Best of the 2017 AUA Annual Meeting

Highlights From the 2017 American Urological Association Annual Meeting, May 12-16, 2017, Boston, MA

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KEY WORDS

Biomarkers • Prostate-specific antigen • Kallikrein • Microbiome • Stem cell therapy • Stress urinary incontinence • Zika virus • Reverse transcription loop-mediated isothermal amplification • Refractory overactive bladder • Meshectomy • Interstitial cystitis/bladder pain syndrome • Pudendal neuromodulation • OnabotulinumtoxinA • Medical expulsive therapy • Percutaneous nephrolithotomy • Disorders of sexual development • Bladder exstrophy • Glans groove

More than 2000 posters, abstracts, and videos were presented at the 2017 American Urological Association (AUA) Annual Meeting, held in Boston, MA, from May 12 to 16, 2017. The editors of *Reviews in Urology* have culled an enormous volume of information from this premier source and present the findings that are most relevant to the practicing urologist.

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Biomarkers for the Early Detection of Prostate Cancer

Diagnosis of prostate cancer is generally made by biopsy, which is prompted by elevated prostate-specific antigen (PSA) levels and/or abnormal digital rectal examination findings.[1,2] However, PSA has poor performance for the detection of cancer,[3,4] which has led to difficulty in determining who is at the greatest risk for the disease, and thus who will most likely benefit from prostate biopsy. Since the introduction of PSA into routine clinical practice in the late 1980s, multiple adjunctive serum and urine biomarkers have been developed. At the 2017 AUA conference, there were multiple studies of prostate cancer diagnostic biomarkers, including many novel markers.

Urine-based Tests

There are several urine-based biomarkers currently in use, including prostate cancer antigen 3 (PCA3) messenger RNA (mRNA),[5] *TMPRSS2-ERG* gene fusion, and the panel SelectMDx (MDxHealth, Irvine, CA), which measures mRNA of the genes *HOXC7*, *DLX1*, and *KLK3*.[6] Additionally, there are several multimarker panels that have been introduced in recent years, including ExoDx Prostate Intelliscore (Exosome Diagnostics, Cambridge, MA; includes exosomal RNA for *ERG*, *PCA3*, and *SPDEF*) and the Michigan Prostate Score (MiPS; includes PCA3 and *TMPRSS2-ERG* mRNA, and serum PSA).[6]

At the 2017 AUA meeting, Lebastchi and colleagues[7] reported their clinical experience with the MiPS. Patients with elevated PSA chose to undergo the test as an alternative to immediate biopsy. In a largely biopsy-naïve cohort of 149 men, only 49% of men ultimately underwent biopsy within the follow-up period. They found that MiPS scores were higher among those who underwent biopsy versus those who did not, and among those who had cancer on biopsy compared with those who had a negative biopsy result.

In a case-control study, Prophet and colleagues[8] assessed urinary concentrations of three different proteins previously identified to have different expression patterns across prostate cancer stages: TIMP1, serpinB1, and semenogelin2. They assessed those concentrations across four groups (n=40 for each): men without prostate cancer, and men with Gleason 6, Gleason ≥8, or metastatic prostate cancer. They found that TIMP1 levels were significantly higher in the control and Gleason 6 samples compared with the Gleason ≥8 and metastatic groups, serpinB1 levels were significantly higher in men with Gleason 6 disease versus Gleason ≥8 disease, and semenogelin2 levels were significantly higher in those with metastatic disease versus control subjects.

Serum-based Tests

Kallikrein-based Tests

Contemporary serum biomarkers are largely dominated by the kallikreins, including percent free PSA (%fPSA),[3] the Prostate Health Index (PHI; a compound marker consisting of total PSA, free PSA and [-2]proPSA),[9] and the 4KScore (OPKO Health, Miami, FL; includes total PSA, free PSA, intact PSA, and hexokinase 2).[6,10]

Tosoian and associates[11,12] examined the use of PHI density (PHI adjusted by prostate volume) to predict significant (≥ National Comprehensive Cancer Network low risk) cancer on biopsy in 118 men undergoing biopsy for elevated PSA. PHI density was found to have discriminative ability (area under the receiver operating characteristic curve [AUC] 0.84) that surpassed PSA (0.52), PSA density (0.70), %fPSA (0.75), and PHI (0.76). The investigators found that using a PHI density cutoff of 0.43 could avoid 38% of unnecessary biopsies at the cost of missing 2% of clinically significant cancers.

Punnen and coworkers[13] validated the 4KScore in a multicenter study in the Veterans Affairs system. In their study, the 4KScore was assessed for its predictive ability of Gleason ≥7 cancer in men undergoing biopsy. Their cohort included 366 men, 56% of whom were African American. The authors found that the 4KScore was superior to a base model combining age, digital rectal examination results, and PSA value (AUC 0.81 vs 0.74, respectively), and that the 4KScore performed similarly in African-American men and men who were not African American (AUC 0.80 vs 0.84).

Ishikawa and coworkers[14] developed a novel method of measuring serum levels of S2,3PSA, an aberrantly glycosylated PSA isoform. They used their assay to measure the ratio of S2,3PSA to free PSA in 103 patients with biopsy-proven prostate cancer and 50 patients with negative prostate biopsy results. They found that their assay had an AUC of 0.85 for the detection of any prostate cancer, compared with 0.66 for total PSA alone.

Klein and colleagues[15] reported a study using another kallikrein-based assay, IsoPSA (Cleveland Diagnostics, Cleveland, OH; also known as PSA/solvent interaction analysis). IsoPSA is a technique of measuring the spectrum of PSA isoforms present in a sample.[16] It is conducted using a two-phase aqueous system, in which bound PSA is measured in each phase; the ratios of the concentrations gives the composite structural index ("K"), which has been shown in the past to outperform PSA for the diagnosis of prostate cancer on biopsy.[17] In the present study, the authors measured IsoPSA in 226 patients undergoing biopsy for elevated PSA levels. Using multivariable logistic regression adjusting for age, they found that IsoPSA had an AUC of 0.82 for the diagnosis of Gleason ≥7 cancer.

Nonkallikrein-based Tests

Focusing on nonkallikrein markers, Tennstedt and associates[18] measured the serum concentrations of multiple proteins (CTSD, ICAM1, THBS1, OLFM4, TIMP1, and HYOU1) in men with elevated PSA values and enlarged prostates (≥35 mL) in order to predict cancer on subsequent biopsy. Of the 474 men in the study, 238 were diagnosed with prostate cancer on biopsy. Using logistic regression and receiver operating characteristics, they found that the combination of two proteins, CTSD and

THBS1, yielded an AUC of 0.83, which was compared with 0.65 for %fPSA. When those two proteins and %fPSA were combined, they reached an AUC of 0.85.

Taking an immunologic-based approach to cancer diagnosis, Freedland and coworkers[19] measured levels of 21 different autoantibodies against prostate cancer-derived peptides in order to predict the presence of cancer at initial biopsy. In 268 men, they found that the autoantibody panel, when combined with PSA and age, had an AUC of 0.73 and 0.74 for the diagnosis of any prostate cancer and Gleason score ≥7 cancer, respectively. Those were compared with AUCs of 0.55 and 0.61, respectively, for PSA and age alone. They found that their test would allow for 24.4% fewer biopsies at the cost of missing 4.9% of Gleason score ≥7 disease.

Alekseev and colleagues[20] measured plasma microRNAs in 188 patients with biopsy-confirmed prostate cancer and 57 patients without a concern for prostate cancer. Testing an array of thousands of microRNAs, they determined that a panel of six microRNAs (hsa-miR-155-5p, hsa-miR-619-5p, hsa-miR-6777-5p, hsa-miR-6085, hsa-miR-6511b-5p, and hsa-miR-6886-5p) was able to predict prostate cancer with an AUC of 0.91.

Miyoshi and associates[21] measured serum dehydroepiandrosterone (DHEA) levels in 203 men with PSA <10 ng/mL undergoing initial biopsy; 85 patients had prostate cancer on biopsy. For predicting Gleason ≥8 disease, they found that the combination of age, PSA, prostate volume, and DHEA level (AUC 0.81) outperformed age, PSA, and prostate volume alone (AUC 0.74).

Tissue-based Tests

ConfirmMDx (MDxHealth, Irvine, CA), is an assay measuring DNA methylation intensity of the cancer-related genes *GSTP1*, *APC*, and *RASSF1*.[22] Applied to the specimens of a prostate biopsy with negative result, the assay has been shown to predict the chance of a subsequent negative result.[23] Van Neste and associates[24] validated ConfirmMDx in a cohort of 237 African-American men. On follow-up biopsy (within 30 mo of the initial biopsy), 107 men were diagnosed with prostate cancer, 35 of whom had Gleason score ≥7. Using a test cutoff derived from an expected 18% chance of finding cancer on repeat biopsy, they found that their test had a negative predictive value of 91% and 96% for the detection of any cancer and Gleason ≥7 cancer, respectively.

These studies represent exciting inroads to developing and refining the next generation of prostate cancer biomarkers. With this development, and with greater integration of these markers into clinical practice, we hope to see a reduction in overdiagnosis and unnecessary prostate biopsies, and improved early detection of clinically significant disease. ■

[Sasha C. Druskin, MD, Alan W. Partin, MD, PhD]

From Microbiome to Genome: The Mysteries of Urologic Chronic Pelvic Pain Are Slowly Unravelling

The impact of the microbiome on urologic chronic pelvic pain (UCPP) was the buzz at the AUA meeting in 2016. In 2017, it was the turn of the genome. However, patients developing interstitial cystitis/bladder pain syndrome (IC/BPS) and chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) are much more complicated, and it appears that the microbiome may be implicated in genetically susceptible individuals with subsequent neurologic and neuromuscular changes manifested in biomarker and symptom patterns.

An elegant study from Allen-Brady and colleagues[25] examined 13 high-risk pedigrees (defined as having a statistical excess [$P < .05$] of IC/BPS cases among relatives who were hospital patients with banked tissue compared with expected number of cases using age- and sex-matched hospital rates for IC/BPS from the Utah population-based genealogy database resource) and found significant genome-wide linkage evidence on chromosome 3 (3p21-3q13). Other regions with suggestive evidence for linkage included areas on chromosome 1, 4, 9, and 14. Evidence presented by Walker and colleagues[26] described a unique mucosal gene expression profile which appeared to differentiate IC/BPS patients from control subjects (epithelial adherens junction signaling pathway), low anesthetic bladder capacity patients from high anesthetic bladder capacity patients (eukaryotic initiation factor 2 signaling pathway) and patients with Hunner lesions from those without lesions (differential expression analysis producing inflammatory disease). Takai and associates[27] explored the potential future of treatment options by investigating the effect of gene therapy with herpes simplex virus vectors encoding poreless TRPV1 or protein phosphatase 1α, a negative regulator of TrpV1, using a rat model of long-lasting cystitis induced by hydrogen peroxide. The potential for gene therapy in appropriate patients may indeed lie in the future.

So how do these genetic differences tie into the microbiome in patients with UCPP? Park[28] showed that next-generation DNA sequencing of urine after prostatic massage identified numerous clinically relevant bacteria that would likely have been missed using traditional urine culture methods,

and showed that CP and CP/CPPS is often polymicrobial. The presence of significant numbers of bacteria in 75% of the patients suggests that more patients suffer from the bacterial form of CP than previously estimated. A National Institutes of Health (NIH)-funded Multidisciplinary Approach to the Study of Chronic Pelvic Pain (MAPP) discovery site at Cedars-Sinai (Los Angeles, CA), led by Ackerman and associates,[29] showed evidence that fungi also appear to be involved. They showed differences in fungal microbiome among some patients with IC/BPS and overactive bladder (OAB). It is further postulated that there may be a genetic predisposition for such a fungal microbiome difference. Even gram-positive bacteria appear to have differential virulence properties that may lead to pain in susceptible mice, as noted in the case of the papers presented by Murphy and coworkers[30] and Mazur and coworkers.[31] Pain responses were shown to be dependent on the genetic background of the host and not on in vivo colonization differences between strains. Could the same phenomenon be happening in human patients? Histamine can increase intestinal permeability—causing a leaky gut—which prompts the body to initiate immune reactions, thereby causing autoimmune diseases, and can also lead to pain through a toll-like receptor-4 inflammatory response. Hessdorfer[32] postulated that histamine-producing bacteria of the *Enterococcus* and *Enterobacteriaceae* family in the gut and vagina could lead to pain in those organs. This ties into a provocative lecture given by Robert Hurst at the Society for Inflammation and Infection in Urology meeting on the role of organ crosstalk and increased permeability in IC/BPS.

The microbiome, genetic predisposition, and complicated interrelated neural pathways appear to work together to produce UCPP. All these systems have to be managed using a multimodal treatment strategy once we understand and can accurately diagnose an individual patient's genetic, microbiome, and neural contributions to their unique urologic pelvic pain. ■

[J. Curtis Nickel, MD]

Highlight in Voiding Dysfunction

Herein are summarized two podium presentations on the current status of stem cell therapy for women with stress urinary incontinence (SUI) and an abstract that won Best Poster award and was highlighted in an AUA Press Conference on detection of Zika virus in the urine.

Carr and colleagues,[33] at the highlight plenary session, presented the multicenter study by Dr. Omochowski that assessed the safety and efficacy of autologous muscle-derived cells for urinary sphincter repair (AMDC-USR) in women with SUI. Women who had three or more stress leaks over 3 days were randomized 2:1 to receive intrasphincteric injection of 150 × 106 AMDC-USR or placebo. A second injection 6 months after first treatment was allowed; 91 AMDC-USR and 50 placebo patients completed 1 year of follow-up and both groups had similar baseline characteristics. No AMDC-USR safety signals were identified and no urinary retention was reported. Due to an unexpectedly high placebo responder rate with the composite endpoint, enrollment was halted at 61% (150/246) of the planned study size. In post hoc analyses, 84% (37/44) of AMDC-USR patients with 50% incontinence episode frequency (IEF) reduction at 12 months also met this endpoint at 2 years. Carr and colleagues[33] concluded that, in women with SUI, AMDC-USR is safe and may provide durable reduction in IEF.

One question that always comes up in SUI research addresses women who still leak after sling or mesh surgery. This author's podium presentation (Carr and associates[34]) focused on post hoc analysis of three regulatory studies to look at effect of AMDC-USR therapy in women with recurrent or persistent SUI after continence surgery is described. The analysis includes data from women in studies who underwent continence surgery such as sling or bladder neck suspension, prior to enrollment, and had IEF three or more stress leaks over 3 days and ≥3 g weight on 24-hour pad test at baseline; 21 women who received AMDC-USR and prior SUI surgery were treated in open-label studies and 17 women were randomized 2:1 to receive 150×10^6 AMDC-USR (n=11) or placebo (n=6) in a double-blind trial. SUI was gauged by 3-day diaries at baseline and 1, 3, 6, and 12 months thereafter for all studies, and at 2 years in the randomized trial. Randomized trial patients were unblinded after 12-month visits.

The authors found that the baseline characteristics were similar in women in the open-label studies and also between the AMDC-USR and placebo groups in the randomized trial. In open-label studies, 67% (12/18) of women who completed their 12-month visit had ≥50% IEF reduction, 44% (8/18) had ≥75% IEF reduction, and 39% (7/18) reported one or no stress leaks over 3 days. Similarly, 12-month responder rates for the randomized trial AMDC-USR group were 72% (8/11) for ≥50% incontinence episodes reduction, 64% (7/11) for ≥75% incontinence episodes reduction, and 36% (4/11) for those with one or no

stress leaks per 3 days. There were no serious adverse events related to AMDC-USR and no urinary retention requiring catheterization was reported. AMDC-USR treatment effect appears durable: 100% (6/6) of patients with ≥50% incontinence episodes reduction at 12 months also met the endpoint at 2 years. In conclusion, AMDC-USR may be a novel, safe, durable therapy for the challenging patient population with recurrent or persistent SUI after continence surgery. Because this population likely has sphincter deficiency, results support the proposed mechanism of AMDC-USR action. Phase 3 trials are ongoing and continue to investigate the effect of AMDC in women with recurrent or persistent SUI after surgery

There is no bigger story in all of medicine over the past year than Zika virus infection, and there is an urgent need for a rapid assay because current testing can take 2 to 4 weeks. Lamb and coworkers[35] noted at the AUA Press Conference, "Our goal was to come up with a fast, accurate, and reliable urine test that is affordable and would be done at the point of care, so you would know your result before you left the doctor's office."

The objective of this study was to develop a urine diagnostic test that could be completed in <30 minutes. Urine samples spiked with Zika virus were tested by conventional real-time polymerase chain reaction (RT-PCR). Samples were also tested using a new methodology we developed that utilizes reverse transcription loop-mediated isothermal amplification (RT-LAMP). These techniques were also validated using samples from Zika virus-infected patients and mosquitoes. Isothermal amplification is faster and more specific than RT-PCR, and does not require trained personnel to read the results. It can also be performed with a heating pack, like the ones used by American troops to heat food packages in the field, whereas RT-PCR requires a thermal cycler. If the commercial version of the assay is approved, it will likely be inexpensive.

The results of the poster presented noted that RT-LAMP could specifically detect Zika virus in Zika virus-positive samples. This could be done in <30 minutes and did not require RNA extraction from the urine. Rapid point-of-care urine detection of Zika virus infection may allow for easy monitoring of potentially exposed individuals, especially pregnant women, couples wanting to conceive, or individuals with suspicious symptoms. Lamb and coworkers[35] noted that the assay development is supported, in part, by the Maureen and Ronald Hirsch family philanthropic fund. ■

[Michael B. Chancellor, MD]

Dr. Michael Chancellor at Beaumont Health System, Royal Oak, MI, is one of the inventors of AMDC technology. Dr. Chancellor receives royalty payments for the AMDC technology and payments for consulting from Cook MyoSite (Pittsburgh, PA), the sponsor of the study.

Female Urology/ Incontinence and Urodynamics

The 2017 AUA meeting delivered a number of interesting presentations related to female urology/ incontinence and urodynamics. Over 150 abstracts were included; Second Options Cases discussed total versus partial mesh removal, management of fistulas, and mixed incontinence, and Plenary Sessions included updates on recent AUA/ Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) guidelines. In all, 15 courses were offered, and outstanding attendance showed a strong interest for urology/incontinence and urodynamics in women among AUA attendees.

SUFU held a half-day meeting on the second day of the AUA; the central theme was urinary incontinence (UI) in women. The SUFU meeting included lectures on treatment of refractory OAB and management of IC/BPS, among others, but the surgical treatment of SUI in women appeared to be the focus of Program chair, Dr. Craig Comiter. These lectures, including one on management of the index patient, appeared to parallel the society's focus on SUI in 2017; the AUA/ SUFU guidelines on the surgical management of SUI were recently updated. Kobashi[36] reviewed the AUA/SUFU 2017 guidelines for the broader AUA audience during a packed plenary session, and teamed up with SUFU President Dr. Gary Lemack[37] to lead a new AUA course focused on the document. The guidelines and course give easy-to-follow, clear statements to guide the treatment of SUI in women. This document is available online through the AUA website.

SUFU has also been developing a clinical care pathway and patient roadmap, in addition to other support, to assist with the management of OAB. This work was highlighted by Brucker and colleagues.[38] Highlighted were the ways in which the current treatment of OAB can be suboptimal, and how the newly developed SUFU OAB Clinical Care Pathway can improve outcomes, enhance adherence, and increase patient satisfaction. The well-attended course gave attendees the opportunity to actively participate through case-based presentation.

A lively crossfire session that centered on partial versus radical meshectomy for vaginal pain was presented. Raz and Twiss[39] defended the radical meshectomy

approach, whereas Goldman and Takacs[40] disagreed with it. The attendees were active during the session, asking questions and sharing experiences, demonstrating that clinicians have different points of view on this topic and more evidence is still needed.

There were several exciting presentations with retrospect data about mesh complications. Although these works will help add new information to our understanding about outcomes, more clarity on the extent of mesh removal is needed. One retrospective study[41] described clinical history and outcomes after vaginal mesh removal. A total of 84 patients underwent vaginal mesh removal; 83% were deemed improved from their status before surgery—preoperative symptoms that improved were mesh erosion ($P < .0001$), vaginal pain ($P < .0001$), vaginal bleeding ($P = .0028$), vaginal discharge ($P = .0127$), dyspareunia ($P = .0024$), and pelvic pain ($P = .0005$). In all, 35% of patients required one or more reoperations, with three being the highest number of revisions needed. The extent of mesh excision was not reported in the abstract. Another mesh-related abstract[42] was a retrospective case series of consecutive patients undergoing removal of mesh graft for treatment of symptomatic mesh-related complications from 2011 to 2016; in the abstract, it is noted that it was a mixed population of partial or complete mesh excision. A total of 147 patients underwent excisions with 14-month follow-up. Before surgery 80% of patients reported pain and 83% had mesh exposure or erosion; 68% improved after surgery.

One of the interesting studies about prolapse[43] suggested that the objective was to determine if frailty was a predictor of the type of prolapse surgery and the odds for postoperative complications. It was a retrospective cohort study that analyzed data from 2005 to 2013. Age was more strongly associated with colpocleisis than frailty; however, frailty was more strongly associated with postoperative complications for all pelvic organ prolapse surgeries.

Chancellor and colleagues presented a novel research method for discovery of urine that engaged multiple stockholders for biomarker development.[44] Samples from men and women from 46 US states were submitted. Analysis discovered three proteins with highly significant difference between IC with ulcers versus IC without ulcers and healthy control subjects. Crowdsourced research can help advance IC/PBS biomarker development and likely has application to other disease states.

In an animal study presented by Ashikari and colleagues,[45] tramadol was investigated for its effects on the urethral continence reflex by using a rat model with SUI induced by vaginal distension with sneezing. Tramadol enhanced urethral baseline pressure by 79%, indicating that it is effective for enhancing the active urethral continence reflex at the spinal level during sneezing.

Another interesting presentation addressed urinary sphincter repair for recurrent or persistent SUI after continence surgery.[34] In this study, the authors described the effect of AMDC-USR on women with recurrent or persistent SUI after continence surgery. The analysis included women in the Cook Myosite-sponsored SUI studies with prior continence surgery who still have SUI; 100% (6/6) of women with ≥50% IEF reduction at 12 months met the endpoint at 2 years. They concluded AMDC-USR may be a novel, safe, and durable therapy for the challenging patient population with recurrent or persistent SUI after continence surgery.

This section also included the topic of OAB, a prevalent condition affecting many of our patients. Chermansky and colleagues,[46] presented an abstract that sought to define the ideal stimulation duration in refractory OAB patients who underwent transcutaneous adhesive pad electrodes (FootStim™; Coulter Translational Research Partners, Pittsburgh, PA) for either 30 minutes or 3 hours daily for a week; 33 women completed the study, of whom 19 underwent stimulation for 3 hours and 14 underwent stimulation for 30 minutes. The response rates were 16/19 (84%) in the 3-hour group and 10/14 (71%) in the 30-minute group. In the 3-hour group IEF decreased from 3.7 to 2.8 leaks/day ($P = .04$) and urgency frequency decreased from 7.6 to 6.6 episodes/day ($P = .03$). Daytime voiding frequency (n=8) and nocturia (n=7) decreased in the 3-hour group. In contrast, only incontinence frequency decreased in the 30-minute group, and this dropped from 5.3 to 4.3 leaks/d ($P = .03$). In the 30-minute group urgency frequency improved in two, nocturia improved in one, and daytime urinary frequency improved in none. FootStim effects persisted in both groups for 4 days after treatment ended. Both durations decreased urge UI frequencies; however, the 3-hour group had better improvement of all OAB symptoms. This may have implications in developing new treatment options utilizing neuromodulation or electrical stimulation.

Another presentation worth highlighting[47] studied the outcomes between pudendal versus sacral neuromodulation compared with 1.2 versus 2.6 years of follow-up, respectively. It was a single-institution prospective cohort analysis. History, pain scores (0-10; none to severe), Global Response Assessment, Interstitial Cystitis

Symptom/Problem Index, and OAB symptom severity/health-related quality of life collected at baseline, 3, and 6 months, and 1 and 2 years, were analyzed with descriptive statistics and repeated measures over 1 year. Both groups experienced modest but similar improvements in pelvic pain. Pudendal neuromodulation was effective in those who failed sacral neuromodulation and was used preferentially in patients with a primary diagnosis of pain.

Finally, an abstract about OAB and onabotulinumtoxinA (onabotA) showed the risk of patients needing clean intermittent catheterization (CIC). Nitti and investigators[48] determined the risk of CIC, and efficacy and quality of life outcomes after treatment with onabotA. They analyzed a total of 1177 subjects. Patients treated with onabotA, 100U in treatment 1 and placebo patients who received open-label onabotA in treatment 2 were grouped by age. Assessments included incidence and duration of CIC, mean and percentage change from baseline in UI episodes, proportions of patients with ≥50% UI reduction, positive response (urinary symptoms improved/greatly improved) on the treatment benefit scale (TBS), and change from baseline in Kings Health Questionnaire (KHQ). CIC rates after onabotA treatment were lowest in the <40-year-old group (1.1%) and increased slightly with age. An important treatment response was noted in all groups including substantial reductions in UI episodes/d, and percentage change in UI. High proportions of patients in all groups achieved ≥50% UI reduction, a positive TBS response, and improvements from baseline in KHQ domain scores. Conclusions from this cohort of onabotA-treated OAB patients who had substantial reductions in UI, improvements in quality of life, and treatment benefit was that the risk of CIC is low but does increase slightly with age. ■

[Maria E. Arcila-Ruiz, MD, Benjamin M. Brucker, MD]

Nephrolithiasis

There were a number of presentations delivered at the 2017 AUA meeting on kidney stones, which covered clinical translational and basic science domains. A review of several of the presentations introducing new and pertinent information to the field of nephrolithiasis follows.

The effectiveness of medical expulsive therapy (MET) to promote ureteral stone passage has recently come under challenge by the results of recent large randomized controlled trials. Meltzer and associates[49] presented the results of a large, multicenter, NIH-sponsored, randomized placebo-controlled trial assessing the effectiveness of tamsulosin to facilitate stone passage in patients harboring ureteral stones. The majority of stones were in the distal ureter and the mean stone diameter was 3.8 mm. There was no difference in stone passage at 28 days as defined by stone visualization or capture at 28 days (52% for tamsulosin, and 49% for placebo). The question that remains is whether MET is fact or fiction. This study points to the latter.

Stone-free status based on the absence of stones on computed tomography (CT) imaging is considered the most transparent method for reporting this outcome. Unfortunately, the literature is replete with studies using the misnomer term *clinically insignificant fragments*, and studies using less sensitive or specific imaging methods, such as plain radiography or ultrasonography. York and associates[50] reported their stone-free rates based on postoperative low-dose CT imaging in 150 patients (202 renal units) with isolated renal calculi treated with flexible ureteroscopy. The stone-free rate per renal unit was 69%. Important consideration in assessing these results is that low-dose CT is less sensitive in patients with higher body mass index (BMI) (>30 kg/m^2) and for the detection of small stones. Thus, the "true" stone-free rate may actually have been lower. The latter could have been a reason for the lower stone-free rate reported by Canvasser and colleagues[51]: 55%, for stones in 84 renal units evaluated with a standard CT protocol. Both groups should be complimented for their transparency.

Transfusion-dependent hemorrhage is a risk associated with percutaneous nephrolithotomy (PCNL). Patients need to be informed of this risk, as well as the risk of other potential complications. Rivera and colleagues[52] reported that 3.3% of 1448 patients subjected to PCNL required blood transfusion. In a multivariate analysis, diabetes and performance of bilateral PCNL were determined to be risk factors for transfusion. This information can be used during preoperative patient counseling to stratify transfusion risk with patients.

Ureteral stone impaction can make ureteroscopic stone removal more challenging and lengthen the procedure. It also is a risk factor for the development of ureteral stricture. Thus, preoperative knowledge of stone impaction may improve surgical scheduling time accuracy, and can be used for preoperative patient counseling. Parkhomenko and associates[53] reported on preoperative CT imaging characteristics that were predictive of stone impaction. These included higher stone volume, greater degrees of hydronephrosis, and increased density (attenuation) of the ureter distal to the stone.

Patients presenting with ureteral stones are initially most commonly

evaluated in an emergency room and many are discharged. There is a risk that patients may not seek follow-up after such encounters. Alruwaily and coworkers[54] reported on automated email notification of patients seen and discharged from the emergency room with ureteral stone to urologists in their department providing care for those afflicted with this problem. This reduced the risk of losing patients to follow-up, emergency room return visits, and time to surgery. This program improved the delivery of care to this cohort.

In patients with recurrent kidney stones and in complex (high-risk) first time-stone formers, 24-hour urine stone risk testing is utilized. It has been reported that many patients do not accurately collect these urine specimens. Accuracy has been assessed by urinary creatinine indexed to body weight. Leva and associates[55] used lean body mass, which is better correlated to urinary creatinine than body weight, as an indicator of collection accuracy in a group of 1319 patients with stones. The accuracy improved from 62% using the standard methodology to 85% when lean body mass was employed. Clinicians should consider the latter indicator of accuracy, as this will reduce the need for recollections.

Patients subjected to PCNL have postoperative pain, and various interventions to reduce this response have been evaluated, with mixed results. Parkhomenko and colleagues[56] performed a randomized, prospective, controlled trial assessing the impact of performing acupuncture 1 hour prior to PCNL. This resulted in a reduction in postoperative pain and narcotic utilization.

Sepsis is a risk of PCNL, even in those with negative preoperative urine culture results. There have been studies demonstrating that a 1-week course of antibiotic therapy in this cohort reduced sepsis and systemic inflammatory response syndrome. Bechis and associates[57] undertook a multicenter, randomized trial in low-risk patients undergoing this procedure comparing a 1-week preoperative course of nitrofurantoin versus no administration. Low risk was defined as a patient without a recent urinary tract infection and devoid of catheters, stents, or nephrostomy tubes before PCNL. There was no significant difference in rates of infectious complications.

Silent ureteral obstruction can develop after ureteroscopic stone removal and was the basis for the AUA clinical effectiveness protocol recommending postoperative imaging after this procedure. Adherence to this recommendation has not been previously assessed. Ahn and coworkers[58] used a private employer-based insurance database to assess compliance with this recommendation. Only 26% of patients underwent an imaging study that could identify obstruction (ultrasound, CT, or intravenous pyelogram) within 3 months of the procedure.

Hyperoxaluria is a recognized risk factor for the development of calcium oxalate kidney stones. Youssef and associates[59] reported that the prevalence of hyperoxaluria is increasing and that it is linked to obesity. Wood and colleagues[60] reported a significant positive correlation with BMI and urinary oxalate excretion in stone formers that further supports this association. In addition, they found a positive correlation with oxalate excretion and glycated hemoglobin levels, linking this to diabetes. Increased urinary oxalate excretion has been reported in patients with diabetes. These associations may be due to increased endogenous oxalate synthesis. Wood and investigators[61] reported increased endogenous oxalate synthesis and urinary oxalate excretion in three different murine models of obesity and diabetes.

Increased climate temperature has been associated with the risk of developing kidney stones. This has been attributed to dehydration in individuals exposed to high environmental temperatures. Tasian and colleagues[62] found that this relationship is stronger in men and attribute this to increased evaporative water loss. This study was comprised of residents of South Carolina. Dallas and associates[63] demonstrated that the positive association between environmental temperature and stone risk in California was only present in areas of high precipitation.

Monocyte and macrophage dysfunction have been hypothesized to be involved in kidney stone formation. Yarlagadda and colleagues[64] exposed a cultured human monocyte cell line to calcium oxalate crystals and found that this produced mitochondrial dysfunction and oxidative stress. Dominguez-Gutierrez and associates[65] exposed cultured primary human monocytes to calcium oxalate and apatite crystals, and found a differential response: differentiation into inflammatory macrophages with calcium oxalate and tissue healing-type macrophages with apatite. Unno and colleagues[66] exposed inflammatory macrophages harvested from the cortical collecting ducts of mice to calcium oxalate crystals. This promoted organelle damage and autophagy.

These studies highlight the advances in care of patients with nephrolithiasis. In addition, they clarify the impact of environmental temperature. The influence of oxidative stress and monocyte/macrophage are also further elucidated. ■

[Dean G. Assimos, MD]

AUA/Society of Pediatric Urology Meeting

The Society of Pediatric Urology (SPU) once again held its annual meeting in conjunction with the 2017 AUA annual meeting. There were 3 full days of pediatric urology education with more than 100 abstracts presented. The scientific program covered a wide range of topics, including disorders of sexual development (DSD), hypospadias, fetal urology, postnatal hydronephrosis, undescended testis, and posterior urethral valves. In addition, there were sessions on pediatric genitourinary tumors, trauma, and renal transplantation, as well as voiding dysfunction and neurogenic bladder. Ritchey[67] discussed the use of partial nephrectomy in patients with unilateral Wilms' tumor. Special breakout session topics included congenitalism and the Pediatric Urology Oncology Workgroup. deVries[68] presented the John Duckett Memorial Lecture entitled "International volunteerism: hands across the world." Dr. deVries is an internationally known leader in pediatric urology volunteer efforts and started her nonprofit, IVUmed in 1994. deVries' programs provide medical care to children in Asia, Latin America, Africa, and the West Bank in Israel.

The International Bladder Exstrophy Consortium: A Model for Sustained Collaboration (Clinical Prize Winner)

Joshi and colleagues[69] reported on an international surgical collaboration between 2009 and 2015 using the complete primary repair of exstrophy (CPRE), the modern staged repair (MSRE), and Mainz II ureterosigmoidostomy (US) as surgical therapies. The entire cohort responded to a comprehensive examination and administration of the International Consultation on Incontinence Modular Questionnaire (ICIQ) in 2016. Almost 75% (57/75) returned for the comprehensive follow-up in 2016. The total group of 75 patients included those with bladder exstrophy (59) and isolated epispadias (16) who underwent CPRE (45 [76%]), MSRE (11 [19%]), and US (3) at a mean age of 3.1 years (CPRE) and 9.3 years (US).

Complications occurred including dehiscence (5) and penopubic fistula (5). Penile ischemia occurred in one undergoing US, and two had ischemia after pubis closure that was resolved by leaving a 1.5-cm diastastis. Vesicoureteral reflux occurred in 72% and 35.3% had renal scar/dysplasia. Urodynamic studies found a median bladder capacity of only 65 mL. Of 45 children responding to the ICIQ, 15 were always incontinent, 12 were incontinent "once a day," and 10 noted incontinence 2 to 3 times per week. Of the US group, two of three had evidence of upper tract changes.

The authors conclude that bladder exstrophy can be surgically treated in a resource-deprived center, assuming there is consistent international collaboration with a skilled host surgical team. Postoperative evaluation must follow a systematized algorithm and compliance with follow-up is mandatory. Reconstruction can be successfully performed in older children. Incontinence rates remain high, with the trade-off being preservation of the upper tracts. In those undergoing US, continence rates are high, with the trade-off of the highest rates of upper tract changes.

Increasing the Diagnosis Rate in Patients with Disorders of Sex Development

Gatti and investigators[70] studied ways to increase the diagnosis rate in patients with DSD. 46, XY DSD includes conditions that vary from ambiguous genitalia (undervirilized males) to female phenotype. The genetic and molecular etiologies are varied and fewer than 50% of these patients have a molecular diagnosis. Next-generation sequencing (NGS) technology has increased diagnoses in other diseases and studies suggest that NGS may be useful in the molecular diagnosis of DSDs.

Comprehensive genetic testing, including routine karyotyping, targeted genetic testing, microarray testing, custom genetic panels, and whole exome sequencing, were used for diagnosis in patients with 46, XY DSD who were enrolled in a DSD registry from 2008 to 2014.

A total of 53 patients with 46, XY DSD underwent testing that included whole exome sequencing if traditional genetic testing did not determine a molecular diagnosis. Overall, 60% of patients received molecular diagnoses. Of the 43 patients who required all available genetic testing, 76% received a molecular diagnosis.

The authors show that NGS testing results in a higher rate of molecular diagnoses than more traditional genetic testing for undervirilized males with 46, XY DSD. Whole exome sequencing may be useful for some patients who receive no diagnosis using traditional testing, whereas others may only be identifiable using emerging epigenetic tests.

Glans Groove, Not Preoperative Testosterone Stimulation, Is the Main Risk Factor for Complications After Post-tubularized Incised Plate Repair

Braga and colleagues[71] reported on the main risk factors for complications following a tubularized incised plate (TIP) repair. Risk factors for complications following TIP repair were evaluated, including glans groove, urethral plate (UP) quality, and preoperative testosterone stimulation (PTS). A prospective study evaluated TIP repairs from 2008 to 2016. The primary outcome was postoperative complications, including fistula, glans dehiscence, and meatal stenosis. Other factors, including age at repair, modified Glans-Urethral Meatus-Shaft (GMS) score, PTS, regional block, ventral curvature, and complications, were recorded. GMS score, calculated using glans groove (deep/moderate and shallow/absent), UP characteristics (robust vs poor spongiosum), meatal location, and ventral curvature (<30°, 30°-70°, >70°) ranged from 4 to 11 (worst).

The meatal location of the 312 consecutive TIP repairs were distal in 235 (75%), midshaft in 48 (15%), and proximal in 29 (9%). Median age and follow-up were 16 (3-171) months and 16±15 months, respectively. PTS was given to 26% and the GMS score was higher in the PTS group versus the group that received no PTS (7.5±1.6 vs 5.4±1.3; $P < .01$) preoperatively; the mean GMS score for PTS patients decreased at the time of surgery but was higher than the group that received no PTS (6±1.4 vs 5.5±1.3; $P < .01$). The complication rate was 12% overall (9% distal, 17% midshaft, 31% proximal).

Statistical analysis showed that, contrary to prior studies, glans width and PTS were not independently associated with complications but a combination of glans groove depth and UP quality was the main independent risk factor associated with TIP complications ($P = .01$).

Interrater Reliability in Interpretation of Neuropathic Pediatric Urodynamic Tracings: An Expanded Multicenter Study

Dudley and coworkers[72] have expanded their recently published study showing moderate interrater reliability for six similarly trained pediatric urologists at a single institution to include pediatric urologists from the Centers for Disease Control and Prevention Urologic and Renal Protocol for the Newborn and Young Child with Spina Bifida to determine if the initial findings are replicated across multiple institutions.

The investigators used REDCap (Research Electronic Data Capture) and developed an anonymous survey with 20 clinical scenarios from patients with neuropathic bladder treated from 2014 and 2015. Each scenario contained the patient history and one urodynamic tracing, including bladder capacity, compliance, and end-fill detrusor pressure, as well as a fluoroscopic image.

Fourteen pediatric urologists at seven institutions completed the survey (82% response rate). Individual tracing variables showed wide ranges of agreement, whereas substantial agreement was observed for fluoroscopic bladder shape. Moderate agreement was noted for bladder safety, end-fill detrusor pressure, and bladder capacity. Electromyography synergy and presence of detrusor overactivity had only fair agreement.

The authors concluded that there is wide interrater reliability (across institutions and within institutions) in the interpretation of pediatric urodynamic tracing components, especially electromyography activity and detrusor overactivity. Standardization is needed and the way to achieve this remains the real challenge. ■

[Ellen Shapiro, MD, FACS, FAAP]

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