Young Urologist Update

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and provide leadership opportunities. The YUC has been hard at work on a number of significant initiatives during the last year.

The YUC is once again proud to present its annual Young Urologists Forum, held during the 2016 AUA Annual Meeting in San Diego on **Monday, May 9 (12:00-1:30 p.m., San Diego Convention Center**). This event is free with your AUA Annual Meeting registration and all attendees are welcome to register and attend.

Educational events at the national and sectional meetings are cornerstones of the YUC outreach, serving to educate our members in a relaxed atmosphere. This year Dr. Neil Baum, professor of clinical urology at Tulane Medical School in New Orleans, will present "Uro-Topia: Developing the Almost Perfect Urology Practice." Dr. Baum regularly speaks to practices, hospitals, and pharmaceutical and medical manufacturing companies on improving communications between physicians and patients, practice management, guerilla marketing, and practice promotion and motivation.

Dr. Baum's presentation will highlight the importance of planning this process and focus on implementing these key elements to create an ideal practice for the young urologist. He will discuss how to use the Internet to attract new patients and how to achieve a first page ranking on a Google search. These techniques are easily implemented and can be accomplished in a cost-effective manner for urologists who are employed physicians, members of large or small group practices and in multispecialty group practices. Lastly, Dr. Baum will discuss the importance of online reputation management and how to make sure doctors' online reviews are mostly positive.

This year the YUC has also greatly expanded its online presence, an effort that began in 2010 with the creation of YUC resource pages on www.AUAnet.org/YoungUrologists. These pages include a variety of tools for young urologists to assist them in launching their careers. In 2015 the AUA introduced Urology Place, an online community for various urology constituent groups, and since then we have become experts in navigating this online community.

This year we will launch the AUA Young Urologists (YU) Community. This community serves as an engagement tool for young urologists to discuss a wide range of topics including difficult cases and treatment options, securing new positions and negotiating contracts, and work-life balance issues. This community is for AUA members only, which further emphasizes the value of AUA membership.

In addition, the Young Urologists Webcast Series has been significantly expanded, providing useful information to young urologists in a concise format. These webcasts can be accessed on www.AUAnet.org/YoungUrologists and the YU Online Community, and include short talks with slides, presented by experts on topics such as social media, practice management, personal finance, student loan debt, and advocacy and public policy.

Young urologists may also find other resources on the YU web pages, including links to relevant websites, career advice and information on topics of interest to young urologists such as maintenance of certification, transitioning from residency to practice and practice development.

Finally, the YUC has focused its efforts on creating an AUA Young Urologist Transition Manual. This manual provides guidance to those chief residents and young urologists who are preparing to transition into practice or have been in practice for 3 years or less. The authors include 2015-2016 YUC members, led by our committee chair, and several authors who worked on the AUA Core Curriculum. We have also included information from MEDIQUS Asset Advisors, our 2015 YU Forum speakers. In addition to the printed manual, an electronic version is available in the Young Urologists Online Community.

The YUC is also working locally to engage young urologists in their AUA Sections. In the last year many YUC representatives have hosted Young Urologist Forums at their annual Section meetings. Presentations at these forums have included the Aspiring Leaders Program; Cultural Diversity in the Workplace; Practical Integration of Advanced Practice Providers into Urologic Practice; How to Preserve Independent, Private Practice: Urologic Practice as an Employer or Employee; International Volunteer Opportunities for Practicing Urologists and Contract Negotiations for the Young Urologist.

The YUC is pleased to recognize those young urologists who have contributed significantly to the planning of Section events and who have been instrumental in engaging their colleagues at the AUA Section or specialty society (SGSU) level. The 2016 Young Urologist of the Year Award winners include Dr. Paulina Reyblat (Western Section), Dr. Tracey Krupski (Mid-Atlantic Section), Dr. Michelle Jo Semins (Northeastern Section) and Dr. Tobias Kohler (North Central Section). These outstanding young urologists will be officially honored at the 2016 Forum in San Diego.

The YUC welcomes requests for future forum topics at the national and section meetings. Questions and comments can be posted through the committee web page (www.AUAnet.org/YoungUrologists). Please feel free to contact us at youngurologists@AUAnet.org. The YUC looks forward to the national meeting in May and we hope to see you at the Young Urologists Forum. ◆

Up-Classification of Transvaginal Mesh for Pelvic Organ Prolapse: A Timeline Review

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The change in classification of transvaginal mesh for the correction of pelvic organ prolapse (POP) from a class II (moderate risk) to a class III (high risk) device recently published by the United States Food and Drug Administration (FDA) on January 4, 2016, was an expected and long anticipated announcement. In May 2014 the FDA released proposed order actions 1) to reclassify transvaginal surgical mesh for POP repair from class II to class III and reclassify instrumentation for the placement of such mesh products from class I to class II, and 2) for an effective date of requirement for premarket approval (PMA) for surgical mesh for POP repair.

All transvaginal mesh products and kits for the correction of POP or stress urinary incontinence were originally brought to market in as little as 90 days via an expedited approval process known as the 510(k) process, which allowed FDA approval to be granted to new mesh kits if they were substantially equivalent to predicate devices. The second order states that within 30 months after the recent date of reclassification (January 4, 2016) the FDA will require a PMA application for mesh reclassified to a class III for those manufacturers who wish to continue to market these products.[1] Without such a PMA, commercial distribution of the device must cease, unless the manufacturer obtains an application for an investigational device exemption (IDE).

As a class II device, mesh products or kits were deemed safe without premarket studies, and only required issuance of performance standards, postmarket surveillance, patient registries, guidelines and recommendations. However, a class III device is one for which insufficient information exists to determine a reasonable assurance of safety and effectiveness, and for which there may be a potential unreasonable risk of illness or injury.[2]

Reporting of complications to the FDA MAUDE (Manufacturer and User Facility Device Experience) database prompted FDA Safety Communications which resulted in a meeting of the Obstetrics and Gynecology Devices Panel of Medical Devices in September 2011. The Panel proposed 1) a reclassification of transvaginal mesh for POP repair from class II to class III, 2) premarket clinical data for surgical mesh for POP repair, emphasizing anatomical outcomes and patient satisfaction with at least 1-year followup, 3) that each mesh product be compared to native tissue repair to establish a reasonable reassurance of safety and efficacy, and 4) that manufacturers should conduct postmarket studies of currently marketed devices.[2]

The FDA followed through on the Panel's recommendation in January 2012 by issuing a Section 522 order to manufacturers to conduct postmarket surveillance studies. Approximately 100 orders were sent to 35 vaginal mesh manufacturers to conduct such studies on transvaginal mesh for POP repair and "mini-slings." The reclassification and postmarket studies orders

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Classification of Transvaginal Mesh for POP

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did not, and do not currently, apply to full-length retropubic or transobturator slings. Several manufacturers voluntarily withdrew some of their mesh products after this announcement.

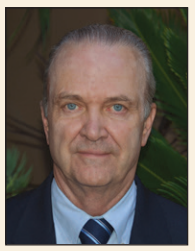
In June 2012 Ethicon withdrew 4 products, including TVT-Secur™ and ProLift stating that the move "was not a recall, but was based on the products' commercial viability in light of changing market dynamics, and is not related to safety or efficacy."[3] Ethicon asked the FDA for permission to discontinue sales of the devices and to suspend requirements for additional studies on its Gynecare line of products.[4] No official recall of devices was formally issued by the FDA since manufacturers voluntarily withdrew certain mesh products that they did not want to enroll into postmarket surveillance studies.

Full length mesh slings and mesh for sacral colpopexy remain class II devices, while mini-slings are currently undergoing postmarket surveillance 522 order studies. The PMA requirements for class III devices must now include at least 1 year of outcome data with an additional 2 to 4 years of postmarket followup, more robust physician labeling (warnings and precautions) and patient labeling that must include an explanation of POP, treatment options, clinical trial data, a statement that surgical mesh is permanent, instructions for postoperative care and a notice of availability of a FDA Safety Communication.[4] The current 522 order studies being conducted by manufacturers will qualify as PMA studies. All existing transvaginal mesh products for POP repair will be required to complete the 522 order studies. The 510(k) process can no longer be used for new products as all new products will be deemed class III and must undergo the PMA process.

It goes without saying that as part of the modern informed consent process, it is now incumbent on physicians to take time to review the reason to use transvaginal surgical mesh for POP repair, review the goals of the FDA Safety Communications and the device classification for the product to be used, document in the chart the informed consent conversation, enumerate the options and alternatives to mesh, document risk stratification based on comorbidities if mesh is to be used, have a separate mesh consent form, distribute patient labeling or websites where the product can be reviewed, disclose financial relationships with manufacturers and other conflicts of interest, document that patient questions were satisfactorily answered, and document that all mesh is permanent and may require revision or removal in the future if pain or complications arise. Transvaginal mesh, whether slings or for anterior compartment repair, is a valuable tool that should continue to be used judiciously in select patients by experienced surgeons performing a meticulous surgical technique with the provision of continuous followup. ◆

1. Effective Date of Requirement for PreMarket Approval for Surgical Mesh for Transvaginal Pelvic Organ Prolapse Repair. Federal Register, Vol 79, No. 84; pp 24642-24648, May 1, 2014.
2. Reclassification of Surgical Mesh for Transvaginal Pelvic Organ Prolapse Repair and Surgical Instrumentation for Urogynecologic Surgical Mesh Procedures: Designations of Special Controls for Urogynecologic Surgical Mesh Instrumentation. Federal Register, Vol 79, No. 84; pp 23634-24642, May 1, 2014.
3. Johnson & Johnson Unit to Halt Urinary Implants. The New York Times, June 5, 2012. Available at http://www.nytimes.com/2012/06/06/business/johnson-johnson-unit-will-stop-selling-urinary-implants.html?_r=0. Accessed February 13, 2016.
4. J&J to Stop Selling Controversial Vaginal Implants. Reuters, June 5, 2012. Available at http://www.reuters.com/article/jj-mesh-idUSL1E8H56QJ20120605. Accessed February 13, 2016.

HAVE YOU *Read?*



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Lo CW, Yang SS, Hsieh C et al: Effectiveness of prophylactic antibiotics against post-ureteroscopic lithotripsy infections: systematic review and meta-analysis. Surg Infect (Larchmt) 2015; 16: 415-420.

In this meta-analysis of 4 trials 500 patients were enrolled and received a single dose of prophylactic antibiotic vs no antibiotic for ureteroscopic lithotripsy (URL). Urinalysis results and the incidence of febrile urinary tract infection (fUTI) were reviewed. The antibiotic altered the urinalyses by reducing the urinary white blood cell count and bacteriuria compared to no medication.

Bacteriuria rates were 0% to 6% for the antibiotic group vs 11% to 21% for the untreated group. The incidence of fUTIs was not reduced by antibiotic prophylaxis but in general the infection rates were low at 1.3% to 5.9%, suggesting that antibiotics given for URL are not beneficial in reducing clinical infection after the procedure.

Brubaker L and Wolfe AJ: The new world of the urinary microbiota in women. Am J Obstet Gynecol 2015; 213: 644-649.

Scott VC, Haake DA, Churchill BM et al: Intracellular bacterial communities: a potential etiology for chronic lower urinary tract symptoms. Urology 2015; 86: 425-431.

These 2 articles are about the currently popular term, microbiome, which is defined as the collection of microorganisms that inhabit an environment, creating a sort of mini-ecosystem. Our human microbiome is made up of communities of symbiotic, commensal and pathogenic bacteria, all of which call our bodies home. It is a term more relevant to the skin and gut than the urinary tract.

These bacteria are identified today by their 16S RNA and, thus, extremely low titers of bacteria can be identified. The articles suggest that lower urinary tract symptoms and pelvic pain in women may be related to very low titers of multiple species of bacteria. However, there is a serious caveat to considering such conclusions. Most women (including those normal and asymptomatic) have squamous metaplasia on the trigone area. This is skin and, as such, it has a flora present consisting of low titers of many different types of commensal organisms that are found in squamous epithelium. These bacteria grow poorly in urine and likely have no clinical effect on the bladder. It is an old and often tested hypothesis that bacteria cause diseases like interstitial cystitis (IC), even if the titers of bacteria are low or even if no organisms are detectable.

The bottom line is if bacteria did cause a bladder problem such as IC, then it is likely that it would be well-known today given that these patients have been treated for more than 50 years with multiple antibiotic regimens, including drug combinations to treat fastidious organisms and chronic prophylaxis, with no obvious beneficial effect. At the end of the day, because nucleic acid technology is available to detect low titers of bacteria does not mean they have clinical significance. Time and data should ultimately determine the relevance of the urinary microbiome.

Mellon MJ, Broghammer JR and Henry GD: The Mulcahy salvage: past and present innovations. J Sex Med, suppl., 2015; 12: 432-436.

Penile prosthesis infections are a significant clinical problem. Devices are infected at implantation, usually by Staphylococcus epidermidis (80% of infections). Infection with this organism is usually indolent with no symptoms or chronic/intermittent pain. The bacteria grow in micro-colonies on the surface of the implant surrounded by a mucin biofilm layer that is impermeable to antibiotics, and they do not grow on the host's tissue.

The bacterial presence and relatively minimal metabolism are likely responsible for degrading the silicone of the device over time, leading to leaks and failures of inflatable penile prostheses (IPPs). In fact 80% of IPPs that fail mechanically are infected with S. epidermidis. Since this is not a problem for semi-rigid devices they have a lower risk of clinical infections.

The good news is that infected implants can be successfully removed and immediately replaced with a new device following a few simple rules. After an infected device is removed, gently irrigate the inside of the device capsule with vancomycin. Before putting in a new device, change gloves because they will pick up the bacteria when the skin is touched. When inserting the new device be careful not to touch it or your hands to the skin, and instead use sponges to accomplish this.

When finished, irrigate the wound with vancomycin. Do not touch the sutures used to close the corpora to skin to prevent bacteria from infecting them. It is best to use a semi-rigid device to minimize the risk of reinfection. Overall there is perhaps a 90% success rate with this replacement method. It is not recommended to replace a device infected with fungus or pseudomonas. ◆