



THE OFFICIAL NEWSMAGAZINE OF THE AMERICAN UROLOGICAL ASSOCIATION

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Jason Robert Gee, MD  
John André Libertino, MD



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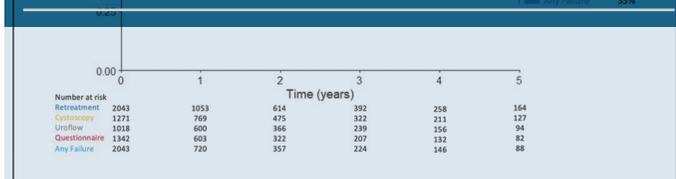
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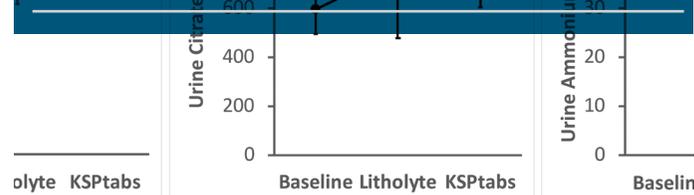
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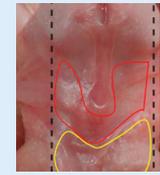


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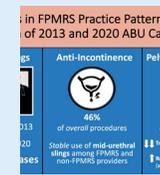
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# Multimodal Therapy for Patients With High-grade, High-risk Prostate Cancer With Long-term Follow-up

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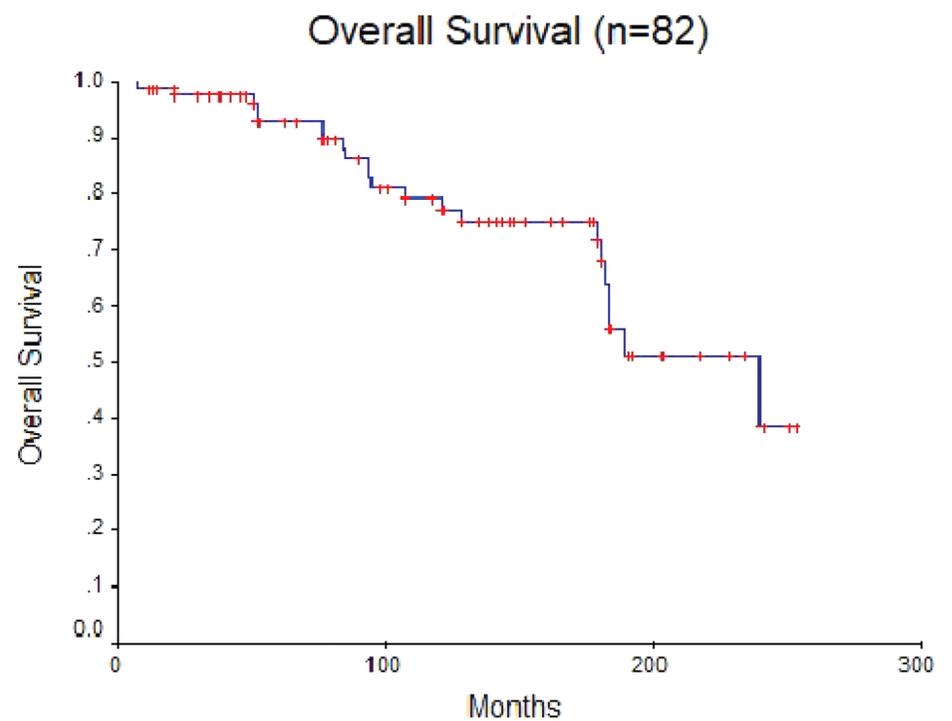
**John André Libertino, MD**  
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The management of high-risk prostate cancer remains challenging. Up to 50% of patients experienced recurrent disease following radical surgery, underscoring a great need for better therapies in treating this disease. It is for this reason that we embarked on a new method of treatment for high-risk prostate cancer.

Multimodal therapy (MMT), a concept and term coined by the senior author (J.A.L.) in originating a novel, prospective, nonrandomized clinical trial of neoadjuvant androgen deprivation therapy, followed by radical surgery and postoperative radiation, was first used in 1990 to treat our initial patient with high-risk prostate cancer. This introduced MMT as a new treatment paradigm for high-risk prostate cancer management. High-risk prostate cancer has been associated with prostate cancer related death in 80%-90% of patients.<sup>1-3</sup> As a result of renewed interest in neoadjuvant therapy prior to radical

surgery with short-term follow-up (3-4 years), we felt obligated to report our long-term experience with MMT (20 years).

From 1990-2012, 82 patients with clinically organ-confined prostate cancer and 10 years median follow-up underwent MMT consisting of neoadjuvant hormonal deprivation followed by radical retropubic prostatectomy and postoperative radiation. High-risk prostate cancer was defined preoperatively as Gleason Score 8-10 or PSA >20. Patients with negative surgical margins were observed initially and treated with salvage radiation therapy in the instance of recurrence. The MMT protocol was well tolerated in all 82 patients with no treatment-related discontinuation of therapy. Final surgical pathology revealed stage pT3-T4 in 58/82 (71%) and nodal involvement in 7/82 (9%). Distant metastatic disease was identified in 10/82 patients (12%). For patients undergoing MMT at 10, 15, and 20 years, cancer-specific survival was 78/82 (95%), 77/82 (94%), and 77/82 (94%; Figure 1), overall survival was 68/82 (83%), 66/82 (80%), and 60/82 (73%; Figure 2), and biochemical recurrence was 61/82 (74%), 51/82



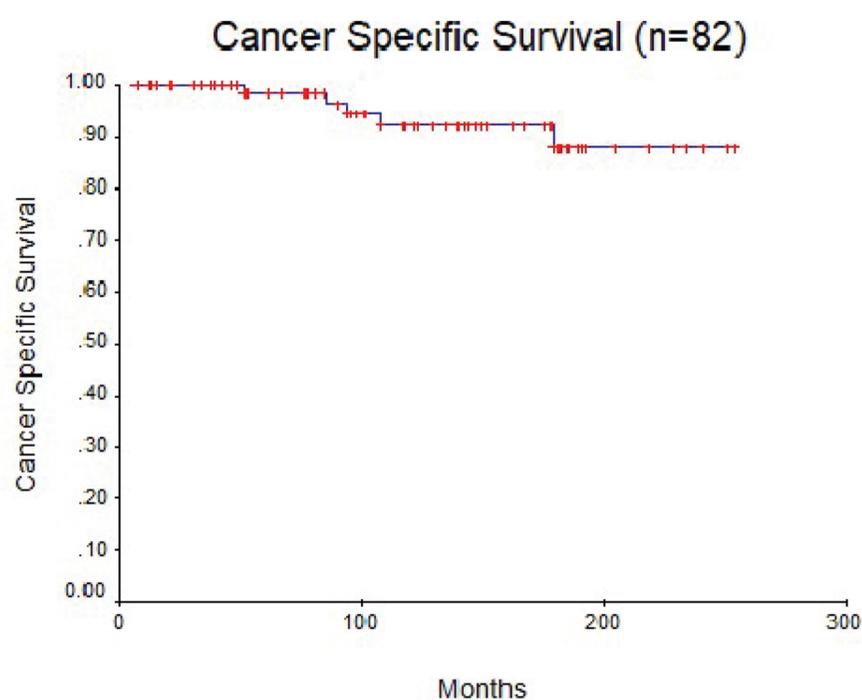
**Figure 2.** Overall survival. Reprinted with permission from Gee et al, *Int J Clin Oncol.* 2021;6(3):125-129.<sup>4</sup>

(62%), and 35/82 (43%; Figure 3). These findings establish the MMT protocol as an effective treatment strategy for high-risk prostate cancer with excellent long-term cancer-specific survival. Recurrence occurring primarily as a rising PSA as opposed to distant metastatic disease sug-

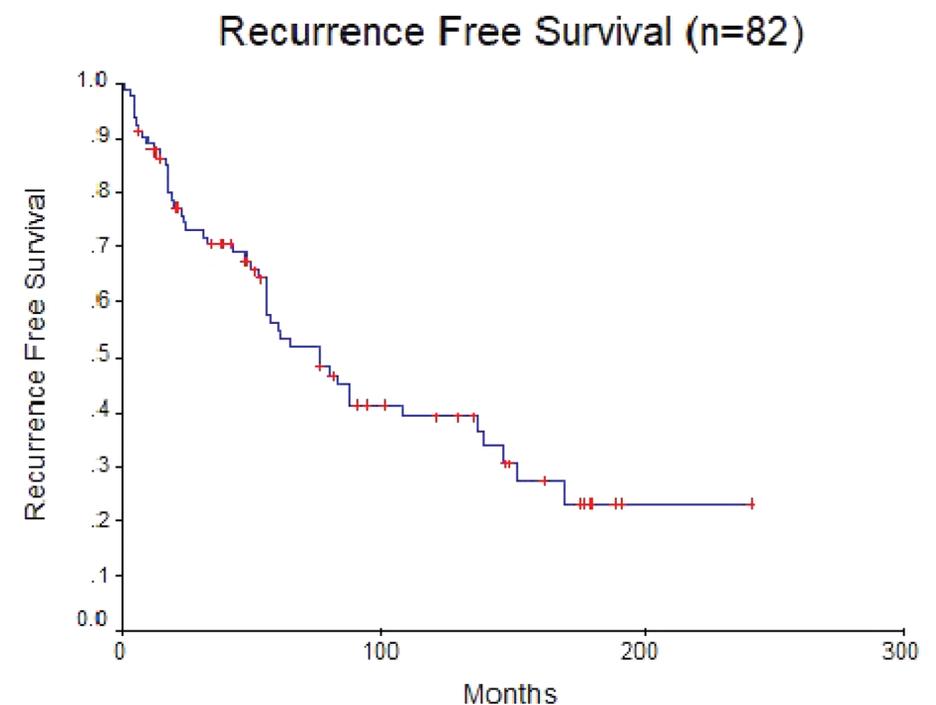
gests limited morbidity, as well, among patients treated with this protocol.

Cure remains the goal in cancer treatment. However, with high-risk prostate cancer, the risk of biochemical recurrence remains

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**Figure 1.** Cancer-specific survival. Reprinted with permission from Gee et al, *Int J Clin Oncol.* 2021;6(3):125-129.<sup>4</sup>



**Figure 3.** Biochemical-free survival. Reprinted with permission from Gee et al, *Int J Clin Oncol.* 2021;6(3):125-129.<sup>4</sup>

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2

We're accepting AUA2023 Late-breaking Abstracts through Monday, February 13, 2023. Submit your ground-breaking science and register for AUA2023 today!

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3

Attend the 2023 Annual Urology Advocacy Summit! Join the urology community in Washington, DC from February 27-March 1, 2023 for the 6th Annual Urology Advocacy Summit, an event designed to expand and strengthen the voice of urology on policy matters impacting our practices and patients. Register today!

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4

Don't forget to nominate an exceptional urology advanced practice provider (APP) for the 2023 APP of the Year Award! Submission deadline is January 31.

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5

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## MULTIMODAL THERAPY FOR PATIENTS WITH HIGH-GRADE, HIGH-RISK PROSTATE CANCER

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“These findings establish the MMT protocol as an effective treatment strategy for high-risk prostate cancer with excellent long-term cancer-specific survival.”

significant, even with the present multimodal treatment strategy. Nevertheless, cancer-specific survival and overall survival remain high

with this strategy, and across studies appear to be higher at given intervals of follow-up than conventional treatment with androgen deprivation therapy and radiation therapy alone.

A secondary goal of our multimodal approach is to achieve lower local recurrence rates and as such fewer disease-related complications. Indeed, it appears that the incidence of local recurrence or symptomatic sequelae of cancer recurrence remains relatively low in our series. And now that we can utilize MRI for more accurate diagnosis and staging, we might expect our outcomes to be even better. For instance, we are now able to diagnose smaller vol-

ume cancers with MRI fusion biopsy which are more amenable to surgical removal. Another important difference with contemporary management is that prostate parametric MRI and PSMA PET-CT staging preoperatively enables more accurate staging of the local extent of disease, thereby affording better patient selection for surgical removal of the prostate, and better determination of duration of therapy and surgical timing following neoadjuvant treatment to optimize surgical outcomes.

For these reasons, with advancing therapies and more sophisticated tools in diagnosing and stratifying prostate cancers translating to earlier detection

and longer lead time leading to longer overall survival with prostate cancer, it appears that the principles of treatment we have established with MMT will lead to even more successful future treatment strategies for high-risk prostate cancer. ■

1. Freedland SJ, Humphries EB, Mangold LA, et al. Risk of prostate cancer-specific mortality following biochemical recurrence after radical prostatectomy. *JAMA*. 2005;294(4):433-439.
2. Meeks JJ, Eastham JA. Radical prostatectomy: positive surgical margins matter. *Urol Oncol*. 2013;31(7):974-979.
3. Chalfin HJ, Dinizo M, Trock BJ, et al. Impact of surgical margin status on prostate-cancer-specific mortality. *BJU Int*. 2012;110(11):1684-1689.
4. Gee JR, Libertino JA. Multimodal therapy for patients with high-grade, high-risk prostate cancer with long-term follow-up. *Int J Clin Oncol*. 2021;6(3):125-129.

## Neuromodulation for Neurogenic Lower Urinary Tract Dysfunction: Reviewing the Latest Evidence

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Sacral neuromodulation (SNM) is an established third-line treatment for idiopathic lower urinary tract dysfunction in patients who failed conservative therapies, such as behavioral and pharmacological strategies.<sup>1</sup> Most studies on SNM have focused on the role of this minimally invasive treatment in patients presenting with idiopathic overactive bladder (OAB), chronic nonobstructive urinary retention, and chronic pelvic pain. However, there is increasing evidence supporting the use of SNM for patients with adult neurogenic lower urinary tract dysfunction (NLUTD). According to the International Continence Society, neurogenic OAB is characterized by “urgency, with or without urgency urinary incontinence, usually with increased daytime frequency and nocturia in the setting of a clinically relevant neurological disorder with at least partially preserved sensation.”<sup>2</sup> Neurogenic OAB is a common presentation of several neurological diseases, including central nervous system lesions (stroke, Parkinson’s

“Neurogenic OAB is a common presentation of several neurological diseases, including central nervous system lesions (stroke, Parkinson’s disease, tumors, etc) and spinal cord lesions.”

disease, tumors, etc) and spinal cord lesions. Studies on SNM for patients with neurological diseases tend to follow the same criteria used for patients with idiopathic lower urinary tract dysfunction.<sup>3</sup> This article critically discusses 2 recently published studies, which focused on the role of SNM in neurourological patients.

van Ophoven et al have performed a systematic literature review and meta-analysis of studies reporting the safety and effec-

tiveness of SNM in patients with NLUTD (neurogenic detrusor overactivity, nonobstructive urinary retention, or a combination of both).<sup>4</sup> Forty-seven studies were included in the systematic literature review. Twenty-one studies comprised of a total of 887 patients were included in the meta-analysis of test SNM. The pooled success rate of SNM test stimulation was 66.2% (95% CI 56.9-74.4). Depending on neurogenic conditions test success rates varied greatly. Twenty-four studies with a total of 428 patients were included in the meta-analysis of permanent SNM. The success rate of pooled permanent SNM was 84.2% (95% CI 77.8-89.0). Among the identified studies, the most common adverse events were loss of effectiveness, infection, pain at the implant site, and lead migration, with adverse event rates of 4.7%, 3.6%, 3.2%, and 3.2%, respectively. These outcomes are consistent with the meta-analysis published by Kessler et al in 2010,<sup>5</sup> which demonstrated a pooled success rate of 68% for the test phase and 92% for permanent SNM implant, with a mean follow-up of 26 months.

More recently, Liechti et al

published a sham-controlled, double-blind, multicenter trial, which included patients with refractory NLUTD at four Swiss referral centers.<sup>6</sup> Patients underwent SNM test phase with lead placement into the sacral foramina S3 (rarely S4). A neurostimulator was implanted for permanent stimulation only in patients presenting with  $\geq 50\%$  improvement in key bladder diary variables (successful test phase). For 2 months, neuromodulation was optimized using subsensory stimulation with individually adjusted parameters. Thereafter, the neurostimulator remained on (SNM ON) or was switched off (SNM OFF; 1:1 random allocation to group SNM ON or SNM OFF) for 2 months, followed by a neurourological reevaluation. Of 124 patients undergoing SNM test phase, 65 (52%) were classified as therapy responders. Of these, 60 patients were randomly assigned to the intervention. After 2 months of intervention, the SNM ON group demonstrated a success rate of 76%. In the SNM OFF group, 42% of patients showed sustained SNM effects despite their

→ Continued on page 6

## NEUROMODULATION FOR NEUROGENIC LOWER URINARY TRACT DYSFUNCTION

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neurostimulator being switched off during the last 2 months (odds ratio, 4.35; 95% confidence interval, 1.43 to 13.21;  $P = .009$ ). This may be seen as the first well-designed randomized controlled trial demonstrating that SNM effectively corrected refractory NLUTD in the short term in well-selected neurourological patients. Subsensory stimulation allowed switching off the implantable neurostimulator in the control group without jeopardizing blinding. Additionally, this study did not detect notable carry-over effects (>2 months), therefore

supporting a need for continuous stimulation in neurourological patients. The heterogeneity of the neurological patient population, which precluded a disease-specific analysis, was the main limitation of this trial.

Although SNM is a promising treatment for neurourological patients, most studies on SNM for NLUTD are based on small sample sizes and heterogeneous populations, which are incompletely characterized in terms of severity of neurological impairment, lacking standardized definitions of suc-

cess and follow-up.<sup>3</sup> On the other hand, the need for serial imaging of the central nervous system in selected neurourological patients has represented a major barrier to the dissemination of SNM. The latest technological developments, such as rechargeable and full-body MRI-compatible devices, may help increase the level of evidence in the near future. ■

1. Rios LA, Averbeck MA, Franca W, Sacomani CA, Almeida FG, Gomes CM. Initial experience with sacral neuromodulation for the treatment of lower urinary tract dysfunction in Brazil. *Int Braz J Urol.* 2016;42(2):312-320.

2. Gajewski JB, Schurch B, Hamid R, et al. An International Continence Society (ICS) report on the terminology for adult neurogenic lower urinary tract dysfunction (ANLUTD). *Neurourol Urodyn.* 2018;37(3):1152-1161.

3. Averbeck MA, Moreno-Palacios J, Aparicio A. Is there a role for sacral neuromodulation in patients with neurogenic lower urinary tract dysfunction? *Int Braz J Urol.* 2020;46(6):891-901.

4. van Ophoven A, Engelberg S, Lilley H, Sievert KD. Systematic literature review and meta-analysis of sacral neuromodulation (SNM) in patients with neurogenic lower urinary tract dysfunction (nLUTD): over 20 years' experience and future directions. *Adv Ther.* 2021;38(4):1987-2006.

5. Kessler TM, La Framboise D, Trelle S, et al. Sacral neuromodulation for neurogenic lower urinary tract dysfunction: systematic review and meta-analysis. *Eur Urol.* 2010;58(6):865-874.

6. Liechti MD, van der Lely S, Knüpfen SC, et al. Sacral neuromodulation for neurogenic lower urinary tract dysfunction. *NEJM Evid.* 2022;1(11):https://doi.org/10.1056/EVIDo2200071.

## Reducing Treatment-related Morbidity in Early-stage Testicular Cancer

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The blessing and curse of testicular cancer is near-uniform curability juxtaposed with the long-term adverse effects of any intervention that these young cancer survivors must contend with for the rest of their lives. While it is “straightforward” to perform an orchiectomy, obtain staging, and then offer observation, adjuvant therapy, locoregional therapy (retroperitoneal lymph node dissection [RPLND] or radiotherapy), or systemic platinum-based therapy, there are many potential opportunities to optimize patient care and reduce treatment-related morbidity. We highlight moments across the testicular cancer treatment journey and disease spectrum that may be underappreciated. These nuanced considerations ensure that we address the concerns of our patients and also minimize overtreatment and undertreatment.

The socioeconomic and psychological impact of a cancer diagnosis and orchiectomy in a young man cannot be overstated.<sup>1</sup> These young men experience significant rates of anxiety, depression, and

financial toxicity that come with a cancer diagnosis and cancer care. It is incumbent upon us to perform a comprehensive psychosocial intake and provide relevant support services. Additionally, history and physical should screen for symptoms and signs of hypogonadism, anxiety, and depression.<sup>2</sup> Prior to orchiectomy, sperm banking and testicular prosthesis should be discussed, which may mitigate downstream fertility concerns and body image changes.<sup>2</sup>

In patients with stage I disease, it is critical to follow serum tumor markers to the nadir for accurate staging. Failure to do so can misclassify a patient as having occult systemic disease and lead to unnecessary chemotherapy. Further, low/stable levels of alpha-fetoprotein and human chorionic gonadotropin can be seen from noncancer causes and should be confirmed to be rising prior to initiation of systemic therapy. While all options should be discussed as part of the shared decision-making process, the overwhelmingly preferred management option for stage I disease is observation for both seminoma and nonseminoma. Since 1981, the Princess Margaret Hospital recommended active surveillance for all stage I tumors.<sup>3</sup> Based on this experience, the relapse rate is 28% with median time to relapse of 7

months.<sup>3</sup> The estimated 5-year cancer-specific survival is 98%-99%.<sup>3</sup> An important exception is for patients with stage I secondary somatic malignancy, who should be directed toward primary RPLND. In seminoma patients, surveillance with MRI should be considered to minimize ionizing radiation exposure. The recent phase III TRISST (TE24 Trial of Imaging and Schedule in Seminomas Testis) trial randomized patients with stage I seminoma to surveillance with CT or MRI. MRI was noninferior to CT at detecting relapse at 72-month median follow-up.<sup>4</sup> Ostensibly these same principles are applicable to patients with nonseminoma histology.

In stage II disease, there are multiple opportunities to optimize treatment. Patients presenting with de novo stage II disease may behave differently from patients who develop metastases confined to the retroperitoneum during surveillance for stage I disease. Patients who develop metastases during surveillance may be ideal candidates for RPLND since their natural history indicates they are less likely to have systemic relapse.

Providers should also recognize that the rate of pN0 in patients with clinical stage II disease approaches 20%-30%. First and foremost, the unequivocal presence of metastases

should be confirmed in small-volume (stage IIA) retroperitoneal metastases to avoid overtreating patients who do not harbor metastases. Our practice is to perform short-interval (6-8 weeks) restaging with axial imaging of the chest, abdomen, and pelvis along with serum tumor markers; if the node involutes, surveillance is preferred; if metastases develop, systemic therapy is pursued. For persistent/slightly enlarging nodes, high-quality nerve-sparing RPLND is our preferred option to avoid the long-term side effects of systemic chemotherapy.

Historically, patients with pathological pN1 disease were observed, while those with pN2/N3 disease received adjuvant or full-dose chemotherapy. More recently, there is evidence to support surveillance in lieu of adjuvant therapy in pathological node-positive stage II disease. Based on a recent series from Indiana University, pathological stage II patients who underwent surveillance experienced 5-year recurrence-free survival of 79%, with no significant differences in relapse rates between pN1, pN2, and pN3 patients.<sup>5</sup> All patients who recurred were successfully treated with chemotherapy at median follow-up of 52 months.<sup>5</sup> These data suggest that most pathological stage II patients

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## REDUCING TREATMENT-RELATED MORBIDITY IN EARLY-STAGE TESTICULAR CANCER

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“The socioeconomic and psychological impact of a cancer diagnosis and orchiectomy in a young man cannot be overstated.<sup>1</sup>”

may be safely observed.

There is renewed interest in RPLND for patients with low-volume stage II seminoma. Emerging evidence from the phase II SEMS (Surgery in Early Metastatic Seminoma) trial suggests that RPLND for stage II seminoma could achieve oncologic outcomes similar to those of nonseminomas.<sup>6</sup> In this multi-institutional single-arm trial, patients with seminoma and lymphadenopathy 1-3 cm underwent RPLND.<sup>6</sup> Recurrence rate was 18% with median follow-up of 24 months.<sup>6</sup> As these data and others mature, RPLND may very well become a standard option for appropriately selected patients with low-volume stage II seminoma.

Fortunately, we are in the midst of a revolution in testicular cancer diagnosis and management as novel sensitive and specific biomarkers enter our armamentarium. Circulating microRNA miR-371a-3p has emerged as such a biomarker, which holds the promise of informing treatment decisions across the testicular cancer spectrum.<sup>7</sup> The reported sensitivity, specificity, and area under the curve for seminoma and nonseminoma are consistently >90%.<sup>7</sup> Notably, miR-371a-3p is unable to detect residual teratoma.<sup>6,8</sup> The diagnostic potential of microRNA is currently being validated in several clinical trials prior to clinical use.

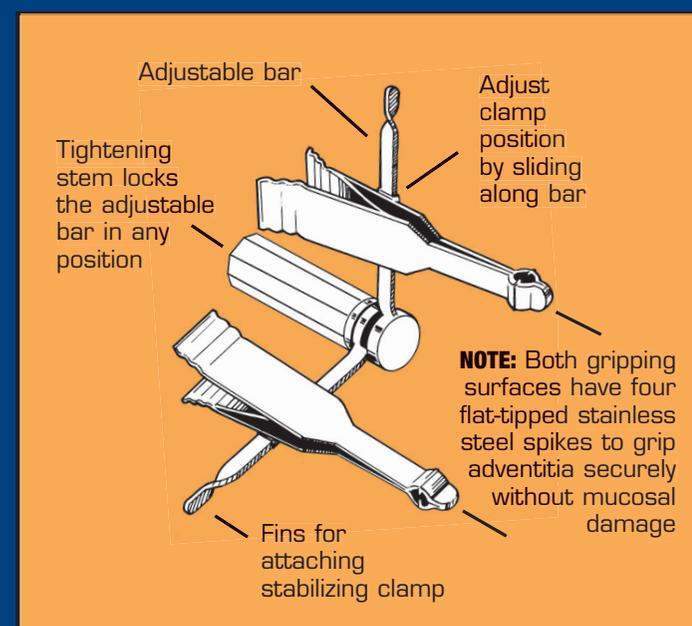
In summary, we draw attention to nuanced considerations that can impact the way we manage testicular cancer patients in an effort to limit treatment-related morbidity. Volume, expertise, and treatment at high-volume centers are important to confirm optimal outcomes.<sup>9</sup> ■

- Stephenson A, Eggener SE, Bass EB, et al. Diagnosis and treatment of early stage testicular cancer: AUA guideline. *J Urol*. 2019;202(2):272-281.
- Sturgeon JF, Moore MJ, Kakiashvili DM, et al. Non-risk-adapted surveillance in clinical stage I nonseminomatous germ cell tumors: the Princess Margaret Hospital's experience. *Eur Urol*. 2011;59(4):556-562.
- Joffe JK, Cafferty FH, Murphy L, et al. Imaging modality and frequency in surveillance of stage I seminoma testicular cancer: results from a randomized, phase III, noninferiority trial (TRISST). *J Clin Oncol*. 2022;40(22):2468-2478.
- Tachibana I, Kern SQ, Douglawi A, et al. Primary retroperitoneal lymph node dissection for patients with pathologic stage II nonseminomatous germ cell tumor-N1, N2, and N3 disease: is adjuvant chemotherapy necessary? *J Clin Oncol*. 2022;10.1200/JCO.22.00118.
- Daneshmand S, Cary C, Masterson TA, et al. SEMS trial: result of a prospective, multi-institutional phase II clinical trial of surgery in early metastatic seminoma. *J Clin Oncol*. 2021;39(6 Suppl):375.
- Fankhauser CD, Nuno MM, Murray MJ, Frazier L, Bagrodia A. Circulating microRNAs for detection of germ cell tumours: a narrative review. *Eur Urol Focus*. 2022;8(3):660-662.
- Leao R, van Agthoven T, Figueiredo A, et al. Serum miRNA predicts viable disease after chemotherapy in patients with testicular nonseminoma germ cell tumor. *J Urol*. 2018;200(1):126-135.
- Woldu SL, Matulay JT, Clinton TN, et al. Impact of hospital case volume on testicular cancer outcomes and practice patterns. *Urol Oncol*. 2018;36(1):14.e7-14.e15.

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1. Schepisi G, De Padova S, De Lisi D, et al. Psychosocial issues in long-term survivors of testicular cancer. *Front Endocrinol (Lausanne)*. 2019;10:113.

# Defining Success After Anterior Urethroplasty: Highlighting the Need for a Universal Definition

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There is not consensus on how to define a successful urethroplasty. The goal of academic, reconstructive urologists is to be objective and data-driven in our approach to urethral stricture disease. However, this push for more objectivity may be contrary to patient-centered care. In the past, urethroplasty had been considered a success if a patient never needed retreatment of their stricture.<sup>1</sup> The limitations of this definition include (1) not accounting for patients who cannot afford further care or seek follow-up care elsewhere, and (2) surgeons having different thresholds to reoperate. Due to a desire to increase the academic rigor of our definition of success after urethroplasty, there has been a move toward using alternative, objective definitions of success. These include the presence of a strong force of stream, lack of recurrence on cystoscopy, and lack of voiding symptoms on validated questionnaires.<sup>2</sup> Unfortunately, this variety of outcomes reported in the literature makes it challenging to compare success rates across studies.

Therefore, we need to come to universal agreement regarding which outcomes to use to define success after urethroplasty. Until we do, we will struggle to progress the field of stricture management. In our study, we sought to evaluate the success of anterior urethroplasty based on different definitions of success in a single cohort. Using the Trauma and Urologic Reconstructive Network of Surgeons multi-institutional database, we evaluated success based on 5 separate definitions of urethroplasty failure. These included: (1) receipt of stricture retreatment, (2) anatomical recurrence on flexible cystoscopy, (3) uroflow maximum flow rate <15 mL/s, (4) symptomatic recurrence using validated questionnaires, and

(5) failure by any of the above definitions. These groups are referred to as “retreatment,” “cystoscopy,” “uroflow,” “questionnaire,” and “any failure.” We included 712 men in our analysis who had undergone a first-time, single-stage, anterior urethroplasty and completed all recommended follow-up. We found that success after urethroplasty changed drastically simply by changing the way success is defined. Specifically, the 1- and 5-year estimated probabilities of success, from highest to lowest, were 94% and 75% for retreatment, 88% and 71% for cystoscopy, 84% and 58% for uroflow, 67% and 37% for questionnaire, and 57% and 23% for any failure ( $P < .001$ ; see Figure).

Our data show marked variability in success rates based on the outcome measure used, and this represents the problem we face in comparing outcomes across studies in the literature. This begs the question of whether there is merit to developing a research-based definition of success after urethroplasty. This could be likened to the American Society for Radiation Oncology definition for biochemical recurrence after radiotherapy for prostate cancer, which is not intended to be a threshold value for initiation of treatment. Rather, it is meant as a research definition to standardize clinical trials.<sup>3</sup> Similarly, a research-based definition of urethroplasty success may be different than clinical success but is essential for clinical trials and multi-institutional comparisons.

Using the “retreatment” definition after urethroplasty would be a patient-centered outcome because it requires no invasive tests or burdensome follow-up. However, this definition’s limitations (as previously stated) and lack of objectivity make it a less-than-ideal outcome measure as a research-based definition of success. Conversely, “cystoscopy” is an excellent option for an objective, reproducible, research-based definition of success. However, it is not a good tool for measuring clinical success because it is costly, invasive, and only 50%-65% of men comply with post-

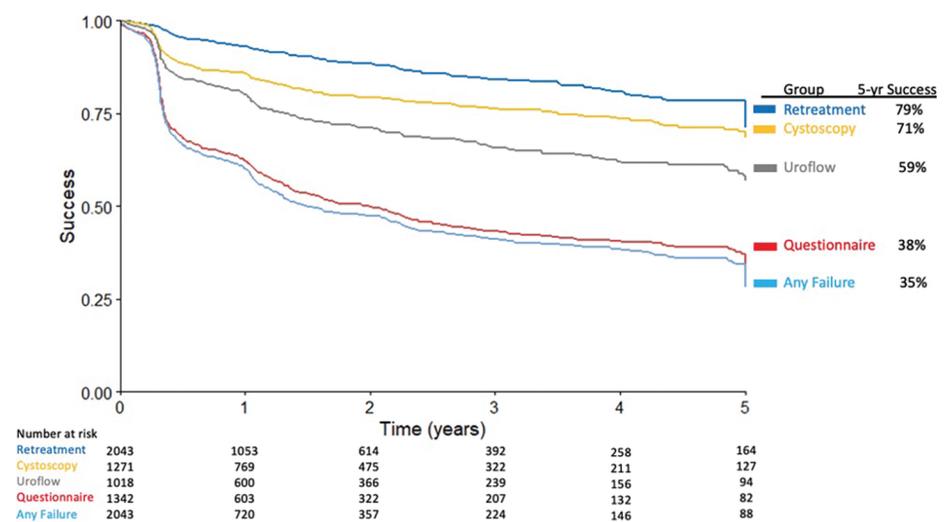


Figure. Kaplan-Meier success estimates following urethroplasty using 5 separate definitions of success.

operative cystoscopy.<sup>4,5</sup> Further, cystoscopy tends to overestimate failures since 35%-42% of men with an anatomical recurrence on cystoscopy are asymptomatic.<sup>4,6,7</sup> As such, cystoscopy may not be ideal for a clinical or research-based definition of success. “Uroflow” is fast, cheap, and noninvasive while also providing objective data postoperatively. This test can, however, be confounded by bladder dysfunction, prostatic enlargement, urethral inflammation, and bladder volume.<sup>8,9</sup> Lastly, “questionnaires” represent the most patient-centered measure to define a successful urethroplasty. However, as previously mentioned, men can develop an asymptomatic recurrence that would go undetected using symptom-based questionnaires. In addition, men may report weak stream not attributable to a stricture recurrence, which is suggested by our data showing success rates by questionnaires were lower than cystoscopy at both 1 and 5 years.

This study was not intended to dictate what the definition of success after urethroplasty should be. Our goal was to provide a fair comparison of success rates in a single group of men using currently available definitions. As a group, urologists could choose 1 or several of these outcomes to be the universal clinical and/or research-based definition of successful urethroplasty moving forward. This common language would surely foster multi-institutional comparisons and meta-analyses with the

goal of optimizing urethral stricture management.

## Acknowledgements

The original versions of this study and the included Figure were published in their original version in *The Journal of Urology*.<sup>10</sup> ■

1. Meeks JJ, Erickson BA, Granieri MA, Gonzalez CM. Stricture recurrence after urethroplasty: a systematic review. *J Urol*. 2009;182(4):1266-1270.
2. Chapple C, Andrich D, Atala A, et al. SIU/ICUD consultation on urethral strictures: the management of anterior urethral stricture disease using substitution urethroplasty. *Urology*. 2014;83(3):S31-S47.
3. Cookson MS, Aus G, Burnett AL, et al. Variation in the definition of biochemical recurrence in patients treated for localized prostate cancer: the American Urological Association Prostate Guidelines for Localized Prostate Cancer Update Panel report and recommendations for a standard in the reporting of surgical outcomes. *J Urol*. 2007;177(2):540-545.
4. Erickson BA, Elliott SP, Voelzke BB, et al. Multi-institutional 1-year bulbar urethroplasty outcomes using a standardized prospective cystoscopic follow-up protocol. *Urology*. 2014;84(1):213-217.
5. Patino G, Cohen AJ, Vanni AJ, et al. Urethrogram: does postoperative contrast extravasation portend stricture recurrence? *Urology*. 2020;145:262-268.
6. Abouassaly R, Angermeier KW. Augmented anastomotic urethroplasty. *J Urol*. 2007;177(6):2211-2216.
7. Baradaran N, Fergus KB, Moses RA, et al. Clinical significance of cystoscopic urethral stricture recurrence after anterior urethroplasty: a multi-institution analysis from Trauma and Urologic Reconstructive Network of Surgeons (TURNS). *World J Urol*. 2019;37(12):2763-2768.
8. Eryıldırım B, Tarhan F, Kuyumcuoğlu U, Erbay E, Pembegül N. Position-related changes in uroflowmetric parameters in healthy young men. *Neurourol Urodyn*. 2006;25(3):249-251.
9. Karl C, Gerlach R, Hannappel J, Lehnen H. Uroflow measurements: their information yield in a long-term investigation of pre- and postoperative measurements. *Urol Int*. 1986;41(4):270-275.
10. Anderson KT, Vanni AJ, Erickson BA, et al. Defining success after anterior urethroplasty: an argument for a universal definition and surveillance protocol. *J Urol*. 2022;208(1):135-143.

# Citrate Alkali Content of Common Over-the-Counter and Medical Food Supplements

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Nephrolithiasis is a growing disease, affecting about 1 in 11 people in the United States each year.<sup>1</sup> Oral alkalinizing agents such as potassium citrate and sodium bicarbonate are commonly prescribed medications for patients with recurrent calcium stones, hypocitraturia, uric acid stones, or cystine stones. However, despite efficacy, long-term adherence with such therapy is as low as 13%.<sup>2</sup> Many insurance formularies may not cover commonly prescribed formulations, and the average monthly cost of medication may be a barrier to adherence for some patients.

This has led to the development of many over-the-counter (OTC) supplements and medical food products, which claim to help prevent stone recurrence, primarily through delivery of alkali salts. Based on the United States Orphan Drug Act, the U.S. Food and Drug Administration (FDA) does not approve or regulate the content, strength, quality, and purity of medical foods. Similarly, in the era of social media and targeted marketing, modern patients are more likely to seek medical information and advice from nonprovider sources. The medical food space has exploded in popularity in the social media era and was valued at \$12.3 billion in 2015 (expected to surpass \$24 billion by 2025).<sup>3</sup> Therefore, manufacturers' claims must be carefully considered by the consumer and provider alike.

One may note that many OTC supplements contain 99 mg or less of potassium (2% of recommended daily allowance). There is a common misconception that this is due to a regulated limit by the FDA. However, this is not the case. Many manufacturers set this limit due to the fact that the FDA considered requiring a warning label for products that contained 100 mg or greater of potassium per serving.<sup>4</sup> Ultimately, the FDA has not ruled on a limit for potassium in supplements. More modern med-

ical foods and supplements have not perpetuated to this limit.<sup>5</sup>

In an effort to evaluate the content of common OTC alkali products, Dai et al purchased 9 common OTC products in 2 batches 6 months apart. Using a single serving of each product, the actual content of citrate was measured with spectrophotometry. Total citrate as alkali and cost per 10 mEq of alkali was also calculated.<sup>6</sup> Results can be seen in the Table.

Total citrate per serving and citrate as alkali can vary greatly, and that variance largely depends on the pH of the product. The cations accompanying citrate in alkali supplements are important in the citraturic response; citrate salts contribute to a systemic alkalinization

“Total citrate per serving and citrate as alkali can vary greatly, and that variance largely depends on the pH of the product.”

effect, whereas the protonated form of citrate (citric acid) does not result in a significant alkali load.<sup>7</sup> The more acidic the solution, the greater percentage of citrate exists in the form of citric acid as hydrogen ions replace the positively charged cations. However, compared to other beverages that have been pro-

posed as dietary alkali alternatives, overall these supplements contain higher alkali concentrations than lemonade (6.1-8 mEq/L), but lower concentrations than orange juice (47.9-63.5 mEq/L).<sup>8</sup>

Alkali citrate per serving varied from 2.3 mEq (Horbäach potassium citrate) to 16.2 mEq (Moonstone powder). Moonstone advertised 60 mEq of citrate, which was accurate if all species of citrate and citric acid were counted, but due to the acidic pH of the solution, the amount of alkali is much lower. Moonstone has since changed the promotional materials to better reflect this. LithoLyte (coffee and powder) delivered 6.4-8.4 mEq of

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**Table.** pH, Measured Citrate, Citrate as Alkali, and Cost per Unit of Citrate Alkali for Common Over-the-Counter Food Products and Supplements

| Product                    | Type         | Serving               | Lot | pH    | Advertised citrate (mEq/serving) | Total citrate (mEq/serving) | Alkali citrate (mEq/serving) | Cost per 10 mEq citrate alkali, \$ |
|----------------------------|--------------|-----------------------|-----|-------|----------------------------------|-----------------------------|------------------------------|------------------------------------|
| Moonstone powder           | Powder       | 1 Pkg (26 g)/16 oz    | 1   | 3.48  | 60.0                             | 64.1                        | 16.2                         | 1.23                               |
|                            |              |                       | 2   | 3.40  | 60.0                             | 63.8                        | 15.1                         | 1.33                               |
| LithoLyte powder           | Powder       | 1 Pkg (1.2 g)/16 oz   | 1   | 9.13  | 10.0 <sup>a</sup>                | 7.1                         | 7.1                          | 0.71                               |
|                            |              |                       | 2   | 9.44  | 10.0 <sup>a</sup>                | 6.4                         | 6.4                          | 0.78                               |
| LithoLyte coffee           | Coffee pod   | 1 Cup coffee (8 oz)   | 1   | 6.34  | 10.0                             | 8.4                         | 6.9                          | 1.46                               |
|                            |              |                       | 2   | 6.38  | 10.0                             | 6.7                         | 5.6                          | 1.80                               |
| Kidney COP                 | Capsule      | 2 Capsules            | 1   | 5.44  | 5.4 <sup>b</sup>                 | 5.4                         | 3.5                          | 0.71                               |
|                            |              |                       | 2   | 5.26  | 5.4 <sup>b</sup>                 | 5.6                         | 3.4                          | 0.73                               |
| KSPTabs                    | Effervescent | 1 Tablet/16 oz        | 1   | 4.89  | 4.5 <sup>b</sup>                 | 26.8                        | 14.5                         | 0.57                               |
|                            |              |                       | 2   | 4.74  | 4.5 <sup>b</sup>                 | 26.9                        | 13.7                         | 0.61                               |
| Litho Balance              | Powder       | 1 Scoop (4.6 g)/16 oz | 1   | 3.98  | 4.4 <sup>b</sup>                 | 28.0                        | 9.7                          | 0.57                               |
|                            |              |                       | 2   | 4.02  | 4.4 <sup>b</sup>                 | 39.0                        | 13.9                         | 0.40                               |
| NOW potassium Citrate      | Powder       | 1/4 Tsp (1.4 g)/8 oz  | 1   | 8.30  | 4.15 <sup>b</sup>                | 12.9                        | 12.8                         | 0.04                               |
|                            |              |                       | 2   | 8.42  | 4.15 <sup>b</sup>                | 12.2                        | 12.1                         | 0.04                               |
| Horbäach potassium citrate | Capsule      | 1 Capsule             | 1   | 7.30  | 2.75 <sup>b</sup>                | 2.5                         | 2.4                          | 0.16                               |
|                            |              |                       | 2   | 7.32  | 2.75 <sup>b</sup>                | 2.4                         | 2.3                          | 0.17                               |
| TheraLith XR               | Tablet       | 2 Tablets             | 1   | 10.78 | 2.12 <sup>b</sup>                | 7.2                         | 7.2                          | 0.52                               |
|                            |              |                       | 2   | 10.76 | 2.12 <sup>b</sup>                | 7.5                         | 7.5                          | 0.49                               |

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<sup>a</sup>Or bicarbonate as a citrate equivalent.

<sup>b</sup>Calculated based on ingredient list and nutrition facts.

## CITRATE ALKALI CONTENT OF COMMON OVER-THE-COUNTER AND MEDICAL FOOD SUPPLEMENTS

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alkali citrate per serving, which was very close to the total citrate calculation owing to the alkaline nature of the solution. This did fall short of the advertised citrate content of 10 mEq. However, LithoLyte advertises that their product contains “10 mEq of Total Citrate” but adds in fine print: “or bicarbonate as a citrate equivalent.” This makes our analysis consistent with their reporting. Horbäach potassium citrate was found to have the lowest amount of citrate alkali. This is due to the fact they limited their product to 99 mg of potassium (2.5 mEq) for reasons noted above. NOW potassium citrate had the lowest cost per alkali (\$0.04/10 mEq).

A major limitation of the Dai et al study was lack of a measured citraturic response. Canvasser et al performed a prospective crossover study measuring pH and citrate exertion in healthy adults given LithoLyte and KSPTabs.<sup>9</sup> Patients were randomized to which was taken first and were

given a 3-day washout between supplements. Dosage dispensed was 2 packets twice daily (daily total of 40 mEq of alkali) for LithoLyte and 1 tablet KSPTabs twice daily (daily total 30 mEq of alkali). Based on measured amount of citrate alkali from Dai et al, the estimated daily dose of alkali citrate would be 28 mEq for the LithoLyte group and 56 mEq for the KSPTabs group. However, there may be additional alkali in the form of bicarbonate.

What Canvasser et al discovered in this study was a statistically significant rise in urine pH for both LithoLyte (6.46-6.66,  $P = .028$ ) and KSPTabs (6.46-6.86,  $P = .037$ ). Urinary citrate increased for both groups but was only significant for the KSPTabs group (597-797 mg/day,  $P = 0.037$ ). The greater rise in urinary citrate is likely due to the greater daily dose of alkali citrate in the KSPTabs group. Interestingly, there was no change from baseline in the urinary potassium

or sodium levels for either product. It is important to note that this cohort was made up of healthy volunteers with normal baseline urinary citrate. The results for hypocitraturic stone formers may differ. Likewise, this study was not powered to demonstrate superiority of one supplement to another. Side effects were noted with both supplements and mild-to-moderate gastrointestinal side effects noted in about 50% of participants. No participants felt the need to stop the supplements early.

While not regulated by the FDA, some OTC alkali products do contain sufficient alkali to generate a clinically citraturic response. However, alkali content of various OTC supplements and food products varies and may differ from advertised values. Further studies are warranted to determine the clinical effectiveness compared to a standard of care pharmacotherapy for the prevention of recurrent stone disease. ■

1. Scales CD Jr, Smith AC, Hanley JM, Saigal CS. Prevalence of kidney stones in the United States. *Eur Urol.* 2012;62(1):160-165.
2. Dauw CA, Yi Y, Bierlein MJ, et al. Factors associated with preventive pharmacological therapy adherence among patients with kidney stones. *Urology.* 2016;93:45-49.
3. Stephens G. Taking the Mystery Out of Medical Foods. [https://www.nutraceuticalsworld.com/issues/2018-04/view\\_columns/taking-the-mystery-out-of-medical-foods/50213](https://www.nutraceuticalsworld.com/issues/2018-04/view_columns/taking-the-mystery-out-of-medical-foods/50213).
4. Food and Drug Administration. List of Drug Products That Have Been Withdrawn or Removed From the Market for Reasons of Safety or Effectiveness. *Federal Register* 1998.
5. National Institutes of Health. Potassium Fact Sheet for Health Professionals. National Institutes of Health, 2022. <https://ods.od.nih.gov/factsheets/Potassium-HealthProfessional/>.
6. Dai JC, Maalouf NM, Hill K, Antonelli JA, Pearle MS, Johnson BA. Alkali citrate content of common over-the-counter and medical food supplements. *J Endourol.* 2022;10.1089/end.2022.0274.
7. Doizi S, Poindexter JR, Pearle MS, et al. Impact of potassium citrate vs citric acid on urinary stone risk in calcium phosphate stone formers. *J Urol.* 2018;200(6):1278-1284.
8. Eisner BH, Asplin JR, Goldfarb DS, Ahmad A, Stoller ML. Citrate, malate and alkali content in commonly consumed diet sodas: implications for nephrolithiasis treatment. *J Urol.* 2010;183(6):2419-2423.
9. Canvasser NE, Rivera M, Bechis SK, et al. Over-the-counter alkali agents to raise urine pH and citrate excretion: a prospective crossover study in healthy adults. *Urology.* 2022;168:72-78.

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# How Pixel Segmentation Can Be the Future of Hypospadias Phenotyping

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Congenital anomalies are described as a variation from a functional and normal phenotype. Hypospadias is no exception. The evolution of hypospadiology has been centered around restoring the anatomy into a more natural and functional phenotype. As such, all efforts made have been on developing and improving technical surgical principles and concepts to master the reconstruction of individuals born with this birth defect. Despite multiple technical advances, there is no single procedure which results in a reproducible and predictable outcome. Prolific surgeons develop an unconscious artistic ability to interpret the phenotype and perform successful reconstructions. This subjectivity has been recognized as a major limitation in hypospadias phenotyping, and for decades surgeons have attempted to overcome this issue by incorporating anthropometric measurements into their assessment of the phenotype. In general, variables such as glans and urethral plate width, ventral curvature, and meatal location have been accepted as predictive variables. Nonetheless, these attempts at increasing objectivity have not resulted in consistently good prediction of surgical outcomes, with the current classifications still having a significant subjective component, particularly when the urethral plate is described. Maybe it is time to stop and redefine how we see the hypospadias phenotype and evaluate how the urethral plate can be described using novel technologies.

A major step in the evolution of surgical reconstruction has been the concept of preserving the urethral plate and incorporating it as part of the reconstruction. Widely accepted surgical techniques such as the meatal advancement glans-

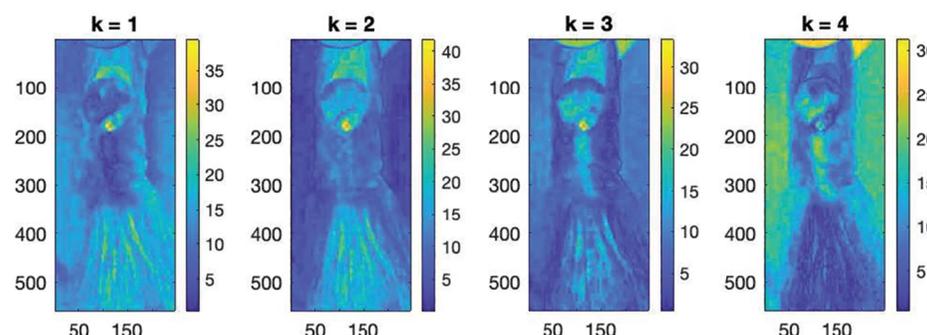


Figure. Heat map output for pixel cluster k-mean analysis.

plasty, Matheiu, tubularized incised plate, and Thiersch Duplay include the urethral plate as the main structure for reconstruction. As an artistic process, surgeons use their skills and knowledge subjectively to evaluate the urethral plate and make a decision about the most suitable technique for the patient. They also define the boundaries and how to use the plate for the reconstruction. Nonetheless, there is a lack of understanding of how an experienced surgeon makes that decision and how that translates to selected tissue quality and wound healing. Histological architecture of the urethral plate and surrounding tissues has been previously explored but it has never been correlated to a standardized phenotyping with subsequent postoperative follow-up.

Reports of urethral plates with abnormal or pathological histology have been described and identified by ongoing research in our group. Patients with abnormal

“Patients with abnormal pathological urethral plate architecture might not have adequate healing, which can impact wound healing independent of the surgical technique.”

pathological urethral plate architecture might not have adequate healing, which can impact wound healing independent of the surgical technique. A preliminary ongoing study using histology tissue mapping has demonstrated a 20% proportion of abnormal histology findings confined within the urethral plate. The most relevant finding has been chronic inflammatory lymphocyte infiltration in the sub-epithelial region. Recognizing the limitation of not being able to have a priori preoperative information before histology analysis is made, we have decided to explore the use of novel pixel analysis technologies to characterize the urethral plate, trying to reduce subjectivity and explore its predictive potential to identify abnormal histological findings.

Based on prior experience using computer vision methods to reduce subjective hypospadias phenotyping, we are currently using pixel cluster analysis to describe and predict the correlation to histological findings (see Figure).<sup>1,2</sup> The current pilot analysis has proven that pixel clustering can discriminate between different urethral plates when compared to the Glans, Meatus, Shaft score. Using principles demonstrated in dermatology and dermoscopy research for digital image analysis, we plan to extrapolate these concepts to our methodology.<sup>3,4</sup> Superpixel segmentation using linear iterative clustering can help identify pathological skin lesions subsequently confirmed on histological analysis. Other image features such as entropy or texture

“Superpixel segmentation using linear iterative clustering can help identify pathological skin lesions subsequently confirmed on histological analysis.”

analysis are approaches that may be informative and will help with urethral plate phenotype description and classification.<sup>4</sup>

Even the more traditional computer vision techniques described above represent a dramatic step forward for objective hypospadias phenotyping. Therefore, we are hopeful that newer, more flexible machine learning methods for computer vision, such as convolutional neural networks (CNNs), will make reliable hypospadias phenotyping easier. These methods haven't been used up to this point due to the requirement for very large samples of images (10K-100K); however, transfer learning has more recently been shown to produce high performing CNNs with far fewer samples needed. CNNs have also been criticized for their lack of interpretability; however, vision transformers have been proposed as a special case of CNNs which learn attention maps and focus on specific areas of the image. These attention maps are interpretable as they produce a heat map over the image, enabling a human to identify which part of the image is most important for the downstream prediction. Importantly, transformers are not data-type specific and indeed were first developed for speech. Therefore, transformer models can also be used to encode other data types such as clinical notes, sequencing data, and more.

Although we see a promising future for machine learning in the

## HOW PIXEL SEGMENTATION CAN BE THE FUTURE OF HYPOSPADIAS PHENOTYPING

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field of hypospadias, we cautiously recognize some limitations.<sup>2</sup> The prevalence of the condition makes it difficult to build a database that is large enough to create and test a neural network algorithm. The complexity and variability of the surgical reconstruction generates a challenging confounding factor that needs to be considered when analyzing data. To mitigate and

overcome this barrier, we plan to collect additional variables that can be informative for the algorithm and create a more comprehensive patient-centered phenotype, which will provide a more stable target or input to any models built. This will include epidemiological, anthropometric, histological, and genetic variables. This will only be possible if standardized clinical

and surgical approaches are implemented for hypospadias repair. Efforts at Seattle Children's Hospital have allowed our group to develop a standardized practice amongst providers. Current ongoing data collection and follow-up are underway. ■

1. Fernandez N, Lorenzo AJ, Rickard M, et al. Digital pattern recognition for the identification and classification of hypospadias using artificial

intelligence vs experienced pediatric urologist. *Urology*. 2021;147:264-269.

2. Khondker A, Kwong JCC, Malik S, et al. The state of artificial intelligence in pediatric urology. *Front Urol*. 2022; <https://www.frontiersin.org/articles/10.3389/fruro.2022.1024662/full>.

3. Winkler JK, Fink C, Toberer F, et al. Association between surgical skin markings in dermoscopic images and diagnostic performance of a deep learning convolutional neural network for melanoma recognition. *JAMA Dermatol*. 2019;155(10):1135-1141.

4. Annaby MH, Elwer AM, Rushdi MA, Rasmy MEM. Melanoma detection using spatial and spectral analysis on superpixel graphs. *J Digit Imaging*. 2021;34(1):162-181.

## Management of Bilateral Renal Masses

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Bilateral renal masses can be challenging for the urologist to manage: identifying the cause of the masses, determining best management strategies, and then educating the patient on the options and decision making process.

Bilateral renal masses can be either benign or malignant.<sup>1</sup> When faced with management of bilateral renal masses, there are multiple diagnoses a urologist must consider to guide appropriate management. Renal metastases are often bilateral small hypoattenuating renal masses most commonly from lung cancer followed by breast cancer, gastric cancer, and melanoma.<sup>1</sup> These masses are often asymptomatic and rarely present with hematuria, and should be suspected in a patient with a known malignancy. Treatment is driven by the primary malignancy.<sup>1</sup> Patients with lymphoma may develop extra-nodal spread to the genitourinary system manifesting as multiple poorly enhancing bilateral renal masses or nephromegaly. Given that primary renal lymphoma is rare, patients often have lymphomatous disease identified elsewhere. Patients with findings suspicious for lymphoma should undergo percutaneous biopsy and be referred to medical oncology for appropriate chemotherapy.<sup>1</sup>

Angiomyolipomas can present as bilateral renal masses, especially in patients with tuberous sclerosis.<sup>1</sup> Asymptomatic masses <4 cm

can be surveilled, while lesions  $\geq 4$  cm should be surgically resected or embolized due to risk of hemorrhage.<sup>2</sup> While oncocytomas, benign renal masses, are usually solitary unilateral masses, patients may develop bilateral oncocytomas, especially in those with Birt-Hogg-Dubé syndrome. Oncocytomas are indistinguishable from renal cell carcinoma (RCC) on imaging.<sup>1</sup>

While most sporadic RCCs are unilateral, bilateral synchronous sporadic RCC has been reported in up to 4% of cases.<sup>3</sup> Patients with bilateral synchronous tumors are also more likely to have multifocal tumors.<sup>4</sup> In a review of the Surveillance, Epidemiology, and End Results database of 274 patients with bilateral synchronous renal masses, 99% of patients were found to have bilateral RCC, with 1 patient having a unilateral oncocytoma. Histological and nuclear grade concordance between renal masses was reportedly high at 93% and 85%, respectively.<sup>5</sup> A single-institution study of bilateral synchronous tumors also reports a high concordance rate between tumors at 87%.<sup>6</sup> Thus, the pathology of one mass is strongly predictive of the other. More recent studies demonstrate similar survival outcomes to patients with unilateral disease, although there was an insignificant increase in local recurrence.<sup>7</sup>

Management considerations of bilateral renal masses concerning for RCC include when to biopsy; whether or not to perform nephron sparing surgery if feasible vs ablation or active surveillance; in the case of surgical removal, which



Figure. Axial and coronal view of CT imaging of bilateral renal masses (biopsy confirmed oncocytoma) in Birt-Hogg-Dubé syndrome.

mass to remove first—the more or less complex tumor; and whether or not to perform simultaneous vs staged excisions. Maximal renal preservation with nephron sparing surgery is of the utmost importance if feasible given the higher incidence of multifocal tumors with bilateral synchronous masses and the increase in all-cause mortality associated with decreased renal function.<sup>8</sup> Our approach to the surgical management of bilateral RCC stems from experience with patients with genetic renal tumor syndromes such as von Hippel-Lindau Disease, in which metastasis has not occurred in patients whose masses are observed until the largest reaches 3 cm in size.<sup>9</sup> Bratslavsky and Linehan discuss their approach at the National Cancer Institute in which they obtain a percutaneous biopsy for patients presenting with bilateral renal masses without a known genetic syndrome.<sup>9</sup> They use this biopsy to drive the need for further genetic workup, and the type and timing of surgical intervention. Patients with familial syndromes, clear cell RCC, papillary type 1 RCC,

chromophobe RCC, and oncocytic neoplasms are observed until the largest mass is 3 cm in size.<sup>9</sup> Tumors concerning for papillary type 2 RCC and hereditary leiomyomatosis and renal cell cancer-associated tumors are more aggressive and managed with early resection with wide margins.<sup>9</sup> Intraoperatively, they describe their retroperitoneal approach with minimal dissection of the hilum, clamping the artery and vein en bloc to preserve the perivascular adventitia, and performing enucleations off clamp as able.<sup>9</sup>

The impact of staged vs simultaneous partial nephrectomy (PN) has been evaluated in several single-institution studies. Packiam et al retrospectively reviewed 107 patients undergoing bilateral vs staged PNs from 1980-2015 and found the simultaneous PN group had improved pooled length of stay (median 6 vs 8 days,  $P < .001$ ), rate of urine leak (3% vs 17%,  $P = .018$ ), rate of Clavien grade 3-4 complications (8% vs 23%,  $P = .44$ ), and lower reduction in estimated

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## MANAGEMENT OF BILATERAL RENAL MASSES

→ Continued from page 12

glomerular filtration rate at 3 and 12 months postoperatively (−6% vs −24% decrease,  $P = .015$ , and −4% vs −22% decrease,  $P < .001$ ).<sup>10</sup> However, this observed difference may be due to significant selection and technical bias, though the only recorded significant differences between the 2 groups were BMI at first surgery (29 vs 32 kg/m<sup>2</sup> for simultaneous vs staged, respectively,  $P = .022$ ), and number of female patients in the cohort.<sup>10</sup> Contrary to this finding, Di Maida et al reviewed 41 patients with synchronous bilateral renal masses between 2008 and 2019 and found no difference in the reduction of estimated glomerular filtration rate at 3 months and last follow-up between simultaneous vs staged surgery (−7.3 vs −7.8,  $P = .31$ ), but did find that staged procedures had a significantly higher cumulative operative time and length of stay.<sup>11</sup>

Disease-free survival was also similar between the 2 approaches.<sup>11</sup> The literature demonstrates that 1- and 2-stage options are feasible and the surgeon should take into account tumor complexity and patient comorbidities to help decide the optimal management.

Whether to resect the more complex or less complex tumor first remains debatable. Surgeons who favor resection of the more complex tumor first argue it is important to optimize oncologic control in case the contralateral resection needs to be delayed due to complications.<sup>10</sup> Those who resect the less complex tumor first prefer to ensure one side can be removed off-clamp prior to resecting the more complex tumor on-clamp if necessary to minimize the risk of acute kidney injury.<sup>11</sup> The latter group does not perform a 1-stage approach if bilateral renal artery clamping is necessary for resection.<sup>11</sup>

Bilateral renal masses most always require a very active discussion with the patient about risks, benefits, treatment options, implications, complications, and concordance. Appropriate diagnosis, hereditary syndromes, maximal renal preservation, the complexity of the tumor, and patient comorbidities are all important aspects to consider. Just like many aspects of oncological urology, there is no one answer for all renal masses as they must be considered on a case-by-case basis. ■

- Roy A, Le O, Silverman PM, Kundra V. Common and uncommon bilateral adult renal masses. *Cancer Imaging*. 2012;12(1):205-211.
- Flum AS, Hamoui N, Said MA, et al. Update on the diagnosis and management of renal angiomyolipoma. *J Urol*. 2016;195(4 Pt 1):834-846.
- Krambeck A, Iwaszko M, Leibovich B, Chevillat J, Frank I, Blute M. Long-term outcome of multiple ipsilateral renal tumours found at the time of planned nephron-sparing surgery. *BJU Int*. 2008;101(11):1375-1379.
- Richstone L, Scherr DS, Reuter VR, et al.

Multifocal renal cortical tumors: frequency, associated clinicopathological features and impact on survival. *J Urol*. 2004;171(2 Pt 1):615-620.

- Rothman J, Crispin PL, Wong YN, Al-Saleem T, Fox E, Uzzo RG. Pathologic concordance of sporadic synchronous bilateral renal masses. *Urology*. 2008;72(1):138-142.
- Arnoux V, Fiard G, Descotes JL, Rambeaud JI, Long JA. Bilateral renal masses: pathologic concordance and impact of temporal presentation. *Minerva Urol Nefrol*. 2012;64(4):287-293.
- Dimarco DS, Lohse CM, Zincke H, Chevillat JC, Blute ML. Long-term survival of patients with unilateral sporadic multifocal renal cell carcinoma according to histologic subtype compared with patients with solitary tumors after radical nephrectomy. *Urology*. 2004;64(3):462-467.
- Go AS, Chertow GM, Fan D, McCulloch CE, Hsu CY. Chronic kidney disease and the risks of death, cardiovascular events, and hospitalization. *N Engl J Med*. 2004;351(13):1296-1305.
- Bratslavsky G, Linehan WM. Long-term management of bilateral, multifocal, recurrent renal carcinoma. *Nat Rev Urol*. 2010;7(5):267-275.
- Packiam VT, Tsivian M, Lohse CM, et al. Simultaneous versus staged partial nephrectomies for bilateral synchronous solid renal masses. *Urol Oncol*. 2020;38(7):640.e13-640.e22.
- Di Maida F, Grosso AA, Sforza S, et al. Surgical management of synchronous, bilateral renal masses: a 1-decade referral center experience. *Eur Urol Focus*. 2022;S2405-4569(22)00033-5.

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# Current Practice Patterns in Female Urology

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The subspecialty of female pelvic medicine and reconstructive surgery (FPMRS) obtained recognition by the American Board of Medical Specialties with an official accreditation in 2011.<sup>1</sup> Subsequently, the American Board of Urology (ABU) subspecialty board certification for FPMRS began in 2013.<sup>2</sup> The subspecialty field incorporates issues such as male and female urinary incontinence, neurogenic lower urinary tract dysfunction, pelvic organ prolapse (POP), recurrent urinary tract infection, painful bladder syndrome, genitourinary fistula, and voiding dysfunction.

Case log data submitted to the ABU are a rich source of data that previously have been used to assess the surgical practice patterns of general and subspecialist urologists.<sup>3,4</sup> As the initial year of subspecialty certification by the ABU, 2013 was the first year that FPMRS practice logs could be submitted, and as such, criteria for FPMRS designation that year were not based on any specific level of prior FPMRS training, but rather having an FPMRS-focused practice with case logs that met a minimum level of FPMRS-related care, as determined by the ABU. These same urologists who took the initial FPMRS certifying examination in 2013 were eligible for FPMRS recertification in 2020. These 2 time points provided unique insight. Case logs from 2013 provided information on those individuals “grandfathered” into the subspecialty;<sup>5</sup> 2020 provided information both on urologists undergoing recertification as well as those who were ready for initial certification after completion of their ACGME-approved FPMRS fellowship.

We identified a total of 229 unique self-designated FPMRS providers in the case log data from 2013 and 2020—131 FPMRS urologists in 2013

“Case log data submitted to the ABU are a rich source of data that previously have been used to assess the surgical practice patterns of general and subspecialist urologists.<sup>3,4</sup>”

and 98 FPMRS urologists in 2020. Of those 229 individual surgeons, 57.2% submitted case logs in 2013, for a total of 41,456 cases between the 2013 and 2020 log years. We stratified cases based on procedure type and whether they were traditionally FPMRS-specific procedures, which included anti-incontinence procedures, abdominal and vaginal approaches for prolapse repair, vesicovaginal fistula repair, and mesh excision/removal. In 2013, of a total of 19,309 cases, 6,882 were FPMRS cases and 12,427 were non-FPMRS cases. There were 22,237 cases in 2020, of which 7,790 were FPMRS-specific and 14,447 were non-FPMRS cases. Overall, non-FPMRS-specific cases were less likely among surgeons who performed a high volume of FPMRS-specific procedures ( $P < .01$ ).

Anti-incontinence procedures consistently constituted 46% of the subspecialty-specific cases in certification logs from both 2013 and 2020. The overwhelming majority (>90%) of procedures performed for management of stress urinary incontinence were sling procedures with either synthetic mesh or autologous fascia. There was a slight increase in sling placement as a proportion of anti-incontinence procedures from 2013 to 2020 (95.6% vs 98.2%), similarly observed as a proportion of overall cases (44% vs 45%). However, based on the case rate adjusted for the number of surgeons per certification year, the number of sling cases per surgeon decreased between the 2 case log years (31.3 in 2013 vs 26.8 in 2020). The re-

mainder of anti-incontinence procedures included transvaginal urethropexy, abdominal/laparoscopic urethropexy, and laparoscopic sling placement.

Mid-urethral sling placement has previously been shown to be the most commonly performed anti-incontinence procedure amongst certifying urologists, regardless of specialty type.<sup>6</sup> The relative increase in the share of sling procedures as a proportion of anti-incontinence procedures without an overall change in total anti-incontinence procedures during the 2 case certification years suggests that factors specific to sling placement may be influencing the sling placement rates, such as a balance between concerns about mesh use and data supporting the higher efficacy of sling placement as compared to other anti-incontinence procedures. Additionally, there may be changes in the proportion of autologous fascia vs synthetic mesh use which is not captured by case logs.

Surgical management of POP similarly changed between the 2013 and 2020 case logs, perhaps another indication of attitudes toward mesh use. Prolapse repair procedures were one of the most common procedure types performed by FPMRS-certifying urologists comprising 45% of submitted cases in 2013 and 2020. The total number of transvaginal mesh/prosthetic graft placement cases in 2013 (741 cases) vs 2020 (338 cases) represents 11% and 4% of total cases performed by FPMRS urologists in 2013 and 2020, respectively. The share of transvaginal mesh/prosthetic graft placement cases for POP as a proportion of transvaginal prolapse repair decreased by half, from 30% to 15%, from 2013 to 2020. Over this same time period, there was an increase in the use of abdominal mesh for prolapse repair, as abdominal mesh increased as both a proportion of total FPMRS cases (from 9% to 15%) and overall prolapse repair procedures (from 24% to 30%). These trends were similar for non-FPMRS providers, likely related to the uptake of robot-assisted laparoscopic sacrocolpopexy among all urologists. Interestingly, the rates of mesh

excision did not change between 2013 and 2020, staying at 8% of all procedures.

The identified CPT (Current Procedural Terminology) codes for transvaginal mesh/prosthesis placement bundle transvaginal mesh and prosthetic graft (xenografts, biologic graft) use, limiting the ability to distinguish between the 2 case types. However, as the 2013 case logs included cases from as early as 2011, it is reasonable to assume that transvaginal mesh kits were used in a significant proportion of these cases, and the subsequent decrease in these cases was at least partially in response to consecutive U.S. Food and Drug Administration (FDA) statements about transvaginal mesh use. In 2019, the FDA banned the distribution of transvaginal mesh kits for POP repair, a follow-up to earlier FDA communications questioning the use of transvaginal mesh for the surgical management of POP, reducing the likelihood that transvaginal mesh was used in these repairs, especially in the case logs submitted for certification in 2020.

As the practice of urology continues to become more subspecialized, it is important to appreciate the impact of subspecialty certification on practice patterns for cases that are considered specific to a certain subspecialty. While highlighting the diversity of FPMRS practice, the data also demonstrate the impact of external factors—FDA communications on transvaginal mesh and training experience—on practice patterns among subspecialists. ■

1. Weissbart SJ, Wein AJ, Smith AL. Female pelvic medicine and reconstructive surgery—what does certification mean?. *Curr Urol Rep*. 2018;19(5):30.
2. American Board of Medical Specialties. *Board Certification and Maintenance of Certification*. 2017. <http://www.abms.org/board-certification>.
3. Jayram G, Matlaga BR. Contemporary practice patterns associated with percutaneous nephrolithotomy among certifying urologists. *J Endourol*. 2014;28(11):1304-1307.
4. Lowrance WT, Eastham JA, Savage C, et al. Contemporary open and robotic radical prostatectomy practice patterns among urologists in the United States. *J Urol*. 2012;187(6):2087-2093.
5. American Board of Urology. *FP-MRS Subspecialty*. 2022. <https://www.abu.org/certification/subspecialties/fpm-rs-subspecialty>.
6. Chughtai BI, Elterman DS, Vertosick E, Maschino A, Eastham JA, Sandhu JS. Midurethral sling is the dominant procedure for female stress urinary incontinence: analysis of case logs from certifying American urologists. *Urology*. 2013;82(6):1267-1271.

# Is 50% Improvement Enough? Revisiting the Definition of Success for Overactive Bladder Therapies

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Overactive bladder (OAB) symptoms of urinary urgency/frequency/incontinence have many influences including age-related degeneration, neural/cerebral pathology, hormonal changes, infection, and anatomical alterations (eg, urethral obstruction). OAB's multifactorial nature precludes a single treatment cure; in fact, one could argue there is no cure. While treatments exist, unfortunately, they are not always successful. In general, the achievable management goal is symptom improvement. What degree of improvement justifies continued treatment? How durable is the success? These crucial issues need to be considered when counseling patients about various OAB treatment options.

Initial management of OAB is conservative and involves education, behavior modification, and pelvic floor rehabilitation. Compliance and, therefore, success with first-line treatments is limited. As a result, many individuals move on to second-line therapy (anticholinergic and beta-adrenergic medications). While many achieve some degree of symptomatic improvement with these measures, cost, side effects, and inadequate efficacy lead to poor patient satisfaction.<sup>1</sup> Third-line OAB treatment options include neuromodulation (sacral neuromodulation [SNM], posterior tibial nerve stimulation [PTNS]) and botulinum toxin (BTX) injections. Historically, a >50% symptomatic improvement has been required to justify continuation of third-line therapies. To our knowledge, the rationale of choosing a 50% threshold is unknown. It seems somewhat arbitrary and is indicative of our failure to truly "cure" the problem.<sup>2</sup>

Over time, reductions in third-line OAB treatment efficacy may lead to patient dissatisfaction, progression to alternate forms of therapy, and additional costs. Ideally one would

be able to identify patients at risk for long-term failure in order to avoid unnecessary costs and frustration. Five-year loss of efficacy was reported in about one-third of patients managed with SNM.<sup>3</sup> Long-term loss of efficacy has also been reported for both PTNS and BTX injections.<sup>4-7</sup>

Intuitively, one would think a patient with an initially higher degree of symptomatic improvement with third-line OAB therapy might fare better in the long term compared to one with a lesser degree of improvement. While this has not been formally studied in a prospective trial, there are suggestions it is true. Foster et al observed that the degree of pad weight reduction and pad usage during SNM was predictive of a patient's willingness to "do it all over again" ( $P = .005$ ) and long-term satisfaction ( $P = .005$ ) with satisfied patients experiencing an 85% reduction in pad weights, whereas dissatisfied patients only experienced a 61% reduction.<sup>8</sup> In a recent study, we reported significantly more patients continued to benefit from SNM over time (mean followup of 46 months) if they experienced a >75% overall improvement compared to those only experiencing a 50%-75% improvement during the initial test phase (68% vs 44%); a >75% improvement in symptoms during testing was a predictor of long-term success.<sup>9</sup>

This begs the question: is a 50%

**“Based on our results, if the improvement threshold to justify SNM implant were increased to >75%, then 44% of our implanted patients who were still benefiting from the stimulation would not have been eligible for the implant.”**

**“Given that options beyond third-line OAB therapies may involve major surgery with significant associated risks both in the short and long term (eg, bladder augmentation, urinary diversion), the use of a 50% improvement threshold to determine eligibility for ongoing treatment for the time being is probably reasonable.”**

improvement in OAB symptoms good enough? If a greater threshold is used to determine treatment efficacy justifying continued treatment, then fewer patients will qualify and receive this treatment. Based on our results, if the improvement threshold to justify SNM implant were increased to >75%, then 44% of our implanted patients who were still benefiting from the stimulation would not have been eligible for the implant. Considering that patients undergoing third-line OAB therapies have failed the more conservative therapies, one could argue that any improvement is better than nothing at all. But one needs to be circumspect given that there can be significant cost associated with the treatment, and the treatment could require frequent visits that might be a burden to the patient (eg, PTNS) and even carry some small risks (eg, device infection with SNM, urinary retention, and UTI with BTX injections). While no study has conclusively shown one third-line OAB option

to be superior to the another, there may be cost differences between them. In fact, a recent treatment cost analysis using the data from the ROSETTA trial comparing SNM to BTX injections (granted 200 units of BTX was used rather than the standard 100 units) showed that SNM, despite similar efficacy with respect to urge incontinence improvement, had significantly higher costs at 2 and 5 years.<sup>10</sup> Given that options beyond third-line OAB therapies may involve major surgery with significant associated risks both in the short and long term (eg, bladder augmentation, urinary diversion), the use of a 50% improvement threshold to determine eligibility for ongoing treatment for the time being is probably reasonable. However, we need to be honest with patients and set realistic expectations regarding their prognosis with these treatments. ■

1. Yeowell G, Smith P, Nazir J, Hakimi Z, Siddiqui E, Fatoye F. Real-world persistence and adherence to oral antimuscarinics and mirabegron in patients with overactive bladder (OAB): a systematic literature review. *BMJ Open*. 2018;8(11):e021889.
2. Goldman HB, Lloyd JC, Noblett KL, et al. International Continence Society best practice statement for use of sacral neuromodulation. *NeuroUrol Urodyn*. 2018;37(5):1823-1848.
3. Siegel S, Noblett K, Mangel J, et al. Five-year follow-up results of a prospective, multicenter study of patients with overactive bladder treated with sacral neuromodulation. *J Urol*. 2018;199(1):229-236.
4. Du C, Berg W, Siegal AR, et al. Real-world compliance with percutaneous tibial nerve stimulation maintenance therapy in an American population. *Urology*. 2021;153:119-123.
5. Dorsthorst MJ, Heesakkers JFPA, van Balken MR. Long-term real-life adherence of percutaneous tibial nerve stimulation in over 400 patients. *NeuroUrol Urodyn*. 2020;39(2):702-706.
6. Marcelissen TA, Rahnama'i MS, Snijkers A, Schurch B, De Vries P. Long-term follow-up of intravesical botulinum toxin-A injections in women with idiopathic overactive bladder symptoms. *World J Urol*. 2017;35(2):307-311.
7. Baron M, Aublé A, Paret F, Pfister C, Cornu JN. Long-term follow-up reveals a low persistence rate of abobotulinumtoxinA injections for idiopathic overactive bladder. *Prog Urol*. 2020;30(12):684-691.
8. Foster RTS, Anoaia EJ, Webster GD, et al. In patients undergoing neuromodulation for intractable urge incontinence a reduction in 24-hr pad weight after the initial test stimulation best predicts long-term patient satisfaction. *NeuroUrol Urodyn*. 2007;26(2):213-217.
9. Charles DK, Everett RG, Prebay ZJ, Landowski TP, O'Connor RC, Guralnick ML. Is a 50% improvement threshold adequate to justify progression from sacral neuromodulation testing to implant? *NeuroUrol Urodyn*. 2021;40(6):1524-1531.
10. Harvie HS, Amundsen CL, Neuwahl SJ, et al. Cost-effectiveness of sacral neuromodulation versus onabotulinumtoxinA for refractory urgency urinary incontinence: results of the ROSETTA randomized trial. *J Urol*. 2020;203(5):969-977.

# Randomized Trials in Male Urethral Stricture Management and What They Tell Us About Outcomes and Surgical Approach

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## Introduction

Management of male urethral stricture disease involves a wide range of treatment options. Current knowledge is well summarized in the AUA and European Association of Urology guidelines. Unfortunately, many of the recommendations are weak and based on low level of evidence or expert opinion. In the area of open surgery for bulbar strictures, there are several controversies and there is a need for good clinical studies, preferably multicenter randomized controlled trials (RCTs). The good news is that there are some well-designed studies to guide us. A PubMed search for the Medical Subject Headings (MeSH) term “anterior urethral strictures” with the filters “randomized controlled trial” and publication date within the last 10 years yields 49 results. We present the most relevant studies concerning male urethral strictures and urethroplasty techniques.

### Does type of graft or flap matter?

Augmentation urethroplasty can be done with skin flaps, skin grafts, and mucosal grafts.

In 1 study, 37 long segment bulbo-penile strictures were operated on with either ventral onlay penile skin graft or a penile skin flap. In this high recurrence risk population, the recurrence rate was 28% after penile skin graft and 21% after penile skin flap (not significant) after a mean follow-up of 3 years.<sup>1</sup>

The “Pee”BuSt trial compared penile skin graft to buccal mucosa graft (BMG) in 100 patients with 18 months of follow-up.<sup>2</sup> It showed

no difference between the 2 groups in surgical outcome or sexual dysfunction.

A study with 30 patients compared lingual mucosa graft vs BMG. The short-term surgical outcomes were similar after a mean follow-up of 14.5 months, but more long-term speech morbidity was seen after long lingual grafts (>7 cm).<sup>3</sup> Hence, lingual grafts are a second choice only for cases where BMG is unavailable.

### Does graft placement matter?

For augmentation techniques with BMG, placement of the graft ventrally or dorsally, and as inlay or onlay, is still debated.

BMG placements were compared in a study of 47 patients with long strictures (26 penile, 17 bulbar, 4 panurethral) where the graft was placed with dorsal onlay or inlay fashion. The authors found no difference in success rates concerning surgical failure (redo operations) between the groups after mean follow-up of 22 and 24 months, respectively. However, the authors regarded the dorsal inlay technique as easier, with shorter operation time and less blood loss.<sup>4</sup> An Egyptian study with 37 patients and follow-up of 6 months showed similar results.<sup>5</sup>

A study of 80 patients with bulbar stricture length more than 2 cm compared dorsal and ventral placement of BMG. The success rate, complication rate, and recurrence rate were similar in both groups after 12-month follow-up.<sup>6</sup>

### Close or not close buccal mucosal graft bed?

As buccal mucosal grafting is common in several urethroplasty techniques, it is also relevant to consider the harvesting method. Another source of debate is whether closing the wound after BMG harvesting is necessary. One study with 34 participants showed less

short-term pain after wound closure, but there was no long-term difference (from 3 weeks to 1 year of follow-up).<sup>7</sup>

Another study with 135 patients showed noninferiority for nonclosure vs closure in intensity for oral pain at any time after urethroplasty (6-month follow-up). However, the length of the graft had a significant effect on oral pain.<sup>8</sup>

### Effect of tissue-sparing techniques

In the last decade, there has been more focus on tissue-sparing techniques in many surgical fields, including urethroplasty. A study exploring the effect of sparing the bulbospongiosus muscle showed improved Male Sexual Health Questionnaire Ejaculatory Dysfunction Short-Form scores and less post-void dribbling.<sup>9</sup>

Another study compared dorsal onlay with circumferential dissection of corpus spongiosum to dorsolateral onlay with dissection on only 1 side. The study included 136 patients and had a mean follow-up of 28 months. It found less erectile dysfunction measured by Brief Male Sexual Function Inventory after dorsolateral onlay.<sup>10</sup>

Our own study, the Scandinavian Urethroplasty Study, compared transecting excision and primary anastomosis to BMG procedure in short bulbar strictures with regard to sexual dysfunction, and found more penile complications after the transecting procedure.<sup>11</sup>

### Studies in the pipeline

Lastly, 2 ongoing RCTs still recruiting patients are worth mentioning. VeSpAR compares vessel-sparing anastomotic repair vs transecting anastomotic repair.<sup>12</sup> Another interesting trial is the DoVe trial, which compares dorsal to ventral onlay buccal mucosa in bulbar strictures.<sup>13</sup> We hope the results of these studies can further guide us to improve urethroplasty techniques.

“A study exploring the effect of sparing the bulbospongiosus muscle showed improved Male Sexual Health Questionnaire Ejaculatory Dysfunction Short-Form scores and less post-void dribbling.”

## Discussion

Many RCTs in the field of urethral stricture management have not been able to show significant differences in success rates or complication rates. This may be due to inadequately powered studies with small study populations or limited follow-up. The levels of complications and reinterventions are relatively low for current urethral stricture treatment methods, hence larger RCTs with adequate follow-up time are still needed. Initiating and conducting clinical RCTs may seem like an impossible task. It is time-consuming and involves a lot of work, while pressure to publish favors retrospective studies or prospective studies with shorter follow-up. Inclusion can be difficult to achieve within an acceptable time frame, rendering results obsolete. Data from randomized studies should be reported in a standardized fashion to facilitate pooling of data. Unfortunately, patient-reported outcome measures encompassing all aspects of outcomes after urethral surgery are not available.

## Conclusion

Several studies of good quality

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## RANDOMIZED TRIALS IN MALE URETHRAL STRICTURE MANAGEMENT

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answer some questions regarding management of urethral strictures. However, large clinical RCTs within the field are still needed to develop the art of urethroplasty. Thus, cooperation between institutions may be necessary to facilitate high-quality research within the field.

1. Hussein MM, Moursy E, Gamal W, Zaki M, Rashed A, Abozaid A. The use of penile skin graft versus penile skin flap in the repair of long bulbo-penile urethral stricture: a prospective randomized study. *Urology*. 2011;77(5):1232-1237.
2. Tyagi S, Parmar KM, Singh SK, et al. 'Pee'BuSt

trial: a single-centre prospective randomized study comparing functional and anatomic outcomes after augmentation urethroplasty with penile skin graft versus buccal mucosa graft for anterior urethral stricture disease. *World J Urol*. 2022;40(2):475-481.

3. Sharma AK, Chandrashekar R, Keshavamurthy R, et al. Lingual versus buccal mucosa graft urethroplasty for anterior urethral stricture: a prospective comparative analysis. *Int J Urol*. 2013;20(12):1199-1203.
4. Aldaqdossi H, El Gamal S, El-Nadey M, El Gamal O, Radwan M, Gaber M. Dorsal onlay (Barbagli technique) versus dorsal inlay (Asopa technique) buccal mucosal graft urethroplasty for anterior urethral stricture: a prospective randomized study. *Int J Urol*. 2014;21(2):185-188.
5. Soliman MG, Abo Farha M, El Abd AS, Abdel Hameed H, El Gamal S. Dorsal onlay urethroplasty using buccal mucosa graft versus penile skin flap for management of long anterior urethral strictures: a prospective randomized study. *Scand J Urol*. 2014;48(5):466-473.
6. Vasudeva P, Nanda B, Kumar A, Kumar N, Singh H, Kumar R. Dorsal versus ventral onlay buccal mucosal graft urethroplasty for long-segment bulbar urethral stricture: a prospective randomized study. *Int J Urol*. 2015;22(10):967-971.
7. Wong E, Fernando A, Alhasso A, Stewart L. Does closure of the buccal mucosal graft bed matter? Results from a randomized controlled trial. *Urology*. 2014;84(5):1223-1227.
8. Soave A, Dahlem R, Pinnschmidt HO, et al. Substitution urethroplasty with closure versus non-closure of the buccal mucosa graft harvest site: a randomized controlled trial with a detailed analysis of oral pain and morbidity. *Eur Urol*. 2018;73(6):910-922.
9. Elkady E, Dawod T, Teleb M, Shabana W. Bulbospongiosus muscle sparing urethroplasty versus standard urethroplasty: a comparative study. *Urology*. 2019;126:217-221.
10. Prakash G, Singh BP, Sinha RJ, Jhanwar A,

Sankhwar S. Is circumferential urethral mobilisation an overdo? A prospective outcome analysis of dorsal onlay and dorso-lateral onlay BMGU for anterior urethral strictures. *Int Braz J Urol*. 2018;44(2):323-329.

11. Nilsen OJ, Holm HV, Ekerhult TO, et al. To transect or not transect: results from the Scandinavian Urethroplasty Study, a multicentre randomised study of bulbar urethroplasty comparing excision and primary anastomosis versus buccal mucosal grafting. *Eur Urol*. 2022;81(4):375-382.
12. Verla W, Waterloos M, Waterschoot M, Van Parys B, Spinoit AF, Lumen N. VeSpAR trial: a randomized controlled trial comparing vessel-sparing anastomotic repair and transecting anastomotic repair in isolated short bulbar urethral strictures. *Trials*. 2020;21(1):782.
13. Lumen N. *DoVe Trial: Dorsal Onlay Versus Ventral Onlay in Isolated Bulbar Urethral Strictures (DoVe)*. 2020. Updated January 24, 2022. <https://clinicaltrials.gov/ct2/show/NCT04551417>.

## MEDICAL ETHICS

## Ethics of Letters of Recommendations

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Letters of recommendation (LORs) are a currency in academic medicine, collected and traded in exchange for positions in residency and fellowship. The goal of an LOR is to provide information about the candidate to interested programs, ideally adding data points which cannot be gleaned from other components of the application. Unfortunately, writing LORs is fraught with ethical pitfalls.

When writing LORs, consider the 3 ethical principles of capacity, veracity, and objectivity.<sup>1</sup> Capacity is the most straightforward; do you know this person well enough to write a letter? It requires firsthand knowledge of the skills on which you are commenting. Verbal reports from other faculty, unless attributed to them, should not be included.

Veracity is thornier. Urology, and particularly subspecialties within urology, are very small fields. Word of mouth, or word written in an LOR, carries a lot of weight in residency and fellow-

ship applications, especially if the writer is known to the reader. This makes sticking to the truth, and the whole truth, even more important. Embellishing strengths in an effort to hide inadequacies in the recommended is not fair to the reader, while underplaying positives due to personal clashes unfairly undercuts the recommended's chances at matching. Expecting programs to "read between the lines" by omitting discussions about certain skills or leaving out key phrases you typically use to distinguish excellent candidates can be misleading. It often feels as though reading LORs is an exercise in translating double-speak; why can't we just write what we mean to say?

If you truly feel you cannot write a fair letter, the best answer is to decline to write. This can send a very negative message to the applicant's program if a letter from, say, the chair or program director is absent. In some cases, this may not be the message you want to send; if wavering, stick to the truth.

In many cases you are being asked to write an LOR precisely because the recommended believes you will say nice things; from the outset objectivity is questionable. Knowing this, it is important to focus on the facts when assessing a candidate. And if objectivity has not been undermined enough, recent

scholarship has shown LORs introduce unconscious bias, especially along gender lines.<sup>2</sup> While unconscious bias cannot be completely eradicated, the first step in mitigating its effect is to be aware that it exists. Online tools exist to query an LOR draft to reduce gender bias.<sup>3</sup>

In an effort to combat many of the snares listed above, some institutions and specialties are moving toward standardized letters. The goal of these is to decrease the narrative, subjective component of the LOR and focus on attributes considered important to the practice of the specialty. Many urology departments have templated letters, listing relevant skills and assigning a superlative (typically from good to outstanding) to the candidate. This allows a more objective comparison of candidates assessed within the same department, and certainly by the same writer.

Emergency medicine has gone one step farther; in 1997 the specialty created the standardized letter of evaluation (SLOE), a templated assessment used across institutions. It has been shown to be easier to write and review, have a higher interrater reliability, provide a greater depth of evaluating the applicant, and be predictive of resident performance on core competencies.<sup>4</sup> Letters can be coauthored by multiple faculty, thus increasing

“Targeted questions probe both strengths and weaknesses, allowing a more balanced and truthful picture to develop.”

the exposure of the writers to the recommended and increasing capacity. Targeted questions probe both strengths and weaknesses, allowing a more balanced and truthful picture to develop. Finally, the decreased reliance on narrative facilitates a more objective impression. Perhaps it is time for urology to abandon the static associated with narrative LORs and create a standardized evaluation, thus creating a much more valuable currency for assessment. ■

1. Larkin GL, Marco CA. Ethics seminars: beyond authorship requirements—ethical considerations in writing letters of recommendation. *Acad Emerg Med*. 2001;8:70.
2. Go C, Sachdev U. Letters of recommendation: nuanced bias or useful affirmation? *J Vasc Surg*. 2021;74(S2):29S.
3. Forth T. *Gender Bias Calculator*. Accessed September 14, 2022. <https://www.tomforth.co.uk/genderbias/>.
4. Love JN, Ronan-Bentle SE, Lane DR, et al. The standardized letter of evaluation for postgraduate training: a concept whose time has come? *Acad Med*. 2016;91(11):1480.

## MEDICAL STUDENT COLUMN

# The Paradox of Men's Health, and What Urology Can Do to Tackle It

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The literature has long demonstrated that men die earlier and at higher rates from the vast majority of the leading causes of death.<sup>1,2</sup> Specifically in the United States, life expectancy in 2020 was 74.2 years for males vs 79.9 years for females—a gap which only widened during the COVID-19 pandemic.<sup>3,4</sup> Moreover, men face higher rates of several chronic conditions including cardiovascular, metabolic, and psychiatric diseases.<sup>5</sup> These patterns are present throughout the world, exacting significant emotional and financial costs on patients, families, and broader society.

This disparity is not well addressed. It's understood that communities holding unfair social advantages—whether based on race, gender, sexual orientation, or economics—experience better health outcomes. Interestingly, however, men typically suffer from poorer health regardless of the advantages afforded to them. Men who belong to a racial minority or the LGBTQ+ community face even greater disparities. Yet because of the paradoxical nature of this trend, awareness surrounding men's health is lacking.

Medicine has slowly begun appreciating the social determinants of health and systemic factors that modulate outcomes. Recent events including the COVID-19 pandemic demonstrated the massive disconnect between medical experts and the lay public. Flaws in science communication exacerbated the pandemic by reducing trust and adherence to recommendations.<sup>6</sup> The paradox of men's health demonstrates many parallels to this trend, and we must work on better communicating and connecting with our male patients to improve outcomes.

Although studies have demonstrated that innate factors such as hormonal and genetic differences

affect longevity, differences also often arise from the gender roles assigned by society. Poorer men's health is often attributed to the phenomenon of toxic masculinity, where men feel pressure to appear self-sufficient and strong. Studies repeatedly demonstrate that men less frequently seek out preventive care, undergo recommended screenings, and adhere to medical advice. Additionally, men demonstrate higher rates of risky activities, violence, illicit drug use, alcohol overuse, and poor nutrition. Most recently with COVID-19, men experienced higher disease burdens given reduced adherence to recommendations including masking and social distancing.<sup>4</sup> These are all preventable factors which harm men's well-being.

Ultimately, men are less likely to perceive risk of harm or seek out care. How can these deep-rooted beliefs be targeted?

I believe that urology holds the answer. Urologists can embrace the opportunity to become thought leaders and trusted advocates for men's health. Granted, urology certainly isn't limited to men, and the field provides important care for all patients. Nonetheless, urology is the closest thing to a specialty devoted to prototypical male issues. Moreover, urologists have a unique relationship with their patients, considering that they often address highly sensitive medical concerns. As a result, urologists have the opportunity to actively engage men on an array of physical and mental health topics—regardless of whether these topics fall within the traditional domains of the genitourinary system.<sup>7</sup> Much like the women's clinic model, which has become profoundly popular and demonstrably beneficial, urologists can lead interdisciplinary work to improve men's health outcomes.<sup>8</sup>

Accordingly, science communication is decidedly relevant to men's health. As trusted providers, urologists must increase their presence in the community via

**“Studies repeatedly demonstrate that men less frequently seek out preventive care, undergo recommended screenings, and adhere to medical advice.”**

engagement with media experts, promotion of government policy rooted in scientific knowledge, and design of social infrastructure to support health-promoting behaviors. They can lead public awareness campaigns, develop educational resources, and directly communicate with patients to normalize healthy decision-making. Ultimately, this visibility can help fight toxic masculinity and risky behaviors.

One well-known example of direct patient engagement is the barbershop initiative, where trusted community members such as barbers perform outreach in concert with providers. One study demonstrated the benefits of this initiative in improving hypertension metrics.<sup>9</sup> This model demonstrates that collaborating with patients in a personable manner can be highly effective. Similar work can be replicated with urology-specific concerns such as prostate cancer screenings or testicular cancer self-examinations. However, urologists can also utilize their unique position to positively affect seemingly unrelated conditions that disproportionately affect men, such as cardiovascular disease or unhealthy lifestyle choices. Given the evolving holistic and multifactorial view of disease, these initiatives will certainly return benefits to urology itself. For instance, erectile dysfunction has deep associations with cardiovascular or mental health.

Social media also offers great promise. As patients increasingly seek medical advice online, urologists must expand their online presence using evidence-based strategies to effectively share information. Countless studies have demonstrated high rates of internet misinformation, demonstrating that work is necessary to expand physicians' online presence in a manner that counteracts anti-science materials while also providing actionable, effective advice to patient audiences.<sup>10-13</sup> We also need to support rigorous research into effective social media and science communication strategies.<sup>14</sup> Offering a trusted voice online can further raise awareness to counter common male misconceptions.

Science communication is difficult yet important. It takes skill to effectively develop trust, demonstrate the value of specific advice, and contextualize nuanced topics for a lay audience.<sup>6</sup> Accordingly, we

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## THE PARADOX OF MEN'S HEALTH, AND WHAT UROLOGY CAN DO TO TACKLE IT

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must start by educating physicians in this realm. Although medical education has rapidly evolved, shifting from a science-heavy focus toward clinical skills and application-based learning, there remains a need for progress. Although future physicians will need far more than a basic science education to effectively serve patients, contemporary medical education paradigms still lack adequate education surrounding social determinants of health, science communication, and the humanities.<sup>6</sup>

Considering this challenge, I am excited to introduce a new initiative—the *AUANews* Medical Student Column. We hope that this platform will encourage trainees to deepen their involvement in urology while contributing to the discourse surrounding the issues affecting our patients, advances in urological research, and general

“We hope that this platform will encourage trainees to deepen their involvement in urology while contributing to the discourse surrounding the issues affecting our patients, advances in urological research, and general topics in medical education.”

topics in medical education. Currently, we hope that this opportunity will help medical students develop their writing and communication skills—hopefully allowing them to better lead their communities in the near future. ■

1. Crimmins EM, Shim H, Zhang YS, Kim JK. Differences between men and women in mortality and the health dimensions of the morbidity process. *Clin Chem*. 2019;65(1):135-145.
2. Rogers RG, Everett BG, Onge JM, Krueger PM. Social, behavioral, and biological factors, and sex differences in mortality. *Demography*. 2010;47(3):555-578.
3. Sherry L, Murphy KDK, Jiaquan Xu, Arias E. Mortality in the United States, 2020. National Center for Health Statistics: Centers for Disease Control and Prevention; 2021.
4. Baker P, White A, Morgan R. Men's health: COVID-19 pandemic highlights need for overdue policy action. *Lancet*. 2020;395(10241):1886-1888.
5. Wittert G, McLachlan R. COVID-19: spiking a focus on men's health. *Obes Res Clin Pract*. 2020;14(4):293-294.
6. Shah YB, Glatter R, Madad S. In layman's terms: the power and problem of science communication. *Disaster Med Public Health Prep*. 2022;16:1-3.
7. Wilson M, Gwyther K, Swann R, et al. Operationalizing positive masculinity: a theoretical synthesis and school-based framework to engage boys and young men. *Health Promot Int*. 2022;37(1):daab031.
8. Houman JJ, Eleswarapu SV, Mills JN. Current and future trends in men's health clinics. *Transl Androl Urol*. 2020;9(Suppl 2):S116-S122.
9. Victor RG, Lynch K, Li N, et al. A cluster-randomized trial of blood-pressure reduction in Black barbershops. *N Engl J Med*. 2018;378(14):1291-1301.
10. Bai G, Fu K, Fu W, Liu G. Quality of internet videos related to pediatric urology in mainland China: a cross-sectional study. *Front Public Health*. 2022;10:924748.
11. Herbert AS, Hassan N, Malik RD, Loeb S, Myrie A. Exploring urological malignancies on Pinterest: content analysis. *JMIR Cancer*. 2022;8(3):e36244.
12. Orsoni X, Bouchet E, Auditeau E, Descazeau A. Does the urologist keep a central place in the medical information delivered to patients? *Prog Urol*. 2022;S1166-7087(22)00398-0.
13. Teplinsky E, Ponce SB, Drake EK, et al. Online medical misinformation in cancer: distinguishing fact from fiction. *JCO Oncol Pract*. 2022;18(8):584-589.
14. Sisi Hu CEK, Hong Y, Lee N, Lee S, Hinnant A. Improving rural White men's attitudes toward clinical trial messaging and participation: effects of framing, exemplars and trust. *Health Ed Res*. 2022;cyac026.



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## RADIOLOGY CORNER

## Left-sided Inferior Vena Cava and a Giant Renal Mass

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## Introduction

Inferior vena cava (IVC) anatomical anomalies are rare, but of high importance in renal surgery. A left-sided IVC is the second most common anomaly of the IVC, and occurs in 0.2%-0.5% of the population.<sup>1-4</sup> The left IVC typically joins the left renal vein, which crosses anterior to the aorta, connecting to the right renal vein to form a normal appearance right-sided IVC. This anomaly is typically found incidentally in imaging studies performed for other reasons. A critical and detailed assessment of these anomalies is important to prevent iatrogenic injuries.

## Clinical Case

This is a 58-year-old female patient who presented with a 2-week onset of left-sided abdominal discomfort and early satiety. A CT scan demonstrated a left-sided IVC and a 19 cm renal mass extending from

the upper pole of the kidney involving the tail of the pancreas and abutting the stomach (Figures 1-3). The patient also had a 2 cm lesion on the superior aspect of the right lobe of the liver concerning for metastasis. CT of the chest and head revealed no evidence of metastasis in the lung and brain. Her case was presented at tumor board, and given that she was in excruciating pain, the consensus was to proceed to the operating room for a radical nephrectomy. Appropriate counseling and consent were obtained, and the patient was made aware that the resection might involve multiple organs in the surrounding area given the size and appearance of the mass on CT.

An exploratory laparotomy was performed, revealing a large renal mass invading the tail of the pancreas, left adrenal gland, posterior aspect of the stomach, and the diaphragm. There was no tumor thrombus in the renal vein and IVC, and we were able to dissect the IVC off the medial aspect of the mass. A left radical nephrectomy, left adrenalectomy, splenectomy, distal pancreatectomy, and resection of the diaphragm were per-

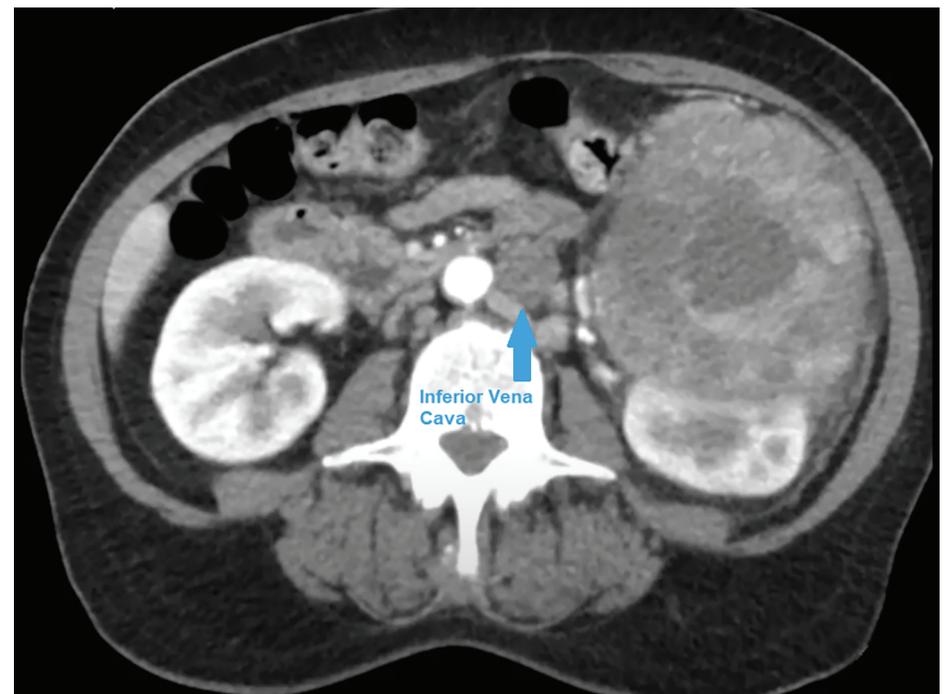


Figure 2. CT of the abdomen and pelvis (axial view) showing a large left-sided renal mass and a left-sided inferior vena cava (arrow).

formed, and the mass was peeled off the posterior aspect of the stomach. Given that the stomach appeared dusky, we performed an indocyanine green angiography with the Quest Spectrum fluorescence camera, which showed no blood flow to the stomach. Hence, we decided to perform a total gastrectomy. The lesion in the liver was also enucleated. Final pathology revealed a liposarcoma of the kidney with local invasion into the tail of the pancreas, spleen, stomach, and diaphragm with negative margins. The liver nodule was a solitary liver metastasis. Her post-operative course was long but uncomplicated. She followed up with medical oncology in the clinic and received chemotherapy. Follow-up imaging at 6 months revealed no evidence of disease.

## Discussion

Left-sided IVC is an uncommon anatomical variant that is typically incidentally found on imaging study. IVC anomalies occur during embryogenesis, and take place around the fourth to eighth week of gestation.<sup>3,5</sup> This occurs due to regression of the right supracardinal vein with persistence of the left supracardinal vein.<sup>3</sup>

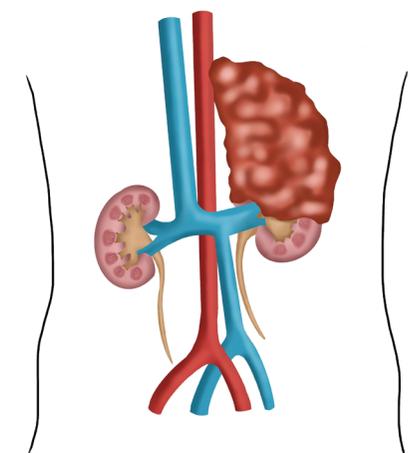


Figure 3. Illustration depicting a left-sided inferior vena cava and large renal mass.

There are multiple other variations in the IVC anatomy, including a double IVC, azygos continuation of the IVC, circumaortic left renal vein, retroaortic left renal vein, double IVC with retroaortic right renal vein and hemiazygos continuation of the IVC, double IVC with retroaortic left renal vein and azygos continuation of the IVC, circumcaval ureter, and absence of infrarenal IVC with preservation of the suprarenal segment.<sup>6</sup>

IVC anomalies are very important during retroperitoneal surgery to prevent iatrogenic injuries. Many

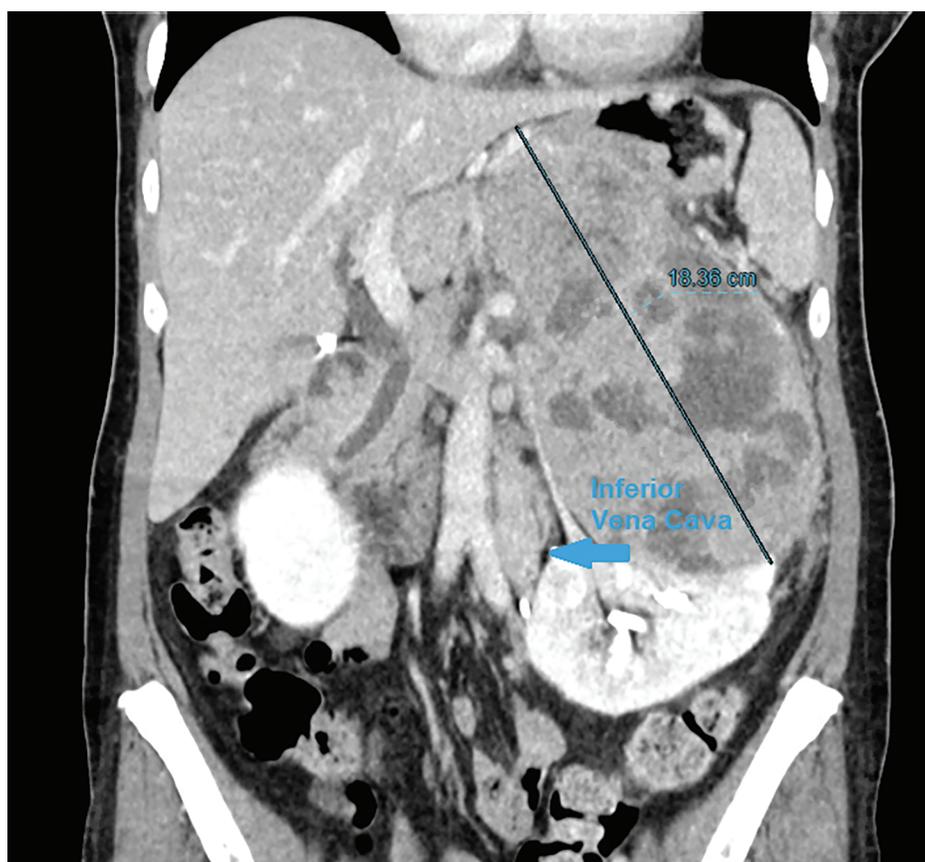


Figure 1. CT of the abdomen and pelvis (coronal view) showing a large left-sided renal mass and a left-sided inferior vena cava (arrow).

## LEFT-SIDED INFERIOR VENA CAVA AND A GIANT RENAL MASS

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of these variants may be confused as para-aortic lymphadenopathy or dilated gonadal vein. When in doubt, cross-sectional contrast-enhanced imaging with 3D reconstruction can be useful to better characterize the anatomy during preoperative planning. Left-sided IVC is also important when trying to access the IVC via a transjugular approach for procedures such as

IVC filter placement, which could result in placement of the filter in the wrong place.<sup>7</sup>

In conclusion, left-sided IVC is a rare anatomical variant that may have significant surgical implications if undiagnosed prior to surgery. Preoperative identification with cross-sectional imaging is critical to prevent iatrogenic surgical complications.

## Conflicts of Interest

The Author has no conflicts of interest to disclose. ■

1. Hoeltl W, Hruby W, Aharinejad S. Renal vein anatomy and its implications for retroperitoneal surgery. *J Urol.* 1990;143(6):1108-1114.
2. Forster J, Biyani CS, Weston PM. A gentle reminder in the laparoscopic era left-sided inferior vena cava. *Int Urol Nephrol.* 2006;38(3-4):439-442.
3. Ghandour A, Partovi S, Karuppasamy K, Rajiah P. Congenital anomalies of the IVC-embryological perspective and clinical relevance. *Cardiovasc*

*Diagn Ther.* 2016;6(6):482-492.

4. Rajabnejad Y, Aliakbarian M, Rajabnejad A, Motie MR. Left-sided inferior vena cava encountered during organ retrieval surgery: report of two cases. *Int J Organ Transplant Med.* 2016;7(4):229-232.
5. Giordano JM, Trout HH III. Anomalies of the inferior vena cava. *J Vasc Surg.* 1986;3(6):924-928.
6. Bass JE, Redwine MD, Kramer LA, Huynh PT, Harris JH Jr. Spectrum of congenital anomalies of the inferior vena cava: cross-sectional imaging findings. *Radiographics.* 2000;20(3):639-652.
7. Tan WP, Sherer BA, Khare N. Unfriendly filter: an unusual cause of hydronephrosis and hematuria. *Urology.* 2016;87:e9-e10.

## Have You Read?

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**Steiner AZ, Hansen KR, Barnhart KT, et al. The effect of antioxidants on male factor infertility: the Males, Antioxidants, and Infertility (MOXI) randomized clinical trial. *Fertil Steril.* 2020;113(3):552-560.**

*Special thanks to Dr Richard Schoor at NYU Long Island.*

Since the discovery that sperm exposed to reactive oxidative species incur damage, physicians have been recommending antioxidant therapy to males in an infertile relationship. The supplement industry began selling antioxidant preparations as fertility aids and despite a paucity of data that these pills did anything for anyone, doctors, even urologists, recommended them; even sold them. The above referenced randomized, placebo-controlled study investigated whether or not commercially available antioxidant preparations improved a man's fertility. Though not a perfect study, it is a good study. From an initial screen of 822 patients, 264 men met inclusion criteria and were randomly assigned to take either a placebo or an antioxidant preparation. Over a period of 3 months, outcomes such as pregnancies, live births, semen analysis, and DNA fragmentation between the 2 groups were analyzed. The investigators found no difference in any outcome between the placebo and investigative arm. In other words, antioxidants, at least in

pill form, don't seem to do much good for men who are sub-fertile. Do these results end the debate on whether or not we as urologist ought to recommend antioxidant pills to our patients? Probably not. The sample size was too small and the follow-up, 3 months, was too short. Since spermatogenesis takes 3 months to complete, one might think that any therapy directed at a man needs at least 3 to 6 months to show effect. So, what is the take home message? Patients can save their money for treatments that work better.

**Brant A, Lewicki P, Wu X, et al. Impact of left-digit age bias in the treatment of localized prostate cancer. *J Urol.* 2022;208(5):997-1006.**

*Special thanks to Drs Rabun Jones and Omer Acar at the University of Illinois at Chicago.*

There are many reasons for which a urologist may recommend surgery vs radiation treatment for localized prostate cancer, and many factors must be considered in the decision-making process. Age is often the first factor to be taken into account when evaluating treatment options for localized prostate cancer.

The authors of this study evaluated whether there is a bias based on the leftmost digit of a patient's age, especially in the context of treatment recommendations for a 69-year-old with localized prostate cancer vs a 70-year-old with the same diagnosis. They reviewed 2 national databases to assess wheth-

er an increase in patient age from 69 to 70 years was associated with a disproportionate change in treatment recommendations and found that there was a significant discontinuity in treatment recommendations between 69 and 70 years of age, regardless of Gleason score. This finding persisted when the bias was examined between White and non-White patients and was largest when evaluating treatment recommendation trends for Gleason 7 disease.

This well-known "left-digit" bias has been studied in every setting from used-car odometers to the cost of a jar of jam, but this is the first time it has been examined in the context of prostate cancer. These findings offer an important reminder that cognitive biases exist and can sneak their way into the interactions with our patients.

**Elliott CS, Dallas K, Shem K, Crew J. Adoption of single-use clean intermittent catheterization policies does not appear to affect genitourinary outcomes in a large spinal cord injury cohort. *J Urol.* 2022;208(5):1055-1074.**

*Special thanks to Drs Rabun Jones and Omer Acar at the University of Illinois at Chicago.*

In an ever-present effort to combat urinary tract infections, Medicare expanded coverage from 4 reused urinary catheters per month to 200 single-use catheters per month in 2008. This policy change expanded access to catheters for patients who perform clean inter-

mittent catheterization, but did it accomplish the intended effect of decreasing urinary tract infections? To answer this question, the authors of this study used The National Spinal Cord Injury Database to evaluate rates of hospitalizations for genitourinary causes in spinal cord injury (SCI) patients who performed clean intermittent catheterization before and after the policy change.

The authors examined hospitalization rates due to all genitourinary causes, including but not limited to urinary tract infections. Interestingly, they found that hospitalization rates increased significantly after 2008 even when controlling for age, biological sex, and hospitalization due to other reasons.

This study suggests that access to single-use catheters does not change hospitalization rates due to genitourinary causes in the SCI patient population. However, the impact of the Medicare coverage change to promote single-use rather than reusable catheters may have had effects that are difficult to quantify in a retrospective population-based study like this. The complicated relationships between insurance coverage, patient-related factors, and provider beliefs, practices, and preferences limit the generalizability of the findings, but the assumed clinical benefit of single-use catheters likely does not outweigh the financial cost and environmental impact associated with them. Could these findings change the hearts and minds of SCI patients and their urologists? ■

## CODING TIPS &amp; TRICKS

## Modifier 25: Appropriate Use Explained

Jonathan Rubenstein, MD, FACS  
Chair, AUA Coding and Reimbursement Committee

When is an evaluation and management (E/M) service billable and when is it not billable on the same day as a medical or surgical procedure? This is an excellent question, and the answer requires an understanding of what is included when a procedural service is valued. As we remember, all procedures, from as seemingly small as an intramuscular injection or urinary catheter placement to as large as the most intensive and invasive major surgical procedure, have a global period associated with it. The global period defines the typical service and work performed and included (and therefore already paid) and therefore also defines what can (and what cannot) be reported concomitantly. It would be wrong to bill twice for the same service, which is called double billing.

The global period (and therefore payment) typically includes all of the work that occurs to perform a service. This includes the same-day pre-service patient evaluation (such as whatever is need to “clear” the patient and prepare the patient for the procedure), obtaining patient consent, marking the patient, writing orders, bringing the patient to the site of service, positioning the patient, prepping and draping the patient, administering anesthesia if needed (if performed by the same provider), performing the intraoperative work itself, and completing the postoperative work associated with the procedure. For 0-day global procedures the global payment includes all typical work performed on the same day of the procedure (the day of the procedure itself is considered day zero), while in the case of 10-day and 90-day global procedures the work also includes all of the work (including hospital and office-based work and visits) within the number of days in the postoperative period. Therefore, based upon an understanding of what is already included in a global period payment, one can then de-

termine if other services are reportable. One should only report those services that are truly separate and identifiable.

When it comes to reporting an E/M code on the same day as a procedure, a modifier is typically placed onto the E/M code as communication to the insurer of the exception to the rule. For example, Modifier 25 describes a “Significant, Separately Identifiable Evaluation and Management Service by the Same Physician or Other Qualified Health Care Professional on the Same Day of the Procedure or Other Service.” Please note that Modifier 25 is easily audited. There have been a number of instances when a urologist or urology group has been investigated and audited for their use of this modifier, some of which have been accused of violation of the False Claims Act. To help guide one for appropriate (and inappropriate use) of Modifier 25, some urology examples are described below.

### Example 1: Scheduled Injection

A patient presents to the office for a scheduled bladder Bacillus Calmette-Guérin instillation. The physician or other qualified health care professional sees and examines the patient, discusses the patient’s current symptoms and plans, checks the urine analysis to prove absence of infection, and determines that the patient is safe to receive the medication. Consent is obtained. The patient is positioned, prepped, and the medication is instilled. The patient is given their discharge instructions. The plan for the next instillation(s) and plan including follow-up cystoscopy is re-reviewed.

Coding: Current Procedural Terminology (CPT) code 51720 *Bladder instillation of anticarcinogenic agent (including retention time)*.

Discussion: In this case CPT code 51720 should be reported, but no other E/M service should additionally be reported. E/M services inherent to the procedure are

already accounted for as part of the valuation of the CPT code and should not be reported separately. CPT code 51720 is a 0-day global procedure, and therefore the services included in the code include the pre-procedure evaluation, consent, positioning, instillation, and post-procedural care. Other 0-day global procedures that are commonly performed in the office setting and are pre-planned, such as, intramuscular injection (for instance, hormone agents), posterior tibial nerve stimulation, urinary catheter placement or exchanges (CPT codes 51701, 51702, 51703, 51705), and urodynamics, would follow the same rules.

### Example 2: Scheduled Injections With New Unrelated Symptoms

A patient presents for routine suprapubic tube exchange. During the visit the patient admits to new onset of right-sided flank pain and low-grade fevers and admits to a history of kidney stones and recurrent urinary tract infections. The provider sends the urine for culture, starts empiric antibiotics, and sends the patient for both bloodwork and a CT scan to evaluate for kidney stones or pyelonephritis.

Coding: CPT code 51705 *Change of cystostomy tube; simple* and established patient E/M code (appended with Modifier 25, based upon insurer).

Discussion: New symptoms and concerns for kidney stones or pyelonephritis are clearly a separate and identifiable reason for visit from the suprapubic tube exchange and therefore an appropriate E/M code should be reported in addition to the CPT code.

### Example 3: Cystoscopy for Microscopic Hematuria Evaluation

A patient presents for cystoscopy for microscopic hematuria

evaluation. The cystoscopy appears to be normal and a urinary cytology is sent. The provider sits down to discuss these findings and the results of the CT urogram with the patient to create a follow-up plan.

Coding: CPT code 52000 *Cystourethroscopy (separate procedure)*.

Discussion: The CPT code for cystoscopy should be reported, but no E/M code should additionally be reported. Per the *Medicare Claims Processing Manual* (Chapter 12, Section 40.1, C), “Visits by the same physician on the same day as a minor surgery or endoscopy are included in the payment for the procedure, unless a significant, separately identifiable service is also performed.” The associated E/M of the cystoscopy is included in the valuation of the code itself, which includes the pre-procedure and post-procedure work. There is no separate and identifiable diagnosis or work being performed to justify reporting an E/M code on the same date.

### Example 4: Cystoscopy for Microscopic Hematuria Evaluation With New Finding

A patient presents for cystoscopy for microscopic hematuria evaluation. Cystoscopy reveals a 3 cm right lateral wall bladder tumor. After the cystoscopy the patient is counseled on this new finding and the plan is discussed, along with a discussion about the risks of bladder tumor resection.

Coding: CPT code 52000 *Cystourethroscopy (separate procedure)* plus an established patient E/M code (appended with Modifier 25, based upon insurer).

Discussion: In addition to the CPT code for cystoscopy for the microscopic hematuria evaluation, it would be appropriate to report an E/M code for a discussion of a new finding of a bladder tumor, which is clearly a separate and identifiable diagnosis from the reason for the visit initially. ■

## Advanced Practice Providers Can Improve Transperineal Biopsy Access

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The prostate biopsy is one of the most common procedures performed in urology practices throughout the United States. It has historically been performed by a urologist using a transrectal approach. While adoption of the transperineal biopsy has become increasingly popular, these procedures continue to be performed by a urologist in the United States. In the United Kingdom, nurse practitioners have been performing prostate biopsies since 1998. More recently, they have played an important role in the country's initiative to transition to transperineal prostate biopsy.

Our department transitioned to transperineal prostate biopsy in 2019. With this transition, we experienced an increase in demand for the procedure. Up to that point, we had been performing most of our prostate biopsies under moderate sedation, as many of these were

performed using MRI fusion. With increased demand for transperineal biopsy, we looked to increase biopsy access for patients. It had been a long-term goal of our department to offer transperineal biopsy with local anesthesia (LATP) in a clinic setting. As we looked to establish this clinic, we soon realized that the demand for transperineal biopsy outpaced physician availability.

Our department has seen success with implementation of advanced practice providers (APPs) performing clinic-based procedures including cystoscopy, percutaneous tibial nerve stimulation, and a myriad of men's health procedures. With a proven track record of our APPs performing procedures and documented success in the United Kingdom with nurse practitioners performing LATP, we moved forward with developing an APP-led transperineal biopsy clinic.

Development of this clinic required a substantial team effort. Our team of APPs, consultants, nurses, technicians, and leadership worked very hard to develop a practice model and training program for APPs to safely and successfully perform LATP.

Our training begins with didactic and direct observation phases. The next step is performing bi-

opsies under direct supervision of trained staff. Each provider's background has been considered when mapping out the training phase. This has generally taken around 3-6 months. Training starts with didactic and hands-on experience with the ultrasound machine, MRI fusion software, and transperineal access device. We utilize a skills lab for the APP to practice on phantom prostates. This allows the provider to become more comfortable with the equipment and software. Next, the APP observes a minimum of 20 transperineal biopsies. Finally, the APP performs a minimum of 20 transperineal biopsies under direct supervision of an experienced consultant or APP. These initial biopsies are generally performed on sedated patients. The APP will transition to LATP once deemed competent by supervising providers. At the completion of training, the APP is prepared to perform both systematic and MRI fusion LATP.

Initial rollout of our APP-led LATP clinic began in late 2020. We saw immediate success with the implementation of this practice. We have been able to increase timely access for patients while preserving quality of care. This practice has allowed surgeons to focus on other aspects of surgical and clinical care

beyond the APP scope of practice. Additionally, APPs performing these biopsies have all reported an increase in job satisfaction due to increased variety in their practice.

Our initial experience with this practice has also highlighted possible challenges for implementation at practices across the country. First and foremost, this type of practice requires support from all stakeholders in the practice. Consultants, administrators, and nursing should all be on board to ensure success. Another challenge to consider is that scope of practice restrictions can vary by state. APPs may be restricted from performing procedures by their state's department of health, board of medicine, or board of nursing.

Today, our team of 3 APPs has performed close to 1,000 LATPs. We have been able to significantly increase access for patients wishing to proceed with LATP. Access has increased by over 100% for our LATP practice. Our preliminary data have shown that these biopsies can be performed safely and effectively by a properly trained APP. We look forward to publishing our finalized data in 2023.

In the future, we believe that APPs will play a greater role in optimizing the clinical pathway for prostate cancer screening. ■

### MEDICOLEGAL COLUMN

## The Importance of Expert Testimony at Trial

**Glenn W. Dopf, JD, LLM**  
*DOPF, P.C., New York, New York*

**Martin B. Adams, JD**  
*DOPF, P.C., New York, New York*

A trial of a medical malpractice action is frequently called a "battle of the experts." Plaintiffs call their experts to establish alleged departures from the standards of good and accepted medical practice and to establish proximate causation between the departures and the claimed injuries. Defendants adduce expert medical testimony to

defend the medical care, show the jury that Defendants at all times conformed to good and accepted standards of medical practice, and prove that Defendants did not proximately cause any injuries.

### Necessity of Expert Medical Testimony

In order to successfully prosecute a medical malpractice action, a Plaintiff must produce at trial expert medical testimony, unless the

alleged malpractice could be understood by a lay jury without the need for expert testimony and that would be an unusual situation. The reason is that the medical issues that Plaintiff must prove generally cannot be evaluated by lay jurors, who lack medical knowledge and lack experience in medical care.

"... as a general rule, a departure from [a] standard of care, whether it be at the diagnostic or treatment stage, must be established by expert testimony, except if the lack of care

is so obvious as to be within the laymen's common knowledge."<sup>1</sup>

### Proof of Urological Malpractice Requires Expert Proof

Courts recognize that a patient's "urological condition, and the treatment he received or should have received for the same, [are]

## THE IMPORTANCE OF EXPERT TESTIMONY AT TRIAL

→ Continued from page 23

matters beyond the obvious common knowledge of the jury.”<sup>2</sup>

In *Sousa v Chaset*, Plaintiff did not offer any expert testimony showing how the Defendant urologist violated any duty of care. The state Supreme Court held that the trial court properly directed a verdict for Defendant on the negligence count. “... plaintiff provided no expert testimony to show how anything [defendant] had done departed from the standard of care that he should have provided... [D]iagnostic tests of a urethroscopy and a cystoscopy, the surgical procedure of a meatotomy, and the possible or probable side effects of specific medications plaintiff was taking are all matters beyond the ordinary knowledge of laypersons...” held the state’s High Court.

### Expert Testimony as to the Standard for Reviewing Medical Records

Expert medical testimony may be required to establish a standard of care and the skill required of a urological surgeon when reviewing a patient’s medical records prior to performance of surgery.

In a malpractice case against a surgeon, Plaintiff alleged that the surgeon was negligent in failing to consult the patient’s past medical record. Plaintiff argued that if his 15-year-old hospital record had been reviewed, then the surgeon would have discovered a problem encountered in the patient’s earlier surgery involving insertion of a catheter and would have been able to properly inform Plaintiff of the possible catheterization problem and the need to perform a cystostomy placement. Plaintiff contended that, if he had received that information, he would not have consent-

ed to the surgery. The surgeon’s motion to dismiss was granted because Plaintiff had no expert witness to establish Defendant’s negligence. “Whether or not physicians have a duty to review a 15-year-old medical record on a patient to ascertain potential complications is not a matter that is so obvious as to be within the comprehension of a layperson,” observed the Appellate Court. “A person untrained in medicine and surgery is certainly not equipped with the necessary information to determine the amount of investigation that is required by a physician prior to undertaking surgery.”<sup>3</sup>

### Dismiss Plaintiff’s Lawsuit at the Close of Plaintiff’s Trial Presentation

A Plaintiff at trial who does not offer sufficient expert medical testimony on both departure and

“A Plaintiff at trial who does not offer sufficient expert medical testimony on both departure and causation issues may find the Judge dismissing the case once Plaintiff’s counsel “rests” (advises the Judge that Plaintiff has completed his or her presentation of proof).”

causation issues may find the Judge dismissing the case once Plaintiff’s counsel “rests” (advises the Judge that Plaintiff has completed his or her presentation of proof).

A plaintiff who “fail[s] to adduce expert testimony to establish the standards of care...; that the defendants departed from good and accepted practice...; or that the [treatment or failure to treat]... proximately caused her injuries... fail[s] to establish a prima facie case of medical malpractice...”<sup>4</sup>

The Defendant-surgeon’s Motion at the close of Plaintiff’s case in *Pieter v Polin* to dismiss the complaint was granted because Plaintiff failed to adduce expert testimony to establish the standards of care applicable to performance and interpretation of cardiac diagnostic tests and the development and execution of treatment plans, interpreting the results of catheterizations, making the determination to proceed with bypass surgery, or performing the surgery. Plaintiff also did not provide any expert medical testimony to show that the performance of a second catheterization or the failure to perform an intravascular ultrasound proximately caused her injuries.

### Pretrial Dismissal if Expert Medical Testimony Is Insufficient

A Plaintiff who does not produce expert medical testimony faces the prospect of having his or her medical malpractice lawsuit dismissed.

Defendants frequently try to get lawsuits dismissed prior to trial, through a written application to the Judge (a “Motion”) for summary judgment. A Defendant will file an expert medical affidavit in support of his or her Motion. If Plaintiff does not respond with sufficient

“A Plaintiff who does not produce expert medical testimony faces the prospect of having his or her medical malpractice lawsuit dismissed.”

expert proof, then the Judge may grant Defendant’s Motion and dismiss the lawsuit before any trial.

A Defendant urologist was granted pretrial Motion for summary judgment in *Ziobron v Squires*, 907 NE2d 118 (Ct App Ind 2008) because Plaintiff failed to meet her burden of rebutting, with an expert opinion, a medical review panel’s finding that the Defendant health care provider met the applicable standard of care. Plaintiff had claimed that the Defendant urologist negligently performed a bladder sling procedure. The Appellate Court held that a urologist’s “method of preparing for [plaintiff’s] surgery, the lifespan of a bladder sling, and the likelihood that a urological patient will re-exhibit urethral hypermobility symptoms or develop a cystocele five years after a bladder sling surgery are not within the realm of a layperson’s knowledge and, thus, require expert testimony.”<sup>5</sup>

In summary, for a patient to prevail at trial, he or she generally must produce expert testimony as to both negligence and causation. Testimony on negligence without causation is insufficient and vice versa. ■

1. *Young v Park*, 417 A.2d 889 (Sup RI 1980).
2. *Sousa v Chaset*, 519 A2d 1132 (Sup RI 1987).
3. *Kennis v Mercy Hosp Med Ctr*, 491 NW2d 161 (Sup Iowa 1992).
4. *Pieter v Polin*, 148 AD3d 1193, 50 NYS3d 509 (2d Dep’t 2017).
5. *Ziobron v Squires*, 907 NE2d 118 (Ct App Ind 2008).

## FROM THE UROLOGY CARE FOUNDATION

# Humanitarian Efforts and Diversity, Equity, and Inclusion Focus for 2023

Harris M. Nagler, MD, FACS  
President, Urology Care Foundation

The Urology Care Foundation (UCF) is a global organization supporting research, patient education, and humanitarian initiatives and, as such, is committed to expanding our patient education materials with a focus on diversity, equity and inclusion and growing our global humanitarian efforts. These efforts are captured in a brand refresh to be more aesthetically pleasing and to strengthen our visual ties with the American Urological Association.

## Global Humanitarian Efforts

The UCF is entering phase 3 of its Humanitarian Program in 2023. As established in the previous 2 phases, the UCF is already recognizing outstanding humanitarian volunteers and supporting humanitarian projects through the Humanitarian Recognition Award and the Humanitarian Grant Program. Thank you to the AUA Sections and individual donors who have established endowments or are in the process of funding endowments to support these projects:

- AUA Humanitarian Endowment Grant
- Richard J. Fox Humanitarian Endowment Grant
- Endourological Society/Raju and Ginny Thomas
- Nathirmal Lalchandani, MD
- Dave Amerson Family
- Indian American Urological Society
- AUA Southeastern Section/Puerto Rico Urological Association
- McCammon Family International Student
- Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction
- Nawazish Ali Mian, MD, Family
- UCF Humanitarian Endowment for Pakistan

- UCF Humanitarian Endowment
- Global Association for the Support of Haitian Urology (in progress)
- AUA South Central Section (in progress)

We have been very fortunate to have been successful on phases 1 and 2. Now, for phase 3, we want to develop young urologists to become experts with the ability to lead meaningful humanitarian initiatives. We'll do this through the UCF Health Equity Fellowship pilot program, which will provide the necessary skills, knowledge, and developmental experiences to its awardees. You will be hearing more about this exciting, innovative initiative in future columns!

## Diversity, Equity, and Inclusion

### Information bundles

As the world's leading nonprofit urological health foundation, the UCF has over 200 patient education materials with more to come!

Yet, we realize the importance of updating our current offerings to make them more widely accessible. This year we're working to amplify our global voice through patient education bundles for at-risk and underrepresented populations. These bundles will have QR codes associated with them for quick and easy access to the materials. Our current offerings include bundles for African American men and women, Hispanic men, the LGBTQIA population and women (Figure 1).

### Webinar series

Additionally, in an effort to expand knowledge, advance research, and improve patient care throughout the urology community, we are formulating a collaborative health equity awareness and education webinar series. This series will include a call to action on important health topics and issues in the urological community such as:

- Innovative patient access programs, including patient navigation

- Barriers to diagnosis, care, and treatment for minority populations
- Research advocacy
- Systemic issues to care—financial barriers, prior authorization, step therapy, etc.

The goals for these webinars include increasing awareness of the importance of cultural competency in urology, providing resources to patients in underrepresented populations, improving patient experiences, and improving patient, caregiver, and provider communication.

## Brand Refresh

The UCF has grown and evolved, and our brand should reflect that. In alignment with the American Urological Association's brand progression, the UCF brand is getting an upgrade. To strengthen the connection with the AUA, we've added the line "powered by trusted experts of the" along with the AUA logo. We've also

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Figure 1. Example of patient education bundle for at-risk and underrepresented populations.

## HUMANITARIAN EFFORTS AND DIVERSITY

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**Buddy Guy's Legends** Friday, April 28, 2023

700 S Wabash Ave  
Chicago, IL 60605

VIP Reception: 6-7 p.m.  
Main Event: 7-10 p.m.

Attire: Casual

Registration opens  
December 6, 2022

Purchase tickets through  
AUA2023 registration or at  
UrologyHealth.org/Benefit

Early Bird Ticket: \$130  
(before February 21, 2023)

Patron Ticket: \$500

A Night to Benefit the  
Urology Care Foundation

Urology Care  
FOUNDATION

**Figure 2.** The 2023 UCF annual benefit will be held at Buddy Guy's Legends on Friday, April 28. Tickets are on sale now (UrologyHealth.org/Benefit).

updated our visual style to include more consistency of brand colors and elements (Figure 1). Additionally, QR codes have been developed to be used throughout our marketing, communications, and resources to allow for a simple, quick scan from a phone. We will direct users to “Learn More” or “Donate.”

### Annual Meeting Benefit

I'm particularly looking forward to our annual benefit in 2023

(Figure 2). This year the event will be held at Buddy Guy's Legends on Friday, April 28. Tickets are on sale now (UrologyHealth.org/Benefit) and the Early Bird pricing lasts through February 21. It's always great fun, and helps the Foundation move forward. I hope to see you there! ■

## FROM THE RESIDENTS & FELLOWS COMMITTEE

# Research Funding Opportunities for Residents and Fellows

**Daniel A. Igel, MD**

*University of Kansas Medical Center, Kansas City*

With the time demands inherent to pursuing surgical residency and fellowship training, acquiring grant funding and pursuing funded research feels like a daunting task to many urology trainees. However, thanks to the generosity of various donors and foundations, there are a number of research funding opportunities open to and often geared specifically toward residents and fellows. Many of these awards have streamlined application processes, with goals that are achievable in the context of clinical training, in contrast to many of the traditional funding opportunities available through the NIH and other national funding mechanisms.

The AUA offers a number of research grants and awards for residents and fellows that facilitate funded clinical, translational, and basic science research. The most well known of these awards are the AUA/Urology Care Foundation (UCF) Research Scholar awards, which have provided over \$29,000,000 of funding to over 650 awardees since 1975. These awards provide \$40,000 of funding per year for either a 1- or 2-year period. Those eligible for the grant are, at the start of the award period, surgeons in clinical urology fellowship programs, PhD researchers in

post-doctoral fellowships, and early-career (less than 5 years out of training) urology faculty. The award does require that one commits 50% of their time during the award period to the project for which they receive the grant. With this structure, this award is often applied for by chief urology residents entering clinical fellowship programs that include sufficient dedicated research time to meet the 50% time and effort requirement for either a 1- or 2-year project. Funding for the grants comes from a variety of sources, including the regional sections, such as the AUA Mid-Atlantic Section William D. Steers, MD Award; subspecialty societies, such as the Endourological Society Joseph Segura, MD Scholarship in Endourology and Stone Management; and industry sources, including companies such as Bristol Myers Squibb. The source of the funding determines the projects the award funds, with the regional sections funding research performed at institutions within the section, and subspecialty societies funding research pertaining to their areas of focus.

The AUA/UCF also offers awards to support research during residency training. The Residency Research Award Program is one such mechanism, which provides \$10,000 of funding for projects 3 to 12 months in length. In order to qualify for this award, one must be

a urology resident within the geographic boundaries of an AUA section during the entire project. This award does require that 80% of one's time be spent on the project, and therefore residents should apply for this award in anticipation of dedicated research time, whether it be a 3- to 6-month research rotation or a dedicated research year. The Leadership in Education, Achievement, and Diversity (LEAD) program is another program offered through the AUA/UCF, which has the same requirements as the Residency Research Award but is specifically for residents from racial and ethnic backgrounds underrepresented in urological research, including those of African American, Hispanic, or Native American ancestry. At the present time this award only supports bladder dysfunction and men's health research based on the source of supporting funding, but the AUA/UCF hope to broaden the research scope of the award in the future.

There are also funding opportunities for residents and fellows available directly from the subspecialty and special interest societies separate from the awards they offer in collaboration with the AUA/UCF, which can vary from year to year. Opportunities available this cycle include a \$25,000 award from Society of Urodynamics, Female Pelvic Medicine, and Urogenital Reconstruction (SUFU) for the study

of neuromodulation, and a \$2,500 award from the Society of Women in Urology (SWIU) for basic, clinical, or translational urological research.

Another avenue for funding that is often overlooked by urology trainees is internal funding mechanisms available at one's local institution. Here at the University of Kansas, one of my co-residents, Dr Stephen Pittman, earned a \$30,000 Clinical Research Pilot Grant to support a randomized controlled clinical trial on renal ultrasound for post-treatment surveillance in renal cell carcinoma. These sorts of mechanisms are available at many institutions, and can provide substantial funding for projects without many of the time requirements and competition that come with national-level grants.

Letters of interest and proposals for these awards are typically due in the months of August to December, so be on the lookout for deadlines. With each of these grants, it is important to identify a mentor early, and if the institution you will be working at has a grant office, reach out to them for support. While applying for these awards does represent a significant time commitment for already-busy residents and fellows, these awards offer a great avenue to help jump-start one's academic career, and provide valuable experience in grant-writing and the scientific process in general. ■

## FROM THE PUBLIC POLICY COUNCIL

## Rise and Renew: A New Year, a New Congress, and a Renewed AUA Advocacy Summit

Eugene Y. Rhee, MD, MBA  
Chair, AUA Public Policy Council

Another election has come and gone and the New Year is upon us. A brand new Congress walks the halls of the Capitol and the opportunity is ripe for new relationships. Strong relationships on Capitol Hill are key for advancing our legislative priorities for the specialty of urology, and these relationships do not form overnight. While AUA staff expends a great deal of energy meeting with lawmakers and their staff to educate them about urology's priorities and concerns, it is up to us—as constituents, voters, and physicians—to tell our legislators our stories. Our personal experiences in residency, clinic, or with our patients are what add stakes to our legislative priorities. The solutions to issues that impact urologists and our patients leave the pages of bill text and come to life when we

meet and talk with our lawmakers. There continues to be much interest in Congress about U.S. health care delivery and the challenges facing us all as urologists.

Fortunately, each year the AUA organizes the Annual Urology Advocacy Summit (AUA Summit) to directly connect us with our lawmakers. The sixth AUA Summit is **February 27 to March 1, 2023** in Washington, DC, and will include educational sessions on our key legislative issues, networking events, and—most importantly—a full day of Capitol Hill meetings. In state delegations, we have an opportunity to meet with lawmakers and their staff to deliver a unified message, enhanced with our own personal stories, urging their action on several pieces of legislation that impact urology and our patients. After the Monday educational sessions, we approach our Tuesday Hill meetings prepped with the

“The solutions to issues that impact urologists and our patients leave the pages of bill text and come to life when we meet and talk with our lawmakers.”

knowledge we need to educate our legislators on the bills pertinent to urology. We come to these meetings with power in our experience and our expertise on behalf of our practices and our patients.

You may be wondering what types of issues we talk about in our Hill meetings, or may feel nervous about speaking with legislators and their staff. We want you to know that

the AUA Summit Planning Advisory Committee works tirelessly to craft an agenda that is relevant to all urological professionals, addresses your needs and concerns, and leaves you prepared and invigorated for your Hill meetings and to continue your advocacy even after you leave DC. We spend weeks holding calls with all the AUA Sections and key urological specialty societies to identify policy issues that resonate with everyone. We aim to craft our training sessions with all levels of advocates in mind, whether it's your first AUA Summit or your sixth.

Finally, we hope that you will also encourage your residents and fellows to attend the AUA Summit this year. The future of urology and urological advocacy depends on them to feel connected with us all and the legislative process. Register and stay up to date as we continue to develop the agenda at [www.AUASummit.org](http://www.AUASummit.org). See you in DC! ■

## Another Solution to Erectile Dysfunction

Neil H. Baum, MD  
Tulane Medical School, New Orleans, Louisiana

Most urologists provide care for men with erectile dysfunction (ED). These men also suffer from hypertension, diabetes, and elevated cholesterol levels. Of course, we can prescribe phosphodiesterase-5 inhibitors (PDE-5Is), often restoring men's potency and ability to engage in sexual intimacy. But are we helping men to lead healthier lifestyles by providing them with a prescription? You will all agree that PDE-5I is the band-aid for the ED problem. Since this medication option is in our armamentarium, we should certainly avail ourselves and our patients of this treatment. However, we could be good urologists and lead men to better life-

style changes if we could encourage them to lead healthier lifestyles, including diet and exercise. Let me share a discussion I have had with men who present with ED and men to whom I have provided PDE-5Is.

I have treated many men with ED, and I have a script to talk to men about lifestyle changes. The conversation with “Mr Smith” might go something like this: “Mr Smith, would you like a pill that decreases your risk of cancer, decreases your cholesterol level, improves your type two diabetes so that you don't need to take diabetic medication, will lower your blood pressure and you will not need to take anti-hypertensive medication, decreases your joint pain in your knees, prevents constipation, solves your insomnia, improves your sex

drive, increases your testosterone level, increases your energy level, improves your sexual performance, and increases the length of your penis by one and a half to two inches?”

Mr Smith, and all the men who hear this spiel, usually respond, “Do you mean there's a pill that can do all of that? I would certainly like a prescription for those pills if the answer is yes.”

I pat Mr Smith on the back and say, “Mr Smith, it's not a pill”... I pause, and I smile .... “It's exercise!” Mr Smith usually giggles and might inquire about how exercise would make his penis longer? My answer is that when he loses his abdominal panniculus, he will be able to see his toes when he showers, and his penis will “appear” longer!

Does this kind of communication impact men with ED to change their behaviors? Few men will take my advice and leave the office to begin an exercise program. However, the discussion offers men an alternative to the quick fix for treating ED and continuing with 5 or more medications a day. I can't tell you how many men have taken my advice and left their anti-hypertensive, cholesterol, and diabetes medications in the medicine cabinet. But I can tell you that I have made men aware that the control of their health is in their hands and legs, and that if they take personal responsibility for their health, including an exercise program, they will lead happier and healthier lives. ■

## OFFICE &amp; SURGICAL TECHNOLOGIES

## New Technologies: Vacuum-assisted Access Sheath (ClearPetra) for Percutaneous Nephrolithotomy

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The Ohio State University, Columbus

Bodo E. Knudsen, MD, FRCSC

The Ohio State University, Columbus

Percutaneous nephrolithotomy (PCNL) is the first-line therapy for management of renal stones larger than 20 mm, per the AUA guidelines.<sup>1</sup> With new advances in technology and technique, miniaturized approaches to PCNL are becoming more common and expanding the indications for the procedure. One such advancement is the introduction of the vacuum-assisted access sheath (VAAS), commercially marketed as the single-use ClearPetra system. This device features a vacuum side port mounted at 45° to the sheath, which is attached to suction through a stone capture system (see Figure). There is a pressure vent incorporated in the side port allowing for rapid adjustments to suction pressure while using this sheath. The sheath is available in multiple sizes from 10Fr/12Fr to 22Fr/24Fr. The manufacturer offers a wide range of VAAS systems, some of which are also advertised for ureteroscopic and cystoscopic use, but our experience is with the mini PCNL system.<sup>2</sup>



**Figure.** ClearPetra vacuum-assisted nephrosotomy access sheath with dilator and suction side port.

Reusable systems, such as the Storz Minimally Invasive PCNL (MIP) system, for mini PCNL utilize the Venturi effect to clear fragments, where the surgeon slowly pulls the scope back out of the sheath and the pieces follow. While quite effective, our experience has been that this tends to work better in the supine position than the prone position due to gravity assistance. Further, there remains some risk of scattering fragments during the lithotripsy portion of the mini PCNL, especially as the surgeon is working through their learning curve. The use of a VAAS may help to reduce the risk of fragments scattering as well as facilitate

more rapid clearance of the pieces. In addition, intrarenal pressure is reduced with the active suction and this may translate into reduced morbidity.<sup>3,4</sup> With the VAAS technology, smaller fragments and stone dust will wash out during laser lithotripsy around the scope without having to pull it back. For larger fragments, the scope is then pulled back into the sheath in a similar fashion to when using the Storz MIP system, but the active suction helps pull the pieces along more forcefully as compared to the Venturi effect alone. Blood clots can also be more readily suctioned out with the VAAS, something that can be quite difficult with the MIP system. The ClearPetra system includes a stone catching trap, so all the fragments removed can be sent for biochemical analysis or culture.

While we primarily utilize a fragmentation approach during mini PCNL, VAAS may increase the feasibility of dusting since the small pieces can be actively removed while continuing to lase the stone. Utilizing a high-powered holmium:YAG laser with pulse modulation or the highly efficient thulium fiber laser may further facilitate the dusting approach. Whether it

is faster than a fragmentation approach remains to be determined.<sup>5</sup>

The development of VAAS for mini PCNL represents an important step in the evolution of percutaneous stone surgery. By increasing the efficiency of the procedure, the indications for mini PCNL may broaden, facilitating smaller tract surgery for more patients. Further research evaluating optimal implementation is needed. Nonetheless, the use of VAAS appears to present tangible benefits over standard mini PCNL and an evolution of the surgical technique. ■

1. Assimos D, Krambeck A, Miller NL, et al. Surgical management of stones: American Urological Association/Endourological Society Guideline, PART II. *J Urol*. 2016;196(4):1161-1169.
2. Micro-Tech Endoscopy. *Clearpetra*. 2021. Accessed April 27, 2021. <https://mtendoscopy.com/hospitals/products/urology/access/clearpetra/>.
3. Zanetti SP, Lievore E, Fontana M, et al. Vacuum-assisted mini-percutaneous nephrolithotomy: a new perspective in fragments clearance and intrarenal pressure control. *World J Urol*. 2021;39(6):1717-1723.
4. Lai D, Chen M, Sheng M, et al. Use of a novel vacuum-assisted access sheath in minimally invasive percutaneous nephrolithotomy: a feasibility study. *J Endourol*. 2020;34(3):339-344.
5. Hardy LA, Vinnichenko V, Fried NM. High power holmium:YAG versus thulium fiber laser treatment of kidney stones in dusting mode: ablation rate and fragment size studies. *Lasers Surg Med*. 2019;51(6):522-530.

### CASE REPORT

## Symptomatic Ureteral Stump After Nephrectomy

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### Introduction and Background

After performing nephrectomy,

the distal ureteral remnant is usually abandoned with no major complications,<sup>1</sup> but in a few patients this remnant may generate symptoms. Ureteral stump syndrome (USS) is a rare but well-known complication that occurs in patients after nephrectomy. These symptoms may appear between months and years after nephrectomy, and they include urinary tract infection (UTI), hematuria, and back pain or low abdominal pain.<sup>2</sup>

“Ureteral stump syndrome (USS) is a rare but well-known complication that occurs in patients after nephrectomy.”

When suspected, diagnosis is easily reached with routine imaging tests such as CT scan.<sup>1,2</sup> Usual treatment consists of resection of the ureteral remnant, but endourological approaches may be an option in some cases.<sup>1</sup> We describe a case of USS after a nephrectomy performed because of pyonephrosis.

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## SYMPTOMATIC URETERAL STUMP AFTER NEPHRECTOMY

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## Case Report

A 28-year-old female patient was received in our center with 14 days of right flank pain and fever. She had a history of urolithiasis and long-term UTI. CT scan evidenced severe right hydronephrosis and multiple homolateral kidney stones distributed in the lower and upper calyces. Serum creatinine was 1.4 mg/mL. Urine culture was obtained and antibiotic therapy was instituted with piperacillin-tazobactam, with unfavorable results.

Open right radical nephrectomy was performed. During the procedure, pyonephrosis and severe inflammatory compromise of perinephric tissues were found. After surgery, the patient had good recovery, with hospital discharge after 7 days.

Three months after surgery, the patient experienced recurrence of right flank pain, hematuria, and UTI. CT scan was performed and a stone in the ureteral stump was found with no other pathological findings (Figure 1).

An endourological approach was selected. Retrograde pyelography was performed and severe leakage was found at low-pressure contrast instillation (Figure 2). With these findings, ureteroscopy was not performed, and laparoscopic ureteral stump resection was proposed.

During the laparoscopic approach, multiple adhesions were found and open surgery was selected. The ureteral stump was com-

pletely resected (Figure 3). After 4 days, the patient was discharged with good recovery. Six months after stump resection, the patient was in good clinical condition with symptom remission.

## Discussion and Literature Review

After performing nephrectomy, the distal ureteral remnant is usually abandoned with no major complications. However, regarding the distal ureter, an unsubstantiated adage exists: "Take the ureter as far down as you can." Complete removal of the ureter minimizes the risk of future morbidity associated with the distal ureteral stump, including febrile UTIs, lower quadrant pain, and hematuria, which comprise USS, although recurrent bacteriuria, hematuria, stones, and even malignancy can also be part of the syndrome.<sup>3</sup> Urine reflux in the ureteral stump occurs due to poor drainage from the stump.<sup>4</sup> Short ureteral stumps drain urine effectively by retained peristaltic activity, and thus USS is less likely to develop in short ureteral stumps.<sup>5</sup>

There have only been a few series showing the natural history of the ureteral stump after nephrectomy and partial ureterectomy in a solitary collecting system.<sup>5</sup> Androulakakis et al suggested that long ureteral stumps act like a bladder diverticulum and predispose patients to developing USS.<sup>5</sup> Performing retrograde ureterography

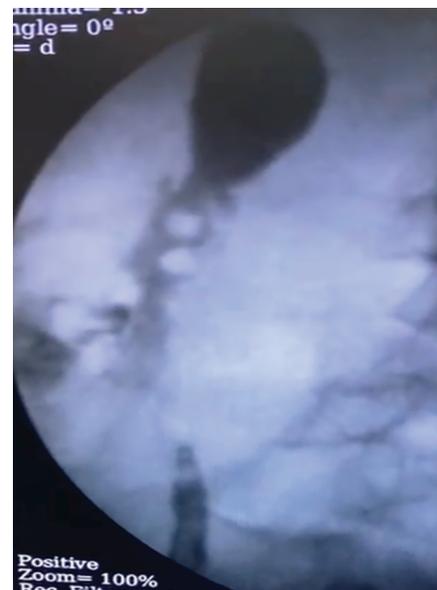


Figure 2. Retrograde pyelography with contrast leak.

or direct full visualization of the ureteral stumps before proceeding with the intended mode of treatment would help to predict the onset of subsequent symptoms. Although very uncommon, a genuine risk of ureteral stump cancer exists and must be evaluated.<sup>5</sup>

Usual treatment consists of resection of the ureteral remnant by open or laparoscopic technique. Endoscopic methods include sub-ureteral injection of polytetrafluoroethylene (Teflon)/dextranomer/hyaluronic acid, or endoscopic fulguration and fibrin glue occlusion of the ureteral lumen.<sup>6</sup> Any of these procedures may potentially be used at initial nephrectomy or reserved for the small number of patients with symptoms attributed to the stump postoperatively.<sup>7</sup>

Surgical removal of the symptomatic distal ureteral stump is safe and effectively relieves symptoms. With a small incision in the groin, good exposure of the ureteral stump is obtained without opening the abdominal cavity, achieving complete resection of the stump. The laparoscopic approach has the advantage that there is no need for a second inguinal incision to handle the distal part of the ureter, such as with open surgery. However, it does not allow dissection of the stump to the bladder base. ■

*Conflict of Interest: The Authors have no conflicts of interest to disclose.*



Figure 3. Resected ureteral stump.



Figure 1. CT scan with residual stone in right ureteral stump.

JM. Endourological treatment of symptomatic ureteral stump postnephrectomy. *Actas Urol Esp.* 2019;43(1):39-43.

- Arora S, Yadav P, Ansari M. Diagnosis and management of symptomatic residual ureteral stump after nephrectomy. *BMJ Case Rep.* 2015;2015:ber2015209441.
- Escolino M, Farina A, Turrà F, et al. Evaluation and outcome of the distal ureteral stump after nephro-ureterectomy in children. A comparison between laparoscopy and retroperitoneoscopy. *J Pediatr Urol.* 2016;12(2):119.e1-119.e8.
- Casale P, Grady RW, Lee RS, Joyner BD, Mitchell ME. Symptomatic refluxing distal ureteral stumps after nephroureterectomy and heminephroureterectomy. What should we do?. *J Urol.* 2005;173(1):204-206.
- Androulakakis PA, Stephanidis A, Antoniou A, Christophoridis C. Outcome of the distal ureteric stump after (hemi) nephrectomy and subtotal ureterectomy for reflux or obstruction *BJU Int.* 2001;88:586-589.
- Biswas K, Singh AG, Ganpule AP, Sabnis RB, Desai MR. Clinical features and management of ureteric stump syndrome: single-centre experience and contemporary literature review. *Asian J Urol.* 2022;9(2):193-196.
- Cain MP, Pope JC, Casale AJ, Adams MC, Keating MA, Rink RC. Natural history of refluxing distal ureteral stumps after nephrectomy and partial ureterectomy for vesicoureteral reflux. *J Urol.* 1998;160(3):1026-1027.

- Fernández-Bautista B, Parente Hernández A, Ortiz Rodríguez R, Burgos Lucena L, Angulo Madero

# Roe vs Wade Member Survey Results

On June 24, 2022, the U.S. Supreme Court issued an opinion on *Dobbs v Jackson Women's Health Organization*. The opinion gives states the power to set their own abortion laws.

On June 25, the AUA Board released a statement on the ruling via social media and an email to members. Following the release of the statement, the AUA received notable feedback from AUA members. The feedback the AUA received was mixed, with some members believing the statement did not go far enough and others stating that the AUA was going too far.

The Board is tasked with carrying out the AUA mission to serve its members: "Our mission is to

promote the highest standards of urological clinical care through education, research, and the formulation of health care policy."

Based on the diversity of feedback from AUA members on the AUA Dobbs statement, the Board decided to survey its members to learn more about the views of our members in an effort to serve the entire membership as best possible. The survey was sent to all domestic members with valid email addresses. A total of 1,653 responses were collected for a total response rate of 12.15%. A total sample size of 1,653 is accurate within 2.5% at the 95% confidence level. Figures 1 through 6 provide details of data collected in the survey. ■

| American Urological Association |                          |                      | Respondent Profile |                          |                      |
|---------------------------------|--------------------------|----------------------|--------------------|--------------------------|----------------------|
|                                 | Total Response (N=1,653) | AUA Domestic Members |                    | Total Response (N=1,653) | AUA Domestic Members |
| <b>Membership Category:</b>     |                          |                      |                    |                          |                      |
| Active/Associate                | 60%                      | 41%                  |                    |                          |                      |
| Senior/Retired                  | 15%                      | 21%                  |                    |                          |                      |
| Residents/Fellows               | 12%                      | 13%                  |                    |                          |                      |
| Advanced Practice Provider      | 5%                       | 11%                  |                    |                          |                      |
| Medical/Graduate Student        | 5%                       | 10%                  |                    |                          |                      |
| Research Scientist              | 2%                       | 2%                   |                    |                          |                      |
| Allied & Affiliate              | 1%                       | 2%                   |                    |                          |                      |
| <b>AUA Section:</b>             |                          |                      |                    |                          |                      |
| Southeastern                    | 21%                      | 20%                  |                    |                          |                      |
| Western                         | 20%                      | 17%                  |                    |                          |                      |
| North Central                   | 18%                      | 17%                  |                    |                          |                      |
| South Central                   | 15%                      | 16%                  |                    |                          |                      |
| Mid-Atlantic                    | 10%                      | 10%                  |                    |                          |                      |
| New York                        | 8%                       | 8%                   |                    |                          |                      |
| New England                     | 5%                       | 6%                   |                    |                          |                      |
| Northeastern                    | 3%                       | 6%                   |                    |                          |                      |
| <b>Age:</b>                     |                          |                      |                    |                          |                      |
| Less than 37 years              | 26%                      | 27%                  |                    |                          |                      |
| 37 to 45 years                  | 20%                      | 17%                  |                    |                          |                      |
| 46 to 54 years                  | 15%                      | 14%                  |                    |                          |                      |
| 55 to 64 years                  | 16%                      | 15%                  |                    |                          |                      |
| 65 years or older               | 23%                      | 27%                  |                    |                          |                      |
| <b>Gender:</b>                  |                          |                      |                    |                          |                      |
| Male                            | 71%                      | 77%                  |                    |                          |                      |
| Female                          | 26%                      | 23%                  |                    |                          |                      |
| Non-binary                      | 0%                       | -                    |                    |                          |                      |
| Transgender                     | 0%                       | -                    |                    |                          |                      |
| Prefer not to disclose          | 3%                       | -                    |                    |                          |                      |

Figure 1. Overview of respondents to the August 2022 AUA membership survey.

| American Urological Association  |       |                     | Summary of Results |          |                  |                  |              |               |                      |          |          |          |          |     |
|--|-------|---------------------|--------------------|----------|------------------|------------------|--------------|---------------|----------------------|----------|----------|----------|----------|-----|
| Should the AUA Develop Positions on Social Issues that are Not Predominantly in the Traditional Urology Clinical and Practice Space? |       |                     |                    |          |                  |                  |              |               |                      |          |          |          |          |     |
| <b>Q.1 Segmentation Analysis</b>   |       |                     |                    |          |                  |                  |              |               |                      |          |          |          |          |     |
|  |       | AUA Member Category |                    |          |                  |                  | Gender       |               |                      |          |          |          |          |     |
|  | Total | Active/Assoc.       | Sr./Retired        | APP      | Resident/Fellows | Medical/Graduate | Male         | Female        | Prefer Not to Answer |          |          |          |          |     |
| Yes  | 45%   | 43%                 | 26%                | 30%      | 71%              | 63%              | 38%          | 65%           | 41%                  |          |          |          |          |     |
| No   | 49%   | 51%                 | 70%                | 56%      | 24%              | 29%              | 58%          | 26%           | 52%                  |          |          |          |          |     |
| Don't Know   | 6%    | 6%                  | 4%                 | 14%      | 5%               | 8%               | 4%           | 9%            | 7%                   |          |          |          |          |     |
| <b>Q.1 Segmentation Analysis</b>   |       |                     |                    |          |                  |                  |              |               |                      |          |          |          |          |     |
|  |       | AUA Section         |                    |          |                  |                  |              | Age           |                      |          |          |          |          |     |
|  | Total | Mid-Atlantic        | New England        | New York | Northeastern     | North Central    | Southeastern | South Central | Western              | Under 37 | 37 to 45 | 46 to 54 | 55 to 64 | 65+ |
| Yes  | 45%   | 47%                 | 56%                | 54%      | 44%              | 45%              | 34%          | 38%           | 53%                  | 64%      | 54%      | 41%      | 26%      | 31% |
| No   | 49%   | 46%                 | 39%                | 42%      | 49%              | 46%              | 60%          | 57%           | 42%                  | 28%      | 41%      | 52%      | 67%      | 67% |
| Don't Know   | 6%    | 7%                  | 5%                 | 4%       | 7%               | 9%               | 6%           | 5%            | 5%                   | 8%       | 5%       | 7%       | 7%       | 2%  |

Base: Total Domestic Members (N=1,653)  
Question: Do you want the AUA to develop positions on social issues that are not predominantly in the traditional urology clinical and practice space (e.g.: gun control, abortion rights, climate change)?

Figure 2. Segmentation analysis of responses to the August 2022 membership survey: "Do you want the AUA to develop positions on social issues that are not predominantly in the traditional urology clinical and practice space (eg, gun control, abortion rights, climate change)?" APP indicates advanced practice provider; Q, question.

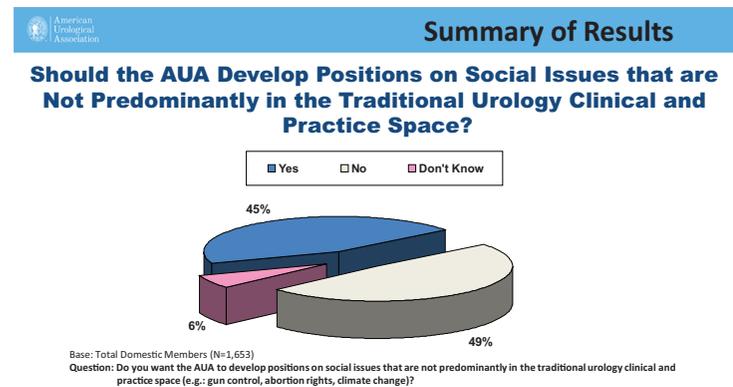


Figure 3. Representation of responses to the August 2022 membership survey question: "Do you want the AUA to develop positions on social issues that are not predominantly in the traditional urology clinical and practice space (eg, gun control, abortion rights, climate change)?"

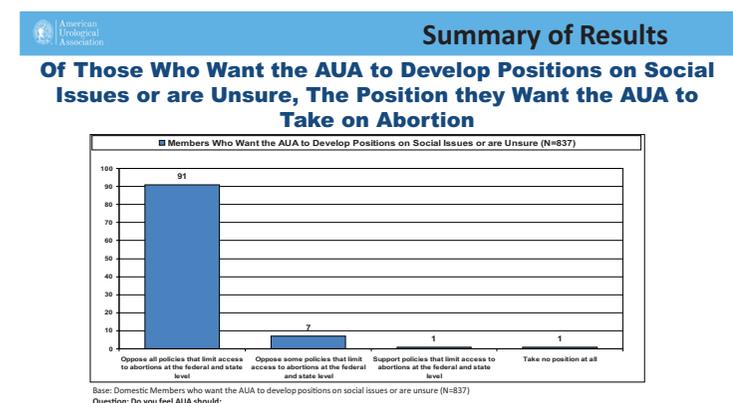


Figure 4. Representation of responses to the base August 2022 membership survey question: "Do you feel the AUA should...?"

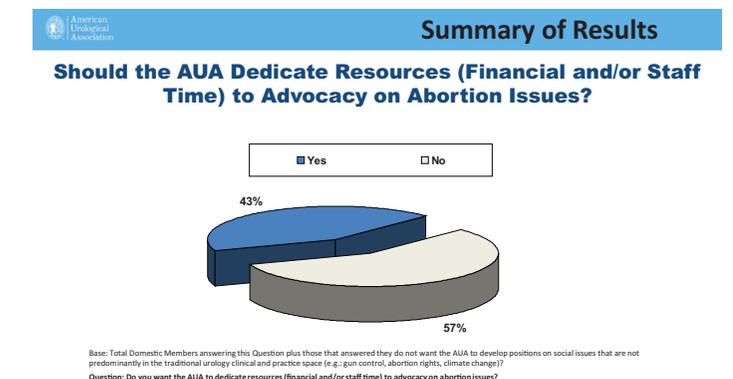


Figure 5. Representation of responses to the August 2022 membership survey question: "Do you want the AUA to dedicate resources (financial and/or staff time) to advocacy on abortion issues?"

| American Urological Association   |       |                     | Summary of Results |          |                  |                  |              |               |                      |          |          |          |          |     |
|---|-------|---------------------|--------------------|----------|------------------|------------------|--------------|---------------|----------------------|----------|----------|----------|----------|-----|
| Should the AUA Dedicate Resources (Financial and/or Staff Time) to Advocacy on Abortion Issues? |       |                     |                    |          |                  |                  |              |               |                      |          |          |          |          |     |
| <b>Q.5 Segmentation Analysis</b>  |       |                     |                    |          |                  |                  |              |               |                      |          |          |          |          |     |
|   |       | AUA Member Category |                    |          |                  |                  | Gender       |               |                      |          |          |          |          |     |
|   | Total | Active/Assoc.       | Sr./Retired        | APP      | Resident/Fellows | Medical/Graduate | Male         | Female        | Prefer Not to Answer |          |          |          |          |     |
| Yes   | 43%   | 40%                 | 18%                | 35%      | 68%              | 65%              | 34%          | 67%           | 41%                  |          |          |          |          |     |
| No  | 57%   | 60%                 | 82%                | 65%      | 32%              | 35%              | 66%          | 33%           | 59%                  |          |          |          |          |     |
| <b>Q.5 Segmentation Analysis</b>  |       |                     |                    |          |                  |                  |              |               |                      |          |          |          |          |     |
|   |       | AUA Section         |                    |          |                  |                  |              | Age           |                      |          |          |          |          |     |
|   | Total | Mid-Atlantic        | New England        | New York | Northeastern     | North Central    | Southeastern | South Central | Western              | Under 37 | 37 to 45 | 46 to 54 | 55 to 64 | 65+ |
| Yes   | 43%   | 48%                 | 54%                | 48%      | 38%              | 45%              | 35%          | 35%           | 49%                  | 64%      | 49%      | 40%      | 25%      | 27% |
| No  | 57%   | 52%                 | 46%                | 52%      | 62%              | 55%              | 65%          | 65%           | 51%                  | 36%      | 51%      | 60%      | 75%      | 73% |

Base: Total Domestic Members answering this Question plus those that answered they do not want the AUA to develop positions on social issues that are not predominantly in the traditional urology clinical and practice space (e.g.: gun control, abortion rights, climate change)  
Question: Do you want the AUA to dedicate resources (financial and/or staff time) to advocacy on abortion issues?

Figure 6. Segmentation analysis of responses to the August 2022 membership survey question: "Do you want the AUA to dedicate resources (financial and/or staff time) to advocacy on abortion issues?" APP indicates advanced practice provider; Q, question.

## UPJ INSIGHT

# Comprehensive Genetic Testing Protocol for Prostate Cancer Patients in a Uro-oncology Practice

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**Ramanathan S, Korman A, Ramanathan S, et al. Positive impact of implementing a comprehensive genetic testing protocol for prostate cancer patients in a multi-disciplinary uro-oncology practice. *Urol Pract.* 2023;10(1);33-39.**

## Study Need and Importance

The 2017 Philadelphia Consensus Conference significantly expanded the indications for genetic testing. However, there remained a lack of clear recommendations regarding the implementation of genetic testing for prostate cancer patients. While the updated 2019 conference guidelines addressed the delivery of genetic testing by

endorsing point-of-care testing, there remains a critical lack of literature concerning the successful deployment of a genetic testing pathway for prostate cancer patients. In this study we aim to evaluate an on-site, guideline-based point-of-care genetic testing process for prostate cancer patients in our practice.

## What We Found

We observed a stark, statistically significant increase in compliance with genetic testing from 34% to nearly 99% after the implementation of this genetic testing workflow. We also noted a similar improvement in patient compliance with post-test genetic counseling, which increased from 0% to 60%. Additionally, we found a marked increase in referral for genetic testing, from 78 patients to 474 patients after the implementation of on-site guideline-based genetic testing without a significant change in the underlying practice volume (see Table).

**“We observed a stark, statistically significant increase in compliance with genetic testing from 34% to nearly 99% after the implementation of this genetic testing workflow.”**

**Table.** Compliance With Genetic Testing and Subsequent Follow-up

|  | Off-site testing | On-site guideline-based testing | P value |
|--|------------------|---------------------------------|---------|
| Count, No.                               | 78               | 474                             | –       |
| Compliance with genetic testing, No. (%) | 26 (33.3)        | 468 (98.7)                      | < .0001 |
| Compliance with follow-up visit, No. (%) | 0 (0.0)          | 262 (60.0)                      | < .0001 |
| Turnaround time, d                       | 38               | 21                              | < .0001 |

## Limitations

Considering that randomization was not conducted, the study design certainly introduces a potential source of bias. Additionally, the smaller sample size of patients recommended for genetic testing prior to the implementation of this workflow may potentially be another source of bias. Furthermore, the small sample size of patients who complied with post-test counseling limits an interpretation of the effect of this process on patient compliance with genetic counseling. We also do not possess robust estimates for the total number of patients who ought to have received genetic testing prior to the introduction of guideline-based genetic testing.

## Interpretations for Patient Care

Nonetheless, our results underscore the importance of a comprehensive model for effectively delivering genetic testing and genetic counseling to prostate cancer patients. Considering the fundamental importance of genetic testing in the uro-oncological management

**“Considering the fundamental importance of genetic testing in the uro-oncological management of prostate cancer, this study presents a unique and significant contribution to the literature by outlining a successful model for providing genetic testing to prostate cancer patients.”**

of prostate cancer, this study presents a unique and significant contribution to the literature by outlining a successful model for providing genetic testing to prostate cancer patients. ■

## JU INSIGHT

# A Phase 2 Trial of Nab-paclitaxel in Combination With Anti-PD1 Therapy in Advanced Urothelial Cancer

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Tsung I, Green E, Palmbo P, et al. A phase 2 trial of nab-paclitaxel in combination with anti-PD1 therapy in advanced urothelial cancer. *J Urol.* 2023; 209(1):121-130.

## Study Need and Importance

Current first-line treatment for advanced urothelial carcinoma (aUC) is platinum-based (preferably cisplatin) combination chemotherapy. In the second-line setting, pembrolizumab immunotherapy is standard. Taxane chemotherapy had shown single-agent activity. We sought to evaluate the combination of nab-paclitaxel (NAB) and pembrolizumab in patients with cisplatin-ineligible or platinum-refractory aUC.

## What We Found

Of 36 response evaluable patients, the confirmed overall response rate was 50% and included 3 complete and 15 partial responses. Target lesion tumor shrinkage occurred in 30 of 36 patients during therapy (see Figure). At a median follow-up of 19.7 months, median duration of response was 4.4 months (95% CI: 4.0-8.6), median progression-free survival 6.8 months (95% CI: 4.4-not reached), and median overall sur-

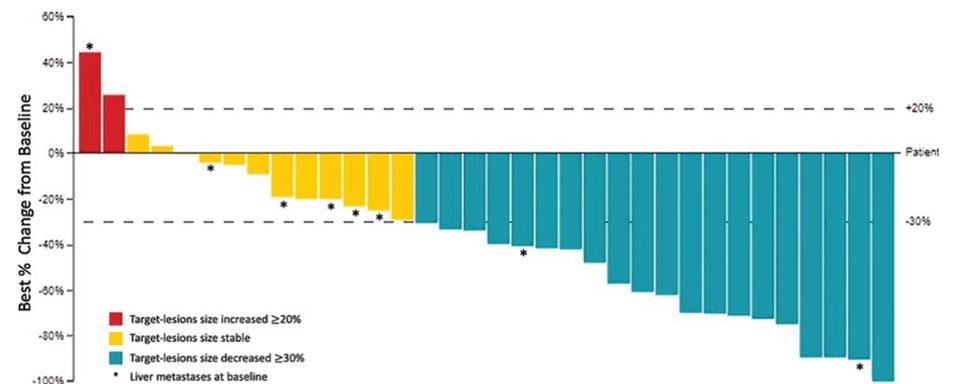


Figure. Waterfall plot of tumor response in patients with advanced urothelial carcinoma (N = 34).

“Of 36 response evaluable patients, the confirmed overall response rate was 50% and included 3 complete and 15 partial responses.”

vival 18.2 months (95% CI: 10.6-not reached). The starting dose of NAB was reduced due to excessive neuropathy. After the reduction in the NAB starting dose, therapy was well tolerated.

## Limitations

Study limitations include small size, single site, and single-arm de-

sign. Only 4 women were enrolled, and data on tumor biomarkers (programmed death-ligand 1 and comprehensive tumor genomic profiling) were incomplete.

## Interpretation for Patient Care

The landscape of treatment options for aUC continues to rapidly evolve with newer combination approaches such as antibody-drug conjugates with checkpoint inhibitors. Our study shows the combination of chemoimmunotherapy using NAB and pembrolizumab also has promising activity and can be an efficacious and feasible option for cisplatin-eligible or platinum-refractory aUC. Chemoimmunotherapy can potentially expand the repertoire of therapy options in later lines of treatment. ■