
Best of AUA 2018
Studies in San Fran span wide-ranging clinical, policy topics

Urologists take steps to stem the crisis

ROBOTICS
Surgery-related injuries are down; first study on a new system for RP released

ARTIFICIAL INTELLIGENCE
AI may improve bladder cancer staging and help determine who needs a prostate MRI

PROSTATE CA SURVEILLANCE
Men's anxiety lessons over time; phi plus mpMRI better than either alone for predicting grade reclassification

T hree new clinical guidelines, potentially practice-changing advances in robotics and artificial intelligence, and research on public health issues such as opioid abuse were among many highlights of the AUA annual meeting in San Francisco.

Health policy and practice management in a changing healthcare landscape, the impact of FDA actions on testosterone replacement and sling surgery, the pros and cons of prostate cancer screening and surveillance, and a new focus on care of transgender patients were also high-interest topics.

In this article, Urology Times recaps AUA 2018 with our report of the meeting’s annual take-home messages. Messages have been edited for space, and some topics are covered exclusively online. For the full report, visit urologytimes.com/take-homes.

New nmCRPC agent shows rapid PSA decline

Treatment also associated with significant extended median metastasis-free survival

Cheryl Guttmann Krader | UT Contributing Editor

SAN FRANCISCO—Treatment with apalutamide (Erleada) resulted in a rapid and substantial decline in PSA, and greater magnitude of PSA decline correlated with improvement in several oncologic endpoints, results from the phase III SPARTAN study showed. In addition, analyses of PSA data collected in the study confirm that a shorter PSA doubling time (PSADT) is a poor prognostic factor for men with...
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The imaging gap in stone disease: Whose fault is it?

STEPHEN Y. NAKADA, MD
Dr. Nakada, a Urology Times editorial consultant, is professor and chairman of the department of urology, University of Wisconsin, Madison.

At this stage, it is generally accepted that urolithiasis is a chronic disease. The recurrence rates, the confounded and controversial “stone-free” rates, the use of shock wave lithotripsy, and even dusting in urology have in total led to the need for more responsible follow-up imaging of our stone patients. Fortunately, the AUA guidelines are clear on this, and Dauw and associates recently reported a clinical gap in this matter, to the tune of 52% (48% get imaged) in the Michigan collaborative database (see page 4).

This report and others bring up several questions: Do the urologists not order the tests, or do patients not show up for the tests? Are finances to blame, insurance coverage, or even distance to care? Is this more common in big group practices or smaller practices? Are patients afraid of ionizing radiation or concerned with rising health care costs, or too busy to make time for testing? Moreover, are patients so disgruntled with their stent pain, or time away from work, that they choose not to follow up as a result?

So what is the solution? At first glance, a lower cost, simple approach would be best. At this point in time, the urology community has struggled to offer this. In addition to imaging gaps, what about medical management of stones? This is also time consuming and costly, and Hollingsworth reported an even larger “gap” between clinical practice and the guidelines (J Urol 2015; 193:885-90). It is my opinion that we must better identify patients with higher risk factors for recurrence and follow them more effectively.

Better use of patient and family education is another important area of improvement to bridge the guidelines gap in managing stone patients. In today’s medical world, there must be a compromise between what is recommended by the guidelines and what is possible in a given clinical scenario, and in my view this may be the new “best possible” care.

From the Board

We must better identify patients with higher risk factors for recurrence and follow them more effectively.

Send your comments to Dr. Nakada
c/o Urology Times, at UT@advantara.com

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From the Board

The imaging gap in stone disease: Whose fault is it?
‘Imaging gap’ seen in post-URS patients

Laird Harrison
UT Correspondent

SAN FRANCISCO—Many urologists don’t follow guidelines calling on them to image their patients after ureteroscopic stone treatment, researchers say.

“We don’t know how patients do if we don’t image them postoperatively. If you leave stones behind, patients typically need care down the line,” said first author Casey A. Dauw, MD, assistant professor of urology at the University of Michigan, Ann Arbor, told Urology Times.

“We feel this is an imaging gap,” said Dr. Dauw, who reported the findings at the AUA annual meeting in San Francisco.

“We don’t know how patients do if we don’t image them postoperatively,” he said. “We need to know our outcomes if we want to be the best at what we do. If you leave stones behind, patients typically need care down the line.”

To determine how well clinicians are following the guideline, Dr. Dauw and his colleagues analyzed data from the Michigan Urologic Surgery Improvement Collaborative Reducing Operative Complications from Kidney Stones (MUSIC ROCKS), a statewide quality improvement collaborative.

Supported by Blue Cross Blue Shield of Michigan, trained abstractors at each practice enter clinical and operative data into a central registry, Dr. Dauw explained. About 44 practices comprising more than 90% of practicing urologists in Michigan participate in MUSIC, he said. MUSIC ROCKS includes 52 urologists from 11 practices in Michigan.

This registry prospectively collected clinical data for patients undergoing ureteroscopic stone treatment, including the number who underwent ultrasound, x-ray, or CT within 60 days.

The authors identified 2,850 patients who underwent the procedure between June 2016 and January 2018. Of these, 48% had postoperative imaging studies, of which 55% were x-rays, 12.9% were ultrasound, 10.1% were CT, and 13.0% were multiple studies.

**Imaging more likely in complex cases**

Patients were more likely to undergo imaging if they had large stones, renal location of stones, or preoperative stents or if a ureteral access sheath was used.

These findings suggest that imaging was more likely to be performed postoperatively in more complex cases, said Dr. Dauw.

But the authors couldn’t find any evidence that the type of imaging varied with such factors.

“As far as correlating with more aggressive imaging like CT scans, we didn’t find any correlation whatsoever,” he said.

The use of postoperative imaging varied widely across the participating practices, with some imaging more than three-fourths of patients and some imaging fewer than one-fourth.

The findings offer an opportunity to improve the quality of care for patients with urinary stone disease in Michigan, Dr. Dauw concluded.

“Our goals going forward are to try to increase imaging appropriately following ureteroscopy,” he said.

But he anticipated challenges.

“Our challenge will be to understand what the right frequency of postoperative imaging should be. We can make a compelling argument that if we are going to achieve our goal of being the best place in the world for kidney stone care, we need to know our outcomes, and one of the ways to do that is to image postoperatively.”

**FIGURE / Post-URS imaging by modality**

A recent multicenter clinical trial revealed no significant support for the use of the alpha-blocker tamsulosin (Flomax) for kidney stones.

The results, published in JAMA Internal Medicine (June 2018 [epub ahead of print]), found no significant effect of patient-reported passage or capture of the stone.

“There is no known medication for helping patients pass kidney stones,” said first author Andrew Meltzer, MD, of the George Washington University School of Medicine and Health Sciences, Washington.

Current guidelines by the AUA call for all patients with stones to receive tamsulosin to help facilitate passage.

“We will likely have to change the guidelines regarding which groups of patients should receive the medication,” Dr. Meltzer said.

During the 6-year trial, patients were randomized to treatment with either tamsulosin, 0.4 mg, or matching placebo daily for 28 days, with few patients reporting stone passage.

The study was funded by the National Institute for Diabetes and Digestive and Kidney Diseases.
Baseline PSA linked with immunotherapy outcomes

Cheryl Guttman Krader
UT Contributing Editor

CHICAGO—Findings from a phase IV registry study are consistent with phase III study data in showing an association between baseline PSA and outcomes in men with asymptomatic/minimally symptomatic metastatic castrate-resistant prostate cancer (mCRPC) treated with sipuleucel-T (Provenge).

The research was presented at the American Society of Clinical Oncology annual meeting in Chicago. It included data from 1,886 men enrolled in PROCEED, a multicenter, open-label observational study of patients being treated with the autologous cellular immunotherapy in the real-world clinical practice setting. Overall survival, time to first anticancer intervention, and time to death due to disease progression were analyzed after stratifying patients into quartiles according to baseline PSA.

For men in the lowest PSA quartile (≤5.27 ng/mL), which was used as the reference group, median (range) time to overall survival was 48 months (range, 44-51 months), median time to first anticancer intervention was 10 months (range, 9-12 months), and median time to death due to disease progression was 57 months (range, 49-not estimable). Pairwise comparisons showed that for each endpoint, the outcome was significantly worse for men in the second (>5.27 to ≤15.08 ng/mL), third (>15.08 to ≤46 ng/mL), and fourth (>46 ng/mL) PSA quartiles than in the reference group.

“PROCEED is not a randomized trial, and there is lead time bias inherent in the registry’s design. Therefore, we cannot use the findings from this analysis to make any conclusive statements about the prognostic significance of PSA for outcomes with sipuleucel-T,” said lead author Oliver Sartor, MD, C.E. & Bernadine Laborde Professor for Cancer Research, Tulane Medical School, New Orleans. “This analysis has strengths, however, in that it includes long-term follow-up for a large patient cohort, and the trend it found for longer overall survival among men in the lowest PSA quartile is concordant with that seen in an exploratory analysis of data from the phase III controlled IMPACT (Immunotherapy for Prostate Adenocarcinoma Treatment) trial.

“Intriguingly, the current analysis also showed that some men in the lowest quartile did very well after starting sipuleucel-T. About 30% of patients in that subgroup went 2 years without requiring additional anticancer treatment and about 40% were still alive after 5 years,” he told Urology Times.

Dr. Sartor pointed out that PSA values for men enrolled in the phase III IMPACT study were much higher than those of men in PROCEED. Cut-offs for the four PSA quartile groups in IMPACT were ≤22.1, 22.1 to 50.1, 50.2 to 134.1, and >134.1 ng/mL, respectively. The analysis of IMPACT data showed that sipuleucel-T extended median overall survival compared with control by 13 months among men in the lowest PSA quartile, 7.1 months among those in the second PSA quartile, and 2.8 months in the highest PSA group.

Patients enrolled in PROCEED received sipuleucel-T per label recommendations—three infusions at 2-week intervals. The patients included in the analysis presented were enrolled in PROCEED between January 2011 and January 2017. They had a median age of 72 years, and the majority were Caucasian (87%). Median follow-up was approximately 47 months, approximately two-thirds of the enrolled men died during available follow-up, and approximately three-fourths of the deaths were due to mCRPC progression.

Few differences among PSA quartiles

Comparisons of patient demographics, baseline disease characteristics, and history of prior prostate cancer treatment identified few major differences among PSA quartile groups. The highest PSA quartile had a higher percentage of African-Americans compared with the lowest PSA quartile group as well as a higher number of men with bone and other metastases. Compared with the lower PSA quartile, a lower percentage of men in the higher PSA quartile group had prior radical prostatectomy and radiation therapy. Patients with a higher baseline PSA more often had prior anticancer therapy.

Identifying factors that correlate with better overall survival in men treated with sipuleucel-T is the subject of ongoing research. Dr. Sartor said that in a paper presented at the 2017 AUA annual meeting in Boston, he reported an analysis of PROCEED data that showed median overall survival for sipuleucel-T-treated men was significantly longer among African-Americans compared with matched Caucasian patients, and the race-related difference was particularly seen among men in the lowest PSA quartile.

Dr. Sartor is a consultant to Dendreon and other companies that market treatments for prostate cancer. For a full list of disclosures, go to bit.ly/PROCEEDdisclosures.

Apalutamide prolongs time to mets in nmCRPC

Treatment benefit evident regardless of metastasis site, data from phase III analysis show

Cheryl Guttman Krader
UT Contributing Editor

CHICAGO—Apalutamide (Erleada) treatment in men with nonmetastatic castrate-resistant prostate cancer (nmCRPC) significantly improves metastasis-free survival (MFS), and its benefit is evident regardless of the site of metastasis, according to a post-hoc analysis of data from the SPARTAN phase III clinical trial data presented at the 2018 American Society of Clinical Oncology annual meeting.

SPARTAN randomized 1,207 men with nmCRPC who were at high risk for developing metastasis (defined by having a PSA doubling time ≤10 months while on continuous androgen deprivation therapy) 2:1 to continuous daily treatment with apalutamide or matching placebo. Metastasis-free survival was analyzed as the primary endpoint, and the results showed that compared with placebo, apalutamide treatment reduced the relative risk of metastasis by 73% and delayed time to metastasis by a median of approximately 2 years (16.2 vs. 40.5 months).

The new analysis showed that treatment with apalutamide did not alter the pattern of metastasis.
The finding that apalutamide consistently prolonged time to metastasis regardless of its anatomic site reinforces the clinical benefit of treatment with this androgen receptor inhibitor.

MATTHEW R. SMITH, MD

APALUTAMIDE continued from page 5

sis. In both study arms, first metastasis occurred at a single site, with bone being the most common anatomic location followed by lymph nodes and viscera. Across the three anatomic sites, apalutamide consistently provided a statistically significant benefit for extending the time to metastasis. (Also see, “New nmCRPC agent shows rapid PSA decline,” page 1.)

“The FDA approval of apalutamide for the treatment of nmCRPC was precedent setting because it was the first time the agency granted an approval to an oncology drug based on improvement in MFS,” lead author Matthew R. Smith, MD, professor of medicine at Harvard Medical School, Boston, told Urology Times. “In SPARTAN, MFS was a composite endpoint defined as the time from randomization to the first detection of distant metastasis on imaging or death. Distant metastasis accounted for most of the events, and we know that in terms of survival, the prognosis for men with metastatic CRPC varies depending on anatomic location of metastasis. 

“The finding that apalutamide consistently prolonged time to metastasis regardless of its anatomic site reinforces the clinical benefit of treatment with this androgen receptor inhibitor,” he said.

Metastasis incidence 22% vs. 48%

In SPARTAN, the incidence of metastasis was 22% (175/806) in the apalutamide arm and 48% in the placebo arm (191/401). The incidence of bone, nodal, and visceral metastasis in the apalutamide arm was 57%, 30%, and 13%, respectively, and it was 52%, 40%, and 8%, respectively in the placebo arm. A single site was involved in the first metastatic event for 92% of apalutamide patients and 86% of men in the control group.

The analyses of time to metastasis showed that apalutamide reduced the relative risk by 73% overall (p<0.001) and by 69% for bone (p<0.001), 81% for nodal metastasis (p<0.001), and 49% for visceral metastasis (p=0.041).

Dr. Smith is a consultant to Janssen Oncology and other companies that market treatments for prostate cancer.
Feedback showed high patient engagement and enthusiasm for the program, Dr. Skolarus said. Target enrollment was achieved relatively quickly, 85% of men in the tailored intervention group received at least three of the four possible newsletters, 89% completed the outcomes assessment at 5 months, and >80% reported satisfaction with the self-management engagement might have a greater positive impact if it is initiated closer to the time of prostate cancer diagnosis and treatment. “Approximately one-third of the participants received initial treatment,” Dr. Skolarus told Urology Times. “Comments we received from men during the process evaluation indicated a desire to have had the self-management materials available earlier in their disease history.”

FDA OKS FIVE NEW UROLOGIC THERAPIES
The summer of 2018 has proven to be fruitful for new products in the field of urology, with the FDA giving the nod to three new drugs and two new devices. Here are the new treatments the agency has approved or cleared since May 23.

New abiraterone formulation
Sun Pharma and Churchill Pharmaceuticals, LLC announced the approval of abiraterone acetate (YONSA), a novel formulation in combination with methylprednisolone, for the treatment of patients with metastatic castration-resistant prostate cancer. YONSA uses proprietary SoluMatrix Fine Particle Technology to create a micronized formulation of abiraterone tablets. The active ingredient is converted in vivo to abiraterone, an androgen biosynthesis inhibitor that inhibits 17α-hydroxylase/C17,20-lyase (CYP17). The CYP17 enzyme is expressed in testicular, adrenal, and prostatic tumor tissues and is required for androgen biosynthesis.

Focal HIFU treatment of the prostate
EDAP TMS SA received FDA 510(k) clearance for its Focal One high-intensity focused ultrasound (HIFU) device for the ablation of prostate tissue. Focal One fuses magnetic resonance and 3-D biopsy data with real-time ultrasound imaging, which allows urologists to view integrated, detailed 3-D images of the prostate on a large monitor and direct high-intensity ultrasound waves to ablate the targeted area. Focal One is the first medical device designed specifically for focal treatment of the prostate, according to EDAP TMS.

Sublingual treatment for nocturia due to nocturnal polyuria
Ferring Pharmaceuticals Inc. announced approval to market desmopressin acetate (NOCDURNA), the first sublingual tablet for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least two times per night to void. The formulation of the sublingual tablet and sex-specific dosing was demonstrated to be effective in reducing nighttime trips to the bathroom in adults 18 years and older. Clinical trials demonstrated an average reduction of nighttime voids of 52% in women and 43% in men relative to mean baseline (reduction of 1.5 and 1.3 voids, respectively).

IV agent for complicated UTI
Achaogen, Inc. announced FDA approval of plazomicin (ZEMDRI), for adults with complicated urinary tract infections, including pyelonephritis, caused by certain Enterobacteriaceae in patients who have limited or no alternative treatment options. Plazomicin, an aminoglycoside, is an intravenous infusion administered once daily. It is designed to retain its potent activity in the face of certain difficult-to-treat multidrug-resistant infections, including carbapenem-resistant (CRE) and extended spectrum beta-lactamase (ESBL)-producing Enterobacteriaceae.

Arterial embolization for BPH
Embolect, Inc. received FDA 510(k) clearance for its next generation family of Sniper Balloon Occlusion Microcatheters, a system for pressure-directed arterial embolization therapy. The Sniper microcatheter alters blood flow dynamics by controlling pressure to increase therapeutic agent delivery into target areas. It is currently used for the treatment of BPH, cancers tumors in the liver and other organs, and uterine fibroids. It is now available in three lengths—110 cm, 130 cm, and 150 cm—enabling physicians to access either femoral or radial arterial sites.

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**T therapy safe in large prostate cancer series**

Recurrence rates consistent with those for PCa treatments, surveillance

**John Schieszer / UT Correspondent**

**SAN FRANCISCO**—It appears to be safe for clinicians to consider testosterone therapy for symptomatic men with testosterone deficiency and a history of prostate cancer, according to new data presented at the AUA annual meeting in San Francisco.

In the largest series to date, investigators found that prostate cancer recurrence rates were consistent with previously published recurrence/progression rates for the various forms of treatment for localized prostate cancer and for men on active surveillance.

Lead study author Abraham Morgentaler, MD, associate clinical professor of urology at Harvard Medical School, Beth Deaconess Medical Center, Boston, said these new findings provide valuable and reassuring information for clinicians and patients with symptomatic testosterone deficiency and a history of prostate cancer.

“There is growing evidence that [testosterone therapy] is not as risky as we once thought, and I think it is time to consider offering it to a larger population of men with prostate cancer who are symptomatic from testosterone deficiency,” Dr. Morgentaler said in an interview with Urology Times.

When he and his co-authors looked at men with prostate cancer who were on active surveillance or had received radiation or radical prostatectomy, there were no significant differences in recurrence rates or progression rates in men who received testosterone therapy, Dr. Morgentaler reported. However, the authors noted some of the data are still rather preliminary. Among 190 men, the progression rate (higher Gleason score) in men on testosterone was 10.6% in 47 men on active surveillance with >4 years mean follow-up and there were no recurrences in five men treated with radical prostatectomy followed by salvage radiation, with a mean follow up of >2 years.

‘Reasonable evidence’ for T in symptomatic men

Dr. Morgentaler said these reassuring results now provide justification for liberalizing the use of testosterone therapy in men with prostate cancer.

“Testosterone therapy has been contraindicated for decades in men with prostate cancer on the basis of weak, circumstantial evidence. This series, the largest to date, provides reasonable evidence that supports its use in symptomatic men,” said Dr. Morgentaler.

The researchers mined electronic medical record databases at a large single center to identify men who received therapy for testosterone deficiency after diagnosis and/or treatment of prostate cancer over the previous 5 years. In this cohort, testosterone was delivered via transdermal gels/liquids, short- and long-acting injections and/or pellets.

There is a limited body of evidence regarding the safety of testosterone therapy in men with a history of prostate cancer, and the authors noted that it continues to be a controversial issue in clinical practice. The team identified 120 men with a diagnosis of both prostate cancer and testosterone deficiency and 222 men received testosterone therapy. The authors excluded 32 men because they had <3 months follow-up or were diagnosed with advanced disease.

A total of 190 men remained in the study and their mean age was 68 years (range, 41-88 years). The mean follow-up was 47.0 months. Among the 190 men, 86 underwent prostatectomy, 49 received radiotherapy, three men underwent high-intensity focused ultrasound (HIFU), and 47 were on active surveillance. The study showed that biochemical recurrences occurred in 10 men after prostatectomy (11.6%), in two men after radiation therapy (4.1%), and in two men after HIFU. Among the men on active surveillance, progression occurred in five men (10.6%).

John Roger Bell, MD, assistant professor of urology at the University of Kentucky, Lexington, said patients with a history of testosterone deficiency after a diagnosis of prostate cancer continue to pose a challenge for clinicians and that these findings are good news.

“This study provides a solid foundation for this question. However, the study is derived from a database and does not present the risk stratification of the patients analyzed. There is also no control arm, and the follow-up is limited at a mean of 47 months,” Dr. Bell told Urology Times.

He said further study utilizing a control arm and performing a subgroup analysis using prostate cancer risk stratification may clarify these data and help elucidate which patients may benefit the most from testosterone therapy.

Dr. Morgentaler is a consultant for Acerus and Aytyu BioScience, and has a research grant from Endo Pharmaceuticals. One of his co-authors is a consultant/adviser for Aytyu BioScience and Eli Lilly. UT

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Source: Abraham Morgentaler, MD

NEW ED GUIDE REFLECTS PARADIGM CHANGE

A new AUA clinical guideline on the diagnosis and treatment of erectile dysfunction is rigorous and evidence based while representing evolution of the field since the AUA last published a guideline on ED in 2005, says Arthur L. Burnett, II, MD, MBA, chair of the guideline development panel.

In an interview at the AUA annual meeting in San Francisco, Dr. Burnett discusses some of the significant differences between the 2018 and 2005 AUA guidelines on ED and how the new guideline addresses novel treatments that are not currently FDA approved. To watch the interview, go to www.urologytimes.com/ED-interview.
Robot-assisted cystectomy: Do the pros outweigh the cons?

Length of stay is shorter with robotic procedure, but operative time is longer

The promise of robot-assisted surgery has been to potentially improve surgical outcomes of complex procedures and maintain cancer control while decreasing perioperative pain and complications, usually in the absence of high-level evidence.

According to recently published results of the Randomized Open versus Robotic Cystectomy (RAZOR) trial, robotic cystectomy was found to be “non-inferior,” yielding similar cancer progression-free survival as the open cystectomy technique (Lancet 2018; 391:2525-36). This is the first multicenter, phase III randomized trial comparing the outcomes of robot-assisted cystectomy with open cystectomy.

After the initial randomization of 350 patients, the investigators successfully completed robotic or open cystectomy in 150 and 152 patients, respectively (excluding those with unresectable or converted cases or consent withdrawal). Some patients (number not mentioned) who previously had open abdominal or pelvic surgery were excluded before randomization. Both open and robotic surgery was performed at each of the 15 participating U.S. centers, but the criteria for surgeon experience was quite minimal at 10 cases in the previous year (open or robotic).

Importantly, the urinary diversion was performed extracorporeally; ie, with an open incision. The type of urinary diversion and the use of neoadjuvant chemotherapy was at the discretion of the surgeon. In the robotic and open cystectomy groups, ileal neobladder was constructed in 24% and 20%, and neoadjuvant chemotherapy was used in 27% and 36%, respectively.

The primary endpoint was to demonstrate non-inferiority of the robotic approach for progression-free survival. The study design allowed for a non-inferiority margin of −15 percentage points, ie, if the survival difference was −12 percentage points for the robotic approach, it would still have met the criteria for non-inferiority. This 15-percentage point allowance given to robotic surgery was thought by the study designer to be a good tradeoff for the potential benefits such as less morbidity and shorter time to adjuvant chemotherapy.

Individual urologists may interpret these results differently, but should this be considered a license to promote the use of the robotic approach for all cystectomies?

The main oncologic outcomes and complication rates in the robotic cystectomy group were similar or non-inferior to open surgery. Are the lower transfusion rate and shorter hospital stay by 1 day in the robotic group valid tradeoffs for the longer operative time and increased cost (direct and indirect)?

As the authors correctly point out, this trial underscores the need for further high-quality trials to assess the true benefits of this and other surgical innovations.

2-year PFS similar in both groups

Two-year progression-free survival was 72.3% in the robotic cystectomy group and 71.6% in the open cystectomy group. The secondary endpoints favoring robotic surgery included lower blood loss and transfusion rate. Initial hospital length of stay was a bit shorter for robotic surgery (6 vs. 7 days). However, ER visits and readmission rates (other studies have reported >25%) are not mentioned.

The overall minor and major complication rate of robotic cystectomy (67%) was similar to that of open cystectomy (69%), except for a few differences. Urinary tract infections were more common in robotic cystectomy (35%) than open cystectomy (26%), but postoperative ileus was similar.

Despite performing the urinary diversion extracorporeally and excluding patients with previous abdominal or pelvic surgery, the median operative time was 67 minutes longer in the robotic cystectomy group. It’s not difficult to conceive a significant increase in the robotic operative time if those patients were to be included.

Radical cystectomy is a major, life-altering intervention, with significant morbidity. Thus, any attempts at incrementally improving outcomes are to be commended, especially in the setting of a randomized controlled trial. Individual urologists may interpret these results differently, but should this be considered a license to promote the use of the robotic approach for all cystectomies?

The main oncologic outcomes and complication rates in the robotic cystectomy group were similar or non-inferior to open surgery. Are the lower transfusion rate and shorter hospital stay by 1 day in the robotic group valid tradeoffs for the longer operative time and increased cost (direct and indirect)?

As the authors correctly point out, this trial underscores the need for further high-quality trials to assess the true benefits of this and other surgical innovations.
When kidneys work overtime to produce too much urine at night, think NOCTIVA

IMPORTANT SAFETY INFORMATION

WARNING: HYponATREMIA

See full prescribing information for complete boxed warning.

- NOCTIVA™ (desmopressin acetate) Nasal Spray can cause hyponatremia. Severe hyponatremia can be life-threatening, leading to seizures, coma, respiratory arrest, or death.
- NOCTIVA is contraindicated in patients at increased risk of severe hyponatremia. See Important Safety Information below for full contraindications.
- Ensure serum sodium is normal before starting or resuming NOCTIVA. Measure serum sodium within 7 days and approximately 1 month after initiating therapy or increasing the dose, and periodically during treatment. More frequently monitor patients ≥65 years of age and those at increased risk of hyponatremia.
- If hyponatremia occurs, NOCTIVA may need to be discontinued.

INDICATIONS AND USAGE

NOCTIVA is a vasopressin analog indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void.

Limitation of Use: Not studied in patients <50 years of age.

CONTRAINDICATIONS

NOCTIVA is contraindicated in patients with the following conditions: hyponatremia or a history of hyponatremia, polydipsia, primary nocturnal enuresis, concomitant use with loop diuretics or systemic or inhaled glucocorticoids, estimated glomerular filtration rate <50 mL/min/1.73 m², syndrome of inappropriate antidiuretic hormone secretion (SIADH), during illnesses that can cause fluid or electrolyte imbalance, congestive heart failure (New York Heart Association Class II-IV), and uncontrolled hypertension.
40 million patients in the US have nocturia,¹,² and in 80% of those cases, it’s caused by nocturnal polyuria,³ the overproduction of urine at night. NOCTIVA treats the problem at the source—in the kidneys.⁴

Through a patented formulation and delivery system administered via a once-nightly nasal spray⁴,⁵:

- NOCTIVA is available in 2 microdoses: 0.83 mcg and 1.66 mcg⁴
- NOCTIVA is rapidly and consistently absorbed within 15 (0.83 mcg) and 45 (1.66 mcg) minutes, depending on the dose⁴,⁴
- Nearly 50% of patients using NOCTIVA 1.66 mcg reduced the number of times they woke up to void by half or more⁴
- Patients experienced clinical effect on the first night of use⁵

To learn more about the first and only FDA-approved treatment for adults with nocturia due to nocturnal polyuria,⁴,⁶ visit www.NOCTIVAHCP.com/UT

WARNINGS AND PRECAUTIONS
- Fluid retention: Not recommended in patients at risk of increased intracranial pressure or history of urinary retention. Monitor volume status in patients with NYHA Class I congestive heart failure.
- Nasal conditions: Discontinue in patients with concurrent nasal conditions that may increase absorption, until resolved.

ADVERSE REACTIONS
Common adverse reactions in clinical trials (incidence >2%) included nasal discomfort, nasopharyngitis, nasal congestion, sneezing, hypertension, back pain, epistaxis, bronchitis, and dizziness.

DRUG INTERACTIONS
Monitor serum sodium more frequently when NOCTIVA is concomitantly used with drugs that may cause water retention and increase the risk for hyponatremia.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Use of NOCTIVA is not recommended.
- Pediatric: Do not use NOCTIVA for primary nocturnal enuresis in children.

To report SUSPECTED ADVERSE REACTIONS, contact Avadel at 1-877-638-4579 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.


Please see Brief Summary of full Prescribing Information on next page.
WARNING: HYponatREMIA

- NOCTIVA can cause hyponatremia. Severe hyponatremia can be life-threatening, leading to seizures, coma, respiratory arrest, or death.
- NOCTIVA is contraindicated in patients at increased risk of severe hyponatremia, such as patients with excessive fluid intake, illnesses that can cause fluid or electrolyte imbalances, and in those using loop diuretics or systemic or inhaled glucocorticoids.
- Ensure serum sodium concentrations are normal before starting or resuming NOCTIVA. Measure serum sodium within 7 days and approximately 1 month after initiating therapy or increasing the dose, and periodically during treatment. More frequently monitor serum sodium in patients 65 years of age and older and in patients at increased risk of hyponatremia.
- If hyponatremia occurs, NOCTIVA may need to be temporarily or permanently discontinued.

INDICATIONS AND USAGE

NOCTIVA is indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void.

Nocturnal polyuria was defined in the NOCTIVA clinical trials as nighttime urine production exceeding one-third of the 24-hour urine production.

Before starting NOCTIVA:
- Evaluate the patient for possible causes for the nocturia, including excessive fluid intake prior to bedtime, and optimize the treatment of underlying conditions that may be contributing to the nocturia.
- Confirm the diagnosis of nocturnal polyuria with a 24-hour urine collection, if one has not been obtained previously.

Limitation of Use: NOCTIVA has not been studied in patients less than 50 years of age.

CONTRAINDICATIONS

NOCTIVA is contraindicated in patients with the following conditions due to an increased risk of severe hyponatremia:
- Hyponatremia or a history of hyponatremia [see Warnings and Precautions]
- Polydipsia
- Primary nocturnal enuresis [see Use in Specific Populations]
- Concomitant use with loop diuretics [see Warnings and Precautions]
- Concomitant use with systemic or inhaled glucocorticoids [see Warnings and Precautions, Drug Interactions]
- Renal impairment with an estimated glomerular filtration rate (eGFR) below 50 mL/min/1.73 m² [see Use in Specific Populations]
- Known or suspected syndrome of inappropriate antidiuretic hormone (SIADH) secretion
- During illnesses that can cause fluid or electrolyte imbalance, such as gastroenteritis, salt-wasting nephropathies, or systemic infection

NOCTIVA is contraindicated in patients with the following conditions because fluid retention increases the risk of worsening the underlying condition:
- Congestive heart failure (New York Heart Association Class II to IV) [see Warnings and Precautions]
- Uncontrolled hypertension

WARNINGS AND PRECAUTIONS

Risk of Hyponatremia: NOCTIVA can cause hyponatremia [see Boxed Warning and Adverse Reactions]. Severe hyponatremia can be life-threatening if it is not promptly diagnosed and treated, leading to seizures, coma, respiratory arrest, or death.

NOCTIVA is contraindicated in patients at increased risk of severe hyponatremia, such as those with excessive fluid intake, those who have illnesses that can cause fluid or electrolyte imbalances, and in those using loop diuretics or systemic or inhaled glucocorticoids [see Boxed Warning, Contraindications, and Drug Interactions].

Before starting or resuming NOCTIVA, ensure that the serum sodium concentration is normal. Consider the 0.83 mcg dose as the starting dose for patients who may be at risk for hyponatremia.

When NOCTIVA is administered, fluid intake in the evening and nighttime hours should be moderated to decrease the risk of hyponatremia. Monitor the serum sodium concentration within 7 days and approximately 1 month of initiating NOCTIVA or increasing the dose, and periodically thereafter. The frequency of serum sodium monitoring should be based on the patient’s risk for hyponatremia. For example, more frequent monitoring is recommended for patients 65 years of age or older or those on concomitant medications that can increase the risk of hyponatremia, such as tricyclic antidepressants, selective serotonin reuptake inhibitors, nonsteroidal anti-inflammatory drugs (NSAIDs), chlorpromazine, carbamazepine, and thiazide diuretics [see Drug Interactions].

If hyponatremia occurs, NOCTIVA may need to be temporarily or permanently discontinued, and treatment for the hyponatremia instituted, depending on the clinical circumstances, including the duration and severity of the hyponatremia.

Fluid Retention: NOCTIVA can cause fluid retention, which can worsen underlying conditions that are susceptible to volume status. Therefore, NOCTIVA is contraindicated in patients with New York Heart Association Class II to IV congestive heart failure or uncontrolled hypertension [see Contraindications]. In addition, NOCTIVA is not recommended in patients at risk for increased intracranial pressure or those with a history of urinary retention, and should be used with caution (e.g., monitoring of volume status) in patients with New York Heart Association Class I congestive heart failure.

Concurrent Nasal Conditions: Discontinue NOCTIVA in patients with concurrent nasal conditions that may increase systemic absorption of NOCTIVA (e.g., atrophy of nasal mucosa, and acute or chronic rhinitis), because the increased absorption may increase the risk of hyponatremia. NOCTIVA can be resumed when these conditions resolve.

ADVERSE REACTIONS

The following adverse reaction is described elsewhere in the labeling:
- Hyponatremia [see Boxed Warning and Warnings and Precautions]

Clinical Trials Experience: Because clinical trials are conducted under widely varying conditions, the adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Two randomized, double-blind, placebo-controlled, multicenter trials conducted in adults 50 years of age and older evaluated the efficacy and safety of NOCTIVA nasal spray compared to placebo. At baseline, 1045 patients treated with NOCTIVA 0.83 mcg or 1.66 mcg, or placebo, had nocturia due to nocturnal polyuria, weakening at least 2 times per night to void. Nocturnal polyuria was defined as nighttime urine production exceeding one-third of the 24-hour urine production. The mean age of the patients studied with nocturia due to nocturnal polyuria was 67 years with 42% between 50 and 64 years of age, and 58% aged 65 years and older. Fifty-seven percent were men and 43% were women. Caucasians comprised 79%, Blacks 12%, Hispanics 6%, and Asians 2% of the trial population.

During these trials, serious adverse reactions were reported in 2%, 2%, and 3% of patients with nocturia due to nocturnal polyuria treated with NOCTIVA 0.83 mcg, NOCTIVA 1.66 mcg, and placebo, respectively. There was one case of hyponatremia in the 1.66 mcg group and one case in the placebo group classified as serious adverse reactions.

Adverse Reactions Leading to Discontinuation: Among patients with nocturia due to nocturnal polyuria, the discontinuation rate due to adverse reactions was 4.0% with NOCTIVA 0.83 mcg, NOCTIVA 1.66 mcg, and placebo, respectively. There was one case of hyponatremia in the 1.66 mcg group and one case in the placebo group classified as serious adverse reactions.

Table 1: Most Common Adverse Reactions (≥2 Incidences) Leading to Discontinuation in Patients With Nocturia Due to Nocturnal Polyuria in 2 Double-Blind, Placebo-Controlled Clinical Trials

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>NOCTIVA 1.66 mcg (n=341)</th>
<th>NOCTIVA 0.83 mcg (n=354)</th>
<th>Placebo (n=349)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypotension/Blood Sodium Decreased</td>
<td>4 (1.2%)</td>
<td>3 (0.9%)</td>
<td>1 (0.3%)</td>
</tr>
<tr>
<td>Nasal Discomfort</td>
<td>2 (0.6%)</td>
<td>0</td>
<td>3 (0.9%)</td>
</tr>
<tr>
<td>Nasal Congestion</td>
<td>2 (0.6%)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Atrophic Fibrillation</td>
<td>2 (0.6%)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Dizziness</td>
<td>0</td>
<td>2 (0.6%)</td>
<td>1 (0.3%)</td>
</tr>
<tr>
<td>Dysuria</td>
<td>1 (0.3%)</td>
<td>2 (0.6%)</td>
<td>0</td>
</tr>
</tbody>
</table>

Most Common Adverse Reactions: Table 2 summarizes the most common adverse reactions reported by patients with nocturia due to nocturnal polyuria. This table shows adverse reactions reported in at least 2% of patients treated with NOCTIVA and at a higher incidence with the 1.66 mcg dose than with placebo.
Table 2: Common Adverse Reactions (Reported by ≥2% of NOCTIVA-Treated Patients and at a Higher Incidence With the 1.66 mcg Dose Than With Placebo) in 2 Double-Blind, Placebo-Controlled Clinical Trials in Patients With Nocturia Due to Nocturnal Polyuria

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>NOCTIVA 1.66 mcg (n=341)</th>
<th>NOCTIVA 0.83 mcg (n=354)</th>
<th>Placebo (n=349)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasal Discomfort</td>
<td>20 (6.5%)</td>
<td>12 (4.4%)</td>
<td>17 (4.9%)</td>
</tr>
<tr>
<td>Nasal Rhinorrhea</td>
<td>13 (3.6%)</td>
<td>8 (2.3%)</td>
<td>10 (2.9%)</td>
</tr>
<tr>
<td>Nasal Congestion</td>
<td>10 (2.9%)</td>
<td>5 (1.4%)</td>
<td>5 (1.4%)</td>
</tr>
<tr>
<td>Sneezing</td>
<td>9 (2.6%)</td>
<td>8 (2.3%)</td>
<td>5 (1.4%)</td>
</tr>
<tr>
<td>Hypertension/Blood Pressure Increased</td>
<td>9 (2.6%)</td>
<td>6 (1.7%)</td>
<td>4 (1.1%)</td>
</tr>
<tr>
<td>Back Pain</td>
<td>8 (2.3%)</td>
<td>4 (1.1%)</td>
<td>3 (0.9%)</td>
</tr>
<tr>
<td>Epistaxis</td>
<td>7 (2.1%)</td>
<td>7 (2.0%)</td>
<td>4 (1.1%)</td>
</tr>
<tr>
<td>Bronchitis</td>
<td>7 (2.1%)</td>
<td>3 (0.8%)</td>
<td>3 (0.9%)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>6 (1.8%)</td>
<td>7 (2.0%)</td>
<td>5 (1.4%)</td>
</tr>
<tr>
<td>Musculoskeletal Ache</td>
<td>6 (1.8%)</td>
<td>4 (1.1%)</td>
<td>5 (1.4%)</td>
</tr>
<tr>
<td>Upper Respiratory Infection</td>
<td>5 (1.5%)</td>
<td>8 (2.3%)</td>
<td>0 (0.3%)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>5 (1.5%)</td>
<td>5 (1.5%)</td>
<td>0 (0.3%)</td>
</tr>
<tr>
<td>Headache</td>
<td>4 (1.1%)</td>
<td>2 (0.6%)</td>
<td>0 (0.3%)</td>
</tr>
<tr>
<td>Drowsiness</td>
<td>4 (1.1%)</td>
<td>2 (0.6%)</td>
<td>1 (0.3%)</td>
</tr>
<tr>
<td>Drooping</td>
<td>3 (0.8%)</td>
<td>2 (0.6%)</td>
<td>0 (0.3%)</td>
</tr>
<tr>
<td>Angina</td>
<td>3 (0.8%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Syncope</td>
<td>2 (0.6%)</td>
<td>1 (0.3%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Urinary Urgency</td>
<td>2 (0.6%)</td>
<td>1 (0.3%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Constipation</td>
<td>2 (0.6%)</td>
<td>1 (0.3%)</td>
<td>0 (0.0%)</td>
</tr>
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</tr>
<tr>
<td>Constipation</td>
<td>2 (0.6%)</td>
<td>1 (0.3%)</td>
<td>0 (0.0%)</td>
</tr>
</tbody>
</table>

No overall changes were observed in the safety profile during the open-label, uncontrolled extension trial with up to 126 weeks of follow-up.

Hyponatremia: Table 3 shows the incidence of serum sodium concentrations below the normal range reported in the 2 placebo-controlled trials.

Table 3: Hyponatremia in 2, Double-Blind, Placebo-Controlled Clinical Trials in Patients With Nocturia Due to Nocturnal Polyuria

<table>
<thead>
<tr>
<th>Serum Sodium Concentrations (mmol/L)</th>
<th>NOCTIVA 1.66 mcg (n=146)</th>
<th>NOCTIVA 0.83 mcg (n=148)</th>
<th>Placebo (n=149)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤125</td>
<td>5 (1.5%)</td>
<td>0 (0.0%)</td>
<td>1 (0.3%)</td>
</tr>
</tbody>
</table>

Of the 5 patients on NOCTIVA 1.66 mcg with serum sodium ≤125 mmol/L, all were 65 years of age or older. Four of the patients were taking concomitant systemic or inhaled glucocorticoid and 3 were taking an NSAID.

Drug interaction potential between NOCTIVA and other medications, and to stop NOCTIVA during illnesses that can cause fluid or electrolyte imbalance [see Boxed Warning, Dosage and Administration, Contraindications, and Warnings and Precautions].

In the U.S. general population, the estimated background rate of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Data

Animal Data: Desmopressin acetate did not cause fetal harm in teratology studies in rats and rabbits at doses of 0.05 to 10 mcg/kg/d, which is approximately <1 times (rat) and 31 times (rabbit) the maximum recommended human dose based on nasal surface area.

Lactation: Desmopressin is present in small amounts in human milk and is poorly absorbed orally by an infant. There is no information on the effects of desmopressin on the breastfed infant on or milk production. The development and health benefits of breastfeeding should be considered along with the mother’s clinical need for NOCTIVA and any potential adverse effects on the breastfed infant from NOCTIVA or from the underlying maternal condition.

Pediatric Use: NOCTIVA is contraindicated for the treatment of nocturnal enuresis because of reports of hyponatremic-related seizures in pediatric patients treated with other intranasal formulations of desmopressin. Studies of NOCTIVA have not been conducted in pediatric patients [see Contraindications].

Geriatric Use: Patients 65 years and older treated with NOCTIVA had a higher incidence of hyponatremia compared to patients less than 65 years old treated with NOCTIVA [see Warnings and Precautions, and Adverse Reactions].

Renal Impairment: Desmopressin is mainly excreted in the urine. The area under the concentration-time curve (AUC) and terminal half-life of desmopressin in renally impaired patients with an eGFR below 50 mL/min/1.73 m² is 3- to 4-fold greater than in patients with an eGFR above 50 mL/min/1.73 m². Therefore, NOCTIVA is contraindicated in patients who have renal impairment with an eGFR below 50 mL/min/1.73 m² [see Contraindications].

Hepatic Impairment: The effect of hepatic impairment on the pharmacokinetics of desmopressin has not been studied.

OVERDOSAGE

Signs of overdose may include effects from hyponatremia such as seizure, altered mental status, cardiac arrhythmias, and worsening edema. Other signs of overdose may include oliguria and rapid weight gain due to fluid retention [see Warnings and Precautions]. In case of overdosage, NOCTIVA should be discontinued immediately, serum sodium should be assessed, and appropriate medical treatment initiated.

PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide and Instructions for Use).

Hyponatremia: Inform patients that NOCTIVA can cause hyponatremia, which may be life-threatening. Inform patients to moderate fluid intake in the evening and nighttime hours, to monitor for symptoms of hyponatremia (such as headache, nausea or vomiting, restlessness, fatigue, drowsiness, dizziness, muscle cramping, or altered mental status), to undergo recommended serum sodium measurements, to inform their health care provider about new medications, and to stop NOCTIVA during illnesses that can cause fluid or electrolyte imbalance [see Boxed Warning, Dosage and Administration, Contraindications, and Warnings and Precautions].

Nasal Conditions: Inform patients to discontinue NOCTIVA if nasal conditions occur that may increase systemic absorption of NOCTIVA (e.g., atrophy of nasal mucosa, and acute or chronic rhinitis). NOCTIVA can be resumed when these conditions resolve [see Warnings and Precautions].

Priming and Dosing: Instruct patients to prime NOCTIVA before using it for the first time by pumping 5 sprays into the air away from the face and to re-prime it by pumping 2 sprays into the air if the bottle has not been used in more than 3 days. Instruct patients not to administer 2 sprays of the 0.83 mcg dose.

Manufactured for: Avadel Specialty Pharmaceuticals, LLC Chesterfield, MO 63005

Rev 03/2018 [Ref 12/2017]

PM-US-NTV-0164-0.4
The argument for surgical management of high-risk PCa

RP can provide superior survival vs. RT, especially in young and healthy men.

High-risk prostate Ca: Definitions, treatment guidelines

D’Amico et al listed the parameters for which different risk stratifications have been based, with high-risk prostate cancer having any of the following three parameters: PSA value >20 ng/mL, biopsy Gleason score 8-10, or clinical stage >T2c (JAMA 1998; 280: 969-74). Definitions for high-risk prostate cancer tend to vary depending on the consortium, and each consortium also indicates some differences in management guidelines (table 1).

Once a patient is classified with localized, high-risk disease, one may consider performing germline genetic testing and genetic counseling, given the 6% prevalence of inherited homologous recombination gene mutations in this subset of patients (N Engl J Med 2016; 375:443-53). Such information can help in considering cancer risk syndromes, assessing for personal risk of second cancers, primary and secondary treatment selection, and predicting risk of progression after local therapy and decreased overall survival.

The issue of radical prostatectomy (RP) versus radiation therapy (RT) for high-risk prostate cancer remains a matter of intense debate. The majority of men with high-risk prostate cancer tend to receive external beam radiation therapy (EBRT) with androgen deprivation therapy (ADT), which is in fact the only Category 1 treatment recommendation by the National Comprehensive Cancer Network for this setting (NCCN Clinical Practice Guidelines in Oncology/Prostate Cancer Version 2.2018; bit.ly/2khXijC). The guideline does note that RP with pelvic lymph node dissection (PLND) may be considered in young, healthier patients without tumor fixation to pelvic sidewall. Likewise, The United Kingdom National Institute for Health and Care Excellence (UK NICE) guidance indicates that men with high-risk localized prostate cancer should be offered a combination of radical radiotherapy and androgen deprivation therapy (BMJ 2014; 348: f7524).

Both the American Urological Association/American Society for Radiation Oncology/Society of Urologic Oncol-

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**TABLE 1 DEFINITIONS, MANAGEMENT OF HIGH-RISK PROSTATE Ca**

<table>
<thead>
<tr>
<th>Source</th>
<th>Definition</th>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>D’Amico</td>
<td>PSA &gt;20 ng/mL, biopsy Gleason score 8–10, or clinical stage &gt;T2c</td>
<td>N/A</td>
</tr>
<tr>
<td>AUA/ASTRO/SUO</td>
<td>PSA &gt;20 ng/mL OR Grade Group 4-5 OR clinical stage &gt;T3</td>
<td>RP with PLND or EBRT</td>
</tr>
<tr>
<td>EAU-ESTRO-ESUR-SIONG</td>
<td>PSA &gt;20 ng/mL OR Gleason score &gt;7 (ISUP grade 4/5) or cT2c; Any PSA, any GS, cT3-4 or cN+ is high-risk locally advanced</td>
<td>RP with PLND or EBRT</td>
</tr>
<tr>
<td>NCCN</td>
<td>High risk: T3a or Gleason score/grade group 4 or Gleason score 4+5/grade group 5 or PSA &gt;20 ng/mL; Very high risk: T3b-T4 OR primary Gleason 5 or &gt;4 cores score 8-10/grade group 4 or 5</td>
<td>EBRT + ADT (2-3 years) (Category 1)</td>
</tr>
<tr>
<td>UK NICE</td>
<td>PSA &gt;20 ng/mL, Gleason score 8-10, and clinical stage &gt;T2c</td>
<td>Radical RT and ADT</td>
</tr>
<tr>
<td>RTOG</td>
<td>PSA 20–100 ng/mL, biopsy Gleason score 8-10, and any clinical stage or clinical stage &gt;T2c or PSA &lt;100 ng/mL and Gleason score 8–10</td>
<td>N/A</td>
</tr>
</tbody>
</table>

1. JAMA 1998; 280: 969-74
2. J Urol 2017; Dec 15 [Epub ahead of print]
4. NCCN Clinical Practice Guidelines in Oncology/Prostate Cancer Version 2.2018; bit.ly/2khXijC
5. BMJ 2014; 348:f7524
Each patient with high-risk prostate cancer should be apprised of the potential need for multimodal treatment.

RP as primary treatment for high-risk prostate Ca

The discrepancies in definitions for high-risk prostate cancer mirror the fact that it is a heterogeneous classification. A significant number will have a more aggressive course that will necessitate close follow-up and prompt administration of additional treatment, but a subset will also be potentially cured by surgery alone. Hence, each patient with high-risk prostate cancer should be apprised of the potential need for multimodal treatment.

The risk of clinical over-staging is constantly present, and men with high-risk disease tend to be triaged toward systemic treatment rather than surgery. It must be noted that the staging parameters used in prostate cancer are far from perfect, in that the digital rectal exam is fraught with inaccuracy, PSA is determined not only by cancer but by benign tissue and inflammation, among other causes, and pathologic downgrading in RP specimens occurs. Furthermore, the proportion of patients with extracapsular extension, seminal vesicle invasion, and lymph node metastasis among men with high-risk cancer was 35% to 71%, 10% to 33%, and 7% to 23%, respectively (J Urol 2007; 178:493-9; discussion 499). This means that a significant number of men deemed not to be candidates for RP actually have organ-confined disease and therefore miss out on a potentially curative surgery.

Given the lack of large, randomized controlled trials to define the optimal treatment for high-risk prostate cancer, the best available information comes from a series of independent studies comparing RP and RT that corrected for selection bias and confounders using propensity score matching (J Urol 2016; 196:309-11). Current available data utilized prostate cancer-specific mortality (CSM) and overall survival (OS) outcomes of surgery and RT, in cohorts ranging from 453 to 68,655 (table 2). After adjustment for known covariates, every study demonstrated improvement with surgery as primary therapy in CSM (HR: 0.64–3.2) and OS (HR: 1.5-1.71). Other than the aforementioned OS and PCM superiority, the use of RP as primary treatment offers several other advantages. Surgery provides a specimen for more accurate pathologic scrutiny and staging, and can therefore be a driver in determining the need for additional treatment (ie, adjuvant radiation plus ADT). Up to 70% of
patients can avoid ADT after surgery as primary treatment for high-risk prostate cancer, sparing patients of metabolic (diabetes, osteoporosis) and cardiovascular (arrhythmias, myocardial infarction) morbidities associated with exposure to hormonal therapy (Urology 2011; 77:946-30). In contrast, primary treatment with RT allows for fewer subsequent therapy options, usually limited to ADT as an adjuvant or salvage option.

Patients who received RT are also known to be at risk for urinary complications, including incontinence, urethral strictures, hematuria, and bladder irritative symptoms. They also have higher incidence of rectal morbidity, rectal or anal procedures, hospital admissions, and open surgical procedures (Lancet Oncol 2014; 15:223-31). The well-established risk of second malignancies in the radiated field and the ill effects toward a person’s immunity and overall health are additional points against RT.

Finally, surgery can also improve the quality of life and provide symptom control in those with LUTS secondary to bladder outlet obstruction, gross hematuria, and renal function deterioration due to ureteral obstruction, among others.

**Surgical considerations**

**Surgical approach.** While there is a trend for robotic surgery to be the preferred surgical approach for localized prostate cancer, some are reluctant to perform minimally invasive approaches for high-risk prostate cancer. With increasing experience with the da Vinci robot, more recent data are showing similar oncologic outcomes between open and robot-assisted laparoscopic radical prostatectomy (RALP) for high-risk disease, as well as comparable results in functional outcomes (potency and continence) and complication rates (BJU Int 2005; 95:751-6; Eur Urol 2015; 67: 212-9). The surgeon’s capability definitely is an important factor in eventual outcomes, and surgery (open or RALP) for high-risk prostate cancer may be better off done in high-volume centers.

**Lymph node dissection.** The therapeutic benefit of lymph node dissection (LND) in prostate cancer is debatable, but for high-risk disease, a potential cancer-specific survival benefit has been shown, particularly when combined with ADT and RT for those with node-positive disease (Eur Urol 2015; 67: 212-9). Extended LND, which allows for removal of a higher number of lymph nodes for high-risk prostate cancer, is advised, with removal of obturator, external, and internal iliac nodes. However, patients must be informed of the risks, including increased blood loss, longer operative time, and risk of lymphoedema formation, among others.

**Neurovascular bundle preservation.** One may consider performing nerve sparing even in high-risk prostate cancer, particularly in patients with organ-confined disease. The judicious use of frozen sections intraoperatively to aid in determining need for wider resections might be worthwhile. Sievert et al have provided insight that the neurovascular bundle in fact composed of several tracks in addition to the main posterolateral band (Eur Urol 2008; 54:1109-6). This therefore allows the possibility of “partial nerve sparing.” If one side has high suspicion for extraprostatic disease, unilateral nerve sparing is also feasible and might allow for better recovery of potency compared to non-nerve sparing.

**Neoadjuvant treatment.** Overall relapse rates, even with adjuvant and salvage therapies, are still considerable, probably due to occult systemic disease, radiation, and/or hormonal resistance. Neoadjuvant treatment is an attractive concept and has been a subject of research using chemotherapy or ADT, but none has so far translated to survival benefit, and therefore currently is not part of the management for high-risk prostate cancer. The RCT evaluating the benefit of docetaxel and leuprolide or goserelin in high-risk prostate cancer patients before RP (NCT00430183) is the only phase III trial available, although results at this point are not yet mature.

**TABLE 2** OUTCOMES FOR PROPENSITY ANALYSES OF RP VS. RT IN HIGH-RISK PROSTATE CANCER

<table>
<thead>
<tr>
<th>Author/year</th>
<th>Study size</th>
<th>Prostate cancer mortality HR, RT vs. RP</th>
<th>Overall survival HR (all p&lt;0.5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tewari et al 2007</td>
<td>453</td>
<td>2.10</td>
<td>N/A</td>
</tr>
<tr>
<td>Albertsen et al 2007</td>
<td>1,618</td>
<td>2.5</td>
<td>1.7</td>
</tr>
<tr>
<td>Merglen et al 2007</td>
<td>844</td>
<td>2.3</td>
<td>1.5</td>
</tr>
<tr>
<td>Zelefsky et al 2010</td>
<td>2,380</td>
<td>3.0 (rate of metastases)</td>
<td>N/A</td>
</tr>
<tr>
<td>Cooperberg et al 2010</td>
<td>7,539</td>
<td>2.21</td>
<td>1.58</td>
</tr>
<tr>
<td>Kibel et al 2012</td>
<td>10,429</td>
<td>1.5</td>
<td>1.6</td>
</tr>
<tr>
<td>Abdollah et al 2012</td>
<td>68,665</td>
<td>2.8</td>
<td>N/A</td>
</tr>
<tr>
<td>Nepple et al 2013</td>
<td>10,361</td>
<td>1.66</td>
<td>1.71</td>
</tr>
<tr>
<td>Shao et al 2014</td>
<td>66,492</td>
<td>1.9</td>
<td>N/A</td>
</tr>
<tr>
<td>Lee et al 2014</td>
<td>376</td>
<td>3.2</td>
<td>N/A</td>
</tr>
<tr>
<td>Sooriakumaran et al 2014</td>
<td>34,052</td>
<td>1.76</td>
<td>N/A</td>
</tr>
<tr>
<td>Sun et al 2014</td>
<td>66,087</td>
<td>2.5</td>
<td>1.5</td>
</tr>
<tr>
<td>Gratzke et al 2015</td>
<td>20,935</td>
<td>1.97</td>
<td>N/A</td>
</tr>
<tr>
<td>Bandini et al 2018</td>
<td>5,500</td>
<td>0.64</td>
<td>N/A</td>
</tr>
</tbody>
</table>

15. Eur Urol 2014; 65:6930700
17. BMJ 2014; 348: g1502
20. World J Urol 2018; May 2 [Epub ahead of print]
PROSTATE CANCER  Presented by Kelvin A. Moses, MD, PhD | Vanderbilt University Medical Center, Nashville, TN

- Updated survival data at 19-year follow-up from the European Randomized Study of Screening for Prostate Cancer showed a significant difference in progression to metastatic disease in men screened for prostate cancer versus controls. There is a significant increase in prostate cancer mortality in the control group, and the separation of curves begins at about 8 years from the time of screening.
- During active surveillance, use of the prostate health index (phi) and multiparametric MRI in combination is a more accurate predictor of grade reclassification at next surveillance biopsy than either test alone.
- Men on active surveillance for prostate cancer show moderate to high levels of anxiety early on, but their anxiety was relieved and improved significantly over time.
- Adverse pathology at radical prostatectomy was observed at a threefold higher rate for favorable intermediate-risk prostate cancer (based on several definitions) versus low-risk disease, a finding with important implications for counseling patients about their potential for disease progression while on surveillance.

KEY TAKE-AWAY:
In a study of high-risk prostate cancer comparing treatment with radical prostatectomy versus radiation therapy and androgen deprivation, there were critical significant differences between the two populations, but Kaplan-Meier curves showed no difference in local failure, distant metastasis failure, and overall survival, indicating that there is likely equivalent efficacy between radical prostatectomy and radiation in this population.

- Follow-up and long-term results of studies of thermal and ultrasonic ablation, including their use as focal therapy, are still pending, but they are promising.
- In the management of oligometastatic disease, treatment of the primary tumor may have a survival benefit over systemic therapy alone. A randomized trial will be undertaken to study this subject.
- A test of the external validity of the Prostate Cancer Intervention versus Observation Trial (PIVOT) using reference cohorts from the SEER database, the National Cancer Database (NCDB), and PLCO trial showed that the PIVOT population was significantly less healthy than the NCDB and PLCO populations where Charlson data were available. Also, overall mortality was 64% in the PIVOT trial versus 8% to 23% in an equivalent population in the other series. PIVOT is thus likely not applicable to clinical practice.
- An examination of the impact of prior local therapy on overall survival in men who eventually reached metastatic castrate-resistant prostate can-

ENDUROLOGY/STONES  Presented by Zeph Okeke, MD | Zucker School of Medicine at Hofstra/Northwell, Hempstead, NY

KEY TAKE-AWAY:
A comparison of disposable and reusable flexible ureteroscopes found that the disposable scopes seem to have better in vitro deflection but that when thicker, less flexible tools occupy the working channel, the reusable scope deflects better.

- In a clinical study, the MOSES Pulse holmium laser was associated with significantly lower fragmentation and procedural times and significantly less retroplulsion of stones than a regular holmium lithotripsy mode, thus improving stone fragmentation efficiency.
- A prototype pulsed Thulium laser fiber demonstrated much more efficient fragmentation of human stones in an in vitro model compared to traditional holmium laser fibers.
- A novel dual-energy single-probe lithotripter had much more efficient stone fragmentation and clearance rates compared to currently available lithotripters.
- In patients undergoing percutaneous renal surgery, high frailty score was significantly associated with increased length of stay and presence of postoperative complications and was predictive of discharge disposition of the patient after hospitalization.
- Fluoroscopy-free retrograde intrarenal surgery was associated with short operative time and a similar stone clearance rate compared to conventional ureteroscopy with fluoroscopy.
- In a study evaluating whether coconut water consumption can prevent kidney stones, citrate excretion in patients consuming coconut water was markedly increased compared to patients consuming water alone.

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of patients and -0.02 ng/mL in 13%. Median time to PSA response was less than 1 month.

• Early results of a randomized clinical trial of diet intervention in men on active surveillance did not show any significant differences in tissue specimens, but future data may have long-term implications.

• A multicenter trial found MRI-targeted biopsy to be noninferior to standard transrectal ultrasound-guided biopsy for diagnosis of clinically significant prostate cancer.

BPH AND LUTS

Presented by Harris E. Foster, Jr., MD
Yale University School of Medicine, New Haven, CT

• Increased free T4 appears to be related to the development of LUTS.
• Men with Peyronie’s disease have a higher rate of LUTS, and a disorder in myofibroblast could explain this association.
• Researchers found only a weak association between obesity and LUTS/overactive bladder.
• Metabolic syndrome and smoking were associated with a higher risk of nocturia in patients undergoing TURP in one study, and another group examining metabolic syndrome also found an increased prevalence of BPH, specifically related to decreased HDL.

• In a study of prostate specimens from radical prostatectomies, local atherosclerosis was associated with increased prostate size.
• A rat model of prostatic inflammation caused bladder overactivity and regulation of growth factors, which may provide some insight into the storage symptoms of LUTS.

• In a study of inflammation in stroma versus non-stroma from human prostate, inflammation found in the stroma was associated with increased severity in LUTS and bladder outlet obstruction.
• A finding that non-adrenergic smooth muscle contraction is mediated by endothelium and thromboxane may explain the limited efficacy of alpha-blockers.
• Researchers noted an androgenic to estrogenic milieu change in obesity that altered the 5-alpha-reductase inhibitor, which may affect response to this therapy.
• A large cohort of men with LUTS/BPH who are untreated may be interested in self-directed care. These men tend to have longer term symptoms that are moderate or severe.

• Tissue-eliminating transurethral prostate procedures achieved superior rates of medication discontinuation compared with tissue-necrosing procedures.
• The combination of anticholinergic and alpha-blocker therapy for LUTS had clinical effects similar to that of alpha-blocker therapy, and there was no increased risk of retention with combination therapy.

• Combination behavioral and drug therapy for LUTS in men resulted in lower urinary frequency.
• Metformin improved IPSS scores in men with LUTS and metabolic syndrome.

• The combination of tamsulosin (Flomax) and tadalafil (Cialis) provided improved LUTS and erectile function versus tamsulosin alone and led to no significant increase in adverse events.

• Three-fourths of men with LUTS have some form of urinary incontinence, predominantly postvoid dribbling, but also have increased bowel and psychological symptoms.

• In older men, higher lean body mass and muscle strength are associated with lower prevalence of incontinence, but changes in BMI and muscle strength did not change incontinence prevalence.

• In a study of postoperative urinary retention, catheter-dependent men who had failed prior surgery and were told they were no longer surgical candidates underwent urodynamics. Most had detrusor underactivity, and 88% were catheter free after repeat surgery.

• Among patients with detrusor underactivity and retention prior to photoselective vaporization of the prostate (PVP), most voided postoperatively despite the diagnosis of detrusor underactivity.

• Post-op urinary retention after joint replacement was higher after knee than hip replacements.

• Predictors of success of the prostatic urethral lift (UroLift) at 5 years were total IPSS, weak stream, and incomplete emptying.

• Water vapor therapy using the Rezum system showed modest improvement in symptoms and flow rate in a large series, and 90% of patients stopped all their BPH medications. A high UTI rate was noted.

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BLADDER CANCER

Presented by Cheryl T. Lee, MD | Ohio State University, Columbus

KEY TAKE-AWAY:
Pembrolizumab (Keytruda) showed promise as neoadjuvant treatment before RC for muscle-invasive urothelial bladder carcinoma.

• A urinary assay based on methylation and mutation markers demonstrated 93% sensitivity, 81% specificity, 99% negative predictive value, and an area under the curve of 0.95 for detecting bladder cancer in a population of patients with microscopic or macroscopic hematuria.
• The WHO 2004 and WHO 1973 classification systems for grading nonmuscle-invasive bladder cancer (NMIBC) have poor reproducibility, and their prognostic value varies among pathologists.
• Using computer-extracted nuclear shape and orientation features assessed on hematoxylin-eosin stained images, deep learning theory may improve grading accuracy for bladder cancer.
• Artificial intelligence and deep learning showed promise as a tool to improve staging of T1 bladder cancer.

• In a prospective randomized study of patients with median (1 cm-3 cm) bladder tumors, en-bloc bipolar ablation for tumor resection was associated with a shorter operation time, catheterization period, and hospital stay compared with monopolar transurethral bladder resection of bladder tumors and a lower recurrence rate at 1 and 3 years.

• A study of practice patterns found risk-aligned surveillance is not commonly done for patients with NMIBC.

• A health-oriented clinical dashboard implemented through the electronic health record is being used to automatically detect gaps in guideline-recommended care for bladder cancer patients.

• In a randomized trial comparing nutritional intervention with an oral liquid nutritional supplement and a multivitamin control in radical cystectomy (RC) patients, the intervention group had a numerically lower complication rate (48% vs. 67%) and a significantly lower rate of sarcopenia development.

• A wearable fitness tracker is a patient-accepted method for collecting data on physical activity after RC.

• Remote vital sign monitoring using a smartphone application had good patient compliance and showed promise as a tool for enabling follow-up of patients after RC.

• Adjuvant radiotherapy improved overall survival for patients with adverse pathologic features after RC.
Improving QOL in Prostate Radiotherapy

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- In patients undergoing TURP, increased surgical duration was associated with an increased complication rate.
- In studies of robotic, high-velocity waterjet prostate resection (Aquablation): Waterjet resection showed noninferior symptom relief versus TURP in men with moderate to severe symptoms, but the rate of retrograde ejaculation was three times higher in the TURP group. Complication rates were lower with waterjet resection versus TURP in men with large prostates and moderate to severe LUTS. Waterjet resection showed a significantly decreased reduction in IPSS in a specific group of patients with large prostates and low flow rates.
- In studies of Holmium laser enucleation of the prostate (HoLEP): Patients undergoing HoLEP who were taking antithrombotics had higher risk of bleeding complications, particularly with double and triple therapy. Another group had no transfusions with HoLEP at 18 years, and only 1.4% of patients needed a redo procedure. In small prostate cases, HoLEP performed just as well as TURP with better reduction in PVR, but it took longer. Almost two-thirds of HoLEP patients can be discharged on the same day.
- In studies of PVP: Obesity did not affect outcomes of 180W PVP (Greenlight XPS-180W) procedures, but operative times were significantly longer. Predictive factors for incontinence after PVP mainly revolved around large prostate size.

And then there was discussion about specific procedures to spare ejaculation after TURP and other types of ablative procedures. Twelve-year experience with resecting the middle lobe only showed an ejaculatory dysfunction rate of only 2.8%. Antegrade ejaculation was preserved at 90% using an ejaculation-preserving PVP.

**PENILE/URETHRAL CANCER**

Presented by Christopher Warlick, MD, PhD
University of Minnesota, Minneapolis

- Lymph node dissection is important for clinical stage N1-N2 urethral cancer. The value of lymph node dissection for clinical N0 disease is less clear, but may depend on the patient population and type of dissection performed.
- A retrospective analysis of patients undergoing fluodeoxyglucose (FDG) positron emission tomography-computed tomography for staging of pelvic lymph nodes in patients with known inguinal metastases of penile cancer showed a sensitivity of 77% and a specificity of 88%.
- In a study of men with squamous cell carcinoma of the penis, there was no difference in 3-year overall survival between negative and positive node dissection patients with micro-metastatic pelvic lymph node involvement.
- In another study of squamous cell carcinoma of the penis, FDG-PET/CT appeared helpful in identifying men with positive pelvic lymph nodes. Men with high-risk inguinal nodal features had a high rate of pelvic micrometastatic disease, but lymph node dissection did not affect overall survival. And men with positive inguinal nodes had a significant rate of contralateral nodal disease identified by sentinel lymph node dissection.
- The PI3K-AKT-mTOR pathway has prognostic significance, and checkpoint inhibitor pathways may be suitable therapeutic targets in penile cancer.

**IMAGING**

Presented by Simpa Salami, MD
University of Michigan, Ann Arbor

**KEY TAKE-AWAY:**

Multiple studies examined the use of artificial intelligence in MRI. The technology can help determine who needs an MRI, improve the interpretation of MRI, and facilitate prostate cancer localization.

- A novel method to measure bladder wall micromotion with M-mode ultrasound was validated in pigs.
- Contrast-enhanced ultrasound was used to detect renal cell carcinoma recurrence following ablation.
- New protocols were offered for low-dose computed tomography (CT) in stone disease.
- Surgeons risk greater exposure to radiation when they are relatively short in stature or stand relatively farther from the source of radiation. A separate study found that lead glasses can reduce the amount of radiation absorbed by the eyes, but still allow up to 56% to pass through.
- Fluorodeoxyglucose positron emission tomography/computed tomography was found to have high specificity but low sensitivity for staging pelvic lymph nodes in patients with penile carcinoma.
- Prostate-specific membrane antigen (PSMA) PET/magnetic resonance imaging improved the detection of prostate cancer recurrence.
- Multiple studies showed that membranous

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*Based on a tertiary clinical literature search performed 11/2014. 89 peer-reviewed articles were accepted according to Inclusion/Exclusion criteria, of which 80% (71 articles) showed favorable outcomes in support of Hem-o-loc Clips. Data on file, Teleflex Incorporated, Report #MLIB-000588.
†Data on file (2013 internal study), Teleflex Incorporated, Report #D001591. Testing conducted on porcine carotids, sample size = 33, p<0.05. Clinical performance cannot be extrapolated from the data. Testing pressures range beyond physiological pressures.

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urethral length predicts urinary continence recovery, and one study showed that perineal ultrasound assessment of pelvic floor function provides accurate assessment of membranous urethral length.
• In a retrospective cohort, 52% of false-positive lesions on MRI fusion prostate needle biopsy were due to inflammation.
• A pig study suggested a step forward for image-guided surgery with a new small-molecule intravenous nerve-binding fluorophore.

OUTCOMES
Presented by Willie Underwood, III, MD, MPH, MSc
Ruswell Park Comprehensive Cancer Center, Buffalo, NY
• Using geo-mapping and spatial analysis of environmental exposures, researchers identified statistically significant clusters of bladder cancer patients in Erie and Niagara counties, New York. Pollutants associated with bladder cancer were present in all these clusters.
• In a similar nationwide analysis, researchers found a statistical correlation between environmental quality and prostate cancer stage at diagnosis. They theorized that environmental factors could explain variations in outcomes for poor and African-American patients.
• In a statistical analysis, Gleason score at the positive surgical margin was more predictive of recurrence of prostate cancer than the highest Gleason score after robot-assisted radical prostatectomy. The authors concluded that the Gleason score at the margin should appear on the pathology report.

MINIMALLY INVASIVE SURGERY
Presented by Jean Joseph, MD, MBA | University of Rochester, Rochester, NY
KEY TAKE-AWAY:
Partial nephrectomy may be considered for patients with complex renal tumors based on a large retrospective study that found no differences in 30-day complication rates or oncologic outcomes comparing it with radical nephrectomy.
• In a small study of patients with adenocortical carcinoma, disease-free survival was superior after open adrenalectomy than after laparoscopic adrenalectomy.
• Outcomes of adrenalectomy are similar whether the procedure is performed by general surgeons (who currently perform 90% of these procedures) or urologists, supporting the idea that urologists should be performing more adrenalectomies.
• Minimally invasive partial nephrectomy can be considered instead of radical nephrectomy for select patients with large clinical T2 renal masses.
• Robot-assisted radical nephrectomy is associated with a modest improvement in perioperative outcomes compared with a laparoscopic technique.
• Minimally invasive surgery is feasible for treatment of kidney cancer with venous thrombus and associated with acceptable oncologic and functional outcomes, but a high rate of complications, even when performed by experienced hands.
• Robot-assisted cystectomy for locally advanced bladder cancer is associated with similar oncologic efficacy compared with open radical cystectomy, but adequate node dissection is important because increased lymph node yield is associated with higher survival.
• In a multicenter study with 30 months follow-up of patients operated on for muscle-invasive bladder cancer, cancer-specific survival was similar in groups undergoing robot-assisted versus open radical cystectomy, but the minimally invasive approach was associated with better perioperative outcomes (operating time, estimated blood loss, transfusion rate, length of stay, and major complications).
• A phase III randomized controlled trial found delayed ligatation of the dorsal vascular complex during robot-assisted radical prostatectomy had no detrimental impact on perioperative outcomes compared with preventive ligation.
• Analysis of EPIC-26 data in patients undergoing laparoscopic radical prostatectomy, brachytherapy, or cryotherapy for localized prostate cancer showed each treatment affects quality of life, but with a unique recovery profile.
• Open and robot-assisted salvage radical prostatectomy were associated with similar complication rates in a study of patients operated on at two tertiary referral centers.
• In men with testis cancer, minimally invasive retroperitoneal lymph node dissection is done less frequently than an open approach and is associated with a higher 30-day readmission rate.
• A 3-D printed silicone vesicourethral anastomosis model exhibited realism and discriminated between expert and novice surgeons.
• Remote expert feedback using social networking was as effective as in-person feedback in helping trainees (medical students) acquire robotic skills.

SEXUAL DYSFUNCTION
Presented by Nelson Bennett, Jr., MD | Northwestern University Feinberg School of Medicine, Chicago
• The AUA released new guidelines on the diagnosis and treatment of testosterone deficiency and diagnosis and treatment of erectile dysfunction.
• On linear regression, time since awakening was not associated with changes in serum testosterone levels in shift workers. There were no significant variations in testosterone levels observed in either morning or afternoon blood draws.
• In a study of human corpus cavernosum tissue, eugonadal testosterone levels indirectly and specifically mediated corporal relaxation via downstream stimulation of nNos, eNos, and cGMP.
• Mice subjected to S-nitrosogluthathione reduction deficiency had significantly smaller litter sizes and smaller testicles, as well as decreased epididymal sperm concentration and motility.
• Transpelvic magnetic stimulation is a novel therapy to enhance penile blood flow. Rabbits were

KEY TAKE-AWAY:
Researchers implemented an alternate multimodal analgesia protocol to decrease opioid requirements for inflatable penile prosthesis patients. The men received acetaminophen, gabapentin, and meloxicam prior to surgery. They then received a pudendal and penile block during the procedure. Afterwards, pain was controlled by acetaminophen, gabapentin, and meloxicam, with narcotics for breakthrough pain. They saw a significant decrease in all pain scores as well as the amount of narcotics prescribed for these patients.
subjected to an electrical field around the pelvis and underwent penile ultrasound. Rabbits that had electrical field stimulation showed a significant increase in peak systolic velocity and a decrease in end-diastolic velocity.

- Researchers presented data on a novel end-to-side nerve grafting procedure for men with post-radical-prostatectomy erectile dysfunction. Erectile function increased significantly; 64% of men who previously had ED were able to obtain erections. In addition, 45% of patients were able to get erections without the use of phosphodies- terase-type-5 inhibitors.

- A multi-institutional international study evaluated 133 patients undergoing penile implant surgery (inflatable or malleable implant). There was a statistically significant increase in not only the length but also the girth of the penis after implantation of the prosthesis. In inflatable prostheses, length increased by 0.6 cm and girth by 1.7 cm. In the malleable group, length increased by 0.2 cm and girth by 0.7 cm.

- Plaque calcification significantly reduces the success of collagenase clostridium histolyticum (XIAFLEX) therapy for Peyronie’s disease. Greater baseline and ventral direction increase the chance of ≥20% curvature improvement.

- In rats with Peyronie’s disease, researchers examined the antifibrotic effect of the anti-transplant drug mycophenolate mofetil (MMF). Rats were either given nothing or TGF beta to induce a plaque. MMF was given 7 or 30 days after induction. Histochemical assessment found fragmentation and degradation of elastin in the tunica albuginea prior to treatment with MMF. The process of degradation and fragmentation was completely reversed by MMF in the 7-day group, and there was even a normal restoration of architecture in the 30-day group.

- The use of a selective serotonin reuptake inhibitor or serotonin-norepinephrine reuptake inhibitor does not appear to change the adverse effect profile of fibanserin (Addyi).

- Daily use of ospemifene (Osphena) improves the quality of the genitourinary tissue in the vulva, vestibule, urethral meatus, and vagina, as assessed by prospective vulvoscopy.

**TRANSPLANTATION**

Presented by Yaw A. Nyame, MD, MBA, MHSA
Cleveland Clinic

- Among nearly 7,000 donor nephrectomies performed between 1995 and 2015 in New York State, urologists were the highest-volume surgeons and urologists were more likely to perform these procedures with a minimally invasive approach. Urologists had lower rates of readmission and lower length of stay than general surgeons and transplant surgeons.

- Readmission among kidney transplant recip-
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- Normothermic Extracorporeal Membrane Exchange, which has been used predominantly in liver transplants, is a unique approach to preserve graft function in deceased kidney donors and was associated with lower rates of delayed graft function when compared to an ultra-rapid organ retrieval protocol.
- The ways in which donors can be identified for transplantation are being redefined. One study showed that in bloc transplantation is possible from very small donors (<10 kg or <8 months of age), and a second found that living donation in patients over age 70 years showed intermediate-term success in graft function.
- Early robotic kidney transplantation studies demonstrated that the wound infections and symptomatic lymphoceles were lower and pain control was better with the robotic approach, but there was no advantage in length of stay and no difference in overall survival and allograft function.
- In a study of renal auto-transplantation, having multiple arteries, having a urinary stent or nephrostomy tube, and/or a positive preoperative urinary tract infection was associated with a high risk of graft failure, a finding that may improve selection of patients for auto-transplantation and/or manage them with antimicrobial therapy prior to transplantation.

INFERTILITY/ANDROLOGY
Presented by Lawrence Jenkins, MD, MBA
Ohio State University, Columbus

- Subclinical varicoceles showed improvements after repair that were similar to those of clinical varicoceles.
- It takes approximately 3 to 6 months after varicocelectomy for the most significant improvement in semen parameters to be seen. Up to 33% of men with total motile sperm count <2 million were upgraded to natural conception range of total motile sperm count >9 million following varicocele repair.
- In men undergoing microsurgical varicocelectomy, mean TUNEL and SCSA values both decreased significantly following repair. The percentage of patients with abnormal TUNEL and SCSA values decreased significantly. Among couples undergoing in vitro fertilization (IVF), the pregnancy rate was 71% and live birth rate was 40%. Pregnancy rates were improved in men whose sperm DNA fragmentation moved from abnormal to normal. Of the couples achieving pregnancy, only the mean difference in TUNEL was significant.
- An AUA review of surgically acquired sperm for assisted reproductive technology found the percentage of cycles using surgically retrieved sperm increased between 2004 and 2015. Pregnancy and perinatal outcomes were similar for treatments using surgical retrieval of sperm and ejaculated sperm among couples undergoing IVF/intracytoplasmic sperm injection (ICSI) for treatment of male factor infertility.
- ICSI outcomes using testicular sperm are not significantly better than ICSI using ejaculated sperm in couples with high sperm DNA fragmentation and prior ICSI failures.
- A multicenter study analyzing surgical sperm retrieval rates in men with non-mosaic Klinefelter’s syndrome undergoing microsurgical testicular sperm extraction (micro-TESE) found that sperm retrieval rate was about 21%. No factor was found to be predictive of successful micro-TESE.
- A retrospective, multicenter, international cohort of 1,200 ICSI cycles with donor eggs found no significant association between advanced paternal age and embryo aneuploidy.

BASIC SCIENCE (MALIGNANT)
Presented by Heinric Williams, MD, MS | Geisinger Commonwealth School of Medicine, Scranton, PA

KEY TAKE-AWAY:

- Fatty acid binding protein 5 (FABP5) is preferentially overexpressed in high-risk prostate cancer. Both FABP5 overexpression and the ratio of FABP5/fatty acid synthase is higher in overweight and obese men compared with normal weight men, and FABP5 overexpression is highest in obese African-Americans.
  - A ketogenic diet significantly inhibited tumor growth in a mouse model of clear cell renal cell carcinoma (RCC).
  - A study using drug-resistant cell lines found intraclass cross-resistance to enzalutamide (XTANDI) and abiraterone (ZYTIGA) and to docetaxel (Taxotere) and cabazitaxel (Jevtana), but no inter-class resistance between the anti-androgens and taxanes.

- Most muscle-invasive bladder cancer tissue demonstrates a mixed pattern of basal and luminal subtypes. The presence of these subtypes has no correlation with clinical parameters, including metastasis, lymphovascular invasion, or lymph node status.
- Findings from genomic characterization and analysis of outcomes of patients who underwent surgical resection for clear cell papillary RCC indicate it is an indolent tumor.
- Gemcitabine/cisplatin therapy was the most efficacious treatment compared with paclitaxel/carboplatin and sunitinib in a mouse model of renal medullary carcinoma.
- Prostate cancer–associated fibroblasts from African-American men exhibit a higher proliferative response to mitogens compared with fibroblasts from Caucasians and increase tumorigenicity of prostate cancer cell lines through enhanced secretion of pro-inflammatory mediators.
- CD4+ T cells infiltrate more into prostate tumors than into normal tissue. Co-culturing of prostate cancer cell lines with CD4+ T cells induces docetaxel resistance that is mediated by secretion of chemokine ligand 5 (CCL5) and can be reversed by treatment with a CCL5 neutralizing antibody.
Plenary session highlights included a panel discussion on fertility preservation in the pediatric cancer patient, a state-of-the-art lecture on the role of antibiotics and imaging in prenatal urinary tract dilation, and the point-counterpoint debate, “Complex surgical cases should be centralized.”

In one Societies for Pediatric Urology abstract, researchers administered an immunosuppressant called cytisine in an attempt to decrease testicular injury at the time of torsion. Testis weight in mice that received cytisine was significantly higher than those that had not, indicating that cytisine prevents testicular atrophy. Additionally, cytisine was shown to prevent testicular fibrosis in rats when administered around the time of a torsion event.

In another SPU abstract, researchers presented a new, validated instrument for parental assessment of genitl appearance in girls with congenital adrenal hyperplasia (CAH) called the Parental Assessment for Children's External genitalia scale for Females (PACE-F). The study established the tool’s validity and demonstrated that PACE-F scores improved significantly after genital reconstruction in patients with CAH. http://spuonline.org/abstracts/2018/22.cgi

Two studies looked at transcutaneous electrical nerve stimulation (TENS) for nocturnal enuresis, and found that while the number of wet nights may decrease somewhat, TENS monotherapy is not an effective treatment for nocturnal enuresis. Multimodal therapy is imperative.

Several studies indicated that dysfunctional voiding appears to be due to a central defect. In one study, PET scans performed before and after nerve stimulation showed very substantial changes in brain activity that correlated with changes in patients’ symptoms. This hypothesis that dysfunctional voiding appears to be due to a central defect was also supported by a retrospective study that showed a correlation between non-neurogenic voiding dysfunction and neural psychiatric disorders in pediatric patients.

Pediatric sacral nerve stimulator explantation rate due to complications is low, while there is a progressively increasing chance for explantation for cure beginning 2 years after implantation.

A video abstract demonstrated some unique issues related to phalloplasty in exstrophy patients and also showed a technique for saphenous vein interposition grafts.

Contemporary ureteral re-implant surgery rates may be lower than what has been published historically, at least in patients with high-grade vesicoureteral reflux (VUR). Separate studies examined high-grade (VUR) patients, and the success rates of both robotic re-implant and open re-implant were much lower than the very high success rates traditionally published for ureteral re-implantation surgery.

In patients undergoing pyeloplasty and ureteral reimplant, routine preoperative screening urine cultures did not decrease the risk of postoperative urinary tract infections.
How to set up e-prescribing for controlled substances
Tool may help reduce drug diversion, callbacks from pharmacists

by most accounts, the United States is in the midst of a public health crisis: premature death from opioid-related problems. In 2016 alone, more than 40,000 people died during this epidemic (JAMA Network Open 2018; 1:e180217). Most agree that the source of the crisis lies in the addictive nature of opiates and historical overprescribing and availability of these drugs (MMWR Morb Mortal Wkly Rep 2017; 66:697-704).

The diversion of prescription drugs is a well-documented event and occurs in urology practices and patient populations. Most states have now created some form of Prescription Drug Monitoring Program (PDMP); typically, the PDMP encourages or requires prescribers to consult a database prior to prescribing controlled substances and/or imposes a reporting requirement on the dispensing of same. Some states have tied continuing education on controlled substance prescribing to professional licensure. Many states have required tamper-proof forms for written prescriptions, some of which are compatible with electronic health record printing. Some states still allow verbal prescriptions for controlled substances under some circumstances.

Yet one of the most powerful tools for streamlining workflow, preventing diversion, and monitoring the prescribing habits of physicians is still not widely adopted—electronic prescribing of controlled substances (EPCS). One vendor estimates that only about 25% of prescribers nationwide are using EPCS, but over 90% of pharmacies are accepting it (bit.ly/EPCSinformation). EPCS has been permitted under federal regulation since 2011 (bit.ly/DEAonEPCS). Local jurisdictions took some time to update their statutes, regulations, and rules (state boards), but EPCS is now technically permitted in all 50 states.

Implementing EPCS in a practice requires multiple steps and the involvement of third parties (often managed by your EHR vendor). The biggest barrier to EPCS may simply be a lack of information on the subject. In this article, I will review the steps necessary to begin EPCS.

Many providers report they find EPCS fast, easy, effective, more convenient for patients, and more secure for peace of mind.

Is your software certified for EPCS?
The first step in the process is to ensure that your e-prescribing software, typically imbedded in an EHR, has been certified for EPCS. You can either ask your vendor or check this website: bit.ly/ePrescribingsoftware. In this author’s experience, most of the EHRs in common use in urology practices across the country have met the certification requirements for EPCS.

The second step in the process is identity proofing. This setup step confirms your identity with a trusted third party, such as a credit bureau or identity management service. (This step may also be managed by your EHR vendor and/or a third party.) Because identity proofing requires access to your credit history, it may be necessary to allow that access by removing an account freeze or enabling your identity protection account (eg, LifeLock, Identity Guard, etc.) The process will match the information you entered with identity records, and you may be asked to answer some security challenge questions. This step is complete when you receive confirmation that your identity has been verified.

The third step, which may happen in conjunction with identity proofing, is establishing a two-factor authentication method. Two-factor authentication typically grants secure access to an account holder based on something they have—like an ATM card or hard token—and something they know, like a PIN or password. Two-factor authentication setup may occur during identity proofing so that the information is tightly coupled to your identity record. Smartphones may allow you to keep the token in a secure application (soft token).

The final step in the setup process is establishing access within the administrative section of your EHR/prescribing software and enabling providers who have completed identity proofing and two-factor authentication to actually use EPCS. This step may require your EHR administrator and someone who has actually completed identity proofing (like a provider) be physically present together.

Many benefits for providers, patients
While the setup is necessarily rigorous, once EPCS has been set up for a provider, it should...
NP, PA incident-to billing: What is (and isn’t) allowed

APPs can report services incident to an MD under a few circumstances

Q: I have a physician assistant working for me. My billing staff and I are in disagreement as to how we should charge “incident to,” can you help?

A: The issue of billing for services provided by the advanced-practice provider (APP) is a complex one. We will try and boil it down.

First, we will remind everyone that “incident to” services can only be provided in the office setting and require that the billing provider is in the facility and not otherwise engaged in a way that will prevent the billing provider from assisting with the patient when the “incident to” service is provided.

An APP (PA or NP) can report services “incident to” an MD under a few circumstances:

• A service is provided in the office setting during which both an APP and an MD/DO have documented participation in the visit. Participation in the visit requires more than a “hello” or a note saying that the MD/DO reviewed the plan of care and agreed to it, without contact with the patient.
• A service is provided solely by the APP that follows a plan of care previously established by an MD/DO during a previous encounter with the patient. The plan of care for the patient must be established during a visit in which the physician has direct patient contact and clearly documents a plan of care for the problem. This does not mean that on each occasion of an “incident to” service performed by an APP that the patient must also see the physician. It does mean there must have been a direct, personal, professional service furnished by the physician to initiate the course of treatment of which the services being performed by the APP is an incidental part.

Visits that cannot be billed incident to:

• APPs cannot see new patients or established patients with a new problem and bill “incident to.” (Those visits should be charged using the APP’s NPL)
• Most carriers have interpreted the combination of these guidelines to mean that any change in treatment plan not initiated during a visit in which the physician is an integral part of the service (direct contact required), or outlined by the physician in a documented care plan, that visit and any subsequent visit for the care are no longer eligible for “incident to” billing.
• A service cannot be charged “incident to” in the hospital. A service that is provided in a facility setting at the same time or at separate times by both an APP and an MD/DO cannot be reported under “incident to” rules. However, a visit in which both an APP and a DO/MD have contact with the patient and each documents that services including HX, PE, and MDM were provided can be reported under the MD/DO provider number under the Shared/Split visit rule, which allows for all services provided by both providers to be reported under a single E/M code by the MD/DO.

Please note that documentation that simply indicates that the MD/DO has reviewed the documentation of the APP and agrees is not sufficient to meet the requirements of a Split/Shared Visit.

Send coding and reimbursement questions to Ray Painter, MD, and Mark Painter c/o Urology Times, at U1@advantara.com. Questions of general interest will be chosen for publication. The information in this column is designed to be authoritative, and every effort has been made to ensure its accuracy at the time it was written. However, readers are encouraged to check with their individual carrier or private payers for updates and to confirm that this information conforms to their specific rules.

E-PRESCRIBING

continued from page 30

be similar to e-prescribing any other drug, with the additional two-factor step. Many providers report they find EPCS fast, easy, effective, more convenient for patients, and more secure for peace of mind (bit.ly/EPCSbenefits). EPCS should reduce or eliminate callbacks from pharmacists. EPCS should ensure that all controlled substance prescribing is now captured in the EHR, providing a more accurate list of medications and history. It will allow accurate reports and monitoring of prescribing activity across larger organizations, enabling physician leaders to recognize irregular prescribing habits and facilitate education about best practices for prescribing controlled substances (bit.ly/CDCopioidguideline).

EPCS comes at a cost—typically a setup fee and a modest per-provider subscription paid to your EHR vendor. There may be a tangible return on this investment if EPCS saves a few seconds or minutes of provider time that might otherwise have been spent on walking to a printer, manually filling out a written prescription, answering phone calls from pharmacists, or dealing with “lost” prescriptions. One need only reflect on the benefits and efficiencies of e-prescribing for all other drugs to question why controlled substances remains the exception instead of the rule.

Bottom line: EPCS is now live in all states, available through most EHR vendors, and probably cost effective in your practice. EPCS may result in less drug diversion and fewer opioid-related deaths in the U.S. Check with your EHR vendor to get started.

RAY PAINTER, MD
MARK PAINTER

Dr. Painter (top) is the president of Physician Reimbursement Systems, Inc., in Denver, and is also publisher of Urology Coding and Reimbursement Sourcebook. Mr. Painter is CEO of PRS Urology SC in Denver.
Take advantage of compounding interest when saving for retirement

Start saving and investing early in order to achieve your financial goals.

Q: I heard that an early-career physician who plans to retire 30 years from now and wants $10,000 of inflation-adjusted monthly income when they retire will need to save over $8,000,000 for their retirement. That’s a lot of money! How do I get there?

A: Everyone’s retirement goals are different. First, ask yourself if you really need that much income in retirement. If the answer is still yes, then comprehensive financial planning is going to be critically important. There are many different areas you will need to shore up: emergency fund, disability insurance, life insurance (if you are planning for yourself and a spouse), tax planning, and an investment strategy, to name a few. Some of these items are necessary to ensure that if something negative happens during your career, you and/or your spouse may still be able to save the required amounts necessary to reach lofty retirement goals. Others are just generally good practice and will help you keep more of what you make and earn the required returns on your investments to reach ambitious goals.

However, the two financial concepts that will potentially have the biggest impact on your ability to achieve your retirement goals are compounding interest and saving and investing as soon as possible.

Compounding interest is an incredibly powerful financial concept. It is fundamentally “interest on interest” and helps your investments grow at a faster rate than just simple interest. How does it work? Let’s say you make an investment, and that investment is supposed to pay you interest or a dividend. Instead of taking the interest or dividend payment as cash and sticking it in your pocket, you instead reinvest it back into the same investment. The next time that investment is designed to pay out interest or a dividend, it does so not only on the original principal investment but also now on the reinvested amount.

Even just saving and investing a modest amount regularly early in your life can have a huge impact on your ability to reach your financial goals.

Think of it as a snowball that you’ve started rolling downhill. As the snowball continues to move downhill, it grows in size and momentum. By the time you reach retirement, this investment-fueled snowball has hopefully grown big enough and has such tremendous momentum that it’s churning out the income you desire on the first day of retirement and the last. The longer you can take advantage of compounding interest before withdrawing the funds, the greater impact compounding interest can have in growing your investment accounts. That’s why starting to save and invest early is critically important.

Whether you have modest or lofty retirement income goals, you improve your chances of reaching those goals if you start saving and investing early. Not only does it give you a longer hill to roll your snowball down, it also allows you to compensate for changing investment markets and any changes that might occur to your financial goals as you progress through your career and life.

Our experience has been that many physicians early in their careers struggle to save. Student loans, down payments for houses, and a general increase in their standard of living consume all their income even though they are making 5 to 10 times as much as they were during their residency or fellowship. Create a budget to keep your spending reasonable and free up funds to start saving and investing as soon as possible. Even just saving and investing a modest amount regularly early in your life can have a huge impact on your ability to reach your financial goals.

Q: Can I still recharacterize my Roth conversion after the new tax bill was passed?

A: Unfortunately, the ability to recharacterize Roth conversions was eliminated under the new tax bill. Previously, investors could convert their traditional individual retirement account contributions into Roth IRA contributions and later, if their circumstances changed, recharacterize it back to a traditional IRA contribution. The prime rationale for converting traditional IRAs to Roth IRAs is people feel their taxes may go up in later years and it’s cheaper to pay them now. But sometimes circumstances change after the conversion and people want to recharacterize their investments back to their original classification.

Under the new tax law, the ability to reconvert from a Roth back to a traditional IRA is no longer available. You can still convert a non-deductible IRA contribution into a Roth IRA, but the move is now irrevocable. UT

The information in this column is designed to be authoritative. The publisher is not engaged in rendering legal, investment, or tax advice.
Letters / We welcome letters to the editor. Please send correspondence to UT@advanstar.com.

USPSTF recommendation a disservice to high-risk men

To the editor:

Although we commend the USPSTF for upgrad- ing the recommendation for PSA- and digital rectal exam-based prostate cancer screening from a “D” to a “C” grade (JAMA 2018; 319:1901–13), we believe that not enough emphasis is placed on screening high-risk groups for prostate cancer.

Our group of 12 board-certified urologists practicing in the Washington, DC metro region sees a high-risk patient population consisting of 60% African-Americans and 22% men over age 70. We reviewed our patient biopsy data before and after the 2012 USPSTF recommendation against PSA screening. We found that, of 1,194 prostate biopsies, 552 were positive (46%) and 60% were high grade (Gleason score 7-10), even though compared to pre-2012 the prostate biopsies decreased by 30% (Rev Urol 2017; 19:25–31). Our data indicate that the high-risk group consists of African-American men, men with a family history of prostate cancer, and healthy men age 70–80 years old and hence requires prostate cancer screening.

We disagree with the USPSTF regarding the basic statistic on which the recommendations are based. According to the USPSTF statement, 100 men need to be diagnosed with prostate cancer in order to avoid one death from prostate cancer. This statistic is derived from clinical trial data and is not consistent with the actual U.S. cancer statistics provided by the American Cancer Society (ACS). According to the ACS, in 2017 there were 161,360 new cases of prostate cancer and 26,730 deaths due to prostate cancer (CA Cancer J Clin 2017; 67:7–30). This means that for 100 men diagnosed with prostate cancer, 16 will die due to prostate cancer. We believe this discrepancy is due to the under-representation of high-risk groups in the clinical trial data upon which the recommendations were based.

A recent analysis of PubMed showed 53 articles that reviewed the clinical value of PSA-based prostate cancer screening found that 75% were in favor of screening (Urology 2017; 104:122-30). Data since the original recommendation against screening in 2012 show increased rates of metastatic disease (Prostate Cancer Prostatic Dis 2016; 19:395-7). We don't want to return to the pre-PSA era in which 30% of newly diagnosed prostate cancer cases were metastatic.

Diagnosis is necessary for proper medical care. All patients with prostate cancer do not undergo surgical or radiation therapy, as some patients are actively observed. In addition, newer technologies like parametric MRI of the prostate gland and genetic testing help to differentiate slow-growing from aggressive prostate cancer. Thus, new clinical tools will guide us in the future treatment of prostate cancer, especially of aggressive tumors.

We strongly believe, as stated in our prior letter published in Urology Times (July 2017, page 39), that PSA-based prostate cancer screening should be made available, especially to African-American men, men with a family history of prostate cancer, and healthy men age 70–80 years old to decrease the morbidity and mortality of prostate cancer.

Navin Shah, MD, and Vladimir Ioffe, MD
Greenbelt, MD
Urology groups react to USPSTF grades

LUGPA: ‘Grave concerns’ about prostate Ca ruling

The final recommendation on screening for prostate cancer issued May 8 by the U.S. Preventive Services Task Force (USPSTF), which gives a “C” grade for PSA testing in men 55-70 years of age, has been met with mixed reviews by prostate cancer-focused organizations, some of which continue to call for legislation to reform the task force itself.

While the AUA issued a statement commending the USPSTF on its recommendations and its process for developing them, LUGPA was sharply critical, expressing “grave concerns” about aspects of its ruling.

Groups advocate for reform bill

Both groups, however, said legislation to reform the USPSTF process, the USPSTF Transparency and Accountability Act of 2017, should be enacted.

The AUA said the task force’s final recommendations “demonstrate the value of involving specialists, patients and the medical community in creating reasonable and thoughtful clinical guidance,” and thanked the USPSTF for soliciting community feedback, engaging urologists to review the evidence on which its recommendations were based, and considering comments from the prostate cancer community.

But it also commended Reps. Marsha Blackburn (R-TN), Bobby Rush (D-IL), and other lawmakers for encouraging the USPSTF to adopt a more transparent process and said their legislation, the USPSTF Transparency and Accountability Act, “is needed to ensure transparency and regular input in the process from interested stakeholders and specialists with appropriate expertise.”

However, LUGPA President Neal Shore, MD, a Myrtle Beach, SC urologist, said the USPSTF’s decision to finalize the draft recommendations released more than a year ago “is the byproduct of a process that is neither open nor transparent.”

The USPSTF’s final recommendation states that men ages 55-69 years should make an individual decision about whether to get PSA-based screening for prostate cancer after discussing potential benefits and harms with their clinician, considering their specific clinical circumstances and incorporating their values in the decision—a “C” recommendation.

For men 70 years of age and older, the USPSTF continues to recommend against PSA-based screening—a “D” recommendation.

“Our organization has grave concerns that the USPSTF continues to minimize the importance of shared decision-making for both older men in good health and younger men at high risk.”

NEAL D. SHORE, MD
LUGPA PRESIDENT

The task force said the final recommendation applies to all adult men who have no signs or symptoms of prostate cancer and who have never been diagnosed with the disease. It includes men at increased risk, such as African-American men and men with a family history of prostate cancer.

“For men who are more interested in the small potential benefit and willing to accept the potential harms, screening may be the right choice for them,” said task force Vice Chair Douglas K. Owens, MD, a general internist and associate director of the Center for Innovation to Implementation at the Veterans Affairs Palo Alto Health System. “Men who place more value on avoiding the potential harms may choose not to be screened.”

The AUA said that although it agrees that “a number of older men are not candidates for prostate cancer testing, we believe that select, older, healthier men may garner a benefit. We urge those men to talk with their doctors about whether prostate cancer testing is right for them.”

LUGPA was sharper in its criticism of the task force recommendations.

“Our organization has grave concerns that the USPSTF continues to minimize the importance of shared decision-making for both older men in good health and younger men at high risk, both populations that may benefit from prostate cancer screening,” Dr. Shore said. “The application of arbitrary age cutoffs negates not only physician’s expertise, understanding and knowledge of an individual patient’s specific health history, but also undermines recent breakthroughs in molecular and genomic testing that facilitate personalized, precision health care delivery.”

Dr. Shore also said that LUGPA does not believe the recommendation of additional research regarding prostate cancer screening in African-American men and those with a family history of prostate cancer is sufficient.

During a congressional briefing sponsored by the Congressional Health Caucus and the Men’s Health Network after the USPSTF issued its final recommendations, Alex H. Krist, MD, MPH, vice chairperson of the task force, acknowledged that screenings “will save a few lives from prostate cancer.” Dr. Krist is professor of family medicine and population health at Virginia Commonwealth University, Richmond and an active clinician.

“We believe that the new recommendation will encourage men to take a more active role in their health and wellness,” said Ana Fadich, MPH, CHES, vice president of the Men’s Health Network. “We are hopeful that the task force will be more inclusive of men age 70 and older in future recommendations.”

More research urged

During the briefing, medical experts and advocates from the Veterans Health Council, the AUA, and ZERO—The End of Prostate Cancer urged the task force to solicit more research for high-risk groups.

“It is clear that the science is important in the work that we’re doing,” said Darrell Sabbs, a health advocate and legislative affairs and community benefits manager for Phoebe Putney Health System. “Prostate cancer can kill, but it doesn’t have to kill. A lot of the data we need has not been found.”

Urologist Nilay Gandhi, MD, of Potomac Urology, Alexandria, VA, said the USPSTF’s prostate cancer recommendations “made us abandon our ‘caveman approach’. It really opened our eyes to overdiagnosis. All of this made us smarter. It’s made us better at detecting more aggressive forms of cancer.”

“Providers, too, need to be educated,” added Raegan Durant, MD, MPH, associate professor in the division of preventive medicine at the University of Alabama at Birmingham. “Individual health institutions can play a role in adopting current guidelines. Screening is only the beginning.”
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- Practice manager

Location
- Ehrman Center, part of a hospital system
- Large referral networks of private and hospital based physicians
- 5 locations, partnered with 4 hospitals
- 3 Mid-level managers
- 8 Front desk and administrative staff
- 10 Medical Assistants
- 3 Billing and coding specialists
- 1 PA
- 4 board certified urologists

Greater Dayton Area
The Greater Dayton Area is a fantastic place to raise a family and offers all the warmth and charm you can find only in the Midwest. There are excellent school districts and a variety of private schools provide residents with quality educational choices. There’s plenty to see and do locally, including our hometown favorite Dayton Dragons baseball team, the world-class Schuster Performing Arts Center, Wright Patterson Air Force Museum and a variety of prestigious championship golf courses. Residents have easy access to major universities, museums, symphonies, professional and minor league football, baseball and hockey, extensive shopping and dining, plus a wide range of housing options. Easy access to the Dayton International Airport provides unlimited travel options.

Dayton is world-class metropolitan community that truly offers the “best of both worlds” – community charm with easy access to metropolitan amenities. This is an opportunity worth considering!

Electronic Medical Record
- NextGen in office, EMR in hospital
- Main office
- 2 procedure rooms
- Digital Olympus scope with video monitor in 2 procedure rooms
- ULYS entail, one purchased in 2018
- Additional office with procedure suite that have the ability to do Hydro, Office, URO, and Prostate therapy.

Facilities
- Basic procedure area including cystoscopy and prostate therapy

Contact Audrey Barker, Physician Recruitment Manager
audrey.barker@ketteringhealth.org (937) 558-3476 (office)
(740) 607-5924 (cell)

Site visits are being scheduled! Contact Joanne Shippoli, Physician Recruitment Manager, joanna.shippoli@ubm.com (937) 558-3476 (office)
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OHIO
Specimen errors carry large consequences

Optimize patient identification by following these steps

In 2007, the Journal of Urology published an article about patient identification errors among prostate needle core biopsy specimens (J Urol 2007; 178:1245-8). The article identified three patients whose biopsy results were positive for adenocarcinoma, yet upon further treatment—either a radical prostatectomy or radiation therapy—no tumor was found.

Root cause analysis (RCA) on patient one was unable to determine where and when the tissue switch occurred. RCA on patient two determined that the pathologist dictated the patient’s biopsy report while looking at biopsy slides of another patient. RCA on patient number three showed that a pathologist released a report that was not transcribed accurately.

Fast forward a little over a decade to an article in the St. Louis Post-Dispatch describing a lab mix-up in the Midwest that identified a patient with invasive and aggressive prostate cancer on biopsy, but upon radical prostatectomy, no cancer could be found (bit.ly/biopsyerror). The article implies a settlement was reached between the patient and his urologist, the lab, and the hospital with which the urologist was affiliated. The patient, who endured an unnecessary removal of his prostate, continues to struggle with incontinence and erectile dysfunction. Concurrently, there was another man out there who was told he is cancer-free, and actually was not. How can this continue to occur, you may be asking.

Lab and pathology testing may seem like one of those areas where if an error is impacting patient diagnosis or treatment, a urologist might not be on the hook. After all, assuming you take the appropriate specimen from the patient, it is then likely passed off to someone for processing, and perhaps then a courier who is responsible for getting it to the lab. Next, it is in the hands of the lab staff and ultimately a pathologist who is trained in making a diagnosis after analyzing the specimen.

**Time, source of error may be undeterminable**

However, as seen in the RCA on patient one above, it may be undeterminable when or where an error with tissue identification occurred. Lab errors involving patient misidentification and labeling can occur in pre-laboratory, laboratory, and post-laboratory workflows. Events such as incorrect patient registration, reliance on incorrect patient data, failure to properly check patient identifiers, labeling specimens outside the presence of the patients, and erroneous entry of results into an electronic medical record are just a few examples of where lab mix-ups can occur (J Med Bioeth 2017; 36:107-12).

Biopsy mix-ups occur rarely—at less than 1%, according to one researcher. But the effects can be catastrophic (bit.ly/biopsyerror). They place providers and institutions at significant risk for litigation, as evidenced by the average of $880 million in wasted medical treatment costs and $698 million in medico/legal expenditures annually (bit.ly/preventingerrors; J Urol 2015; 193:1170-7). An important consideration in why these types of errors continue to occur over decades is that they may not be readily apparent to the operator when they occur.

Accurate patient identification is an important national patient safety goal with both The Joint Commission and the College of American Pathologists. Though some believe a rate of zero error or zero harm is unattainable due to the significant number of human interactions with each discrete specimen, actions can be implemented to prevent these errors.

The Joint Commission directive is clear that containers used for blood and other biologic specimens are to be labeled in the presence of the patient, whether in the hospital, ambulatory, or lab setting. This requires identifying the patient at the time of specimen collection by two identifiers, typically name and date of birth.

Each organization has different processes, technology, and systems in place for the handling of surgical and other biologic specimens. Use of hospital- or clinic-approved workflows and avoiding workarounds is advised and may include practices such as: use of barcode technology and avoidance of handwriting, confirmation of specimen and associated patient by more than one health care worker and in the presence of the patient, dedicated workspace for processing each specimen, ability for EMR order and information to crosswalk into lab software to avoid transcription errors, color-coded lab cassettes, policy on avoiding distractions at critical times of patient identification, real-time audits and direct observation of processes for immediate feedback and correction of issues, and promotion of active engagement during all processes.

Although the percentage of prostate biopsy mix-ups is low, each one is significant, potentially impacting two patients, not just one. The process of collecting a specimen from a patient and the subsequent handling and processing before a result is ready is rife with human interaction. All organizations should view proper patient identification as a patient safety imperative and work to optimize this process as much as possible.  

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**The Joint Commission directive is clear that containers used for blood and other biologic specimens are to be labeled in the presence of the patient whether in the hospital, ambulatory, or lab setting.**
Most common adverse events reported include hematuria, dysuria, micturition urgency, pelvic pain, and urge incontinence. Most symptoms were mild to moderate in severity and resolved within two to four weeks after the procedure.

* Images courtesy of Dr. Euclid deSouza

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Managing a Retained Stent with Impacted Upper Ureteric Stones: The Limits of RIRS

Chong Tsung Wen, MD

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