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– FOCUS ISSUE –

Clinical Trials

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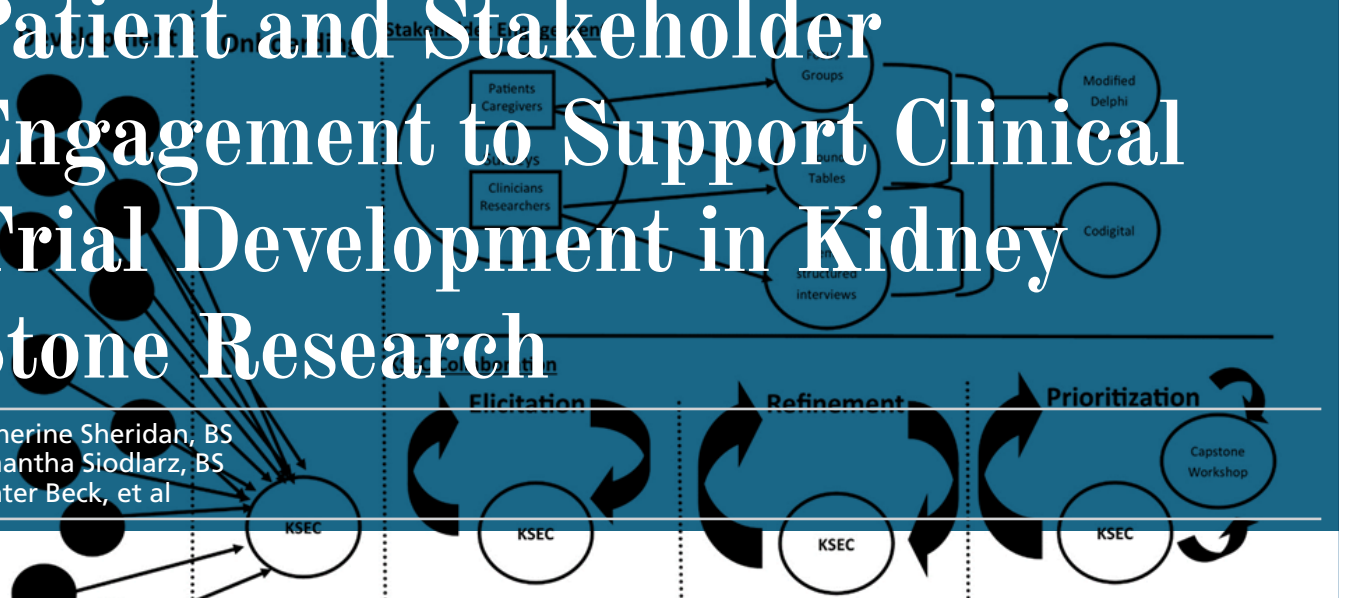

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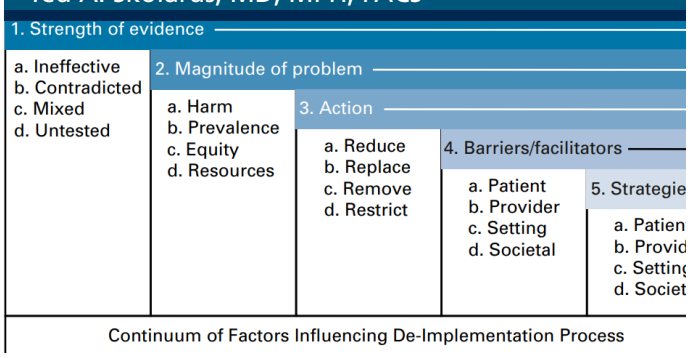

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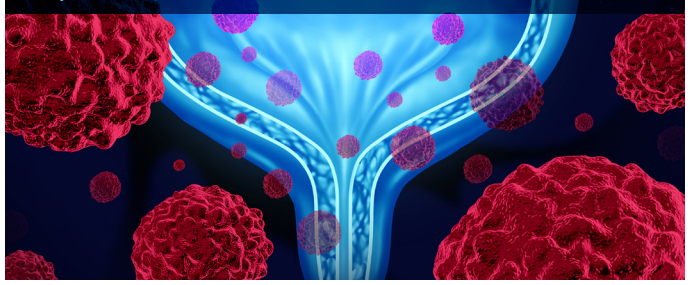

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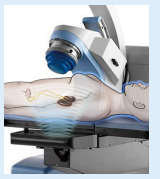

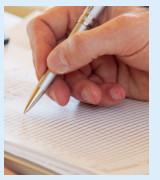

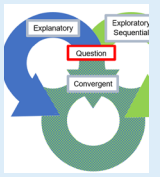

CLINICAL NEWS

NEWS FROM THE AUA

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CLINICAL TRIALS

Clinical Trials for Patients With Stones From the United Kingdom

Matthew Bultitude, MBBS, MSc, FRCS(Urol)
Guy's and St Thomas' Hospital, London, United Kingdom

The National Institute for Health and Care Research (NIHR) was formed in 2006 with the aim of delivering large research trials in the United Kingdom (UK). This has seen 3 large, randomized trials in stone disease funded in the last decade, 2 of which are published in high-impact journals and the other is eagerly awaited (see Figure). But that doesn't tell the whole story of stone research in the UK, and in this article, I am also going to highlight the work of the British Association of Urological Researchers in Training (BURST) and The Urology Foundation (TUF) in driving forward clinical stone research in the UK, as well as discuss the 3 large NIHR studies. Of course, there are other trials taking place in individual units that cannot be mentioned in 1 short article, which is only focused on larger national studies.

The BURST Research Collaborative is an international group founded in 2015 comprised mostly of urological residents.[1] The aim is to produce high-impact multicenter audit and research which can improve patient care. This has been a huge success with several large studies demonstrating the power of this collaboration. Examples of early trials were IDENTIFY, a large multicenter study of 11,000 patients across 100 units in 26 countries to identify risk factors for cancer in patients presenting with hematuria.[2] This led to the publication of a risk calculator for use in patients with hematuria.[3] In urolithiasis the MIMIC study analyzed 4,170 patients with acute presentation of stone disease in 71 centers across 4 countries, which showed no benefit to inflammatory markers C-reactive protein or white blood cell count in prediction of stone passage, nor was there a benefit to medical expulsive therapy.[4] This also led to a risk calculator for stone passage in patients presenting with ureteric colic.[5]

TUF is a UK-based charity funding research, fellowships, and training in all areas of urology.[6] In 2021 they set up the TUF Trials Unit with the aim of providing an infrastructure to take forward promising clinical research ideas from urology units across the UK. Following a competitive process involving The British Association of Urological Surgeons, TUF partnered with the Clinical Trials Unit in Aberdeen to act as their partner in taking forward these research proposals, and they currently have 15 projects that are being worked up in all areas of urology. One such project which has been proposed by BURST is to run a randomized trial in stent placement in uncomplicated ureteroscopy, a common clinical dilemma. However, at the time of writing, funding is still pending for this trial, and it is not clear if this will go ahead.

The Centre for Healthcare Randomized Trials is part of the Clinical Trials Unit in Aberdeen and was responsible for the 3 large NHIR-funded trials, with Professor Sam McClinton as the Chief Investigator for all 3 trials. The first was the SUSPEND trial, which was a multicenter trial of 1,167 patients in the UK randomized to tamsulosin, nifedipine, or placebo for patients with ureteric stones.[7] This showed no benefit to medical expulsive therapy and was in keeping with other well-conducted large, randomized trials from Australia and the United States.

Figure. Clinical trials for patients with stones.

The second NIHR trial was the Therapeutic Interventions for Stones in the Ureter trial randomizing patients needing intervention for ureteric stones between shockwave lithotripsy (ESWL) and ureteroscopy.[8] This trial, published in *European Urology*, showed noninferiority of up to 2 sessions of ESWL to ureteroscopy (with a noninferiority margin of 20%), although an absolute benefit to ureteroscopy of 11.7%. However, with overall success for ESWL of 77.9% in avoiding surgical intervention, this has shown the potential importance of ESWL in the acute stone pathway for these patients.

The third study is a clinical and cost-effectiveness trial for treatment of stones in the lower pole of the kidney–the PUrE study.[9] This study, which has now closed and is awaiting publication, was comprised of 2 separate randomized trials. The first randomized stones

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less than 10 mm in the lower pole between ESWL and flexible ureteroscopy. The second, for stones between 10-25 mm, randomized patients between flexible ureteroscopy and percutaneous nephrolithotomy. Overall, 625 patients have been entered, and the results will surely advise clinicians and guidelines on how these stones should be treated.

In summary, the UK has produced 3 impactful high-quality randomized trials via NIHR funding over the last few years. But with the infrastructure in place to take forward clinical ideas and BURST showing the power of national and international collaboration, the future is bright for further important stone research from the UK. ■

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CLINICAL TRIALS

Embarking Upon a Clinical Research Enterprise in the Independent Private Practice Setting

Thomas Paivanas, MHSA
TAP&A, Annandale, Virginia

Arletta van Breda, RN, MSN, CCRC, CIP
Big Sky Research, LLC, Bozman, Montana

Introduction

Every independent private practice clinical research enterprise (CRE) is unique, being a reflection of

- Size, operations, and service scope of the overall clinical practice.
- Geography and choreography of patients across offices and location of research enterprise.
- Local medical-political-reimbursement environment.
- Personalities and politics.

As such, the path for implementation of a CRE can either be an onerous and frustrating one, or a challenging and exciting one. We propose an approach to best expedite the latter. Note that there are many exhaustive lists and overviews of tangible and intangible requirements and functions of a CRE which will not be covered here but are provided in references.[1,2] So how best to proceed and navigate this challenging path?

1. Know yourself: Strengths and weaknesses, interests, and especially your disinterests. Have a realistic assessment of your managerial skills and your risk tolerance for business. It is imperative to enter this process with eyes wide open, as it is essential to be intimately familiar with all aspects of the art, science, and business of establishing a CRE.[1-3]
2. Invest in yourself: What knowledge and skill set do you need to develop? Where are the gaps in your knowledge and experience? Aggressively seek out multiple other successful principal investigators (PIs) in other private practice settings to visit and understand how their CRE programs evolved. Yours will be different with core research functions uniquely addressed for your practice environment. However, there are courses and accreditations that should be immediately sought out to add to your foundational research knowledge.[1,2] One must commit to being a lifelong learner in all aspects of research.
3. Establish a critical partnership with the practice CEO/

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Table 1. Ensuring Stakeholder Understanding of the Quantifiable Benefits of Conducting Research to the Patient, the Clinician Scientist/Research Medical Director, and to the Practice Is Imperative to Garnering Support and Resource Development

To the clinician scientist/ research medical director	To the practice	To the patient
• Fulfilling a relentless commitment to expanding therapeutic options at every stage of their patient's disease • Intellectual stimulation and excitement, ie, personal and professional reward • Gain direct professional experience using new technologies, medicines, or procedures in clinical practice setting • Variation from typical clinical practice, ie, potential for modification of call and clinical hours • Development of new skill sets, ie, business operations, business development, clinical management, etc • Financial remuneration ideally commensurate with meeting clinical and economic program objectives (caveat—see employment contract) • Opportunity for semiautonomous practice within content of larger clinical practice • Extra-practice engagements with other like-minded clinical scientists and academic colleagues from across United States, perhaps even internationally	• Professional differentiation of the group practice and specific physician partners in the medical consumer marketplace • Will drive the early adoption of new technologies, medicines, and procedures into the broader clinical group practice • Clearer differentiation of practice quality in the medical marketplace, thereby increasing attractiveness for inclusion by commercial insurer provider panels, ACOs, and other collaborative endeavors • Provide the practice with leverage in direct payer negotiations and potentially with hospital collaborations • Stronger professional differentiation to referring providers not only within their PSA but outside the PSA on a regional, state, or even national basis, ie, identification as a "destination service"	• Availability of SOTA therapeutic options at every stage of their disease • The ability to provide truly individualized and more personal care • The opportunity to access and ensure continuity of SOTA care close to their home and their established support services network • Opens up options for care under a research protocol where there might otherwise be financial challenges impeding access to care (managed care constraints, underinsured or uninsured, other coverage restrictions) • Increased confidence in their physician that they are not only current, but ahead of the curve regarding the practice of urological medicine

Abbreviations: ACO, accountable care organization; PSA, primary service area; SOTA, state-of-the-art.
Data were derived from Shore et al.[1]

EMBARKING UPON A CLINICAL RESEARCH ENTERPRISE

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administrator: This relationship is often underappreciated, wasting the opportunity to minimize practice-wide conflict, resulting in unnecessary misunderstandings, and in huge delays in program development. This journey of development should be taken arm in arm with the CEO over a series of meetings to discuss the following:

a. Outline and align areas for mutual education and personal support. The process of amalgamating business and medicinal knowledge creates mutual respect. Collaboratively establish the mission and vision of the CRE. Delineate the tangible and intangible benefits of CRE to the patient, the practice, and the PI (Table 1). Appreciate the needs and concern of the key stakeholders involved in the CRE (see Figure). The PI/CEO alignment on understanding these metrics is essential in collaboratively and realistically setting expectations for success and the commitment of resources.

b. Effect Strategic Business Planning–underscores why collaborative development is essential as few physicians are schooled in this area.

   i. Assess Opportunistic Fit–With current/proposed clinical products and services. Carefully define and propose measures of quality, volume, and bottom-line impact of the CRE.

   ii. Establish Goals and Objectives–Types, number, and nature of research, typically a rolling 3-year timeframe to measure success and provide basis for flexing resources!

   iii. Resource Requirements and Projections–Note an exhaustive understanding of functions needs to be developed before framing out infrastructure. Staff (research, administrative, technical, and especially financial), space, equipment, organizational relationships (pathology, imaging, clinic, etc; Table 2).[1]

   iv. Pro Forma Development–A concise summation of all of the above. What information do your equity partners need to see to commit and support the CRE (activity, fixed and variable, direct and indirect revenues/expenses, overhead, etc)? This involves quality and volumes, and not just bottom-line projections. Your CEO partner is invaluable in this process.

4. Evangelically garner partner support: Typically only 30% will be enfranchised into supporting your CRE (unpublished data, internal report from The CUSP Clinical Research Consortium/The CUSP Group LLC, November 7, 2020).

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Table 2. Key Characteristics Necessary for a Robust Research Enterprise (Whether Joining or Building One)

- A refined research mission and vision: areas of interest, capacity and long-term expectations
- Clear committed research leadership: medical, clinical, technical, and administrative
- Robust research infrastructure:
  - Sufficient number of trained/knowledgeable staff
  - Exemplarily administrative support
  - Adequate equipment/facilities
  - Dedicated IT resources
  - Comradery
- Strong practice/organizational commitment and support
  - Funding: OH support, clarity regarding compensation penalties and rewards
  - Protected time: Clinical vs administrative tradeoffs
  - Referral systems: Building formal and informal systems to identify and recruit subjects
  - Clinical practice integration: How do you complement and supplement clinical care in your practice/institution and avoid becoming an island?
- Personal/professional opportunity to curate relationships (part overall practice/institutional support of research)
  - Within research core/practice
  - With internal and external clinicians
  - Other research scientists
  - Research sponsors

Abbreviations: IT, information technology; OH, overhead.

Figure. Key critical stakeholders in the successful clinical research enterprise in the tertiary community private practice setting. CEO indicates chief executive officer; CRC, clinical research coordinator; FDA, Food and Drug Administration; IT, information technology; PI, principal investigator.

EMBARKING UPON A CLINICAL RESEARCH ENTERPRISE

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Identify key critical physician partners not only for referrals, but also as potential subinvestigators. A vigorous evangelical approach must be embraced to continuously educate and to allay fears about patient control and financial loss, and mitigate disinterest if not outright resistance!

5. Plan to implement: If you have been successful up to this point, educating yourself, establishing CEO partnership, and curating clinical partner support, you are ready to begin blueprinting for implementation. This needs to be an exhaustive process involving a broad range of staff and needs to be well communicated to all practice stakeholders. Monitoring feedback and control are essential.[1-3]

Conclusions and Recommendations

- Seek extra-practice camaraderie and intellectual collaboration. This will nurture your soul, as well as build your reputation, and open trial opportunities. Research is all about relationships.
- This is a long road. Understanding the need for persistence and tenacity is critical to your satisfaction and happiness.
- Choose collaborators and staff carefully. It is easy to become encumbered and difficult to disengage.
- Expect everything to change with success, with challenges, with you/your program maturation. If you welcome and embrace thoughtful change, you will be happier and more successful.
- Know what you don't know! Either learn it or find someone that can manage it in your stead. Note, however, that the CRE is a feudal venture, so you are always ultimately responsible. Choose wisely.
- You need a strategic business plan that meets the needs of your stakeholder audiences. There is no one template for a viable and successful research program. Every practice will have unique geography consideration, patient choreography, personalities, and of course politics.
- The CEO/administrator is your first and key critical stakeholder. In many ways they hold the keys to your kingdom in opening time, resources, service support, and facilities. You want to have them as a partner and ally from day 1.
- Your partners, in turn, fuel the CRE practice and you must enfranchise and then garner strategic support and collaboration. But you must be realistic about expectations about collaboration and support.
- Function then infrastructure, otherwise you will find yourself limited or painted into a corner.
- Note lessons that can be learned the hard way (Table 3). ■

Table 3. Lessons Learned the Hard Way

• Success requires time, but an essential ingredient for a successful clinician scientist is persistence! Clearly understand the personal and professional commitment to becoming a successful researcher in any setting • You must be a jack of many trades—you cannot avoid or abrogate these responsibilities • Have thorough knowledge about the science you are researching • Establish a critical mass of colleagues within your research enterprise. You must be a leader of multidisciplinary team(s) • Evangelize research with physician partners to build consistent referrals • Ensure that research becomes an integral part of the continuum of clinical services for patients at all stages of their disease and progression. Research operations must seamlessly interface with practice clinical operations
• Never forget the business of research • Effect a thorough direct and indirect cost analysis of each study. Often physicians only think about top-line revenue as they are not trained in the business of medicine. It is naïve to believe because you are skilled at surgery/medicine you are also an efficient businessperson. • Constantly monitor P&L of the research group/division • Establish and curate a reputation for high-quality research with sponsors, research colleagues, referring physicians, and the patient community • Due diligence—look (prepare) before you leap: mentor, organizational commitment to research (money, staff, facilities, protected time, remuneration)

Abbreviations: P&L, profit and loss.

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CLINICAL TRIALS

Why Consider Genitourinary Oncology Research in the Community?

David Morris, MD, FACS
Urology Associates, PC, Nashville, Tennessee

Guatam Jayram, MD
Urology Associates, PC, Nashville, Tennessee

Daniel R. Saltzstein, MD
Urology San Antonio, Texas

Ronald Tutrone, MD, FACS, CPI
United Urology Group, Baltimore, Maryland
Chesapeake Urology, Baltimore, Maryland

Paul Sieber, MD
Keystone Urology Specialists, Lancaster, Pennsylvania

Gordon A. Brown, DO, FACOS
Summit Health-South, Voorhees, New Jersey

Recent rapid advancements in genitourinary oncology therapeutics and diagnostics are a direct result of well-designed and executed clinical trials, bringing new therapies and devices to the marketplace while also expanding on the indications for already approved products. The "menu" of options for urological cancer patients is growing at an unprecedented rate, and large independent groups are having to adjust accordingly. Independent research programs benefit our patients, our practices, and our physician investigators, while aligning us with our academic colleagues. In this commentary we discuss why continued development of independent clinical trials infrastructure is healthy for our patients and practices while recognizing obstacles to program success.

Practice Level

Independent, large urology groups have recognized the benefits of an efficiently run and well-managed research department for over a decade. These programs increase visibility, legitimacy, and revenue for our practices, and fit in nicely with an independent group's ancillary service lines. Additionally, community patients are highly sought after in research settings as these patients often represent a more realistic and diversified array of disease, comorbidity, and socioeconomic

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WHY CONSIDER GENITOURINARY ONCOLOGY RESEARCH IN THE COMMUNITY?

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status than those typically recruited at academic sites. The phrase "real-world data" has recently been popularized as it applies to this concept, and many trial sponsors recognize the importance of patient diversity.

Successful management of practice-related research endeavors can be done efficiently with low overhead while meeting the needs of both sponsors and patients. Initiating an independent clinical trials program requires an understanding of practice-specific infrastructure limitations and insight into the contracting process, which may dictate what type of trials a site can conduct. Smaller sites and those without procedural or advanced therapeutics capabilities may focus initially on registrational trials, retrospective analyses, or biomarker trials with easy to obtain blood, urine, or tissue. The evolution to phase 3 and interventional (drug or surgical) trials occurs over time as the program becomes more successful and sophisticated with trials oversight, administration, and contract negotiation.

Obtaining experience in trial interventions enables a large practice to gain valuable experience with a therapeutic that may become standard of care, giving them a potential head start at expanding therapeutic resources. In a competitive health care climate, developing and honing a successful clinical trials program has substantial benefit to the practice. Practices incorporating trials have greater impact in their communities and often have better access to multidisciplinary cancer care. Many new physician recruits are aware of and have performed research at their recent academic institutions, and many fellowship-trained graduates are interested in continuing this expertise in an independent setting.

> "Practices incorporating trials have greater impact in their communities and often have better access to multidisciplinary cancer care."

> "Collaborative groups championed by the Society for Urologic Oncology and the AUA, focusing on clinical trials research, have proven extremely successful in fostering the relationship between independent practice and academic urologists."

Negotiating effective contracts with sponsors will be essential to the continued growth of clinical trials research at the practice level. Sponsors have special interest and motivation toward high-performing independent sites given low barriers to entry, fewer regulatory obstacles, and ease in site activations and patient recruitment. When contracts are negotiated properly, revenues from clinical research can support other clinical endeavors. In an environment of declining patient evaluation and management reimbursement, research programs may supplement practice income with minimal additional overhead, making them attractive options to maintain practice growth.

Physician Level

Physician-led research programs have several benefits for participating doctors. They include personal career development, establishing leadership roles within the practice, maintaining practice diversity, and an opportunity for aging surgeons to transition their role within the practice.

For physicians with a desire to remain academically productive outside of academic organizations, clinical research allows integration with outside academic investigators, colleagues, and industry sponsors. Collaborative groups championed by the Society for Urologic Oncology and the AUA, focusing on clinical trials research, have proven extremely successful in fostering the relationship between independent practice and academic urologists. Collaboratives have improved trial recruitment, allowing sponsors to reach accrual more quickly while providing them with access to potentially underrepresented patient populations.

Patient Level

The final and most important reason to pursue a clinical trials program is patient benefit. Patients are increasingly aware of growing options in cancer care and utilizing a personalized approach toward their disease. Many patients are interested in organ-preserving options, and being able to offer a noninvasive surgical alternative (eg, an intravesical trial in lieu of radical cystectomy) can be a huge win for patients. The strict protocols and frequent visits used in clinical trials are often helpful in minimizing treatment-related morbidity and optimizing surveillance for these patients.

Obstacles

Despite these benefits, there are hurdles that independent sites must address to allow for high-level clinical research. There needs to be a practice level commitment of capital and resources to ensure appropriate research support. As part of this practice commitment, infrastructure and staffing requirements need to be prospectively outlined and modified based on the level of research sophistication and trial type to support and grow the program. A clinical research manager or coordinator may incur additional cost but can be invaluable in assessing these needs and allowing for the trial portfolio to continue to grow.

> "While historically the time and resources needed to maintain these programs were restrictive, many direct and indirect benefits to the practice now allow these programs to be viable and help all stakeholders within the practice."

Groups must also commit to certain space requirements that would allow for research activities to occur. Clinical exam space is often necessary for patient visits as well as coordinator office facilities and binder and source document storage. Physicians and investigators carry the ultimate responsibility for trial activity, including patient safety, regulatory reporting, and source document recording, which can continue for several years after trial closing. Opening a trial at a site represents a commitment to fulfill those responsibilities or arrange transfer to another responsible physician if their practice shifts focus.

In conclusion, there are several benefits of pursuing clinical research in community urology. While historically the time and resources needed to maintain these programs were restrictive, many direct and indirect benefits to the practice now allow these programs to be viable and help all stakeholders within the practice. As evidence and approvals in genitourinary oncology continue to expand, it is important that institutions that have research or advanced therapeutic capabilities consider entering the clinical trials space to continue to be advocates for our patients and provide contemporary and conscientious care. ■

CLINICAL TRIALS

How to Incorporate Urologic Oncology Fellowship Learnings When Starting Practice

Lauren Folgosa Cooley, MD, PhD
Atlantic Urology Clinics, Myrtle Beach, South Carolina
Carolina Urologic Research Center, Myrtle Beach, South Carolina

Valentina Grajales, MD
The University of Texas MD Anderson Cancer Center, Houston

Alberto Alberto Martini, MD
The University of Texas MD Anderson Cancer Center, Houston

Starting practice after fellowship, whether in an academic or community setting, can be daunting. However, fellows completing a urologic oncology clinical, research, or combined fellowship have a unique set of skills to aid in this transition (see Figure). In general, during a urologic oncology fellowship, a fellow spends 1 year conducting research and 1 year furthering their clinical and operative oncology skills prior to completing training. Fellows arrive at their practices with a fund of clinical knowledge, research experience, and surgical expertise, but putting these skills into action and building a practice takes refinement, mentorship, and networking.

New attendings should have a vision of their ideal practice. What subspecialties of oncology do they wish to practice? What are their research goals? Discussing these goals early with your department or practice helps to establish your referral base and your schedule. Furthermore, this helps with refinement of your operative and research skills as you are focusing on the diagnoses, cases, and projects that interest you.

Mentorship throughout your career is important but is especially helpful during transitions. During residency and fellowship, new attendings have already gathered many mentors who have helped shape their careers. Maintaining and continuing to grow those connections will prove very fruitful early in practice to discuss cases, complications, and research ideas, as well as successes and challenges in life. Furthermore, seek out new mentors. These will be urologists within your practice as well as physicians and colleagues in other departments. Being available, introducing yourself, attending meetings, and joining in on combination specialty cases will be helpful to establish these relationships.

Building networks may look different in academic and community practice settings. In academic centers there are already established connections and often weekly meetings between departments such as urology, medical oncology, radiation oncology, and other surgical subspecialities. Therefore, collaborative cases and discussions about patients are often easier than in community practice initially. It is still important, however, to be available for colleagues and collaborative to build your connections and mentors during the early transition into practice. These mentors will be critical as you refine your clinical and surgical skills, establish your lab or clinical research efforts, and build your practice. Establishing yourself in a community practice initially can be difficult given nonurologist colleagues are not housed under one roof. Therefore, it is important to start meeting your medical oncology, radiation oncology, and medical or surgical colleagues early. Regardless of your practice setting, it is also important to seek networks outside of your institution. Local, national, and international networks help you to stay current and forward thinking for new innovations and treatments to challenge the current standard of care.

> "Building networks may look different in academic and community practice settings."

Lastly, as parting words of advice to fellows transitioning into practice: (1) pick a practice or institution that will allow you to achieve your career goals; (2) have confidence in your operative and research training and know that surgeons are constantly refining their skills; (3) be a forward thinker and not complacent with the status quo of the current standard of care; (4) proactively seek out mentors early and often throughout your career; and (5) establish local, national, and international networks. ■

> "Regardless of your practice setting, it is also important to seek networks outside of your institution."

Figure. Fellowship learnings essential for practice. Created with BioRender.com.

CLINICAL TRIALS

Patient and Stakeholder Engagement to Support Clinical Trial Development in Kidney Stone Research

Katherine Sheridan, BS
Medical College of Wisconsin, Milwaukee
Children's Wisconsin Milwaukee

Samantha Siodlarz, BS
Medical College of Wisconsin, Milwaukee
Children's Wisconsin Milwaukee

Hunter Beck
Patient-Caregiver Stakeholder, Kidney Stone Engagement Core, Milwaukee, Wisconsin

Bryan Clinstman, CPA
Patient-Caregiver Stakeholder, Kidney Stone Engagement Core, Milwaukee, Wisconsin

Casey Dauw, MD
University of Michigan Health System, Ann Arbor

Kim Hollander, BSc
Oxalosis and Hyperoxaluria Foundation, New Paltz, New York

Dirk Lange, PhD
The Stone Centre at Vancouver General Hospital, University of British Columbia, Canada

Kristi Ouimet
Patient-Caregiver Stakeholder, Kidney Stone Engagement Core, Milwaukee, Wisconsin

Carswell Ouimet
Patient-Caregiver Stakeholder, Kidney Stone Engagement Core, Milwaukee, Wisconsin

Kristina Penniston, PhD, RDN
University of Wisconsin School of Medicine and Public Health, Madison

Charles D. Scales Jr, MD, MSHS
Duke Surgical Center for Outcomes Research, Duke Clinical Research Institute, Duke University School of Medicine, Durham, North Carolina

Ryan Spiardi, DO, MSCE
University of Pennsylvania, Philadelphia

Kristin Whitmore, MA, BA
Patient-Caregiver Stakeholder, Kidney Stone Engagement Core, Milwaukee, Wisconsin

Mike Witt, PhD, MBA
Patient-Caregiver Stakeholder, Kidney Stone Engagement Core, Milwaukee, Wisconsin

Gregory E. Tasian, MD, MSc, MSCE
The Children's Hospital of Philadelphia, Pennsylvania
Perelman School of Medicine, University of Pennsylvania, Philadelphia

Jonathan S. Ellison, MD
Medical College of Wisconsin and Children's Wisconsin Milwaukee

Engaging with patients, caregivers, clinicians and researchers can provide invaluable insight into developing, maintaining, and completing valuable comparative effectiveness research. Specific to clinical trial design, patient and stakeholder engagement can be applied at multiple steps in the process, including identification of research questions, selection of key trial outcomes including relevance to patients and stakeholders, input on pragmatic and patient-centered trial design, and contextualization of results (see Table).[1] While some of these aspects lend themselves well to structured prioritization, others are best accomplished through semistructured feedback, discussion, and broader consensus building.[2] For instance, creating a list of topics and/or outcomes to be included may be accomplished with prioritization.[3] More nuanced decisions in terms of hypothesis setting or contextualization of results often require more free-form discussion and consensus.[4] Meanwhile, decisions related to specific elements of trial design (ie, format of patient-facing data, timing of follow-up) may be accomplished via seeking semistructured feedback from the stakeholder team.[5] In order to better understand the patient voice and provide a mechanism for supporting the kidney stone community, we developed the Kidney Stone Engagement Core (KSEC). KSEC is comprised of 16 individuals, including 8 clinicians and researchers, 6 patients with kidney stones, 1 caregiver of a patient with kidney stones, and 1 patient advocate. We will review our lessons learned in creating and engaging a stakeholder-based team, focused on prioritization of research topics for comparative effectiveness trials in kidney stone disease.

Table. Stakeholder Engagement Opportunities and Mechanisms Throughout the Clinical Trial Process

Research phase	Step	Mechanism of engagement
Preparation	Topic selection	Prioritization of research topics
	Framing the question	Consensus via discussion
	Selection and comparators of outcomes	Prioritization of outcomes
	Creation of a conceptual framework	Consensus via discussion
Execution	Analysis plan	Semistructured feedback
	Data collection	Semistructured feedback
	Reviewing and interpreting the results	Consensus via discussion
Translation	Translation	Consensus building
	Dissemination	Consensus building

By including a diverse population, we ensured a range of voices represented the breadth of experiences with kidney stone disease. We intentionally sought out representation of youth (patients and caregivers) and those with rare genetic diseases (ie, primary hyperoxaluria) as well as the experiences of patients more representative of the typical epidemiology of kidney stone disease. Recruitment into the KSEC was best accomplished by referral from a trusted

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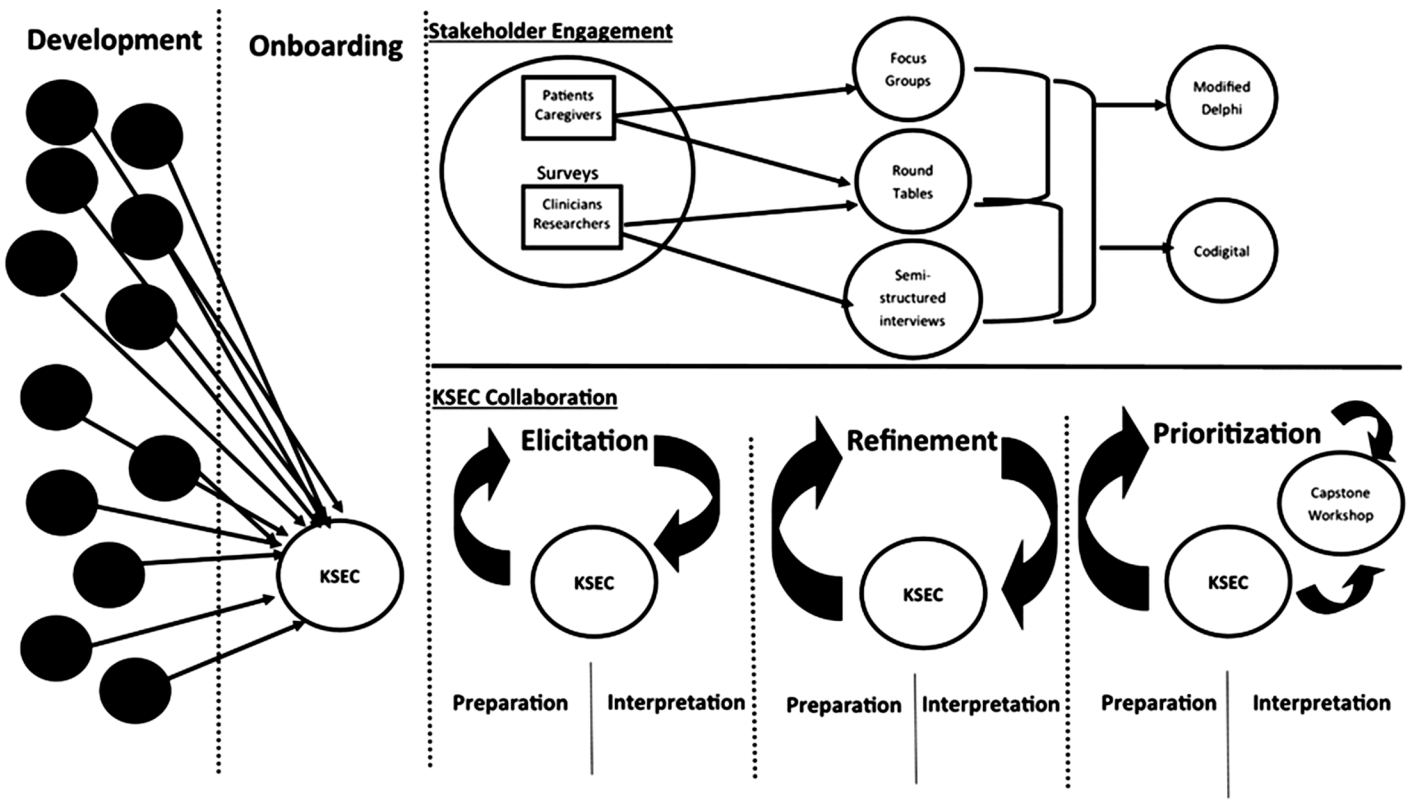

Figure. Stakeholder engagement and Kidney Stone Engagement Core (KSEC) collaboration diagram, defining distinct processes for engagement and KSEC collaborative efforts.

PATIENT AND STAKEHOLDER ENGAGEMENT TO SUPPORT CLINICAL TRIAL

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> "We intentionally sought out representation of youth (patients and caregivers) and those with rare genetic diseases (ie, primary hyperoxaluria) as well as the experiences of patients more representative of the typical epidemiology of kidney stone disease."

source (typically, for the patients or caregivers, their long-standing provider) and personal communication with the KSEC team before signing on to the project.

Regulatory and Logistical Support of a Stakeholder Group

Our team worked closely with our institution in order to define the roles of the KSEC membership. Each KSEC member was contracted through our host institution as an independent contractor (consultant). Within this structure, we were able to follow a standardized process of remuneration already in place for independent contractors and an agreed upon payment schedule. Our engagement team helped to track the hourly engagement of the members to reduce logistical burdens on the stakeholders. Creation and involvement of the KSEC was included in our Institutional Review Board–approved protocol so as to explicitly distinguish the KSEC members from research participants. In our model, KSEC members do not review individualized data, reducing regulatory burden on the group. This model still allows for KSEC to participate in the process related to recruitment materials and review of aggregate results. Introductory meetings and onboarding were important elements to level-set goals and expectations. We chose to use the Fyreworks platform, https://fyreworkstraining.com/, supported by the Patient-Centered Outcomes Research Institute, as a standard educational curriculum for the group. We developed a roadmap, as seen in the Figure, to help guide our team as we worked through each phase of the project.

Maintaining Engagement

Engaging with the KSEC provided valuable insight in working in an engagement-style project. As we moved throughout the project, we developed a better understanding of each member's time and availability to participate. By seeking KSEC member feedback, we improved our processes to amplify productivity by providing more direct timelines and expectations regarding specific KSEC tasks and responsibilities, recording each bimonthly team meeting, and conducting additional one-on-one meetings for members who wished to have additional feedback. We altered our meeting structure in year 2 of the project to allow for shorter, more frequent meetings acknowledging individual availability may fluctuate from month to month. This flexibility is especially important when including individuals with active urological disease, as health concerns may impede the ability of any 1 member to participate at a given time. Thus, structuring an overlapping representation across the stakeholder group and a flexible workflow allowed us to optimize this varying engagement over time while maintaining the enthusiasm of our core group.

Optimizing Efficient Communication

From specific feedback from the group, we utilized a cloud-based shared drive (Google Docs) so that each KSEC member had access for editing, reviewing, and tracking for all project elements. Additionally, in periods of time-sensitive workflow, we structured smaller group meetings to enhance engagement. We found that the KSEC worked especially well with these small group "sprints" with tasks that were both time-sensitive and nuanced, such as translating our elicited themes into research topics for prioritization.

The Value of Stakeholder Collaboration

KSEC members have found value in the opportunity to make a difference and connect to individuals in the broader kidney stone disease community including those who have similar experiences and/or clinical paths. These individuals find a voice in clinical research, thereby ensuring that their concerns and opinions are being heard by the clinical research communities. Most importantly, this also allowed KSEC members to help guide the direction of future research to ensure that it addresses outcomes most relevant to the patient and other stakeholder communities. Throughout semistructured interviews, focus groups, and prioritization Delphi strategies, the kidney stone community has communicated their enthusiasm towards our project by providing stories, perspectives, and opinions. Additionally, our KSEC members have noted a sense of pride and satisfaction in being involved in our group and providing meaningful input that will benefit the community. Several members have voiced that because of the difficulties and unpredictable nature of their kidney stone disease, the opportunity to participate in the KSEC was an outlet to demonstrate active agency over the disease. As expressed by one of our team members: "…Because of the diversity of our team, the research conducted has the ability to help many people. Patients can refer to the work to assist in their own treatment, caregivers can gain insight, and the medical professionals can use our work to aid in the treatment plans for their own patients. This work allows for the conversation to keep being had and best practices to keep being developed." ■

> "As expressed by one of our team members: '… Because of the diversity of our team, the research conducted has the ability to help many people. Patients can refer to the work to assist in their own treatment, caregivers can gain insight, and the medical professionals can use our work to aid in the treatment plans for their own patients. This work allows for the conversation to keep being had and best practices to keep being developed.' "

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CLINICAL TRIALS

Patients as Partners in the Modern Clinical Trial Landscape

Christine E. Lentowski, MS, MBA
UroGen Pharma, Princeton, New Jersey

The modern clinical trial landscape reflects innovative study designs, technological advancements, and regulatory updates. Of paramount importance, however, is the evolution of viewing patients as partners with regulators and industry in the development of new treatments and the conduct of clinical trials.

The Food and Drug Administration engages in patient-focused drug development meetings to better understand the unmet needs of patients regarding clinical research. Other forums have also been established to give patients and caregivers opportunities to partner with regulators such as patient listening sessions and the Patient Engagement Collaborative.[1]

Given the value of patients as partners, UroGen Pharma has implemented several approaches to make clinical trials more patient focused.[2–4] These include eConsent to enable a more convenient and robust informed consent process, a hybrid study design featuring patient treatment in the home,[5] new technology to capture patient-reported outcomes, and support for patient travel to clinical trial sites.

Patients have more options to explore clinical trials, and industry continues to find ways to incorporate the patient voice into clinical trials. The Bladder Cancer Advocacy Network has committed to connecting patients and caregivers with new clinical trial options[6] and information about new treatments.[7] Partnership between patients and patient advocacy groups, regulators, and industry has generated a more patient-focused clinical trial landscape. ■

> "Partnership between patients and patient advocacy groups, regulators, and industry has generated a more patient-focused clinical trial landscape."

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CLINICAL TRIALS

Addressing Overuse Through De-implementation Trials and Practice

Ted A. Skolarus, MD, MPH, FACS
University of Chicago, Illinois

Overuse is common in health care. Defined by the Institute of Medicine in 1998 as "a health care service [that] is provided under circumstances in which its potential for harm exceeds the possible benefit,"[1] overuse has been estimated to cost the US health care system over $100 billion annually, distracting funds from higher value, evidence-based care delivery.[2] The extent of unnecessary tests and procedures drove the Choosing Wisely campaign's efforts in partnership with over 80 societies to address over 700 tests and treatments that were unnecessary or overused.[3]

There are many reasons we overuse services ranging from diagnostic and prognostic uncertainty, outdated practice styles, and insufficient evidence, to fear of missing a diagnosis, defensive medicine (ie, avoiding malpractice), patient preference, and even revenue generation in fee-for-service systems.[4] Indeed, indication creep, where evidence from clinical trials drives interventions and services into broader, untested populations typically with less severe disease, is also at play.[5] From off-label drug use to excessive imaging, indication creep can foster overuse, limiting benefits to those with milder disease and exposing patients not included in trials to harms.

Addressing overuse is complicated. While Choosing Wisely popularized overuse awareness and in partnership with the AUA defined 15 mostly don't do items (see Table), how best to accomplish not doing these services was missing.[3] When "less is more," doing less can be challenging, even for those with the best of intentions. Moreover, some things are easier to do less often, while others are more challenging, especially when we are used to doing them. For example,

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Table. AUA Choosing Wisely Guidance Addressing Overuse

	Recommendation	Discussion
1	A routine bone scan is unnecessary in men with very low-risk or low-risk prostate cancer.	Very low-risk or low-risk patients (defined by using commonly accepted categories, such as AUA guidelines) are unlikely to have disease identified by bone scan.
2	Don't prescribe testosterone to men with erectile dysfunction who have normal testosterone levels.	While testosterone treatment is shown to increase sexual interest, there appears to be no significant influence on erectile function, at least not in men with normal testosterone levels.
3	Don't order creatinine or upper-tract imaging for patients with BPH.	When an initial evaluation shows only the presence of LUTS, if the symptoms are not significantly bothersome to the patient or if the patient doesn't desire treatment, no further evaluation is recommended.
4	Don't treat an elevated PSA with antibiotics for patients not experiencing other symptoms.	It had previously been suggested that a course of antibiotics might lead to a decrease in an initially raised PSA and reduce the need for prostate biopsy; however, there is a lack of clinical studies to show that antibiotics actually decrease PSA levels.
5	Don't routinely perform ultrasound on boys with cryptorchidism.	Ultrasound has been found to have poor diagnostic performance in the localization of testes that cannot be felt through physical examination.
6	Don't prescribe antimicrobials to patients using indwelling or intermittent catheterization of the bladder unless there are signs and symptoms of urinary tract infection.	Antibiotics in the absence of signs and symptoms (which may include fever; altered mental status or malaise with no other cause; floor pelvic pain; flank or suprapubic tenderness; hematuria; dysuria; urinary urgency or frequency; and, in spinal cord injury patients, increased spasticity, autonomic dysreflexia, or sense of unease) are not efficacious and risk inducing resistance to antimicrobials.
7	Don't obtain CT scan of the pelvis for asymptomatic men with low-risk or very low-risk clinically localized prostate cancer.	CT scan of the pelvis is very unlikely to provide actionable information in men with low-risk prostate cancer (one commonly accepted definition of low-risk prostate cancer is Gleason score <7, PSA <10.0 ng/mL, tumor stage of T2 or less, very low-risk is Gleason score <7, PSA <10 ng/ml, tumor stage T1-T2a, less than 34% of biopsy cores positive, no core with more than 50% involved, and PSA density of <.15 ng/mL/cc).
8	Don't remove synthetic vaginal mesh in asymptomatic patients.	There is no clear benefit to mesh removal in the absence of symptoms, and mesh removal in this circumstance exposes the patient to potential complications such as bladder injury, rectal injury, and fistula formation.
9	Offer PSA screening for detecting prostate cancer only after engaging in shared decision-making.	Shared decision-making (between health care provider and patient and, in some cases, family members) is an excellent strategy for making health care decisions when there is more than 1 medically reasonable option.
10	Don't diagnose microhematuria solely on the results of a urine dipstick (macroscopic urinalysis).	Microhematuria is defined only on urine microscopy: 3 or more red blood cells per high-powered field on microscopy of a properly collected urinary specimen.
11	Don't treat low-risk clinically localized prostate cancer (eg, Gleason score is <7, PSA <10.0 ng/mL, and tumor stage T2 or less) without discussing active surveillance as part of the shared decision-making process.	The ultimate choice of treatment should be based on shared decision-making and individualized to the patient's disease characteristics, his overall health, and his personal preferences.
12	Don't treat uncomplicated cystitis in women with fluoroquinolones if other oral antibiotic treatment options exist.	Due to serious potential side effects associated with the use of fluoroquinolone antibiotics, these drugs should not be prescribed as first-line therapy for uncomplicated cystitis in women.
13	Don't continue opioid analgesia beyond the immediate postoperative period; prescribe the lowest effective dose and number of doses required to address the expected pain.	The use of opioid analgesia for pain is often appropriate in surgical patient care.
14	Don't obtain urine cytology or urine markers as a part of the routine evaluation of the asymptomatic patient with microhematuria.	Insufficient evidence exists for the use of urine cytology and urine markers in the routine evaluation of the asymptomatic patient with microhematuria, including BTA assays, NMP assays, and FISH assays to detect chromosomal alterations.
15	Don't routinely use CT to screen pediatric patients with suspected nephrolithiasis.	Given the link between radiation exposure from CT in children and increased cancer risk, imaging test selection should adhere to the principle of ALARA to minimize radiation exposure.

Abbreviations: ALARA, as low as reasonably achievable; BPH, benign prostatic hyperplasia; BTA, bladder tumor antigen; CT, computed tomography; FISH, fluorescence in situ hybridization; LUTS, lower urinary tract symptoms; NMP, nuclear matrix protein; PSA, prostate-specific antigen.

ADDRESSING OVERUSE THROUGH DE-IMPLEMENTATION TRIALS AND PRACTICE

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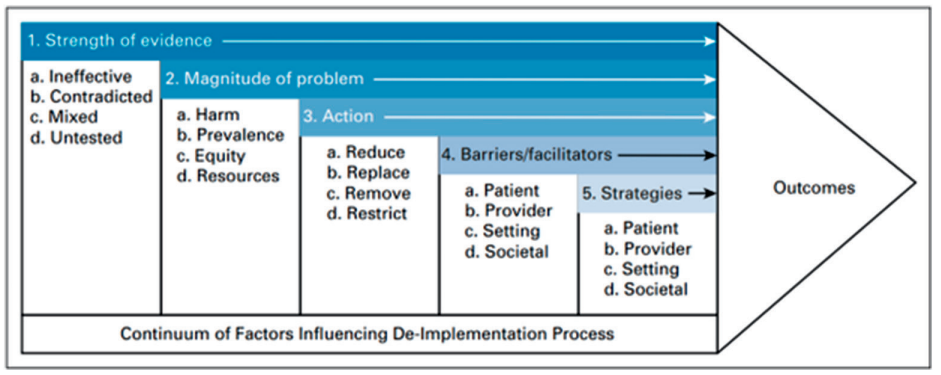

Figure. Framework for de-implementation in cancer care delivery. Adapted with permission from Norton WE et al. *J Clin Oncol*. 2019;37(2):93-96.[7]

using bone scans to stage low-risk prostate cancer used to be widespread, even after it was deemed overuse. While some providers were able to stop ordering, others needed more time and motivation, creating opportunities to test strategies to help do less.[6]

Developing and testing strategies and interventions to address overuse, and in effect "do less," is central to the science and practice of de-implementation. Also termed de-adoption and de-intensification, de-implementation can be considered a counterbalance to overuse. Illustrated in the Figure is a systematic framework for de-implementation in cancer care delivery, though it can be extrapolated to overuse in general.[7] Starting with the strength of evidence for a given overuse intervention (ie, no longer considered effective, for example, routine cytology in asymptomatic microhematuria) the magnitude of the overuse problem can be characterized, barriers and facilitators to reducing/replacing/removing/restricting the practice can be explored, and multilevel strategies (eg, provider, clinic) can be developed and tested. Strategies might include best practice alerts, audit and feedback, pre-authorization, including formulary restriction, shared decision-making, and academic detailing to audit overuse practices, and guide improvement strategies.

> "Also termed de-adoption and de-intensification, de-implementation can be considered a counterbalance to overuse."

However, compared to overuse literature, the de-implementation literature and evidence-base is only emerging. How best to "do less" needs further study, including through rigorous clinical trials. For example, we are investigating doing less ADT overuse in monotherapy in localized prostate cancer and biochemically recurrent, nonmetastatic disease, comparing behavioral theory-informed de-implementation strategies in a cluster randomized trial.[8] We need others to look across and beyond AUA's Choosing Wisely recommendations to help our field build the evidence base for doing less, yet doing more for our patients. ■

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CLINICAL TRIALS

Patient Engagement in a Bladder Cancer Clinical Trial

Lori A. Roscoe, PhD
University of South Florida, Tampa
Advocate Advisory Board, CISTO

Jennifer M. Taylor, MD, MPH
Baylor College of Medicine, Houston, Texas
External Advisory Board, CISTO

Stephanie Chisolm, PhD
Bladder Cancer Advocacy Network, Bethesda, Maryland

Solange Mecham, BA
University of Washington, Seattle

Jenney R. Lee, MA
University of Washington, Seattle

Angela B. Smith, MD, MS
University of North Carolina at Chapel Hill

John L. Gore, MD, MS
University of Washington, Seattle

Charles C. Peyton, MD
University of Alabama at Birmingham

Patient engagement in a bladder cancer clinical trial is an ongoing, valuable, iterative process that relies on building trusting relationships between various stakeholders, including patients, clinicians, external advisory board (EAB) members, advocacy organizations, and principal investigators (PIs). Patient involvement in studies of bladder cancer may be particularly valuable due to its high recurrence rate, long-term invasive testing, long-term high cost,[1] and limited treatment options, including the life-changing aspects of undergoing radical cystectomy. Best practice statements are readily available for all clinicians.[2] However, navigating treatment decisions based on patient preferences is particularly more challenging and nuanced than following algorithmic guidelines. Patients, family members, and physicians need evidence about clinical outcomes and subsequent quality of life based on patient-centered, real-world evidence.

In the age of complex and competitive anticancer drug trials, high-quality patient-centered trials examining factors influencing treatment decisions are rare and require dedicated routine patient engagement. The Comparison of Intravesical Therapy and Surgery as Treatment Options (CISTO) is a prospective, observational cohort study of bacillus Calmette-Guérin–unresponsive nonmuscle-invasive bladder cancer patients comparing patient-reported and patient-centered clinical outcomes (eg, recurrence-free survival) between those undergoing radical cystectomy and those receiving bladder-sparing therapies.[3] This pragmatic clinical trial will provide evidence to maximize informed decision-making for patients, family members, and clinicians based on patient-reported outcomes and treatment preferences while maintaining rigor in its research methods.[4] The study illustrates a real-world example of patient engagement in bladder cancer trials.

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PATIENT ENGAGEMENT IN A BLADDER CANCER CLINICAL TRIAL

→ Continued from page 12

The CISTO study is fundamentally a patient-centered trial: patients participated in prioritizing research questions identified important outcomes, helped draft the grant proposal, reviewed survey questionnaires, helped establish ways to engage and interest potential patient participants, and brainstormed about recruitment challenges. Future patient engagement will focus on plans for the dissemination of study results to various stakeholders. Creating a patient engagement cohort began with a collaboration between the CISTO research team and the Bladder Cancer Advocacy Network to develop a patient survey network to identify patient research priorities and important stakeholders. Subsequently advocate advisory board (AAB) and EAB members were recruited; a full description of the development of the patient (and public) engagement plan is available elsewhere.[4]

The physician-patient research team has learned valuable lessons in successfully engaging patients in clinical trials. Regular meetings are essential, even if there are no pressing issues to discuss, as this schedule enables relationship-building and trust. Good meeting etiquette is important, such as regular email communication, providing materials and agendas in advance, and respectful leadership and facilitation to allow for full participation. Opportunities for AAB and EAB members to meet each other and invitations to participate in Annual Meetings are also important. Stipends for AAB members also reinforce the importance of patient voices in the study protocol.

> "The CISTO study is fundamentally a patient-centered trial: patients participated in prioritizing research questions, identified important outcomes, helped draft the grant proposal, reviewed survey questionnaires, helped establish ways to engage and interest potential patient participants, and brainstormed about recruitment challenges."

Exemplary patient engagement such as this can exist at the national study administrative level, but can only be carried out locally with active study PIs who champion recruitment and patient engagement at a local level. Multiple barriers to patient recruitment to bladder cancer trials exist; specifically, the recruitment and retention of clinical research professionals (CRPs) has received national attention lately. Data indicate an increase in unfilled CRP positions leading to unstable clinical trial recruitment efforts and diminishing patient engagement.[5] As such, it is important that leadership of any successful bladder cancer trial provide organization, ample operational resources, and suggestions for local strategies to overcome these barriers. Site PIs must remember the first line of patient engagement in a trial starts with CRP personnel, not necessarily routine clinic staff. Thus recruiting, securing, and supporting a highly trained, diverse CRP workforce is essential to success.

Bladder cancer trials, particularly nonmuscle-invasive bladder cancer studies, often provide a unique, long-term patient-provider engagement experience due to frequent treatment failures and progression to clinical trial options. Patient engagement in clinical trial discussions starts at the time of diagnosis when the disease natural history is reviewed. Collaborative efforts and infrastructure between site PIs, CRPs, ancillary workforce, and patients are irrefutably important. Site PIs routinely have busy clinical schedules and serve as a PI on multiple studies. Thus, it is important for patients to understand that the primary contact for management while on study is not necessarily the physician who enrolled them. Engaging patients up front at the time of enrollment to ask questions and set expectations is required. CRPs are critical in educating patients on scheduling, paperwork, time commitment outside of treatment sessions or surgeries, follow-up, etc. Robust institutional research enterprise support, national study support (or industry support), institutional infrastructure, clinical referral base, CRP personnel, and the PI championing the study predict success and optimize patient engagement.

> "Exemplary patient engagement such as this can exist at the national study administrative level, but can only be carried out locally with active study PIs who champion recruitment and patient engagement at a local level."

The benefits of patient engagement in bladder cancer studies are many. Pragmatic, well-designed clinical trials must combine patient input, such as patient-reported outcomes and treatment preferences, along with rigorous research methodologies in order to provide evidence to maximize informed decision-making for patients, family members, and clinicians.[6]

The broad inclusion criteria and pragmatic design of trials such as CISTO will also improve the generalizability and usefulness of study results. For example, physicians can use the CISTO study results in decision-making conversations with patients, knowing that the data were generated in partnership with real patients facing similar clinical dilemmas.

From the patient perspective, being a member of the AAB for CISTO has had great benefits. As one AAB member relates, when they agreed to participate in the AAB, they could hardly say the words "bladder cancer." AAB membership presented a group of individuals who understood and accepted their story, and were open to sharing theirs. To become acquainted with a talented, committed, passionate group of clinicians/researchers dedicated to better understanding bladder cancer, patients with bladder cancer, and the challenging decision-making that bladder cancer requires has been an experience of affirmation and hope. The ability to "give back" and "pay it forward," while clichéd, have given many patient advocates' bladder cancer journeys meaning and purpose, because the contributions of patients to CISTO will pay great benefits to future bladder cancer patients, their family members, and their clinical teams.

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CLINICAL TRIALS

Sip^{IT} Behavioral Intervention Clinical Trial to Increase Fluid Intake for Kidney Stone Prevention

James Marks, BS
Penn State Health Milton S. Hershey Medical Center, Hershey, Pennsylvania

David E. Conroy, PhD
Penn State University, University Park, Pennsylvania

Necole M. Streeper, MD
Penn State Health Milton S. Hershey Medical Center, Hershey, Pennsylvania

Kidney stone prevalence continues to rise but producing 2.5 L of urine daily is associated with a 50%-60% decreased risk of stone recurrence.[1-3] Unfortunately, adherence to fluid intake recommendations for prevention has been limited.[4] Patients report that their thirst is not sufficient to drive the recommended level of fluid consumption and they forget to drink due to their many competing priorities in daily life. With the majority of US adults owning a smartphone that can connect to digital tools, use of technology is increasingly popular to track a variety of health goals.[5,6] Interest has grown in the potential to leverage mobile, wearable, and connected technologies to improve fluid intake monitoring and support behavior change in this population.[7] Smartphone applications and connected water bottles to track daily fluid intake volume are commercially available, but little evidence exists concerning their efficacy for modifying behavior to increase fluid intake and urine output or preventing kidney stones.

The sip^{IT} behavioral intervention is a just-in-time reminder system developed for kidney stone patients who struggle to meet the recommended fluid intake guidelines. It is capable of automatically tracking fluid intake using a connected water bottle and wearing a smartwatch with drinking gesture detection, as well as the ability to manually input drinks using the companion mobile app.[8] If a periodic fluid intake goal is not met, participants receive a message reminding them to drink. These reminder messages are delivered as multimedia messages and were designed to delight recipients while reactivating their fluid intake goal pursuit. Messages are limited to moments of vulnerability when participants are not on track to reach their fluid intake goal. By making reminder messages lapse contingent, disruptions and burden are reduced.

Figure. Connected water bottle, HidrateSpark Pro. Printed with permission of HidrateSpark.

We have conducted 2 studies on sip^{IT} in preparation for our ongoing trial. The first study established proof-of-concept for the intervention and suggested that it reduced some common barriers to fluid intake and increased the experience of drinking-related automaticity (ie a key indicator that participants were forming habits for fluid intake).[8] The second study evaluated mini sip^{IT}, a reduced-cost version of the intervention using only the connected water bottle and its companion mobile app for self-tracking. Almost all participants (n=26) adhered to the program daily. Critically, a significant increase in 24-hour urine volume was observed after the 1-month intervention.[9] This study of the mini sip^{IT} intervention was among the first to indicate that a technology-based behavioral intervention may be capable of significantly increasing 24-hour urine volume in adults, a key component of prevention guidelines that is associated with reduced risk of stone recurrence.[1,2,9,10]

> "If a periodic fluid intake goal is not met, participants receive a message reminding them to drink. These reminder messages are delivered as multimedia messages and were designed to delight recipients while reactivating their fluid intake goal pursuit. "

> "Messages are limited to moments of vulnerability when participants are not on track to reach their fluid intake goal."

Our ongoing National Institute of Diabetes and Digestive and Kidney Diseases-funded sip^{IT} clinical trial is a randomized control trial working to further examine the impact of the sip^{IT} behavioral intervention in kidney stone patients. The trial is currently ongoing and aims to enroll 216 participants who will be randomized to sip^{IT} behavioral intervention or usual care (ie, print materials with education about the guidelines and encouragement to increase fluid intake enough to produce 2.5 L/d of urine). Enrollment is anticipated to conclude in early 2024. The primary outcome of the trial is to assess 24-hour urine volume after 3 months (with intermediate and follow-up assessments at 1 and 12 months). Secondary outcomes include changes in 24-hour urine supersaturations, and habit strength for fluid intake from baseline to the 1-, 3-, and 12-month follow-up assessments. Interested individuals with a history of kidney stones in the past 5 years and no conditions precluding high fluid intake, conditions with high fluid losses, or conditions that preclude ability to collect 24-hour urine sample are being enrolled in the trial. Participants completed a baseline 24-hour urine collection, and those with a volume <2.0 L were eligible for the trial. During baseline, all participants received education (usual care) on increasing fluid intake for prevention of kidney stones. Participants randomized into the sip^{IT} arm were educated on use of a smartwatch (Fitbit Sense) with a custom app that processes signals from the inertial sensors to detect drinking gestures, the connected water bottle (HidrateSpark Pro, see Figure), and both the Fitbit and Hidrate smartphone apps. Staff trained each participant on

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SIP[IT] BEHAVIORAL INTERVENTION CLINICAL TRIAL

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tracking fluid intake using the devices and participants were contacted by study staff if data was not being received from the watch, bottle, or smartphone applications for >3 days during the study period.

Our clinical trial and the ongoing Prevention of Urinary Stones With Hydration (PUSH) clinical trial are 2 recent National Institutes of Health–funded clinical trials to determine if behavioral intervention technologies can be efficacious for increasing urine volume and reducing risk for kidney stone recurrence. Future studies will aim to assess whether behavior change has led to habit formation and whether high fluid intake for stone prevention persists once the technology is discontinued. We look forward to results from these clinical trials to better understand how behavioral science can improve adherence to fluid intake goals for stone prevention.

Interested readers can find publications from our work and patient-oriented educational materials from the sip[IT] trial online at: https://davideconroy.weebly.com/fluid-intake.html

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CLINICAL TRIALS

Behavioral Modification Trials in Urology

Suraj Pursnani, MD
Penn State Health Milton S. Hershey Medical Center, Hershey, Pennsylvania

Alyssa Cutshaw, BS
Penn State University, University Park, Pennsylvania

David E. Conroy, PhD
Penn State University, University Park, Pennsylvania

Necole M. Streeper, MD
Penn State Health Milton S. Hershey Medical Center, Hershey, Pennsylvania

Behavioral modification has been found to optimize genitourinary (GU) health in various conditions, including preventing kidney stones, enhancing sexual function, preventing GU cancers, and addressing overactive bladder and benign prostatic hyperplasia related urinary symptoms. Long-term adherence is the ultimate goal of health behavior change interventions. A behavioral intervention can lead to a change in motivation, which can result in behavior change and ultimately an improvement in health outcomes. Targets for intervention can include smoking cessation, diet modification, weight loss, increasing physical activity, and voiding habits. Recently, there has been interest in leveraging technology that incorporates behavior change techniques to support behavioral modification and overcome challenges of lifestyle changes, specifically for increasing fluid intake for kidney stone prevention. There have been few clinical trials using behavioral modification, including behavior change techniques within urology to improve both health and surgical outcomes.

For kidney stone disease, there have been ongoing clinical trials using technology with behavioral change techniques to increase fluid intake for prevention. Stone recurrence rates can be high; however, behavioral modifications with increased fluid intake and dietary modification can lower recurrence risks significantly. Unfortunately, it can be difficult for patients to adhere to these recommendations amidst the varied demands of daily life. The sip[IT] behavioral intervention was developed using patient-input, as a just-in-time reminder system to improve fluid intake for kidney stone prevention.[1] It tracks fluid intake automatically through a connected water bottle and drinking gesture detection with a smartwatch, and sends just-in-time reminders via text messaging when fluid intake goals are not met.[1] We currently are enrolling patients in a randomized control clinical trial funded by the National Institute of Diabetes and Digestive and Kidney Diseases, with initial results expected in early 2025. We previously conducted 2 studies of the sip[IT] intervention with patients. In the first study, we provided proof-of-concept for this just-in-time behavioral intervention based on findings that patients reported reductions in major barriers to fluid intake and increases in the experienced automaticity of fluid intake (an indicator of habit strength). In the second study, we evaluated the effects of a mini-sip[IT] behavioral intervention that incorporated only the connected water bottle and its companion mobile app on 24-hour urine volume after 1 month of using mini-sip[IT].[2] We found that 90% of participants (n=26) adhered to the behavioral intervention daily through tracking of connected water bottle usage and there was a significant increase in 24-hour urine volume at the end of the 1-month trial.[2] Additionally, 73% of participants had increased 24-hour urine volumes, and 42% of participants had volumes greater than 2 liters after 1 month follow-up.[2] In addition to our work described above, the Prevention of Urinary Stones with Hydration (PUSH) Study is an ongoing clinical trial that incorporates a behavioral intervention program with a goal to increase and maintain high fluid intake for kidney stone prevention.[3] Those in the intervention arm receive a prescription for fluid intake, financial incentives, automated adherence interventions, and structured problem-solving as behavioral interventions.[3] Forthcoming results from these trials will help to understand which approaches to behavior change create long-term habit formation and how strategies need to be individualized as there is likely no one-size-fits-all approach.

> "Stone recurrence rates can be high; however, behavioral modifications with increased fluid intake and dietary modification can lower recurrence risks significantly."

Within urology, there are trials that focus on nontechnology-based behavioral modifications as well. Behavioral interventions are the first line, nonoperative treatment for overactive bladder and urge

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BEHAVIORAL MODIFICATION TRIALS IN UROLOGY

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urinary incontinence (UI). Common targets of behavioral interventions for this include regulating fluid intake, eliminating caffeine and other bladder irritants from the diet, weight control, smoking cessation, and timed voiding. Bladder training and pelvic floor muscle exercises are also behavioral training techniques included in the behavioral toolkit for UI.[4] A trial by Diokno et al evaluated the effectiveness of group session teaching of behavioral modifications in managing female UI.[5] Those in the intervention arm underwent a single group session lecture conducted by 2 trained urology nurses on behavioral modifications. The group session was followed by an assessment 2-4 weeks later and 6-8 weeks later. They found that, within the intervention arm, there was a significant reduction in UI severity, increase in pelvic floor muscle strength, and reduction in voiding frequency with group session teaching.[5]

Smoking cessation reduces risk of most GU cancers and also can improve surgical outcomes, particularly in urinary tract reconstruction and GU prostheses. A study by Bjurlin et al enrolled adult smokers from a single institution urology clinic between 2009 and 2011 in a prospective, brief intervention trial.[6] Patients in the intervention arm received a 5-minute brief smoking cessation intervention with the primary outcome being abstinence at 1 year and the secondary outcome was number of attempts to quit.[6] They found a 12.1% quit rate in the brief smoking cessation intervention vs 2.6% in the usual care group.[6] Patients who received the intervention were also significantly more likely to attempt to quit.[6] Smoking cessation remains a vexing challenge, but this study highlights the significant impact urologists can make in smoking cessation with just a brief intervention.

The combination of physical activity, dietary modifications, and smoking cessation can improve cardiovascular health, but importantly for the urologic population, it can enhance sexual and erectile function. By 2025, the prevalence of erectile dysfunction (ED) worldwide will be over 300 million cases.[7] As a result, targeting modifiable behavioral risk factors for ED is of increasing interest. Esposito et al performed a randomized controlled trial of 110 obese men with ED with the behavioral intervention arm receiving a detailed individualized program to reduce weight by 10% or more through diet modification and increase in physical activity.[8] The intervention included behavior change techniques including goal-setting and self-monitoring with food diaries, in addition to behavioral and psychological therapy.[8] Those in the intervention group had a significant decrease in body mass index, increase in physical activity, and improved sexual function.[8]

There are multiple GU conditions that can benefit from behavioral interventions. There is a paucity of clinical trials in several areas where patient outcomes could improve with leveraging behavioral science. Urologists should work with scientists specializing in behavior change to help improve the impact of behavioral modification interventions on various GU conditions. ■

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CLINICAL TRIALS

Why Is It So Hard to Accrue to Randomized Surgical Trials and What Can Be Done About It?

Andrew Vickers, PhD
Memorial Sloan Kettering Cancer Center, New York, New York

It is getting so hard to accrue to randomized trials in urologic surgery that we have pretty much stopped doing them altogether. This is perhaps most apparent if one visits surgery sessions at the AUA Annual Meeting. The most typical presentation describes how a surgeon changed technique, say from using cautery to an athermal approach, and then compares results before and after the change. Alternatively, researchers may report the results of surgeons who happen to do an operation one way vs those who use an alternative approach. Randomized trials are not unknown, but they are generally so small as to virtually guarantee nonsignificant results. The first 3 trials I saw at AUA2023 had sample sizes of 120, 40, and 146, and none had significant results. The third trial had such low statistical power, the chance of a significant result was the same for an effective as for an ineffective treatment.

The advantages of randomized trials over observational studies do not warrant repeating here. What does need reemphasizing is that, if observational studies are unreliable, and if the evidence base of much urological surgery comprises observational studies, then the evidence base of much urological surgery is unreliable.

I can't say that I blame urologists for the current dire state of affairs. The problem is that the sort of randomized trial methodologies that have become common in recent years are no longer appropriate for urological research. Trials have become extremely complex, with dozens of eligibility criteria, multiple end points, and an overwhelming regulatory burden. As such, the cost per patient is very high, $25,000 or more. Moreover, it is increasingly hard to get patients to consent to trials, at least in part because they are so complex. Patient consent forms are now often 20 pages or longer, despite clear data that the longer the consent form, the less patients understand.[1] Patients who don't understand trials don't go on them.

These problems are redoubled because we expect only small differences between alternative surgical approaches and therefore require very large trials. If a urological procedure has, say, a 25% adverse event rate, and we think a surgical modification would reduce risk to 20%, the sample size would be 2,000. I doubt that any funding body would be interested in contributing the $50 million required for a trial of, say, fascial sparing vs conventional radical prostatectomy, and it would be hard to find 2,000 patients willing to take part.

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WHY IS IT SO HARD TO ACCRUE TO RANDOMIZED SURGICAL TRIALS

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At Memorial Sloan Kettering Cancer Center (MSKCC), we take 2 approaches to allow randomized trials in urology and other surgical areas. The first is dramatic trial simplification. Instead of 50, 70, or even 100 eligibility criteria,[2] we generally have no more than 3 or 4. Indeed in some trials we have only a single criterion based on the uncertainty principle[2]: if the doctor is uncertain which of 2 procedures is best, then the patient is eligible to be randomized between them. We also reduce the number of research tests, end points, visits, and questionnaires, generally to zero, using instead data taken in routine care. The principle is, "If a researcher wants to know it, a doctor should want to know it." As a researcher, I need to record whether a particular patient on a trial has recurred. But the patient's urologist will also want to know about the recurrence in order to consider salvage treatment. We have described this approach as a "clinically integrated randomized trial"[3] because the clinical experience of the patient and provider are almost identical, irrespective of whether the patient is on or off study.

Once we have simplified trials, we then take a patient-centric approach to lower barriers to accrual. This is partly achieved directly by trial simplification: we can tell patients that, if they agree to take part, they won't have to do any additional tests, procedures, appointments, or questionnaires. But we add 2 other tweaks to randomization. The first is to randomize the doctor, not the patient. The doctor will use one approach for a period of, say, 3 months, then switch for a few months, and then switch back. We have found that patients feel very comfortable hearing: "I will evaluate you and decide what is in your best interests. Only if I'm really not sure, I'm truly 50:50 on the best approach, will I do what the computer recommends." This is in some distinction to "I'm going to flip a coin to decide what treatment to give you." The second alternative to traditional randomization is called "2-stage consent." Just as it sounds, this breaks up consent into 2 stages. In the first stage, patients are told that the hospital is conducting research, asked for consent about data collection and then told that, if they agree, their name will be "put in a hat" and they may be randomly selected to hear about a novel treatment approach. Patients who consent are then randomized. Those randomized to the control group are not contacted further; those randomized to the experimental arm then undergo a second consent where they are told about the new treatment and asked if they would like to try it (and if not, due to the intent-to-treat principle, they are analyzed in the experimental arm irrespective of their answer). We have demonstrated that 2-stage consent is highly acceptable to both patients and doctors, maintains excellent understanding of consent and has a low refusal at second-stage consent.[4] One doctor told us, "I'm never going back to traditional consent, ever."

Using these methodological approaches, MSKCC has completed 7 single-center randomized trials, with several more underway and accruing rapidly. Only 1 trial was externally funded. Total accrual is approaching 10,000, including several large trials in radical prostatectomy[5,6] and nephrectomy.[7]

There is little doubt that the US clinical trial system is shuddering to a halt, especially for surgical trials. At MSKCC we have shown that simple modifications to the traditional approach are possible and can dramatically improve clinical trials. ■

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PROSTATE CANCER

Approaching Rural-Urban Prostate Cancer Disparities Through Mixed-methods Research Design

Michael G. Stencel, DO
Charleston Area Medical Center, West Virginia

Benjamin J. Davies, MD
University of Pittsburgh Medical Center, Pennsylvania

Lindsay M. Sabik, PhD
University of Pittsburgh, Pennsylvania

Kimberly J. Rak, PhD
University of Pittsburgh, Pennsylvania

Bruce L. Jacobs, MD
University of Pittsburgh Medical Center, Pennsylvania

Not all men with prostate cancer receive the same level of care. Addressing the chasm between the best and worst outcomes has been a major focus of disparities research for decades and has revealed underlying social determinants that are associated with prostate cancer outcomes. For example, Black men present with advanced or metastatic prostate cancer more often than White men, but when socioeconomic factors are controlled for, stage disparities are diminished.[1] Likewise, underinsured men with prostate cancer tend to have higher stage and worse outcomes.[2] Equally compelling, however, is the urban-rural divide among men with prostate cancer. Rural men are less likely to receive definitive care and have poorer outcomes compared to their urban counterparts.[3,4] Identifying barriers to care and levers for improvement is essential for quality care delivery.

Urban-Rural Prostate Cancer Disparity

There are many potential reasons why men with prostate cancer living in rural locales tend to have worse outcomes compared to their urban equivalents, including increased travel distance, less robust preventive care, and treatment delays.[3] Another major barrier is a lower per capita concentration of urologists in rural areas. Despite the existing underabundance, even fewer young urologists are choosing to practice in rural areas, which will exacerbate the rural urologist shortage in the future.[5] Rural physicians face

> "Identifying barriers to care and levers for improvement is essential for quality care delivery."

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APPROACHING RURAL-URBAN PROSTATE CANCER DISPARITIES

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unique challenges when providing care. A recent study investigated barriers to rural health care by interviewing providers and identified cost, geographic dispersion, and provider shortages as the most significant barriers to providing care to rural residents.[6] Despite a relatively small body of qualitative literature in prostate cancer, this study is an example of how qualitative research can yield fruitful data, especially when examining rural cancer disparities.

Relative Strengths of Quantitative and Qualitative Methods

The strengths of quantitative and qualitative methods complement each other well. Quantitative methods strengths include the ability to answer questions about rare diseases and effects of an intervention, and produce broadly generalizable, concrete data. The vast majority of existing literature utilizes some form of quantitative data from sources such as electronic health records, insurance claims, or cancer registry databases. Yet, quantitative data lack the depth of qualitative data and are limited by the rigidity of predetermined variables and numeric output. On the contrary, qualitative methods are not limited by these constraints and are well suited to characterize experiences, attitudes, and perspectives. Qualitative methods exist on a spectrum that may include large focus groups down to 1-on-1 semistructured interview, any of which is inherently nimble and allows latitude for the interviewee to provide unanticipated feedback, or interviewer to explore a response in greater detail. Qualitative approaches leverage open-ended questions to provide highly detailed information and opinions.

Applying Qualitative Methods to Address Rural Disparities

Qualitative methods applied to urban-rural disparities in prostate cancer might revolve around barriers to prostate cancer screening, treatment, or survivorship. They could be structured as focus groups or 1-on-1 interviews to discuss differences in perceptions between treatment options and concern for treatment side effects.[7] During data gathering, the flexibility to explore interesting or unexpected themes as they emerge is a major strength of qualitative designs. For example, an ongoing qualitative study on the impact of rurality for men referred for prostate cancer at the University of Pittsburgh Medical Center has revealed travel distance and financial considerations as major themes, but also finds that barriers may be mitigated by reputation and referring provider recommendation. In this way, qualitative research can generate hypotheses.

Mixed Is Better

Imagine layering the strengths of quantitative data, along with the ability to assign context, perspective, and meaning. Incorporating both approaches, mixed methods provides a depth of understanding greater than either approach by itself. There are 3 basic approaches to mixed methods (see Figure)[8]: (1) exploratory sequential, where qualitative data are collected first, and then support quantitative approaches, (2) explanatory design, which begins with quantitative data that refine subsequent qualitative methods, and (3) convergent approach, where quantitative and qualitative approaches occur simultaneously. The research question should dictate the approach, but any approach will allow the investigator to pursue emerging and unanticipated questions and is inherently flexible, repeatable, or redirectable.

Virtually any research question can be addressed using mixed methods study design. For example, a group investigating treatment preferences for men with metastatic prostate cancer utilized an exploratory sequential design where small group sessions identified several themes that were then used to design a survey to explore treatment preferences within a larger cohort.[9] Mixed methods design is uniquely suited to address urban-rural differences among men with prostate cancer because it not only can identify quantitative data, but also can incorporate valuable patient and provider perspectives. In this way, mixed methods can provide more robust data than either method alone. Despite the advantages of mixed methods, it requires expertise in both qualitative and quantitative methods, which likely has curbed more ubiquitous use. A best practice statement was issued in 2011 by the National Institutes of Health that underscored the importance of mixed methods to address future health problems and improve scientific power and quality of data.[10] Disparities among men with prostate cancer, including urban-rural differences, remain an area ripe for the application of mixed methods.

Much is needed to bridge the gap between men who experience the best and worst outcomes. Blending qualitative and quantitative methods is an effective tool researchers should wield to combat pervasive prostate cancer disparities. ■

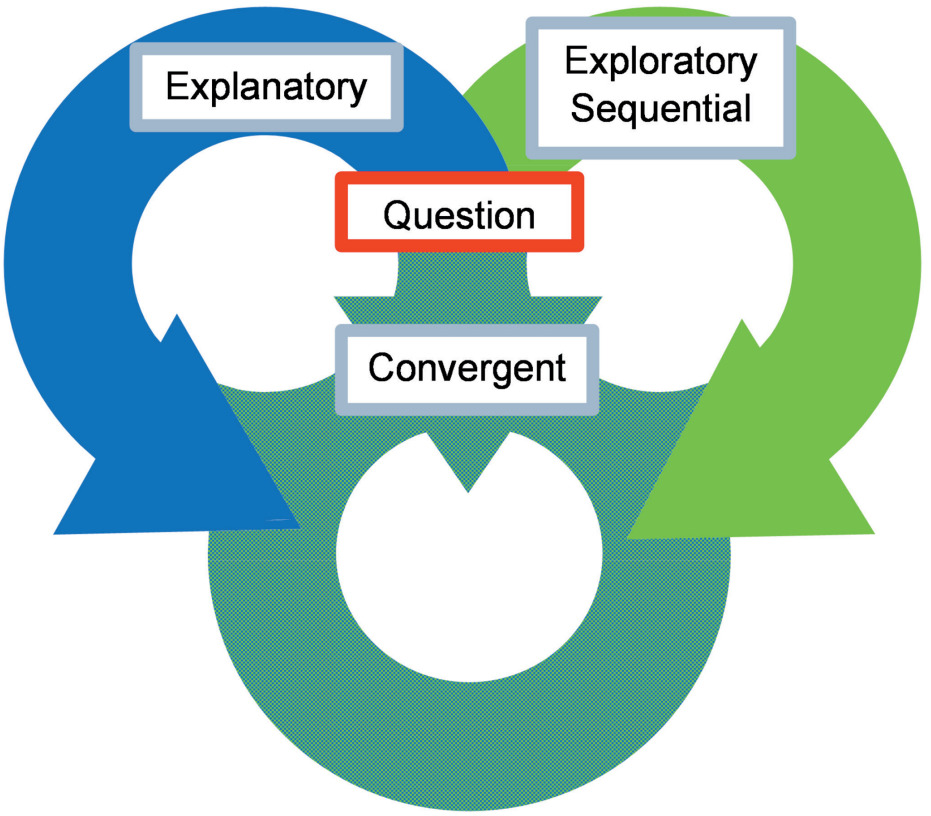

Figure. Diagram illustrating the interrelatedness of each mixed methods approach. From a central research question, any of the 3 approaches may be employed. As the study progresses, the previous method may provide feedback for a different approach. Green arrow indicates qualitative methods (exploratory sequential), blue arrow indicates quantitative methods (explanatory), while blue/green checkered arrow indicates simultaneous mixed methods (convergent).

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Palliative Care and Urology

John N. Cabri, MD
The David Geffen School of Medicine at UCLA, Los Angeles, California

Jonathan Bergman, MD, MPH
The David Geffen School of Medicine at UCLA, Los Angeles, California
Los Angeles County Department of Health Services, California
Veterans Health Administration Greater Los Angeles, California

Palliative care is an interdisciplinary approach to managing patients with advanced disease, with a focus on quality of life, symptom and pain control, and assessment of patient and family goals. Early consultation with palliative care among individuals with advanced disease carries enormous benefits to patients, families, and health systems. Patients live longer and have improved symptom control and quality of life. Families benefit from higher satisfaction with care and lower caregiver distress. Due to better communication between providers and patients and their families, unnecessary health care utilization and cost of care are reduced dramatically. Due to these benefits, organizations including the National Academy of Medicine, the World Health Organization, the American Society of Clinical Oncology, and the AUA (among others) recommend early palliative care for patients with advanced disease. However, the palliative care workforce is insufficient to support the full range of patient needs.[1-4] These shortages are expected to worsen over time, as increased palliative care specialist training is unlikely to maintain pace with the aging population. Underserved populations have less reliable access to palliative care, exacerbating their disparities in advanced disease outcomes.[5]

As a clinical specialty, urology is well positioned to lead efforts at improving palliative care use among patients with advanced urological health conditions. The relationship between a patient and their urologist is often deeper and more intricately woven than with most other practitioners. A man with advanced stage prostate cancer, for instance, has known his urologist for an average of 13 years; a woman with advanced voiding dysfunction has likely been cared for by her urologist for several decades.[6,7] Although the palliative care needs of urological patients are substantial, the breadth of patients needing palliative care support vastly exceeds the capacity of the current palliative care workforce.[4,8]

Against this backdrop of palliative care needs and challenges, the AUA focused its 2021-2022 Quality Improvement Summit on Opportunities to Improve Palliative Care in Urology. The summit brought together a diverse panel of experts from urology, palliative care, broader surgical specialties, psychiatry, nursing, social work, and pain management to discuss a variety of topics, including management of the disease course of individuals with advanced urological diseases, identification of the aspects of palliative care services that can be efficiently and efficaciously offered in a urology practice, overview of the current palliative care workforce, and development of a health services and educational agenda that advances urologist–palliative care partnerships. Through the conference, urologists from across the country delineated how a urology-centered primary palliative care intervention could be structured and what implementation barriers would need to be removed. The AUA buttressed the palliative care model in urology by incorporating it into our profession's Core Curriculum and creating a dedicated teaching slide set.

The conceptual model for how urologists could pioneer creation of an implementable, scalable model of primary palliative care is shown in the UroPal figure (Figure 1). The team of interdisciplinary providers includes urologists, oncologists, primary care providers, nurses, chaplains, geriatricians, social workers, palliative care providers, psychiatrists, and nurses, with a urologist at the hub

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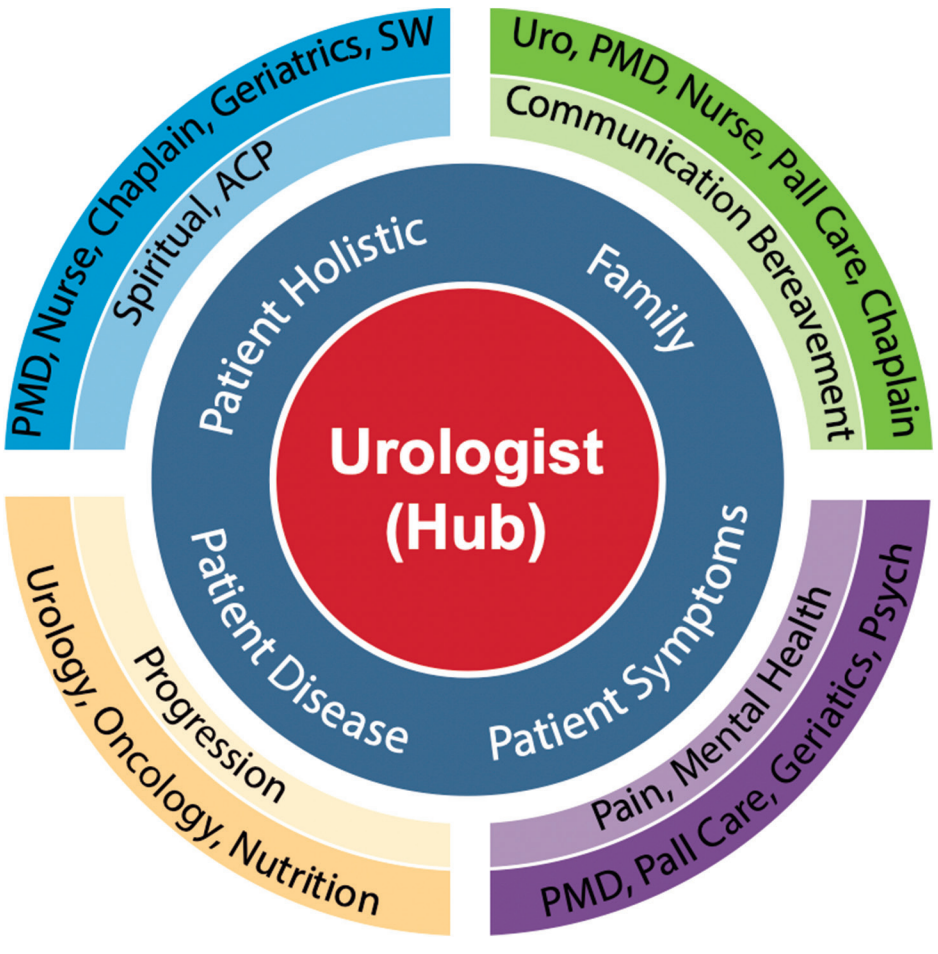

Figure 1. UroPal conceptual model. ACP indicates advance care planning; PMD, primary medical doctor; Psych, psychiatry; SW, social work.

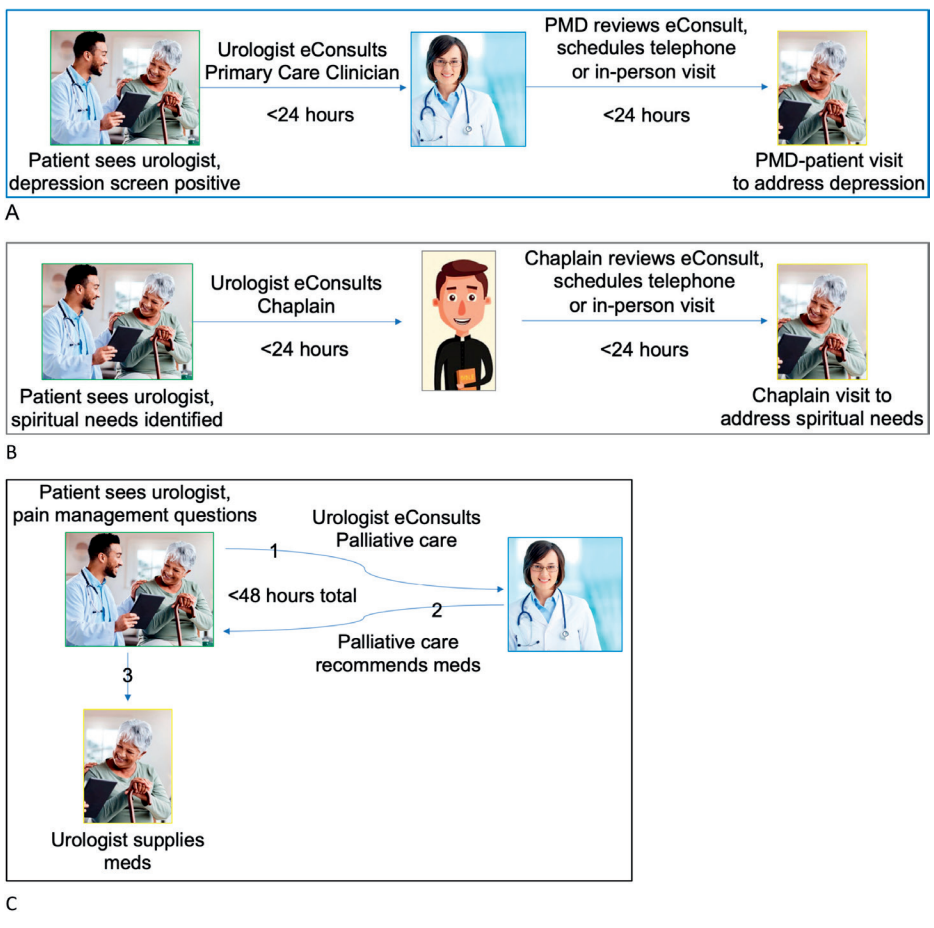

Figure 2. eConsult integration of UroPal. A-C, Examples of eConsult-mediated interdisciplinary care. PMD indicates primary medical doctor.

PALLIATIVE CARE AND UROLOGY

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of care as the "quarterback." To connect the care hub with spoke providers, platforms like electronic consultation (eConsult) could be used to enable communication among providers and with patients and families. eConsult within an integrated system has been successfully deployed in the Los Angeles County Department of Health Services, where it maximized efficiency and effectiveness while improving access to urological care.[9] Instituting a similar framework, as shown in Figure 2, may help urologists achieve a successful primary palliative care model. Everyone agrees that targeted palliative care is essential; urologists are uniquely positioned to achieve what, to date, has remained aspirational. ■

Conflict of Interest Disclosures: None.
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Robotic Pyeloplasty in Infants for Ureteropelvic Junction Obstruction: Is It Time for a New Gold Standard?

Victor H. Figueroa, MD, MHPE
Clinica FOSCAL, Bucaramanga, Colombia

Nicolas Fernandez, MD, PHD
Seattle Children's Hospital, Seattle, Washington

Ana Maria Ortiz-Zableh, MD
Clinica FOSCAL, Bucaramanga, Colombia

Andres Felipe Quiñones, MD
Clinica FOSCAL, Bucaramanga, Colombia

The gold-standard for the treatment of ureteropelvic junction obstruction in the pediatric population has historically been the Anderson-Hynes dismembered open pyeloplasty described in 1949.[1] However, there has been technological advantages with minimally invasive surgery in recent years, both in laparoscopy and robotic-assisted surgery, allowing these approaches to be comparable in efficiency and safety when compared to the gold standard. Advantages of minimally invasive surgery over open surgery in reducing postoperative pain and hospital stay in many cases, and improving aesthetic results as well, have been reported.[2]

The first laparoscopic pyeloplasty in pediatrics was described in 1995 by Peters et al.[3] It has been confirmed as a safe and effective procedure, but surgically demanding due to the requirement of intracorporeal suturing, reduced intraperitoneal space (1 liter), surgeon ergonomics, and a steep learning surgical curve.[4] It was not until the DaVinci robotic surgery system was launched on the market in 2002 that the surgical technique of robot-assisted pyeloplasty began to be widely used, with the first series of cases described in 2006 by Lee et al.[5] Since, it has become the most common urological robot-assisted surgical procedure in the pediatric population, with a very high success rate (95%-100%).[4,6,7] Initially this procedure had been recommended for patients older than 18-24 months and more than 10 kg due to its limited intraperitoneal space.[8] However, thanks to an increase in robotic surgical expertise some authors have suggested this surgery could be performed safely in younger children.[9] Some authors have performed a robotic approach in patients as young as 3 months old, but a minimum age limit has not been defined.[10]

In order to define in which infants this approach is feasible, Finkelstein et al,[2] in a very interesting publication, reviewed 45 infants between 3 to 12 months old that underwent robot-assisted interventions, either for upper or lower urinary tract pathology. Their work consisted in measuring the distance between the anterior superior iliac spines (ASIS), and the puboxyphoid distance (PXD) in the preoperative assessment. Subsequently, recording the number of robotic arms collisions during the surgery was registered. They found that there were fewer collisions in patients with an ASIS distance greater than 13 cm ($P < .001$) and a PXD distance greater than 15 cm ($P < .001$; Figure 1) Dr Peters considers it critically important to have a constant mental image of the instrument dynamics within the body as well as outside to properly perform the procedure,[9] and so the ASIS and PXD measures are a useful guide that can help define the feasibility of the approach.

More precise movements in small working spaces, surgical field magnification, reduction of tremor, and three-dimensional optics are the classic arguments reported by most surgeons that support robot-assisted surgery.[11] It is the authors' opinion that robot-assisted surgery's advantage in infants is the ability to perform a reconstructive procedure in situ. The ability to perform the anastomosis without distorting the anatomy that is otherwise required when the pelvis and ureter have to be externalized during open surgery avoids leaving the anastomosis at a nondependent location and it reduces the chances of missing a crossing vessel (although rare, we have seen infant cases due to crossing vessels) and malrotated kidneys to leave the anastomosis in a location that will continue to be compressed. Based on our experience with inanimate models, we have been able to improve the efficiency in small robotic cases without compromising the efficiency and safety during these procedures. Lombardo et al[12] shared their results of 44 patients under 1 year who underwent robotic pyeloplasty between 2010 and 2021. Their success rate was 100% at 19 months of follow-up

"Some authors have performed a robotic approach in patients as young as 3 months old, but a minimum age limit has not been defined.[10]"

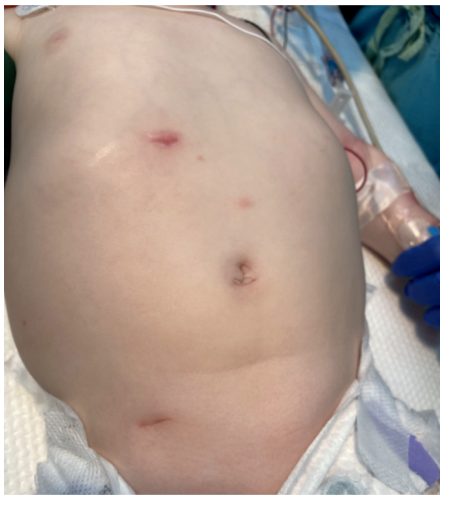

Figure 1. Four-month-old male and 8.5 kg. Incisions after robot assisted pyeloplasty. Distance between ports was 4 cm. Procedure performed with Da Vinci XI system.

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ROBOTIC PYELOPLASTY IN INFANTS FOR URETEROPELVIC JUNCTION OBSTRUCTION

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with postoperative complications in 7 patients (15.6%), mainly urinary tract infections. Interestingly, the advantages of this technology seem to stand out compared to an open approach in challenging reconstruction cases with complex anatomy, such as duplex collecting systems, redo cases, ectopic kidneys, horseshoe kidneys, renal malrotation, and long ureteral strictures.[13] In our experience, we have a cohort of 48 robot-assisted pyeloplasties compared to open pyeloplasties. Demographics are described in Table 1. In our cohort, operative times did not show a statistical difference between the two arms (Figure 2, A). A similar trend was seen for length of stay and pain scores (Figure 2, B and C). One interesting area our group has been working on is improving nonoperative times to reduce costs and improve efficiency. Our protocol for robot-assisted surgery demonstrated shorter in-room times by reducing the nonoperative time (Figure 3). This can be the way to reduce the known high costs of robot-assisted surgery along with other measures.

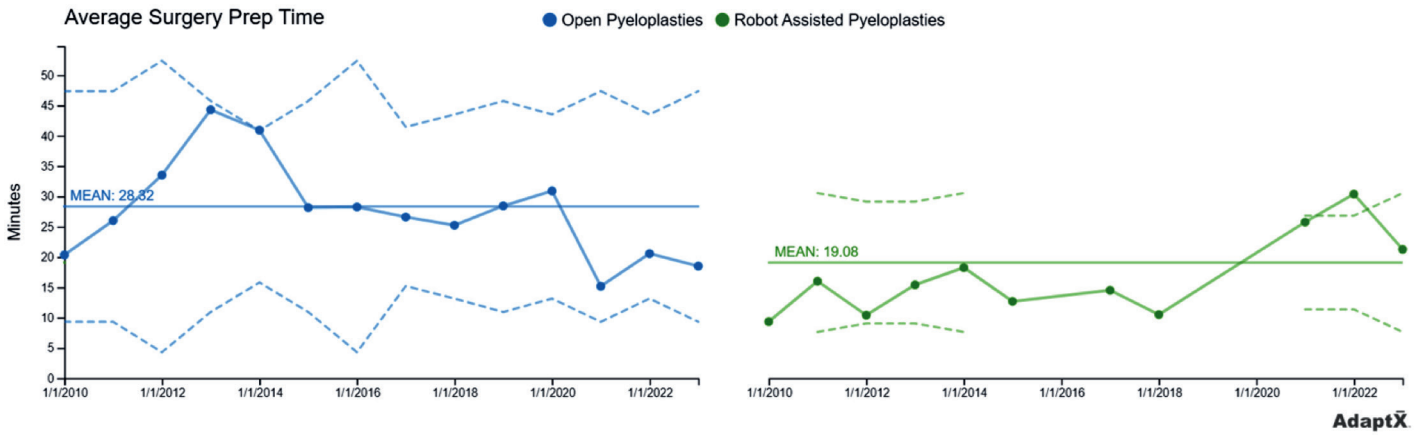

Figure 3. Comparison of average surgery prep time between open pyeloplasty and robot-assisted pyeloplasty.

However, this ever-growing technology presents some potential drawbacks associated with higher costs to the health system related to equipment, its maintenance, and materials.[12,14,15] It is also important to note that the robot is not available in all pediatric centers and, unfortunately, not all pediatric urologists are trained in robotic surgery, especially in developing countries. Pediatric urology fellowship programs should develop standardized robotics training curricula or protocols.[13] The surgical competence in robotic-assisted pyeloplasty has not yet been defined. In adults, robotic pyeloplasty requires an average of 77 cases to acquire the learning

> "Lombardo et al[12] shared their results of 44 patients under 1 year who underwent robotic pyeloplasty between 2010 and 2021. Their success rate was 100% at 19 months of follow-up with postoperative complications in 7 patients (15.6%), mainly urinary tract infections."

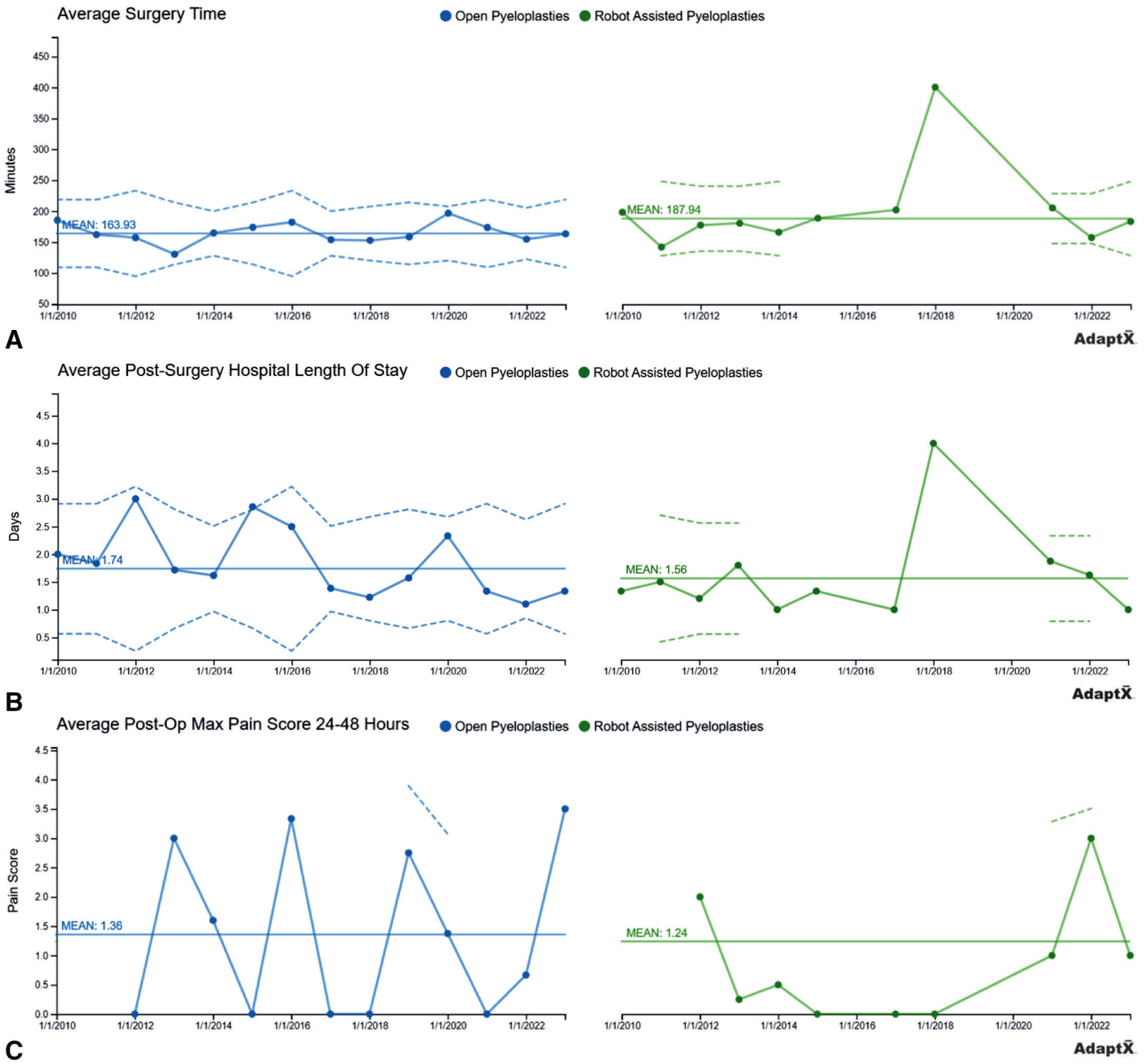

Figure 2. Comparison of average surgery time (A), average postsurgery hospital length of stay (B), and average post-op max pain score 24-48 hours (C) between open pyeloplasty and robot-assisted pyeloplasty.

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ROBOTIC PYELOPLASTY IN INFANTS FOR URETEROPELVIC JUNCTION OBSTRUCTION

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Table. Demographics of Children Who Underwent Robot-assisted Pyeloplasties and Open Pyeloplasties

Characteristic	Open pyeloplasties (N=107)	Robot-assisted pyeloplasties (N=48)
Demographics		
Patient birth sex, No. (%)		
Male	77 (71.96)	34 (70.83)
Female	30 (28.04)	14 (29.17)
Patient age, mo	3.25 (0-12)	4.5 (0-12)
Patient weight, kg	7.97 (4.08-15.08)	8.97 (5.46-13.1)
ASA score, No. (%)		
2	84 (78.5)	31 (64.58)
1	15 (14.02)	16 (33.33)
3	8 (7.48)	1 (2.08)
Patient race and ethnicity, No. (5)		
Non-Hispanic White	53 (49.53)	22 (45.83)
Hispanic	23 (21.5)	8 (16.67)
Asian	7 (6.54)	6 (12.5)
Unknown/refused	7 (6.54)	6 (12.5)
2 or more races	4 (3.74)	4 (8.33)
Other	13 (12.15)	2 (4.17)
Blocks, No. (%)		
Block type		
None	42 (39.25)	31 (64.58)
Peripheral block	42 (39.25)	10 (20.83)
Centroneuraxis block	24 (22.43)	8 (16.67)

Abbreviations: ASA, American Society of Anesthesiologists.

curve.[16] Currently, in most training hospitals, the acquisition of robotic skills depends mainly on the availability of an experienced surgeon to act as a mentor to properly guide the trainee until he becomes competent.[13] Evidence has shown that the learning curve in robotic surgery is shorter compared to laparoscopy. A study by Liu et al[17] indicated that at least 18 cases were required to achieve proficiency in laparoscopic pyeloplasty, compared with 13 cases for the robotic approach. Other authors have suggested that experienced surgeons should perform at least 25-50 robotic-assisted pyeloplasties in young children or adolescents before performing this procedure in an infant.[18]

Almost a decade has passed since the introduction of robotic-assisted pyeloplasty in infants. This procedure has proven to be a feasible and safe procedure with a similar success rate to open pyeloplasty and has been rapidly adopted by many pediatric urologists around the world to treat upper tract congenital malformations in infants due to its advantages with visualization and magnification of the surgical field and tissue manipulation. Although the question of whether robotic pyeloplasty is the new gold standard in infants will remain for now, it is clear that the better role of robotic-assisted surgery extends to cases where open and laparoscopic approaches have met their limitations in complex reconstructive cases. ■

> "The ability to perform the anastomosis without distorting the anatomy that is otherwise required when the pelvis and ureter have to be externalized during open surgery avoids leaving the anastomosis at a nondependent location and it reduces the chances of missing a crossing vessel (although rare, we have seen infant cases due to crossing vessels) and malrotated kidneys to leave the anastomosis in a location that will continue to be compressed."

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Primary Question: How Has the Average Number of Radical Prostatectomies Performed by Urologists Changed Over Time?

Daniel J. Lee, MD, MS
University of Pennsylvania, Philadelphia

Hung-Jui Tan, MD, MSHPM
University of North Carolina at Chapel Hill

Raymond Fang, MSC, MASC

Rachel Mbassa, MPH
University of California, San Francisco

Richard Matulewicz, MD, MSCI
Memorial Sloan Kettering Cancer Center, New York, New York

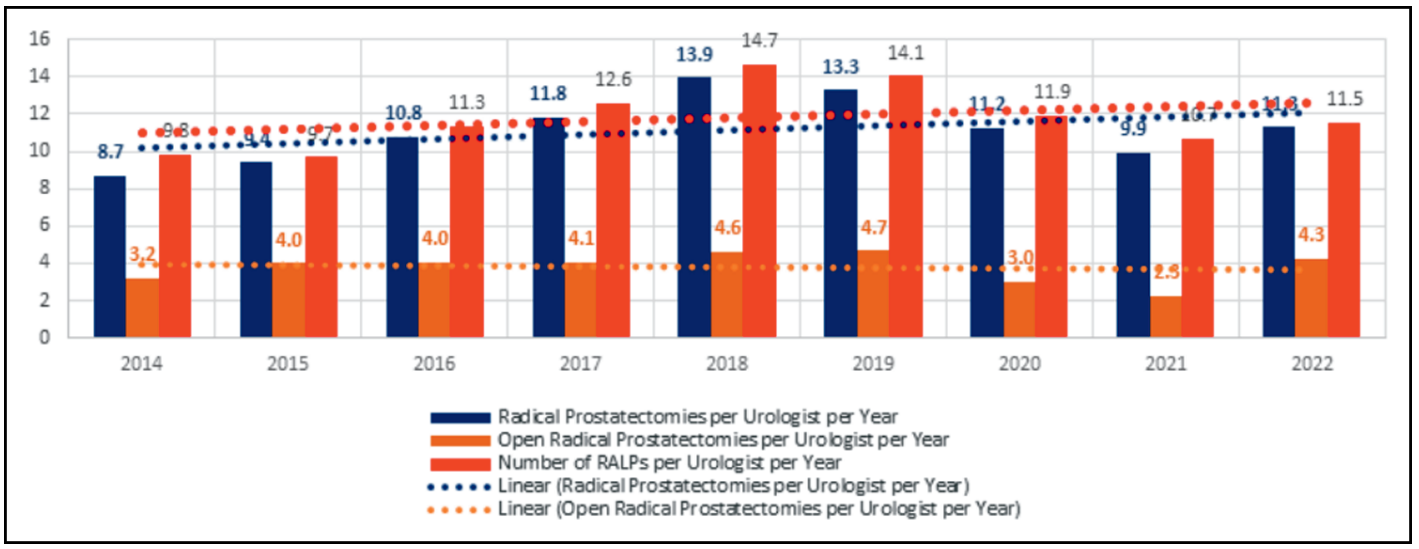

Figure. Number of robotic vs open radical prostatectomies per urologist per year. RALP indicates robotic-assisted laparoscopic prostatectomy.

Although many aspects of the radical prostatectomy have changed over the past 40 years,[1] it remains a complex and challenging procedure. Many studies have demonstrated that more extensive surgical experience and higher prostatectomy volumes are associated with better overall survival, fewer complications, and improved patient functional outcomes.[2-4] Yet, a prior assessment found that the majority of surgeons performing radical prostatectomy in the US did less than 10 of them each year.[5] Many things have changed over the past 10 years, including the utilization of advanced imaging to detect metastatic disease, broadened criteria for active surveillance, widespread diffusion of robotic surgery, and changing prostate cancer screening recommendations. However, the current practice patterns of radical prostatectomy have not been well characterized, and real-world evidence of contemporary national trends is lacking.

We sought to evaluate the average number of radical prostatectomies performed per surgeon per year over time. Using the AUA Quality (AQUA) Registry, we measured the proportion of robotic-assisted laparoscopic prostatectomies compared to open radical prostatectomies (ORP) performed per urologic surgeon per year. Surgeons were included if they performed at least 1 prostatectomy and had more than 10 separate outpatient encounters in the corresponding year in the AQUA Registry from 2014-2021.

Over the 8-year period, the average number of radical prostatectomies per year remained relatively steady, ranging from 8.7-13.9 prostatectomies per surgeon per year (see Figure). The average number of ORP per surgeon has also remained relatively steady, ranging from 2.3-4.7 ORP per surgeon per year. In our cohort of surgeons in the AQUA Registry, the proportion of surgeons performing open vs robotic prostatectomies has declined every year, from 46% in 2014 to 23% in 2021. With respect to volume, 60% of urologists performing a radical prostatectomy will do fewer than 5 prostatectomies per year, and 30% will do only 1 prostatectomy per year. Only 20% of surgeons in the AQUA Registry performing prostatectomies do 15 or more prostatectomies per year. The percentage of prostatectomies performed per year with a robotic approach compared to the total number of prostatectomies increased from 83% in 2014 to 94.8% in 2021.

There are several notable findings from this analysis. First, the large majority of urologists performing prostatectomies have low annual volumes. These data confirm and expand on the study by Savage et al,[5] which looked at data from a single year in 2005 in New York State, whereas the AQUA Registry provides data from more than 200 practices and 2,100 urologists around the country. Second, there has been a dramatic decrease in the proportion of AQUA urologists performing ORP during the study period. Potentially hastened by the retirement of older surgeons during the COVID-19 pandemic, this decrease likely reflects a more general trend since the adoption of robotic surgery. While robotic-assisted laparoscopic prostatectomy accounts for 80%-90% of all prostatectomies performed in this nationwide quality data registry, the percent of surgeons still doing ORP has dropped significantly and continues to decrease. This change in practice patterns has significant implications on access to surgeons comfortable with open procedures, residency training, and competency as robotic procedures become more prevalent in residency, and health care policy, where the constant pressures to improve outcomes and efficiency need to consider regionalization and reduced access. Although our analysis is limited by potential selection bias for only those urologists included in the AQUA Registry, this is the largest national quality registry in urology across multiple geographic and practice settings. Future analyses with the AQUA Data Registry will examine how these trends vary by region and surgeon characteristics and ultimately impact patient –outcomes. ■

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X-Ray Safety for the Endourologist

Kevin Morgan, MD
University of Florida, Gainesville

Benjamin K. Canales, MD
University of Florida, Gainesville

Russell Terry, MD
University of Florida, Gainesville

Introduction

Imaging studies that utilize ionizing radiation are essential in the diagnosis and treatment of a variety of urologic conditions. With kidney stone disease increasing worldwide, endourological procedures utilizing fluoroscopy will undoubtedly continue to be performed in increasing numbers. While most radiation generated by fluoroscopy is either absorbed by the patient or reaches the image detector, ~0.1% of emitted x-rays "scatter" to be absorbed by the urologist or nearby staff. Occupational standards recommend doses of no more than 5 rem (50 mSV, or ~75 KUBs) to the entire body and 50 rem (500 mSV, ~50 CTs) to a single organ annually.[1] Numerous nonmalignant (cataracts, arthropathy) and malignant (lymphoma, leukemia, etc) conditions have been linked to ionizing radiation.[2] Endourologists must therefore understand the potential harm of occupational radiation exposure and implement strategies to mitigate or eliminate it during these procedures.

ALARA

ALARA (As Low As Reasonably Achievable) principles are designed to limit radiation exposure to patients and medical staff. They are divided into 3 categories: minimizing fluoroscopy time, maximizing distance away from the radiation source, and shielding. Of all these, minimizing fluoroscopy time is reported as the most effective means of reducing radiation exposure.[2] Strategies to mitigate ionizing radiation are summarized in the Table.

Fluoroscopy Unit Components and Settings

Fluoroscopy units emit x-ray beams from the x-ray tube (Figure 1). By ensuring the tube is underneath the patient, urologists can minimize radiation exposure to their head and upper torso. The image intensifier (or detector) captures x-ray beams and converts them into an image to be displayed on the monitor. Positioning the image intensifier as close as possible to the patient will improve the quality of the image and reduce the necessary radiation dose (Figure 2). The collimator uses apertures (varying size holes) to determine the shape and size of the x-ray beam. By partially closing the aperture, collimation reduces the total x-ray dose that leaves the tube and thus, decreases both patient and scattered dose.

Fluoroscopic images can be produced and captured via 2 different modes. Continuous imaging captures ~30 frames per second (fps), while pulsed imaging captures 1-15 fps, thereby decreasing effective fluoroscopy time and absorbed dose. In a prospective study of endourology patients, a change in unit default settings from continuous to pulsed imaging reduced entrance skin dose by over 30%.[3] Two other elements that have been shown to reduce effective fluoroscopy time are use of a laser aiming beam attachment on the intensifier and last image hold, a feature in which the previous fluoroscopic image continues to be displayed on the monitor.[2]

Urologist Factors

To best manage spot fluoroscopy times, the urologist should always employ a user-controlled foot pedal. Furthermore, by simply tracking fluoroscopy time and incorporating this into the operative note, urologists may decrease radiation utilization.[4] While they do not serve a protective role, dosimeters, both badge and ring types, ensure that cumulative radiation exposure is monitored over time.

Distance from the radiation source is another important consideration in radiation safety and should be maximized when possible. According to the Inverse Square Law, which states that radiation intensity is inversely proportional to the square of the distance from the source ($I = 1/d^2$),[2] fluoroscopic radiation exposure decreases by 75% for every doubling of distance from the source. At most relevant fluoroscopy doses, radiation exposure is therefore expected to revert to background noise at a distance of approximately 3 meters from the x-ray source.

Shielding is the last line of defense for the operating room staff within the radiation field. Examples of different protective shields include lead-impregnated eyeglasses, thyroid shields, chest and pelvic aprons, and gloves. Although the tradeoff of a thicker lead apron is a heavier weight, the amount of radiation attenuated by aprons is estimated to be 90% for 0.25 mm thickness, 95% for 0.35 mm, and 99% for 0.5 mm.[5] It is critical to handle and store aprons appropriately so that the lead does not crack, and aprons should be tested regularly to ensure proper shielding.

Table. Strategies for Mitigating Occupational Ionizing Radiation

Fluoroscopy unit settings	Urologist factors	Fluoroscopy alternatives
X-ray tube underneath patient	Control the foot pedal	Ultrasound guidance
Pulsed fluoroscopy with <4 fps	Limit fluoroscopy use and track personal times	Endoscopic guidance (PCNL)
Image intensifier close to patient	Wear dosimeter	Tactile feedback
Last-image hold	Use of laser aiming beam	Visual cues
Narrow field of view with collimation	Wear high-quality, comfortable shielding	MRI (procedures such as cystourethrogram)

Abbreviations: MRI, magnetic resonance imaging; PCNL, percutaneous nephrolithotomy.

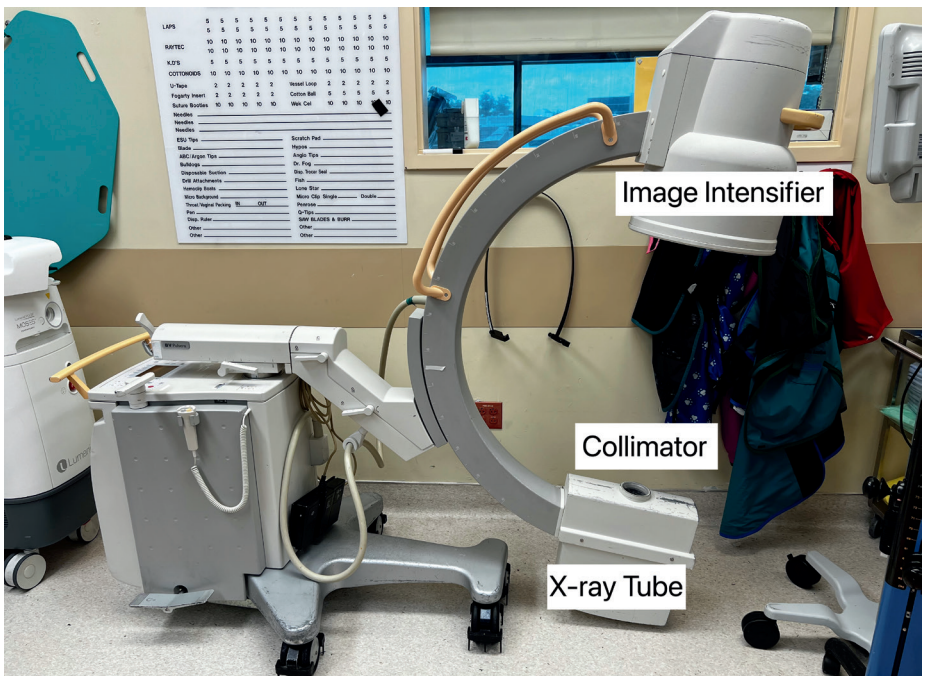

Figure 1. Fluoroscopy unit components. The x-ray tube emits x-rays. The image intensifier captures x-ray beams and converts them into an image. The collimator uses apertures to determine the shape and size of the x-ray beam.

Fluoroscopy Alternative Strategies

A variety of techniques have been described to reduce or eliminate fluoroscopy from procedures that have traditionally relied on it. Hsi and Harper described a zero-dose fluoroscopy technique for ureteroscopy utilizing tactile feedback and visual cues for ureteral access.[6] Although incurring more cost, endoscopic guided percutaneous nephrolithotomy (PCNL) access may reduce fluoroscopy time when compared to conventional PCNL access. Surgeon-directed renal ultrasound is a well-established radiation-free imaging modality for guiding percutaneous renal access during PCNL

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X-RAY SAFETY FOR THE ENDOUROLOGIST

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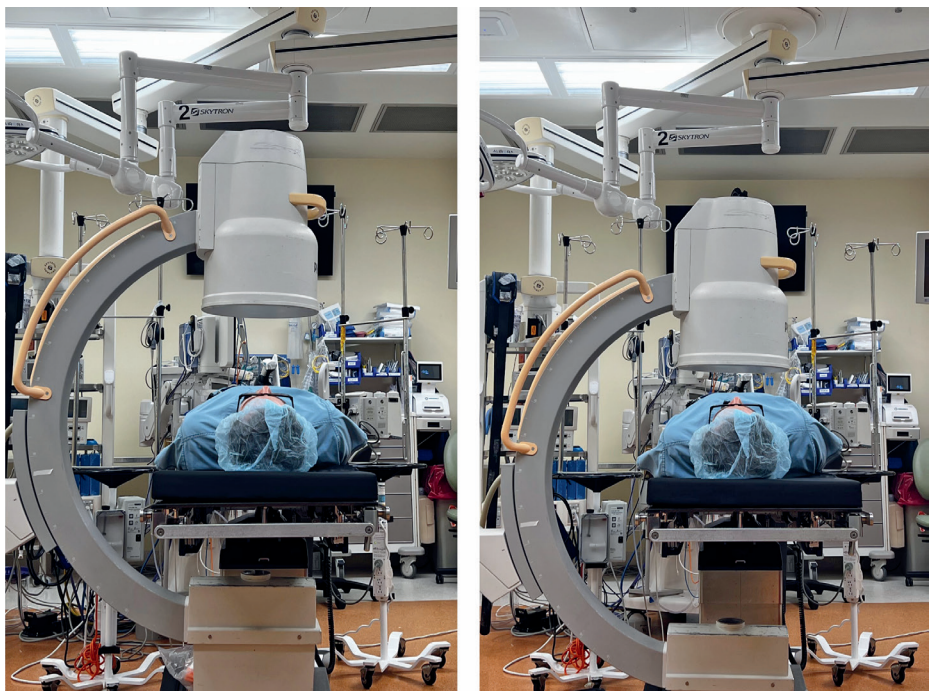

Figure 2. A, The image intensifier is positioned well above the patient, and the x-ray tube is close to the patient. This will result in a higher absorbed dose and a lower quality image. B, The image intensifier is positioned closer to the patient, and the x-ray tube is well below the patient. This will result in a lower absorbed dose and a higher quality image.

as well as ureteroscopy and stent placement. MRI, while unlikely to replace fluoroscopy for most image-guided procedures, holds some promise in cystourethrography and is replacing fluoroscopic-guided procedures outside the field of urology (ie, conventional angiograms, defecography).

Adherence to Radiation Safety

Despite the known risks of radiation exposure, ALARA principles are not always followed by urologists. In a survey of Endourology Society members, while 97% of respondents wore lead aprons, only 68% wore thyroid shields, 34.3% wore dosimeters, and 17.3% wore lead-impregnated glasses.[7] Surveys have suggested that American Urology trainees are not adequately trained in radiation exposure safety.[8] Recently, a radiation safety training program implemented in a urology residency program was shown to reduce fluoroscopy time by 56%.[9] Virtual reality simulation training for urology trainees was also shown to reduce fluoroscopy time in PCNL.[10]

Conclusion

As the leaders in the operating room or clinic, urologists must understand the potential hazardous effects of ionizing radiation and work to mitigate these risks for their staff. ALARA principles may be adhered to by optimizing fluoroscopy unit settings, limiting fluoroscopy time, shielding, and implementing procedure-specific fluoroscopy alternatives. ■

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POINT-COUNTERPOINT

Posterior Urethral Stenosis After Prostate Cancer Radiotherapy, What Is the Best Perineal Approach: Transecting Anastomotic vs Dorsal Buccal Inlay

Bryan Voelzke, MD, MS
Spokane Urology, Washington

Transecting anastomotic posterior urethral stenosis following prostate cancer radiotherapy is an unfortunate outcome in the field of urologic reconstruction. The delayed impact of radiation-induced tissue ischemia and vascular insufficiency negatively impact surgical reconstruction outcomes and require careful consideration regarding optimal surgical candidates. Limited bladder capacity (<200 mL), concomitant radiation cystitis, pubic osteomyelitis, and/or dystrophic prostatic urethra calcification are considered absolute contraindications for surgical reconstruction in my practice. Concomitant stress urinary incontinence requires special counseling and can impact objective and subjective surgical outcomes. Most patients are at an advanced age with potentially complex medical issues that can also impact candidacy for surgery. Consideration of all these variables is necessary before proceeding with surgical reconstruction.

Transecting anastomotic urethroplasty has historically been considered the definitive method of surgical reconstruction. A concern of transecting anastomotic urethroplasty, though, is the impact of urethral transection on immediate/delayed tissue vascularity. Subsequent surgical approaches for radiated urethral stricture patients have been published to address this concern. These include antegrade robotic transvesical buccal graft inlay, antegrade YV bladder neck reconstruction, perineal dorsal buccal graft urethroplasty, and perineal ventral buccal graft urethroplasty with gracilis interposition muscle flap.[1-3] Antegrade approaches can reduce iatrogenic stress incontinence among select postradiation patients with an intact external urinary sphincter and bladder neck stenosis (ie, antegrade robotic approaches for the post-transurethral resection of the prostate radiated patient with bladder neck stenosis).

I have continued to employ transecting anastomotic urethroplasty as the primary surgical approach in my practice; however, the alternative above-mentioned approaches have also immensely benefited my patients. My use of the transecting approach is based upon reliable surgical success among carefully

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TRANSECTING ANASTOMOTIC VS DORSAL BUCCAL INLAY

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screened patients. We have previously published a multi-institutional study from the Trauma and Urologic Reconstruction Network of Surgeons.[4] A total of 137 patients underwent transecting anastomotic urethroplasty. Patients with single and combined radiation for prostate cancer were included. Adjunctive techniques such as corporal splitting (71.5%), partial perineal prostatectomy (37.2%), gracilis interposition muscle flap (23.4%), partial pubectomy (12.4%), combined antegrade approach (5.8%), salvage prostatectomy (2.2%), and/or complete pubectomy (0.7%) were at the discretion of the surgeon based upon operative findings. The overwhelming majority of patients had bulbomembranous urethral strictures. Prostate involvement (most commonly an extension of the membranous urethral stricture into the prostate apex) was present in half of patients and a small subset had bladder neck involvement (9.5%) or a rectourethral fistula (2.2%). Average stricture length was 2.3 cm, and average patient age was 69 (50-86) years old. Cystoscopy was utilized to assess surgical outcome. Overall success at a mean followup of 32 months was 86.9%.

Subsequent artificial urinary sphincter was performed in 22% of the cohort, with the majority via a transcorporal cuff to reduce the risk of urethral erosion. Among these patients with mixed stricture location, 20% developed subsequent cuff erosion. In a separate published series of men with bulbomembranous urethral strictures alone, we compared stress incontinence among men with radiated strictures or pelvic fracture urethral injuries.[5] We used an outcome measure to assess the occurrence of any degree of stress incontinence. De novo stress incontinence was reported in 33% of the postradiated men (vs 12% pelvic fracture cohort); however, only 16% of the radiated cohort underwent subsequent urinary sphincter.

The surgical approach for transecting anastomotic urethroplasty follows the same approach to a patient with a pelvic fracture associated urethral stricture. A suprapubic tube is placed 1 month before surgery to allow for urethral rest. Bladder capacity is assessed at that time, and patients are strongly advised against surgery based upon above-mentioned contraindications, if noted. A perineal incision is performed with dissection performed to the level of the stricture based upon preoperative fluoroscopic imaging. The urethra is mobilized circumferentially. Before urethral transection, the tissue plane above the dorsal proximal bulbar urethra is carefully dissected in a proximal manner toward the prostate apex to increase surgical exposure. Careful dissection along the ventral plane of the proximal bulbomembranous urethra is performed in anticipation of urethral transection. Rectal exam can be performed to confirm proximity to the rectum during this dissection. The urethra is then transected. Additional dissection via scalpel and/or metzenbaum scissors is performed predominately along the dorsal plane of the urethra to gain exposure cephalad to the stricture. Van Buren sounds can be passed via the suprapubic tube tract to aid location of the proximal urethral lumen, if needed. Urethral calibration to 30F is performed.

Urethral mobilization of the distal transected bulbar urethra is always necessary to allow a tension-free urethral anastomosis. Corporal splitting can be performed to gain additional urethral mobilization for the planned anastomosis. I have rarely performed an infrapubic partial pubectomy. If performed, gracilis interposition muscle flap is utilized to place along the exposed bone to reduce the risk of pubic osteomyelitis. I will also use a gracilis interposition muscle flap for large tissue defects and/or for patients with combined radiation. Cystoscopy is performed in all patients prior to anastomosis. Twelve-suture interrupted anastomosis is performed akin to a clock face with 4/0 PDS utilized at 12:00, 3:00, 6:00, and 9:00. The remaining sutures are 5/0 PDS. The suprapubic catheter is left in place in addition to the urethral catheter (1 is capped). Voiding cystourethrography is performed in 4 weeks. Cystoscopy is performed in additional to use of a patient reported outcome measure at 3 months following surgery. For patients with stress incontinence, artificial urinary sphincter is performed at 6 months after confirming urethral repair stability on cystoscopy at 3 and 6 months. I have erred on the side of a looser cuff and utilize a transcorporal cuff among these patients to augment success. I am encouraged by innovations to improve outcomes and quality of life among men with radiated urethral strictures and welcome the increased attention on this subject to inform the urology audience pertaining surgical approaches. ■

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Posterior Urethral Stenosis After Prostate Cancer Radiotherapy, What Is the Best Perineal Approach: Dorsal Buccal Onlay

Dmitriy Nikolavsky, MD
SUNY Upstate Medical University, Syracuse, New York

In describing the optimal approach for posterior urethral stenosis after radiotherapy, or after procedures for benign prostatic hyperplasia, the goals and principles to the surgical approach would include (1) relief of the patient's obstruction with improvement in symptoms, (2) preservation of continence, (3) minimal urethral dissection/mobilization, (4) preservation of bulbar blood supply (by avoiding transection), (5) avoidance of dissection near the radiated rectum, especially in patients with prior prostatectomy, and (6) avoidance of an anastomosis between a radiated proximal segment and distal urethral segment with compromised vascularity. In that context, I would argue that excision and primary anastomosis (EPA) is the opposite of the "ideal" or "intelligently designed" technique for a radiated urethral stenosis. The EPA and associated gap-bridging maneuvers were designed as an operation for a different disease:

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> "Let's examine the data that demonstrate clearly why nontransecting approaches to posterior urethral stenosis are a preferred approach in a challenging patient population."

the traumatically disrupted urethra, where the scarring occurs at the site of injury and must be excised, allowing anastomosis of the patent/healthy (unirradiated) urethral lumens. Importantly, patients with urethral scar secondary to trauma often have more than adequate urethral blood supply both proximal and distal to the area of traumatic insult. In patients with posterior urethral stenosis following radiation therapy, however, the urethral segment proximal to the stenosis is often affected by radiation therapy and thus has impaired blood supply. This is a key difference between these patient populations and further disruption of urethral blood supply with transection via EPA urethroplasty would only portend worse outcomes than substitution urethroplasty.

Accordingly, some of the largest series reporting outcomes following transecting EPA for radiation induced urethral strictures have demonstrated notably lower rates of failure compared to nonradiated counterparts.[1-5] Also concerning, contemporary studies consistently report high rates of stress urinary incontinence after this operation.[1-5] The latest of the above-referenced studies was authored by Dr Voelzke and colleagues from 10 institutions describing outcomes of the largest to date patient cohort of 137 patients at a mean followup of 32.3 mo (12-118) and incontinence rates of 32% (ranging 18%-70% between centers).[5] Remarkably, a significant proportion of patients required additional auxiliary maneuvers to complete anastomoses, including corporal splitting (71.5%), partial pubectomy (12.4%), partial prostatectomy (37.2%), gracilis flap (23.4%), and abdominal counter-incision (5.6%). Who would consider a urethroplasty that requires such aggressive, tedious, and often challenging maneuvers as "minimally invasive"?

Further, Chung and associates demonstrated that when this operation is applied as the first-line therapy for a stenotic, but not disrupted, bulbomembranous/sphincteric urethra in patients after radiation, it unsurprisingly produces higher rates of incontinence than in patients with pelvic fracture-associated urethral injuries (33% vs 12%).[6]

Let's examine the data that demonstrate clearly why nontransecting approaches to posterior urethral stenosis are a preferred approach in a challenging patient population. Employing either a Kulkarni one-sided dissection or ventral approach, one can preserve the bulbar blood supply (at least unilaterally if not bilaterally), avoid circumferential urethral dissection (including near the rectum), avoid excision of the sphincter, and eliminate the reliance on radiated and vascularly compromised ends to heal properly. Currently only a few studies exist demonstrating benefits of a nontransecting buccal mucosa graft (BMG) augmentation techniques in patients with postradiation posterior stenosis. Ahai et al published single-center outcomes of ventral BMG for radiated strictures on 36 patients with a success rate of 71% at 26 months and demonstrating lower rates of de-novo SUI at 10.5%.[7]

Policastro and colleagues reported on a multicenter cohort of 79 patients with posterior stenosis after radiation therapy uniformly treated with dorsal onlay BMG placed through a one-sided approach (Kulkarni-type dissection) (see Figure).[8,9] In this cohort, no additional auxiliary maneuvers were used (no gracilis flap, pubectomy, corporal splitting, or abdominal counter-incision). A majority of patients (65%) returned home on the same day after the operation or after a 23-hour stay. At a mean follow up of 29.6 months (12-88), recurrence-free rate was 82.3% and the rate of de novo stress urinary incontinence (SUI) was only 8%.

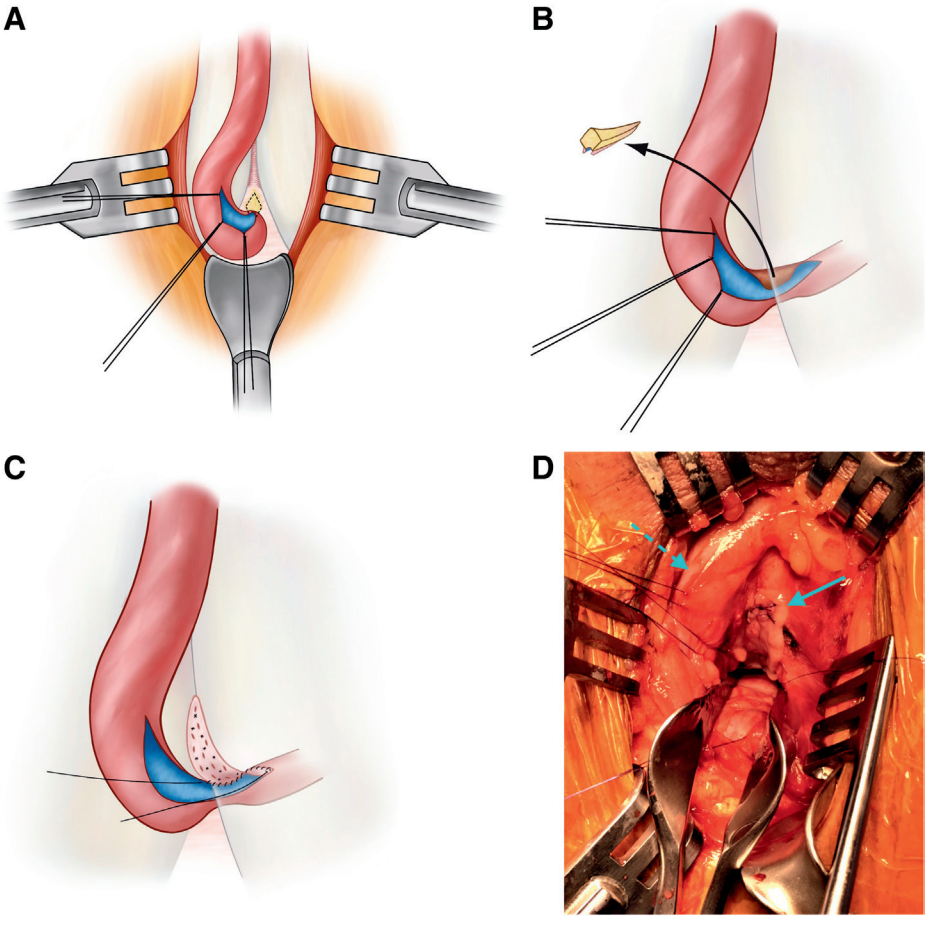

Figure. Dorsal onlay urethroplasty. A, Lateral dissection of urethra and dorsal urethrotomy. Dotted line indicates area to be excised. B, Intercrural tissue is excised anterior between 1 and 11 o'clock positions. C, Buccal mucosa is sutured to proximal apex of urethrotomy and quilted on corpora cavernosa. D, Intraoperative image shows repair of bulbomembranous urethral stricture. Bulbar urethra with dorsal urethrotomy is rotated toward patient right (dashed arrow). Elliptical buccal mucosal graft (solid arrow) is quilted to underlying corpora cavernosa. Nasal speculum is placed in bladder through proximal urethral lumen. Reprinted with permission from Blakely S et al, *J Urol*. 2016; 195(5):1501-1507.[9]

> "It has been hypothesized that choosing transecting urethroplasty may compromise the future longevity of subsequent AUS."

Additionally, regardless of the rates of de novo SUI, a significant proportion of patients in all postradiation stenosis series are reported to have persistent SUI and require subsequent artificial urinary sphincter (AUS) placement. It has been hypothesized that choosing transecting urethroplasty may compromise the future longevity of subsequent AUS. A large multinational study spearheaded by MedStar/Georgetown Medical School and presented at AUA2023 by Davis and associates demonstrated dismal outcomes in patients with prior transecting urethroplasty that undergo subsequent AUS placement. Specifically, the risk of AUS explanation due to erosion/infection/urethral atrophy are higher (53%) than patients who undergo prior nontransecting urethroplasty (29%).[10]

To summarize, these early findings are promising in several different ways: (1) nontransecting BMG augmentation techniques are feasible in select patients after radiation, with excellent urethral patency rates, (2) BMG can be placed into and survive in a graft bed that may be considered suboptimal, including in patients with prior radiation, (3) dorsal onlay BMG urethroplasty allows avoidance of invasive

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auxiliary maneuvers, (4) de novo SUI rates are lower compared to historically higher rates observed with excisional (read "sphincter excision") techniques, and (5) preservation of urethral continuity and urethral vascularity may be important if not for other reasons, at least in the interest of improved longevity of future AUS placement. Given these advantages, I argue that dorsal onlay BMG urethroplasty should be used as a first-choice reconstructive option for patients with prior radiation and associated posterior stenosis. In contrast, EPA has only a limited role in a select population of patients, specifically with less common conditions such as complete lumen obliteration, vesico-urethral anastomotic disruption, or necrotic cavities where excision is mandatory. ■

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Adjuncts to Removal of Lower Pole Stone Debris: Historical, Current, and Future Options

Orlando Diaz-Ramos
Universidad Central del Caribe School of Medicine, Bayamon. Puerto Rico

Tyler Sheetz, MD
University of California San Diego

Roger L. Sur, MD
University of California San Diego

Introduction

Dating back to the early 1800s, lithotripsy was conceived with the utilization of galvanic current to dissolve calculi.[1] Over the years, the technique underwent extensive refinement, progressing from galvanic current to platinum electrodes, electrohydraulic shock waves, laser, ultrasound, and other technologies capable of breaking down stones.[1] While lithotripsy has had a significant impact on the treatment of renal stones, a challenge arises with accumulation of debris resulting from stone fragmentation. Gravity tends to direct debris to the lower pole of the kidney, posing a significant issue in clearance and recurrence rates. Consequently, the development of adjunctive techniques to alleviate the accumulation of lower calyceal stone debris has progressed alongside stone-breaking techniques (see Table).

Historical Techniques

Just prior to the introduction of flexible ureteroscopy, shock wave lithotripsy (SWL) became commonplace for renal stones in the 1980s. Despite its initial popularity, its suboptimal clearance rates in lower pole stone cases eventually became apparent. Nevertheless, investigations into therapies to supplement to SWL yielded positive results. For example, percussion therapy involving vibratory flank massage is effective in improving stone-free rates and reducing stone recurrence with minimal complications.[2] Often percussion, diuresis, and inversion therapies are combined to enhance the passage of lower calyceal stone debris after SWL. While out of favor, the implementation of percussion, diuresis, and inversion for treating lower calyceal stone debris continues to be used selectively today in adults and children motivated to avoid further surgery.[3,4]

One of the first effective adjuncts for flexible ureteroscopy was electrohydraulic lithotripsy (EHL). Initially utilized in the 1950s, Denstedt and Clayman reported their success using 1.9F EHL probes for ureteroscopy (URS) in 1996.[5] At the time, only EHL and laser lithotripsy probes were sufficiently malleable to be used for flexible URS to gain access to lower calyceal stones, and EHL was significantly less expensive. The study reported a fragmentation rate of 94% for lower calyceal stone debris, without any intraoperative complications or damage to the ureteral or renal mucosa.[5] The late 1990s also brought about the advent of the modern nitinol basket,[6] which permitted not only stone removal but also transpositioning of stones from the lower pole for more effective lithotripsy.[7]

Table. Techniques for Clearance of Lower Calyceal Stones

	Utility	Reference
Historical		
Electrohydraulic lithotripsy	URS	[5]
Percussion therapy	URS, ESWL	[2–4]
Inversion therapy	URS, ESWL	[3, 4]
Diuretic therapy	URS, ESWL, PCNL	[3, 4]
Contemporary		
Vacuum-assisted renal access sheath	PCNL	[11]
Vacuum-assisted ureteral access sheath	URS	[19]
SURE	URS	[12]
FANS	URS	[13]
Glue-clot autologous blood technique	URS, PCNL	[14]
Emerging		
Biocompatible polysaccharide adhesive	URS, PCNL	[15]
Ultrasonic propulsion	Extracorporeal	[16]
Burst wave lithotripsy	Extracorporeal	[16]
Robot-assisted ureteroscopy	URS	[17, 18]

Abbreviations: ESWL, extracorporeal shock wave lithotripsy; FANS, flexible and navigable ureteral access sheath; PCNL, percutaneous nephrolithotomy; SURE, steerable ureteroscopic renal evacuation; URS, ureteroscopy.

Current/Contemporary Options

A host of recent ureteroscopic innovations have improved treatment of lower pole stones. Digital and single use ureteroscopy permit not only superior visualization but also minimal concerns for scope

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ADJUNCTS TO REMOVAL OF LOWER POLE STONE DEBRIS

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damage during complex, unfavorable angled cases. Modern lithotripsy utilizes multiple laser options that did not exist previously. Lasers are not only delivering higher power (120 watts) but also varying pulse widths. Pulse modulation holmium:YAG technology permits superior fragmentation with minimal retropulsion compared to standard holmium:YAG lasers.[8] Thulium fiber lasers afford another option in lithotripsy that create exceptionally tiny fragments permitting possible true dust formation, and the latest thulium:YAG may represent a hybrid of the above 2 options.[9]

Percutaneous treatment of the lower pole has also become more feasible with the miniaturization of scopes. Mini–percutaneous nephrolithotomy (PCNL) permits efficacy of standard PCNL with lower morbidity.[10] An adjunct to mini-PCNL is the ClearPetra device, a disposable vacuum-assisted renal access sheath, which touts improved initial stone-free rate with decreased operative time and complication rate.[11]

The aspiration of lower calyceal stone fragments after URS/laser lithotripsy can be performed with steerable ureteroscopic renal evacuation using the CVAC aspiration device (Figure 1). Given its ability to be steered to different target calyces (Figure 2), CVAC demonstrated improved proportion of stones removed and stone-free rates compared with standard basket extraction, with similar complication profile. In patients with lower calyceal stone debris, it was more effective and faster in removing stones.[12]

Similarly, FANS (flexible and navigable suction ureteral access sheaths) are equipped with a flexible 10-cm proximal portion, which may be navigated to the desired calyx via flexible URS, facilitating removal of lower calyceal stone debris. In one study, the use of FANS helped decrease the systemic inflammatory response following URS, as it maintains low intrarenal pressure and temperature.[13]

The glue-clot technique involves injecting autologous patient blood through the ureteroscope and allowing it clot, acting as a biologic "glue" to adhere to stone fragments, thus facilitating easier basket removal.[14] The glue-clot procedure is regarded as an elegant technique that has brought improvements in the effective clearance of lower calyceal stone fragments. Furthermore, its success has inspired the exploration of new bioadhesive techniques aimed at further enhancing the results already achieved with the glue-clot technique.

Future/Emerging Adjuncts

Emerging technologies for lower calyceal stone debris clearance can be divided into biochemical and technical advances. A novel biocompatible adhesive for intrarenal embedding and endoscopic removal of small residual fragments was recently investigated in an ex vivo porcine kidney model.[15] Two liquid biocompatible polysaccharide substrates are combined endoscopically using a 3F catheter and form a gel at a temperature of 37 °C, creating an adhesive mass that surrounds and encapsulates the stone fragments. This method bears resemblance to the glue-clot technique but without the need to extract blood from the patient and has shown promising results.[15]

One potentially revolutionary technical advance in lithotripsy is ultrasonic propulsion and burst wave lithotripsy, which involves using an ultrasound probe (Figure 3) to manipulate, reposition, or break up kidney stones in the awake patient (Figure 4). One pilot study included 29 patients, with 19 experiencing stone movement. Burst wave lithotripsy successfully fragmented the stones

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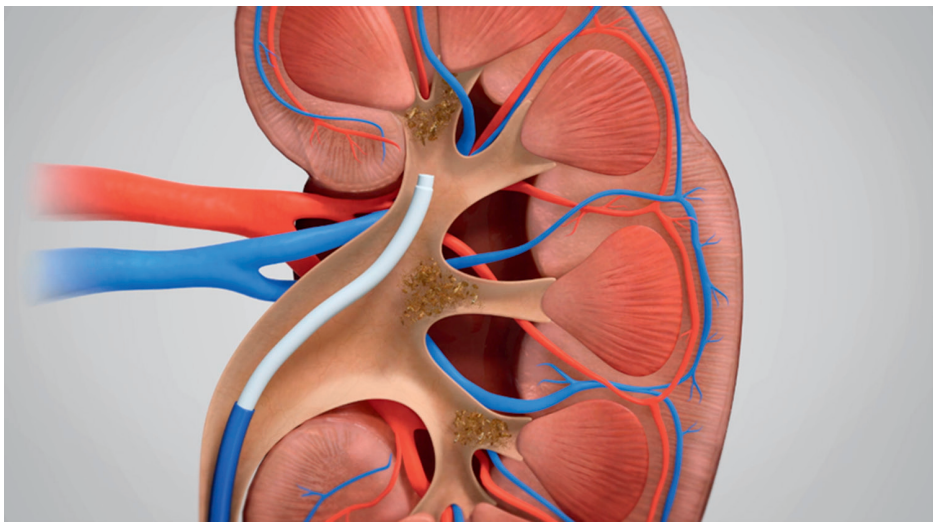

Figure 2. The CVAC device is deployed through a 12F/14F ureteral access sheath and guided through the renal collecting system fluoroscopically or by ultrasound. © 2023 Calyxo, Inc. Reprinted with permission.

Figure 3. The SonoMotion ultrasonic propulsion probe is larger than a conventional diagnostic ultrasound probe but contains both diagnostic and treatment modalities. © 2023 SonoMotion Technologies, Inc. SonoMotion technologies are investigational devices that are currently limited by US law to investigational use. Reprinted with permission.

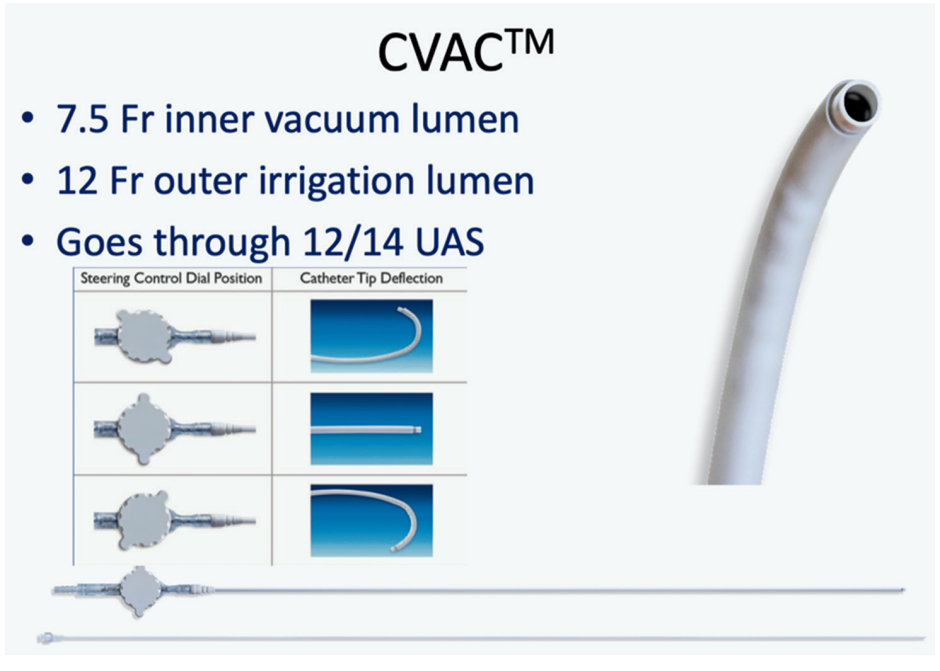

Figure 1. The CVAC device removes stone fragments via a 7.5F inner vacuum lumen and a 12F outer irrigation lumen. UAS indicates ureteral access sheath. © 2023 Calyxo, Inc. Reprinted with permission.

> "Pulse modulation holmium:YAG technology permits sufragmentation with minimal retropulsion compared to standard holmium:YAG lasers.[8]"

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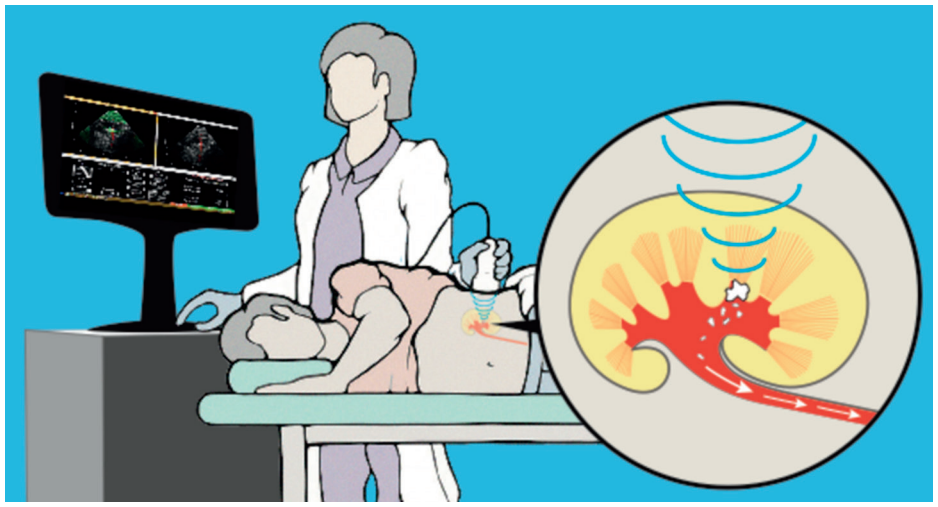

Figure 4. Burst wave lithotropsy can be performed on an awake patient using skills borrowed from diagnostic ultrasonography. © 2023 SonoMotion Technologies, Inc. Illustrated by Carol Marinelli, University of Washington. Reprinted with permission.

in 7 cases.[16] During the 2-week followup, 18 out of 21 patients (86%) with distal ureteral stones successfully passed their stones. On average, the time to stone passage was approximately 4 days.[16]

Lastly, robotic surgery has revolutionized laparoscopic urologic surgery over the last 20 years. A promising future direction for lithotripsy involves robot-assisted ureteroscopy, which touts an increased range of motion, instrument stability, and improved ergonomics compared to conventional ureteroscopy.[17,18] Optimization of this technology is likely to expand its role in lithotripsy and lower calyceal stone treatment in the near future. ■

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ASCO 2023 RECAP

Highlights of Genitourinary Cancer: Prostate and Testicular Cancer

Caroline S. Jansen, PhD
Emory University School of Medicine, Atlanta, Georgia
Winship Cancer Institute of Emory University, Atlanta, Georgia

Mehmet Asim Bilen, MD
Emory University School of Medicine, Atlanta, Georgia
Winship Cancer Institute of Emory University, Atlanta, Georgia

The ecosystem of therapy in genitourinary (GU) cancers is evolving and progressing, with emerging data continuing to shape clinical treatment regimens. Here we will highlight 4 key abstracts presented at the ASCO (American Society of Clinical Oncology) 2023 Annual Meeting, which may impact management of patients with advanced prostate cancer and testicular cancer (seminoma).

Abstract LBA5000, discussing local therapy in metastatic prostate cancer, reports the PEACE-1 trial, which compared standard of care (SOC) therapy alone or with abiraterone, radiotherapy, or abiraterone+radiotherapy.[1] This is a multicenter, open-label, randomized, phase 3 study that required patients to have de novo castration-sensitive prostate cancer (mCSPC) with >1 bone lesion and investigated co-primary end points of radiographic progression-free survival (rPFS) and overall survival (OS). Enrolled patients were well balanced between arms, with about 43% of patients with low-volume disease (LVD). In patients with LVD, patients randomized to SOC+abiraterone+radiotherapy had improved rPFS compared to SOC+abiraterone (HR = 0.65), without improvement in OS (HR = 0.98). There was no difference in rPFS between patients receiving SOC vs SOC+radiotherapy. The investigators reported significant improvement in time to serious GU events in patients with LVD receiving radiotherapy.

These results are important, given recent data regarding local treatment of mCSPC. In 2018, the HORRAD trial established the benefit of radiotherapy on PSA progression but did not reveal improvement in OS between androgen deprivation therapy (ADT) vs ADT+-radiotherapy.[2] However, this trial did not provide data on volume of disease. Similarly, the STAMPEDE trial (Arm H) demonstrated benefit of radiotherapy in failure-free survival but no difference in OS in the general population.[3] However, subgroup analysis of patients with low metastatic disease burden revealed a significant difference in both failure-free and OS. Most recently, the phase 2 OMPCa-Shanghai trial reported significantly higher rates of rPFS and OS in patients with oligometastatic prostate cancer receiving ADT+local treatment (surgery or radiotherapy) compared to ADT alone, though the majority of

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participants underwent surgery as local therapy.[4]

In summary, the data suggest that prostate radiotherapy with intensified systemic treatment may improve rPFS and reduce serious GU events in patients with LVD. However, this is without detectable impact on OS in PEACE-1 and HORRAD, but with improvement in STAMPEDE (Arm H) and OMPCa-Shanghai. An additional trial, SWOG1802, will be important to help answer this question, which is enrolling patients with mCSPC, randomized to systemic therapy with or without local treatment, with primary end point of OS. Results are eagerly anticipated to further inform management of patients with LVD mCSPC.

Abstracts 5004 and 5005 reported utilization of poly-(ADP-ribose) polymerase (PARP) combination therapy in patients with mCRPC. Aberrations in DNA repair genes are common in mCRPC, leading to recent approvals of PARP inhibitors (PARPi) for biomarker-positive mCRPC. Additionally, it is suggested that PARPi may increase activity of novel hormonal agents (NHAs), and NHAs may increase susceptibility to PARPi. The PROPEL trial demonstrated superior rPFS with olaparib/niraparib+abiraterone vs placebo+abiraterone in all-comer, first-line mCRPC patients, but the MAGNITUDE trial showed benefit only in patients with homologous recombination repair (HRR) mutations (ie, biomarker-positive patients).[5,6] The TALAPRO-2 trial, comparing talazoparib+enzalutamide or placebo+enzalutamide, reported similar benefit in rPFS in the overall population. Abstract 5004 reports the results from the TALAPRO-2 HRR+ cohort (n=399).[7] In HRR-deficient tumors, talazoparib+enzalutamide demonstrated improved rPFS (HR = 0.45) and a favorable trend toward improved OS (HR = 0.69), though OS data are yet to mature. Abstract 5004 reinforces that PARPi+NHA combinations are active in mCRPC, with a more robust benefit in HRR-deficient patients. However, an important limitation of these studies is that only a minority of patients received NHAs before development of castration resistance. Management of mCSPC has progressed to include early administration of NHAs and prior to development of castration resistance, which may limit the direct applicability of these results. While this limitation is a consideration, it is encouraging to see CRPC treatment options continuing to progress and include precision medicine approaches.

Table. Key Points From 2023 American Society of Clinical Oncology Highlights of Genitourinary Cancer: Prostate and Testicular Cancer

Abstract No.	Trial name	Trial arms	Key findings	Implications for practice
LBA5000	PEACE-1	SOC, SOC+abiraterone, SOC+radiotherapy, SOC+abiraterone+radiotherapy	Improved rPFS, time to serious GU events for SOC+abiraterone+radiotherapy arm compared to SOC+abiraterone in low-volume mCSPC. No difference in OS	Radiotherapy with intensified systemic therapy appears to improve rPFS and prevent serious GU events in men with low-volume mCSPC
5004	TALAPRO-2	Talazoparib+enzalutamide, placebo+enzalutamide	Improved rPFS for talazoparib+enzalutamide arm (HR = 0.45) in HRR-deficient mCRPC	PARPi+NHA combinations are active in mCRPC, with a more robust benefit in HRR-deficient patients
5005	LuPARP	^{177}Lu-PSMA-617+olaparib	No DLTs, 1 treatment-related SAE (febrile neutropenia), no grade 4 AEs reported. Of patients 65% achieved PSA50 response (75% at higher doses)	Encouraging safety and early efficacy data, future study will determine efficacy of this combination
5008	SWENOTECA / COTRIMS	RPLND in patients with relapsed CS1 or primary CS2A/B	Overall recurrence rate 22%, median survival 10.2 mo. Low risk of mortality/morbidity.	RPLND is a treatment option with low morbidity and mortality in patients with clinically low-volume retroperitoneal disease

Abbreviations: AE, adverse event; CS, clinical stage; DLT, dose-limiting toxicity; GU, genitourinary; HR, hazard ratio; HRR, homologous recombination repair; mCSPC, metastatic castration-sensitive prostate cancer; NHA, novel hormonal agent; OS, overall survival; PARPi, poly-(ADP-ribose) polymerase inhibitor; PSA50, 50% decline in PSA; PSMA, prostate-specific membrane antigen; rPFS, radiographic progression-free survival; RPLND, retroperitoneal lymph node dissection; SAE, severe adverse event; SOC, standard of care.

> "In summary, the data suggest that prostate radiotherapy with intensified systemic treatment may improve rPFS and reduce serious GU events in patients with LVD."

Abstract 5005 reports LuPARP, a phase 1 trial of ^{177}Lu–prostate-specific membrane antigen (PSMA)–617+olaparib in mCRPC patients.[8] ^{177}Lu-PSMA-617 delivers radiation to PSMA+ tumors, causing predominantly single-strand breaks over more lethal double-strand breaks. PARP is essential in repairing these single-strand breaks, mediating the primary (~25%) and acquired (~100%) resistance to ^{177}Lu-PSMA-617 in mCRPC patients. The combination of ^{177}Lu-PSMA-617 with PARPi is suggested to leverage the DNA-damaging and immune modulating effects of radioligand therapy, which is supported by preclinical and clinical studies, such as ^{177}Lu-DOTATATE.[9] The LuPARP trial enrolled 48 patients, with primary objectives of identifying dose-limiting toxicities and recommended phase 2 dose, and secondary objectives of toxicity, rPFS, and PSA response rate. Of the patients, 67% received prior NHA and 38% had RECIST-measurable disease at enrollment. Safety analysis was highly favorable, with no dose-limiting toxicities. Of the patients, 65% achieved 50% decline in PSA response (75% of patients with higher-dose treatment). Overall, this trial reports encouraging safety and early efficacy data. Dose expansion and larger trials will be important in establishing further efficacy. Notably, this abstract also reported interesting correlative analysis, demonstrating heterogeneity in circulating tumor cells, despite requiring PSMA–positron emission tomography–avid disease, underscoring the importance of translational research efforts to understand the biology of the tumor microenvironment and how this affects clinical outcomes.

Abstract 5008 reported the role of primary retroperitoneal lymph node dissection (RPLND) in stage IIA-IIC seminomas (SWENOTECA/COTRIMS trial).[10] Current treatment for stage 2 seminoma includes radiotherapy/chemotherapy. Cure rates are exceptionally high, though late mortality effects materialize at 20+ years, including emergence of secondary cancers. This study enrolled 94 patients from 5 centers, with either relapsed CS (clinical stage) 1 or primary CS2A/B, who underwent RPLND. The overall recurrence rate was 9.6% with all but 1 in the first year following RPLND. Overall, this trial demonstrates that RPLND is a treatment option with low morbidity and mortality in patients with clinically low-volume retroperitoneal disease, which is consistent with a recent phase 2 trial of RPLND,[11] reporting 22% recurrence rate and low complication rates. Additional follow-up, including patient reported-outcomes, will be useful to ensure no additional safety signals.

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In conclusion, these abstracts highlight exciting new data in GU oncology, with particular implications in treatment of advanced prostate cancer and seminoma-type testicular cancer. Key discoveries are summarized in the Table. ■

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ASCO 2023 RECAP

Combination Therapies Come of Age in Kidney Cancer

Soki Kashima, MD, PhD
Yale School of Medicine, New Haven, Connecticut
Yale Cancer Center, Yale School of Medicine, New Haven, Connecticut
Akita University School of Medicine, Japan

Patrick A. Kenney, MD
Yale School of Medicine, New Haven, Connecticut

David A. Braun, MD, PhD
Yale School of Medicine, New Haven, Connecticut
Yale Cancer Center, Yale School of Medicine, New Haven, Connecticut

The management of advanced clear cell renal cell carcinoma (RCC) has been transformed by the introduction of immunotherapies and now combination therapies (Figure 1). As we have entered this combination therapy era, it is important to understand the historical context in which these advances have come about, to examine the durability of combination immunotherapy strategies in the first-line metastatic setting, and to critically evaluate the potential role of immunotherapy-based combination strategies after progression on prior immune checkpoint inhibition (ICI; particularly blockade of the PD-1 pathway).

Historically, early cytokine-based immunotherapies (interferon alfa and particularly high-dose interleukin-2) provided benefit for a small number of patients with RCC, but the median overall survival was still only around 1 year. In the mid-2000s, molecularly targeted therapies, particularly tyrosine kinase inhibitors (TKIs) that inhibit angiogenesis by targeting the vascular endothelial growth factor receptor, substantially improved the lives of patients with advanced RCC, increasing median overall survival to approximately 2 years. However, TKI therapies did not generally lead to long-term survival or cure in any patients. In 2015, ICI targeting the PD-1 pathway was shown to prolong overall survival in the TKI-refractory setting, and then beginning in 2018, a series of combination strategies emerged in the first-line setting, all based on a backbone of blocking the PD-1 pathway, and all demonstrating benefit over the TKI sunitinib. Long-term follow-up from the CheckMate-214 study of the combination of 2 ICIs (nivolumab plus ipilimumab) showed durable responses in a subset of patients a median overall survival of approximately 4 years. The combination of PD-1 blockade with a TKI showed promising early results in a series of trials (KEYNOTE 426, JAVELIN Renal 101, CheckMate-9ER, CLEAR), with high response rates and low primary progressive disease rates. With longer-term follow-up, we are now in a position to assess the durability of these responses.

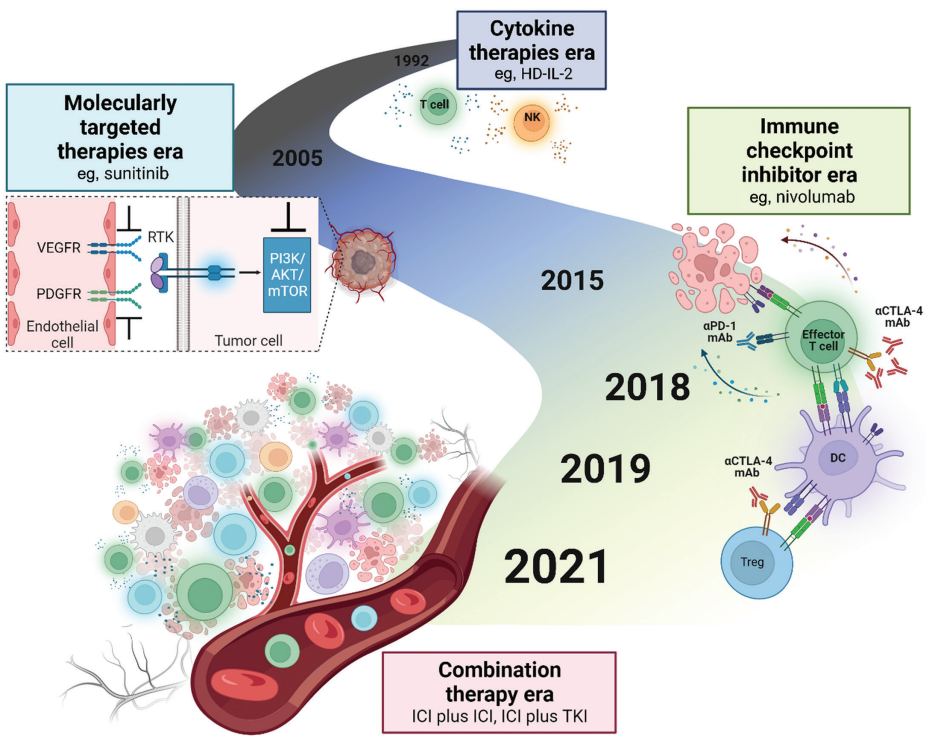

Figure 1. The evolving landscape of systemic therapies for advanced cell renal cell carcinoma. ICI indicates immune checkpoint inhibition; TKI, tyrosine kinase inhibitor. Adapted from Kashima S and Braun DA, *Urol Clin North Am*. 2023;50(2):335-349.

In long-term follow-up of 2 of these ICI+TKI trials, KEYNOTE 426 (pembrolizumab plus axitinib) presented by Dr Brian Rini and CLEAR (pembrolizumab plus lenvatinib) presented by Dr Thomas Hutson, these regimens continued to show very high objective response rates and maintained their significant progression-free and overall survival benefits over sunitinib. However, while the magnitude of benefit appeared stable over time for the "pure" immunotherapy approach of nivolumab plus ipilimumab, qualitatively there appeared to potentially be less benefit of the ICI+TKI approach over time, at least raising the question of the durability of these approaches.

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This is particularly highlighted by duration of response data–for the pure immunotherapy combination of nivolumab plus ipilimumab, the majority of patients (56%) who have an initial response still maintain that response 5 years later. By contrast, for the ICI+TKI regimens, the median duration of response was about 2 years–framed another way, more than half of patients who achieve an initial response with an ICI+TKI regimen will no longer have a response approximately 2 years later.

How do these presentations impact our practice (Figure 2)? For most clear cell RCC patients with IMDC (International Metastatic RCC Database Consortium) intermediate- or poor-risk disease, we first ask whether there are widespread metastases, or oligometastatic disease potentially amenable to locally directed therapies. For widespread metastatic disease, we also specifically look for sarcomatoid histology, as nivolumab plus ipilimumab has very high response rates (and even complete responses) in patients with RCC with sarcomatoid features. For patients with clear cell RCC without sarcomatoid histology, we ask the fundamental question–does this patient require a rapid response? For those patients with rapidly progressive disease and potential impending visceral crisis, they may never live to receive a second-line of therapy, and so we utilize ICI+TKI regimens, given their very high objective response rates and low primary progressive disease rates. However, for most clear cell RCC patients, where we have time to consider not just what the response will be in 3 or 6 months but also in 3 years, we typically choose a pure immunotherapy approach with nivolumab plus ipilimumab because of the potential durability of response and consider the role of cytoreductive nephrectomy. The impact of cytoreduction is likely dependent on a variety of factors including drug regimen. The role of nephrectomy and selection criteria remain unclear and are expected to continue to evolve with changing drug landscape.

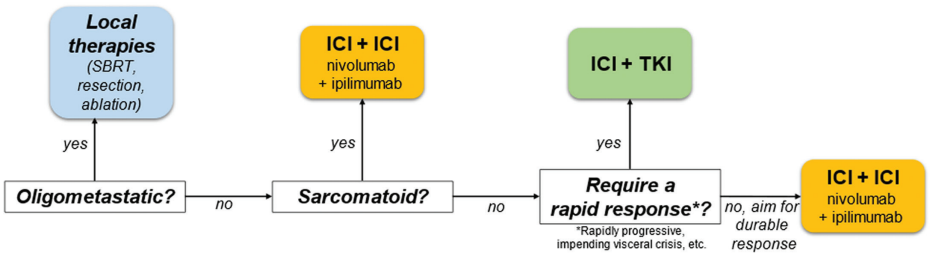

Figure 2. Treatment considerations for advanced clear cell renal cell carcinoma (IMDC [International Metastatic RCC Database Consortium] intermediate-/poor-risk disease). These represent our own views, and there are numerous reasonable approaches to therapy. This approach assumes clear cell renal cell carcinoma, patient who requires treatment (not active surveillance), no contraindication to immune checkpoint inhibition (ICI), and IMDC intermediate-/poor-risk disease. Actual treatment decisions made collaboratively with the patient. SBRT indicates stereotactic body radiation therapy; TKI, tyrosine kinase inhibitor. Adapted from Braun DA et al, Abstract presented at: American Society of Clinical Oncology Annual Meeting; July 5, 2023; Chicago, Illinois.

> "To move to an era of cure for more or even most patients with advanced RCC, we need improved immunotherapy approaches."

For the IMDC favorable-risk population, while there are clear objective response and progression-free survival benefits for the ICI+TKI combinations, the updated results presented at ASCO (American Society of Clinical Oncology) 2023 demonstrated no overall survival benefit for the combination strategy over sunitinib alone. This raises more questions than it answers and highlights the need for additional trials to clarify the best strategy for patients with favorable risk disease.

What is the optimal therapy for patients whose RCC tumors have progressed on anti-PD-1-based therapies? While the use of single-agent TKI (such as cabozantinib, axitinib, or in a later line tivozanib) or the combination of lenvatinib plus everolimus are standard approaches, there is a growing practice of rechallenging with an ICI+TKI. This approach was supported both by retrospective and phase 2 prospective data, demonstrating response rates up to 60% with this ICI+TKI rechallenge approach. To systematically evaluate this strategy, Dr Toni Choueiri and colleagues conducted the CONTACT-03 study, randomizing patients with disease progression on prior PD-1 blockade to either cabozantinib alone (TKI; control arm) or cabozantinib plus the anti-PD-L1 drug atezolizumab (experimental arm). The results, presented by Dr Choueiri, showed no clinical benefit with the addition of atezolizumab–no improvement in response rate, duration of response, primary progressive disease rate, progression-free or overall survival. Toxicity, however, was notably higher in the combination arm, with higher grade 3-4 adverse events and more than double the rate of serious treatment-related adverse events. There are some notable limitations of this study–primarily the use of the anti-PD-L1 agent atezolizumab, which, while it has known clinical activity in RCC, is not an approved drug for this disease. This issue will be addressed by the ongoing TiNivo-2 study, a similar trial that uses the more standard anti-PD-1 agent nivolumab in combination with the TKI tivozanib. Further, there are always individual exceptions where certain clinical scenarios indicate a patient might benefit from such an ICI rechallenge. Nevertheless, with this well-conducted, randomized, phase 3 study, it should no longer be routine practice to treat with combination ICI+TKI after progression on prior anti-PD-1 therapy.

These seminal studies presented at ASCO 2023 show the RCC community how far we have come with systemic therapies, but also how far we still have to go. We need to continue trials that further optimize existing therapies, which will hopefully improve the length and quality of life for patients with advanced RCC. However, we also need to listen to our patients–as demonstrated by a recent KCCure (Kidney Cancer Research Alliance) survey of RCC patients (presented by D Battle, ASCO 2023), their top goal remains cure. We should not be shy about trying to achieve it. We are in the proof-of-concept phase, where a limited subset of RCC patients treated with dual ICI therapy can achieve long-term clinical benefit or potentially even cure. To move to an era of cure for more or even most patients with advanced RCC, we need improved immunotherapy approaches. We need to better understand the fundamental immunobiology of RCC, and we need to utilize all of the tools in our therapeutic toolkits–releasing the immune brakes with ICIs, pressing on the immune gas pedal with cytokines and other immune agonists, and adding a steering wheel with antigen-directed therapies. ■

ASCO 2023 RECAP

First-line Lenvatinib + Pembrolizumab Treatment Across Nonclear Cell Renal Cell Carcinomas

Om Balar, BS
Memorial Sloan Kettering Cancer Center, New York, New York

Gopa Iyer, MD
Memorial Sloan Kettering Cancer Center, New York, New York

Chung-Han Lee, MD, PhD
Memorial Sloan Kettering Cancer Center, New York, New York

Kidney cancer is the seventh most common type of cancer in men and the 10th most common type of cancer in women. Clear cell renal cell carcinoma (ccRCC) represents the most common histology of kidney cancer, accounting for nearly 80% of patients. All other histologies of kidney cancer have been collectively grouped as non-ccRCC (nccRCC), which includes papillary, chromophobe, unclassified RCC, and other subtypes.[1,2] As the most common histology, most novel regimens were specifically developed for ccRCC, where use of vascular endothelial growth factor (VEGF)–targeted therapies and immunotherapies have significantly improved patient outcomes. Currently, the standards of care for ccRCC are PD-1–based immune checkpoint inhibitor (ICI) combinations including combinations with anti–CTLA-4 immunotherapies or VEGF-targeted tyrosine kinase inhibitor (TKI) therapies based on multiple randomized phase 3 clinical trials demonstrating superiority as compared to TKI monotherapy.[3-6] Due to the rarity and heterogeneity of nccRCC, randomized trials for this disease group have been limited. Thus, despite the advances in ccRCC, the current standard of care for nccRCC is TKI monotherapy with cabozantinib receiving a National Comprehensive Cancer Network preferred designation.[7] Furthermore, our clinical understanding of how to treat nccRCC has lagged our ability to histologically classify nccRCC. In most clinical studies, nccRCC is evaluated in the aggregate, with occasional studies excluding specific histologies.

Lenvatinib is a multitargeted TKI directed towards VEGFR1-3 and FGFR1-4, and pembrolizumab is an anti–PD-1 ICI. The combination of lenvatinib and pembrolizumab (LEN/PEM) was Food and Drug Administration–approved for ccRCC based on the results of the CLEAR study, where it demonstrated improved objective response rate, progression-free survival, and overall survival in comparison to sunitinib.[4] Study KEYNOTE-B61 is a single-arm global phase 2 clinical trial evaluating the safety and efficacy of LEN/PEM in patients with metastatic nccRCC.[8] A total of 158 patients were treated including 93 patients with papillary, 29 chromophobe, 21 unclassified, 6 translocation-associated, and 9 other histologies. Across the entire cohort, 78 (49%) had objective response, which included 9 patients (6%) with a complete response. The median progression-free survival was 17.9 months (95% CI 14, not reached). At the 12-month landmark analysis, 63% of patients remained progression-free and 82% of patients remained alive. Across all different histological subtypes, International Metastatic Renal Cell Carcinoma Database Consortium risk categories, and sarcomatoid feature status objective responses were seen. Notably, an objective response rate of 28% was seen in patient with chromophobe histology, which is an immune cell excluded histology. These data demonstrate promising antitumor activity and support the combination of LEN/PEM in patients with nccRCC.

> "Due to the rarity and heterogeneity of nccRCC, randomized trials for this disease group have been limited. Thusly, despite the advances in ccRCC, the current standard of care for nccRCC is TKI monotherapy with cabozantinib receiving a National Comprehensive Cancer Network preferred designation."

Currently, only 1 TKI/ICI regimen has a National Comprehensive Cancer Network–designated recommendation, cabozantinib in combination with nivolumab (CABO/NIVO). In patients with papillary, unclassified, and translocation histologies (N=40), the combination of CABO/NIVO demonstrated an objective response rate of 48%, and a median progression-free survival of 13 months (95% CI 7,16), while in patients with chromophobe histology did not show any objective responses.[9,10] At landmark analyses, 51% of patients remained progression-free at 12 months and 23% of patients at 24 months. The overall survival was 70% at 18 months and 44% at 36 months.

The single-arm design of both the CABO/NIVO and LEN/PEM trials limit comparisons between the studied treatment combination and the previous standard of care. Though top-line objective response data appear similar between CABO/NIVO and LEN/PEM, comparisons between the 2 trials are not possible due to multiple significant differences. KEYNOTE-B61 included only treatment-naïve patients, while CABO/NIVO included treatment-naïve and patients with 1 prior systemic therapy; KEYNOTE-B61 is a global multicenter trial, while CABO/NIVO was a single-center study. Furthermore, due to the heterogeneity of nccRCC, it is also challenging to know whether the distributions of histologies in the trials were similar. Due to these differences in the studies, it is not possible to know the degree of overlap between patients who would respond to LEN/PEM vs CABO/NIVO. Taken as a whole, TKI/ICI combinations can demonstrate robust clinical activity in patients with nccRCC; however, randomized trials demonstrating superiority compared to prior standards of care are not yet available. Pending randomized trials to compare the regimens, robust translational studies may help identify specific populations and histologies which may preferentially benefit from regimens. ■

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ASCO 2023 RECAP

Standard vs Extended Lymphadenectomy Performed at Radical Cystectomy for Muscle Invasive Urothelial Cancer

Seth P. Lerner, MD
Baylor College of Medicine, Dan L Duncan Cancer Center, Houston, Texas

Catherine Tangen, PhD
SWOG Statistics and Data Management Center, Fred Hutchinson Cancer Center, Seattle, Washington

Robert Svatek, MD
University of Texas Health San Antonio

SWOG S1011 is a randomized Phase 3 trial that tested the hypothesis that an extended bilateral pelvic and iliac lymphadenectomy performed at the time of radical cystectomy would be associated with improved disease-free (DFS) and overall survival (OS) compared to a bilateral standard pelvic lymphadenectomy. Eligible patients had predominant urothelial cancer clinical stage T2-4aN0-2 and neoadjuvant chemotherapy (NAC) was allowed. We registered 659 and randomized 592 eligible patients at 27 sites in the United States and Canada, and the surgery was performed by 37 credentialed surgeons. Patients were stratified by type and receipt of NAC, T2 vs T3-4a, and PS 0-1 vs 2, and randomized intraoperatively after intraabdominal and pelvic exploration ruled out unresectable disease (T4b) and lymph node metastases in the extended template. The standard template included external and internal iliac nodes with circumferential mobilization of the external iliac artery and vein and the obturator nodes, with complete removal of all potential node-bearing tissue from the pelvic sidewall to the bladder (Figure 1). The extended template included bilateral common iliac and presciatic (or Fossa of Marseilles) and the presacral nodes. Surgeons could extend the node dissection up to the inferior mesenteric artery to include the distal aorta and inferior vena cava nodes (Figure 2) but were required only to go up to the aortic bifurcation based on surgeon preference.

> "In summary, we successfully completed this innovative surgical trial and answered a critical question regarding the anatomic extent of pelvic lymphadenectomy performed at the time of radical cystectomy for curable muscle-invasive urothelial bladder cancer."

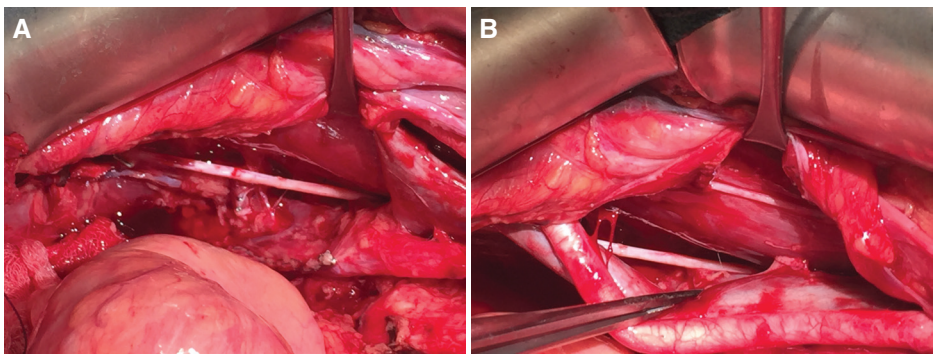

Figure 1. Standard pelvic lymph node dissection includes external and internal iliac and obturator (A) and extends laterally to the pelvic sidewall and genitofemoral nerve (B).

Clinical stage was T2 in 71% of patients in both arms; hydronephrosis was present in 26% and variant histology in 13%. NAC was administered in 57% of patients, with 87% receiving cisplatin-based treatment, which far exceeds that reported in any contemporary cohort through the course of the trial. Pathologic tumor stage was similar in both arms with pT0N0 in 20% of patients while 38% were <pT2N0. Pathologic pelvic lymph node metastases were present in 24% and 26% of standard lymph node dissection (SLND) and extended lymph node dissection (ELND), respectively. The median number of nodes (range) was 24 (6-61) and 39 (15, 94), respectively.

Median follow-up was 6.1 years and there was no difference in DFS or OS between the 2 arms. The estimated 5-year DFS probability was 55% for ELND and 58% for SLND (HR = 1.11 [95% CI 0.87, 1.42], 2-sided $P = .40$). Similarly, for OS the 5-year OS probability was 59% and 63%, respectively (HR = 1.11 [95% CI 0.87, 1.42], 2-sided $P = .40$). The DFS and OS event rates were progressively higher with more advanced pathologic tumor stage; patients with node metastasis had the highest event rates. We compared DFS and OS by the prespecified stratification factors and pathologic stage, and there was an association of pathologic stage pT3-pT4aN0 with better DFS with an HR of 1.91 (95% CI 1.19, 3.06) and OS HR of 2.05 (1.25, 3.36), but this is hypothesis-generating only.

We analyzed toxicity and focused on grade 3-5 events regardless of attribution to the node dissection. The most common grade 3 and 4 toxicities were anemia, urinary tract infections, wound infections, ileus, and venous thrombotic events. Grade 4 sepsis occurred in 3.7% and 6.2% in SLND and ELND, respectively. Fatal events occurred in 1.5% of patients within 30 days of surgery and 4.4% within 90 days and were more common in the ELND arm compared to the SLND (2.7% vs 0.3% and 6% vs 6.5% vs 2.4% at 30 and 90 days, respectively).

In summary, we successfully completed this innovative surgical trial and answered a critical question regarding the anatomic extent of pelvic lymphadenectomy performed at the time of radical cystectomy for curable muscle-invasive urothelial bladder cancer. Juergen Gschwend led a similar multicenter trial in Germany (LEA) and reported that there was no benefit to an extended node dissection. There are several key differences between these 2 trials: (1) in the LEA trial patients with clinical T1 disease were eligible; (2) in SWOG S1011 a majority received NAC while this was not allowed in the LEA trial; (3) the standard or "limited" dissection did not include the nodes posterior to the obturator nerve. This trial was recently updated at the European Association of Urology 2023 meeting, with long-term outcomes still showing no benefit for time to progression and OS with a signal of possible benefit for cancer-specific survival.

SWOG S1011 and the LEA trial thus clearly establish that a bilateral standard bilateral pelvic lymphadenectomy is standard of care for patients undergoing radical cystectomy for cT2-4a/N0-2 urothelial cancer. ■

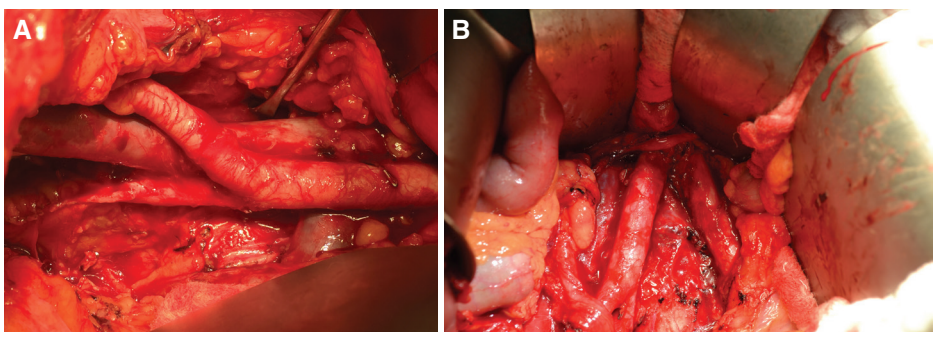

Figure 2. Extended pelvic lymph node dissection includes bilateral common iliac, presciatic fossa laterally (A) and presacral fascia (B).

ASCO 2023 RECAP

Personalizing Androgen Deprivation Therapy in Patients With High-risk Localized Prostate Cancer Using Artificial Intelligence

Andrew J. Armstrong, MD, ScM, FACP
Duke University, Durham, North Carolina

At the 2023 ASCO Annual Meeting, we presented data on the first successfully validated predictive biomarker of long-term androgen deprivation therapy (LT-ADT) benefit with radiation therapy (RT) in men with localized high-risk prostate cancer. We developed and validated this biomarker using an artificial intelligence (AI)-derived digital pathology-based platform across multiple NRG cooperative group trials of localized high and intermediate risk prostate cancer, with external validation in the phase 3 NRG/RTOG 9202 trial. The predictive AI biomarker identified 34% of high-risk men that could derive similar benefit with short-term ADT (ST-ADT), thus avoiding the side effects of prolonged ADT.

Currently, men with high-risk, locally advanced prostate cancer who choose to pursue radiotherapy are also treated with LT-ADT.[1,2] Despite the proven clinical benefits of LT-ADT on preventing metastasis and improving overall survival in these patients,[3] LT-ADT is associated with increased morbidity due to treatment side effects including muscle and bone loss, potential cognitive impacts, fatigue, cardiovascular risks, and hot flashes.[4] ST-ADT may have a lower risk of toxic side effects and reduce non-prostate cancer related mortality.[2] There is a clear unmet need for predictive biomarkers to identify men with high-risk localized prostate cancer who have an excellent prognosis and do not benefit from LT-ADT, and can thus be spared the risks of LT-ADT. While existing genomic and clinical risk stratification tools are prognostic, they have not shown predictive utility for ADT duration. ArteraAI, a precision medicine company developing AI tests to personalize cancer therapy, utilizes a multimodal artificial intelligence platform

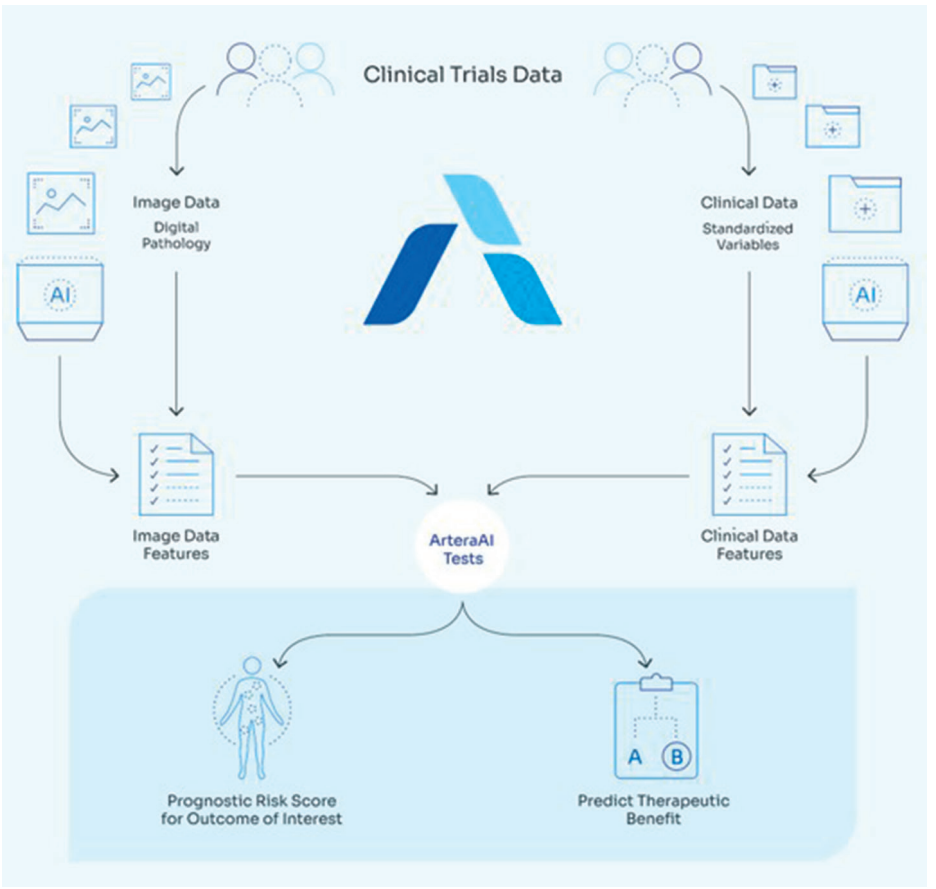

Figure 1. ArteraAI multimodal artificial intelligence (AI) platform for prognostic and predictive biomarker development.

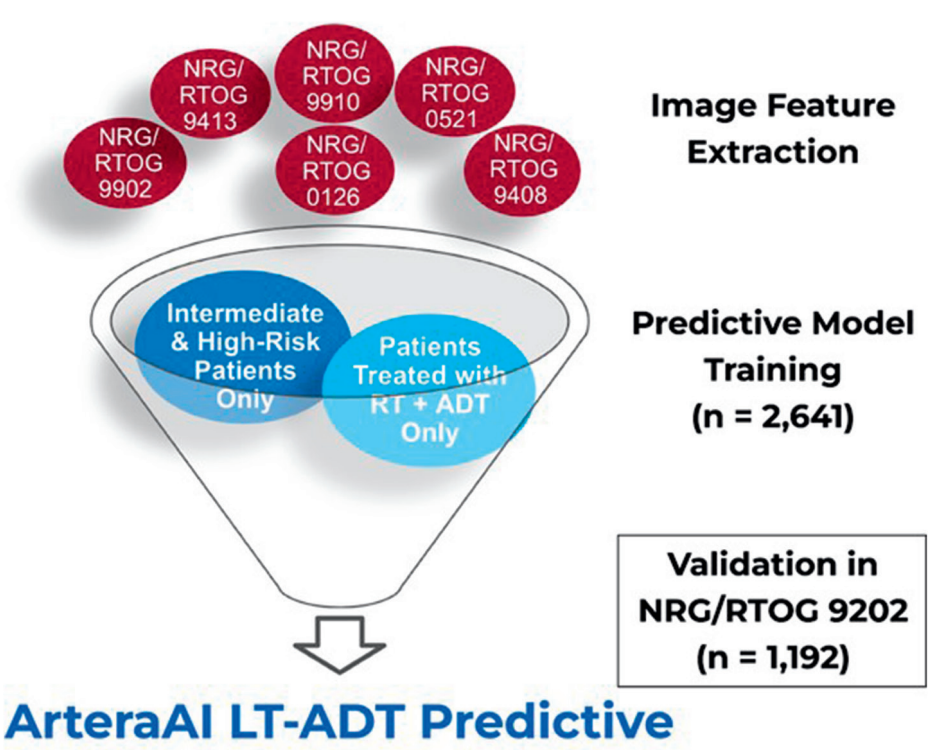

Figure 2. NRG/RTOG trials and patient population characteristics used for the development of ArteraAI predictive biomarker for use of long-term (LT) androgen deprivation therapy (ADT) in high-risk prostate cancer. RT indicates radiation therapy.

that leverages digital pathology and clinical data such as PSA, stage, age, and Gleason sum to provide AI-driven solutions for prognostic[5] and predictive[6] biomarkers in localized prostate cancer (Figure 1). The ArteraAI Prostate Test is now supported by National Comprehensive Cancer Network guidelines (1.2023) as a risk stratification tool for localized prostate cancer.

Our team leveraged data from 6 prospective phase 3 randomized trials to develop and validate an AI-derived biomarker that can predict which men with higher-risk localized disease are more or less likely to benefit from longer-term ADT with RT (Figure 2). ArteraAI clinical prediction models are intended to support physician decision making by predicting whether a patient will have an improved outcome in response to treatment and are not intended to replace pathologists to diagnose and risk stratify patients. Generalizability is a crucial aspect when developing and evaluating AI models to ensure applicability across populations. The LT-ADT predictive biomarker was developed using data from prostate biopsies across multiple academic and community sites across North America and African American men composed 21% of the cohort.

Digitized whole slide images of H&E-stained biopsies at time of diagnosis, as well as clinical and outcome data (follow-up >8 years) from 2,641 patients were used for model development to predict the benefit of LT-ADT on distant metastasis (DM). We then validated the ArteraAI LT-ADT predictive model using data from NRG/RTOG 9202,[7] a phase 3 clinical trial that randomized men with intermediate to high-risk disease to either ST-ADT (4 months) or LT-ADT (28 months). Of note, explainability of AI models is an ongoing area of research and

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PERSONALIZING ANDROGEN DEPRIVATION THERAPY IN PATIENTS

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a topic of much debate as AI advances in health care. As a first step towards understanding what components of our model are driving predictive utility, we evaluated the weighted contribution of image and individual clinical components on model performance and found that image features contributed the most to the ArteraAI LT-ADT predictive biomarker (42.6%). Further investigation will be required to assess the underlying biology driving prediction of ADT benefit.

Predictive utility for the ArteraAI model was evaluated for ADT duration with Fine-Gray or Cox PH interaction models. Event rates were estimated by the cumulative incidence method. Results in the overall validation cohort showed estimated 15-year DM risks for the RT+LT-ADT group vs RT+ST-ADT group were 17% vs 26%, respectively (HR 0.64, 95% CI 0.50-0.82, $P < .001$), similar to the results of the prior long-term report of the clinical study.[7] Among patients identified as biomarker positive, the estimated 15-year DM risks for the RT+LT-ADT group vs RT+ST-ADT group was 19% vs 33%, respectively (HR 0.55, 95% CI 0.41-0.73, $P < .001$, Figure 3). In contrast, patients identified as biomarker negative did not have a significant treatment benefit, where the estimated 15-year DM risk was 11% for both treatment groups (HR 1.06, 95% CI 0.61-1.84, $P = .84$, Figure 3). A significant interaction between treatment and predictive model for time to DM was observed with a P value of .04 (Figure 3), meaning the test was not only prognostic but also predictive of LTADT benefits.

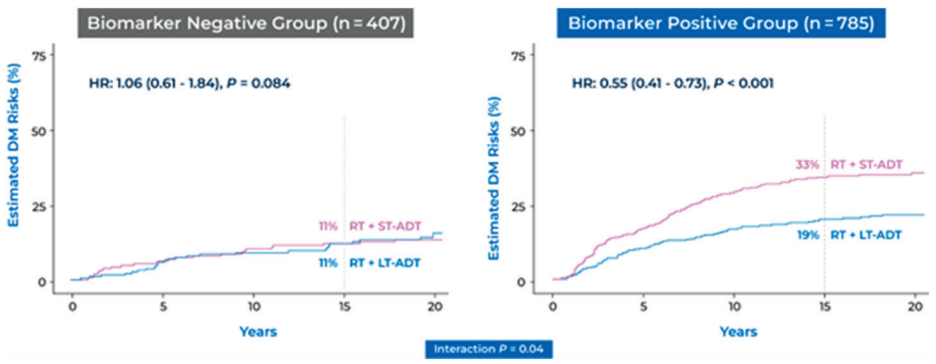

Figure 3. Cumulative incidence plots for biomarker positive and biomarker negative subgroups in the validation cohort (NRG/RTOG 9202) for distant metastasis (DM). HR indicates hazard ratio; LT-ADT, long-term androgen deprivation therapy; RT, radiation therapy; ST-ADT, short-term androgen deprivation therapy.

These results confirm successful validation of this predictive biomarker for LT-ADT benefit with RT in localized high-risk prostate cancer using an AI-derived digital pathology-based platform in the phase 3 NRG/RTOG 9202 trial. The ArteraAI LT-ADT predictive biomarker showed an absolute difference of 14% in 15-year DM estimated risk between RT+LT-ADT and RT+ST-ADT, in the biomarker positive group, with no significant difference observed between treatment groups in biomarker negative patients and identifies 34% of men who could derive similar benefit with ST-ADT, avoiding the side effects of prolonged ADT.

Further clinical impact of this research comes from the observation that approximately 20% of AI biomarker positive men still suffer from distant metastases at 15 years despite receiving LT-ADT (Figure 3). This suggests that this group of men may benefit from further treatment intensification, such as potent AR inhibitors or taxanes or even PET guided radiotherapy and should be the subject of future clinical trial investigation. There is much promise in the use of AI in prostate cancer, and more and more questions are currently being addressed, including the need for potent AR inhibitors or the need for adjuvant radiotherapy.

Future validation studies in prospective clinical trials are needed for these new questions and for the 40% of intermediate-risk men who tested positive for the AI biomarker, suggesting they may benefit from LT-ADT. Despite their resource-intensive nature and rarity, prioritizing such validation work is important to assess the performance and generalizability of AI models in real-time clinical settings. ■

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ASCO 2023 RECAP

Patient-reported Quality of Life and Survival Outcomes: CHAARTED Trial in Prostate Cancer

Daniel Sentana, MD
Beth Israel Deaconess Medical Center, Boston, Massachusetts

Chemohormonal therapy, meaning androgen deprivation therapy (ADT) plus docetaxel (ADT+D), showed improved overall survival (OS) compared to ADT alone in men with metastatic hormone-sensitive prostate cancer (mHSPC) in the ECOG-ACRIN Cancer Research Group E3805 study (CHAARTED [ChemoHormonal Therapy Versus Androgen Ablation Randomized Trial for Extensive Disease in Prostate Cancer]).[1] Docetaxel became standard of care for patients with high volume of disease, defined as either visceral metastases or ≥4 bone lesions with ≥1 beyond the vertebral bodies and pelvis, as longer follow-up revealed that the benefit was limited to this cohort.[2] Additionally, the patient-reported outcomes collected throughout the study found that patients on ADT+D had significantly higher quality of life (QOL) at 12 months than those who only received ADT, even accounting for temporarily lower QOL at 3 months.[3]

Understanding the prognostic value of QOL is paramount to patients and providers alike, particularly in mHSPC where multiple treatment options have been shown to be beneficial but there is often ambiguity in deciding the right sequencing and timing.[4,5] Based on these findings, we wanted to retrospectively evaluate the relationship between QOL and OS in men treated with ADT+D vs ADT alone. We chose baseline QOL and 3-month time point as we felt they likely reflected peak disease burden and treatment side effects, respectively. We focused on the Functional Assessment of Cancer Therapy–Prostate (FACT-P) out of the QOL instruments used in the trial, as it assesses the global QOL specifically for prostate cancer patients.[6] The

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PATIENT-REPORTED QUALITY OF LIFE AND SURVIVAL OUTCOMES

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Table 1. Association Between Functional Assessment of Cancer Therapy–Prostate Total Score (Quartile) and Overall Survival

	UVA n=790			MVAk n=705		
Baseline FACT-P total score	N	HR (95% CI)	*P* value	N	HR (95% CI)	*P* value
[43.7, 108]	187	-	-	187	-	-
[108, 123]	166	0.80 (0.62, 1.02)	.07	165	0.85 (0.67, 1.10)	.22
[123, 134]	176	0.70 (0.55, 0.90)	.005	176	0.94 (0.73, 1.21)	.61
[134, 156]	177	0.70 (0.55, 0.90)	.005	177	0.80 (0.62, 1.04)	.09
3-mo FACT-P total score						
[39.6, 105]	165	-	-	165	-	-
[105, 121]	160	0.89 (0.69, 1.15)	.39	160	0.9 (0.69, 1.17)	.42
[121, 133]	163	0.81 (0.63, 1.05)	.11	163	0.86 (0.66, 1.12)	.26
[133, 155]	158	0.71 (0.55, 0.93)	.011	158	0.76 (0.58, 1)	**.05**

Abbreviations: CI, confidence interval; FACT-P, Functional Assessment of Cancer Therapy–Prostate; HR, hazard ratio; MVA, multivariate analysis; UVA, univariate analysis.
Adjusted for treatment arm, performance status, disease volume, Gleason score, and prior local therapy.
Bold value indicates statistical significance.

Table 2. Association Between Treatment Arm and Overall Survival Within the Best and Worst 25% of 3-month Functional Assessment of Cancer Therapy–Prostate Scores

	Best 25% 3-mo FACT-P score			Worst 25% 3-mo FACT-P score		
	MVA (n=158)			MVA (n=165)		
Treatment arm	N	HR (95% CI)	*P* value	N	HR (95% CI)	*P* value
ADT alone	89	-	-	79	-	-
ADT+D	73	1.11 (0.73, 1.67)	.63	87	0.69 (0.48, 0.99)	**.047**

Abbreviations: ADT, androgen deprivation therapy; CI, confidence interval; D, docetaxel; FACT-P, Functional Assessment of Cancer Therapy–Prostate; HR, hazard ratio; MVA, multivariate analysis. Bold value indicates statistical significance.

study population of CHAARTED has been previously described,[1] but it is worth highlighting that most patients in this trial were younger men with good performance status, who had high risk and high volume of disease, and often had first presented with metastatic cancer.

In our main analysis, we tested the association between FACT-P total score and OS. We divided the FACT-P score range by quartiles, where higher scores indicate better QOL. On univariate analysis, there appeared to be a link with survival and higher scores in both baseline and 3-month time points. However, once the analysis adjusted for treatment arm, performance status, disease volume, Gleason score, and prior local therapy (all of which are independently prognostic variables), this relationship between QOL and OS was only sustained for 3-month scores, while perhaps there was a suggestive trend for baseline scores (Table 1).

Examining the survival at the extremes of QOL (the highest and lowest quartiles) at 3 months, we saw that ADT+D patients had no difference in survival between the patients with the highest and lowest QOL. On the other hand, patients who only received ADT had a very different survival probability between the patients with the highest and lowest QOL (see Figure). When we tested the association between treatment arm and 3-month QOL within the highest and lowest quartiles, we saw that patients with the highest QOL didn't appear to derive a benefit from docetaxel. On the other hand, patients with the poorest QOL did seem to have better survival if they received docetaxel (Table 2).

To sum up, our exploratory analysis revealed an association between 3-month QOL assessed by FACT-P and OS in mHSPC patients. Moreover, the patients who had the poorest QOL, or the most symptomatic, had a survival benefit with ADT+D, independent of disease volume. Conversely, patients with the highest QOL, so the least symptomatic, did not appear to benefit from docetaxel even again independent of disease volume. Naturally, this is a retrospective analysis that the original study was not powered for, as its primary objective was median OS. That said, the dedicated collection of patient-reported outcomes during the trial did provide a sufficiently large data set to test the association between QOL and survival.

> "Based on these findings, we wanted to retrospectively evaluate the relationship between QOL and OS in men treated with ADT+D vs ADT alone."

We think these findings are thought provoking since medical oncologists are trying to find out how patient-reported outcomes can supplement routine clinical care.[7,8] Knowing a patient's baseline QOL and at 3 months into chemohormonal treatment could help inform whether it makes sense for patients to continue

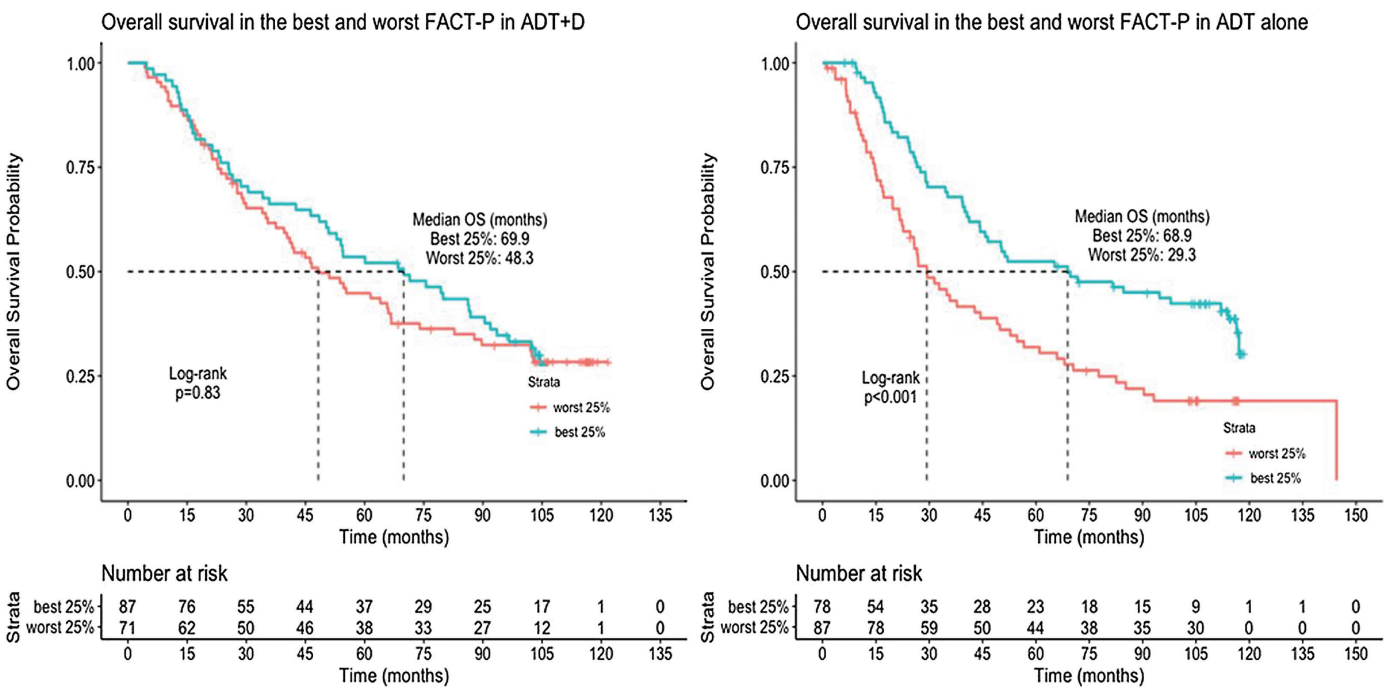

Figure. Kaplan-Meier curve by 3-month Functional Assessment of Cancer Therapy–Prostate (FACT-P) score (best 25% and worst 25%) and treatment arm. ADT indicates androgen deprivation therapy; ADT+D, androgen deprivation therapy plus docetaxel; OS, overall survival.

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PATIENT-REPORTED QUALITY OF LIFE AND SURVIVAL OUTCOMES

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with treatment or rather may not benefit from intensification. Since the field moves faster than we can study it, future trials should prospectively evaluate whether these findings can be replicated in the triplet era of mHSPC, where chemohormonal treatment is currently being used. ■

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AUA2023: REFLECTIONS

Treatment of Fungal Urinary Tract Infections

A. Lenore Ackerman, MD, PhD
David Geffen School of Medicine at the University of California, Los Angeles

In the past 10 years, we have faced the realization that humans host a "microbiome"–abundant, polymicrobial communities that exist on body surfaces and in viscera. In a healthy state, these communities are diverse, environment-specific, and carefully balanced, serving an important role in maintaining organ homeostasis.[1] But in the urinary tract, as in other organ systems, the microbiome is not just bacteria, it is an ecosystem of interacting microbes, including fungi. Yet our dogma is still that the presence of urinary fungi is pathologic–an abnormal "infection" that places individuals at risk of complications. But now that we understand that urinary fungi are physiologic, what do we really know about fungal infections of the urinary tract?

There are 2 mechanisms by which fungi can infect the urinary tract; one is as a result of ascending infection, in which infections begin in the bladder and ascend to the kidney, and the other is via hematogenous dissemination to the kidneys. Interestingly, at least in animal models, the kidneys are the most susceptible of all organs to hematogenous spread. Distinguishing between these clinical scenarios can be challenging. The vast majority of fungal infections of the kidney and bladder involve *Candida albicans* or other *Candida* species. While a variety of other fungi have been reported as genitourinary pathogens, typically these reports involve the kidneys as a result of disseminated infection from other sites.

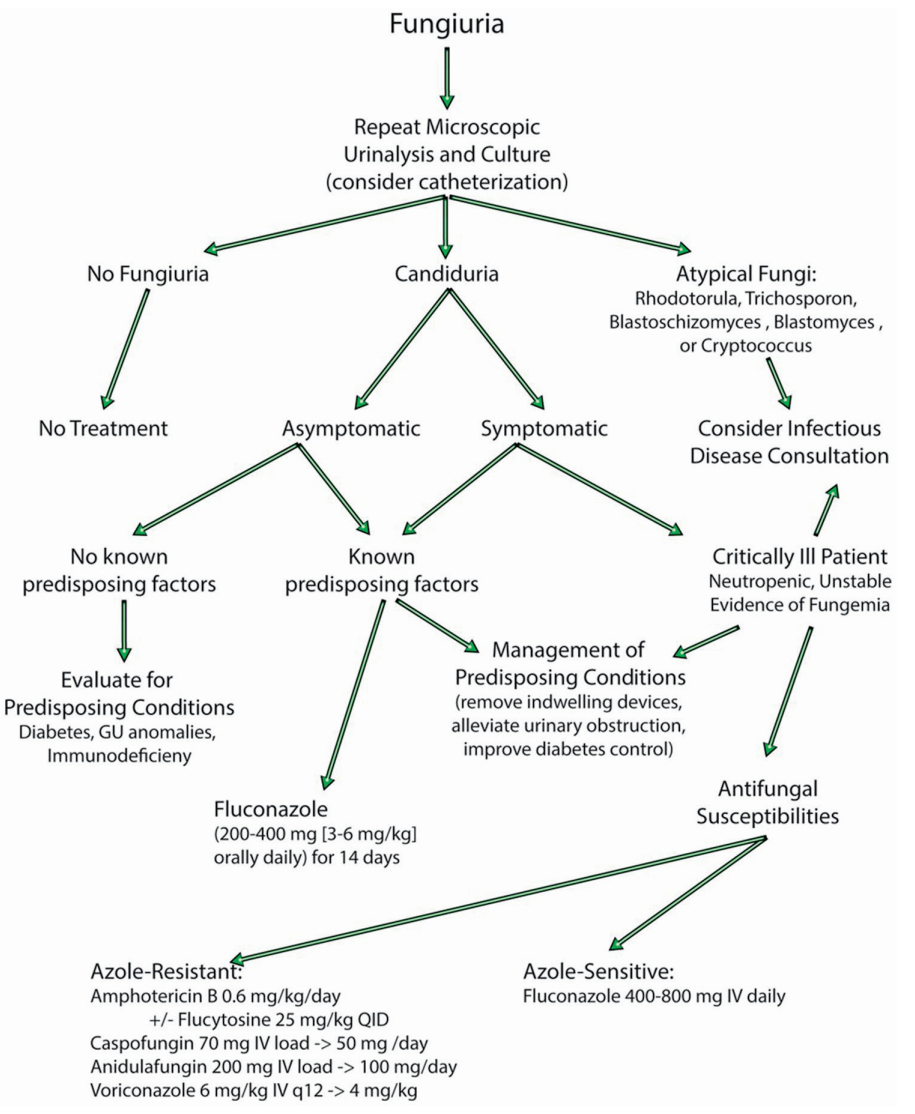

Figure. Management of fungiuria. Fungiuria in most healthy, immunocompetent individuals is of minimal clinical significance and likely to resolve spontaneously. In those with predisposing risk factors, treatment should attempt to resolve what factors can be reasonably addressed. In high-risk individuals and those in whom atypical fungal pathogens are identified, infectious disease consultation may be appropriate. GU indicates genitourinary; IV, intravenous; QID, 4 times daily. Data were derived from Pappas et al.[2]

How are fungal infections managed? The Infectious Disease Society of America has comprehensive guidelines on the treatment of fungal infections,[2] the pharmacologic management of which is simplified here (see Figure). If there is no fungiuria, there should be no treatment. If the culture demonstrates atypical fungi (any non-*Candida* species), it is wise to consult an infectious disease colleague. For Candidal infections, the mainstay of treatment is fluconazole, but as *Candida* can rapidly develop resistance to fluconazole, obtaining fungal susceptibilities is recommended to ensure early recognition of azole resistance and appropriate tailoring of antifungals. Nonazole antifungals have significant side effects and require intensive monitoring, so it is wise to involve physicians with experience prescribing these medications. These challenges and side effects have prompted attempts to manage fungiuria with intravesical amphotericin. However, fungiuria usually recurs immediately upon discontinuation of treatment.

These treatment pathways are helpful if the treating physician has a high suspicion for a urinary fungal infection confirmed by culture. But it is not always clear when to suspect urinary fungi as the causative agent in a patient's illness. As with urinary bacteria, detection of urinary fungi does not necessarily mean infection. It is much more commonly a sign of colonization; the challenge is in knowing when to treat and who is at risk for more serious complications.

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TREATMENT OF FUNGAL URINARY TRACT INFECTIONS

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Instinctively, we worry about fungiuria causing ascending infection, fungal balls, or abscesses, but outside of hospitalized patients, these sequelae are extremely uncommon. Even in high-risk patients, such as immunocompromised individuals, ascending infection is rare. In one study of chronically immunosuppressed transplant patients, only 1 in 100 subjects with candiduria progressed to candidemia. In contrast, candiduria after candidemia from other sources was common.[3,4] At a single medical center, only 0.2% of all urine samples were positive for fungi, almost all of which were *Candida*. Of that group, only 14 people in more than 100,000 (0.001%) received treatment with antifungals.[4,5]

Combine those statistics with molecular genetics studies examining fungal strains in patients with both fungiuria and fungemia. Only one-third of these infections had matching strains of *Candida* in blood and urine, suggesting that the poor condition of the patient may drive fungal overgrowth systemically. The mortality rate amongst patients with candiduria is high at almost 20%, but less than half of a percent of those deaths could be attributed to candidemia, signifying how fundamentally sick most of these patients are to begin with.

In support of this concept is the substantial documentation of patient risk factors for the progression of fungal urinary infections. Progressive or ascending fungal urinary infections almost always occur in patients who are already sick with some combination of immune system impairment (other illness, diabetes, malignancy) and a urinary tract abnormality, most commonly an obstruction (such as a stone or benign prostatic hyperplasia) or an indwelling urinary device, such as a Foley catheter or nephrostomy tube.

Thus, as urologists, we have a specific role in the management of fungal infection: improving the management of urologic predisposing risk factors. We must relieve obstructions, remove indwelling devices, if possible, exchange them if not possible, and do so using the least invasive approach possible. If there is suspicion of systemic fungal infection, imaging to look for fungal balls, hydronephrosis, or abscesses may be indicated as these could benefit from procedural intervention. This focus on modifying these risk factors comes from the fact that antifungals are often limited in their efficacy. Eradication of urinary fungi in patients treated with antifungals is less than 50%, which is not significantly different than the rates of resolution of fungiuria after removal of indwelling devices.[3]

As a contributing factor, 85% of patients with fungiuria had some other nonfungal infection treated with antibiotics in the month prior, the most common of which was urinary tract infection in 44%. Fungal populations can expand >1,000-fold after antibiotic treatment, promoting fungiuria, and increasing the risk of later fungemia. This might suggest that ongoing efforts at antibiotic stewardship are even more critical than we might expect; recent increases in pathogenic fungal infections may represent an additional aspect of the global "collateral damage" associated with antibiotic overuse.

In summary, while candiduria is common in some populations, invasive candidemia is rare and primarily restricted to patients who are already very ill. Thus, the decision to proceed with antifungals should be based on the patient's relative risk and the likelihood they will benefit from therapy. If there is suspicion of a systemic infection, every attempt should be made to resolve underlying risk factors–control the diabetes, remove indwelling devices, relieve urinary tract obstruction–as these interventions alone can be as effective as antifungals. ■

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AUA2023 TAKE HOME MESSAGES

Kidney Cancer

Amy N. Luckenbaugh, MD
Vanderbilt University Medical Center, Nashville, Tennessee

AUA2023 was filled with groundbreaking kidney cancer research. There were a total of 120 posters, 72 podiums, 11 video abstracts, 3 plenaries, and 1 late-breaking abstract on kidney cancer. The sessions covered a variety of topics, including new diagnostic tools, updated active surveillance data, surgical studies, and systemic therapy studies. Below a few important abstracts will be highlighted.

One of the most exciting and important abstracts was regarding a new diagnostic tool for clear cell renal cell carcinoma. Girentuximab is a monoclonal antibody that targets carbonic anhydrase IX. In the open-label ZIRCON study ^{89}Zr-DFO-girentuximab was administered to patients with a renal mass ≤4 cm and positron emission tomography/CT was performed in 300 patients. ^{89}Zr-DFO-girentuximab was both sensitive and specific for clear cell renal cell carcinoma, even across 3 independent readers. Overall sensitivity was 85.5%, specificity 89.5%, and positive predictive value 93.4%.[1] Availability and utilization of this positron emission tomography/CT may allow for improved counseling, as well as avoiding the need for biopsy in those with positive tests. Importantly, this is excellent for identifying clear cell renal cell carcinoma; however, a negative test does not rule out other forms of renal cell carcinoma.

Continuing along the theme of small renal masses, 12-year data from the DISSRM registry were presented. This registry compared active surveillance for small renal masses to primary intervention. They found nearly equivalent cancer-specific survival for those undergoing active surveillance vs primary intervention at 12 years of follow-up. Overall, patients with renal masses <2 cm were very unlikely to cross over to treatment (10.28%), while those with masses >3 cm were more likely to cross over to treatment (25.76%, HR 13.93 [95% CI: 7.25-26.74], $P < .01$).[2] Importantly, delayed intervention was safe, with no impact on recurrence-free survival. These data emphasize the safety of monitoring small renal masses. Urologists should continue to engage in shared decision-making with patients, and offer active monitoring as a management strategy, especially for small renal masses <2 cm in size.

Transitioning to advanced renal cell carcinoma, there were several abstracts highlighting cytoreductive

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KIDNEY CANCER

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nephrectomy in the immune checkpoint inhibitor era. Overall, cytoreductive nephrectomy following immunotherapy is feasible and safe with minimal impact on complications. In 1 study, patients who underwent immunotherapy experienced a decrease in tumor size and complexity, as well as a decrease in size of thrombus. The majority of patients had both negative margins and no postoperative complications (67.9%).[3] A second study demonstrated that 9% of patients undergoing cytoreductive nephrectomy following immune checkpoint inhibition experienced a complete pathologic response, with 100% of those patients being disease-free and alive at 3 years of follow-up.[4] Lastly, cytoreductive nephrectomy in all patients was shown to have an impact on patient-reported outcomes, with an improvement in patient quality of life postoperatively, with less reported worry about cancer progression following cytoreductive nephrectomy.[5]

In summary, it was a pivotal year for kidney cancer with emerging diagnostic tools, long-term data on monitoring small renal masses, and a glimpse of data supporting cytoreductive nephrectomy in the immune checkpoint inhibitor era. It will be interesting to see further developments in these areas to determine the long-term impact on patient care and outcomes. ■

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AUA2023 BEST POSTERS

Postchemotherapy Retroperitoneal Lymph Node Dissection for Seminoma: Is Surgery Effective?

Isamu Tachibana, MD
Indiana University School of Medicine, Indianapolis

Clint Cary, MD
Indiana University School of Medicine, Indianapolis

Timothy A. Masterson, MD
Indiana University School of Medicine, Indianapolis

Metastatic testicular seminoma that has metastasized to the retroperitoneum and beyond will principally be managed with cisplatin-based combination chemotherapy. Despite high treatment response, residual retroperitoneal disease will often be seen. The role of postchemotherapy retroperitoneal lymph node dissection (PC-RPLND) for residual seminoma remains uncertain. Based on National Comprehensive Cancer Network guidelines, resection of a residual mass concerning for persistent seminomatous disease may be attempted.[1] However, previous studies have demonstrated high rates of necrosis in the final pathology among these series.[2] Based on prior experience, surgical management can have worse efficacy and increased morbidity compared to nonseminomatous germ cell tumor, and the decision between further chemotherapy and PC-RPLND as second-line therapy can be challenging. Salvage chemotherapy is effective but is associated with short- and long-term morbidity.[3] Surgical efficacy in this setting seems to be limited, and in our previously described experience 9 patients out of 36 patients (25%) experienced no evidence of disease without postoperative salvage therapy.[4] However, the study included patients who had multiple lines of preoperative chemotherapy. We sought to study the efficacy of PC-RPLND after first line chemotherapy to determine if careful selection of patients could lead to surgical success without affecting the ability to receive any systemic salvage therapies if necessary or causing life-threatening morbidity.

Out of 889 patients who underwent PC-RPLND at Indiana University between January 2011 and December 2021, only 14 patients were operated on for seminoma. One patient was excluded for lack of follow-up. Out of 13 patients, only 3 patients were disease-free with surgery only (23.1%). Median follow-up time was 29.9 months (IQR: 22.6-53.7). Two patients died of disease. The remaining 8 patients were treated successfully with salvage chemotherapy.

All surgical candidates were first carefully selected to ensure that patients had active disease demonstrated by either clear progression of disease on standard CT imaging, elevated serum tumor markers, or progression of fluorodeoxyglucose (FDG) avidity on positron emission tomography (PET) imaging. Several prior studies by Decoene[5] and Cathomas[6] et al have shown a high false-positive rate when only using FDG PET acidity to select patients for PC-RPLND.

Of the included patients, 8 patients had confirmed disease recurrence by increasing growth on standard imaging. Two patients were followed with sequential use of FDG PET scan and demonstrated growth and increasing standardized uptake value positivity. Two patients had a CT scan with increasing growth, then had a FDG PET scan to show that the mass was positive. One patient was followed with serial FDG PET scans and had a shrinking mass but developed new avidity in that lesion and elected to undergo surgery.

> "With the toxicities of HDCT and the desmoplastic reaction of seminoma associated with surgical treatment, the decision to treat residual masses needs careful consideration."

Additionally, patients were selected if they were felt to be poor candidates for salvage chemotherapy or based on the feasibility of surgery without having to perform adjunctive procedures (nephrectomy or vascular grafting) that may add significant morbidity. Preoperative CT scans of cured patients are listed in the Figure, and a patient with recurrent seminoma who was felt to require significant additional procedures with PC-RPLND who went on to receive high-dose chemotherapy (HDCT) only is also included in the Figure. Despite the careful selection of patients for surgery, 4 patients required a concurrent nephrectomy, 1 patient required an aortic graft replacement, 2 patients required a partial ureterectomy with ureteroureterostomy, and 3 patients required some form of caval resection. Two patients had partial resection

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POSTCHEMOTHERAPY RETROPERITONEAL LYMPH NODE DISSECTION FOR SEMINOMA

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of the cava without grafting, and 1 patient required caval graft replacement. Even with careful consideration for surgical candidate to minimize morbidity, these cases remain challenging due to the desmoplastic reaction associated with seminoma.

Management of residual masses after chemotherapy for seminoma differs significantly from nonseminoma germ cell tumors. Limitations of diagnostic imaging with high rates of false positivity mean that the chance for overtreatment with a salvage chemotherapy or surgery is possible. With the toxicities of HDCT and the desmoplastic reaction of seminoma associated with surgical treatment, the decision to treat residual masses needs careful consideration.

PC-RPLNDs for active seminoma after first-line chemotherapy occur far less frequently than nonseminoma. At Indiana University, 23.1% of patients (3 out of 13) were disease-free after surgery despite careful selection, and even then, many required additional procedures such as nephrectomy or vascular grafting. With HDCT having success rates with 2-year progression-free survival of 90%, surgery should be reserved for select scenarios.[3] PC-RPLND for seminoma should only be utilized in rare scenarios such as a patient with concerns for life-threatening toxicity from HDCT. This decision is complicated and should involve a multidisciplinary effort from high-volume centers. ■

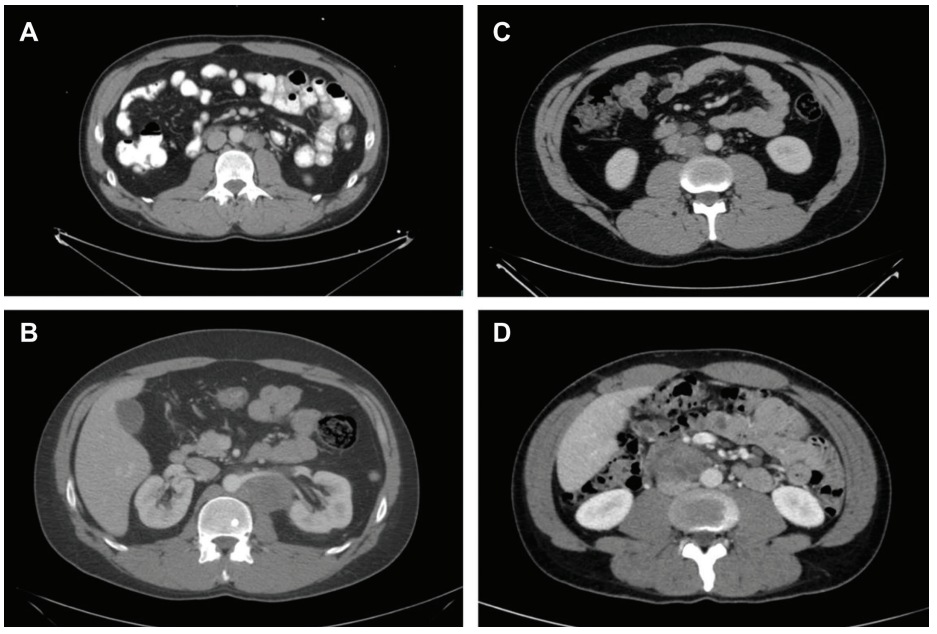

Figure. CT scans after first-line chemotherapy with seminoma and before salvage treatment. A and C, Patients were felt to be surgically resectable with minimal morbidity and were cured. B, Patient was expected to tolerate salvage chemotherapy poorly so elected to pursue surgery and was cured. D, Patient who was felt to require additional procedures during surgery and had high-dose chemotherapy.

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VOICES

The Imperative of Diversity in Peer Review

D. Robert Siemens, MD, FRCSC
Editor, The Journal of Urology®

Melissa Kaufman, MD, PhD, FACS
Associate Editor, The Journal of Urology®

Peer review plays a vital role in evidence-based medicine as the initial mechanism through which research is evaluated on the pathway to publication. Peer review is simultaneously a privilege and an extraordinary responsibility with which we should all be engaged. The practice of peer review has become completely integrated and essential for validating our medical literature. Our current system is designed to provide integrity and accuracy in published material, especially with our contemporary challenges of unethical practices such as nefarious use of artificial intelligence and the propagation of papermills.

Our current iteration of peer review is an inherently human endeavor. Authors anticipate and deserve a fair and unbiased critique to improve their manuscript and correct any errors prior to publication. However, the entire system relies on the volunteer efforts of engaged stakeholders and historical concepts relying on the memory of a handful of dedicated content experts guiding the decisions of editors, as a filter that allows promising research to pass, seems quaint. It is well understood that the inter-rater reliability between reviewers is modest at best and just because a publication claims peer review it does not mean that is without flaws in analysis or message. Indeed, as discussed below, structural racism, bias, conflict of interest, and fraud must be recognized and then intentionally and actively addressed to manifest a dynamic shift in culture for the betterment of our literature, and ultimately our patients.

To mitigate concerns with our current peer review process several proposed solutions have emerged. Preprint servers, such as bioRxiv, allow for public review and discussion prior to formal peer review processes and have become mainstream for many disciplines. *The Journal of Urology®* has incorporated preprints into our workflow although overall penetrance in the urological publishing world remains low. Some journals have experimented with compensation for peer reviewers, and others avoid formal peer review altogether in favor of continuous "public" adjudication and debate. The traditional single anonymous peer review model has been challenged by "blinding" of reviewers and authors alike as double-anonymous endeavors. At *The Journal or Urology®*, we have over a year's experience with enhancing transparency and inclusivity for our peer review process. After submission, the manuscript is evaluated by the in-house editorial team to detect major flaws and triage the manuscript to determine suitability for the mission of the journal prior to dissemination for peer review. Additionally, manuscripts moving through the peer review process undergo an in-depth statistical review. Given the breadth of scope in urology, these complex tasks require a deep lineup of editorial board members and reviewers with diverse voices and experiences. Over the last year we have

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THE IMPERATIVE OF DIVERSITY IN PEER REVIEW

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expanded and diversified our editorial board at *The Journal of Urology®*, including an open call for engaged members to apply, particularly researchers with specific expertise and interest in diversity and equity initiatives. As mentioned above, *The Journal of Urology®* has additionally instituted an open peer review process to promote transparency with allowance for reviewer concerns of anonymity in select situations. Actively collecting demographic data from our authors and reviewers to define our deficiencies and develop strategies to enhance diversity is also underway.

Today, the critical importance of diversity in peer review within scientific literature cannot be overstated. Introducing diversity among peer reviewers is essential to embrace individuals with varied perspectives, backgrounds, and experiences. This diversity fosters a broader range of insights and evaluations, leading to more comprehensive and well-rounded assessments of submitted papers. In a system of limited diversity, bias may intrude regarding the content and social context of the manuscript, affirmation or declination of the reviewer's beliefs, publication bias favoring positive outcomes, conflicts of interest, as well as conservatism against innovative research. When different viewpoints converge in the peer review process, it reduces the risk of such biases and promotes decisions based on scientific merit rather than personal preferences/experiences.

A diverse peer review process directly enhances the quality and relevance of scientific literature. Different cultures, regions, and disciplines offer unique insights and approaches to problem-solving. By involving experts from diverse backgrounds, research is more likely to address global challenges comprehensively and incorporate perspectives that otherwise might be overlooked. Additionally, diversity in peer review helps identify potential limitations or blind spots in our research, leading to more robust conclusions and recommendations. This, in turn, strengthens the overall scientific knowledge base and promotes more meaningful advancements.

Moreover, our efforts to advocate for diversity in peer review are crucial to model inclusivity and equity for the scientific community. Historically, we are all aware of underrepresentation and marginalization in society and therefore science, often culminating in a biased evaluation process. By actively involving a diverse pool of peer reviewers, we can address these disparities and work toward a more inclusive scientific environment. As an academic exercise, participating in peer review provides a curated opportunity to stay current with the latest advancements and research trends in one's field. Manuscript evaluation also hones critical evaluation skills. As a reviewer, one must carefully analyze the strengths and weaknesses of research papers, identify methodological flaws, and offer constructive feedback to authors. These skills are transferable and can be applied to one's own research, improving the quality and rigor of their own manuscripts and grant applications. Finally, opportunities to excel at peer review enhance one's expertise and credibility in the academic community. The recognition of knowledge and competence in a field can bolster one's reputation and provide collaboration opportunities, invitations to lecture at conferences, and potential leadership roles in academic or research institutions. This inclusivity encourages a broader range of researchers to participate in scientific discourse, fostering innovation and breakthroughs from a wider array of perspectives. As we continue to advance our insights into the traditional limitations of our own perspectives in urology, intentional efforts embracing diversity in peer review must remain a top priority to optimize ethically sustainable service for the entirety of our discipline and patient population. ■

Seventeen Inches: Health Care Lessons From a College Baseball Coach

Neil Baum, MD
Tulane University School of Medicine, New Orleans, Louisiana

As health care has become more complicated, physicians are often asked to perform tasks and accept decisions from others that negatively impact the doctor-patient relationship. I am certain that there are times when we are put in a position by our patients, our staff, our colleagues, and payors to bend the rules or to make concessions that are not always in the patient's best interest. We have been in situations where we are forced to compromise on what we should do and end up accommodating others out of expediency. I want to share a speech by John Scolinos, legendary baseball coach for Pepperdine University, who gave advice from his many years as a baseball coach, but also advice that can apply to all of us in the health care profession.

Coach Scolinos was invited to address the American Baseball Coaches Association's convention.

He said, "You're probably all wondering why I'm wearing a home plate around my neck. I stand before you today to share what I've learned about home plate in 78 years in baseball."

He began by asking how wide the baseball home plate was for Little League, and someone in the audience answered, "Seventeen inches." He asked about the plate width for high school baseball, college baseball, and the major leagues, and the answer was always 17 inches.

Scolinos asked, "What do they do with a Major League pitcher who can't throw the ball over those 17 inches?" After a long pause, he said, "They send him to play in Siberia or the Minor Leagues."

"What they don't do is say, 'We'll help you out and make it 18 inches or 19 inches. If that still doesn't work for you to throw strikes, we'll make it 20 inches, so you have a better chance of hitting it. If you can't hit that, let us know so we can make it even wider, say 25 inches.'"

Scolinos asked, "Tell me, what do we do when your best player shows up late to practice? What is your reaction when your team rules forbid facial hair, and a guy shows up unshaven? What if they are caught drinking? Do we hold them accountable? Or do we change the rules to fit them? Do we widen home plate?"

Coach Scolinos continued, "This is the problem in our homes today. With our marriages, how we parent and discipline our children. We don't teach accountability to our kids, and there is no consequence for failing to meet standards and follow directions. What we do is widen the plate!"

He paused, then pointed to the top of the house, removed a red and blue Sharpie, and drew a small American flag. "This is the problem in our schools today. The quality of our education is going downhill fast, and teachers have been stripped of the tools they need to be successful and to educate and discipline our young people. We are allowing others to widen home plate! Where is that getting us?"

"If I am lucky," Coach Scolinos concluded, "you will remember one thing from this old coach today. It is this: if we fail to hold ourselves accountable, a standard of what we know to be right; if we fail to hold our spouses and our children to the same standards; if we are unwilling or unable to provide

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SEVENTEEN INCHES: HEALTH CARE LESSONS FROM A COLLEGE BASEBALL COACH

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consequences when they do not meet the standard, and if our schools and churches and our government fail to hold themselves accountable to those they serve, there is but one thing that will occur… dark days are ahead!"

His message can be applied to the practice of medicine. We fault young doctors for only working 80 hours a week and not developing the resiliency that older physicians experienced as young, training doctors. Our burnout rate exceeds 50% of physicians, fellows, residents, and even medical students. Yet, many in our profession still need to address this problem which has reached epidemic proportions.

> "We expect patients to accept that the doctor is 30-60 minutes delayed in seeing patients because the previous patients took more time. We can do better; the plate is still 17 inches!"

We expect patients to accept that the doctor is 30-60 minutes delayed in seeing patients because the previous patients took more time. We can do better; the plate is still 17 inches!

We tolerate employees who do not dress professionally. We don't admonish staff for using their cell phones while at work and checking their Facebook nonmedically related messages.

We have accepted insurance companies denying requests for procedures and medications that are appropriate for patients without realizing that this is not in the best interest of our patients.

We have tolerated being told we cannot communicate with patients about their weight, smoking status, and lack of exercise because it isn't politically correct.

We have all accepted patients calling us in the evening or on the weekends asking us to refill the medications that they have been using for months or years but forgot to call during office hours. When we ask for the number of their pharmacy and agree to refill their medications, we have lowered the bar and increased the plate size. You can be sure the patient will call you again at their convenience rather than yours.

Bottom line: Coach Scolinos has a message that resonates way beyond baseball and has applications for the entire health care profession. Let's begin questioning what our country, government, and profession have become and how to fix it. Coach Scolinos' take-home message is, "Don't widen the plate; it's still 17 inches!" ■

> "We have accepted insurance companies denying requests for procedures and medications that are appropriate for patients without realizing that this is not in the best interest of our patients."

Coach Lou Holtz and Pharmaceutical Representatives

Neil Baum, MD
Tulane University School of Medicine, New Orleans, Louisiana

Today with the necessity of seeing more patients, many physicians refuse to see pharmaceutical representatives (PRs). However, PRs serve as a great resource, and finding a way to make their visits more efficient and focused is an objective we all must strive for.

I recall requesting an interview with Lou Holtz, the head football coach at Notre Dame. His secretary informed me of the date and time that the interview would take place. Before the secretary concluded our conversation, she told me that Coach Holtz would allow 10 minutes for the interview. Ten minutes to interview one of the most famous coaches of all that time. How could I possibly do this in such a short time?

I called several friends in the media and asked how to accomplish the interview in just 10 minutes. They suggested that I submit the questions I wanted to ask Coach Holtz so he might think about his answers before the call and that I could focus on recording his answers. I sent the coach 5 questions and called at the designated time. He answered the questions in 9 minutes! I asked him if he wanted to see the article before I submitted it to the publisher, and he said, "No, Neil, that won't be necessary; I know you will do a good job!" At precisely 10 minutes after initiating the call, he hung up. Mission accomplished.

The same technique can be used with PRs. When a representative comes to the office and asks to see the doctor, they are given a note that I can meet with them. However, I ask them to complete a form listing the 2 or 3 issues or details they would like to discuss, and the form asks if they can accomplish this in 7.5 minutes. (I like providing an odd number so they know I will check my watch.) I also have an hourglass that I flip over when the meeting starts to remind them that they are "on the clock" or "in the sand." As a trade-off to the PR, I will try to see them on time (see Figure).

Figure. Use of an hourglass to indicate the importance of keeping the visit timely.

This technique focuses the PR to discuss only the topics they have placed on the form and encourages them to be brief with their visit.

> "If you are a physician with a time issue because you are seeing more patients, try this technique."

If you are a physician with a time issue because you are seeing more patients, try this technique. You will find that you will still be able to see PRs without a negative impact to your schedule.

Bottom line: Pharm reps can be an asset to our practices. However, as we are in a time crunch, it is necessary to streamline their visit. This can be accomplished by asking them to create an agenda prior to the visit. ■

SPECIALTY SOCIETIES

Take Home Messages From the 2023 Canadian Urological Association Annual Meeting

Lysanne Campeau, MD, CM, PhD, FRCSC
McGill University, Montreal, Canada

Girish Kulkarni, MD, PhD, FRCSC
Toronto, University of Toronto, Canada

The 78th Annual Meeting of the Canadian Urological Association (CUA) took place in bustling Montreal, Quebec, Canada from June 23-25, 2023, and hosted 962 registered participants–a record number! The entire meeting was masterfully organized and held under the tenure, guidance, and leadership of the CUA past-president, Dr Armen Aprikian.

The comprehensive program boasted a wide array of topics to enhance our knowledge and promote lively discussions among attendees. A total of 11 state-of-the-art speakers, both domestic and international, delivered captivating presentations on topics ranging from endourology to genitourinary malignancies to functional reconstructive urological surgeries. The scientific program also included an impressive 200 abstracts, with 30 podium presentations.

The meeting kicked off with an enlightening talk by Dr Mamta Gautam entitled, "Wellness as a Shared Responsibility," which set a reflective tone to our meeting and was very well received by attendees. Dr Nicole Miller then shared her pearls of wisdom on holmium laser enucleation of the prostate, followed by a practical and entertaining talk by Dr Darron Smith on endourology. At our first annual dedicated Women in Urology State-of-the-Art talk, Dr Monica Farcas shared a fascinating introduction to an innovation pathway, and we closed the day with Dr Stéphane Bolduc's CUA Scholarship Foundation lecture on his research adventures from urogenital tissue engineering to clinical investigation, followed by the awarding of this year's scholarship recipients.

> "The scientific program also included an impressive 200 abstracts, with 30 podium presentations."

On day 2, Dr Nicholas Cost presented his work on the cytotoxic effect on the lower urinary tract of childhood cancer survivors. Our very own Dr Curtis Nickel gave a captivating talk about his search for the wild saw palmetto berry and a cautionary tale about all urological supplements. The focus then switched to prostate cancer, with Dr Eleni Efstathiou presenting on redefining precision in prostate cancer, followed by the Canadian Urological Oncology Group Lecture on prostate cancer systemic therapy delivered by Dr Kim Chi.

On the third and final day, Dr Lee Zhao presented his creative and engaging perspective on robotics for reoperative surgery, and Dr Bernie Bochner presented on the contemporary surgical management of high-risk bladder cancer. Last, but certainly not least, Dr Irwin Goldstein, a native Montrealer, concluded the series of state-of-the-art lectures with his talk on female sexual function and dysfunction, shedding light on this often-overlooked field of urology.

In addition to the state-of-the-art lectures, there were 7 highly engaging educational fora, carefully curated by our scientific program committee to cover pertinent topics for both academic and community-based practitioners.

The first forum addressed the latest advances on urolithiasis. We then had a comprehensive and multidisciplinary review of approaches to pelvic pain, providing very practical and useful management options. On the second day, a panel of pediatric and adult urologists presented on the transitional care of neurogenic bladder patients, followed by an educational forum on the management of advance prostate cancer. The final day featured a panel of urologists, medical oncologists, and radiation oncologists discussing bladder preservation treatment options for bladder cancer and a review on the nonsurgical treatment of small renal masses. Finally, our last forum was a multidisciplinary presentation on urological care for the LGBTQ+ patient population.

Concurrently, several affiliated organizations also held meetings at the event, including the Genitourinary Medical Oncologists of Canada, the Urology Nurses of Canada, the Functional and Reconstructive Urology Society of Canada, the Pediatric Urologists of Canada, and the Canadian Endourology Group.

The enjoyment of the weekend was further enhanced by a social program that included a networking night at the iconic Montreal Windsor station, and a memorable President's Banquet to close the event.

The CUA Annual Meeting always provides a wonderful opportunity to engage in informative, cutting-edge educational sessions and to network with peers in an intimate setting, and this year's highly successful iteration was no exception. ■

AUA LEADERSHIP PROGRAM

AUA Leadership Class 2023-2024: Where Will It Take Me?

Paul Chung, MD, FACS
Sidney Kimmel Medical College, Thomas Jefferson University, Philadelphia, Pennsylvania

It is an honor to be part of the 2023-2024 AUA Leadership Program (LP) which kicked off July 28-30, 2023. The program, which started in 2004, has a strong legacy, developing leaders and contributors within the AUA. This year the program was increased to 3 members per section and includes numerous already accomplished urologists. Being part of the LP is an exciting opportunity to receive mentorship from existing leaders and to be amongst motivated urologists from other subspecialties and career paths. My goal in participating in the LP is to develop leadership skills which will improve my growth within the AUA, subspecialty societies, my home institution, and my department, which will in turn broaden future career opportunities.

Although I have been part of the AUA since I was a medical student, it was not until participating in the LP that I understood the governance of the AUA. Did you know that the AUA has approximately 150 employees and over 900 volunteers who help the AUA, AUA Research and Education, Urology Care Foundation, and AUA PAC function? Knowing the structure of the AUA and having a better understanding of the behind-the-scenes activities allows me to better appreciate the support, education, planning, and legislation that is being done on our behalf. I am now motivated to be part of the AUA volunteer team and understand how to get involved so that I can give to the organization which has fostered my growth.

The LP is an opportunity to engage with colleagues from other institutions and subspecialties with varied experiences who are at different points of their careers. As part of the LP, we are divided into small groups and tasked to complete a capstone project aimed to better understand a need within urology. My team will identify the challenges of urologists working in rural and underserved communities as part of the effort to increase the urology workforce. These projects are often outside of our regular research interests and require us to leverage our best time management, communication, and teamwork skills on top of our regular commitments.

The LP helps me to recognize that leadership takes numerous forms and exists in numerous microcosms (ie in the operating room, in the clinic, as a resident educator, as a medical student mentor). We engage in leadership education designed to help us maximize the best of our own personalities and those around us to achieve maximum results. I appreciate the opportunity to participate in the LP, which will surely be a pivotal point in my career. I will utilize the skills developed to improve myself and those around me. I'm excited to see the path my career may take and how the LP will help along the way. ■

MEDICAL STUDENT COLUMN

Nurturing the Next Generation of Urologists: Mentorship and Its Personal Impact on Medical Students in the Preclinical Years

James Dornbush, BSA
AU/UGA Medical Partnership, Medical College of Georgia, Athens

At the Medical College of Georgia AU/UGA Medical Partnership, students are encouraged to conduct research at outside institutions during the summer between their M1 and M2 years. Reflecting on my recent research experience in urology under the guidance of Dr Ranjith Ramasamy at the University of Miami (Figure 1), I have come to recognize the importance of mentorship during this formative time.

Medical school's preclinical years mark a pivotal transition for medical students to the rigor of their new coursework–the adjustment to medical school is often described as "drinking from a firehose." This period lays the groundwork for our future careers, shaping our understanding of basic medical principles while instilling the values of compassion and empathy. Unfortunately, access to various specialties remains limited during this stage,[1] with exposure restricted to what appears in the curriculum, student interest groups, and self-organized shadowing opportunities. Waiting until clinical rotations for exposure to more specialized medical fields may hinder a student's residency application, especially when research within the specialty of interest is strongly associated with success in the Match.[2,3] Therefore, mentorship is a critical factor that can enable medical students to discover and be productive in subspecialities earlier in their education.[4]

> "The basic science that I was drilling into my memory less than a month ago was now essential for our patient in the proper identification of their immature sperm."

Moreover, the preclinical years often overwhelm students with complex scientific concepts and vast clinical information, making it challenging to see the real-world application of the curriculum and its implications for patient care. In my own experience, I frequently found

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NURTURING THE NEXT GENERATION OF UROLOGISTS

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myself losing sight of the practical significance of my studies. My mentor, Dr Ramasamy, served to bridge the gap between theoretical knowledge and its practical implications. In this way, a mentor can act as a guiding light, enhancing a medical student's exposure, experience, and research within a field.

My final unit of first year was the reproductive unit, a welcome change of pace to cater towards my interests in urology. It consisted of several interesting case studies, including ambiguous genitalia, nutcracker syndrome, and infertility secondary to nonobstructive azoospermia. As part of this, I found myself memorizing the stages of spermatogenesis and their histology. Fast forward to my research summer, where Dr Ramasamy had me perform operating room microscopy on the testis tissue to confirm the presence of sperm during testicular biopsy. In this case, the patient had maturation arrest. The basic science that I was drilling into my memory less than a month ago was now essential for our patient in the proper identification of their immature sperm. Dr Ramasamy's guidance not only provided transparency on the real-world implications of my medical education but also served as motivation for my future studies, with the goal of delivering exceptional patient care.

> "Mentorship encompasses not only the transfer of knowledge but also the mentor's commitment to the student's growth and development."

Throughout my summer research experience, the transformative value of personal investment from a mentor became evident. Dr Ramasamy displayed genuine interest in my growth as a future physician, extending his mentorship beyond the clinic. For example, Dr Ramasamy understood that my wife and I were moving to Miami, a city where we had no established connections, and took proactive measures to ensure our smooth integration. Hosting team-wide social functions and engaging in one-on-one activities like lunches, chats over cortaditos, ping pong matches, and weight-lifting sessions helped us get to know one another on a personal level. In these moments, I was comfortable to share my aspirations, strengths, and weaknesses so he could then tailor his mentorship to my individual needs.

This personal investment fostered trust and rapport, creating a safe environment for open communication and idea exchange. As a result, I felt confident to share my thoughts, ask questions, and actively contribute to the team. Dr Ramasamy's dedication to my development translated into my increased commitment and dedication to the research projects we undertook. Beyond academic and research guidance, he also provided valuable insights on work-life balance and staying motivated during challenging times.

Lastly, Dr Ramasamy focused on expanding my professional network by introducing me to other urologists and researchers, both in-person and online. Not only did this allow me to expand my understanding of urology as a career, but it also connected me with other physician-scientists for additional research opportunities. This was especially insightful, as I was able to observe how different clinicians tailor their practice with their patients. In addition, he helped me establish myself on Twitter/X, which is especially important given its increased usage within the urology community.[5, 6]

Figure 1. James Dornbush, BSA (left) and Ranjith Ramasamy, MD (right).

My experience in urology research under Dr Ramasamy's mentorship has highlighted the indispensable role of mentorship during a medical student's preclinical years. Mentorship encompasses not only the transfer of knowledge but also the mentor's commitment to the student's growth and development. Through this experience, I have come to understand that mentorship goes beyond imparting information; it lies in their willingness to invest personally in their mentee, empowering students to explore their passions, overcome challenges, and embrace their roles as future physicians. ■

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CASE REPORT

Squamous Cell Carcinoma of the Renal Pelvis Associated With Nephrolithiasis and Perirenal Abscess

Desiree Draeger, MD
Medical University of Rostock, Germany

Annette Zimpfer, MD, FIAC
Institute of Pathology, Medical University of Rostock, Germany

Oliver Hakenberg, MD, PhD, FEBU
Medical University of Rostock, Germany

Case Report

A 55-year-old man presented with recurrent episodes of septicemia due to nephrolithiasis and right-sided hydronephrosis. A perirenal abscess of the right kidney with nephrolithiasis was described on CT scanning (Figure 1). In the past, there had been several interventions for recurrent stone disease. Also, the patient had been suffering from a neurogenic bladder disorder due to meningomyelocele and spina bifida. For 20 years, this had been managed by indwelling urinary catheter only. Five years ago, he underwent simple cystectomy with an ileal conduit. Other comorbidities were diabetes mellitus and arterial hypertension. The CT scan showed a nonfunctioning right kidney, the abscess was surgically drained, and a nephrectomy was performed. Surprisingly, pathology showed a locally advanced and squamous cell carcinoma of the renal pelvis (pT4 pN2 (2/4) V1 L1 Pn1 R2 G3; Figure 2). A 1.5 cm stone was also found in the renal pelvis.

The postoperative course was unremarkable. Due to the incomplete resection in the perinephric adipose tissue, systemic chemotherapy with cisplatin/paclitaxel/ifosphamide was advised but refused by the patient. Instead, immunotherapy with pembrolizumab was initiated. The patient received a total of 3 cycles with progressive deterioration of his general condition. Three months after the surgery, the patient was hospitalized again in septic shock and disease progression with cutaneous metastases. Palliative care was implemented, and the patient died a few days later.

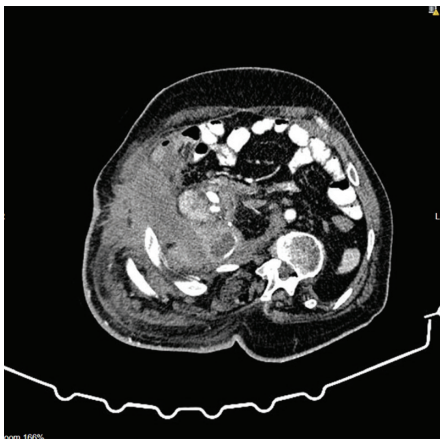

Figure 1. CT demonstrated a large abscess formation of the right kidney and calculi in the pelvis.

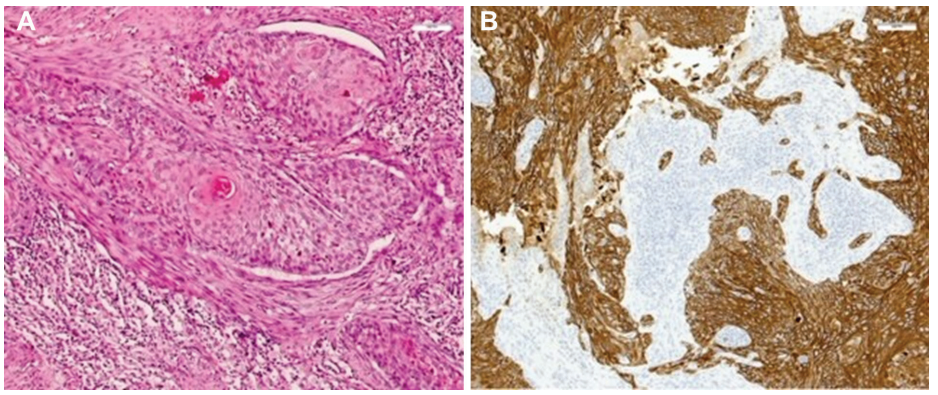

Figure 2. Squamous cell carcinoma of the renal pelvis. A, Hematoxylin and eosin–stained sections revealed a moderately to weakly differentiated solid carcinoma with squamous morphology and focal keratinization against an inflammatory background. Original magnification ×100. B, Squamous cell differentiation was further highlighted by positive CK5/6 immunohistochemistry. Original magnification ×100.

Discussion

Upper urinary tract tumors constitute 5% of all urothelial cancers. Squamous cell carcinomas (SCC) are even more rare in this localization, amounting to just 0.5% of all upper urinary tract tumors. SCCs of the urothelium usually occur in late adulthood (aged 50–70 years) and are usually diagnosed after surgery and at advanced stages. There are no typical clinical and radiological properties. Due to their rarity and the often-advanced stage at the time of diagnosis, SCC of the renal pelvis and ureter are a therapeutic challenge. Since the first description of this entity in 1878 (Hedenius and Waldenstroem), fewer than 400 cases have been published worldwide. Accordingly, there are neither evidence-based guidelines nor extensive experience in any one center. Treatment recommendations are based on the case series published to date.[1,2] In 48% of cases, the cause is of SCC development from urothelium is considered to be nephrolithiasis with chronic irritation and inflammation of the urothelium of the renal pelvis.[2-4] CT and ultrasound are important tools to evaluate renal malignancies. However, the diagnosis of renal pelvic SCC is difficult because both CT and ultrasound in such cases usually show only calculi and hydronephrosis due to obstruction.[5,6] Adjuvant (cisplatin-based) chemotherapy and radiotherapy have no lasting benefits for overall survival of renal SCC.[7] Five-year overall survival is approximately 10% and most of these patients die within 1 year of diagnosis.[8,9] When diagnosed in early stages, a potentially curative option is radical nephroureterectomy, but the prognosis remains difficult.

> "Treatment is primarily surgical. In advanced stages, systemic therapy may be used analogous to the treatment schemes for squamous cell carcinoma of nonurological origin."

Clinical Practice Points

SCC of the upper urinary tract are rare and have a poor prognosis due to the usually late diagnosis and the lack of evidence-based treatment strategies. Treatment is primarily surgical. In advanced stages, systemic therapy may be used analogous to the treatment schemes for squamous cell carcinoma of nonurological origin. ■

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Experience of an Incoming Urology Resident at the AUA Intern Academy

Julie A. Klock, MD, MS
Glickman Urologic and Kidney Institute, Cleveland Clinic, Ohio

Howard B. Goldman, MD
Glickman Urologic and Kidney Institute, Cleveland Clinic, Ohio

There is a specific inflection point that many recently graduated physicians experience: the moment when the scale tips from the elation of matching to the fear of not being prepared to take on the responsibility of being a resident.

I am no exception to this rule. Like many friends and colleagues, I was committed to being the best medical student I could be, specifically for urology subinternships and away rotations. My feeling of mastery over the content at the medical student level has since faded away into questioning, well, everything.

When news of the AUA Intern Academy arrived in my inbox, I could only hope that I would have the opportunity to attend. I was fortunate enough to be starting residency at the site chosen for this year's course, Cleveland Clinic's campus in Cleveland, Ohio, and to have the program offer attendance to its junior residents.

The course began with an introductory lecture from Drs Sammy Elsamra and Ahmed Ghazi. Then, we proceeded to the first of 6 hands-on skills sessions. Each rotation was scheduled for 2 hours. There were 3 assigned for the first day, with the remaining 3 on day 2.

Endoscopy: The endoscopy station was set up with 2 main goals: (1) to practice cystoscopy and complete a cannulation and stent removal, and (2) to practice ureteroscopy and to basket a stone. Both stations had ample instruction from our faculty and vendor representatives. It was an excellent opportunity to work with endoscopy equipment and practice the dexterity required to do some of the most common urologic procedures.

Catheterization: The catheterization station began with education on troubleshooting difficult catheterizations and hands-on practice for bladder irrigation. The second portion was practice with difficult catheterizations using 3D printed models of different anatomical impediments. We had hands-on scope experience at this station, which was affirming after our prior training in the endoscopy station.

Communication skills: This station was one of the most surprising. While not directly related to surgical skills, it was a chance to dynamically experience medical decision-making, communication, and their consequences. Each group worked through a series of case studies via role play. Discussion and improvisation were encouraged. It was a very thought-provoking station.

Ultrasound: This station covered transrectal ultrasound as well as ultrasound of the bladder and kidney. The transrectal ultrasound portion covered the different types of probes and prostate biopsy methods and offered us a chance to ultrasound a model prostate and take a biopsy. This was a great first experience for many of us who had not done this before. The kidney station was designed to practice getting percutaneous access to the kidney. This excellent experience brought to light many of the challenges and solutions to gaining percutaneous access. The bladder station covered the different types of probes–when they should be used, how to calculate bladder volume, and suprapubic tube placement using ultrasound guidance.

> "There is a specific inflection point that many recently graduated physicians experience: the moment when the scale tips from the elation of matching to the fear of not being prepared to take on the responsibility of being a resident."

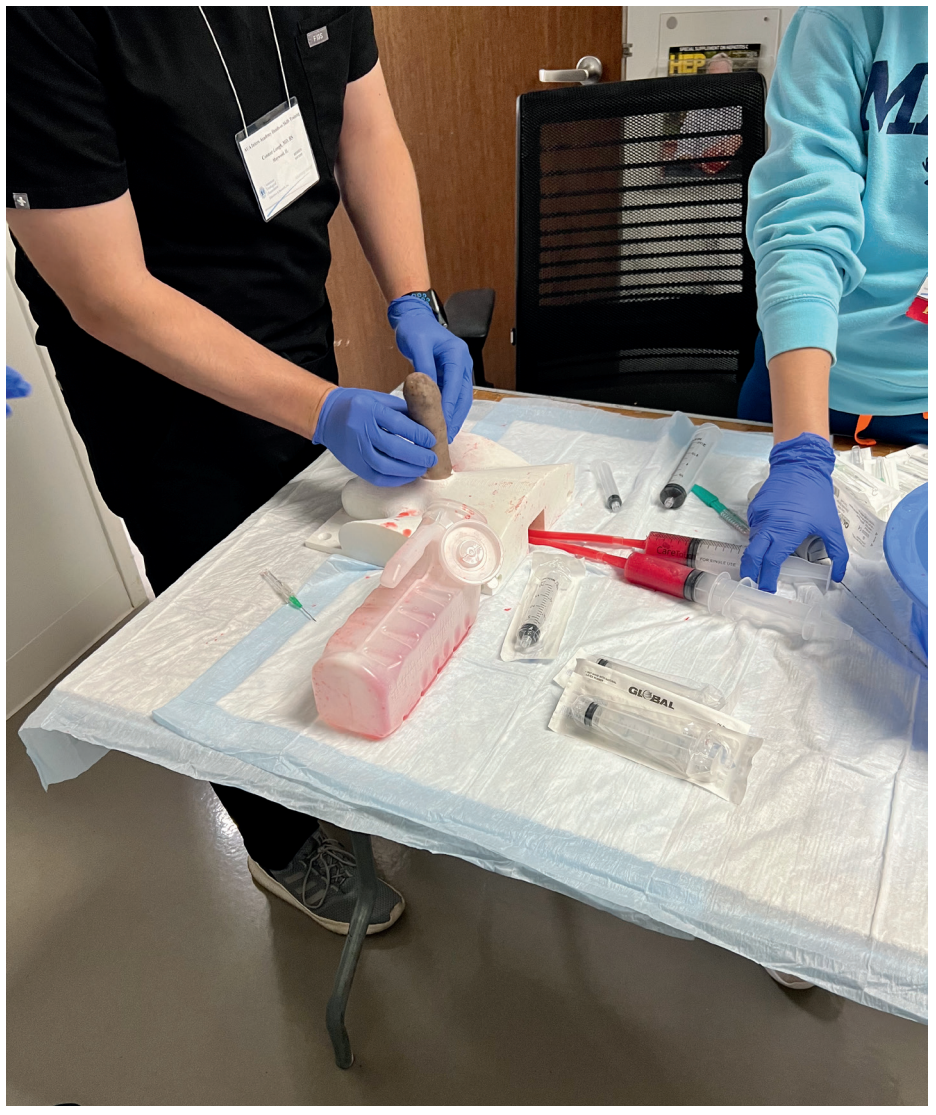

Figure. Priapism model from the lab of Dr Ghazi.

Priapism: The priapism station had one of the best simulation models I have worked with (from Dr Ghazi's lab, see Figure). The model was anatomically correct, with cavernosal bodies that could be continuously filled with fake blood. In this station, we discussed the etiology and management of priapism before practicing aspiration, irrigation, and shunts on the model.

Surgical skills: I have always loved surgical skills, so my expectation for this station was high. Like the other blocks, I was happily surprised by the breadth and depth of content. We began by discussing the different types of suture material and needles. We then practiced knot tying and various suture styles. There was 1 faculty member per table of 6 trainees, and this ratio was optimal for timely feedback, challenges, and discussion. This was a real treat compared to what is possible in a typical workday.

After the 2 days of hands-on training, getting to know peers and faculty from across the country, and asking as many questions as needed, I felt much more prepared for the upcoming year. Each faculty member was kind and approachable, with a trove of knowledge and a love of teaching. The equipment and representatives were second to none. It was an invaluable experience to have this amount of hands-on practice before working with patients.

While intern year remains daunting, the AUA Intern Academy did an excellent job preparing us for what is to come. ■

FROM THE RESIDENTS & FELLOWS COMMITTEE

Preventing Injuries Before They Happen: Incorporating Surgical Ergonomics Education Into Urologic Residency Training

Miyad Movassaghi, MD
Columbia University Medical Center, New York, New York

Its clear prevention is key. The concept and practice of ergonomics has gained significant awareness in recent years, but it continues to remain poorly understood and underutilized by health care workers, including practicing urologists and trainees.

Throughout their training, surgical residents and fellows spend most of their time focusing on learning anatomy, disease processes, and how to perform and get through cases in the operating room, while proper posture and technique take a back seat. Maintaining awkward positions or ergonomic stressors in the operating room for extended periods of time can lead to a variety of injuries known as work-related musculoskeletal disorders (WRMDs).[1] If left unchecked, these stressors can progress into debilitating neck, shoulder, and back pains that can result in career-ending injuries. In fact, a recent meta-analysis, which included over 5,000 surgeons, found that 2 in 3 surgeons reported experiencing a WRMD during their lifetime, with 30% of individuals surveyed reporting seeking medical care for their symptoms.[2]

> "Throughout their training, surgical residents and fellows spend most of their time focusing on learning anatomy, disease processes, and how to perform and get through cases in the operating room, while proper posture and technique take a back seat."

Unfortunately, urologists are far from immune to WRMDs. Nearly 90% of practicing urologists surveyed by *Urology Times* reported having experienced pain in the last year attributed to their work, with 1 in 3 urologists reporting that they experienced pain more than once per week. Additionally, nearly 70% of urologists reported having used nonsteroidal anti-inflammatory drugs to cope with musculoskeletal pain while operating.[3] Trainees seem to experience similar rates of injuries, albeit much earlier in the careers. In a recent study by Childs et al, two-thirds of urology residents surveyed experienced work-related pain or injuries during their training.[4]

So what can we do? There are many evidence-based ergonomic recommendations for the various surgical approaches that urologists use involving open, robotic-assisted, laparoscopic, and endoscopic procedures. Making simple adjustments to equipment (ie, monitor height, C-arm, pedal placement, light and energy sources contralateral to monitors) and body positioning (ie, optimal wrist, neck, elbow angles, seated vs standing posture), obtaining fitted loupes, taking microbreaks, and stretching during or between cases have been shown to reduce the risk of work-related discomfort and pain while improving operative performance and career longevity.[1,5] The earlier these principles can be adopted, the less likely potentially career-threatening injuries develop.

> "Making simple adjustments to equipment (ie, monitor height, C-arm, pedal placement, light and energy sources contralateral to monitors) and body positioning (ie, optimal wrist, neck, elbow angles, seated vs standing posture), obtaining fitted loupes, taking microbreaks, and stretching during or between cases have been shown to reduce the risk of work-related discomfort and pain while improving operative performance and career longevity.[1,5]"

Any chance at reducing WRMDs among surgeons needs to start with early surgical ergonomics education. Park et al found that 59% of laparoscopy-practicing general surgeons surveyed reported slight to no awareness of surgical ergonomic recommendations.[6] This comes as no surprise, as few residency programs have incorporated education on surgical ergonomics. In fact, a study by Epstein et al found that only 1.5% of general surgery residency program directors reported having some type of formal surgical ergonomics education as a part of their curriculum.[7] These rates are likely similar in our field, further highlighting the need for surgical subspecialities to assess the feasibility and impact of implementing ergonomics education into their training programs.

Coupled with this nescience is a culture that prizes resilience under stressful situations, often conditioning trainees and practicing surgeons to "work through the pain," prioritizing the health and safety of patients while neglecting their own comfort and well-being. And it's often this mentality that backfires when untreated injuries lead to major health problems later on in a surgeon's career. A new focus on improving health with ergonomic interventions needs to start at the trainee level. Residency is an opportune time to do this and can help reduce rates of workplace injuries and improve career longevity and overall well-being.

> "A new focus on improving health with ergonomic interventions needs to start at the trainee level. Residency is an opportune time to do this and can help reduce rates of workplace injuries and improve career longevity and overall well-being."

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PREVENTING INJURIES BEFORE THEY HAPPEN

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level. Residency is an opportune time to do this and can help reduce rates of workplace injuries and improve career longevity and overall well-being. ■

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

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Gamifying Robotic Surgical Simulation Training

George W. Moran, MD
Columbia University Irving Medical Center, New York, New York

Justin A. Lee, MD
Columbia University Irving Medical Center, New York, New York

Gina M. Badalato, MD
Columbia University Irving Medical Center, New York, New York

Christopher B. Anderson, MD, MPH
Columbia University Irving Medical Center, New York, New York

Gamification, using principles of game design like competition and rewards, has been shown to be an effective way of enhancing resident training in various specialities.[1-4] This has been particularly true in surgical fields, where skill acquisition is paramount and trainees often identify themselves as competitive and comfortable working in teams.

When we piloted gamified robotic surgical simulation training (sim) at Columbia University Irving Medical Center in 2020, using the Intuitive Surgical da Vinci Skills Simulator (also known as "the backpack"), we saw a significant increase in time residents spent on sim exercises and found that most residents reported increased confidence in their surgical skills, autonomy in the operating room, and anticipated future sim training.[5] Our preliminary experience showed us that gamification can provide a framework for sim practice that is instructive, motivating, and fun for residents. Understanding that there is no substitute for live surgery, we gained confidence that time spent training effectively with sim could improve performance and training gains in the operating room.

Exciting developments in sim are pushing the field forward across multiple fronts. Recent advances include high-fidelity hydrogel models with imbedded force sensors[6] and automated performance metrics.[7] We believe that centers with accessible da Vinci Xi robots that are unable to obtain these new technologies can still do sim effectively using cheap and easily attainable supplies. Furthermore, we believe there is still work to be done to engage trainees in sim and build consensus on what amount and type of sim training benefits urology trainees most. Gamification enables us to incentivize goal-directed training, instructing the resident who is already juggling clinical duties, board study, and research activities on what surgical skills to practice and what level of competency to aim for.

> "In the first half of the academic year, mid- and senior-level residents (PGY-3s, -4s, and -5s in a 6-year program) completed a dry lab curriculum designed to develop key technical skills including efficiency, precise cutting, tissue handling, retraction and third arm use, dissection, needle control, knot tying, and 3D problem solving."

This year, we built a sim curriculum of our own and began testing the merits of gamification more rigorously. In the first half of the academic year, mid- and senior-level residents (PGY-3s, -4s, and -5s in a 6-year program) completed a dry lab curriculum designed to develop key technical skills including efficiency, precise cutting, tissue handling, retraction and third arm use, dissection, needle control, knot tying, and 3D problem solving. Our aim was to supplement existing virtual reality training platforms with models made from supplies that anyone can find in a supply closet or grocery store. Our first training block included 3 "skill modules," each of which was designed to target at least 1 key technical skill. For example, a module designed to train needle control, knot tying, and appropriate use of tension involves sewing together 2 boggy teabags without displacing or tearing them (Figure 1). The block ended with 1 "anatomic module," which, rather than focusing on developing a discrete skill, is meant to simulate a challenging step of a commonly performed robotic surgery. We used materials such as a Foley catheter, dish sponge, and paper cup to build a simulated vesicourethral anastomosis (Figure 2). Residents were provided videos demonstrating how to build each module so they could practice on their own.

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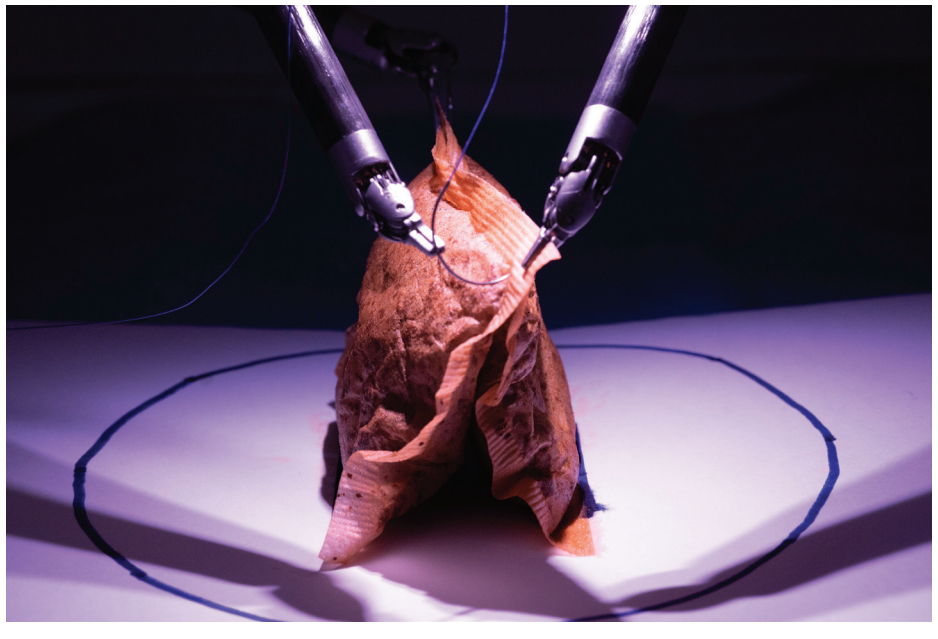

Figure 1. "Teabags" training module.

GAMIFYING ROBOTIC SURGICAL SIMULATION TRAINING

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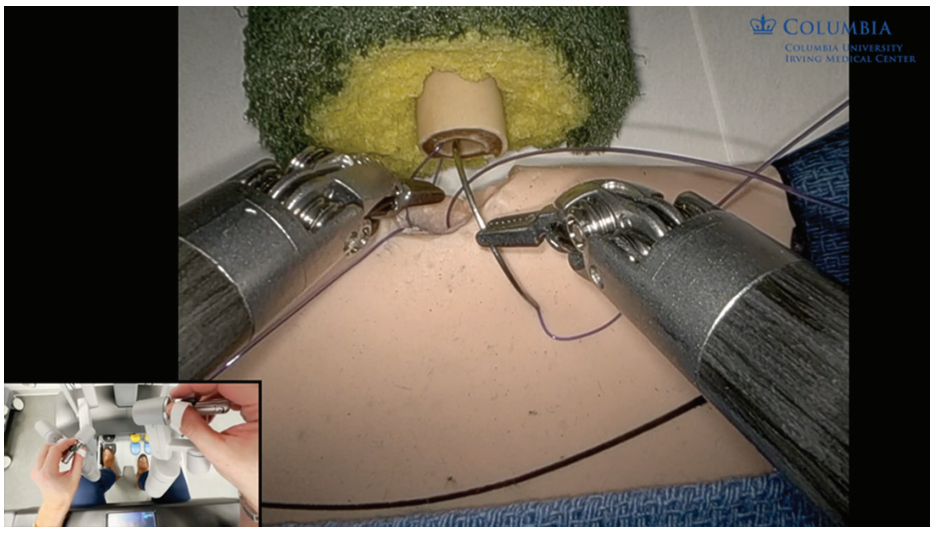

Figure 2. Video of an expert robotic surgeon completing the vesicourethral anastomosis module.

In the second half of the year, this curriculum was gamified by making it a team competition. All residents were assigned to teams with attending coaches. At the start of each month, we sent out a scoring rubric and a narrated video of an expert robotic surgeon completing the module of the month, so residents came to each session knowing exactly what they needed to do to score well. In addition to the traditional surgeon's-eye view, we also nested a synced video of the surgeon's hands as a "picture-in-picture" in the corner (Figure 2). We believe that this will allow trainees to develop proper technique more readily, with appropriate attention to disciplined hand and arm positioning. We also sent out online scorecards, by which residents could score their own performance on each module. In the teabag module, for example, a competitor loses points if the teabag is dragged out of place, if the suture line does not sit exactly at the margin between the tea pouch and its circumferential collar, or if the suture was pulled too hard and tears a hole in the teabag (Figure 3). Team scores were totaled at the end of each month to determine the winner of the round, and the team with the best win-loss record was crowned as champions. We have been prospectively testing the validity of these modules, with attending urologists grading each module's ability to simulate important surgical maneuvers, while scores from surgeons at each level, from attendings down to junior residents, are compared for each module.

> "We have been prospectively testing the validity of these modules, with attending urologists grading each module's ability to simulate important surgical maneuvers, while scores from surgeons at each level, from attendings down to junior residents, are compared for each module."

In the coming year, we plan to share our curriculum and best practices on an open access website and hope to allow users to keep track of their scores, host competitions within and across institutions, and share their own experiences and ideas for sim. By providing a virtual platform dedicated to gamifying sim that is accessible to all training programs, our objective is to increase interactivity and fun, and foster the exchange of ideas that will help us build consensus on the optimal use of robotic sim in urology training.

This endeavor, which we have named GAMERS (GU Alliance for Maximizing Education From Robotic Simulation), is funded entirely by a grant from the Society of Academic Urologists.

We invite all those interested in learning more about our modules and gamified curriculum, as well as future opportunities for collaboration, to register via the QR code below (Figure 4). ■

Figure 4. QR code.

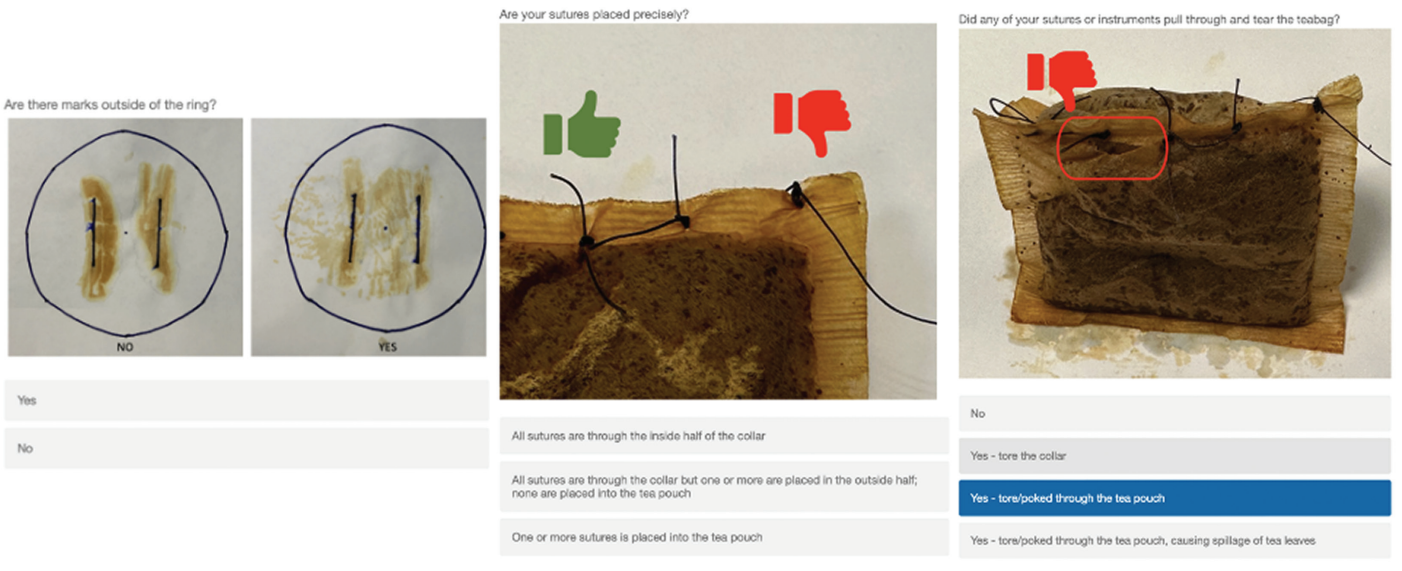

Figure 3. Scorecard for self-assessment on the "Teabags" module.

Conflict of Interest Disclosures: The Authors have no conflicts of interest to disclose.
Ethics Statement: This study received institutional review board approval *(IRB No. AAAT2309).*

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MEDICAL STUDENT COLUMN

Breaking Down Barriers: Celebrating Pioneers and Advancing Diversity in Urology

Nader Shayegh, BA
Howard University College of Medicine, Washington, DC

Pamela W. Coleman, MD, FACS, FPMRS
Howard University College of Medicine, Washington, DC

Historically Black Colleges and Universities (HBCUs) have played an essential role in producing pioneers and Black innovators in urology. R. Frank Jones, the first Black urologist in the United States, graduated from Howard University College of Medicine in 1922. Dr Jones was pivotal in establishing the first urologic training program at Howard University Hospital, formerly Freedmen's Hospital, in 1947. He considered this his "greatest professional contribution," as stated in the Profiles of the National Medical Association (1972).[1] Howard University Hospital's urology suite is named after Dr Jones for his many contributions to the field. The Figure shows his original gold cystoscope, which is still located in Howard University Hospital. Dr Jones's dedication to the field of urology and his pioneering efforts have laid the groundwork for the many Black urologists who followed in his footsteps, many of whom graduated from HBCUs.

The importance of equitable representation in medicine has recently been underscored by a series of decisions from the Supreme Court, striking down student loan forgiveness programs and their declaration that affirmative action is unconstitutional. These latest changes highlight the urgent need to address the financial burden faced by Black students and the systemic barriers that hinder equitable access to higher education. Additionally, these decisions have far-reaching implications for pursuing diversity and representation in the medical field, especially urology. To build a diverse health care system, we must improve access to high-quality and culturally responsive medical education and training for future Black physicians representing various communities.

Figure. R. Frank Jones's gifted golden cystourethroscope at Howard University Hospital.

Although HBCUs comprise only 2.4% of all medical colleges, they significantly impact the diversity of the medical field. HBCUs are home to 31% Black chairs, 10% Black faculty, and 14% Black students.[2] It is essential to acknowledge that the onus of improving racial diversity in the medical field should not solely rest on HBCUs. While these institutions play a vital role in supporting Black medical professionals, all academic institutions must act toward achieving equitable representation in the health care system.

The field of urology must reflect the communities it serves, and this requires a concerted effort from all medical schools and residency programs to improve diversity through sponsoring mentorship opportunities, offering specialized training programs, and increasing funding for research. HBCUs have a rich history of educating Black students who often encounter barriers to higher education. These institutions offer tailored programs supporting Black students excelling in medical school and beyond, including comprehensive premedical preparation, academic support services, research opportunities, mentorship, networking, scholarships, and community engagement activities. By leveraging these resources, HBCUs significantly promote representation in medicine and address health care disparities.

> "HBCUs are home to 31% Black chairs, 10% Black faculty, and 14% Black students.[2]"

> "The field of urology must reflect the communities it serves, and this requires a concerted effort from all medical schools and residency programs to improve diversity through sponsoring mentorship opportunities, offering specialized training programs, and increasing funding for research."

The lack of progress in increasing the representation of Black urologists highlights the need for interventions to address this disparity and promote diversity within the field. Simons et al in 2021 analyzed

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BREAKING DOWN BARRIERS: CELEBRATING PIONEERS AND ADVANCING DIVERSITY IN UROLOGY

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data from 2007-2008 to 2019-2020 and found a decrease in the proportion of Black urology applicants (–0.13% per year). The proportion of Black individuals in the urology resident population showed no significant change (–0.03% per year), despite an overall increase in the total number of residents. These findings underscore the attrition of Black urologists at critical stages of their education and highlight the need for interventions to address this disparity and promote diversity within the urology workforce.[3] According to the AUA's 2021 Annual Census report, "The State of the Urology Workforce and Practice in the United States," only 321 African American/Black practicing urologists were identified, comprising just 2.4% of the total number of practicing urologists in 2021.[4] This is concerning as African Americans comprise 12.1% of the population and are disproportionately affected by many urologic conditions. This is especially true when considering the higher mortality rates of Black women in various urologic cancers and the significant underrepresentation of Black female urologists.[5] Moreover, Black men experience higher rates of prostate cancer. They are also more likely to experience aggressive forms of the disease, higher mortality rates, and delays in accessing treatment than White men.[6]

The underrepresentation of doctors who are ethnically alike to their patients can have severe consequences for patient outcomes and may increase barriers to care. A study by Nagdee et al found that patients have better health outcomes when their health care providers share their cultural background.[7] Black patients must have access to urologists who can address implicit health biases in care and provide a more appropriate, culturally responsive understanding of this population's unique health needs. During my time at Howard University College of Medicine, I have witnessed the profound impact of representation in medicine. Seeing patients' faces brighten and their willingness to disclose sensitive family history at the bedside, I realized the significance of shared cultural backgrounds between doctors and patients. This connection is crucial considering the long history of health disparities, exploitation, and deep-rooted distrust among the Black community. By prioritizing representation in urology and all other areas of medicine, we can rebuild trust, address historical injustices, and work toward a more equitable health care system that values and uplifts all patients.

As the American population continues to diversify, the field of urology must reflect the communities it serves. We must celebrate diversity—only then can we hope to improve the disparities that have long plagued health outcomes for Black patients. As we move forward, let us strive to build upon the foundation laid by those who came before us and make a concentrated effort to improve access and support for future generations of Black urologists.

Acknowledgments

We thank Dean Andrea A. Hayes Dixon, MD, FACS, FAAP, and the Division of Surgery at Howard University College of Medicine. ■

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AUA LEADERSHIP PROGRAM

AUA Leadership Program: Opportunity Awaits

Steve Riggs, MD, MBA
Atrium Health, Charlotte, North Carolina

I am honored to be selected as 1 of 28 members to the 10th AUA Leadership Class. Notably, 10 is my favorite number (and that of Lionel Messi), so I am optimistic this will be a special journey. At the time of this writing, I have benefited from significant interaction in small groups as well as with the entire class. Following a virtual introduction, 2 things stood out. First, the AUA is very interested in engaging and growing the next series of leaders. Second, our class is filled with diverse, talented individuals.

Selfishly, I am excited to get to know my classmates and to explore who they are, what they do, and hear about their life stories. We all have hopes, dreams, and fears, and I am sanguine that our class will create a space of shared vulnerability united through a common purpose.

Leadership is the ability to influence others to understand and agree on what needs to be done and how to do it. Importantly, it includes the process of facilitating individual and collective efforts to accomplish shared objectives. During our leadership weekend, we were introduced to the leadership, structure, and mission of the AUA. My hope is that by understanding the AUA's organizational leadership and priorities we can engage and align with its mission and purpose.

I see opportunity for us to grow as a group, whose collective effort and impact will be greater than that for each of us individually. As we get to know each other, our networks will multiply and our evolution as connectors will amplify logarithmically. This is the power of like-minded individuals working towards a common purpose.

I am excited to be a part of this extraordinary program. We have all come volitionally to contribute, learn, and promote the AUA. I hope we can all be uncomfortable together, take chances, challenge each other, and do our part to set and carry out the vision for the AUA. ■

CODING TIPS & TRICKS

Coding for Sacral Nerve Stimulation Procedures

Johnathan Rubenstein, MD
Chair, AUA Coding and Reimbursement Committee

Sacral nerve stimulation procedures are reported using the following Current Procedural Terminology (CPT) codes (with their associated descriptors):

CPT 64561: Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement), including image guidance, if performed

CPT 64581: Open implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)

CPT 64585: Revision or removal of peripheral neurostimulator electrode array

CPT 64590: Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling (note: on January 1, 2024, the code descriptor for CPT 64590 will be revised as: Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver)

CPT 64595: Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver

CPT 95971 and 95972: Electronic analysis of implanted neurostimulator pulse generator/transmitter, with simple (95971) or complex (95972) programming by physician or other qualified health care professional

Instructions for use of the following codes:

Array placement (or replacement): Use CPT code 64561 or 64581. Note: The correct code to report for array placement is based upon on the surgical technique used, not the type of lead placed (temporary or permanent), nor whether the array is tunneled or not.

- Report 64561 for percutaneous placement of an electrode array into a sacral foramen. The CPT codebook specifically states that this code "may be used to report either the temporary or permanent placement of percutaneous electrode arrays" if a percutaneous approach is used. Fluoroscopy and other imaging modalities to help guide placement are included and not separately reportable. If performed bilaterally, append Modifier 50. This code has a 10-day global period. Removal of temporary leads should not be reported, whether performed within the global period or not.

"Report 64561 for percutaneous placement of an electrode array into a sacral foramen. The CPT codebook specifically states that this code "may be used to report either the temporary or permanent placement of percutaneous electrode arrays" if a percutaneous approach is used."

- In contrast, CPT 64581 should be reported for the open placement of an array. The surgical technique describes a midline incision with cutdown to the sacrum and direct placement of the array into the sacral foramen. (Note that the previous ambiguous wording describing "incision for" placement led to confusion and has since been updated to clarify that this is a true open procedure, which was the originally described technique for array placement.) CPT 64581 has a 90-day global period.

Pulse generator placement (or replacement): Use CPT code 64590.

The work includes the creation of a pocket and attachment of the generator or receiver to a separately placed (whether concomitantly or not) electrode array. CPT 64590 has a 10-day global period. Both CPT codes 64561 and 64581 can be reported along with CPT code 64590 when the procedures are performed at the same surgical session. This code should not be used to report placing a generator or receiver without attachment to a separately placed array.

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CODING FOR SACRAL NERVE STIMULATION PROCEDURES

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Revision or removal of electrode array: Use CPT code 64585.

CPT code 64585 should not be reported for the removal of temporary (untined) leads, even outside of the global period. CPT 64585 should not be reported for the replacement of leads, which instead would be reported using CPT code 64561 (or 64581 if done open). CPT 64585 is bundled to placement codes 64561 and 64581 if done on the same side. CPT 64585 has a 10-day global period.

Revision or removal of generator/receiver: Use CPT code 64595.

CPT code 64595 would be reported for removal of the generator/receiver, whereas removal and replacement should be reported with CPT 64590. CPT 64595 has a 10-day global period. There is an @NCCI Edit "1" for 64585 with 64561 and 64581, and also 64590 with 64595, meaning if an array is removed from one side and a new array is placed on the contralateral side, both can be reported using the appropriate modifier, and if a generator/receiver is removed from one side and then a new generator/receiver is placed on the contralateral side, then both can be reported using an appropriate modifier.

CPT 95971 and 95972: Electronic analysis of implanted neurostimulator pulse generator/transmitter, with simple (95971) or complex (95972) programming by physician or other qualified health care professional.

Programming may be performed in the operating room, postoperative care unit, inpatient, and/or outpatient setting. Programming a neurostimulator in the operating room is not inherent in the service represented by the implantation code and therefore may be reported by either the implanting surgeon or other qualified health care professional, when performed. If the programming is performed by a device representative then it should not be reported by the physician. Codes 95971 (Simple programming) should be reported for adjustment of 1 to 3 parameter(s), whereas CPT code 95972 (Complex programming) should be reported for adjustment of more than 3 parameters. For purposes of counting the number of parameters being programmed, a single parameter that is adjusted 2 or more times during a programming session counts as 1 parameter.

> "Both CPT codes 64561 and 64581 can be reported along with CPT code 64590 when the procedures are performed at the same surgical session."

Code 95970: Electronic analysis of the implanted brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve neurostimulator pulse generator/transmitter without programming.

Test stimulation to confirm correct target site placement of the electrode array(s) and/or to confirm the functional status of the system is inherent to placement and is not separately reported as electronic analysis or programming of the neurostimulator system so should not be reported with implantation codes (eg, 64561, 64581, 64590, or 64595) or with electronic analysis with programming (CPT codes 95971 or 95972).

CORRECT CPT CODES TO REPORT BASED UPON PROCEDURE PERFORMED

Peripheral nerve evaluation (PNE): CPT code 64561 (appended with modifier 50 if performed bilateral). Test stimulation (CPT code 95970) is included in the placement code so would not be separately reported.

Generator implantation (or replacement): CPT code 64590 (and 95972 if performed by surgeon).

Note: CPT 95972 should be reported for complex programming if performed by the physician or other qualified health care professional, not by a device representative.

Full system implant (array and generator/receiver): CPT codes 64561 and 64590 (and 95972 if programming by surgeon).

CPT code 64581 may be reported in place of CPT code 64561 (only) if the placement is performed in an open cutdown approach using a midline incision, exposure of the sacrum and direct placement of the array into the sacral foramen.

Revision or removal without reimplantation: CPT code 64585 (lead) or 64595 (generator/receiver) or both.

Note: These codes are both bundled to the placement code so should not be used if removal and replacing leads and/or a generator/receiver.

Removal with replacement of generator/receiver: CPT code 64590 (and 95972 if programming by surgeon).

Note: CPT code 64590 includes removal of the previous generator or receiver; one should not additionally report CPT code 64595 for removal if performed on the same side.

Removal with replacement of lead and generator/receiver on the same side: CPT codes 64561 and 64590 (and 95972 if programming performed by surgeon).

Again, CPT code 64581 may be reported in place of CPT code 64561 (only) if the placement is performed in an open cutdown approach using a midline incision, exposure of the sacrum and direct placement of the array into the sacral foramen.

Removal with replacement of lead and generator/receiver on contralateral sides: CPT codes 64561 (or 64581 for open placement with cutdown to sacrum) and 64590 (and 95972 if programming by surgeon), and CPT codes 64585 and 64595 with modifier. ■

Fellowship Training in Urologic Oncology: What's in It for You?

Kristen R. Scarpato, MD, MPH, FACS
Vanderbilt University Medical Center, Nashville, Tennessee

Aditya Bagrodia, MD, FACS
University of California, San Diego

This year, the Society of Urologic Oncology (SUO) will host its 24th Annual Winter Meeting in December in Washington, DC. Since the organization's first formal meeting in May 1984, the SUO has become the primary source of education, research collaboration, and community for urologic oncologists. For decades, leaders in the field have acknowledged the importance of distinguishing urologic oncology as a distinct subspecialty given the unique challenges faced by cancer patients and the tangible benefits of sharing data and experience across institutions. The discipline has grown from a small group of dedicated urologists to more than 1,000 urologic oncologists and trainees today. Despite these achievements, modern residency training and a favorable job market for general urologists may have some trainees contemplating the utility of additional time in training for this subspecialization. What's in it for you?

The first SUO fellowships were formally recognized in 2000, at which point specific training objectives and an educational curriculum were developed, detailing a minimum of 2 years with 1 year dedicated to clinical training and 1 primarily research. Today, there are 37 accredited SUO fellowship programs. An annual self-assessment exam was initiated in 2007, the OKAT (Oncology Knowledge Assessment Test), and is taken yearly by fellows. The initiation of formal training and testing in urologic oncology is based on its multifaceted core and thus has always necessitated multidisciplinary care and collaboration. Fellows learn from and together with medical oncologists, radiation oncologists, pharmacists, palliative care specialists, and others. The urologic oncologist is often the first provider a patient facing a new cancer diagnosis encounters; it is critical that they are well-versed in coordinating the multifaceted care. Training infrastructure has largely remained unchanged (although this is an active topic of discussion), yet possible career paths following an SUO fellowship have evolved and can be uniquely tailored to an individual's goals and interests.

> "The initiation of formal training and testing in urologic oncology is based on its multifaceted core and thus has always necessitated multidisciplinary care and collaboration."

While the historical perception of a urologic oncologist is a surgeon who only performs major, complex oncologic surgeries associated with long inpatient hospitalizations, a career in urologic oncology today can and often does look quite different. Some urologic oncologists choose to focus on minimally invasive or even ablative procedures while others are dedicated to the medical management of advanced urologic diseases, like castration-resistant prostate cancer. Still others focus on genomics or advanced imaging techniques. Through robust training, SUO fellows become experts in oncology, contributing to both the practice and advancement of the field. This robust, disease-focused knowledge base coupled with ongoing advances in technology allow SUO graduates the ability to tailor clinical practice in a manner that suits their preference and lifestyle, while pursuing varied interests in education, health policy, clinical trials, or industry.

The SUO has supported and sponsored its young members since its inception and as the community has evolved, younger voices are increasingly being heard and valued. The Young Urologic Oncologists (YUO) section was born in 2004 to further encourage and develop aspiring urologic oncologists and those in their early career. Today, the YUO has formal representation with a voting member on the SUO board of directors. The YUO gathers each year the night before the start of the SUO winter meeting to acknowledge research from YUO members, discuss timely issues surrounding career development and professionalism, and enjoy in a shared community. Recognizing a need, the YUO recently developed a virtual lecture series dedicated to education surrounding relevant clinical and nonclinical topics. These webinars are widely attended by fellows and residents from across the country.

The face of urologic oncology today looks different, too. Women urologic oncologists have long been gathering at SUO meetings to network and discuss topics unique to women in the field. As the number of women in the subspeciality has steadily grown, the SUO officially established the Women in Urologic Oncology in 2019 to acknowledge, support, and mentor urologic oncologists who are women. Further, during the SUO annual meeting, a special recognition is given in the form of the Women in Urologic Oncology Best Abstract Award. This prestigious accolade is awarded to a female trainee presenter, highlighting her outstanding work and contributions in the field.

Recent literature highlights the prevalence of burnout and lack of work-life equilibrium within urology. The opportunity to find value and meaning in work, while simultaneously feeling valued appears limited to some and the benefits of additional training are not always readily apparent. An SUO fellowship provides a deep understanding of urologic malignancy and specialized surgical training for complex and advanced oncologic patients, along with the tools for impactful research. Furthermore, in this dynamic field, there is an abundance of opportunity amidst a community of sponsors, mentors, collaborators, and friends–key ingredients for a satisfying and successful career.

> "For decades, leaders in the field have acknowledged the importance of distinguishing urologic oncology as a distinct subspecialty given the unique challenges faced by cancer patients and the tangible benefits of sharing data and experience across institutions. The discipline has grown from a small group of dedicated urologists to more than 1,000 urologic oncologists and trainees today."

Acknowledgments

This article was written on behalf of the Young Urologic Oncologists Executive Committee. ■

Developing Online Urology-specific Standardized Letters of Recommendation for Residency Match

Behnam Nabavizadeh, MD
Weill Cornell Medicine, New York, New York

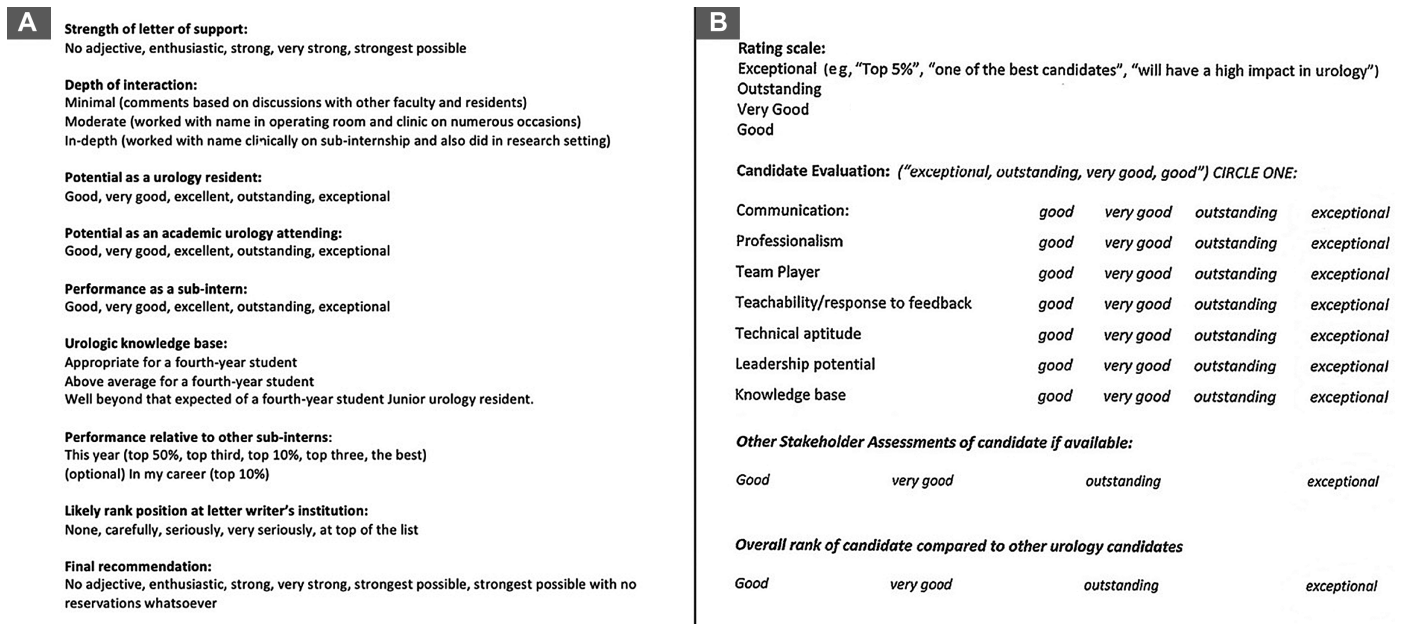
Benjamin N. Breyer, MD, MAS
University of California San Francisco

Richard K. Lee, MD, MBA
Weill Cornell Medicine, New York, New York

Discriminating between top urology residency applicants is challenging but is vital to the continued success of individual programs and the field of urology. The resident selection process is complex and varies among the programs. Programs generally use a variety of methods to choose candidates for interviews and establish the rank list. While factors such as clerkship grades, United States Medical Licensing Examination (USMLE) scores, class rank, research experience, and visa status continue to play an important role in the resident selection process, most urology program directors agree that letters of recommendation are the most important factor.[1]

In the field of urology, letter writers tend to use narrative letters of recommendation (NLORs) which do not have a uniform structure. Previous studies have found the commonly used NLORs to be highly flattering and ambiguous, contain gender bias, and have very low interobserver reliability in their interpretations.[2-6] In order to overcome the shortcomings of NLORs, standardized letters of recommendation (SLORs) were introduced. Such letters are easier to write and interpret compared to the NLORs. The SLOR was initially started by emergency medicine in 1997, and followed by other specialties such as otolaryngology in 2012, plastic surgery in 2012, dermatology in 2014, and orthopedic surgery in 2017.[3,7-10]

> "In an effort to improve the current formats and create an optimal urology-specific SLOR, we are conducting a study supported by the SAU, where we have designed and validated a survey tool to seek recommendations from urology faculty across the country."



A

Strength of letter of support:
No adjective, enthusiastic, strong, very strong, strongest possible

Depth of interaction:
Minimal (comments based on discussions with other faculty and residents)
Moderate (worked with name in operating room and clinic on numerous occasions)
In-depth (worked with name clinically on sub-internship and also did in research setting)

Potential as a urology resident:
Good, very good, excellent, outstanding, exceptional

Potential as an academic urology attending:
Good, very good, excellent, outstanding, exceptional

Performance as a sub-intern:
Good, very good, excellent, outstanding, exceptional

Urologic knowledge base:
Appropriate for a fourth-year student
Above average for a fourth-year student
Well beyond that expected of a fourth-year student Junior urology resident.

Performance relative to other sub-interns:
This year (top 50%, top third, top 10%, top three, the best)
(optional) In my career (top 10%)

Likely rank position at letter writer's institution:
None, carefully, seriously, very seriously, at top of the list

Final recommendation:
No adjective, enthusiastic, strong, very strong, strongest possible, strongest possible with no reservations whatsoever

B

Rating scale:
Exceptional (eg, "Top 5%", "one of the best candidates", "will have a high impact in urology")
Outstanding
Very Good
Good

Candidate Evaluation: *("exceptional, outstanding, very good, good") CIRCLE ONE:*

Communication:	*good*	*very good*	*outstanding*	*exceptional*
Professionalism	*good*	*very good*	*outstanding*	*exceptional*
Team Player	*good*	*very good*	*outstanding*	*exceptional*
Teachability/response to feedback	*good*	*very good*	*outstanding*	*exceptional*
Technical aptitude	*good*	*very good*	*outstanding*	*exceptional*
Leadership potential	*good*	*very good*	*outstanding*	*exceptional*
Knowledge base	*good*	*very good*	*outstanding*	*exceptional*

Other Stakeholder Assessments of candidate if available:

Good *very good* *outstanding* *exceptional*

Overall rank of candidate compared to other urology candidates

Good *very good* *outstanding* *exceptional*

Figure. Domains of the 2 standardized letters of recommendation (A and B) used in urology residency applications. Reprinted with permission from Nabavizadeh B et al, *Urology*. 2021;158:18-25.[11]

The Current State of SLORs in Urology

SLORs in urology were first launched for the 2020-2021 residency match cycle. We have previously investigated the use of SLORs in the Urology Residency Match.[11] We found 2 main formats of SLOR among 2020-2021 Urology Match applications. Format 1 was originally proposed by Dr David Penson, and format 2 was distributed by the Society of Academic Urologists (SAU; see Figure). In that study, we observed some meaningful correlations between domain ratings and application metrics such as USMLE Step 1 and Step 2 Clinical Knowledge scores, and percentage of Honors in core clinical clerkships. A recent study on linguistic analysis of urology NLOR demonstrated that letters written for match-successful applicants had more power words, which was also the case for the NLORs written for male urology applicants compared to female urology applicants.[6] The authors found an implicit gender bias in urology NLORs. However, in our study of urology SLORs, no statistically significant differences were found between female and male applicants in terms of domain ratings.[11] This is of utmost importance especially in a field like urology where gender imbalance is a real concern.

We also looked for other potential biases in the report of current formats of SLOR. No significant differences were found in domain ratings with regard to applicants' race, depth of interaction between letter writers and applicants, and gender of letter writers. However, we found a marked ceiling effect where most applicants were rated among top tiers in both formats of urology SLORs, which may have several underpinnings such as using Likert-like scales in the current SLOR formats and limited number of domains, which may make it difficult to capture the distinguishing features of highly competitive urology applicants. In another study, we evaluated the differences in applicant characteristics and SLOR domain ratings based on the match results. We found matched applicants were more likely to have higher domain ratings compared

> "Previous studies have found the commonly used NLORs to be highly flattering and ambiguous, contain gender bias, and have very low interobserver reliability in their interpretations.[2-6] In order to overcome the shortcomings of NLORs, standardized letters of recommendation (SLORs) were introduced."

→ Continued on page 59

DEVELOPING ONLINE UROLOGY-SPECIFIC STANDARDIZED LETTERS OF RECOMMENDATION FOR RESIDENCY MATCH

→ Continued from page 58

to unmatched applicants.[12] Furthermore, several key domains of format 1 SLOR (ie, "potential as a urology resident," "potential as an academic urology attending," "performance as a subintern," and "likely rank position") were associated with successful match into urology.

Improving the Urology SLORs

The current urology SLORs are not without flaws and mainly suffer from grade inflation as discussed above. After their introduction, urology SLORs have not undergone revisions, and no formal evaluation of such letters has been performed to gauge satisfaction with their use among urologists. Urology still remains one of the most competitive specialties to match into.[11] Additionally, given the transition of USMLE Step 1 score reporting to pass/fail, there is an emerging need for a reliable assessment tool that can help distinguish between highly qualified urology applicants. In an effort to improve the current formats and create an optimal urology-specific SLOR, we are conducting a study supported by the SAU, where we have designed and validated a survey tool to seek recommendations from urology faculty across the country. We will analyze their feedback and implement changes to SLOR format based on their feedback. In addition, in collaboration with SAU and the AUA, we will launch a secure website that urology faculties can utilize to generate electronic SLORs (eSLORs). After verification, any practicing urologist would be able to set up an account to enter content electronically and generate an eSLOR. An individual barcode will automatically be assigned to each eSLOR which can be used for authentication purposes. The final eSLOR can be uploaded to the Electronic Residency Application Service website. The website will also be capable of storing data that can be tracked over time and used for future research. Before widespread launch, a β version of the website will be activated for a small number of urology faculties to test the website function and provide feedback. ■

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AUA ADVOCACY

Health Policy in Action: Highlights From the Hill

Ruchika Talwar, MD
Vanderbilt University Medical Center, Nashville, Tennessee

As the AUA's 2022-2023 Logan H. Holtgrewe Legislative Fellow, I had the honor of participating in a summer Congressional fellowship on Capitol Hill, in the office of Congressman Darren Soto (D-FL-09; Figure 1). Over the span of nearly 2 months, I took over the Congressman's health care portfolio, which, as a member of the House Energy and Commerce Committee that handles health issues, often included integral legislation on Medicare payment and coverage, prescription drug pricing, improving maternal health coverage, and preserving access to reproductive health care services. Further, I was responsible for attending health care hearings from various Congressional committees and federal agencies, then briefing the Congressman and his legislative team on these hearings. As a health fellow, I also met with all constituent and stakeholder groups who wanted to discuss any health-related issue–much like the urologists who discuss the AUA's legislative priorities during the annual AUA Summit. This time, I sat on the opposite end of the table.

It's hard for me to quantify the amount that I learned during my time on the Hill, although I can list some of my favorite moments (including filing a bill, submitting amendments to the NDAA [National Defense Authorization Act], and meeting the Democratic Whip Katherine Clark; Figure 2). As opposed to spelling out all of these individual experiences, instead I'd like to focus on the most valuable takeaway from the fellowship experience: my renewed optimism in our systems of government.

Any time you scroll through your Twitter/X timeline or turn on the news (regardless of whether it's CNN or Fox), it's easy to feel that our elected representatives are always at odds with one another, struggling to agree, deadlocked in their obstinance. This is exactly what I expected to walk into on my first day. Thankfully, I could not have been more wrong. Although the stories of compromise, teamwork, and decency don't make headlines (because they don't sell), the vast majority of interactions between members and offices are cordial, goal-oriented, and solve actual problems. Remember, almost every aspect of Congress is bipartisan. Every committee has Republican and Democratic members. Nearly every Congressional letter has a Democratic and Republican lead. To successfully be passed, most bills also require bipartisan cosponsorship. There is no way around teamwork and compromise–and stuff really does get done. Even in my short tenure in Congress, I witnessed firsthand this spirit of camaraderie between Congressman Soto, the member I worked with and a Democrat, and Congressman Neal Dunn, a Republican and retired urologist, during a meeting I led to discuss innovative solutions to drug pricing and insurance reform (Figure 3).

My passion and drive for urologic and health advocacy were renewed when I saw how often the legislative staff in my office referenced prior constituent meetings during discussions about positions that the Congressman should take on a specific issue. Our voices as physicians really do matter, and our elected representatives rely on us to share our expertise as they try to improve the US health care system. I was always called upon to provide input on issues that were directly or indirectly related to health care, and the team valued my practical experience as a patient-facing clinician. But you don't need to be on Capitol Hill to develop this kind of relationship with your member. In fact, by offering yourself as a resource to your local office, you'd be surprised how often the legislative team will reach out asking for your opinion.

I am grateful for the support of the entire AUA community and AUA leadership for my time as Congressman Soto's Health Fellow, but I know that this experience is only the start of a strong partnership with the Congressman to improve the quality of urologic care that we provide for our patients. ■

Figure 1. Congressman Darren Soto (D-FL-09) congratulates Dr Ruchika Talwar on completing her Holtgrewe Legislative Fellowship.

Figure 2. Dr Ruchika Talwar meeting with Democratic Whip Katherine Clark (D-MA-05).

Figure 3. Dr Ruchika Talwar hosts a discussion on drug pricing and insurance reform with Congressman and retired urologist Dr Neal Dunn (R-FL-02), and Congressman Darren Soto (D-FL-09).

Have You Read?

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

Watson RA. Enlisting probiotics to combat recurrent urinary tract infections in women–a military strategy for meeting the challenge. *Antibiotics (Basel)*. 2023;12(1):167.

Special thanks to Dr Richard Watson at the Hackensack Meridian School of Medicine.

"Enlisting Probiotics to Combat Recurrent Urinary Tract Infections in Women" employs a military frame of reference–applying terms such as "battlefield," "enemy," "weapon," and "target" to aid in conceptualizing a more effective attack on the problem of chronic cystitis in women.

A revolution in the understanding of recurrent urinary tract infections is upon us. What everyone has always known is no longer a certainty. Urine in the healthy bladder is not sterile. In fact, bladder health depends on the presence of a complex, dynamically interactive "repertoire" of intravesical bacteria, the urobiome. At the same time, within the bowel, a complementary repertoire, the gut microbiome, is also exercising significant influence on bladder well-being.

Antibiotic therapy provides a quick fix for the short-term treatment of acute bladder infections at the cost of a profound, long-term disruption in the homeostasis of interactions between the urobiome and the gut microbiome.

Probiotics, lactobacilli in particular, have been shown to have therapeutic activity against bacterial uropathogens. However, the activity varies significantly between probiotic species and strains. Ingesting large amounts of randomly selected probiotics orally has met with limited success. Selection of a specific lactobacillus with demonstrated activity against the infecting bacteria within the individually targeted patient, *cura personalis*, offers the hope of both immediate and long-term benefits for the chronically infected bladder.

Bioengineering may lead to development of "designer lactobacilli" specifically crafted for individualized patient care. Direct instillation of the selected lactobacillus strain into the targeted patient's bladder may provide optimal treatment results with impressive immediate and long-term benefits.

While no easy task lies ahead, events seem to be bringing us to the brink of a major leap forward. Many important pieces are falling into place. We might have at hand an extraordinary opportunity to spearhead a major advance in the prevention and control of recurrent urinary tract infections in women. Probiotic intravesical organic therapy may prove pivotal to this radically new approach.

O'Connor EM, Croghan SM, Baird O, et al. A prospective multi-institutional study using a novel safety valve for the prevention of catheter balloon inflation injury of the urethra. *J Urol*. 2023;210(1):179-185.

Special thanks to Drs Andrew Lai and Mahmoud Mima at the University of Illinois at Chicago.

We urologists have all had a consult for urinary retention where physical examination revealed the Foley catheter to be neatly secured to the patient's knee cap. Urethral injuries from catheter balloon inflation are often a source of great frustration for the urologist, anxiety for the nurse or other practitioner placing a catheter, and of course, significant pain and morbidity for the patient. The authors of this study aimed to evaluate the efficacy of a transurethral catheterization safety valve in preventing these types of balloon injuries. The valve is attached to the balloon-inflating syringe that avoids urethral injury by venting the syringe fluid if there is too much pressure on the balloon when it is not in the bladder. Over a 12-month period across multiple institutions with this device, there were no balloon-related injuries. In contrast, in just a 3-month period during the study when the valve was not used, 18 balloon-related injuries were reported. Clearly, this innovative device is promising and unsurprisingly was associated with significantly lower costs and improvement of patients' quality-adjusted life years. It is only a matter of time until this device is widely adopted.

Masterson TA, Molina M, Ledesma B, et al. Platelet-rich plasma for the treatment of erectile dysfunction: a prospective, randomized, double-blind, placlinical trial. *J Urol*. 2023;210(1):154-161.

Special thanks to Drs Rabun Jones and Mahmoud Mima at the University of Illinois at Chicago.

Platelet-rich plasma is a restorative therapy used in sports medicine and orthopedics and is gaining popularity as a treatment for erectile dysfunction. It's created by centrifuging a patient's own blood and collecting the layer that contains platelets and growth factors, resulting in a concentrated sample that can be injected anywhere to promote tissue regeneration. There are clinics throughout the United States that currently offer platelet-rich plasma treatments for erectile dysfunction, although only limited data support its use. The authors of this study examined the safety and efficacy of a protocol involving intracavernosal injection of 5 mL of platelet-rich plasma compared to a sham injection of normal saline. Injections were administered twice and 1 month apart. Patients had mild to moderate erectile dysfunction as determined by scores of 11-25 on the International Index of Erectile Function. The investigators observed no clinically significant difference in either the primary outcome of International Index of Erectile Function scores or a secondary outcome of penile vascular parameters 6 months after 2 sessions of treatment. There was no difference noted in the rate or severity of adverse events, which included a hematoma and new plaque formation. This randomized, double-blind, placebo-controlled trial supported that platelet-rich plasma therapy with the studied protocol is safe but failed to demonstrate clinical efficacy. Certainly, the current protocols for platelet-rich plasma vary widely, so there might be some recipe out there that may prove useful. Until then, this particular protocol doesn't appear to make a difference. ■

"Urine in the healthy bladder is not sterile. In fact, bladder health depends on the presence of a complex, dynamically interactive "repertoire" of intravesical bacteria, the urobiome."

JU INSIGHT

Artificial Intelligence-powered Large Language Models to Disseminate Health Information in Urology

Ryan J. Davis, BS
Keck School of Medicine, University of Southern California, Los Angeles
Artificial Intelligence Center at USC Urology, USC Institute of Urology, University of Southern California, Los Angeles

Michael B. Eppler, BA
Keck School of Medicine, University of Southern California, Los Angeles
Artificial Intelligence Center at USC Urology, USC Institute of Urology, University of Southern California, Los Angeles

Oluwatobiloba Ayo-Ajibola, BS
Keck School of Medicine, University of Southern California, Los Angeles
Artificial Intelligence Center at USC Urology, USC Institute of Urology, University of Southern California, Los Angeles

Jeffrey C. Loh-Doyle, MD
Keck School of Medicine, University of Southern California, Los Angeles
Artificial Intelligence Center at USC Urology, USC Institute of Urology, University of Southern California, Los Angeles

Jamal Nabhani, MD
Keck School of Medicine, University of Southern California, Los Angeles
Artificial Intelligence Center at USC Urology, USC Institute of Urology, University of Southern California, Los Angeles

Mary Samplaski, MD
Keck School of Medicine, University of Southern California, Los Angeles
Artificial Intelligence Center at USC Urology, USC Institute of Urology, University of Southern California, Los Angeles

Inderbir S. Gill, MD
Keck School of Medicine, University of Southern California, Los Angeles
Artificial Intelligence Center at USC Urology, USC Institute of Urology, University of Southern California, Los Angeles

Giovanni E. Cacciamani, MD
Keck School of Medicine, University of Southern California, Los Angeles
Artificial Intelligence Center at USC Urology, USC Institute of Urology, University of Southern California, Los Angeles

Davis R, Eppler M, Ayo-Ajibola O, et al. Evaluating the effectiveness of artificial intelligence-powered large language models application in disseminating appropriate and readable health information in urology. *J Urol.* 2023;210(4):688-694.

Study Need and Importance

In 2022, Version 3.5 of ChatGPT, an artificial intelligence-powered large language model (LLM) was released. Its adoption immediately burgeoned, and given that patients most commonly use the Internet as a primary medical information source, there is reason to believe they will adopt ChatGPT for medical information too. Urological patients may be particularly likely to use ChatGPT, as situations requiring urological care are broad ranging, with diverse treatment options from office procedures to major open surgery. No study has been done to assess ChatGPT's urological advice, and thus our study aimed to do so by assessing appropriateness, readability, and other qualities of ChatGPT-generated urological information.

What We Found

The Figure contains a flowchart of the study methodology. Fourteen of 18 (77.8%) responses were deemed appropriate. No significant differences were found between treatment- and symptom-related questions, nor between oncologic, benign, and treatment-related questions. The most common reason from urologist-graders for low scores was missing information. The most concerning missing information includes a missed differential diagnosis of acute retention for a classic presentation of acute retention. The mean (SD) Flesch Reading Ease score was 35.5 (10.2), and the mean Flesh-Kincaid Reading Grade Level score was 13.5 (1.74), indicating college-level readability of responses.

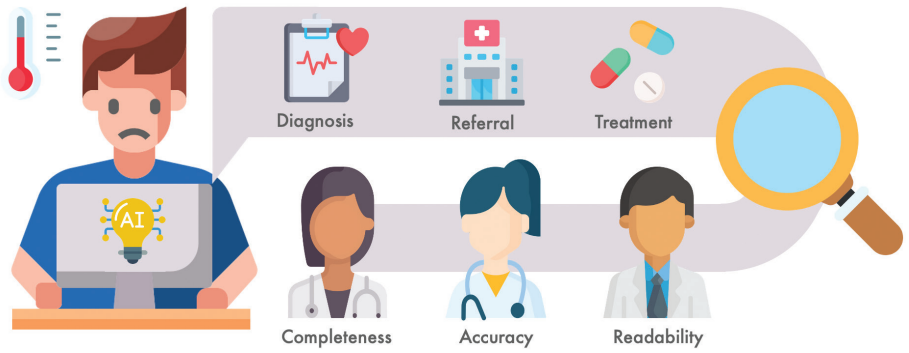

Figure. Flowchart of study methodology. We pretended to be laypeople searching ChatGPT to find medical information about urological conditions in terms of diagnosis, treatment, and referral. Our team evaluated the completeness, accuracy, and readability of this information.

> "While the advent of LLMs is an exciting prospect for bridging the information gap between urology patients and time-constrained physicians, they may give inappropriate advice, inappropriately triage emergent medical situations, and write at too high a readability level for the average patient."

Limitations

We used a small sample of questions and physician-graders. ChatGPT responses to the same question change each time the question is asked. ChatGPT is only 1 artificial intelligence-powered LLM of others that are available. Finally, ChatGPT is not designed specifically for medical use in mind.

Interpretation for Patient Care

While the advent of LLMs is an exciting prospect for bridging the information gap between urology patients and time-constrained physicians, they may give inappropriate advice, inappropriately triage emergent medical situations, and write at too high a readability level for the average patient. Patients should proceed to use with caution. ■

JU INSIGHT

Metastasis Histopathology Impact on Outcomes for Surgically Resected Metastatic Renal Cell Carcinoma

Rodrigo Rodrigues Pessoa, MD
Mayo Clinic, Rochester, Minnesota

Reza Nabavizadeh, MD
Mayo Clinic, Rochester, Minnesota

Fernando Quevedo, MD
Mayo Clinic, Rochester, Minnesota

Daniel D. Joyce, MD
Mayo Clinic, Rochester, Minnesota

Christine M. Lohse, MS
Mayo Clinic, Rochester, Minnesota

Vidit Sharma, MD
Mayo Clinic, Rochester, Minnesota

Brian A. Costello, MD
Mayo Clinic, Rochester, Minnesota

Stephen A. Boorjian, MD
Mayo Clinic, Rochester, Minnesota

R. Houston Thompson, MD
Mayo Clinic, Rochester, Minnesota

Bradley C. Leibovich, MD
Mayo Clinic, Rochester, Minnesota

John C. Cheville, MD
Mayo Clinic, Rochester, Minnesota

Pessoa RR, Nabavizadeh R, Quevedo F, et al. The impact of metastasis histopathology on oncologic outcomes for patients with surgically resected metastatic renal cell carcinoma. *J Urol.* 2023;210(4):611-618.

Study Need and Importance

Current prognostic nomograms for survival among patients with metastatic renal cell carcinoma do not include histopathological features of the metastasis for prediction of oncologic outcomes. In this study, we evaluated the performance of models using primary and metastatic tumor features to predict cancer-specific survival (CSS) among patients with metastatic clear cell renal cell carcinoma who underwent complete metastasectomy.

What We Found

Using our nephrectomy registry, we identified 266 patients who had undergone nephrectomy from 1970 to 2019 for clear cell renal cell carcinoma and complete resection of a single site of metastasis. Relevant clinical and histopathological features readily available to clinicians and with proven association with survival among patients with metastatic renal cell carcinoma were collected. Grade and necrosis from the primary tumor and metastasis were used to calculate 2 versions of the Leibovich score. A third model comprised of anatomical site of the metastasis, timing of metastasectomy in relation to nephrectomy, and grade, necrosis, and sarcomatoid differentiation from the metastasis was also studied. Predictive abilities of these 3 models were compared using c-indexes from Cox proportional hazards models. We demonstrated that both the Leibovich score using grade and necrosis from the metastasis (c=0.679) as well as an additional model with metastatic features only (c=0.707) provided comparable predictive ability for CSS to the originally described score (c=0.675) calculated with primary tumor histopathological features.

Limitations

Our models should only be used for patients with clear cell renal cell carcinoma who have undergone complete metastasectomy, and cannot be extrapolated for use with tissue obtained from biopsy of metastatic sites at this time.

Interpretation for Patient Care

We found that histopathological features of the metastasis can be used to predict CSS for patients with surgically resected metastatic clear cell renal cell carcinoma. Moreover, sarcomatoid features within the metastatic site provide independent prognostic information. Our study argues for investigating whether metastatic biopsy features would prove as useful as resected metastatic specimen data. ■

JU INSIGHT

Enhanced Recovery After Surgery for Complete Primary Repair of Bladder Exstrophy

Andrea K. Balthazar, MD, MPH*
Boston Children's Hospital, Massachusetts

Julia B. Finkelstein, MD, MPH*
Boston Children's Hospital, Massachusetts

Vivian Williams, MSN, RN, CPNP
Boston Children's Hospital, Massachusetts

Ted Lee, MD, MSc
Boston Children's Hospital, Massachusetts

Debra Lajoie, JD, PhD, MSN, RN
Boston Children's Hospital, Massachusetts

Tanya Logvinenko, PhD
Boston Children's Hospital, Massachusetts

Young-Jo Kim, MD, PhD
Boston Children's Hospital, Massachusetts

Sabeena Chacko, MD
Boston Children's Hospital, Massachusetts

Joseph G. Borer, MD
Boston Children's Hospital, Massachusetts

Richard S. Lee, MD
Boston Children's Hospital, Massachusetts

**Co-first authors.*

Balthazar AK, Finkelstein JB, Williams V, et al. Enhanced recovery after surgery for an uncommon complex urological procedure: the complete primary repair of bladder exstrophy. *J Urol.* 2023; 210(4):696-703.

Study Need and Importance

Enhanced recovery after surgery (ERAS) protocols are designed to optimize perioperative care and expedite recovery. Historically, complete primary repair of bladder exstrophy (CPRE) has included postoperative recovery in the intensive care unit and extended length of stay. There are no guidelines or published studies that discuss ERAS principles in the bladder exstrophy population.

What We Found

The outcomes of 10 post-ERAS patients were compared with a historical cohort of 30 CPRE patients (2013-2020). The median overall length of stay significantly decreased from 14.5 to 9 days to 6.5 days (P= .0001, see Table). Refinement of the CPRE-ERAS pathway required an iterative learning process to maximally adapt enhanced recovery interventions to the needs of our specific patient population, which

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ENHANCED RECOVERY AFTER SURGERY FOR COMPLETE PRIMARY REPAIR

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ultimately resulted in the elimination of intensive care unit use after final pathway implementation (n=4). Postoperatively, no ERAS patient required escalation of care, and there was no difference in emergency department visits or readmissions.

Limitations

We describe implementation of a CPRE-ERAS pathway at a single, freestanding children's hospital. The small, unmatched cohort lends itself to the introduction of biases. The observed significant results only imply an association between ERAS implementation and the outcomes. Additionally, given the comprehensive nature of the CPRE-ERAS protocol, we are unable to decipher which elements had the most critical impact on intraoperative metrics and postoperative outcomes.

Table. A Comparison of the Primary Study Outcome: Length of Stay

	Pre-ERAS (N=30)	Post-ERAS[a] Phase 1 (N=6)	Post-ERAS[a] Phase 2 (N=4)	*P* value
ICU LOS, median (IQR), d	2.5 (2-4)	1.5 (1-2)	0 (0-0)	**.003**
Overall LOS, median (IQR), d	14.5 (13-19.8)	9.0 (8.3-12)	6.5 (6-7)	**.001**

Abbreviations: ERAS, enhanced recovery after surgery; ICU, intensive care unit; IQR, interquartile range; LOS, length of stay.
Bolded values indicate statistical significance.
[a]The post-ERAS cohort is grouped as those patients who underwent complete primary repair of bladder exstrophy (CPRE) during Phase 1 (initial CPRE-ERAS pathway, June 2020-April 2021) and Phase 2 (final CPRE-ERAS pathway, May 2021-December 2021).

Interpretation for Patient Care

Applying ERAS principles to CPRE was associated with improved patient outcomes and effective resource utilization. We believe that agreement and collaboration toward a common goal, engaging key stakeholders, and educational efforts were crucial to improving the care of bladder exstrophy patients. Although ERAS has typically been utilized for high-volume procedures, our study highlights that an enhanced recovery pathway is both feasible and adaptable to less common urological surgeries. ■

> "Although ERAS has typically been utilized for high-volume procedures, our study highlights that an enhanced recovery pathway is both feasible and adaptable to less common urological surgeries."

JU INSIGHT

Robotic Bladder Autotransplant: Preclinical Studies Preparing for First-in-human Bladder Transplant

Nima Nassiri, MD
Catherine & Joseph Aresty Department of Urology, USC Institute of Urology, Keck School of Medicine, University of Southern California, Los Angeles

Giovanni Cacciamani, MD
Catherine & Joseph Aresty Department of Urology, USC Institute of Urology, Keck School of Medicine, University of Southern California, Los Angeles

Inderbir S. Gill, MD
Catherine & Joseph Aresty Department of Urology, USC Institute of Urology, Keck School o f Medicine, University of Southern California, Los Angeles

Nassiri N, Cacciamani G, Gill IS. Robotic bladder autotransplantation: preclinical studies in preparation for first-in-human bladder transplant. *J Urol.* 2023;210(4):600-610.

Study Need and Importance

Patients with terminal bladder pathology currently have only 1 option for urinary reconstruction using a vascularized segment of intestine, which can expose them to various potential complications. These include infections, stones, progressive kidney dysfunction, weight loss, and metabolic issues. Furthermore, the risks of short- and long-term complications, including reoperation, can be substantial. If bladder transplantation were possible, it could provide patients with a more normal bladder substitute, circumventing some of these issues. Herein, careful patient selection would have to be paramount, since immunosuppression and possible intermittent catheterization would have to be deemed acceptable trade-offs, medically and logistically. To date, human vascularized bladder transplantation has not been successfully performed.

What We Found

We developed bladder transplantation in 3 incremental, stepwise, preclinical, vascularized models: porcine, pulsatile-perfused cadavers, and finally heart-beating brain-dead human research donors. We describe the technique for bladder transplantation, including robotic recovery of the vascularized composite bladder allograft,

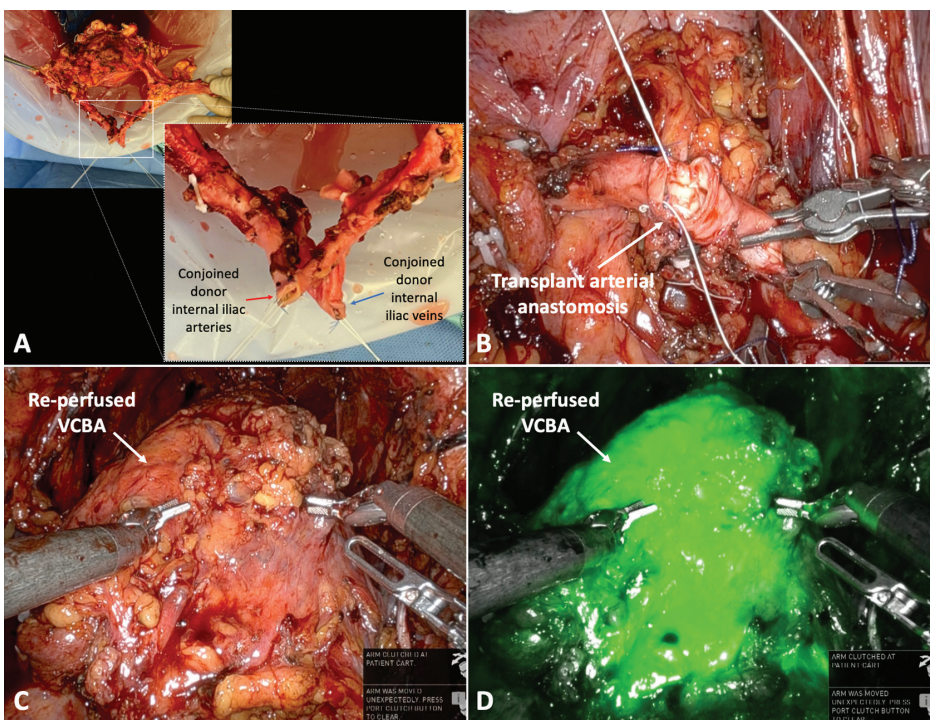

Figure. Robotic bladder autotransplantation. A, Back-table vascular reconstruction. B, Vascular reanastomosis. C, Reperfusion. D, Indocyanine green immunofluorescence of the reperfused vascularized composite bladder allograft (VCBA).

→ Continued on page 65

ROBOTIC BLADDER AUTOTRANSPLANT: PRECLINICAL STUDIES PREPARING

→ Continued from page 64

back-table vascular reconstruction, and robotic autotransplantation (see Figure). We demonstrate technical success, defined as adequate perfusion of the allograft as confirmed by direct visualization, real-time intraoperative immunofluorescence, and cystoscopy, with sustained allograft perfusion documented for up to 12 hours post-transplantation.

Limitations

Several questions remain as regards emptying characteristics and long-term compliance of the transplanted bladder, immunogenicity of the transplanted bladder, characteristics of bladder transplant rejection, and patient acceptance of this potential approach compared to standard treatment options.

Interpretation for Patient Care

We report the first known description of preclinical bladder autotransplantation in brain-dead but heart-beating human research donors and describe the robotic technique for bladder transplantation. This is in preparation for a first-in-human trial under a UNOS (United Network for Organ Sharing)–approved genitourinary vascularized composite bladder allotransplantation program (NCT 05462561). If successful, bladder transplantation could offer highly selected patients with terminal benign bladder pathology an alternative treatment option that circumvents the known complications of traditional urinary diversion. ■

JU INSIGHT

Risk Stratification by Quantification of Perineural Cancer Invasion on Prostate Needle Core Biopsy

Yuki Teramoto, MD, PhD
University of Rochester Medical Center, New York

Ying Wang, MD, PhD
University of Rochester Medical Center, New York

Hiroshi Miyamoto, MD, PhD
University of Rochester Medical Center, New York

Teramoto Y, Wang Y, Miyamoto H. Risk stratification by quantification of perineural cancer invasion on prostate needle core biopsy: should it be counted?. *J Urol.* 2023;210(4):639-648.

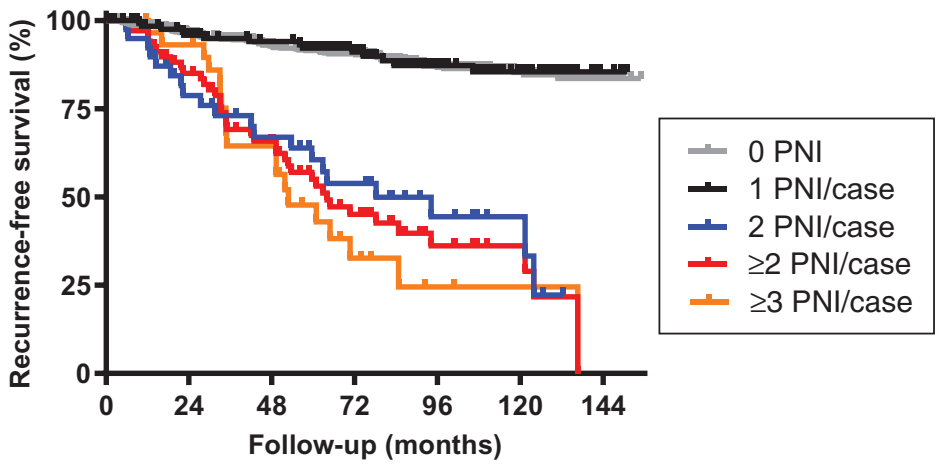

Figure. Kaplan-Meier curves for postoperative recurrence-free survival according to the number of perineural invasion (PNI) foci per biopsy.

Study Need and Importance

The presence of perineural invasion (PNI) by prostate cancer, particularly on biopsy, has been implicated in adverse pathology, including extraprostatic extension, and resultant unfavorable oncologic outcomes. By contrast, the prognostic role of PNI quantification on prostate biopsy remains poorly understood. Notably, pathologists do not routinely count the number of PNI foci in prostate cancer specimens, and a subset of them even report its detection on biopsy as a case-level summary.

What We Found

In each biopsy specimen from 724 men who had subsequently undergone radical prostatectomy, up to 10 PNI foci were identified. The prognosis was found to be comparable between those with 0 vs 1 PNI ($P = .9$), whereas the risk of biochemical recurrence in those with 2 ($P < .001$) or ≥2 ($P < .001$) PNI was significantly higher, compared to those with 1 PNI (see Figure). There was no significant difference in recurrence-free survival between those with 2 vs 3 ($P = .3$) or ≥3 ($P = .3$) PNI. Interestingly, patients with multifocal PNI detected in only 1 biopsy site had a significantly higher risk of recurrence than those with single PNI ($P < .001$). Additionally, >1 PNI per 10-mm tumor (vs ≤1 PNI; $P = .008$) was associated with worse recurrence-free survival. Meanwhile, the inclusion of multifocal PNI in the CAPRA (Cancer of the Prostate Risk Assessment) score considerably improved postoperative risk stratification.

Limitations

The limitations of our study included its retrospective nature from a single institution and analysis of only radical prostatectomy cases with no adjuvant therapy prior to recurrence. Furthermore, we did not assess the impact of PNI counting on targeted biopsy being increasingly used.

> "The prognosis was found to be comparable between those with 0 vs 1 PNI ($P = .9$), whereas the risk of biochemical recurrence in those with 2 ($P < .001$) or ≥2 ($P < .001$) PNI was significantly higher, compared to those with 1 PNI (see Figure)."

Interpretations for Patient Care

PNI quantification on prostate biopsy likely provides useful information for a more accurate prediction of postoperative patient outcomes. Pathologists may then need to report the presence of PNI in every biopsy site or at least specify single vs multifocal PNI. ■

JU INSIGHT

Sex Differences in Bladder Management, Symptoms, and Satisfaction After Spinal Cord Injury

Jeremy B. Myers, MD
University of Utah, Salt Lake City

John T. Stoffel, MD
University of Michigan, Ann Arbor

Sean P. Elliott, MD, MS
University of Minnesota, Minneapolis

Blayne Welk, MD, MSc
Western University, London, Ontario, Canada

Jennifer S. Herrick, MS
University of Utah, Salt Lake City

Sara M. Lenherr, MD, MS
University of Utah, Salt Lake City

For the Neurogenic Bladder Research Group

Myers JB, Stoffel JT, Elliott SP, Welk B, Herrick JS, Lenherr SM. Sex differences in bladder management, symptoms, and satisfaction after spinal cord injury. *J Urol.* 2023;210(4):659-669.

Study Need and Importance

Bladder-related quality of life (QoL) after spinal cord injury (SCI) is complex and sits at the intersection of demographics, injury characteristics, complications from SCI, and psychosocial aspects of health-related QoL. One of the most potentially important demographic factors affecting QoL is sex. Bladder-related QoL is very important to individuals with SCI as bladder and bowel function are some of the leading health-related concerns for these individuals, sometimes even over mobility.

What We Found

In the Neurogenic Bladder Research Group SCI Registry (see Figure), we analyzed bladder-related QoL in women and men to establish which factors for each group were associated with worse bladder symptoms and satisfaction. We found that women utilized bladder surgery at a much higher rate than men, especially bladder augmentation with or without a catheterizable channel (19.3% vs 4.4%; $P < .001$). In an adjusted analysis, overall bladder symptoms were less in both women and men who utilized either indwelling catheters (IDCs) or had surgery in comparison to clean intermittent catheterization. An interaction analysis showed that women had fewer bladder symptoms with IDCs and surgery compared to the decrease in men associated with these bladder managements. In women, surgery, greater independence, and better positive affect and well-being were all associated with better bladder satisfaction.

Figure. Investigators and patient stakeholders for the Neurogenic Bladder Research Group Spinal Cord Injury Registry Study, a prospective study of bladder-related quality of life after spinal cord injury.

> "In the Neurogenic Bladder Research Group SCI Registry (see Figure), we analyzed bladder-related QoL in women and men to establish which factors for each group were associated with worse bladder symptoms and satisfaction."

> "An interaction analysis showed that women had fewer bladder symptoms with IDCs and surgery compared to the decrease in men associated with these bladder managements."

Limitations

We only tested for the interaction of sex in our primary outcome (overall bladder symptoms); for secondary outcomes we can only comment on which variables have important associations with bladder symptoms and satisfactions within each sex, and not on differences between sexes.

Interpretation for Patient Care

In women, the higher use of surgery, along with the observation that surgery was associated with fewer bladder symptoms and higher satisfaction compared to clean intermittent catheterization, demonstrates the important role of surgery in bladder-related QoL. Participants of both sexes using IDCs had fewer associated bladder symptoms. ■

JU INSIGHT

Free PSA and Clinically Significant and Fatal Prostate Cancer in the PLCO Screening Trial

Kendrick Yim, MD
Brigham and Women's Hospital, Boston, Massachusetts

Chaoran Ma, MD, PhD
Brigham and Women's Hospital and Harvard Medical School, Boston, Massachusetts

Sigrid Carlsson, MD, PhD, MPH
Memorial Sloan Kettering Cancer Center, New York, New York
Sahlgrenska Academy at Gothenburg University, Gothenburg, Sweden

Hans Lilja, MD, PhD
Memorial Sloan Kettering Cancer Center, New York, New York
Lund University, Malmö, Sweden

Lorelei Mucci, ScD, MPH
Harvard T.H. Chan School of Public Health, Boston, Massachusetts

Kathryn Penney, ScD
Brigham and Women's Hospital and Harvard Medical School, Boston, Massachusetts
Harvard T.H. Chan School of Public Health, Boston, Massachusetts

Adam S. Kibel, MD
Brigham and Women's Hospital, Boston, Massachusetts

Scott Eggener, MD
University of Chicago, Illinois

Mark A. Preston, MD, MPH
Brigham and Women's Hospital, Boston, Massachusetts

Yim K, Ma C, Carlsson S, et al. Free PSA and clinically significant and fatal prostate cancer in the PLCO Screening Trial. *J Urol.* 2023;10.1097/210(4):630-638.

Study Need and Importance

Questions remain regarding the best PSA screening protocol to maximize capture of clinically significant prostate cancer (csPCa) while minimizing overdiagnosis and overtreatment of indolent disease. Free PSA (fPSA) is readily available, cheap, and has been associated with overall prostate cancer (PCa) diagnosis. We sought to evaluate if a single PSA combined with percent free PSA (%fPSA) would help further risk-stratify men for screening and increase diagnostic accuracy for csPCa and fatal PCa utilizing data from PLCO (Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial).

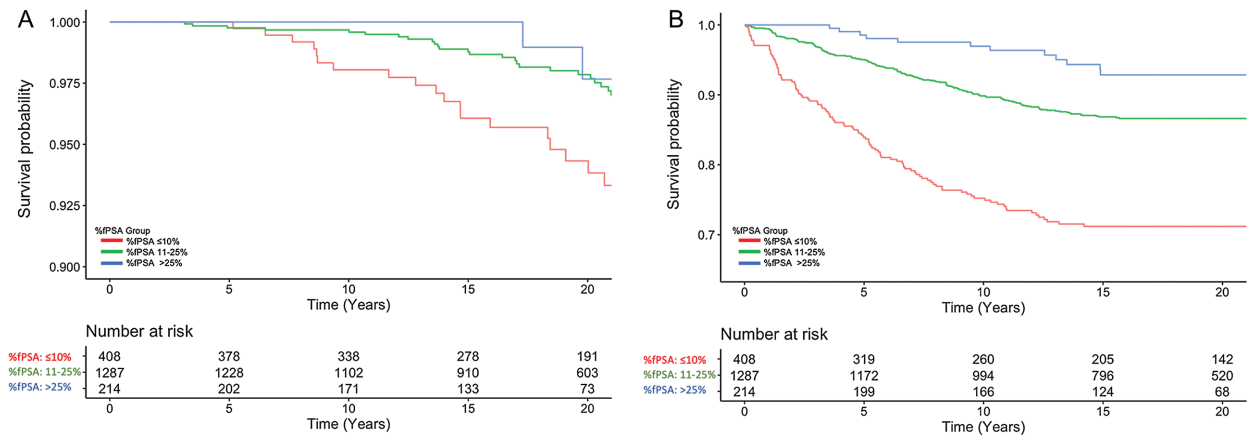

Figure. A, Kaplan-Meier analysis of fatal prostate cancer in men with baseline PSA ≥2 ng/mL stratified by percent free PSA (%fPSA; ≤10%, 11%-25%, >25%; log-rank $P = .002$). B, Kaplan-Meier analysis of clinically significant prostate cancer in men with baseline PSA ≥2 ng/mL stratified by %fPSA (≤10%, 11%-25%, >25%; log-rank $P < .001$).

> "We sought to evaluate if a single PSA combined with percent free PSA (%fPSA) would help further risk-stratify men for screening and increase diagnostic accuracy for csPCa and fatal PCa utilizing data from PLCO (Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial)."

What We Found

Regardless of age or racial background, addition of %fPSA to total PSA improved prediction of csPCa and fatal PCa in men with a total PSA ≥2 ng/mL. Cumulative incidence of fatal PCa for men with baseline PSA ≥2 ng/mL and %fPSA ≤10 was 3.2% and 6.1% at 15 and 25 years, respectively, compared to 0.03% and 1.1% for men with %fPSA >25%. Those with %fPSA ≤10% had significantly worse csPCa and fatal PCa-free survival compared to %fPSA 11%-25% and >25% (see Figure). Adjusting for age, digital rectal exam, family history of PCa, and total PSA, %fPSA was associated with csPCa (HR 1.05, $P < .001$) per 1% decrease.

Limitations

Within PLCO, fewer than 20% of men in the intervention arm had a fPSA measured. Initial selection for fPSA drawing was random, but to increase racial diversity, non-White race groups were prioritized for inclusion. Lastly, only a single fPSA value at enrollment was evaluated. There may be additional value with repeat testing.

> "Regardless of age or racial background, addition of %fPSA to total PSA improved prediction of csPCa and fatal PCa in men with a total PSA ≥2 ng/mL."

Interpretation for Patient Care

This is the largest prospective study examining %fPSA and PCa outcomes with long-term follow-up of 20 years. We suggest that fPSA reporting should be expanded to a total PSA of 2-10 ng/mL and also inform risk of csPCa. fPSA should be utilized in risk-stratified PSA screening strategies to help decrease overdiagnosis/overtreatment of indolent PCa and improve identification of those men at highest risk of csPCa. ■

JU INSIGHT

The Reduction of Male Lower Urinary Tract Symptoms Is Associated With a Decreased Risk of Death

Blayne Welk, MD, MSc
Western University, London, Ontario, Canada

J. Andrew McClure, MSc
London Health Sciences Center, Ontario, Canada

Welk B, McClure JA. The reduction of male lower urinary tract symptoms is associated with a decreased risk of death. *J Urol.* 2023;210(4):670-677.

Study Need and Importance

Male urinary symptoms are common and bothersome. Despite this, men generally seek treatment only when symptoms are significantly bothersome. While research has established the negative medical complications associated with male urinary symptoms, the connection between these symptoms and mortality has not been well studied.

What We Found

We used data from the MTOPS (Medical Treatment of Prostate Symptoms) randomized study which had the following arms: placebo, alpha blocker (doxazosin), 5-alpha reductase inhibitor (finasteride), and combination therapy (doxazosin and finasteride). Among the 3,046 men, we found that reducing urinary symptoms (as measured by the AUA Symptom Score) resulted in a statistically significant reduction in the risk of mortality. This effect was quite pronounced: the hazard of death decreased by 12% if the AUA Symptom Score decreased by 3 points. This effect persisted in sensitivity analyses when we censored men at the time of transurethral prostatectomy, adjusted for confounders, and shortened the observation period after the last study visit. Importantly, the reduced risk of mortality was seen with both the storage and the voiding domains independently (see Table). The mechanism of this effect is not clear and may be from direct nonurinary benefits from the medications, or it may represent a causal relationship with untreated urinary symptoms increasing the risk of falls, poor sleep, and impaired mental health.

Table. Exploratory Analysis of the Individual Components of the AUA Symptom Score on the Risk of Death

	Hazard ratio	*P* value
Model 1: Quality-of-life question score change (per 1-point improvement)	0.84 (0.73-0.95)	< .01
Model 2: Storage symptom score change (per 1-point improvement)	0.94 (0.88-0.99)	.04
Model 3: Voiding symptom score change (per 1-point improvement)	0.95 (0.91-0.99)	.03
Model 4: Nocturia score change (per 1-point improvement)	0.90 (0.76-1.06)	.2

All models were adjusted for age and treatment assignment. A hazard ratio less than 1 indicates a lower risk of death.

Limitations

This is still a historical cohort, and the impact of changes in clinical care and the predominance of newer alpha blockers are not clear. This effect needs to be further studied in other treatment areas for male urinary symptoms (such as overactive bladder medications or procedural interventions) to better understand this relationship.

Interpretation for Patient Care

It is possible that medical interventions for male urinary symptoms may help reduce mortality risk for men. ■

JU INSIGHT

Subcoronal Incision for Inflatable Penile Prosthesis Does Not Risk Glans Necrosis

Sung Hun Park, MD
Sewum Prosthetic Urology Center of Excellence, Seoul, South Korea

Steven K. Wilson, MD
Institute for Urologic Excellence, La Quinta, California

Lexiaochuan Wen, MD
Mayo Clinic, Rochester, Minnesota

Park SH, Wilson SK, Wen L. Subcoronal incision for inflatable penile prosthesis does not risk glans necrosis. *J Urol.* 2023;210(4):678-687.

Study Need and Importance

The subcoronal incision for inflatable penile prosthesis (IPP) surgery provides excellent corporal exposure and has the added benefit of being well tolerated under local anesthesia. Historical reports have implicated the subcoronal incision as a major risk factor for glans vascular compromise. As a result, many implant surgeons are understandably wary of adopting this technique. Here, we report the largest series of 898 subcoronal IPP surgeries performed by a single surgeon to delineate the true incidence of glans necrosis/ischemia and characterize the commonly encountered complications associated with this unique approach for IPP placement.

What We Found

The most common complications were distal penile edema (74.7%) and incisional paresthesia (20.6%), both of which were self-limiting (see Table). Distal penile skin necrosis developed in 5 patients (0.5%), characterized by dusky tissue and incisional wound dehiscence. All 5 patients had a prior circumcision, and the specific placement of the incision relative to the prior scar was deemed as the primary cause. Among these cases, 3 healed with wet-to-dry dressing, 1 required tissue grafting, and 1 necessitated device explantation.

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SUBCORONAL INCISION FOR INFLATABLE PENILE PROSTHESIS DOES NOT RISK GLANS NECROSIS

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Table. Complications Specific to Subcoronal Incision Approach for Inflatable Penile Prosthesis Placement

Complication	No. (%)
Transient distal penile edema	673 (74.9)
Transient subcoronal incision paresthesia	189 (20.6)
Distal penile skin necrosis	5 (0.5)
Device infection	2 (0.2)
Glans vascular compromise (ischemia/necrosis)	0 (0)

Device infection was rare (0.2%). No reports of glans vascular compromise were observed. All first-time implants (817) were successfully completed under local anesthesia with or without adjunctive conscious sedation.

Limitations

This study is limited by its retrospective design. All surgeries were performed by an experienced surgeon who specializes in this approach, which may account for the low complication rates. The majority (96%) of patients in this series are ethnically Korean, and the data may not apply to a more diverse population.

> "In experienced hands, the subcoronal approach for IPP placement is safe and does not pose a risk of glans ischemia."

Interpretations for Patient Care

In experienced hands, the subcoronal approach for IPP placement is safe and does not pose a risk of glans ischemia. It is most suitable for routine IPP placement and is compatible with office-based sedation techniques. ■

UPJ INSIGHT

Predicting Surgical Experience After Robotic Radical Prostatectomy Simulation Using Machine Learning

Nathan Schuler, MS
Johns Hopkins University, Baltimore, Maryland

Lauren Shepard, MS
Johns Hopkins University, Baltimore, Maryland

Aaron Saxton, MD
University of Rochester Medical Center, New York

Jillian Russo
Case Western Reserve University, Cleveland, Ohio

Daniel Johnston, BS
University of Rochester School of Medicine and Dentistry, New York

Patrick Saba, MS
SUNY Upstate Medical University Norton College of Medicine, Syracuse, New York

Tyler Holler, MPH
University of Rochester Medical Center, New York

Andrea Smith, MS
Intuitive Surgical, Inc, Peachtree Corners, Georgia

Sue Kulason, PhD
Intuitive Surgical, Inc, Peachtree Corners, Georgia

Andrew Yee, PhD
Intuitive Surgical, Inc, Peachtree Corners, Georgia

Ahmed Ghazi, MD, FEBU, MHPE
Johns Hopkins University, Baltimore, Maryland

Schuler N, Shepard L, Saxton A, et al. Predicting surgical experience after robotic nerve-sparing radical prostatectomy simulation using a machine learning–based multimodal analysis of objective performance metrics. *Urol Pract.* 2023;10(5):447-455.

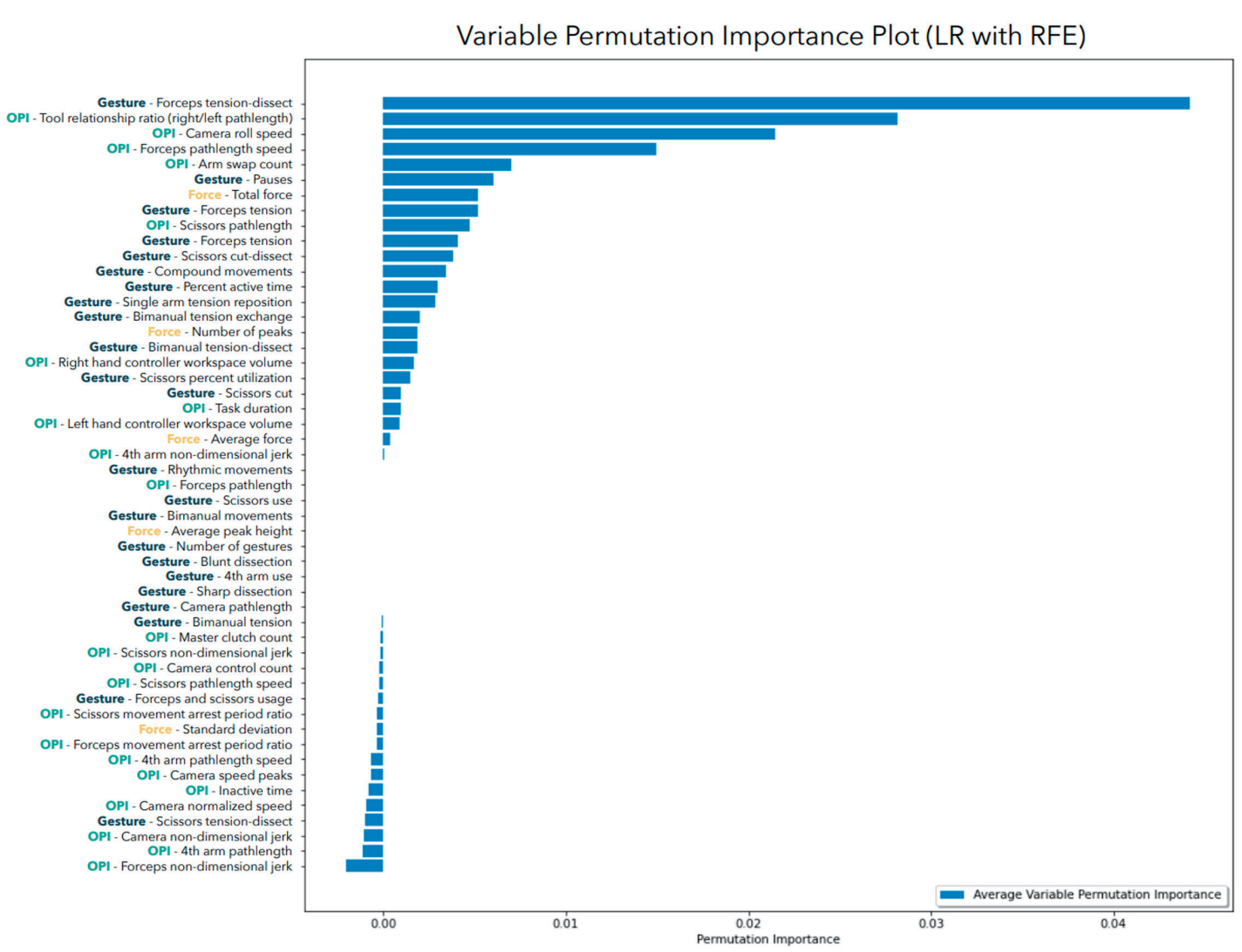

Figure. Variable permutation importance for best performing supervised classification algorithm. LR indicates logistic regression; OPI, objective performance indicators; RFE, recursive feature elimination.

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PREDICTING SURGICAL EXPERIENCE AFTER ROBOTIC RADICAL

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Study Need and Importance

Nerve-sparing radical prostatectomy represents the current standard of care for localized prostate cancer, prioritizing oncologic outcomes while secondarily seeking to limit injury to the surrounding neurovascular bundle. Current video-based evaluation standards require expert review, are time-consuming to perform, and are subjective to reviewer bias. Encompassing 14.7% of all new cancer diagnoses in the United States in 2023, improving assessment and training of this procedure for prostate cancer management has potential for substantial benefit to patients. Machine learning has recently been employed to objectively assess surgical skills in several surgical tasks, offering promising alternatives to the current standard.

What We Found

We combined robotic kinematic data from the da Vinci console, surgical gesture (cut, dissect, clip, retract) data collected from video review, and model-integrated force sensor data from within our validated hydrogel nerve-sparing robot-assisted radical prostatectomy simulation platform. Using supervised classification algorithms, we were able to achieve receiver operating characteristic area under curve scores of 0.96 and maximum accuracy of 86% in predicting completion of a published learning curve of 250 cases for nerve sparing during the procedure.

Limitations

This study featured a limited sample size (n=35) and did not include patient postoperative outcome data from participants.

Interpretation for Patient Care

We have identified a series of surgical dissection actions and explainable kinematic-based objective metrics that are common to high-volume surgeons (see Figure), and have demonstrated the ability of these metrics to predict procedure-specific experience with the highest accuracy of any similar published works. Surgeons looking to improve their own techniques can use these metrics as a guide for structured, objective feedback and self-evaluation. Further discussion and evaluation on factors contributing towards these metrics offer a clear pathway towards shortening the learning curve and optimizing patient outcomes sooner within the surgeon career timeline. ■

UPJ INSIGHT

Impact of Inflation Reduction Act on Out-of-Pocket Costs for Medicare Beneficiaries With Prostate Cancer

Brian D. Cortese, BS
Perelman School of Medicine, University of Pennsylvania, Philadelphia
Wharton School of Business, University of Pennsylvania, Philadelphia

Stacie B. Dusetzina, PhD
Vanderbilt University Medical Center, Nashville, Tennessee

Bashir Al Hussein Al Awamlh, MD
Vanderbilt University Medical Center, Nashville, Tennessee

David F. Penson, MD, MPH
Vanderbilt University Medical Center, Nashville, Tennessee

Sam S. Chang, MD, MBA
Vanderbilt University Medical Center, Nashville, Tennessee

Daniel A. Barocas, MD, MPH
Vanderbilt University Medical Center, Nashville, Tennessee

Amy N. Luckenbaugh, MD
Vanderbilt University Medical Center, Nashville, Tennessee

Kristen R. Scarpato, MD
Vanderbilt University Medical Center, Nashville, Tennessee

Kelvin A. Moses, MD, PhD
Vanderbilt University Medical Center, Nashville, Tennessee

Ruchika Talwar, MD
Vanderbilt University Medical Center, Nashville, Tennessee

Cortese BD, Dusetzina SB, Al Hussein Al Awamlh B, et al. Estimating the impact of the Inflation Reduction Act on the out-of-pocket costs for Medicare beneficiaries with advanced prostate cancer. *Urol Pract.* 2023; 10(5):476-483.

Study Need and Importance

Although combination systemic therapy treatment regimens for metastatic, hormone-sensitive prostate cancer have been effective at reducing mortality, both clinician-administered (Part B) and self-administered (Part D) medications can cause financial toxicity for patients. In 2025, the Inflation Reduction Act (IRA) will limit out-of-pocket spending for self-administered (Part D) drugs to $2,000. Herein, we compare out-of-pocket spending for common treatment regimens for advanced prostate cancer before and after implementation of the IRA.

What We Found

We found that when beneficiaries lack supplemental Part B coverage, they could be responsible for a 20% coinsurance leading to an out-of-pocket contribution ranging from $150 to $600. Currently, out-of-pocket costs for Part D beneficiaries ranged from $464 to $11,336 per year. Under the IRA, annual out-of-pocket costs for 2 regimens remained the same: androgen deprivation therapy (ADT) and docetaxel, as well as for ADT, abiraterone, and prednisone. However, annual savings for regimens that included branded self-administered drugs subject to the $2,000 out-of-pocket cap were estimated to be $9,336

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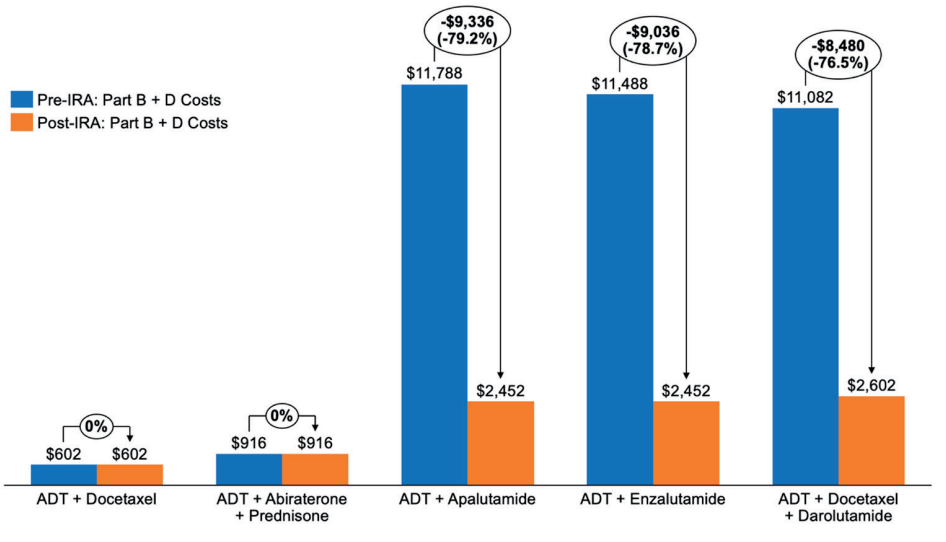

Figure. Annual beneficiary out-of-pocket costs and savings pre- and post-implementation of the Inflation Reduction Act (IRA) for AUA guideline–recommended advanced prostate cancer treatment. ADT indicates androgen deprivation therapy.

IMPACT OF INFLATION REDUCTION ACT ON OUT-OF-POCKET COSTS

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(79.2%) for ADT and apalutamide; $9,036 (78.7%) for ADT and enzalutamide; and $8,480 (76.5%) for ADT, docetaxel, and darolutamide.

Limitations

Our analysis uses a standard benefit design with no deductible that may not apply to all beneficiaries, assuming ADT in our study consists of clinician-administered leuprolide 45 mg intramuscular q 6 months despite emergence of relugolix as an equally efficacious self-administered option, using 2021 volume data to estimate the number of beneficiaries impacted, and only including 1 triple-agent regimen with emerging evidence (see Figure).

Interpretation for Patient Care

The $2,000 spending cap introduced by the IRA may decrease out-of-pocket costs and reduce financial toxicity due to advanced prostate cancer treatment. We aim to highlight the financial impact of the IRA on patient out-of-pocket costs for patients on combination systemic therapy for advanced prostate cancer. ■

UPJ INSIGHT

Comparison of Intermittent and Continuous Androgen Deprivation Therapy in Prostate Cancer Patients

Benjamin Becker, MD
Texas Tech University Health Sciences Center, School of Medicine, Lubbock

Stephanie Stroever, PhD, MPH
Texas Tech University Health Sciences Center, School of Medicine, Lubbock

Anish Reddy, MD
Texas Tech University Health Sciences Center, School of Medicine, Lubbock

Werner T. W. de Riese, MD, PhD
Texas Tech University Health Sciences Center, School of Medicine, Lubbock

Becker B, Stroever S, Reddy A, de Riese WTW. Comparison of intermittent and continuous androgen deprivation therapy in prostate cancer patients: an up-to-date meta-analysis for urologists and medical providers. *Urol Pract.* 2023;10(5):424-434.

Study Need and Importance

Androgen deprivation therapy (ADT) has been the standard of care for recurrent, locally advanced, and metastatic prostate cancer (PCa) for many decades. The pharmacological development of luteinizing hormone-releasing hormone agonists in the 1980s led to the option of reversible medical castration and the idea of intermittent ADT (iADT). This clinical concept of iADT was first studied in in vitro tumor and animal models demonstrating extended preservation of hormonal response and increased time to castration resistance. Then followed clinical studies in humans. Although many urologists are administering iADT, current guidelines still recommend continuous ADT (cADT) over iADT. The purpose of this meta-analysis is to provide an update and guidance on these 2 forms of ADT.

> "As patients with PCa live for many years, we also compared non-PCa mortality (all other causes of death including other forms of cancer) under ADT, which revealed a trend of iADT to be advantageous over cADT although this did not reach statistical significance (see Figure)."

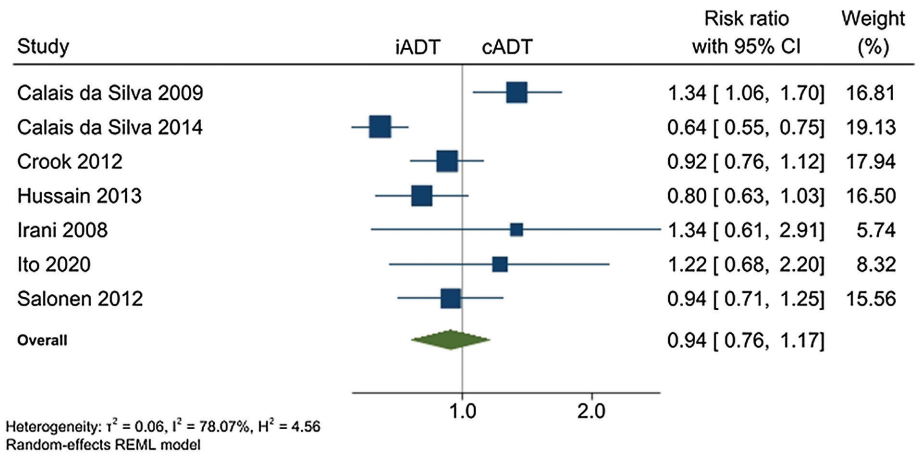

Figure. Forest plot generated using nonprostate cancer mortality data from each randomized clinical trial. Heterogeneity outcomes are also included. cADT indicates continuous androgen deprivation therapy; CI, confidence interval; iADT, intermittent androgen deprivation therapy.

What We Found

The data presented show that median follow-up was fairly consistent between the randomized clinical trials completed within the last 21 years. The meta-analysis did not show any advantage of cADT over iADT in PCa-specific mortality. As patients with PCa live for many years, we also compared non-PCa mortality (all other causes of death including other forms of cancer) under ADT, which revealed a trend of iADT to be advantageous over cADT although this did not reach statistical significance (see Figure).

Limitations

This meta-analysis showed elevated heterogeneity in study protocols and wide confidence intervals due to inadequate patient recruitment, implicating that future studies must implement standardized protocols and focus on recruiting larger sample sizes with longer and similar follow-up periods.

Interpretation for Patient Care

Currently, iADT and cADT can be considered as equivalent in long-term treatment outcomes. As iADT is more cost-efficient (less financial toxicity) and less likely to yield adverse side effects under treatment, future guidelines should consider and emphasize these advantages of iADT in comparison to cADT. ■

UPJ INSIGHT

Urology Research and Patient Understanding: Large Language Models to Generate Layperson Summaries

Michael B. Eppler, BA
Keck School of Medicine, University of Southern California, Los Angeles

Conner Ganjavi, BS
Keck School of Medicine, University of Southern California, Los Angeles

J. Everett Knudsen, BS
Keck School of Medicine, University of Southern California, Los Angeles

Ryan J. Davis, BS
Keck School of Medicine, University of Southern California, Los Angeles

Oluwatobiloba Ayo-Ajibola, BS
Keck School of Medicine, University of Southern California, Los Angeles

Aditya Desai, BA
Keck School of Medicine, University of Southern California, Los Angeles

Lorenzo Storino Ramacciotti, MD
Keck School of Medicine, University of Southern California, Los Angeles

Andrew Chen, MD
Keck School of Medicine, University of Southern California, Los Angeles

Andre De Castro Abreu, MD
Keck School of Medicine, University of Southern California, Los Angeles

Mihir M. Desai, MD
Keck School of Medicine, University of Southern California, Los Angeles

Inderbir S. Gill, MD
Keck School of Medicine, University of Southern California, Los Angeles

Giovanni E. Cacciamani, MD
Keck School of Medicine, University of Southern California, Los Angeles

Eppler MB, Ganjavi C, Knudsen JE, et al. Bridging the gap between urological research and patient understanding: the role of large language models in automated generation of layperson's summaries. *Urol Pract.* 2023;10(5):436-443.

Study Need and Importance

There is currently a global focus on translating complicated research into simple language for the general public, as recommended by the European Union's 2014 Clinical Trials Regulation and the "Good Lay Summary Practice" guidelines (2021). Clear and concise summaries are important to ensure understanding by a wide audience. To optimize these summaries, strategies such as shorter sentences, fewer syllables, and less use of passive verbs can be employed. Innovative natural language processors like ChatGPT have the potential to create comprehensive and understandable summaries, but their effectiveness and usefulness should be studied first.

What We Found

ChatGPT-generated patient summary outputs were produced in a short amount of time (less than 20 seconds) with an improvement in multiple readability metrics (Global Readability Score, Flesch Kincade Reading Ease, Flesch Kincaid Grade Level, Gunning Fog Score, Smog Index, Coleman Liau Index, and Automated Readability Index) when compared to both original abstracts and original patient summaries. Furthermore, physicians independently rated the ChatGPT patient summaries with a high correctness rate (>85%) and clarity score.

Limitations

Study limitations primarily relate to uncertainties associated with ChatGPT's capabilities. Although ChatGPT has been shown to be reliable, there are still questions regarding its consistency and accuracy. Furthermore, while ChatGPT is currently accessible for free, newer and superior versions may eventually become restricted to paying users. It is essential to note that this study's focus was on urology and urological literature, and therefore its findings should be validated across surgical and medical specialties.

Interpretation for Patient Care

Discussions are ongoing about the various uses of large language models, such as ChatGPT, in patient care. Potential applications include simplifying and customizing discharge summaries and at-home care instructions for patients. Summarizing medical research to improve patient comprehension has already proven beneficial to patient care, and this research reveals a possible tool to assist in that process. ■

UPJ INSIGHT

Deimplementation of Computed Tomography Urogram for Low- to Intermediate-risk Microscopic Hematuria

Sarah A. Birken, PhD
Wake Forest University School of Medicine, Winston-Salem, North Carolina

Richard Matulewicz, MD, MSCI, MS
Memorial Sloan Kettering Cancer Center, New York, New York

Ram Pathak, MD
Mayo Clinic, Rochester, Minnesota

Cheyenne R. Wagi, MA, MPH
Wake Forest University School of Medicine, Winston-Salem, North Carolina

Alexandra G. Peluso, MS
Wake Forest University School of Medicine, Winston-Salem, North Carolina

Richa Bundy, MPH
Wake Forest University School of Medicine, Winston-Salem, North Carolina

Lauren Witek, MS
Wake Forest University School of Medicine, Winston-Salem, North Carolina

Bridget Krol, BS
Wake Forest University School of Medicine, Winston-Salem, North Carolina

Michael L. Parchman, MD, MPH
Kaiser Permanente Washington Health Research Institute, Seattle

Matthew Nielsen, MD, MS
School of Medicine, University of North Carolina at Chapel Hill

Ajay Dharod, MD, FACP
Wake Forest University School of Medicine, Winston-Salem, North Carolina
Wake Forest Center for Healthcare Innovation, Winston-Salem, North Carolina
Wake Forest Center for Biomedical Informatics, Winston-Salem, North Carolina

Birken SA, Matulewicz R, Pathak R, et al. Toward the deimplementation of computed tomography urogram for patients with low- to intermediate-risk microscopic hematuria: a mixed-method study of factors influencing continued use. *Urol Pract.* 2023;10(5):511-519.

Study Need and Importance

Until 2020, the AUA recommended that all patients with microscopic hematuria be evaluated using computed tomography urogram (CTU). In 2020, the AUA risk-stratified its guidelines, recommending

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DEIMPLEMENTATION OF COMPUTED TOMOGRAPHY UROGRAM

→ Continued from page 72

ultrasound instead of CTU for patients with low- to intermediate-risk microscopic hematuria. Accordingly, continued use of CTU for these patients represents low-value care. To support the selection of strategies to support risk-stratified microscopic hematuria evaluation, we assessed changes in clinical practice following the AUA's 2020 guideline revision and factors influencing clinicians' microscopic hematuria evaluation approach.

What We Found

In this mixed-method study, our quantitative results found declines in low-value CTU following the AUA's revision of microscopic hematuria evaluation guidelines, with more substantial declines among urology providers than nonurology providers, although these differences were not statistically significant (see Table). Our qualitative findings corroborated quantitative findings by suggesting that urologists' access to revised guidelines, which emphasize the risk of CTU, and nonurology providers' deference to urology providers contributed to differences in CTU following guideline revisions.

> "Issuing guidelines with implementation guidance may facilitate the deimplementation of low-value urological care that guideline developers seek."

Limitations

We used retrospective data from in a single academic tertiary medical center in the southeastern US; findings may not generalize to other institutions. We were unable to classify 328 (46%) patients due electronic health record data limitations, potentially yielding more conservative estimates of AUA guideline adherence. Our qualitative findings may not be transferrable to many providers; despite significant recruitment efforts, we were unable to interview as many providers as planned.

Table. Low-value Computed Tomography Urogram Orders

	Pre-guideline change in CTs ordered for low to intermediate risk, No. (%)	Post-guideline change in CTs ordered for low to intermediate risk, No. (%)
Urology	101 (55.2[a])	39 (35.5)
Nonurology	34 (69.4)	22 (51.2)
Total	135 (58.2[b])	61 (39.9)

Abbreviations: CT, computed tomography.
[a]Percent of low-/intermediate-risk CTs, of all CTs, ordered by provider type.
[b]Percent of all CTs (n=232) low, intermediate, or high risk, ordered by either provider type.

Interpretation for Patient Care

Our findings suggest high-leverage, evidence-based strategies to reduce low-value care, including disseminating guidelines to nonurology providers and using algorithms to support clinical decision-making. Issuing guidelines with implementation guidance may facilitate the deimplementation of low-value urological care that guideline developers seek. ■

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SPECIALTY SOCIETIES

Princeton IV Consensus Conference Proceedings: PDE5 Inhibitors and Cardiac Health

Arthur L. Burnett, MD, MBA
The Johns Hopkins University School of Medicine, Baltimore, Maryland

In the years since the last Princeton Consensus Conference was held in 2010, significant advancements have been made in the biomedical knowledge and clinical experience surrounding phosphodiesterase type 5 inhibitor (PDE5i) therapy for erectile dysfunction (ED). In particular, new data have emerged particularly with respect to the safety and potential cardioprotective benefit of this therapy.

In this light, the next Princeton Conference was conceived: the Princeton IV Consensus Guidelines Conference. Held on March 10-11, 2023, at the Huntington Medical Research Institute in Pasadena, California, this meeting convened an interdisciplinary panel of scientists and clinical practitioners, representing cardiology, urology, internal medicine, family practice, psychology, and sexual medicine (see Figure). The panel addressed current clinical practice considerations surrounding cardiovascular health and sexual function in both men and women, with special attention given to the use of PDE5i.

The Conference involved a thorough review of the extant literature relevant to this subject matter and then generation of new recommendations for clinical management. Panel members delivered presentations as assigned on a host of topics, which were followed by group deliberation. The range of topic areas included: the psychological effect of ED and the benefits of including mental health care; phosphodiesterase type 5 regulatory biology in vasculature and mechanisms of action of PDE5i; drug-drug interactions with PDE5i, including the effects of nitrates; optimizing the use of PDE5i in the treatment of ED; adverse events and potential cardiovascular benefits of using PDE5i; adulteration of dietary supplements with PDE5i; proposals and concerns related to over-the-counter PDE5i administration; alternative non-PDE5i therapies for ED, including intracavernosal injection therapy and penile prostheses; novel restorative interventions proposed for treating ED, such as stem cells, platelet rich plasma, and low intensity shock waves; perspectives on PDE5i use in women; and recommendations for future studies using PDE5i in sexual medicine. A deliberate decision was made to defer the topic of testosterone therapy with cardiovascular outcomes, while awaiting the imminent completion of studies in this arena which may impact guideline recommendations.

Figure. The Princeton IV Consensus Conference panel members. Front row, left to right: Sharon Parish, MD; Tom Lue, MD, ScD; Kevin McVary, MD; Arthur Burnett, MD, MBA; Robert Kloner, MD, PhD; Raymond Rosen, PhD, Martin Miner, MD; Noel Kim, PhD; Ira Sharlip, MD; back row, left to right, Richard Sadovsky, MD; Peter Ganz, MD; Michael Blaha, MD; Mark Hirsh, MD; John Mulhall, MD, MSc; Irwin Goldstein, MD; Hossein Sadeghi-Nejad, MD; Tobias Kohler, MD.

> "The Conference involved a thorough review of the extant literature relevant to this subject matter and then generation of new recommendations for clinical management."

> "The panel issued recommendations for managing and optimizing sexual health incorporating factors of cardiovascular fitness."

The panel issued recommendations for managing and optimizing sexual health incorporating factors of cardiovascular fitness. A salient feature of this endeavor was the formulation of algorithms to assist in the clinical management of the patient presenting with ED. These algorithms were derived in part from recent recommendations of the American College of Cardiology and the American Heart Association, with additional reference to the utility of CT coronary artery calcium scoring.

The program content of the Conference is meant to offer a resource for practitioners of all professional backgrounds in caring for patients presenting with sexual dysfunction, particularly in the course of administering PDE5i therapy for ED. With this purpose in mind, the findings and recommendations of this Conference will be introduced as a state-of-the-art presentation at the 24th Annual Fall Scientific Meeting of the Sexual Medicine Society of North America, to be held November 16-19, 2023, in San Diego, California. All are welcomed to attend and discuss. The proceedings of the Conference will be communicated additionally as forthcoming journal publications for wider audience access. ■

FROM THE AUA PUBLIC POLICY COUNCIL

Advocacy for the Busy Urologist

Eugene Y. Rhee, MD, MBA
Chair, AUA Public Policy Council

We are busy. Between clinical, academic, and personal demands, I know that advocacy may not be in the forefront of your mind. However, there is truth to the adage, "If you're not at the table, you're on the menu." Our voices, as constituents and urologists, are not only important, but imperative to a successful urologic advocacy. The AUA's Advocacy teams build our organization's policy initiatives on the foundation of our members' concerns and ambitions. We recognize the hectic schedules of our members and we see firsthand the ways in which our physicians go above and beyond for their patients and practices on a day-to-day basis. Yet without our members' voices throughout the advocacy process, the AUA's ability to make an impact is limited. Here are 5 ways you can make a meaningful difference, regardless of how much time you can give.

If you have 30 seconds…

Sign up for our action alerts! The AUA regularly posts advocacy action updates on our Action Center page. Subscribe to these alerts to stay informed on real-time, active campaigns the AUA is advocating for and sponsoring on Capitol Hill. Additionally, you can utilize this platform to send prewritten messages to your lawmakers demonstrating your support.

If you have 5 minutes…

Please consider learning more about AUAPAC! AUAPAC proudly and transparently supports a broad list of federal candidates who understand and advocate for policy issues that impact urology. By regularly meeting with members of Congress and their staff members who serve on committees with jurisdiction on health care policy, AUAPAC demonstrates our tireless commitment to the priorities of the urologic community.

If you have 15 minutes…

> "The AUA's Advocacy teams build our organization's policy initiatives on the foundation of our members' concerns and ambitions."

Call your lawmakers and share your opinion with your elected official! As constituents and medical professionals, your perspective on health policy is highly valued by your representative or senators. You can contact your local officials too. To see what bills the AUA is tracking in your state, visit the State Advocacy webpage on AUAnet.org.

If you have a few hours…

Think about scheduling a district visit with your lawmaker! The Legislative and Political Affairs Department staff at the AUA are always available to help in scheduling or preparing for meetings with elected officials or their staff members. The power of personal anecdotes delivered in an in-person meeting–whether that be in a lawmaker's office or at your own practice–is immeasurable.

If you have a few days…

Please join us in Washington, DC, for our 7th Annual Urology Advocacy Summit! This year's event is February 26-28, 2024, at the JW Marriott. Previous attendees regularly praise the unique environment and energy of the AUA Summit and enjoy meeting directly with their federal lawmakers on Capitol Hill. If you have ever wanted to engage in advocacy, this is the event for you. We hope you will consider joining us to learn more about top advocacy priorities and then immediately use your voice on the Hill. ■