings.

> "What if we could create a space where people can come together and share about pressure points, personal and professional challenges, difficult cases, and complications?"

Many thanks to the development team volunteers (Tony Casale, MD, Yvonne Chan, MD, Christina Ching, MD, Chris Cooper, MD, Hillary Copp, MD, Tanya Davis, MD, Dave Ewalt, MD, Candace Granberg, MD, Kate Hubert, MD, Chris Kimber, MD, John Makari, MD, Max Maizels, MD, Leslie McQuiston, MD, Adam Rensing, MD, Michaella Prasad, MD, Vijaya Vemulakonda, MD, Patience Wildenfels, MD, Jennifer Yang, MD) for their engagement in creating ENCOMPUS. We acknowledge that there is no model that will suit everyone, and adjustments will certainly be needed over time. ENCOMPUS is one opportunity to build a foundation for a stronger community. ■

1. *Dr. Lorna Breen Heroes' Foundation*. Accessed April 10, 2023. https://drlornabreen.org/remove barriers.

MEDICAL STUDENT COLUMN

Piloting a Winter Externship for Preclinical Students to Increase Exposure to Urology

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The day-to-day work of a urologist is mystifying to most new medical students. Genitourinary issues can be uncomfortable to discuss with family and friends, and without personal connections or shadowing opportunities, many medical students are not exposed to a career in urology until late in their medical education.

The continuous growth of basic medical sciences, coupled with the earlier onset of clinical rotations, has crowded the preclinical curriculum; currently 50% of medical schools do not require urology lectures or coursework.[1] Moreover, during third-year clerkships, students will typically rotate in only one surgical subspecialty, of which urology may not be an option. Simultaneously, urology, like many surgical specialties, has become an increasingly competitive match. More than 500 applicants competed for 386 positions in the 2023 Urology Residency Match, with only 75% successfully matching.[2] Additionally, 15% of applicants in the 2023 Urology Match were previous graduates, up from 11% in the previous year.[2] This increasing number of re-applicants concurs with the observation that urology is a highly desirable field but often requires a research portfolio to match successfully.

Deciding during clinical rotations that you are attracted to the field makes it difficult to build a competitive resume before applying to the match. The average matched urology applicant in 2021 had 4 published articles and 9 other research items.[3] For many students, their only option is to take a year off to conduct research to increase their likelihood of matching, further delaying the start of their lengthy residency training and subsequent career.

At Sidney Kimmel Medical College (SKMC), our urology interest group, the Jefferson Urology Society (JUS), has attempted to address these issues by providing opportunities for exposure to the field during the preclinical years. In 2020, we initiated a 2-week Winter Externship for first- and second-year medical students interested in urology. The Winter Externship is a 2-week rotation occurring when third-year clerkship students are on winter break. This allows first- and second-year students to interact directly with residents and attendings and gain a realistic understanding of the field. This past winter, 5 first- and second-year students at SKMC participated. During their externship, students were able to scrub into a range of cases from robotic-assisted prostatectomies to percutaneous nephrolithotomies and penile prosthesis implantations. On days when students were not assisting in the operating room, they had the opportunity to shadow in the clinic. With access to attendings in reconstructive surgery, neuro-urology, and urologic oncology, students were able to observe many subspecialties within the field, helping to dispel the misconception that urology is a narrow field. The externship also helped students develop relationships with attendings and residents, resulting in several ongoing research projects. The feedback from participants has been overwhelmingly positive.

Comments from participants included:

> "We were surprised to see the diversity in the field. Before the externship, my understanding of urology was limited to treating kidney stones or UTIs; seeing prostatectomies and trauma reconstructions showed us the breadth involved."

> "I was impressed by the technological innovation; I was able to observe while an attending skillfully used a daVinci robot to navigate around the obturator nerve."

> "Spending time with the residents exposed us to the lively personalities that urologists are known for and increased my attraction to the field."

Medical schools with a mandatory clinical rotation in urology match more students than those that do not, as do medical schools that include a preclinical urology course in their curriculum.[4] Urology interest groups also are correlated with increased numbers of urology residency applicants.[5] However, groups such as JUS exist at only 21% of medical schools.[6]

For many urology departments, the framework to implement a winter externship is already in place because it is designed to mimic a third-year rotation. Based on the experience of the JUS, there are 2 key factors to implementing a similar program. The first step is to outline the program goals. In our program at SKMC, we wanted to give students the same experience as a third-year student on rotation, so the JUS leadership met with the program director for advice on how to accomplish this endeavor. Because the fourth-year student members of JUS already had completed their rotations, they took the lead on teaching the students how to use the hospital electronic medical record system and how to scrub into cases. The JUS student leadership then led an orientation day in which they taught basic suturing skills and explained the common procedures occurring in the operating rooms. Practical steps that needed to be taken included ensuring all participants had access to scrubs and that their badges allowed them to swipe into the operating rooms. The second factor is that it is essential to build a good working relationship with the urology residency leadership (ie, program director and associate program director(s), program coordinator, and chief residents) to facilitate the program's implementation in the department. It should be perceived as a win-win for all parties involved. Participants come away with increased interest in the field and greater preparation for their rotations and sub-internships in the near future.

In summary, medical student exposure to urology often is limited. Studies of the factors influencing medical students' decision to pursue a career in urology support the importance of early exposure to the field.[6] Medical schools with a mandatory clinical rotation in urology match more students than those that do not, as do medical schools that include a preclinical urology course in their curriculum.[4] Urology interest groups play an important role in stimulating interest in the field and helping to navigate the application process. Implementing programs, such as the SKMC Urology Winter Externship, can promote early commitment and maximize the chance of matching in this dynamic and increasingly competitive specialty. ■

1. Slaughenhoupt B, Ogunyemi O, Giannopoulos M, Sauder C, Leverson G. An update on the current status of medical student urology education in the United States. *Urology.* 2014;84(4):743-747.
2. American Urological Association. *Urology and Specialty Matches.* Accessed March 15, 2023, https://www.auanet.org/meetings-and-education/for-residents/urology-and-specialty-matches.
3. Bell S, Hunt T, Castro Bigalli A, Randolph J, Gusev A. Urology Match 2021: characteristics and outcomes of successful applicants amid COVID-19. Paper presented at: 90th Annual Meeting of the New England Section of the American Urological Association; October 14-16, 2019; Burlington, VT.
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Moving Toward an Objective Hypospadias Classification System

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The severity of the disease and the available repair options depend on the degree of hypospadias present. As a result, many different categorization systems have been created to evaluate the severity of hypospadias depending on the location of the urethral meatus. Unfortunately, the true location of spongiosal bifurcation is not reliably considered by these classification schemes. Certain forms of distal hypospadias are linked to proximal spongiosal hypoplasia and penile curvature (which may necessitate extensive or staged surgical treatment), whereas other, seemingly severe occurrences of proximal hypospadias can provide less of a surgical challenge where favorable anatomy is already present. Surgeons who specialize in treating hypospadias have known for quite some time that the location of the external meatus does not give any clear indication of the degree of the condition or the difficulty of its surgical correction.[1,2] It was also demonstrated that meatal position is not a reliable predictor of postoperative problems, demonstrating the importance of looking at the full hypospadias complex rather than just the meatus.[3] A method for objectively evaluating the severity of hypospadias stays an important challenge in the field.[4] Some tools to standardize the quantification of urethral plate quality and penile curvature have been introduced.[5-7]

Merriman et al proposed the Glans-Urethral Meatus-Shaft (GMS) classification scheme, which takes into account not only the placement of the meatus but also glans characteristics such as size, existence, and aspect of glans groove, and degree of ventral curvature.[8] Nonetheless, there is still a great deal of subjectivity involved in assessing these clinical characteristics.[1] Despite ongoing efforts to standardize, this variation in evaluation and classification hinders fair comparisons of results between institutions and surgeons. Lately, machine learning algorithms have emulated expert human classification of patients with distal/proximal hypospadias, potentially paving the way for future therapeutic applications and standardization of these technologies.[9] As with any grading system, the optimum categorization for the intensity of hypospadias should be objective and simple to reproduce.

Abbas introduced the urethral defect–based categorization system, where the urethral defect ratio was computed by dividing the magnitude of urethral defect (distance between glandular knobs and bifurcation of the corpus spongiosum) by stretched penile length.[10] The degree of hypospadias was then classified into 3 distinct classes (urethral defect ratio 0.5, 0.5-0.99, and 1.0; Figure 1).

The urethral defect–based categorization system also sheds new light on other crucial aspects of hypospadias, such as potential etiological/genetic causes and a family history of comparable defects. For instance, grade 1 is commonly associated with the familial occurrences and history of hypospadias in another family member, whereas grade 3 is related to the concept with pathologies related to placental insufficiency and preterm, etc. Similarly, cases of grade 3 carry a high risk of concomitant genital and extragenital abnormalities, which should be searched for and adequately addressed (Figure 2). ■

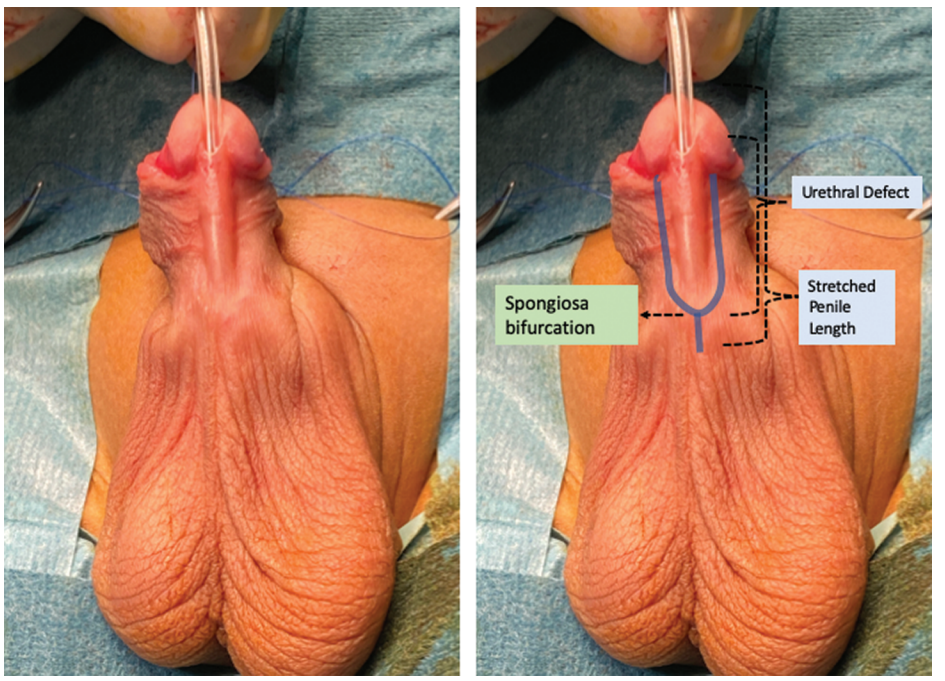

Figure 2. Intraoperative image of the ventral aspect of the penile shaft of a hypospadias case that traditionally is categorized as glanular hypospadias based on meatal-based classification schemes. On the contrary, the urethral defect ratio system is based on the location of the spongiosa bifurcation in relation to the penile length. In this particular case, the stretched penile length is 53 mm, and the urethral defect (ie, the distance between the glanular knobs and the spongiosa bifurcation) is 32 mm. Therefore, urethral defect ratio = urethral defect/stretched penile length (32/53) = 0.6, which represents class 2.

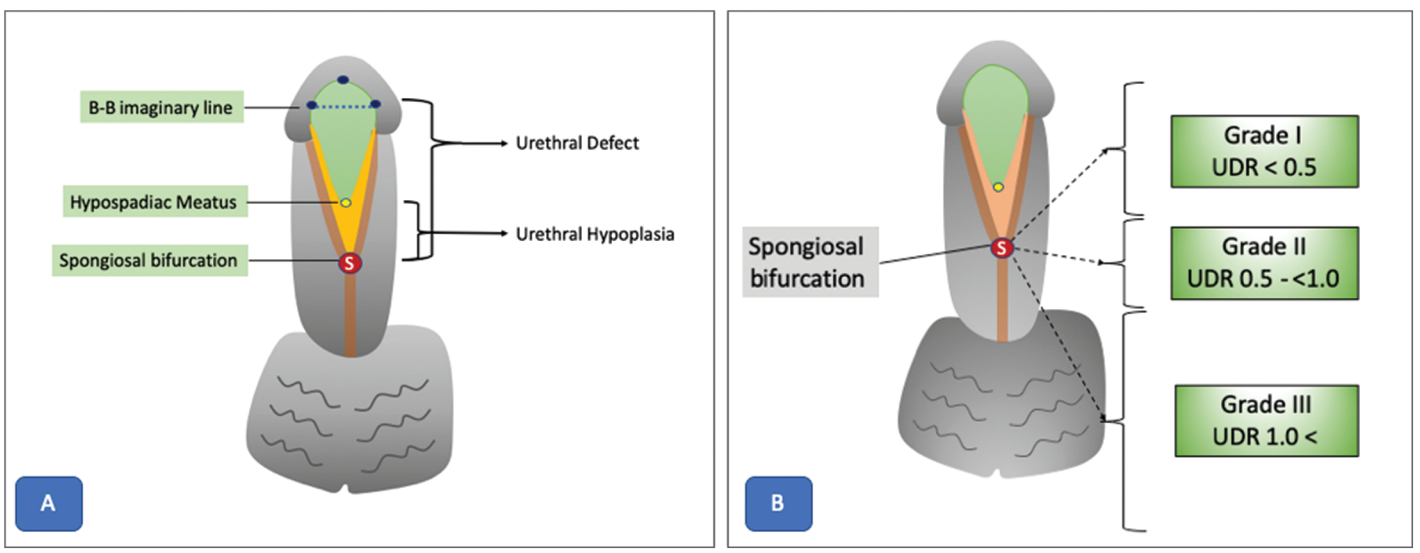

Figure 1. Anatomical variables utilized for the determination of the urethral defect–based categorization system. B-B indicates the imaginary line between the 2 glanular knobs; UDR, urethral defect ratio.

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Urological Applications for ChatGPT

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If I had to select one game changer in urology over the past 12 months, clearly it would be using artificial intelligence (AI) and ChatGPT (for generative pertaining transformer) for managing both clinical and nonclinical aspects of a urological practice. This article discusses 4 potential applications of ChatGPT for urology and how this novel technology can improve the efficiency and productivity a urological practice.

First you must register at https://openai.com. Because of limited space, I will only describe what I entered in the Chat box and a few paragraphs of each response.

1. Enter in the Chat box, "Write a job description for a medical assistant in a urology practice."

Forty-five seconds later, the following response was received on my computer:

Job Title: Medical Assistant (Urology)

Job Summary: We are seeking a skilled Medical Assistant to join our urology practice. In this role, you will work closely with our team of healthcare professionals to provide exceptional patient care and support. Your primary responsibilities will include assisting with patient intake, performing routine clinical tasks, and maintaining accurate medical records.

Key Responsibilities:

- Greet patients and escort them to exam rooms.
- Take vital signs, review medical history and reason for visit with patient.
- Assist physician during examinations and procedures.
- Perform routine clinical tasks such as urine tests, blood draws, and specimen collections.
- Administer medications as directed by physician.
- Clean and sterilize medical equipment.
- Maintain accurate and up-to-date medical records.
- Coordinate patient referrals and follow-up appointments.
- Provide patients with education and resources related to their condition.
- Participate in team meetings and assist with administrative tasks as needed.

2. To request a handout on frequently asked questions (FAQs) for PSA screening, enter in the Chat box, "Provide the FAQs on PSA screening." Here are the responses from ChatGPT:
   1. What is a PSA test? A PSA test is a blood test that measures the level of prostate-specific antigen (PSA) in the blood. PSA is a protein produced by the prostate gland, and high levels of PSA can indicate the presence of prostate cancer.
   2. When should I get a PSA test? The American Cancer Society recommends that men discuss the benefits and risks of PSA screening with their doctor starting at age 50 for men at average risk of prostate cancer. Men at higher risk, such as African American men or men with a family history of prostate cancer, may want to consider getting screened earlier.
   3. Is a high PSA level always an indication of prostate cancer? No, a high PSA level does not always mean that a man has prostate cancer. Other factors, such as an enlarged prostate or an infection, can also cause PSA levels to rise.
   4. What happens if my PSA level is high? If your PSA level is high, your doctor may recommend further testing, such as a biopsy, to determine whether you have prostate cancer.

3. Enter in Chat box, "Write a blog on the importance of nutrition in urologic diseases."

Nutrition is an important part of managing urologic diseases, including conditions that affect the kidneys, bladder, and prostate. Making dietary changes can help to improve your overall health and manage symptoms associated with urologic diseases. Here are some tips on nutrition for urologic diseases:

Kidney Disease:

If you have kidney disease, it's important to limit your intake of sodium, potassium, and phosphorus. Sodium can increase blood pressure and lead to fluid retention, while potassium and phosphorus can accumulate in the body and cause complications. To limit these minerals, you should:

- Avoid processed and packaged foods, which often contain high amounts of sodium, potassium, and phosphorus.
- Choose fresh fruits and vegetables that are lower in potassium, such as apples, berries, and green beans.
- Limit dairy products, which are high in phosphorus.
- Use herbs and spices to flavor your food instead of salt.

Bladder Disease:

Bladder conditions such as interstitial cystitis (IC) can cause discomfort and pain. Certain foods and drinks can aggravate symptoms and should be avoided, such as:

- Acidic foods and drinks like citrus fruits, tomatoes, and coffee
- Spicy foods like hot peppers and chili powder
- Carbonated drinks and alcohol
- Artificial sweeteners

4. Creating a letter to the insurance company to obtain authorization for multiparametric MRI:

Enter in the Chat box, "Write a letter to UnitedHealthcare regarding patient John Doe (membership ID XXXXXXXX, Birthdate XX/XX/XXXX) who has an elevated PSA level, 8.3 ng/ml, a free/total PSA ratio of 19% (normal is greater than 25%). I am requesting a multiparametric MRI and a prostate biopsy to complete his evaluation for prostate cancer. Please provide recent references regarding the appropriateness of this procedure. Signed Dr. Neil Baum, with carbon copy (c.c.) to John Doe."

The following letter was generated in less than 45 seconds, and another 60 seconds was required for the nurse or the medical assistant to add the patient's name and identification number.

Dear UnitedHealthcare,

I am writing to request approval for a multiparametric MRI and prostate biopsy for patient <John Doe>, who holds a membership ID of XXXXXXXX and was born on XX/XX/XXXX. Upon examination, Mr. <Doe's> PSA levels were found to be elevated at 8.3 ng/ml, with a free/total PSA ratio of 19% (normal is greater than 25%). Given these findings, I strongly recommend a multiparametric MRI and prostate biopsy to assess the condition of Mr. Doe's prostate gland and determine if further treatment is necessary.

I request that you approve this study for Mr. Doe's benefit and ensure that he receives the care he needs.

I am including recent references that document the appropriateness of mpMRI in the management of men with an elevated PSA level. These are references from peer-reviewed literature on the value of mpMRI in the management of patients with elevated PSA levels. I believe it is essential to remain up to date on the latest advancements and recommendations in the field.

Thank you for your attention to this matter. Please do not hesitate to contact me if you have any questions or require additional information.

Sincerely,
Dr. Neil Baum
c.c. John Doe
(8 current references were included)

Bottom Line: I hope these abbreviated examples demonstrate the useful application of ChatGPT for urological practices. I would be interested in hearing from you if you have discovered additional applications of this exciting technology. If you want the complete responses that I received from ChatGPT, contact me at doctorwhiz@gmail.com. ■

The Rejuvenated Bladder and Opportunities for the Future

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Age-associated lower urinary tract (LUT) disorders (LUTDs) erode quality of life for millions and increase enormously the costs for both health care and eldercare.[1] The specific factors that are associated with aging and lead to LUTDs are not well understood and vary among patients, though changes in the structure and function of both cellular and extracellular components of the LUT are most likely to be important contributing factors. These pathological changes and their consequent physiological disorders converge to produce LUT symptoms and signs including urgency, urinary incontinence, impaired bladder contractility, increased residual urine, nocturia, decreased bladder sensation, and other attendant conditions including urinary tract infection. Health providers often underestimate the detrimental effects of LUTDs on patients' lives, especially in the older population. Since demographic studies indicate a steep increase in LUTDs beginning in the fifth decade of life in both sexes that worsens with advanced age,[2] the burden of LUTDs is particularly high in the elderly.

Oxidative damage is a known contributor to and driving factor of multiple age-associated diseases.[3] While the underlying causes of LUTDs in older adults remain to be established, one of the most widely accepted hypotheses is that LUTDs arise because of increased oxidative stress, for example generation of reactive oxygen species (ROS) due to mitochondrial dysfunction.[4] In this regard, chronic ischemia and associated oxidative stress increase with age, and accumulation of oxidative damage–associated with increased ROS–over time negatively affects all components of the LUT system yielding the LUT system prone to LUTDs regardless of the proximal initiating cause. Despite evidence supporting a role for oxidative damage in the pathophysiology of age-associated disorders, numerous clinical trials have failed to show a benefit of antioxidants for the prevention and/or treatment of such disorders. This suggests that antioxidants per se are insufficient to treat LUTDs and that a treatment that engages multiple mechanisms, including ROS reduction, is required.

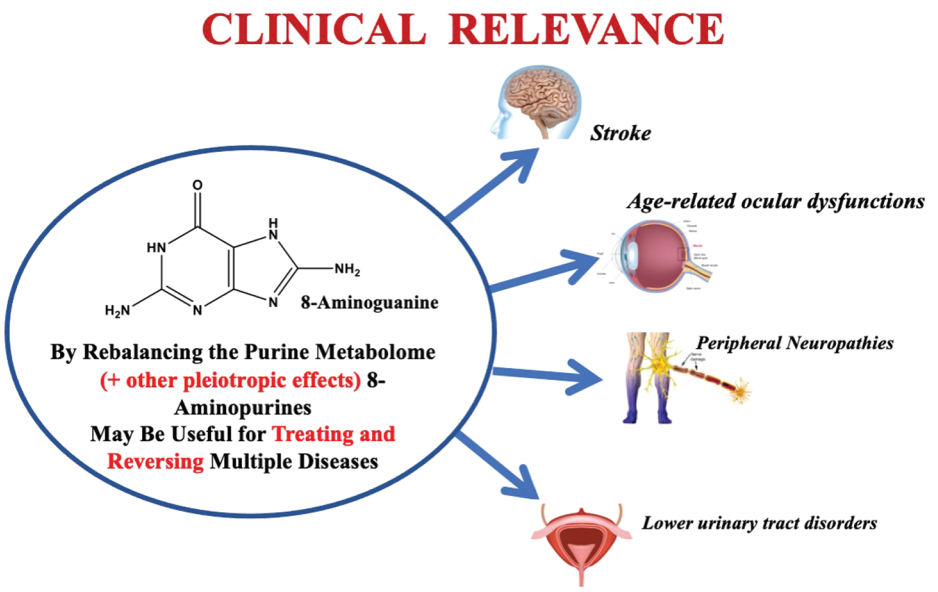

Figure 2. Clinical relevance of 8-aminoguanine.

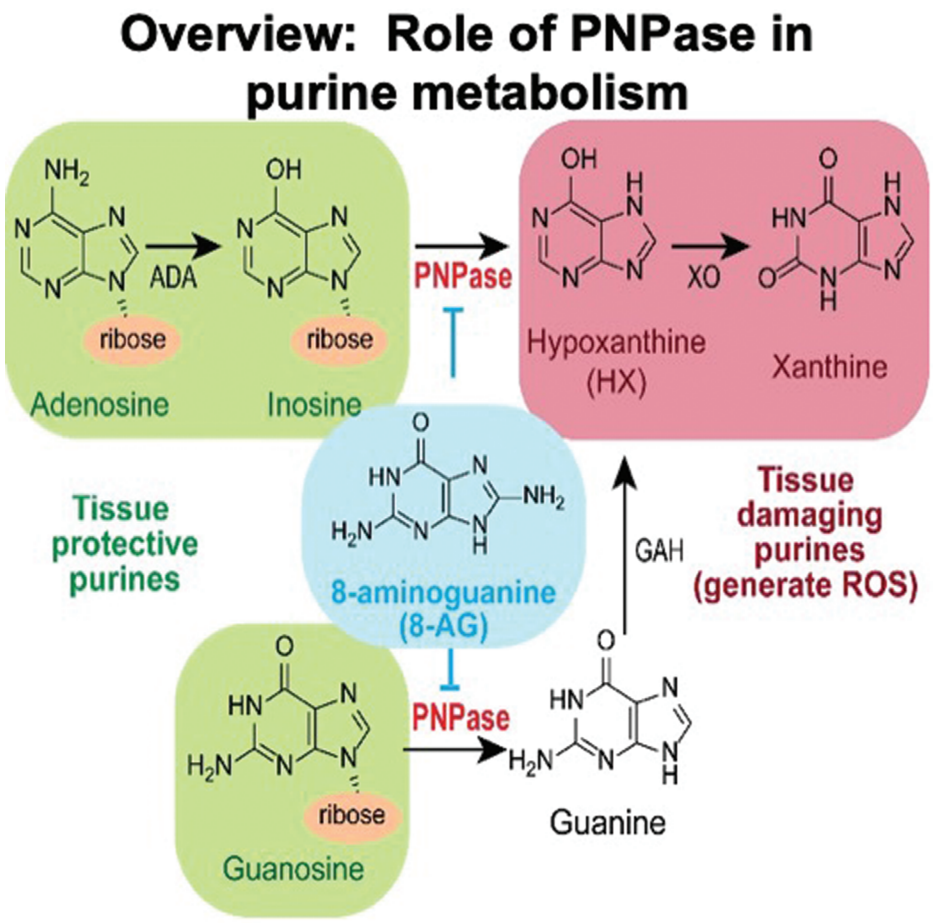

Figure 1. Role of purine nucleoside phosphorylase (PNPase) in purine metabolism. ROS indicates reactive oxygen species.

There is emerging evidence that changes in levels/activity of an enzyme called purine nucleoside phosphorylase (PNPase) contribute to the extent and magnitude of both oxidative injury and inflammation leading to cellular damage.[5] PNPase metabolizes "tissue-protective" anti-inflammatory purine metabolites to "tissue-damaging" ROS-generating metabolites (Figure 1); thereby, PNPase may contribute to age-related inflammation and ROS production leading to LUT injury. A recent report that decreases in "tissue-protective" purines in COVID-19 patients are associated with acute kidney injury[6] provides evidence that abnormally low levels of protective purines (ie, adenosine, inosine, and guanosine) may contribute to a broad range of disorders including those impacting the LUT.

To test our hypothesis that PNPase contributes to the pathophysiology of LUTDs, we tested the concept that "redirecting the purine metabolism" in the urinary bladder using 8-aminoguanine (8-AG), an inhibitor of PNPase, would reverse LUTDs by increasing uroprotective and decreasing urodamaging purine metabolites. Indeed, we observed that 8-AG provides beneficial effects on the LUT and reverses age-related changes in both bladder structure and function.[7,8] Our preclinical studies were performed in rats near the end of their life span that had already developed severe

"There is emerging evidence that changes in levels/activity of an enzyme called purine nucleoside phosphorylase (PNPase) contribute to the extent and magnitude of both oxidative injury and inflammation leading to cellular damage."

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THE REJUVENATED BLADDER AND OPPORTUNITIES FOR THE FUTURE

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bladder pathologies which were unlikely to be reversed by any treatment. However, PNPase inhibition with 8-AG completely reversed all of the molecular, cellular, and functional bladder abnormalities associated with aging. It is conceivable that these remarkable results with 8-AG were due not only to inhibition of PNPase, but also to other pleiotropic effects of 8-AG.

Though additional studies are required to validate the potential of 8-AG treatment for LUTDs, these and other findings support the conclusion that 8-substituted amino purines (such as 8-AG) should be included in the drug development pipeline for LUTDs. In addition to LUTDs, 8-AG exhibits wide-ranging beneficial effects on the form and function of other organ systems negatively impacted by aging, for example, retinal degeneration (Figure 2). These and other findings suggest that an inhibitor of PNPase may be "geroprotective," targeting fundamental mechanisms of aging (eg, oxidative damage, inflammation, senescence) that make aging a risk factor for LUTDs in the older adult. We have observed that 8-AG increases life span in hypertensive Dahl SS rats on a high-salt diet by completely preventing strokes,[9] providing additional support that 8-AG may be a geroprotector which could improve frailty in patients. Though further evidence of safety and efficacy is needed, PNPase inhibitors could offer an effective pharmacological treatment approach—either alone or as an adjunct with current treatments, which could lead to a reduction in the dose of a monotherapy, thus reducing the risk of side effects. This could result in better outcomes (improving efficacy and tolerability) for age-associated LUTDs as well as other age-related diseases. ■

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Cadaveric vs Silicone Simulator Training in Holmium Laser Enucleation of the Prostate: Master Class

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Endoscopic enucleation of the prostate has been endorsed by guidelines as a size-independent option for the surgical management of benign prostatic hyperplasia (BPH). However, despite strong evidence in favor of holmium laser enucleation of the prostate (HoLEP) over other BPH treatment modalities, such as transurethral resection of the prostate and simple prostatectomy, HoLEP remains significantly underutilized. Reports from claim databases estimated that HoLEP accounts for less than 5% of all prostate surgeries performed annually in the United States.[1] This scarcity, along with the perceived steep learning curve, impeded access for trainees to learn a much sought for procedure. Furthermore, other than the limited number of fellowships, there is a lack of standardized and applied training programs and models for urologists willing to learn HoLEP.

In response to this need, we organized the inaugural "Texas HoLEP Master Class" at UT Health San Antonio. A comprehensive curriculum was designed to provide trainees with the necessary knowledge to overcome the initial learning curve and gain access to the tools required to initiate an endoscopic enucleation of the prostate program. The hands-on part of the master class included training on fresh cadavers for the first time in the United States, as well as training on silicone simulation models.

Human cadavers have been shown to be an effective platform for skills training among different specialties, from basic skills to complex open and laparoscopic procedures.[2] Their anatomical accuracy and similarity to live tissue allow the trainees to hone their skills in a safe setting without patient-related risks. However, cost, limited availability, and challenging logistics have limited their adoption in surgical training. Furthermore, little is known about the suitability of human cadavers as a training model for HoLEP. A recent European study performed on 2

Figure. Hands-on training modules in Texas HoLEP master class: A, Cadaver training model. B, Hall setup for cadaver training. C, Hall setup for simulator training. D, Trainees performing HoLEP on cadavers under faculty supervision.

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CADAVERIC VS SILICONE SIMULATOR TRAINING IN HOLMIUM LASER ENUCLEATION OF THE PROSTATE

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cadavers demonstrated the validity of human cadaveric models for use in HoLEP training.[3] To our knowledge, human cadavers were never used previously on a training scale for HoLEP in the United States.

Cadavers can be fresh, frozen, or embalmed. Embalmed cadavers have longer shelf life than fresh or frozen cadavers, making them a more sensible choice for training programs that need the cadavers for a long time.[4] However, the embalming process alters the texture of the tissues and disrupts tissue planes; as such, fresh cadavers were used as our HoLEP training models.

Synthetic silicone and 3 D-printed simulators have been introduced as efficient models for surgical training and recently have undergone significant advances.[5] They offer close resemblance to live tissue and help in the development of trainees' spatial awareness in the early phases of training. Several silicone synthetic models are available for multiple procedures, including transurethral resection of the prostate and, more recently, HoLEP. They have been favored over virtual simulation machines, which currently do not deliver an equivalent experience to real tissue handling.

On January 27 and 28, 2023, the inaugural Texas HoLEP Master Class was organized at UT Health San Antonio. Forty-eight urologists registered–the group came from various practice settings and had different levels of experience. The master class was organized over 2 days; the first day included live surgery transmission of 2 HoLEP cases from the operating room, didactics covering all aspects of prostate enucleation, and a moderated panel covering tips and tricks of the procedure as well as management of complications. The second day was limited to 20 trainees. Each trainee practiced HoLEP on a synthetic silicone simulator, as well as on a fresh cadaver under faculty supervision (see Figure). A previously proposed 10-step technique for surgeons in training also was demonstrated.[6]

> "This event demonstrated the feasibility, effectiveness, and sustainability of performing a hands-on training program that involves cadaveric training for HoLEP."

Executing a cadaveric HoLEP training workshop required close collaboration and communication among the organizing team members. Running 10 high-powered lasers at the same time required renting a special generator to ensure that the lasers were set up and operated safely and effectively. Adequate staffing was critical to ensure a constant supply of irrigation fluid and efficient disposal of drained fluid during the training sessions. Because the cadavers after HoLEP training were intact, they were utilized subsequently in other training workshops to minimize the cost.

Upon course completion, participants completed a questionnaire assessing their satisfaction of using the cadaveric models and compared it with their experience with the silicone simulators.

The majority of trainees agreed that compared with the synthetic silicone simulators, the cadaveric training models served as a more realistic representation of anatomy (95%). With regard to the steps of the procedure, most of the trainees believed the cadaveric models were superior to the simulators in realistic representation of bladder neck incision (91%), median lobe dissection (100%), development of the enucleation plane (100%), early sphincter release (95%), dissecting from 2-10 o'clock (100%), dissecting from 4-10 o'clock (95%), incision of the anterior commissure (100%), and final anterior dissection (100%). Trainees also agreed that tissue reaction to laser energy (91%) and surgical feedback (100%) were superior in the cadaveric models. When asked which training platform trainees would prefer to have access to in the future, 9.5% preferred both silicon simulators and cadavers, and 90.5% preferred cadavers only. Overall, the cadaveric models were perceived to be a better construct for teaching the HoLEP procedure.

This event demonstrated the feasibility, effectiveness, and sustainability of performing a hands-on training program that involves cadaveric training for HoLEP. In light of the positive feedback from attendees and faculty, the decision was made to hold the master class annually. Similar educational events are important to meet the needs of a growing number of urologists interested in learning HoLEP. ■

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Familyfirst Messenger Application

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New York Medical College, New York

Randy Perecman
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The Familyfirst Messenger application is a provider to the family communication platform. Familyfirst Messenger is a one-way messaging mobile platform for iPhone and Android devices that is compliant with HIPAA (Health Insurance Portability and Accountability Act of 1996). Family members can now free themselves from the confines of the waiting room, as information about their loved ones can be accessible wherever there is Wi-Fi or a cell signal. Families that are located in other states or abroad are made to feel as if they are close to their loved ones.

This application has become mainstream in hospitals and skilled nursing facilities, including one of the larger academic health care systems–The Westchester Medical Center Health Network–located throughout New York State.

A Pioneer in Hospital Communication

I co-founded the Familyfirst application (iOS; Android) with my college roommate's son, Randy. Until this point of my career, I had no prior experience with technology, beyond the typical daily use of an iPhone. Despite my inexperience in the technology world, I began the mission to build a robust software solution for an issue we all have experienced as a medical provider or family member.

Randy and I have different skillsets that were channeled toward designing this application. My clinical and administrative roles have provided me with a unique exposure to the many different facets of health care. I am able to recognize workflows that need improvement, with a vision of

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FAMILYFIRST MESSENGER APPLICATION

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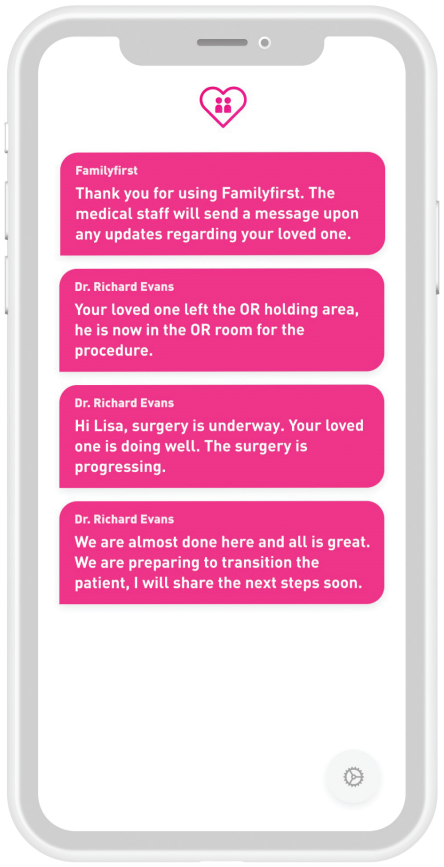

Figure 1. Messages are displayed on the family member's device.

how physicians and nurses can operationalize for success. Randy has the expertise of software engineering to complement and implement the thought process. We have since expanded our software team to enable the application's evolution.

The application allows family members to receive real-time updates before, during, and after surgery. The medical staff can send messages at any time to the family members of their patients. Family communication has been shown to reduce a family's anxiety and stress level.[1,2] Familyfirst was not designed to replace face-to-face communication but to help enhance direct contact when desired. Physicians now have an efficient means of communication to schedule a convenient meeting time and place to review the surgical and medical events with the family.

Families are enrolled into Familyfirst remotely (anywhere in the world) or onsite in the hospital. The medical providers or family members do not expose their personal information. Cell phone numbers or email addresses are not used to make the connection, thus preserving privacy for both sides.

The app is a free download for all family members. Familyfirst has been designed to require a minimum number of clicks to avoid user "burnout." Each provider is instructed on how to use the app through a 5-minute tutorial or with a user-friendly dropdown knowledge reference located within the app.

The messages are translated automatically into any language on the family member's device. The messages that the provider chooses to send can either be selected from a prefabricated library or an original custom message can be composed spontaneously.

Family members interface with Familyfirst on the mobile app (iOS and Android) to read messages anytime and anywhere (Figure 1). However, the medical staff has convenient access to the website (web) app, located on all of the hospitals' computer stations (Figure 2). The web app enables providers to send the family messages from the operating room, intensive care units (ICUs), or from any mobile computer station while on morning and afternoon rounds.

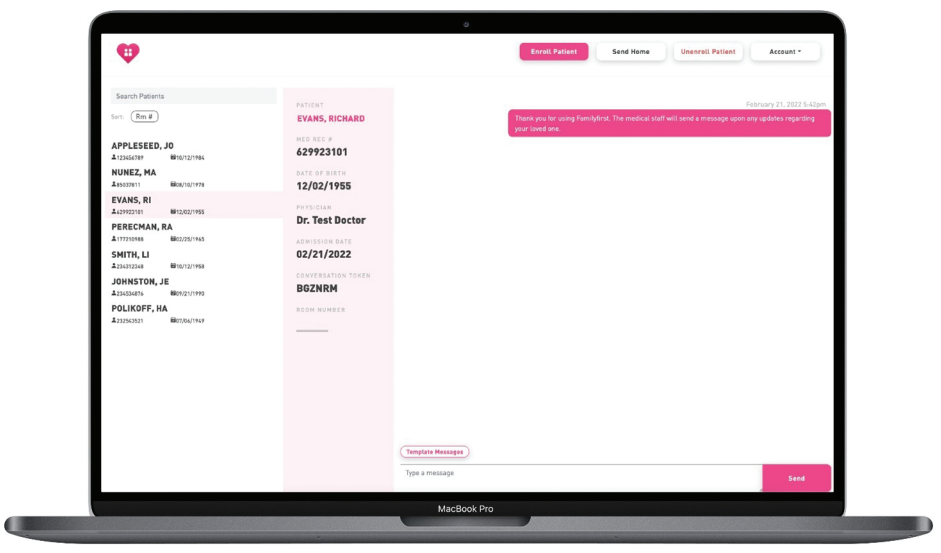

Figure 2. Medical staff have access to the web app on the hospital's computers to review and send messages.

There has been a disconnect in communication between medical providers and a patient's family, which became most apparent to me during my years of caring for active and retired U.S. servicewomen and -men at the Minneapolis Veterans Administration Hospital.

> "Communication is a clear indicator of how we move information in society. We need to continue to innovate and adopt technology that exemplifies our dedication to our patients and their families."

Throughout the United States, families are left adrift to wonder and worry about the status of their loved ones during the preoperative, intraoperative, and postoperative phases of care. Currently, families rely on an occasional telephone call or are left to stare at an "airport" screen in the hospital waiting room for status updates. Families are forced to forego meals and restroom needs while sitting in the surgical or ICU waiting rooms for hours, with the fear of missing the medical provider's information.

ICU nurses spend a disproportionate segment of their shift answering calls from concerned family members who are desperate for information. Globally, hospitals have faced a nursing shortage, which has already challenged bedside care.[3,4] Now, hospital staff can provide morning and evening updates to family members through the application and allow nurses to have additional precious bedside care time.

Providers are focused on the medical and surgical care they provide, but hospital systems have their own agenda. In addition to providing excellent care for their community, hospital systems strive to have top Press Ganey (outpatient survey) and Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS, inpatient survey) scores.

Hospital costs have spiraled, whereas reimbursements have declined. Hospitals strive to obtain top HCAHPS scores as a vital means to an additional income stream. Those hospitals that achieve the best HCAHPS scores are eligible for a bonus payment. The funds are dispersed from a Medicare pool annually. Top-box scores also help to boost a hospital's image within the community upon the publication of hospital ratings. Therefore, hospital systems have a dual purpose to optimize communication within the hospital environment.

Digital Medicine Expands

Physicians are in a unique position to understand the aspects of health care that require improvement. Digital medical companies need physician leadership to lead health care innovation.

Communication is a clear indicator of how we move information in society. We need to continue to innovate and adopt technology that exemplifies our dedication to our patients and their families. However, we must always protect the privacy of our patients and ensure HIPAA compliance within software platforms.

Urologists have contributed to medical device innovations through collaborating with Industry. Familyfirst Messenger is a digital innovation co-developed and led by a urologist. The development of our communication solution is a by-product of clinical requirements guiding software engineering.

We, as physicians, are in the perfect position to recognize health care impediments and lead change through digital solutions. ■

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2023 Practice Management and Coding Program: Invest in Yourself, Your Practice Team, and Your Future!

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"The goal of all learning is action, not knowledge."
–John C. Maxwell

In today's ever-changing medical landscape, it is essential for urological practices to keep abreast of the contemporary issues facing the specialty and be prepared with actionable solutions to maintain, optimize, and improve business operations while delivering high-quality patient care.

On July 13-14, 2023, we are honored to combine our expertise and experience in the practice management and coding arena of 50+ years to deliver the robust AUA Practice Management & Coding Program. This program addresses the hot topics facing today's urology practices and offers practical advice on how to survive and thrive in the current environment. Designed specifically with the practice administrator and coder in mind, this program provides relevant cutting-edge management and leadership education with an increased emphasis on coding and reimbursement.

This education is part of the AUA Institute for Leadership & Business, an initiative established by the AUA in 2022 to support leadership development and business acumen within the urological community. The AUA recognizes the tremendous value of business and leadership training for all urology professionals–throughout all stages of their career. Through the Institute for Leadership & Business, the AUA offers education, programs, and resources to support your needs and professional growth.

> "This program addresses the hot topics facing today's urology practices and offers practical advice on how to survive and thrive in the current environment."

Since the COVID-19 pandemic began in 2020, practices have been forced to continually adapt and adjust their business practices to maintain their bottom line, which directly affects the quality of patient care and cost of services. During the practice management session on Thursday, July 13, we will address many of the issues affecting the bottom line of our urological practices by engaging in practical discussions that offer real-life solutions. The Thursday session will fully focus on practice management-related topics presented by industry experts that include:

- Maintaining practice independence
- Outsourcing for practice growth and efficiencies
- Utilizing advanced practice providers for optimal patient care and office efficiency
- Mitigating the burden of prior authorizations
- Tools and analytics for determining the practice impact of changes to the Physician Fee Schedule and reimbursement

The second day of the program will fully focus on coding and reimbursement. As coding and reimbursement is ever changing and ever evolving, it requires a tremendous effort at the practice level to maintain relevant and current coding, reimbursement, and billing procedures. Our Friday program will deliver essential, timely education and updates for direct implementation into your practice to optimize and improve business operations. Friday will feature coding experts who will provide a thorough, in-depth analysis of the most current coding and reimbursement updates and topics that include:

- Evaluation & management services update
- 2023 CPT (Current Procedural Terminology) code changes: need to know updates and clarifications
- Billing in the ambulatory surgery center
- Correct use of modifiers–case scenarios and discussion
- Public health emergency updates
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We urge you to invest in yourself, your practice team, and your future! Join us for the AUA Practice Management & Coding Program that will be held virtually on July 13-14, 2023. Visit AUAUniversity for more information and to register (https://auau.auanet.org/node/37927). ■

Healthy Men Should Undergo Baseline PSA Screening: A Call for Clear Guidance

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PSA screening fell out of favor among physicians over the past decade. In large part, this was due to professional guidelines based on short-term results of trials, including faulty data from the PLCO (Prostate, Lung, Colorectal, and Ovarian) Cancer Screening Trial. The subsequent realization that the vast majority of men in the control arm of the PLCO Trial had PSA testing, negating its conclusions,[1] the accrual of longer-term data from European Randomized Study of Screening for Prostate Cancer (ERSPC) sites, as well as modeling studies based on randomized and epidemiological data all increasingly suggest the benefits of screening outweigh its harms.[2]

Despite this increasingly clear evidence, screening rates have not recovered. For instance, one recent Veterans Health Administration study found that 37% of men were screened in 2019, as compared to ~50% prior to 2012.[3] Further, more prostate cancers are being diagnosed at higher grades and stages, with mortality now potentially increasing, reversing decades of progress resultant from screening.[4] As professional societies, including the AUA, the American Cancer Society, and the United States Preventive Services Task Force, gear up for another round of guideline updates, we believe clear guidance from these organizations is critical.

While continuous efforts to improve shared decision-making in prostate cancer screening are valued, data suggest that real shared decision-making and the use of decision aids are challenging to implement and are almost certainly not being performed adequately, with a minority of men reporting shared decision-making, despite years of utilization of such language

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HEALTHY MEN SHOULD UNDERGO BASELINE PSA SCREENING

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by guideline panels.[5-7] In our view, this focus on providing tools for discussion, rather than issuing clear guidance regarding screening, is a disservice to patients and their doctors. A guidelines panel's goal should be to issue clear guidance based on expert assessment. Such clarity is desperately needed, as a generation of primary care physicians were trained not to perform PSA screening and, at best, consider screening controversial.

In our view, it is now clear that PSA screening, as an initial triage test to assess prostate cancer risk, is beneficial for otherwise healthy men beginning in their 40s or early 50s. This is based on the observed time-dependent increase in the benefits of screening, which were not incorporated in prior guidelines. To illustrate this point, imagine an extreme example—examining the tradeoffs of screening 1 year after beginning a screening program. Obviously, there would be substantial harm from treatment, such as impotence and incontinence, and no mortality benefit because no patient with lethal cancer will be cured by local therapy within 1 year. While it should be obvious that 1 year from screening is too short an interval, policy makers arbitrarily selected intervals of 9 or 13 years to examine the tradeoffs of screening, which is also too short, as many men begin screening in their 50s, and the harms of prostate cancer metastasis and death often don't present until men are in their 70s or 80s.

When the long-term tradeoffs of PSA screening are modeled,[2] even using very conservative assumptions, we found that the number of excess diagnoses to prevent 1 prostate cancer death at 25 years was 11, with estimates well into the single digits depending on model parameters. This is consistent with longer-term data from the ERSPC as well as recent reports from ERSPC sites with longer follow-up.[8,9] Importantly, these numbers are comparable to the number needed to treat to cause 1 case of urinary incontinence or impotence from prostate cancer treatments.[2,10,11] Although a simplification, if the tradeoffs of screening approximate 1 case of impotence or incontinence to prevent 1 death from prostate cancer, to say nothing of those whose metastatic disease is prevented, in our view, the benefits of screening clearly outweigh its harms. Recent work suggests that for Black men, or other men at high risk, these tradeoffs are almost certainly even more favorable.[12]

Based on these observations and the recent improvements in prostate cancer screening and diagnostics, including the potential use of MRI as a triage test and active surveillance for indolent cancer, it is our opinion that PSA screening be recommended for all healthy men. The focus on optimizing screening with complex algorithms and flowcharts, while well intentioned, misses the reality that many patients, including men at high risk who stand to benefit most, are not undergoing screening at all. A straightforward message and clear guidance are needed from expert panels in this regard. ■

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Vibegron for Overactive Bladder Treatment in Older Adults: Results From the EMPOWUR Trial

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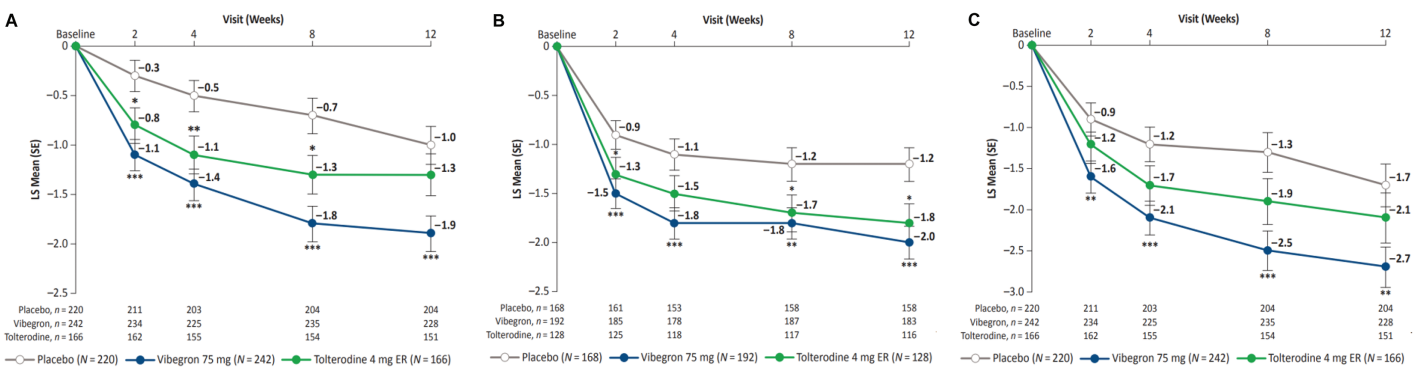

Figure. Change from baseline in average daily number of micturitions (A), urge urinary incontinence episodes (B), and urgency episodes (C) for patients aged ≥65 years. ER indicates extended release; LS, least squares; SE, standard error. Adapted and reprinted with permission from Varano et al. *Drugs Aging*. 38(2):137.[8]

Overactive bladder (OAB) is a common condition, with symptoms including urinary urgency and frequency with or without urge urinary incontinence (UUI). Among adults aged ≥76 years, 51% of women and 49% of men report experiencing OAB symptoms at least sometimes.[1] When weighing treatment options for older adult patients with OAB, it is especially important to consider their comorbidities and current medications, as well as any other potential risks of treatment.

American Urological Association guidelines recommend behavioral therapy, with or without pharmacological management, including anticholinergics or β_3-adrenergic receptor agonists, as first-line treatment for OAB.[2] While anticholinergics may be effective for some patients, they can result in bothersome and persistence-limiting side effects such as constipation and dry mouth.[2] More concerning for older adults with OAB, a recent study found an increased incidence of falls/fractures[3] and a meta-analysis of 6 studies[4] suggested an increase in dementia risk in patients treated with anticholinergics.

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VIBEGRON FOR OVERACTIVE BLADDER TREATMENT IN OLDER ADULTS

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The American Geriatrics Society Beers Criteria recommend reducing or avoiding unnecessary anticholinergics in older adults because of risks of confusion, dry mouth, constipation, and other anticholinergic-related effects.[5]

β_3-adrenergic receptor agonists treat OAB through a distinct mechanism of action from anticholinergics. Vibegron is a β_3-adrenergic receptor agonist approved in 2020 for the treatment of OAB, based in part on evidence from EMPOWUR, an international, phase 3, randomized, controlled trial that randomly assigned patients to once-daily vibegron 75 mg, placebo, or active control (tolterodine 4 mg extended release) for 12 weeks.[6] Importantly, 42.9% of patients in EMPOWUR were ≥65 years of age. In EMPOWUR, treatment with vibegron was associated with reduced daily micturitions, urgency episodes, and UUI episodes relative to placebo at week 12. Adverse events (AEs) with incidence ≥2% in the vibegron arm and greater than with placebo were headache (4.0% vs 2.4%), nasopharyngitis (2.8% vs 1.7%), diarrhea (2.2% vs 1.1%), and nausea (2.2% vs 1.1%).

Vibegron was also assessed in a 40-week extension trial, in which patients who received vibegron or tolterodine in EMPOWUR continued on the same treatment for an additional 40 weeks, whereas patients who received placebo were randomized 1:1 to vibegron or tolterodine.[7] Similar to the 12-week trial, 46.5% of patients in the extension study were ≥65 years of age. Results from the EMPOWUR extension trial were similar to the primary study. Improvements in micturitions, urgency episodes, and UUI episodes were maintained over 52 weeks of vibegron treatment, with no meaningful differences between vibegron and tolterodine in the incidence or severity of AEs.

A subanalysis of the EMPOWUR trial was conducted to assess the efficacy and safety of vibegron in 628 patients aged ≥65 years, including a subset of 179 patients aged ≥75 years.[8] Patients aged ≥65 and ≥75 years experienced reductions in mean daily micturitions, urgency episodes, and UUI episodes, similar to the overall EMPOWUR population (see Figure; see Varano et al for the complete data[8]). At week 12, among patients aged ≥65 years receiving vibegron, 50.0% had a ≥75% reduction in UUI episodes and 38.7% had a ≥50% reduction in urgency episodes, compared with 29.8% and 28.8% of patients receiving placebo, respectively. The incidence of AEs among patients aged ≥65 and ≥75 years receiving vibegron was generally similar to those receiving tolterodine and the overall study population. Dry mouth, a common anticholinergic AE, occurred more frequently with tolterodine than with vibegron.

In EMPOWUR patients ≥65 years of age, the efficacy and safety of vibegron were similar to the results from the overall study population.[8] Vibegron treatment reduced daily micturitions, UUI episodes, and urgency episodes in older adults after 12 weeks. Likewise, older adults who received vibegron experienced AEs at similar rates to the overall study population. These results suggest that the efficacy and safety of vibegron in older adults with OAB are consistent with its label.

Older adults are at increased risk of experiencing cardiovascular events; thus, it is important to assess whether any new medication carries a risk of causing or exacerbating hypertension. Notably, adults ≥65 years of age in EMPOWUR experienced AEs of hypertension at similar rates to the overall population, and treatment with vibegron did not increase the incidence of hypertension relative to tolterodine or placebo.[8] Furthermore, a sensitive ambulatory blood pressure monitoring study found that vibegron treatment was not associated with elevated blood pressure, even in patients who were ≥66 years of age or those with preexisting hypertension, compared with placebo.[9] Taken together, these results suggest that vibegron may be particularly useful to treat OAB symptoms in older adults with hypertension.

Older adults with OAB are also more likely than those without OAB to take multiple medications to treat comorbid conditions, so it is important to assess the potential for drug-drug interactions when considering a new medication, particularly when using multiple anticholinergics to limit the increased risk of cognitive decline, delirium, and falls or fractures.[10] Importantly, vibegron does not inhibit CYP2D6, limiting the possibility of interactions with numerous medications that are CYP2D6 substrates and that may be prescribed to treat conditions that commonly cooccur with OAB, such as cardiovascular disease and depression. This may make vibegron a useful treatment for patients with polypharmacy.

Dysphagia may be common among older adults. Crushing vibegron is supported by its prescribing information; a clinical study has shown that vibegron can be crushed and administered with applesauce without meaningful changes to its pharmacokinetics.[11] Vibegron may be a valuable alternative for older adults with swallowing difficulties, particularly in the long-term care setting.

Overall, the available clinical data support vibegron use in older adults with OAB. The EMPOWUR trial enrolled a substantial population of adults ≥65 years of age, and a subgroup analysis indicated that efficacy and safety in adults aged ≥65 years was similar to the overall trial population.[8] Using anticholinergic medications to treat OAB may be inappropriate for many older adults due to risks including incident dementia and falls. Vibegron should be accessible for most older adults through Medicare Part D, making it a practical option for anticholinergic deescalation for many patients. The clinical characteristics of vibegron–including its nonanticholinergic mechanism of action, absence of hypertension risk, and absence of CYP2D6 inhibition, along with the option to safely administer as a crushed tablet–make it a valuable treatment option for older adults with OAB.

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Conflicts of Interest

The author is a consultant for Astellas, AzuraBio, UroCure, and Urovant Sciences; is an investigator and meeting participant/lecturer for Astellas and Urovant Sciences; and holds other interests in AzuraBio and UroCure. ■

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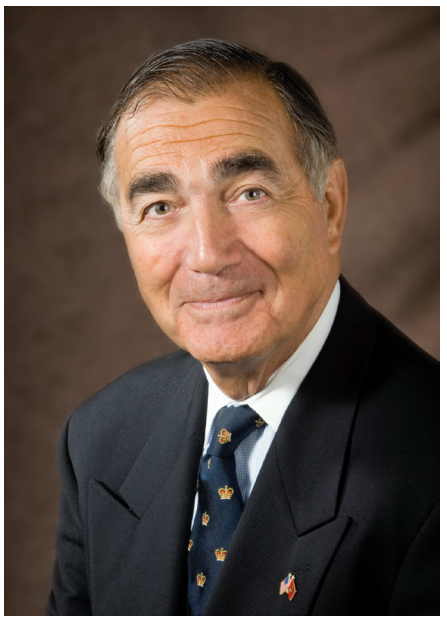
GIANTS OF UROLOGY

Robert S. Waldbaum, MD (1938-2023)

Joph Steckel, MD
Northwell Health, New York, New York

On January 29, 2023, Robert S. Waldbaum, MD, age 84, passed away peacefully in his home in Manhasset, New York, surrounded by his loving family. A lifelong New Yorker, Dr Waldbaum grew up in Brooklyn and was accepted into Columbia University at the age of 15 as a Ford Foundation Scholar. He graduated with honors and then attended Columbia College of Physicians and Surgeons, where he was elected as a member of Alpha Omega Alpha, the national medical honor society. Dr Waldbaum also was the president of his medical school class. He proudly served as a naval surgeon with the Second Battalion Third Marine Division, an experience he cherished throughout his life. He was a surgical resident at Columbia Presbyterian Hospital and a urology resident at the New York Hospital, training under Dr Victor Marshall. Dr Waldbaum was the founding chairman of the Department of Urology at North Shore University Hospital,



Manhasset, New York. He served as a chairman of the medical board and a trustee of the North Shore LIJ Health System (now Northwell). He was the founding partner and president of Urology Associates, a private urology practice, for over 35 years. In addition, Dr Waldbaum served as the chairman of the Urology Section of the Academy of Medicine. He was the president of the New York Section of the American Urological Association as well as their national historian. In addition, he served on the AUA's Board of Directors.

Throughout his illustrious career, Dr Waldbaum received may honors and lifetime achievement awards, including the Russell Lavengood Distinguished Service Award from the AUA and the John Lattimer Award from the National Kidney Foundation. In addition, North Shore LIJ and Dr Waldbaum's patients endowed a chair in his honor, the Waldbaum Gardner Professorship in Urology.

> "Dr Waldbaum was truly a giant in urology who trained and influenced so many urology residents throughout his career."

As his close friend and urology partner for over 30 years, I would emphatically declare that Bob would be proudest of what he would consider his greatest accomplishment–his family. He was adored by his 3 daughters, Nicole Moser, Alexandra "Ali" Kinnie, and Hillary Waldbaum, as well as his sons-in-law, Michael Moser and Bob Kinnie. He shared a loving relationship with his 4 grandchildren, Cameron and Charlotte Moser, and Emma and Jack Kinnie. He was forever blessed to have shared a fairy-tale marriage with the love of his life and best friend, Ruth Waldbaum, MD. Throughout their 59 years of marriage, they shared all of life's experiences together–exotic travel, golf, gardening, theater, opera, and skiing.

Dr Waldbaum was truly a giant in urology who trained and influenced so many urology residents throughout his career. He not only educated them in urology but taught them how to practice and perfect urological care for each patient. He will be dearly missed but forever remembered. ■

Treatment of Asymptomatic Renal Stones: What's the Recent Evidence?

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Asymptomatic renal stones are commonly detected incidentally with more ubiquitous use of imaging in medicine today.[1] They pose an important issue that should rely on shared decision-making with the patient, weighing the morbidity of surgery with the potential for future symptomatic disease. Surgical treatment of asymptomatic stones may benefit the patient by avoiding future symptomatic progression or stone growth that may lead to emergency department (ED) visits or inconvenient need for urgent surgical intervention.[2] In some patients there can be associated anxiety and concern over potential acute progression to a symptomatic event, which would favor early surgical intervention. However, in some patients observation of asymptomatic renal stones may be favored due to low likelihood of need for future surgical intervention due to stone location or small size, patient comorbidities that increase risk of surgery, stability of stone over long period of observation, or patient preference due to asymptomatic nature.[3] Ultimately, both observation and surgical treatment are acceptable options in most cases of asymptomatic nonobstructing renal stones.[2,3] Review of the current evidence will facilitate patient counseling to make the best decision for the individual patient.

Evidence to date has largely been retrospective with small cohorts and short follow-up periods. However, recently, Sorensen et al performed a randomized controlled trial comparing the treatment of small (≤6 mm) asymptomatic stones (secondary) via ureteroscopy at the time of treatment for primary ureteral or contralateral kidney stones (N=38) vs observation (N=35) with a mean follow-up of 4.2 years.[4] This study included both ipsilateral and contralateral secondary asymptomatic stones. The primary outcome was relapse, which they characterized as stone growth on imaging (>1 mm), ED visits (trial side), or subsequent surgery of secondary stones.[4] They found that the treatment group had significantly fewer relapses (16%) compared to the control group (63%; hazard ratio 0.18; 95% confidence interval 0.07 to 0.44) over 4 years with a minimal increase in median operative time of 25.6 minutes (IQR, 18.5 to 35.2).[4] This new evidence clearly shows the benefit of treating secondary

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TREATMENT OF ASYMPTOMATIC RENAL STONES

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small asymptomatic renal stones for those already undergoing surgical intervention for primary stones that are either symptomatic or determined to be at high risk of causing a symptomatic event.

Treatment of contralateral asymptomatic stones with single-session bilateral surgery may require additional consideration. Several studies have shown the safety of single-session bilateral surgery; however, one should weigh the risks, including the potential for 2 ureteral stents, secondary procedures, increased surgical time depending on stone size, and increased risk of morbidity for more comorbid patients. Certainly, it is beneficial if the bilateral surgery can be safely done in 1 session; however, the question remains if the findings from the Sorensen et al study can be applied to larger stones.[4] They showed a minimal increase in operative time; however, the median stone size of the secondary asymptomatic stones was 3 mm in the treatment group (IQR 3-4) and 4 mm in the control group (2-4). We know that prolonged operative time is associated with increased risk of complications, and if the overall surgery time expected is greater than 90 minutes (due to overall stone size or other factors), consideration for a staged approach should be given.[5] In addition, Li et al performed a retrospective study looking at the concurrent treatment of contralateral asymptomatic renal stones (either single session or staged) and found no difference in the need for future surgical interventions at 2 years for stones ≤6 mm, suggesting that observation is also reasonable within that time frame.[6] The question then arises, how small is too small a secondary stone size to consider contralateral surgery? In other words, should we be doing bilateral surgery on the contralateral side for punctate stones? Often these can be Randall's plaques instead of treatable stones, which are difficult to distinguish on imaging.

One should also consider the high rate of residual stones after surgery; thus, surgery doesn't always rid the patient of small asymptomatic stones.[7] This is important to discuss with patients to manage expectations. Previous studies suggest that there is potentially a higher risk of adverse stone events in patients with asymptomatic residual fragments following surgery compared to those with untreated asymptomatic renal stones, since the residual fragment will likely become detached after treatment.

The last consideration is that most of the studies evaluating the treatment or observation of asymptomatic renal stones have only included traditional measurements of success, such as a reduction in ED visits, clinical progression to symptomatic disease, and need for future surgical intervention. There is value added in also including patient-reported outcome measurements such as health-related quality of life that may aid clinicians to better discuss the goals of treatment and improve the definition of success.[8]

Overall, urologists need to look to their patients for input to individualize treatment decisions through shared decision-making for asymptomatic kidney stones and use the evidence to help guide the conversation. Consider the goals of treatment and take into account patient preference to optimize quality of life, in addition to traditional stone and patient factors. It is important to discuss and set realistic patient expectations, especially in the case of the asymptomatic stone. Future work should include additional well-designed randomized controlled trials with longer follow-up periods to better define when treatment should be favored over observation and patient-reported outcome measurements in addition to traditional measurements for determination of success. The overall goal should be to maximize stone removal in a single procedure without causing additional morbidity when treatment is favored and avoiding unnecessary procedures. ■

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Posterior Tibial Nerve Stimulation for Lower Urinary Tract Dysfunction in Children

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Posterior tibial nerve stimulation (PTNS) is a third-line treatment option for overactive bladder (OAB) in adults after behavioral modifications and pharmacotherapy per the American Urological Association guideline on nonneurogenic OAB. However, it can also be used to treat children, as dysfunctional lower urinary tract symptoms (LUTS) and lower urinary tract dysfunction are prevalent in approximately 20% of otherwise healthy school-age children.[1] The United States Food and Drug Administration (FDA) approved sacral neuromodulation for OAB in 1997, followed by PTNS as a peripheral target treatment alternative in 2000. PTNS is not considered off label for use in children since no targeted age was specified at the time of approval. Current FDA-approved devices for office-based PTNS include NURO and Urgent PC. Recently, the FDA approved a novel PTNS device for adults, eCoin, that can be implanted peripherally at the posterior tibial nerve.

The exact mechanism of action of PTNS is unknown, although the practice is likely derived from ancient Chinese acupuncture. The posterior tibial nerve is a mixed peripheral sensory motor nerve that originates at the L4-S3 level of the spinal cord, which overlaps with the origin of parasympathetic nerves of the bladder (L5-S3). Similar to sacral nerve stimulation, tibial nerve simulation is hypothesized to reorganize and regulate spinal reflexes as well as provide afferent signaling to the micturition center that helps restore the balance of excitatory and inhibitory signals affecting bladder function.[2] These changes lead to downstream effects such as decreased bladder overactivity.

Office-based PTNS generally involves continuous stimulation with an external device for 30 minutes

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POSTERIOR TIBIAL NERVE STIMULATION FOR LOWER URINARY TRACT DYSFUNCTION IN CHILDREN

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Figure. Demonstration of needle placement for posterior tibial nerve stimulation session.

weekly over a 12-week treatment period in an outpatient setting. Ideally, the treatments do not occur less than 4 days or more than 10 days apart. The intensity of the stimulation varies depending on the needle's proximity to the tibial nerve. Appropriate placement is indicated by big toe flexion or a patient's subjective sensation of stimulation in the foot and toes. With traditional PTNS, a 34-gauge needle about 4 cm in length is placed about 3 cm cephalad to the medial malleolus. The transducer wire is clipped to base of the needle at the skin insertion site, and a grounding pad is placed on the arch of the same foot. The patient can lie supine or sit upright in a chair with the therapy foot elevated. A demonstration of needle placement and transducer wire setup with the stimulation device connected to the grounding pad sticker is shown in the Figure. As a less invasive alternative, transcutaneous PTNS may also be performed by placing surface electrodes on tibial nerve innervation sites.

Several prospective and retrospective studies on PTNS in children without a control group have shown promising results. These studies generally include children with a mean age of 9-12 years with persistent LUTS despite 1-2 years of behavioral modifications and pharmacotherapy. PTNS has been shown to improve or resolve a variety of LUTS including frequency and urgency in the majority of treated patients,[3] increase bladder capacity,[4] increase voided volumes, and decrease post-void residual for at least 50% of patients with dysfunctional voiding and about 30% of patients with OAB.[5] Additionally, studies of PTNS in these children have shown normalization of uroflowmetry curve in at least 40% of patients[4] and improved quality of life for both children and parents.[6] Of note, PTNS appeared to be less effective in patients with neurogenic bladder, with neurogenic bladder patients having no significant changes in symptoms or urodynamic parameters in 1 study[3] and having only 14% improvement in LUTS immediately after completing the treatment cycle compared to 78% nonneurogenic patients in another study.[5]

While there are currently no randomized controlled trials (RCTs) comparing traditional PTNS to sham treatment, RCTs comparing transcutaneous PTNS with sham treatment have conflicting results. A double-blind RCT in children with nonneurogenic OAB showed that both treatment and sham groups had improvement in urodynamic parameters, the sham group had more "very good" responses than the treatment group (66% vs 45%), and the majority of patients in both groups perceived receiving stimulation (85% in treatment group, 70% in sham group).[7] Conversely, a single-blind RCT in a similar population showed full and partial response rates (based on symptom severity) of 67% and 24%, respectively, in the treatment group, vs only 0% and 6% in the sham group.[8] A more recent single-blind RCT in children with dysfunctional voiding showed improvements in Dysfunctional Voiding and Incontinence Symptoms Score for both treatment and sham groups that were sustained at 2 years following completion of the treatment cycle, although the treatment group had a higher cure rate (50% cured and 20% improved, vs 20% cured and 40% improved).[9] Given these mixed results, a double-blind RCT comparing PTNS, transcutaneous PTNS, and sham treatment is underway.[10] A summary of studies on PTNS in children is provided in the Table.

We have been using PTNS for highly selected pediatric patients for almost 1 year now at the Children's Hospital of Philadelphia. Our selection criteria include the following: refractory OAB (ie, has tried urotherapy >6 months and has failed at least 1 antimuscarinic and/or b-3 agonist, documented voided volumes <50% expected bladder capacity) and refractory dysfunctional voiding (ie, has tried urotherapy >6 months and has failed biofeedback and/or pelvic floor physical therapy). We do not routinely obtain spinal MRI or urodynamic study in straightforward cases. Patients on antimuscarinic or β-3 agonist therapy often continue those medications during PTNS treatment. Our data have yet to mature, but preliminary results are promising and mirror improvements in symptom score seen in the literature.

> "Of note, PTNS appeared to be less effective in patients with neurogenic bladder, with neurogenic bladder patients having no significant changes in symptoms or urodynamic parameters in 1 study[3] and having only 14% improvement in LUTS immediately after completing the treatment cycle compared to 78% nonneurogenic patients in another study."

PTNS is a reasonable third-line option for children with persistent LUTS despite medications, behavioral modifications, and other nonsurgical approaches such as biofeedback. Although the magnitude of improvement is variable from study to study, PTNS appears to improve symptoms and objective voiding parameters in many children with 1 of 2 lower urinary tract dysfunction conditions: OAB

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POSTERIOR TIBIAL NERVE STIMULATION FOR LOWER URINARY TRACT DYSFUNCTION IN CHILDREN

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Table. Summary of Studies on Posterior Tibial Nerve Stimulation in Children

Study	Type	Treatment comparison	Indication for PTNS	Treatment schedule	Follow-up	Results
Hoebeke et al, 2002[4]	Prospective	PTNS only	Nonneurogenic LUTS that persisted after ≥2 y of behavioral modifications and pharmacotherapy	30 Min weekly 20 Hz Mean 10 sessions	After completion of PTNS cycle	Overall response 84% 43% of abnormal uroflows improved Mean bladder capacity increased
De Gennaro et al, 2004[3]	Prospective	PTNS only	Unresponsive LUTS after ≥2 y of behavioral modifications and pharmacotherapy	30 Min weekly 20 Hz/0-10 mA 12 wk	During and after completion of PTNS cycle	OAB: 80% improved Nonneurogenic urinary retention: 71% improved NGB: no improvement
Capitanucci et al, 2009[5]	Prospective	PTNS only	Unresponsive LUTS after 12 mo of behavioral modifications and pharmacotherapy	30 Min weekly 20 Hz/0-10 mA 12 wk	After completion of PTNS cycle, then every 6 mo for 2 y	78% Symptom improvement in nonneurogenic patients 14% Improvement in patients with NGB
De Wall et al, 2022[6]	Mixed methods/ retrospective	PTNS only	Nonneurogenic LUTD after median 1.5 y of mostly urotherapy and antimuscarinics	30 Min weekly 20 Hz/0-10 mA 12 wk	After completion of PTNS cycle	Complete response in 10%; partial response in 32% Increased average and max voided volume Improved QOL in parents and children
Lecompte et al, 2015[11]	Retrospective	Transcutaneous PTNS only	Fecal leaks ± urinary leaks despite ≥2 y of various nonoperative managements for FI, anticholinergics if needed	20 Min daily by patient at home 10 Hz/10-25 mA 6 mo	After completion of PTNS cycle	After completion of PTNS cycle
Barroso et al, 2013[12]	Prospective	PTNS vs parasacral TENS	Nonneurogenic OAB	PTNS: 30 min weekly 20 Hz/pulse width 400 µs 12 wk Parasacral TENS: 20 min 3×/wk 10 Hz, pulse width 700 µs 20 sessions total	After completion of treatment cycle	PTNS: 9% symptom resolution Parasacral TENS: 70% symptom resolution DVSS scores decreased equally in both groups
Boudaoud et al, 2015[7]	Double-blind RCT	Transcutaneous PTNS vs sham	Nonneurogenic OAB despite ≥6 consecutive mo of anticholinergic medication	30 Min twice weekly for 12 wk Treatment: 10 Hz/10 mA, pulse width 200 µs Sham: no stim	After completion of treatment cycle	Treatment group had 5 very good (45%), 1 medium (10%), 5 poor responses (45%) Sham group had 9 very good (66%), 3 poor (33%) responses
Patidar et al, 2015[8]	Single-blind RCT	Transcutaneous PTNS vs sham	Nonneurogenic OAB unresponsive to behavioral therapy and ≥6 mo of anticholinergic medication	30 Min weekly for 12 wk Treatment: 20 Hz/ 0-10 mA, pulse width 200 µs Sham: no stim	After completion of treatment cycle	Treated group: 67% full response, 24% partial response Sham group: 0% full response, 6% partial response
Jafarov et al, 2020[9]	Single-blind RCT	Transcutaneous PTNS vs sham	Nonneurogenic functional voiding disorder, discontinued medical treatment due to side effects or inefficacy, off medical treatment for ≥3 mo	30 Min weekly for 12 wk Treatment: 10-25 mA Sham: no stim	2 Wk after completion of treatment cycle, then 2 y after	Treated group: 50% cured, 20% improved, 30% no change Sham group: 20% cured, 40% improved, 40% no change Results stable at 2 y

Abbreviations: DVSS, Dysfunctional Voiding Scoring System; FI, fecal incontinence; LUTD, lower urinary tract dysfunction; LUTS, lower urinary tract symptoms; max, maximum; NGB, neurogenic bladder; OAB, overactive bladder; PTNS, percutaneous tibial nerve stimulation; QOL, quality of life; RCT, randomized controlled trial; stim, stimulation; TENS, transcutaneous electrical nerve stimulation.

and dysfunctional voiding. While transcutaneous PTNS provides a less invasive option, its efficacy compared to traditional PTNS has not been well established. Future studies to clarify the placebo effect, optimize patient selection, and explore long-term outcomes may help better define the role of PTNS for pediatric LUTS. ■

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The Outcomes and Techniques for Posterior Urethroplasty in Men Resulting From Pelvic Radiotherapy

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Urethral stenosis after radiotherapy is a complex entity with a broad scope of associated symptoms including high rates of incontinence, lower urinary tract symptoms, sexual dysfunction, subjective pain, and bowel dysfunction. This multifocal nature creates a uniquely challenging condition to treat. Compared to nonradiated posterior urethral injuries, presurgical assessment of men with postradiation urethral stenosis necessitates a more thorough evaluation. Limited bladder capacity secondary to radiation, radiation cystitis, concomitant stress urinary incontinence (SUI), and/or dystrophic calcification of the prostate fossa can negatively impact surgical candidacy. Radiated urethral stenosis can present many years after initial radiation therapy with a significant number of men at a more advanced age with potentially complex medical issues that can also hinder definitive management. Careful preoperative evaluation is paramount, as the aim is to improve quality of life following potential surgical reconstruction.

My preoperative evaluation of men with radiated urethral stenosis includes a retrograde urethrogram and voiding cystourethrogram. The retrograde urethrogram will reveal stricture length and location. The voiding cystourethrogram can be helpful to provide a basic understanding of bladder neck integrity and bladder volume/health. The bulbomembranous urethra is the most common location of stenosis following radiation therapy. A transurethral resection defect at the bladder neck and/or limited bladder capacity should prompt additional preoperative counseling to explain appropriate expectations and possibly alternative treatment options (see Figure). A detailed history and exam should focus on past urological procedures, possible prostate cancer recurrence, and patient goals for potential treatment. If the patient is an acceptable candidate, I recommend a suprapubic catheter with antegrade cystoscopy before tentative surgery. If the patient already has a suprapubic catheter, I will attempt cystoscopy via the suprapubic tract in the office. Bladder capacity, bladder tissue health, and the prostate fossa are examined. Bladder capacity <200 mL, hemorrhagic cystitis, and prostate dystrophic calcification are absolute contraindications in my experience.

Bladder capacity between 200 and 300 mL in the presence of stress incontinence is a relative contraindication in my practice, as these patients will require an artificial urinary sphincter after potentially successful urethral reconstruction. Reduced bladder compliance secondary to radiation-induced bladder fibrosis can result in reduced quality of life secondary to subjectively bothersome frequency/urgency and/or persistent stress incontinence post-artificial urinary sphincter. In my experience, adjuvant treatments to improve bladder compliance such as bladder botulinum toxin are less durable among these radiated patients. As such, I will generally recommend urinary diversion in lieu of definitive urethral reconstruction in these patients.

Postoperative stress incontinence is presumed to be secondary to radiotherapy-associated internal sphincter deficiency. We have previously published data regarding the incidence of stress incontinence among patients without preoperative stress incontinence or an endoscopic prostate procedure.[1] The incidence of de novo stress incontinence following posterior urethroplasty was 33%; however, 75% of these men with de novo SUI had extension of the radiated bulbomembranous urethral stricture into the prostate apex. The degree of stress incontinence was subjectively minimal, though, as only 17% of the affected men (5% of the total cohort) with de novo SUI required an artificial urinary sphincter. I typically wait 6 months after urethral reconstruction with confirmation of a stable urethral repair on 2 successive endoscopic procedures. Transcorporal urinary sphincter cuff placement is commonly employed to maximize success.

While endoscopic treatment is a treatment option for radiated urethral stenosis, long-term success rates of endoscopic treatments are dismal.[2] As such, urethral reconstruction via posterior anastomotic urethroplasty is preferred for definitive management. Analysis of reconstruction outcomes can be challenging because historically they are smaller series from single centers of excellence. TURNS (Trauma and Urologic Reconstructive Network of Surgeons) is a multicenter network of reconstructive surgeons across multiple academic and nonacademic centers with an effort to provide more generalizable outcomes in the field of urological reconstruction (TURNSResearch.org). We have previously published our outcomes among 137 patients with radiated urethral stenosis from 10 TURNS centers.[3] Single and dual radiation patients were included in the analysis. Overall success was 86.9%, with increasing patient age and stenosis length noted to be risk factors for recurrence on multivariate analysis. Placement of a gracilis interposition muscle flap in the surgical field was at the discretion of the physician based on operative findings (ie, large wound defect following excision of radiated urethral stricture, history of dual radiation, need for partial pubectomy during reconstruction, etc). Artificial urinary sphincter was performed in 30 subsequent men with 5 subsequent urethral erosions (16.7%). A transcorporal approach during the urinary sphincter surgery was frequently utilized (83%).

While posterior anastomotic urethroplasty via a transperineal incision is the most common surgical approach, other surgical options are also possible in select patients. Robotic transabdominal surgery combined with a possible transperineal approach is an emerging procedure for men with radiated urethral stenosis proximal to the genitourinary diaphragm.[4] The surgery begins via a robot-assisted transabdominal dissection. Transecting posterior urethroplasty is performed with concomitant prostatectomy if the prostate is present. For stenosis cephalad to a viable external sphincter, a solely robotic transabdominal approach can spare iatrogenic stress incontinence (and subsequent artificial urinary sphincter) which is expected following a sole transperineal approach that violates the external sphincter to achieve potential surgical success. A combined open transperineal approach can be utilized if a gap persists following excision of radiated tissue between the bladder neck and distal urethra. In men with radiated urethral stenosis in the absence of complete urethral obstruction, a ventral buccal graft supported by a gracilis interposition muscle flap is another surgical option. This approach is useful if the radiated stricture is long, precluding traditional excision and anastomosis of the impacted urethral segment. The gracilis interposition muscle flap is fixed to the ventral buccal graft and necessary to aid graft success in the radiated field.[5]

Urological complications following radiation therapy will continue to

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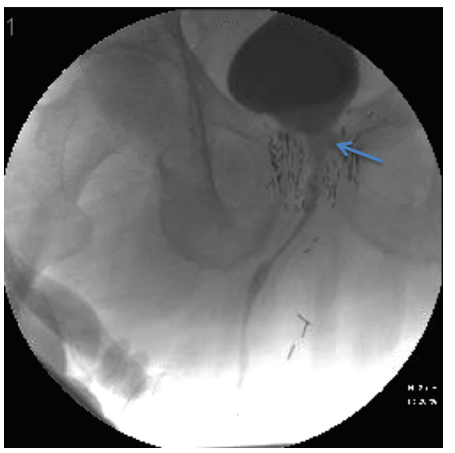

Figure. Voiding cystourethrogram of a patient with a past history of prostate cancer treated by brachytherapy. There is a visible transurethral defect (arrow) in addition to a bulbomembranous urethral stricture. Prior to his prostate cancer diagnosis, he underwent prostate Rezūm treatment. On antegrade cystoscopy, he was noted to have dystrophic calcification. Definitive open urethral reconstruction would be high risk for this patient.

THE OUTCOMES AND TECHNIQUES FOR POSTERIOR URETHROPLASTY IN MEN RESULTING

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be an issue faced by urologists; however, there are viable reconstruction options with notable success in appropriately screened patients. Referral to experienced reconstructive urologists is recommended among these complex patients. ■

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PRACTICE TIPS & TRICKS

Down the Drain: I Lost a Biopsy Sample but Gained a Valuable Lesson

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It was 1976 and I was a junior resident in urology at Baylor College of Medicine in Houston. I was assigned to a pathology rotation, where my job was to process specimens taken at surgery, dictate a gross description of each specimen, and then place them into the cassettes that would be used to make the permanent sections.

While I was transferring a prostate biopsy, it slipped from the forceps and was washed down the drain of the sink. I took the drain trap apart as I searched for the 0.5-mm × 10-mm sliver of tissue, but I could not locate it. I felt terrible and shared the news with the director of the pathology lab, who recommended that I report what had happened with the biopsy to the urological surgeon, Dr Herbert Seybold.

I called Dr Seybold and he told me to meet him in the lobby of the hospital at 4 pm. I worried what would transpire at that meeting. I even imagined that I would be reported to the program chairman and might be asked to leave the program.

Dr Seybold was in the lobby promptly at 4 pm, and together we walked to the business office. He asked for the head of the department and explained what had happened. He wanted to repeat the procedure the following day and asked not to charge the patient for the extra day in the hospital or for the second operating room procedure as this was a problem caused by the hospital and was not the patient's fault.

We then went to the operating room and met with the head of anesthesiology and asked if the department would not bill the patient for the anesthesia for the second procedure. The anesthesiologist was very sympathetic, and he agreed to waive the additional fee.

Then we went to the patient's bedside to inform the patient of the event. Dr Seybold sat down beside the patient and explained that the specimen was lost. He did not blame me but did state that the specimen was lost in the pathology lab. He told the patient that the procedure would be the first case the next day and that he would ask the lab for an expedited reading of the slide. The patient was clearly disappointed but agreed to the plan of action as presented by Dr Seybold.

Dr Seybold then took me to one of the private conference rooms and told me that what I had just witnessed was the proper way to handle a complication. He told me that all urologists can expect to have complications and that mistakes will be made. He said the best way to manage these issues is to be forthright and honest, tell the patients the truth and accept full responsibility. Patients will understand an honest mistake if the doctor is truthful. It is when urologists make excuses or falsify the facts that patients become angry, hostile, and litigious. Rarely will a patient become a problem if the urologist tells the truth.

I have passed this invaluable lesson on to medical students and residents whom I have mentored over the years. This advice worked well many years ago and it is still good advice today. I believe Dr Seybold's message will be helpful to every urologist and every physician who is confronted with a problem or a complication.

What happened to the patient? I accompanied Dr Seybold to the operating room for the second procedure, hand-carried the tissue sample to the lab, and oh-so-carefully placed it into the appropriate cassette. The final path report was benign and all 3 of us–Dr Seybold, the patient, and I–breathed a tremendous sigh of relief. ■

Have You Read?

Craig Niederberger, MD, FACS
College of Medicine and College of Engineering, University of Illinois at Chicago

Tsubouchi K, Arima H, Abe M, et al. Effect of pharmacotherapy for overactive bladder on the incidence of and factors related to urinary tract infection: a systematic review and meta-analysis. *J Urol*. 2023;209(4):665-674.

Special thanks to Drs Ahmad Hefnawy and Omer Acar at the University of Illinois at Chicago.

With about 50 million people affected worldwide, overactive bladder is a highly prevalent clinical condition. Its management generally follows a stepwise approach in which medications such as antimuscarinics and Beta 3 agonists play important roles. Urinary tract infections have not been particularly evaluated as an adverse effect of these medications. This study was performed to better understand the relationship between antimuscarinics, Beta 3 agonists, and the development of urinary tract infections.

This meta-analysis included 33 studies with more than 35,000 patients. It was found that antimuscarinics increased the primary end point of urinary tract infections with a relative risk of 1.23 compared to placebo and also increased the risk of secondary end points including urinary retention, dysuria, or increased residual urine volume with a relative risk of 2.88 compared to placebo. Beta 3 agonists did not significantly increase the risk of either end point.

This study highlights clinically relevant differences between classes of drugs that are commonly used in the management of overactive bladder. It does have some limitations such as the heterogenous patient populations among the included studies, lack of information regarding infection severity, and that there were no direct head-to-head comparison studies between antimuscarinics and Beta 3 agonists.

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HAVE YOU READ?

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Nevertheless, it provides valuable insights to take into consideration while planning pharmacotherapy in patients with overactive bladder.

Couture F, Hadj-Mimoune S, Michael S, Podasca TB, Noël-Lamy M, Richard PO. Evolution of Bosniak IIF renal cysts and impact of the 2019 Bosniak classification. *J Urol.* 2023;209(4):694-700.

Special thanks to Drs Jason Huang and Mahmoud Mima at the University of Illinois at Chicago.

Renal cysts are one of the most common radiographic "incidentalomas" encountered by the urologist. The 2019 revised Bosniak IIF classification system was meant to reduce overdiagnosis and decrease follow-up and treatment of benign cysts. But how has this updated classification affected cysts diagnosed based on the 2005 classification system?

The authors sought to answer that question with a retrospective study at their institution in Quebec. They evaluated imaging characteristics and medical charts of 181 patients with Bosniak IIF cysts diagnosed between 2000 and 2018. Applying the 2019 criteria, 76% of these would have been downgraded to Bosniak II cysts initially, and only 1 of these progressed to a Bosniak IV cyst, a rate of 2.2%. Of the true Bosniak IIF cysts, 3 progressed during the median follow-up period of approximately 4 years, a rate of 7.0% progression.

Although these are retrospective data on a relatively modest cohort, this study provides helpful data validating the modern Bosniak IIF classification. A low but significant number of cysts may progress, but active surveillance remains a safe management option for patients.

Benidir T, Austhof E, Ward RD, et al. Impact of prostate urethral lift device on prostate magnetic resonance image quality. *J Urol.* 2023;209(4):752-761.

Special thanks to Drs Andrew Lai and Simone Crivellaro at the University of Illinois at Chicago.

New technology and innovation have continued to allow us to offer minimally invasive options to treat our bread and butter urological conditions. This study cautions us for when 2 new technologies interact in practice. We have seen the rise of prostatic urethral lift devices to treat benign prostatic enlargement in patients wishing to reduce the risk of retrograde ejaculation, and we have also seen the rise of prostatic magnetic resonance images in the early workup for prostate cancer. These authors observed that the presence of the urethral lift clips negatively affects image quality of the prostate, particularly in the mid-basal transition zone. It also impacts the diffusion-weighted images in one-third of the images studied. While this case series was only derived from a single institution, we as urologists should counsel our patients on the possible impact of prostate cancer detection for patients considering a urethral lift procedure. ■

FROM THE AUA EDUCATION COUNCIL

Educational Resources for Residents and Residency Training Programs

Jay D. Raman, MD, FACS, FRCS (Glas)
Chair, AUA Office of Education

"If opportunity doesn't knock, build a door."

–Milton Berle

The Office of Education for the AUA is committed to providing the most opportunities and options to help urology residents and residency programs. Research is the basis of our action. We survey our members including residents to understand your needs and concerns, but also reach out to residency programs to ensure that we are strong partners and understand their environment, resources, and systems. The AUA and the Society of Academic Urologists also work together to align new initiatives and ensure that our collective efforts are complementary and not competitive.

The AUA's residency education options are strong and growing. Here is our recommended list of action items to help residents take the maximum advantage of educational resources:

1) **Join the AUA** for the incredible amount of member benefits, especially around education.
2) **Download the AUA*University* app.** This member-benefit app allows you to search across all of AUA's clinical library of content including AUA Guidelines, *The Journal of Urology*®, the surgical video library, the AUA Update Series, and the Core Curriculum. The AUA Core Curriculum, in particular, continues to be the cornerstone of residency education from the AUA. This content is reviewed annually and includes teaching videos and PowerPoint presentations.
3) **Subscribe to the AUA*University* podcast and YouTube channel.** These free resources are available to all and provide an easily accessible way to stay current on clinical discussions.
4) **Participate in AUA's Annual Meeting.** The AUA Annual Meeting is an experience. As a resident, come see the leaders and experts in the field present at the plenary and courses. Learn directly from those who are changing urological practice. Take advantage of the networking and social events to meet new colleagues and seek out mentors. The AUA2023 Annual Meeting offered over 490 hours of education. If you were not able to join all of those sessions, the virtual program is available to Annual Meeting registrants until August 31, 2023.
5) **Subscribe to the SASP (Self-assessment Study Program) and the AUA Update Series.** These tried and true resources continue to support residents' needs. If you were not aware, the SASP app provides a feature that allows residency program directors to assign a deck of questions to a resident and for the resident to send back their answers. This tool was designed to help support specific areas of educational need.
6) **Participate in the brand new AUA Intern Academy.** The AUA Intern Academy is a new initiative created specifically to meet the needs of early-career urology residents (primarily postgraduate year 1) and will include both in-person Hands-on Skills Training (June 10-11) and virtual components (July-September). The aim of this new program is to apply standardized and foundational urological skills to the first year of residency practice in order to improve clinical proficiency and promote patient safety. For more information or to register, go to AUA*University* (https://auau.auanet.org).
7) **Subscribe to the brand new AUA Leadership and Business podcast.** This new podcast launched in January 2023 and focuses on content to help residents transition into practice and for all urologists to be successful leaders and managers.

The AUA Office of Education truly understands the reality of limited resources and time and is working on new ways to offer Residency Programs these resources with discounts and in an efficient way to reduce administrative burdens.

If you have any questions or recommendations, please email education@auanet.org. We welcome an open dialogue with our members. ■

FROM THE AUA RESEARCH COUNCIL

Expanding the Global Reach of AUA Urological Research Support

Steven Kaplan, MD, FACS
Chair, AUA Office of Research

The American Urological Association (AUA) Office of Research offers a large array of opportunities for urological researchers, particularly early career researchers. We administer 7 distinct grant programs that support the research experiences of medical students, postdoctoral fellows, residents, and faculty to further develop the pipeline of urological researchers at a time when this type of research is underfunded and underemphasized. We offer mentoring support through our Urology Scientific Mentoring and Training (USMART) Academy and Early Career Investigator Workshop (ECIW) to help early career researchers gain the skills and confidence they need to compete for research funding. Our research education offerings include in-person and online courses on grant writing, building your own research laboratory, practicing independent research, and identifying research challenges specific to urology. In addition, we kicked off the inaugural Innovation Nexus, the research incubator powered by the AUA, in April 2023 to showcase the next generation of urology innovators and facilitate future urological discovery.

Although we offer a wide range of research support programs, many of these programs are limited to AUA members within sections and do not fully include international urology researchers. To address this gap, we have 2 grant mechanisms open to international applicants, specific Early Career Investigator Showcase opportunities for international researchers, online courses open to all members and nonmembers, and a strong emphasis on international participation within the Innovation Nexus program. These efforts are a good start, but the AUA Research Council has identified a clear need to further engage international stakeholders as a strategic goal through 2025. International urology researchers often face additional challenges due to resource constraints, lack of research infrastructure, varying health care systems, workforce shortages, and technology limitations. We recognize the need to improve our global reach in supporting the unique needs of urological researchers across the world with AUA-sponsored research education, grants, and investigator support.

In early 2023, we created the International Research Work Group. The mission of the work group is to determine the needs of international urology researchers and guide the enhancement of AUA Office of Research education opportunities for these researchers, as well as to attract more international grant applications for AUA awards. Work group members were first nominated by international societies via a request from the AUA International Membership Committee. Nominees were required to have a strong track record of urological research and an interest in increasing urological discovery and innovation, collaborating with the AUA and with urological researchers from around the world and improving AUA offerings to the international research community. A total of 37 researchers were nominated from 16 countries. The AUA Office of Research and International Programs staff reviewed the nominations and made selections based on research experience, country and region, specialty area, career stage, and committee diversity. The selected work group members represent all AUA regions and 11 different countries. We would like to congratulate the following individuals on their appointments to the AUA International Research Work Group (see Table).

Table. AUA International Research Work Group

Luciano Nunez Bragayrac, MD	Peru
Eric Chung, FRACS, MBBS	Australia
Sudip Das Gupta, MS, MBBS	Bangladesh
Fawzy Farag, MD, PhD	Egypt
Yasser Farahat, MD, PhD, FEBU, FRCS (Urol)	United Arab Emirates
Rodrigo García-Baquero, MD, PhD	Spain
Claudia Kesch, PD Dr. med.	Germany
Vaibhav Modgil, MD, MSc, BM	United Kingdom
Nicola Pavan, MD, FEBU	Italy
Shinichi Sakamoto, MD, PhD	Japan
Hegel Trujillo-Santamaria, MD	Mexico

AUA Secretary Dr John Denstedt; AUA Secretary-elect Dr David Penson; and AUA Assistant Secretaries Dr Aseem Shukla, Dr Jorge Gutierrez-Aceves, and Dr Jose Karam also will advise the work group. We will augment the work group with several additional members in the coming weeks to maximize global representation.

The International Research Work Group held its initial meeting in February 2023. The first task for this group will be to create and distribute an International Urology Researcher Needs Assessment survey to determine how the AUA can best support international researchers in engaging in current or newly created AUA and Urology Care Foundation research programs. The working group will meet monthly via video conference over the course of the next year to create the survey, analyze the results, and make recommendations to the AUA to fill gaps in community needs. Using this information, the work group will make a series of recommendations for improving and enhancing Office of Research programs and then work with the Research Council to implement these recommendations.

“In early 2023, we created the International Research Work Group. The mission of the work group is to determine the needs of international urology researchers and guide the enhancement of AUA Office of Research education opportunities for these researchers, as well as to attract more international grant applications for AUA awards.”

The AUA Office of Research is committed to expanding the global reach of our research education, grants, and support programs. Whether through additional online offerings, adaptation of current course content, new or modified grant mechanisms, or additional mentoring services, we will strive to meet the needs of international urology researchers and increase their engagement with the AUA. The need for global health research has never been greater. It is time to reduce international barriers to working together as we improve urological care and discovery. Please join us in these efforts and, as always, feel free to reach out to me personally at Steven.Kaplan@mountsinai.org or tweet at @MaleHealthDoc. ■

FROM THE RESIDENTS & FELLOWS COMMITTEE

The Role of Artificial Intelligence in Urological Practice

Tina Lulla, MD
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Artificial Intelligence (AI) refers to the ability of a machine to independently replicate intellectual processes typical of human cognition. The use of AI across fields, including medicine, continues to grow as this technology becomes more ubiquitous.

> "The application of AI capabilities within the context of medical imaging is known as radiomics. Images can be analyzed for features, including shape, texture, intensity; these data then can be analyzed and associated with a clinical outcome."

By 2025, the growth rate of AI applications in health care is expected to be 24.5%.[1] The application of AI in urology ranges from diagnostic and prognostic roles to applications in surgical education and treatments. AI provides more accuracy and can aid in clinical decision-making and, therefore, will likely be an integral part of the health care system moving forward.[2]

The application of AI capabilities within the context of medical imaging is known as radiomics. Images can be analyzed for features, including shape, texture, intensity; these data then can be analyzed and associated with a clinical outcome. Within urological oncology, this analysis is applied to aid in cancer diagnosis. A study comparing a radiomics model interpretation of prostate MRI and that of radiologists showed that the radiomics model was able to outperform radiologists in diagnosing prostate cancer using the Prostate Imaging Reporting & Data System.[3] In practice, we also can use machine learning to automatically segment transrectal ultrasound images of the prostate to aid in such procedures as fusion biopsies with smaller margins of error than when manually segmented.[4] Imaging also can be analyzed for prognosis. For example, in urolithiasis, AI technology can predict stone composition and potential stone passage, enabling urologists to make informed decisions regarding medical expulsive therapy vs surgical intervention.[2] Along the same lines, researchers can use AI analysis to predict patients who may have early biochemical recurrence after prostatectomy, allowing appropriate treatment plans to be formulated to improve outcomes and quality of life.[5]

For surgical education and training, AI can be used to provide in-depth analysis of robotic surgery and assist in these surgeries. Machine learning can analyze data from the da Vinci Surgical System, including instrument kinetic data, motion tracking, and systems event data (ie, camera movement or energy usage) in conjunction with the surgical video itself and report metrics associated with surgical efficiency.[6] Comparing these metrics between expert and novice surgeons shows differences between the 2 groups and can provide further guidance and feedback to trainees during robotic cases. Trainees will be able to reflect on this information to better track their performance on specific steps, as well as the overall surgery. As more work in this field is completed, it may help to standardize robotic training across institutions.

In conclusion, AI is transforming the field of urology and enabling urologists to provide more accurate diagnoses, personalized treatment plans, and innovated surgical technique. This will ultimately lead to improved health care costs and patient outcomes by avoiding unnecessary tests and procedures and focusing on more targeted treatments. As the technology continues to advance and become widely available, it will change the way urologists practice and train across the country. As a junior trainee, it is an exciting opportunity to see this technology become implemented and how our current practice techniques continue to be modified and improved. ■

> "In conclusion, AI is transforming the field of urology and enabling urologists to provide more accurate diagnoses, personalized treatment plans, and innovated surgical technique."

Since its inception in 2002, the Residents and Fellows Committee has represented the voice of trainee members of the AUA. The Committee's mission is to address the educational and professional needs of urology residents and fellows and promote engagement between residents and fellows and the AUA. The Committee welcomes your input and feedback! To contact the Committee, or to inquire about ways to get more involved, please email rescommittee@AUAnet.org.

> "For surgical education and training, AI can be used to provide in-depth analysis of robotic surgery and assist in these surgeries."

1. Grand View Research. *Healthcare Predictive Analytics Market Analysis by Application (Operations Management, Financial, Population Health, Clinical), By End-Use (Payers, Providers), By Region (North America, Europe, Asia Pacific, Latin America, MEA) and Segment Forecasts, 2018–2025.* 2016. https://www.grandviewresearch.com/industry-analysis/healthcare-predictive-analytics-market.
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JU INSIGHT

Extended Lymph Node Sampling During Surgery for Pediatric Renal Tumors and Postoperative Complication Rates

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Walker JP, Han DS, Nicklawsky A, et al. Extended lymph node sampling during surgery for pediatric renal tumors concerning for malignancy does not increase postoperative complication rates. *J Urol.* 2023;209(6): 1186-1193.

Study Need and Importance

Lymph node sampling (LNS) is a requirement during the removal of a suspected malignant renal mass in children, but no standardized LNS template exists. Unfortunately, LNS is often omitted or low yield, which can impact staging accuracy and treatment paradigms. Suggestions to formalize an LNS template during the surgery for pediatric renal tumors in order to increase protocol compliance and lymph node yield (LNY) have been met with concerns over also increasing the likelihood of having a surgical complication.

We hypothesized that higher LNY would not be associated with an increase in clinically significant complications. Our aim was to demonstrate the safety of a more extensive LNS during extirpative renal tumor surgery in the pediatric population.

What We Found

At our institution, in patients 0-18 years old undergoing surgery with LNS for a suspected renal malignancy, major postoperative complications were rare (15%) and there was no relationship between LNY and clinically significant complications 5 months postoperatively ($P = .6$; see Table and Figure).

Limitations

This study was retrospective in nature and may have suffered from incomplete data and/or loss to follow-up. We believe those limitations were minimized due to the geographically isolated position of our institution, which should make it less likely that patients would seek care at other facilities, especially for major complications. Since our data were collected from a single, high-volume institution, the results may not be generalizable to smaller-volume centers.

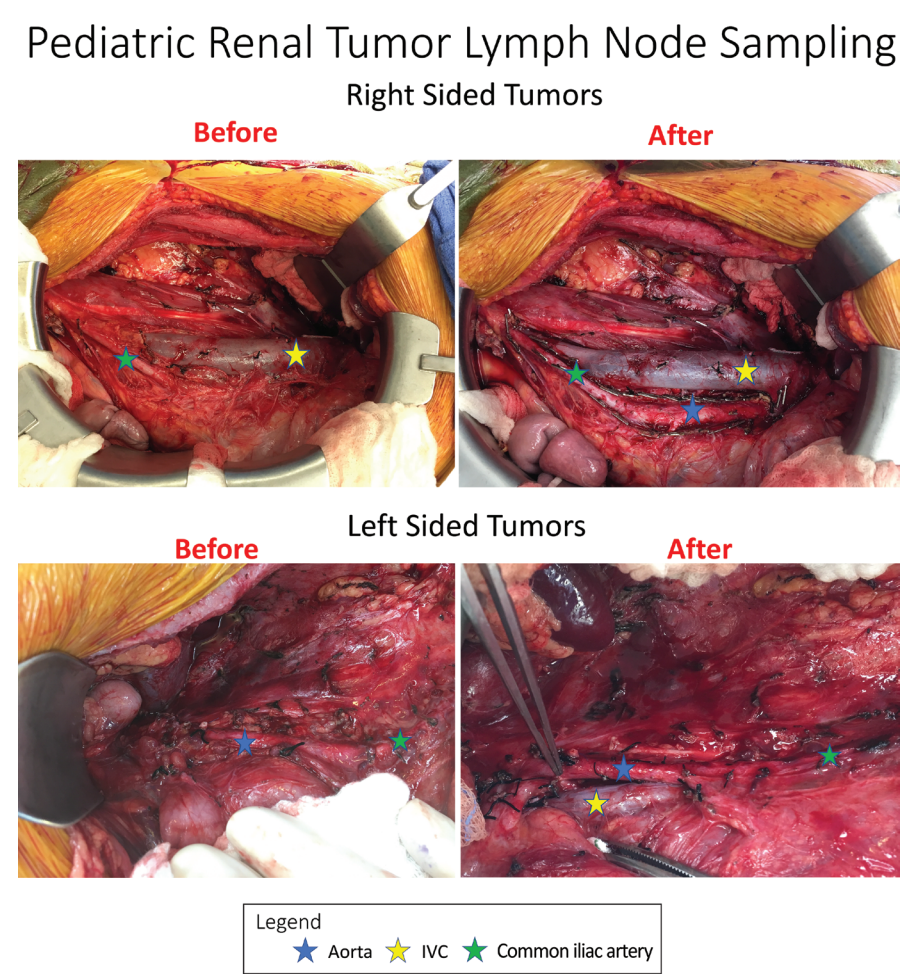

Figure. Example of lymph node sampling templates for right- and left-sided pediatric renal tumors. Right, peri-hilar, para-caval, and interaortocaval lymph node packets. Left, peri-hilar, para-aortic, and interaortocaval lymph node packets. Blue star indicates aorta; yellow star, IVC; green star, common iliac artery.

Table. Multivariable Logistic Regression Model of Select Variables on Clinically Significant Surgical Complications

Parameter	Odds ratio (95% CI)	*P* value
No. LNs (continuous)	0.98 (0.93, 1.04)	.6
Intraoperative fluid volume, cc	1.00 (1.00, 1.00)	.01

Abbreviations: CI, confidence interval; LN, lymph node.

Interpretation for Patient Care

We hope that our results will encourage more research into the use of a standardized LNS template and its effect on protocol adherence, staging accuracy, LNY, and event-free and overall survival in pediatric patients with malignant renal tumors. ■

JU INSIGHT

Long-term Urological Outcomes in Pelvic Genitourinary Rhabdomyosarcoma: A 48-Year Single-center Experience

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**Posthumous Acknowledgments: The authors would like to express their endless gratitude for the many decades of mentorship, support, and teaching from Dr Alan B. Retik (1932-2022), who over the course of his long career served as Urologist-in-Chief, Surgeon-in-Chief, and Emeritus Urologist-in-Chief at Boston Children's Hospital. The immense impact Dr Retik had on his patients, trainees, and the field of urology cannot be overstated.*

Wang H-HS, Zhang TR, Ramakrishnan VM, Valovska MT, Retik AB, Lee RS. Long-term urological outcomes in pelvic genitourinary rhabdomyosarcoma: a 48-year single-center experience. *J Urol.* 2023;209(6):1202-1209.

Study Need and Importance

Rhabdomyosarcoma (RMS) is a rare pediatric soft tissue sarcoma affecting the genitourinary (GU) system in 15%-20% of cases. Although multimodal therapy with chemotherapy, radiation, and surgery has improved survival rates, morbidity is high. Yet, there are few long-term data on urinary and sexual function and quality of life.

What We Found

From 1970-2018, 51 patients at our institution were treated for GU RMS of the bladder, prostate, pelvis, vagina, and uterus with a median follow-up of 21 years. Twenty-six patients (51%) underwent up-front radical surgery (eg, cystoprostatectomy, pelvic exenteration) with staged continence mechanism creation (n=17). These patients had higher rates of continence (96.2% vs 58.3%, $P = .003$) compared to the 12 who initially underwent organ-sparing surgery (eg, partial cystectomy); other outcomes were comparable between the 2 groups (see Table). One-third (n=4) of organ-spared patients required additional major corrective surgery. In survey results from the AUA Symptom Score, International Index of Erectile Function, and Female Sexual Function Index, urinary complaints were mild, but both male and female patients reported significant sexual dysfunction.

Table. Postoperative Outcomes in Patients Managed With Radical vs Organ-sparing Surgery

Complication	Radical (n=26) No. (%)	Organ sparing (n=12) No. (%)	*P* value
Urolithiasis	10 (38.5)	2 (16.7)	.18
Recurrent UTI or pyelonephritis	7 (26.9)	3 (25.0)	.9
Urinary incontinence	1 (3.8)	5 (41.7)	.003
Stricture	5 (19.2)	1 (8.3)	.39
Fistula	2 (7.7)	0 (0)	.32

Abbreviation: UTI, urinary tract infection.

Limitations

Although this work represents one of the largest RMS populations reported, our cohort is relatively small and limited to a single-center retrospective analysis. The group is also heterogeneous, encompassing multiple types of GU RMS. We were not able to present oncologic outcomes given limitations in data collection. Finally, survey results were patient reported and subject to bias.

Interpretation for Patient Care

Although current Children's Oncology Group protocols emphasize multimodal therapy with bladder conservation in GU RMS, our institutional experience in up-front radical surgery has demonstrated comparable or even favorable urological outcomes. Radical surgery should remain an option for appropriately selected patients. Regardless of treatment strategy, nearly all patients reported very poor sexual function. ■

JU INSIGHT

Characterization of Stone Events in Patients With Type 3 Primary Hyperoxaluria

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Arnous MG, Vaughan L, Mehta RA, Schulte PJ, Lieske JC, Milliner DS. Characterization of stone events in patients with type 3 primary hyperoxaluria. *J Urol.* 2023;209(6):1141-1150.

Study Need and Importance

Primary hyperoxaluria type 3 (PH3) is a rare genetic disorder that

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CHARACTERIZATION OF STONE EVENTS IN PATIENTS

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> "Calcium oxalate supersaturation was associated with an increased rate of lifetime stone events, even after adjusting for age at first event."

typically results in frequently recurring symptomatic kidney stone events and possible kidney damage. However, the factors affecting stone formation and risk for kidney function loss in PH3 patients remain unclear. In this study, we investigated urine parameters associated with symptomatic stones in PH3 patients and their correlation with disease outcomes in the Rare Kidney Stone Consortium Primary Hyperoxaluria Registry.

What We Found

We found that more than 90% of the PH3 patients developed kidney stones, with a high number of symptomatic stone events throughout their lifetimes (see Figure). Calcium oxalate supersaturation was associated with an increased rate of lifetime stone events, even after adjusting for age at first event. By the fourth decade of life, PH3 patients had a lower estimated glomerular filtration rate compared to the general population.

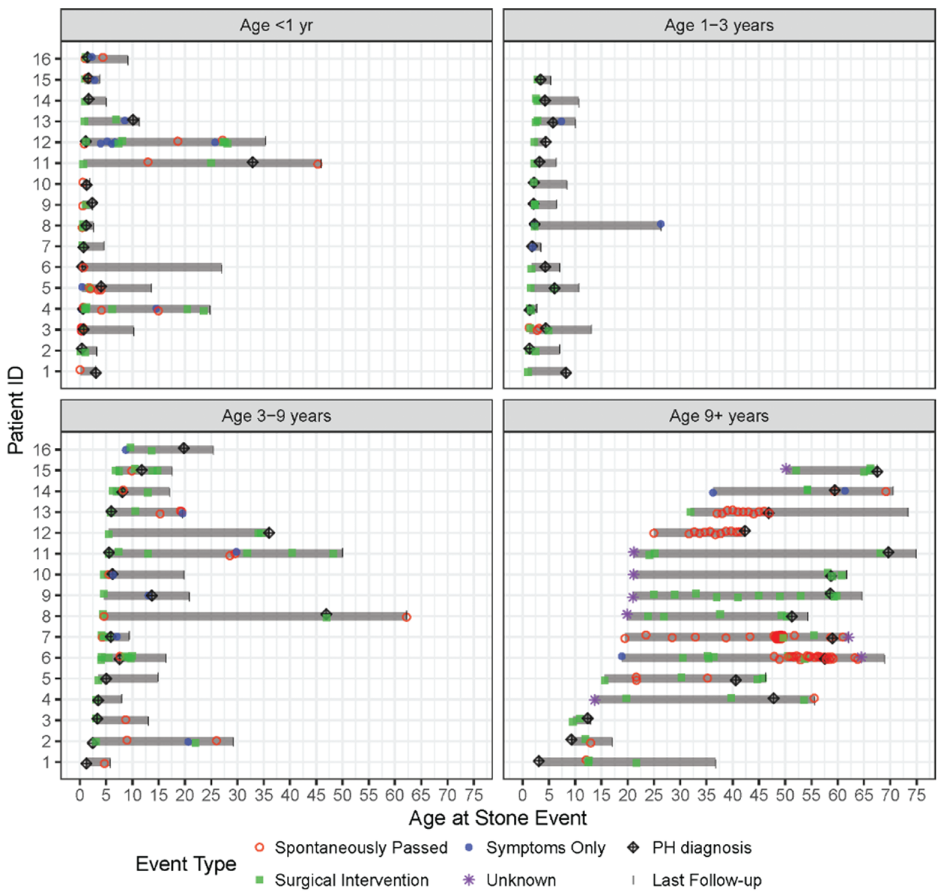

Figure. Patient trajectories by age at each stone event, stratified by age at the first stone event quartile, among patients with at least 1 stone event (N=62). Patients are ordered by age at their first stone event. Stone event types are distinguished by shape and color, as well as age at primary hyperoxaluria (PH) diagnosis and age at the last follow-up.

Limitations

Due to the rarity of the disease, the relative recent discovery of the causative gene, and the lack of universal and affordable genetic testing, a relatively small number of patients and length of follow-up for study are possible limitations of our study.

Interpretation for Patient Care

Our results suggest that earlier genetic testing for patients with typical symptoms or a family history of PH3 is crucial in order to initiate available dietary and pharmacological treatments. There remains an urgent need for more effective therapeutic agents to reduce urinary oxalate excretion and number of stone events, and to prevent kidney damage over the lifetime of affected patients. Our evidence suggests urinary calcium oxalate supersaturation may be a promising shorter-term biomarker to judge treatment effect. Our study provides important insights into the stone disease burden of PH3 patients and highlights the need for further research in this area. ■

JU INSIGHT

Ureteral Stent Placement, Emergency Department Visits, and Opioid Prescriptions Among Youth

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Tasian GE, Maltenfort MG, Rove K, et al. Ureteral stent placement prior to definitive stone treatment is associated with higher postoperative emergency department visits and opioid prescriptions for youth having ureteroscopy or shock wave lithotripsy. *J Urol.* 2023;209(6): 1194-1201.

Study Need and Importance

Ureteral stents cause pain and urinary symptoms for most patients; however, the impact of ureteral stents among pediatric patients undergoing kidney stone surgery is poorly understood. We determined the association between ureteral stents and emergency department (ED) visits and opioid prescriptions for youth having ureteroscopy or shock wave lithotripsy (SWL) to improve the evidence base that informs clinical decision-making for the rapidly growing population of patients with early-onset kidney stone disease.

What We Found

In a retrospective cohort study conducted at 6 pediatric health systems that participate in PEDSnet, a clinical research network that aggregates electronic health data, we found that ureteral stents placed before or concurrent with ureteroscopy or SWL were

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URETERAL STENT PLACEMENT, EMERGENCY DEPARTMENT VISITS, AND OPIOID PRESCRIPTIONS AMONG YOUTH

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Table. Adjusted Incidence Rate Ratios for Patients Having Primary Stent Placement Compared to Patients Not Having Stent Placement

	Incidence rate ratio for primary stent	95% CI	*P* value
Emergency department visits			
Shock wave lithotripsy and ureteroscopy	1.33	1.02-1.73	.04
Shock wave lithotripsy only	2.29	1.10-4.75	.03
Ureteroscopy only	1.24	0.94-1.64	.12
Opioid prescriptions			
Shock wave lithotripsy and ureteroscopy	1.30	1.10-1.53	.00
Shock wave lithotripsy only	2.06	1.07-3.98	.03
Ureteroscopy only	1.26	1.07-1.49	.006

Abbreviation: CI, confidence interval.
Multivariable Poisson models were adjusted for Pediatric Medical Complexity Algorithm level, surgery during the pandemic, sex, race/ethnicity, PEDSnet site, distance from site, and stone location.

associated with a 33% higher rate of ED visits and a 30% higher rate of opioid prescriptions within 120 days of the index procedure (see Table). These associations were driven by stents placed before definitive surgery and were higher in magnitude for SWL. Our results strengthen the evidence for the AUA and Endourological Society guidelines, which currently are supported only by expert opinion, to recommend against routine "pre-stenting."

Limitations

Limitations introduced by the retrospective observational design include selection bias, unmeasured confounding, and lack of clinically important information such as surgical indications, infection, or whether the stent was left on a string.

Interpretation for Patient Care

These results suggest that performing definitive surgery, when possible, rather than "pre-stenting" could reduce the number of pediatric patients who receive stents and reduce postoperative ED visits and opioid prescriptions. To this end, studies are needed to identify situations for which stents could safely be omitted. ■

> "Our results strengthen the evidence for the AUA and Endourological Society guidelines, which currently are supported only by expert opinion, to recommend against routine 'pre-stenting.'"

JU INSIGHT

Clinically Important Differences for Pain and Urinary Symptoms in Urological Chronic Pelvic Pain Syndrome

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Stephens-Shields AJ, Lai HH, Landis JR, et al. Clinically important differences for pain and urinary symptoms in urological chronic pelvic pain syndrome: a MAPP network study. *J Urol.* 2023;209(6):1132-1140.

Study Need and Importance

Phenotypic heterogeneity in individuals with interstitial cystitis/bladder pain syndrome and chronic prostatitis/chronic pelvic pain syndrome, collectively termed urological chronic pelvic pain syndromes, has led to challenges in selecting primary end points in therapeutic trials. Clinically important differences (CIDs) are defined as magnitudes of change in symptoms that patients perceive as meaningful. Using longitudinal data from the MAPP (Multidisciplinary Approach to the Study of Chronic Pelvic Pain) Research Network, we determined CIDs for the pelvic pain severity (PPS) index and the urinary symptom severity (USS) index, 2 novel symptom measures. We derive CIDs using absolute and percent change and evaluate differences in CIDs across phenotypic subgroups, including sex-diagnosis, presence or absence of Hunner lesions, and widespread or localized pain.

What We Found

Among all participants an absolute reduction of 6.8 in the 28-point PPS and 3.5 in the 25-point USS was meaningful based on regression methodology; this increased to a

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CLINICALLY IMPORTANT DIFFERENCES FOR PAIN

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reduction of 8.7 in PPS among participants with moderate to severe pelvic pain at baseline. Participants with Hunner lesions or a likely neuropathic phenotype required larger absolute decreases in PPS to feel improved (see Figure). Females required larger reductions in USS than males to feel improved, regardless of diagnosis. Percent change CID ranged from 30% to 50% and was more consistent across phenotypic subgroups than absolute change.

Limitations

This study used a single Global Responses Assessment (GRA) as the anchor to determine CIDs for pain and urinary symptoms, with lower correlation between the GRA and USS than the GRA and PPS.

Interpretation for Patient Care

CIDs in pain and urinary measures differ according to phenotypic characteristics. Percent change in improvement or worsening of symptoms, which was more consistent across phenotypic subgroups, is a viable approach for assessing outcomes in clinical management and future therapeutic trials. ■

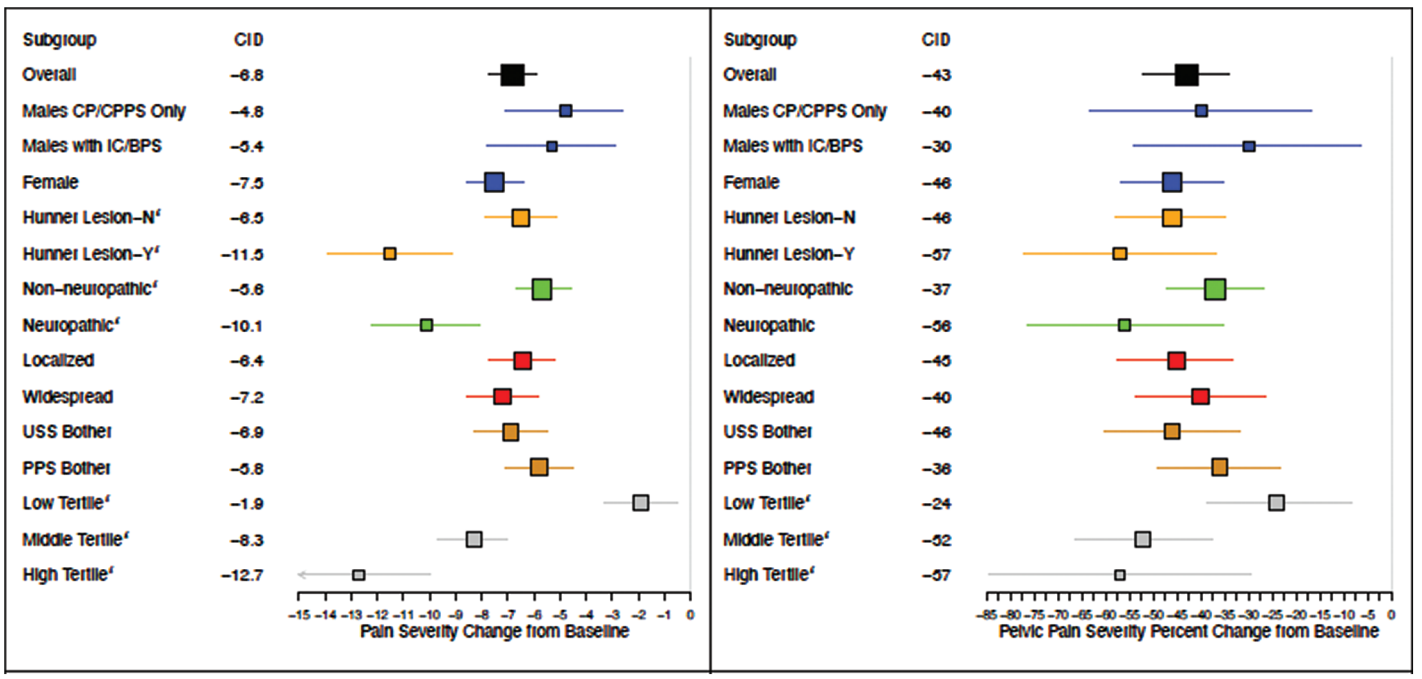

Figure. Estimates of absolute (left) and percent (right) clinically important differences for pelvic pain severity (PPS). Marker size is proportional to sample size; whiskers represent pointwise 95% confidence intervals. CID indicates clinically important differences; CP/CPPS, chronic prostatitis/chronic pelvic pain syndrome; IC/BPS, interstitial cystitis/bladder pain syndrome; N, no; USS, urinary symptom severity; Y, yes.

JU INSIGHT

Impact of Expanded Definition of Family History on Active Surveillance Outcomes for Prostate Cancer

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Schneider AC, Chandrasekar T, Bowler N, et al. Impact of an expanded definition of family history on outcomes of active surveillance for prostate cancer. *J Urol.* 2023;209(6):1112-1119.

Study Need and Importance

A family history (FH) of prostate cancer (PC) is a well-established risk factor for the development of PC, but an FH including other malignancies suggestive of a hereditary cancer syndrome (HCS; eg, breast, ovarian, and pancreatic cancer) is increasingly recognized as a risk factor as well. The role of a broader definition of FH as a risk factor for patients on active surveillance (AS) for PC has not been investigated. Here, we evaluate the impact of an expanded definition of FH on AS outcomes under the hypothesis that patients at high genetic risk based on their FH are at increased risk of disease progression.

What We Found

Using a novel scoring metric to capture multigeneration FH data among the 855 evaluable patients in our AS cohort, we found that patients with an FH suggestive of HCS (but not those with FH of PC alone) have an increased hazard of biopsy progression (see Figure) and progression to treatment on AS, compared to patients with-

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IMPACT OF EXPANDED DEFINITION OF FAMILY HISTORY

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> "Patients with an FH suggestive of HCS can still be safely offered AS but should be counseled about the higher risk of biopsy progression. These patients warrant closer monitoring compared to patients without a strong FH."

out such FH. However, the subset of patients with an FH suggestive of HCS who underwent delayed treatment after a period of AS did not experience higher rates of adverse pathology at prostatectomy or biochemical recurrence.

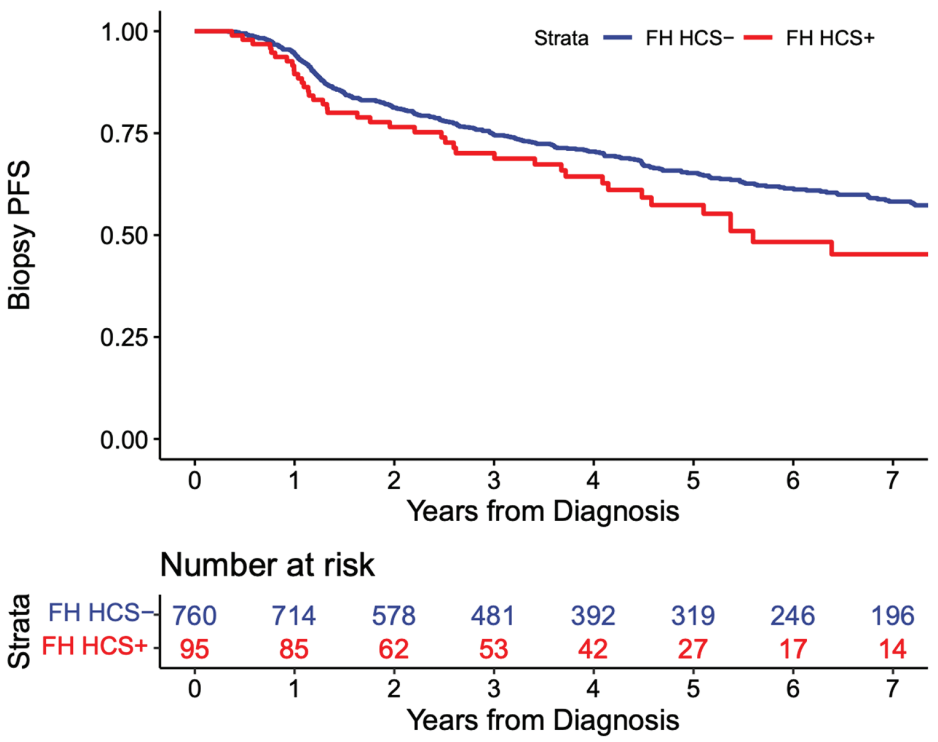

Figure. Kaplan-Meier curve of biopsy progression-free survival (PFS) for patients with vs without a strong family history (FH) suggestive of a hereditary cancer syndrome (HCS).

Limitations

Longer follow-up is required to assess late outcomes of AS. Data partially predate the introduction of MRI into our AS program. Our novel FH scoring metric also warrants validation in future studies. Furthermore, FH was not systematically obtained by a genetic counselor; therefore, differences in documenting FH could have resulted in observer bias.

Interpretation for Patient Care

Patients with an FH suggestive of HCS can still be safely offered AS but should be counseled about the higher risk of biopsy progression. These patients warrant closer monitoring compared to patients without a strong FH. Our data support the wider inclusion of an expanded definition of FH in counseling patients considering AS. ■

JU INSIGHT

Mini-percutaneous Nephrolithotomy or Flexible Ureteroscopic Lithotripsy for 1- to 2-cm Renal Stones

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Dutta R, Mithal P, Klein I, Patel M, Gutierrez-Aceves J. Outcomes and costs following mini-percutaneous nephrolithotomy or flexible ureteroscopic lithotripsy for 1- to 2-cm renal stones: data from a prospective, randomized clinical trial. *J Urol.* 2023;209(6):1151-1158.

Study Need and Importance

Both mini-percutaneous nephrolithotomy (mPCNL) and ureteroscopic lithotripsy (URS) are options for treating renal stones sized 1-2 cm. Limited direct comparisons of outcomes and procedural costs between the 2 surgical techniques exist.

What We Found

In a randomized controlled clinical trial, mPCNL with a urologist obtaining percutaneous access significantly outperformed URS in rendering patients stone-free using both 0-mm and 2-mm residual stone burden cutoffs. There were no differences in surgical time, 30-day complications, the necessity for a secondary stone procedure, or pre- to postoperative serum creatinine change. Fluoroscopy time and length of stay were both higher in the mPCNL cohort, as the authors' practice at the study time was to keep all mPCNL patients in the hospital for observation for 1 night. Although costs were higher in the mPCNL cohort, this was offset by a higher revenue, resulting in no significant change in total hospital operating margin.

Limitations

Although postoperative imaging was standardized to low-dose stone protocol computed tomography, the timing of the scan varied between groups (postoperative day 1 for mPCNL patients staying overnight and postoperative day 1-30 for URS patients). Finally, all surgery was performed by a single endourologist with expertise in both surgical techniques, limiting the generalizability of our findings given the variations in comfort and training in urologists performing stone surgery.

Interpretation for Patient Care

mPCNL is more likely to render patients stone free than flexible ureteroscopy. There are no differences, on average, in short-term complications, operating times, and operating margins between the 2 surgeries. ■

UPJ INSIGHT

International Iohexol Shortage: Alternative Contrast Agents and Imaging Procedures for the Urologist

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Lardieri G, Kennady EH, Yeaman C, Schenkman N. International iohexol shortage: alternative contrast agents and imaging procedures for the urologist. *Urol Pract.* 2023;10(3):270-277.

Study Need and Importance

The recent COVID-19–related international contrast shortage greatly affected the practice of urology, which relies heavily on contrasted imaging for diagnostic studies and procedures. Prior studies have described the use of alternative contrast agents, alternative imaging procedures, and contrast conservation strategies in urological care. We sought to perform a review of these studies and develop a resource to guide the practicing urologist in the setting of the current, and any future, iodinated contrast shortage.

What We Found

Older iodinated contrast agents such as ioxaglate and diatrizoate can replace iohexol for intravascular and intraluminal imaging in patients without renal impairment. Gadolinium-based agents such as Gadavist can also be used intraluminally for procedures and diagnostic imaging. Imaging and procedure alternatives include air contrast pyelography, contrast-enhanced ultrasound, voiding urosonography, and low tube voltage CT urography (see Table). Iohexol conservation strategies include contrast dose reduction and use of contrast management devices for vial splitting.

Table. Alternative Strategies for Intraluminal Contrast Use

Procedure	Alternative procedure	Alternative contrast media
Retrograde urethrography	MR urethrography or ultrasound (nontrauma, when clinically appropriate)	Gadolinium-based contrast or other iodinated-based contrast media
Cystography/urodynamics	Urodynamics without video cystography when clinically appropriate	Gadolinium-based contrast or other iodinated-based contrast media
Retrograde ureteropyelography		Gadolinium-based contrast or other iodinated-based contrast media
Percutaneous access of kidney	Direct visualization, ultrasound, RetroPerc	Gadolinium-based contrast, other iodinated-based contrast media, gas contrast

Abbreviation: MR, magnetic resonance.

Limitations

The review is limited to the existing literature and was not performed systematically.

Interpretation for Patient Care

The COVID-19–related contrast shortage caused significant hardship for urological care internationally, leading to delayed contrasted imaging studies and urological procedures. This review can be used by the urologist to mitigate the lasting effects of the current shortage and to prepare in the event of a future iodinated contrast shortage. ■

UPJ INSIGHT

Changes in Billing and Reimbursement for Urology Office Visits Before and After Medicare Payment Reforms

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Lee AJ, Saxton A, Hassig S, Quarrier SO, Bandari J. Changes in billing and reimbursement for urology office visits before and after Medicare payment reforms. *Urol Pract.* 2023;10(3):220-228.

Study Need and Importance

The medical system faces ongoing financial pressures from changes in reimbursement through Medicare. The impact of these Medicare reimbursement changes on urology office visit reimbursements has not been fully examined. This study aims to analyze the impact of urology office visit Medicare reimbursements from 2010-2021, with a focus on 2021 Medicare payment reforms.

What We Found

The 2021 mean visit reimbursement was $110.95, up from $99.42 in 2020 and $94.44 in 2010 (both $P < .001$). From 2010 to 2020, all Current Procedural Terminology (CPT) codes except for 99211 had a decrease in mean reimbursement. From 2020 to 2021, there was an increase in mean reimbursement for CPT codes 99205 and 99212-99215, and decreases in 99202, 99204, and 99211 ($P < .001$). New and established patient urology office visits

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CHANGES IN BILLING AND REIMBURSEMENT

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had significant migration of billing codes from 2010 to 2021 ($P < .001$). New patient visits were most commonly as 99204, which increased from 47% in 2010 to 65% in 2021 ($P < .001$). The most commonly billed established patient urology visit was 99213 until 2021 when 99214 became the most common at 46% ($P < .001$).

Limitations

These data are limited to Medicare beneficiaries and may not be generalizable of all urology patients and billing practices. Second, these findings must be taken in the context of changes in billing guidelines in 2021, and long-term trends on the new billing system cannot be examined at this time. Lastly, most recent data must take into consideration the impact of the COVID-19 pandemic on the medical system and practice patterns.

> "This study aims to analyze the impact of urology office visit Medicare reimbursements from 2010-2021, with a focus on 2021 Medicare payment reforms."

Interpretation for Patient Care

Urologists have seen increases in mean real reimbursements for office visits both before and after 2021 Medicare payment reform. Contributing factors consisted of increased established patient visit reimbursements, decreased new patient visit reimbursements, and generally higher levels of CPT code billings. Practice patterns may have also changed, with urologists billing for more time per patient visit in the office. ■

UPJ INSIGHT

Outcome Measures and Inclusion/Exclusion Criteria in Benign Prostatic Hyperplasia Trials on ClinicalTrials.gov

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Tram M, Zipkin J, Srivastava S, Welliver C. Outcome measures and inclusion/exclusion criteria in benign prostatic hyperplasia trials on ClinicalTrials.gov. *Urol Pract.* 2023;10(3):253-260.

Study Need and Importance

Clinical trials are essential to evaluate new treatments for benign prostatic hyperplasia. ClinicalTrials.gov is a public registry that provides access to ongoing and completed studies. Our study investigated benign prostatic hyperplasia trials registered on ClinicalTrials.gov. We were concerned that studies utilized different outcome measures and inclusion criteria, which may limit the ability to both understand trial outcomes and compare results across trials.

What We Found

Out of 411 registered and examined trials, the most common primary or secondary outcome measure was the International Prostate Symptom Score (IPSS), which was used in only 65% of studies (see Figure). Maximum urinary flow (Q_{max}) was the second most common outcome measure (40% of studies). No other outcome was measured in more than 30% of studies. Inclusion criteria varied between studies, with the most common being a minimum IPSS (49%), maximum Q_{max} (35%), and minimum prostate volume (26%). The most common minimum IPSS for inclusion was 13 (35% of studies that used IPSS).

> "We were concerned that studies utilized different outcome measures and inclusion criteria, which may limit the ability to both understand trial outcomes and compare results across trials."

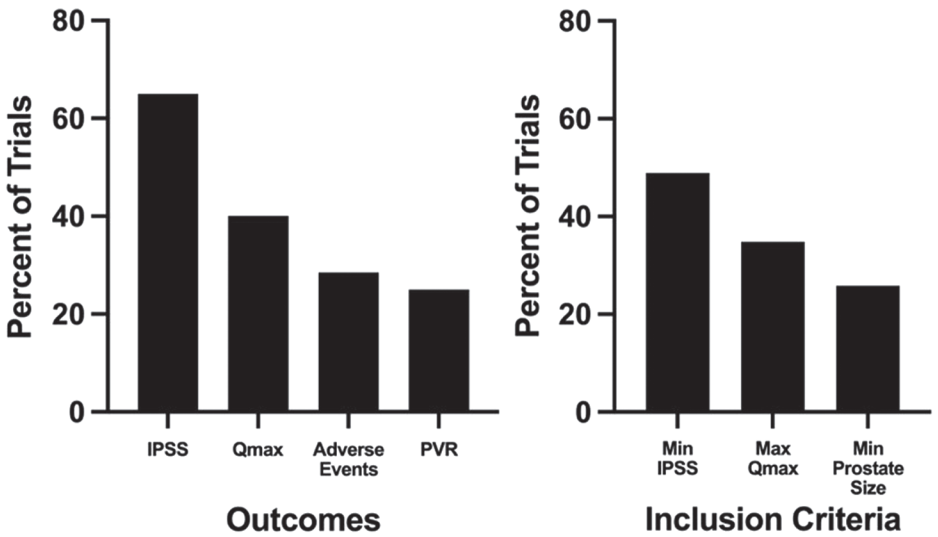

Figure. Use of different outcome measures and inclusion criteria. IPPS indicates International Prostate Symptom Score; PVR, post-void residual; Qmax, maximum urinary flow.

Exclusion criteria were often vague (eg, "other chronic medical condition that would make it difficult to participate"), making it difficult to understand the patient population in some studies.

Limitations

This study examined information

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OUTCOME MEASURES AND INCLUSION/EXCLUSION

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on ClinicalTrials.gov, which does not standardize reporting of outcomes or study criteria. Additional details may have been included in the manuscript of published studies that were not reported on the website.

Interpretation for Patient Care

Most trials utilized IPSS as an outcome. However, only 65% used this validated and ubiquitous questionnaire as a primary or secondary outcome. There were significant differences in the inclusion criteria in the examined studies. Exclusion criteria were too often vague, making it difficult to understand the patient population in studies.

Future research should consider using standardized outcome measures (like IPSS and Q_{max}) when assessing urinary symptoms/function and well-defined inclusion/exclusion criteria. ■

FOCAL THERAPY

Active Surveillance for the Small Renal Mass

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Introduction

Small renal masses (SRMs) are enhancing asymptomatic lesions in the kidney that measure 4 cm or less and represent nearly half of newly diagnosed kidney cancers.[1] The incidence of SRMs is rising due to the widespread use of cross-sectional imaging studies such as CT and MRI.[1]

The traditional management of SRMs has been surgical resection with partial/radical nephrectomy, or ablative therapies such as cryotherapy/radiofrequency ablation. More recently, active surveillance (AS) has emerged as a mainstay treatment option for SRMs. The uptake of AS, however, has been low with reports suggesting only 10% of eligible patients undergoing AS.[2]

AS

When an SRM is detected, oncologic staging is an important first step. Nguyen et al studied over 24,000 renal tumors and found that the prevalence of metastasis at presentation was 1.4%, 2.5%, 4.7%, and 7.4% for tumors 0-1 cm, 1-2 cm, 2-3 cm, and 3-4 cm, respectively.[3] This highlights that a few patients with SRMs will present with metastatic disease.

On AS, patients undergo abdominal imaging every 3-6 months for 1 year, then every 6-12 months thereafter with a chest x-ray annually, although the need for chest imaging has been debated. Treatment is generally recommended for rapid growth rates >0.5 cm/y, increased tumor diameter >4 cm, detection of metastatic disease, or patient preference. In a cohort of 544 SRMs treated with AS, the rates of intervention were 9%, 22%, 29%, 35%, and 42% at 1, 2, 3, 4, and 5 years, respectively.[4]

For patients with solid SRMs, 20%-30% are benign lesions, with the most common histology being oncocytoma.[5] Of the remaining SRMs that are renal cell carcinomas (RCCs), 70%-80% are low grade with little metastatic potential.[6] SRMs grow at a rate of approximately 0.28 cm/y and the 3-year risk of metastatic progression is ~2%.[7,8] A systematic review found that tumors that metastasized were larger at presentation (4.1 vs 2.3 cm, $P < .0001$) and had a higher growth rate (0.8 vs 0.3 cm/y, $P = .0001$).[9]

Cancer-specific survival for patients on AS vs primary intervention is similar. The results from a prospective, nonrandomized trial reported 5-year cancer-specific survival rates of 99% and 100% for primary intervention and AS, respectively ($P = .30$). It should be noted, however, that 5-year overall survival was worse for AS compared to primary intervention (75% vs 92%, $P = .06$), but this is likely explained by the fact that AS patients were older, had worse Eastern Cooperative Oncology Group scores, had more total comorbidities, and were more likely to have multiple or bilateral lesions.[10] Although the short-term safety of AS has been established, the longer-term outcomes beyond 3 years remain to be reported.

The Role of Renal Mass Biopsy

Renal mass biopsy (RMB) can help identify the underlying histology of SRMs to help drive clinical management. In a single center's 13-year experience, RMB was able to identify a wide variety of benign and malignant histologies.[11] The diagnostic rate of RMB in a systematic review of over 5,000 patients was greater than 90% with a sensitivity of 99.1% and specificity of 99.7%. The rate of subtype concordance of RMB of SRMs with final surgical pathology was 96%.[12]

In a biopsy-characterized cohort of SRMs, clear cell RCC grew faster than papillary type 1 SRMs (0.25 vs 0.02 cm/y on average, $P = .0003$). Some clear cell RCCs showed accelerated growth only after an initial period of stability. The rate of metastatic progression was 4% in this study, with all metastatic patients having clear cell histology. Of note, one patient who developed metastatic disease showed no local tumor growth after 2 years on AS.[13] A tumor-specific, genomic signature–informed approach will be crucial for optimizing patient selection for AS and minimizing the risk of disease under- or overtreatment.

Current Guideline Recommendations

Guidelines from the American Urological Association in 2021, Canadian Urological Association in 2022, European Association of Urology in 2022, and American Society of Clinical Oncology in 2017 are fairly consistent with respect to the use of AS for SRMs. All of them recommend AS as the preferred management strategy for patients with significant comorbidity, limited life expectancy, excessive perioperative risk, or marginal renal function. The Canadian Urological Association guideline recommends AS as the preferred option for all patients with SRMs <2 cm. For tumors between 2-4 cm, there was no consensus on the preferred management strategy, with 40% of guideline members feeling that definitive treatment with surgery or ablation should be the option of choice. Shared decision-making and using RMB when it will impact management are common amongst guidelines. Other special considerations which may impact AS decisions are that thermal ablation is most effective for tumors less than 3 cm, and the complexity of the partial nephrectomy required for surgical extirpation.

Future Directions

There has been recent interest in using imaging modalities to predict SRM histology. A retrospective analysis found that MRI had a sensitivity of 85% and 80% for detecting clear cell and papillary RCC, respectively, but fared worse for predicting chromophobe, oncocytoma, and fat-poor angiomyolipomas.[14] The ZIRCON study,

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presented at the 2023 American Society of Clinical Oncology Genitourinary Symposium, evaluated a novel positron emission tomography/CT-based imaging modality using ^{89}Zr-DFO-girentuximab. Girentuximab is a monoclonal antibody that binds to carbonic anhydrase IX, an enzyme highly expressed in clear cell RCC. The study included 300 patients with indeterminate renal masses who underwent positron emission tomography/CT imaging prior to surgery, and the results showed a sensitivity and specificity of 86% and 87%, respectively, for detecting clear cell RCC.[15] The imaging modality may emerge as an adjunct or replacement for RMBs in select situations.

Conclusion

AS has emerged as a safe and effective option for the management of SRMs. RMB can help identify the underlying histology of the SRM to inform clinical management. Patients are best served through an individualized approach to management considering tumor factors (such as size, growth rate, histology, and location) and patient factors (such as age, competing health risks, and preferences). ■

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