



Inside this issue:

*BPH Therapy* 2

*Robotic Surgery in Children* 2

*Botox—An New Wrinkle on an Old Drug* 3

*USPSTF draft recommendations on PSA* 4

*Safety Update— Actos and Bladder Cancer* 8

*FDA Advisory— Transvaginal Mesh* 9

*Kidney Stones* 10



### Happy New Year from VUA

Welcome to VUA, this Fall, we have welcomed our newest urologist, Dr. Lipika McCauley to the practice and she is currently accepting new patients. She comes to us locally from the University of Arizona at Tucson.

In the previous months, there have been several announcements by the media in relation to urologic medicine. In the Summer, the FDA issued recommendations on mesh product use in pelvic floor prolapse, and Dr. Blick codifies a comprehensive explanation of the misconception of the risks and misinterpretation of the complications that have driven patient fears.

Another announcement came regarding the relationship of Actos to bladder cancer. Dr. Blunt examines the FDA guidance on the use of Actos with patients who have bladder cancer and those who are at risk of developing bladder cancer. There are about 2.3 million patients taking Actos annually and the FDA reports up to a

40% risk of developing bladder cancer with patients on Actos for more than a year. The risk has a direct relationship to the duration of taking Actos and the dose of the medication.

Finally, the draft resolution by the US Preventative Services Task Force (USPSTF) issued a grade D for using PSA to screen prostate cancer. This recommendation was actually concluded in 2009, but delayed because of the negative public reception to another recommendation in limiting breast cancer screening with mammograms which was also issued in 2009. Dr. Hua explains the research studies (PLCO and ERSPC) behind this draft recommendation and how it will negatively affect patients at risk for prostate cancer.



Lipika McCauley, M.D. is highly trained from our own University of Arizona at Tucson

## Benign Prostatic Hypertrophy—Therapy



Dr. Torre Rhoades, M.D.  
Fellowship-Trained in Urologic  
Oncology

The size of the Prostate on DRE does not necessarily correlate to the severity of obstructive and irritative voiding symptoms

Patients can often get confused on the treatment for Benign Prostatic Hypertrophy (BPH) with what is discussed for prostate cancer. The two entities inherently may present the same symptoms but have subtle difference in therapy.

There are three main anatomical locations within the prostate. The peripheral zone is on the outside of the prostate and this is the area that is palpated on the digital rectal exam. Seventy percent of prostate cancers are found in this area however this has no correlation with the obstructive component of benign prostatic hyperplasia (BPH). Men who present with obstructive and irritative voiding symptoms may have an enlarged transition zone making it difficult for them to void. As men age there are several changes that occur within the transition zone. There is an increase in the amount of prostatic stroma and an increase in the number of alpha one A receptors in the prostate stroma. The alpha one receptors mediate the contraction of the prostatic smooth muscle. The prostatic stroma can grow into the lumen of the prostatic urethra and cause a physical obstruction.

Men who are symptomatic from BPH can be started on

medical therapy to help reduce their symptoms and improve their quality of life. Alpha one A blockers helps men in a short period of time by relaxing the smooth muscle within the prostatic urethra and bladder neck. This is the most important factor contributing to lower urinary tract symptoms from BPH. Five alpha reductase inhibitors block the conversion of testosterone to dihydrotestosterone. This helps shrink the prostatic stroma and alleviate the lower urinary tract symptoms. These medications can shrink the prostate by twenty five percent however the time period until improvement is noticed can take three to six months however the patient will continue to have improvement in their symptoms up to eighteen months from the time he started the medication.

Some men present at a later stage of BPH and meet the criteria for surgical management or they have failed conservative medical management. Men who have recurrent and or persistent urinary tract infections from BPH or urinary retention should undergo a procedure to reduce the blockage from the prostate. Other indications are men with persistent hematuria from the prostate, bladder

stones, and renal insufficiency from an obstructed prostate. There are minimally invasive procedures that can be done in the office such as transurethral microwave thermotherapy and transurethral needle ablation. These procedures are done based on the experience of the urologist. Procedures that are done in the operating room include holmium enucleation, laser vaporization, transurethral resection of the prostate, and open or robotic prostatectomy. The prostatectomy is reserved for men who have a prostate that is greater than one hundred grams. When the procedure is performed the capsule of the prostate is left in situ with the core of the prostate being removed. Each procedure has its own benefit and potential short comings which are all addressed with the patient before the procedure is decided upon. The majority of men who decide that they no longer want to experience the decreased quality of life from the lack of poor sleep and having to void frequently with a slow stream are extremely happy they decided to have this procedure, they only wish they would have done it a long time ago as they commonly state that they suffered for a long time.



Dr. Ben O. Donovan, MD  
Fellowship-trained Pediatric  
Urologist

## Robotic Surgery in Children

The use of the Da Vinci Robot to assist in laparoscopic surgery has been in use in the adult population for some time. More recently, robot surgery has expanded to the pediatric population. This newer technology has enhanced our ability to perform technically chal-

lenging techniques in minimally invasive surgery and is ideal for the challenges faced with the smaller pediatric patient. Smaller incisions, less post operative pain and shorter hospital stays can all be expected after performing surgery using this minimally inva-

sive technology. We are pleased that we now have this technology at Banner Thunderbird hospital and can provide state of the art Pediatric Robot surgery (such as ureteral reimplant and pyeloplasty) for our patients on the west side of the valley.

## *Botox: A New Wrinkle on an Old Drug*

Like most people, I thought that Botox was simply used for cosmetic purposes. I vividly remember sitting slack-jawed at an American Urological Association meeting a number of years ago, listening, with ten thousand other Urologists, as one of our colleagues described his experience injecting Botox into the bladder to help overactive bladder symptoms that would not respond to traditional medical therapy. Since that time, Botox has left the confines of the Plastic Surgeon's clinic and has been used for a number of conditions, including excessive sweating, strabismus (cross-eyed), and chronic migraines. Other doctors have been using Botox, albeit outside of the FDA-approved list of uses, for TMJ, movement disorders (due to stroke, Cerebral Palsy, or Parkinson's Disease), pain from diabetic neuropathy, and Painful Bladder Syndrome. In August, the FDA approved Botox for helping to control urinary incontinence, thus giving us another weapon against a condition that affects an estimated one out of three women in the United States.

Overactive Bladder (OAB) is found in up to 34 million American adults, more than asthma, diabetes, and Alzheimer's Disease. It is estimated that we spend 12 billion dollars a year on diapers, medications, Doctor's visits, and hospitalizations, all related to OAB. Treatment options have been notoriously unsatisfying and studies confirm that only 13% of patients choose to stay on the medication prescribed for this condition. Intuitively, that leaves a whopping 87% of patients who are not satisfied with medical therapy and con-

tinue to suffer, usually in silence and in diapers.

Botox offers a remarkable way of controlling overactive bladder symptoms, without the use of oral medications. This is a simple five to ten minute procedure that can be offered under local anesthesia or a "twilight sleep" if so desired. Botox is injected just under the lining of the bladder using a small fiberoptic camera through the urethra (the tube leading from the bladder to the outside). Most studies show that the effects of Botox last about six months, but can certainly last longer.

One of the most frustrating and potentially debilitating conditions our patients face is Interstitial Cystitis/Painful Bladder Syndrome and Chronic Pelvic Pain. Botox has some use here, but the results have been less than encouraging. We do believe that Botox can be helpful if you suffer from these conditions, but only when used with other treatment modalities.

Another very exciting use for Botox affects one out of every two men over the age of fifty: enlargement of the prostate (BPH). Although there are only a few studies looking at Botox for this condition, the results have been astounding with dramatic improvements in all subjective and objective data points. These results lasted about a year, but this is a year without the expense and potential side effects of medications for BPH.

The doctors at Valley Urologic Associates have served as Principal Investigators for a national Botox study and we are very happy to be able to offer this remarkable treatment op-

tion to our patients. Please ask your Doctor during your visit with us if Botox may be of benefit to you.



*Dr. Jonathan Agins, M.D.*

**About 87% of Overactive Bladder patients continue to suffer when they fail medical therapy**

## PSA Screening—USPSTF Draft Recommendation



Dr. Vi Hua, M.D.

On October 7, 2011, the U.S. Preventive Services Task Force (USPSTF) released new draft recommendations against prostate-specific antigen (PSA)-based screening for prostate cancer, asserting that there is "moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits," and discouraged the use of the test by issuing it a Grade D rat-

cancer mortality since the PSA was introduced.

Prostate cancer kills about 33,000 men annually and excluding skin cancer, it is the most commonly diagnosed cancer among men in the US. Prostate cancer is diagnosed in 1 in 6 men and kill about 1 in 36. PSA was generally accepted as a screening test in the early 1990s, and the incidence of prostate cancer climbed

"one will likely die with prostate cancer rather than die of it" predicated many lectures on prostate cancer. The teaching may paraphrase the ability of PSA to discover prostate cancer at very early stages, and created a stage T1c—those cancers diagnosed by PSA alone. However, there are forms of prostate cancer that are very aggressive, cause mortality much faster, and often at

**USPSTF sends a confusing and very wrong message about prostate cancer screening using PSA.**

SEER® Relative Survival (Percent) By Year of Diagnosis, All Races, Males

Survival Time	Year of Diagnosis																						
	1975-1979	1980-1984	1985-1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007		
1-year	91.0	94.0	95.9	97.7	98.8	99.6	99.4	99.2	98.9	99.3	99.5	99.6	99.7	99.9	100.0	99.9	99.9	100.0	99.9	99.9	99.9	99.9	
2-year	85.1	87.9	91.5	94.8	97.4	98.4	98.2	98.1	97.8	98.2	98.9	99.1	99.7	99.7	100.0	99.9	99.8	99.9	99.8	99.9	99.8	99.9	
3-year	78.8	82.0	87.2	92.4	95.9	97.8	97.0	96.8	97.1	97.6	98.6	98.6	99.7	99.3	100.0	99.9	99.6	99.9	99.8				
4-year	73.6	76.8	83.8	90.3	94.4	97.2	96.5	95.6	96.5	97.0	98.1	98.4	99.4	99.1	100.0	99.9	99.6	99.9					
5-year	69.2	72.4	80.9	88.9	93.0	96.4	95.5	94.8	95.8	96.7	97.7	98.4	99.4	99.1	100.0	99.9	99.4						
6-year	65.6	68.8	78.2	87.4	91.5	95.2	94.7	94.0	95.4	96.3	97.5	98.2	99.4	98.8	100.0	99.9							
7-year	62.1	65.3	75.7	85.3	90.8	94.3	93.6	93.1	95.0	95.6	97.4	98.0	99.4	98.8	100.0								
8-year	58.9	62.3	73.7	83.7	89.6	93.0	93.0	92.5	94.8	95.1	97.3	98.0	99.1	98.7									
9-year	56.1	60.0	71.7	82.5	88.5	92.1	91.7	91.7	94.4	94.7	97.0	97.5	99.0										
10-year	53.5	58.1	69.9	80.7	87.6	91.1	90.8	91.2	93.8	94.5	96.9	97.2											
11-year	51.0	55.8	68.2	79.2	86.2	90.6	90.3	90.1	93.1	94.3	96.8												
12-year	48.7	53.8	66.4	78.3	85.5	89.9	88.9	89.3	92.3	94.0													
13-year	46.9	52.0	64.7	77.6	84.5	89.0	88.4	88.7	91.4														
14-year	45.1	50.4	63.3	76.5	84.1	88.4	87.8	87.8															
15-year	43.9	49.1	61.7	75.5	83.2	87.7	86.7																
16-year	42.1	47.2	60.1	73.8	82.1	86.8																	
17-year	40.5	46.1	59.6	72.7	81.8																		
18-year	39.1	44.7	58.5	72.1																			
19-year	38.3	43.3	58.0																				
20-year	37.3	41.9																					

ing. These recommendations are made by a panel of internists and public health officials after reviewing recent research by the Prostate Lung Colorectal Ovarian (PLCO) Cancer Screening Trial and the European Randomized Study of Screening for Prostate Cancer (ERSPC). Their main concern for men was the over-diagnosis of prostate cancer, over-treatment of prostate cancer, leading to minimal differences in overall mortality. The panel overemphasizes heavily on the harms of screening and treatment, and does not give any credibility the lives saved by screening. It fails to mention the multiple flaws in the PLCO and ERSPC studies, nor an actual 50% risk reduction in prostate cancer mortality with longer follow-up, nor the substantial decrease in prostate

dramatically, but the incidence or newly diagnosed cases of prostate cancer have been dropping at a rate of 2.4% annually from 2000 to 2006. The SEER database at the National Cancer Institute shows that the relative mortality based on the year of diagnosis has improved dramatically since the advent of the PSA test in 1990 (Table 23-9). ([http://seer.cancer.gov/csr/1975\\_2008/browse\\_csr.php?section=23&page=sect\\_23\\_table.09.html](http://seer.cancer.gov/csr/1975_2008/browse_csr.php?section=23&page=sect_23_table.09.html))

Prostate cancer screening has been controversial for many years generally because prostate cancer grows slowly and does not always cause death before a patient dies of another cause (i.e. a heart attack). In medical school, the phrase

a younger age. Two large screening studies, the Prostate Lung Colorectal Ovarian Cancer Screening (PLCO) study in the US and the European Randomized Screening Study of Screening for Prostate Cancer (ERSPC) showed dramatically different results. Neither the PLCO nor the ERSPC study showed a difference in overall mortality, but the ERSPC showed a 20% risk reduction in death from prostate cancer with the number needed to treat (or how many men you have to treat to save one life) being around 48 at 9 years of follow-up. With a screening study, one would expect a "lead-time" bias, or cancers you would detect earlier by PSA than when they would have surfaced with symptoms. This would lead to a "stage migration" as expected

because one would find cancers earlier, and they would be more likely organ-confined or lower stage than an advanced cancer that has spread beyond the organ. Interestingly, the PLCO showed minimal difference in stage, while the ERSPC showed almost twice as much men with advanced stage T3 and Gleason score >7 at diagnosis in the Control Arm (men that were not screened) (Table 5).  
(www.europeanurology.com/)

ance of biopsy was so low, any positive effect of screening would not be realized as the men in the screening arm simply ignored the recommendation. Lastly, the PLCO did not comply with the simplest minimal standards of running a trial- having the needed power to demonstrate a statistical effect.

On the other hand, the ERSPC trial was not centralized, and consisted of multiple

estimated the reduction in risk will grow to at least a 31% with longer follow-up.

In August of 2010, the Göteborg cohort from the population of Swedish men studied as part of the larger ERSPC study published their results separately at 14 years of follow-up. They demonstrated a 50% risk reduction in prostate cancer-specific mortality, and reduced the number-needed-to-treat to 12 and the number

**Table 5** Surrogate endpoints in the European Randomized Study of Screening for Prostate Cancer trial vs the Prostate, Lung, Colorectal and Ovary trial†

	ERSPC		PLCO***	
	S arm	C arm	S arm	C arm
Gleason score >7*	6.1%	10.6%	32.0%	37.7%
T ≥T3*	8.6%	15.7%	3.5%	4.5%
M1PC**	0.23	0.39	-	-

ERSPC = European Randomized Study of Screening for Prostate Cancer; PLCO = Prostate, Lung, Colorectal and Ovary† Reduction in S arm:Gleason >7: 63% in ERSPC versus 14% in PLCO T ≥T3: 45% in ERSPC versus 22% in PLCOM1PC: 41% in ERSPC versus ? in PLCO

**The Flaws**

There were multiple flaws in the PLCO study. About 44% of men had screening (had at least one PSA level) prior to randomization and there was contamination of 52% during the study (men getting PSA level when they were not supposed to) in the Control Arm. Secondly, compliance with biopsy recommendations was very low (30%) in the Screening Arm. Only about 30% of men in the Screening Arm underwent the biopsy when recommended to do so. Thus, one can see that the most aggressive cancers were selectively removed from the study by the pre-study testing and/or contamination, which would obviate any difference a screening test would show. Secondly, when compli-

centers. Each center would have its own data, and in such an environment, one would argue that, at best, it is a meta-analysis. Such an analysis would not be categorized as Level 1 evidence in medical research (randomized controlled trial). The rates of pre-treatment were not ascertained (we do not know how many men in Europe received a PSA test before entering the trial). The experts speculate that this would be lower than in the US because PSA is not widely used in Europe as it is here in the US. Beneficially, the rate of contamination was much lower (only up to 15% at most). The ERSPC trial at the publish date demonstrated 20% risk reduction from prostate cancer mortality at 9 years, and secondary follow up had

needed to screen to 293 (to save one life). (<http://www.ncbi.nlm.nih.gov/pubmed/20598634>).

**The Harms**

Another argument made by the USPSTF was the harm to men in screening. The most detrimental of prostate biopsy is infection, urosepsis and death. In a study of 1438 men, there were an infection rate of 2.2%, a sepsis rate of 0.2% and no deaths reported. In our experience, we rarely have men develop fever and sepsis after biopsy. Almost all of the men improve with intravenous antibiotics in less than a week. ([www.ncbi.nlm.nih.gov/pubmed/21316093](http://www.ncbi.nlm.nih.gov/pubmed/21316093))

The USPSTF also mentioned the harms of prostate cancer treatment. This argument

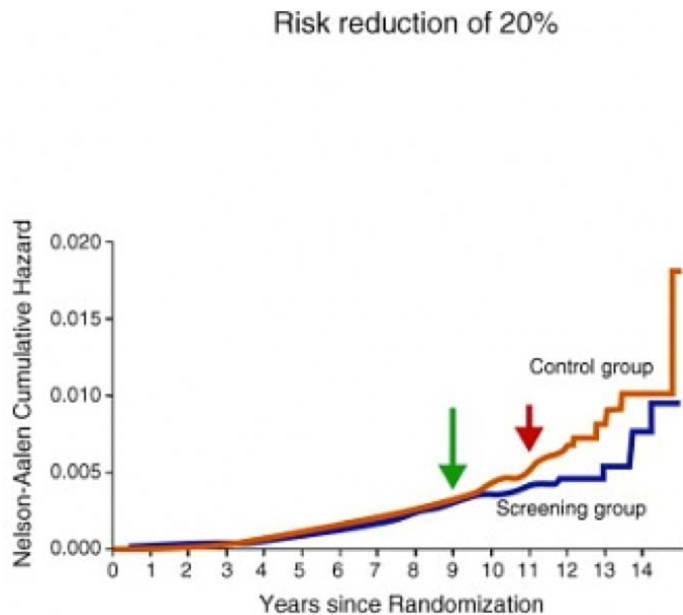
With further follow-up, the Göteborg cohort from the population of Swedish men demonstrated a 50% risk reduction in mortality due to prostate cancer.

should not be made if the purpose of the panel is to decipher if PSA is beneficial. Nevertheless, data used in their collection reflect some antiquated results. Surgery for prostate cancer has migrated to the use of the da Vinci robot, and in contemporary studies, the risk of total incontinence at 12 months to be at 0.8% with 93% of men resuming intercourse after surgery who had no preoperative erectile dysfunction (<http://www.ncbi.nlm.nih.gov/pubmed/17097214>). With surgery, a patient must rely on the surgeon experience in providing the best outcomes as there is a clear learning curve with the Da Vinci Robot.

Acute toxicity using radiation has changed dramatically, even in the past three years, with the advent of IGRT. Equipment/technology changes rapidly, and current data shows a dramatic difference between IGRT and non-IGRT methods in delivering radiation (<http://www.ncbi.nlm.nih.gov/pubmed/22035354>). In contrast to surgery, a patient must carefully decipher the equipment/technology delivering the radiation as this optimize outcomes with minimal side effects.

**Why Treatment**

What happens to prostate cancer if one would not treat it. The Urologic community has accepted this method of “treatment” for low grade cancers. “Active Surveillance” conveys that men are monitored closely for cancer progression but are NOT treated. The natural history of prostate cancer can be aggressive, or it can be indolent. There are models that predict what happens to prostate cancer when left untreated. With those middle



grade cancers (Gleason 7), about 24-34% of men would die of prostate cancer if left untreated. In cases of higher grade cancers (Gleason 8-10) about 63-83% of men would die of the disease if left untreated. (<http://cebp.aacrjournals.org/content/20/5/740.abstract>).

If we are to ignore PSA, there is no discussion with the physician about the benefits. One would then ignore the opportunity it affords to find the men who will present with the higher grade Gleason 8-10 prostate cancer who will benefit from early detection. If the number needed to treat is at 12, can we all ethically play Russian roulette with a 12-chambered revolver in not treating prostate cancer.

**The Costs**

The US spends about \$20,000 to \$25,000 over the first 60 months when initially treating prostate cancer -varying by choice of treatment (<http://www.physorg.com/news201758175.html>). If the treatment is successful, a yearly PSA monitoring the cancer is all that is needed. In contrast, if the cancer metastasizes, the costs are dramatically more, upwards of \$230,000 to \$355,000 before the end of life ([www.cancernetwork.com/display/article/10165/88183](http://www.cancernetwork.com/display/article/10165/88183)). Lets just say that the over-treatment would lead to more costs than to “accept” those with prostate cancer who are going to die of the disease- one would then ask- how much productivity would you

**The costs of treating localized prostate cancer is less than 10% of treating a patient with metastatic cancer.**

RapidArc™

One revolution is all it takes.



## USPSTF on PSA Screening (Continued)

save in preventing one death? Using an average per capita US GDP of \$33,000, if we were to save one productive life so that the person can work another 15 years (age 50-65), it would generate \$495,000 for our economy, not mentioning the tax revenue from that individual.

### Medicolegal

Research can demonstrate low risks, but as physicians we are held to the highest standards. If a patient has a bad outcome because a simple blood test is not ordered, we are held liable, regardless of research studies. A lawyer can simply argue to a jury that a simple blood test could have saved the plaintiff's life. We as physicians are victims, in essence, to the worst of "selection bias." Regardless of research showing a test may not be indicated for screening, we are held liable for the 1 in however many who will have a bad outcome because the test was not done. There have been many published malpractice cases regarding missed diagnoses of prostate cancer based on NOT acting on the PSA level. Unless Congress reforms our litigious medical environment, even if the USPSTF draft recommendations hold firm, patients will likely see multiple disclaimer forms with PSA screening - as currently given with, for example, HIV screening.

### Conclusion

If one would put PSA screening in perspective, we would need to use the simplest analogy. Imagine that you buy a new car, if it starts to squeak



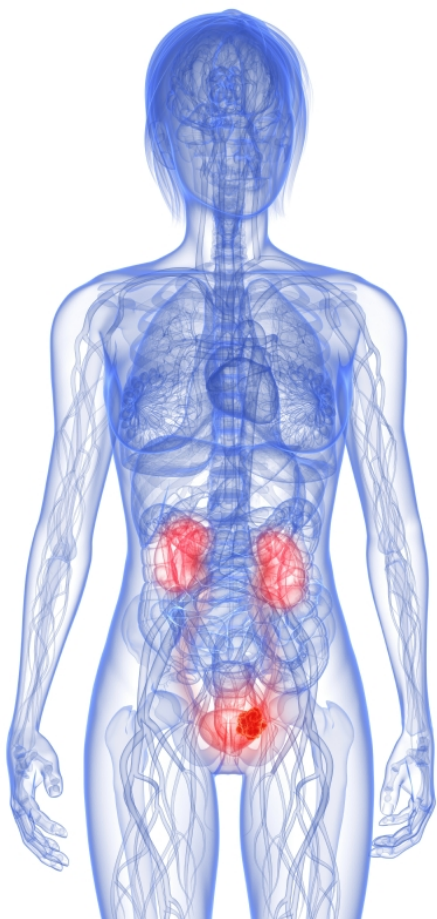
when you brake, it is most likely the brakes. If you have driven the car for many years, and then there is a squeak, there may be a million things that can make that sound. In order to evaluate your car, you would simply take it to the mechanic, and inspect the brakes. You can then easily decipher if there is indeed a brake problem that can throw you off the road or cause an accident in the immediate future. Alternately, you can at times have another 5000 miles or so to drive before problems occur. At the very least, you have that choice and the ability to accept or mitigate the risks in observation. However, if one simply ignores the squeaking sound, one may be facing imminent danger even without knowing so. Take the above analogy and put the PSA test in perspective - would a patient simply ignore its existence if it affords the opportunity to save one's life. Prostate cancer screening will remain controversial, and as an advocate, it should be done with adequate counseling, and thorough discussion of the risks and benefits.

### How you can help

There are proposals that Medicare may no longer reimburse physicians/patients for screening recommendations grade D. This may be detrimental to men at risk of prostate cancer. If you feel you are also an advocate, please visit the American Urological Association web site at [www.auanet.org](http://www.auanet.org), and make your voice heard by writing your congressional representative or senator, or simply writing the USPSTF. ([http://www.auanet.org/content/health-policy/government-relations-and-advocacy/in-the-news/uspstf-psa-recommendations.cfm?WT.mc\\_id=EML6621MKT](http://www.auanet.org/content/health-policy/government-relations-and-advocacy/in-the-news/uspstf-psa-recommendations.cfm?WT.mc_id=EML6621MKT))

**Before Medicare stops paying for the PSA level, write your congressional representatives and contact the AUA at [www.auanet.org](http://www.auanet.org)**

## Safety Update—Actos and Bladder Cancer



Actos (pioglitazone) is a drug commonly prescribed to control blood sugar in Type 2 Diabetes patients. It is prescribed as the single-ingredient agent Actos and is also sold in combination with Metformin, another Type 2 diabetes agent, as Actosplus Met and Actosplus Met XR. Between January 2010 and October 2010, approximately 2.3 million patients filled a prescription for a pioglitazone-containing product from outpatient retail pharmacies.

In June 2011 the FDA released a safety communication to the public that stated that the use of the diabetes medica-

tion Actos for more than one year may be associated with a 40% increased risk for bladder cancer when compared to baseline risk. The risk of bladder cancer also appears to increase with longer exposure to pioglitazone as well as higher doses. This information was based on a review from data from a planned five-year interim analysis of an ongoing ten-year epidemiological study. Similar studies in Europe have also suggested increased risk of bladder cancer with pioglitazone. Based on the results of that study, France has suspended the use of pioglitazone and Germany has recom-

mended not starting pioglitazone in new patients.

The FDA will continue to evaluate results of the ongoing ten-year epidemiological study and continue to review the European data. At the present time changes have been made to the Warning and Precautions section of the Actos drug label but it remains on the market. Current patient information and recommendations in regards to the use of pioglitazone are as follows:

- Recognize that there may be an increased chance of developing bladder cancer when you take pioglitazone.
- Make sure you inform your doctor if you have a history of bladder cancer.
- You should not take pioglitazone if you are receiving treatment for bladder cancer.
- Tell your doctor immediately if you have any of the following potential symptoms of bladder cancer: blood or red color in the urine; urgent need to urinate or pain while urination; pain in the lower back or abdomen.
- Read the Medication Guide you get along with your pioglitazone medicine, it explains the risks associated with the use of pioglitazone.
- Talk to your healthcare professional if you have questions or concerns about pioglitazone medicines.



Dr. Lynn W. Blunt, M.D.

**Over 2.3 million patients are on Actos in the US. Use of Actos for 1 year is associated with a 40% risk of bladder cancer.**



## FDA Advisory— Transvaginal Mesh



As many of you are aware, on July 13, 2011, the FDA released an “Update on the Safety and Effectiveness of Transvaginal Placement (TVM) of Surgical Mesh for Pelvic Organ Prolapse (POP)”. I am writing this newsletter in an effort to provide you with a better understanding and a more balanced perspective of the complications that can occur with all forms of vaginal surgery. I am hoping that the following discussion will be educational and relieve you of any unnecessary concerns.

As an expert in pelvic floor reconstruction and a valued leader in the field, I recognize the events that have led to the FDA’s report, and I agree with many of the points covered in the FDA’s Safety Communication. However, I am of the strong opinion that the recent FDA UPDATE fails to convey an accurate perspective to the public, to the press, and unfortunately, to the legal community. I also feel that several key conclusions in the UPDATE are not consistent with the scientific literature pertaining

to vaginal mesh and are inconsistent with the clinical realities we encounter as surgeons caring for women with severe prolapse and incontinence.

In an effort to respond to the FDA UPDATE, the Prolapse Surgeons Network released a report that reviewed the evidence supporting the use of mesh in correcting pelvic organ prolapse (POP). It is a 10 page report; however, I have outlined and simplified the main points below:

The FDA UPDATE defines “1503 reports associated with POP repairs” from 2008 to 2010. This is 5x greater than the reports from 2005 to 2007. However, the FDA failed to mention that 225,000 TVM procedures were performed during that time period, creating a complication rate of only 0.67%. So, the complication rate has not increased; rather, it is a reflection of the wide acceptance of TVM by many specialists in POP surgery and an increase in the overall rate of the procedures that are being performed.

The FDA UPDATE implies

that the risk of complication is higher with mesh than with native tissue repairs. This statement is not properly qualified and has been misleading to non-clinicians. Because non-mesh repairs don’t use an FDA-monitored device, there is no systematic reporting mechanism in place. It is important to understand that all treatment options (with or without mesh) for POP repairs involve significant risks. The FDA UPDATE portrays mesh repairs as uniquely hazardous, providing no broader perspective regarding the significant risks and/or higher recurrence rates associated with its alternatives.

The FDA UPDATE lists the following complications associated with the use of mesh: mesh erosion, pain, infection, bleeding, pain with intercourse, organ perforation, and urinary problems. These risks do exist, but the FDA fails to mention that they also exist for traditional non-mesh surgery as well (with the exception of mesh erosion)

The FDA UPDATE states that mesh placed abdominally results in lower rates of complications than transvaginal mesh placement. The FDA does not mention that the mesh used in all cases is basically the same. The FDA does not imply that mesh erosion exists regardless of the approach (abdominally or transvaginally). The complication rates for TVM are variable, and the FDA does not mention that the variation is likely due to surgical technique (and experience), not the mesh



*Dr. Shawn D. Blick, M.D.  
President and Founder*

**Of the 225,000 transvaginal placement of surgical mesh procedures in the FDA report, there was a 0.67% complication rate**

itself. While the rates of “complication” may be higher with TVM (compared to an abdominal approach), the severity of the complications associated with the abdominal approach may be greater (abd. wall hernias, small bowel injury or obstruction etc.)

The FDA UPDATE states that “mesh augmentation may provide an anatomic benefit compared to traditional POP repair without mesh”; however, the statement “this anatomic benefit may not result in better symptomatic results” is highly debatable. This is due to the fact that many of the favorable results in the literature fail to reach “statistical significance” due to study design. Given the latest data, it would be equally true to state, “this anatomical benefit may result in better symptomatic results.”

FDA UPDATE states that mesh erosion is a potential complication of TVM. However, the statement that “even multiple surgeries will not resolve the complication” is inaccurate. There are no published case reports in which mesh erosion from TVM does not resolve after 2 returns to the operating room.

Chronic pain after TVM may be difficult to resolve despite multiple surgeries, but chronic post-operative pain is a risk with non-mesh repairs as well, and can also be difficult to resolve.

In terms of clinical results, there were no studies that showed any difference in the change in vaginal length after surgery between the mesh and non-mesh arms of the studies. If there is shrinkage of the

vagina with TVM, it does not appear to affect vaginal length anymore than does the trimming of the vagina wall during traditional non-mesh repairs.

Based on 7 randomized controlled clinical trials of TVM, one study showed that pain on intercourse was worse with the “non-mesh” group. In all of the other studies, sexual function was reported to be the same in mesh and non-mesh groups.

The FDA UPDATE stated that “in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications”. This statement is very misleading. Studies actually show that, in many cases, traditional POP repairs (without mesh) have high failure rates. We agree that POP can be successfully treated without mesh in many cases, but not necessarily most.

There is limited long-term data on all forms of prolapse repair. The FDA fails to state that the long-term data on non mesh repairs suggests a very high failure rate. They also fail to mention that long term data on TVM for urinary incontinence does not show any untoward effects of mesh long term that were not present in the short term.

As you can see, the FDA has presented a biased view of transvaginal mesh placement. There are many considerations that are not represented in their report, creating unnecessary fear and apprehension in patients and in the community at large. We recognize the FDA’s mission to monitor manufactured devices in pelvic surgery and to advocate for

patient’s safety and best interests. Certainly, most of the surgical community will agree that proper informed consent regarding the risks, benefits, and alternatives of a procedure is critical. However, the FDA UPDATE has led patients to believe that there is a “mesh problem” or that something toxic has been or will be placed within them. This is definitely not the case!!! We do not have mesh problems; rather, we have surgical skill and experience problems.

As a leader and a trainer of other doctors in vaginal surgery, I have performed over 100 pelvic floor cases per year over the last 8 years. Over the last 3 years, I have been using mesh repairs in the majority of my cases. After reviewing my own data related to mesh repairs, I can report that over 90% of our patients are satisfied with the procedure, and we have only encountered a 3% mesh extrusion rate. All of our mesh extrusions have been manageable with simple intra-operative excision. Furthermore, we have no reported cases of chronic pelvic pain or pain on intercourse. Overwhelmingly, patients have been happy with their procedures, supporting the role that vaginal mesh provides to the “toolbox” for many surgeons who treat advanced pelvic organ prolapse.

**Dr. Blick has performed over 100 pelvic floor cases in the last 8 years with over a 90% satisfaction rate.**

## *A Review of Kidney Stones*

Kidney stones are the formation of crystalline structures in the urinary tract (which includes the kidneys, ureters, and bladder). These stones can cause pain, infection, and kidney damage. Stones can be small, from 1 mm to very large, filling up an entire kidney. For patients experiencing their first stone episode, the pain can be so severe and sudden that it stops them in their tracks. Without prior knowledge of what a stone episode feels like, it can be confusing and frightening to go through this amount of discomfort, which is usually described as the worst pain someone has ever experienced. A trip to the emergency room is usually required to make the diagnosis and provide treatment for an active kidney stone. X-rays, usually a CT scan, can be used to confirm that a stone is present.

Stone pain is often described as stabbing and extremely severe. Women commonly say that it is worse than having a child. The pain can start in the upper back (flank) and then migrate to the abdomen and groin. Changing positions does not help relieve the pain. The pain of a kidney stone is primarily due to blockage of the urine drainage coming down the small tube called the “ureter” that connects a kidney to the bladder. It is thought that the increased pressure stretches the kidney and ureter, causing the pain. This is why stone pain can come and go in waves, as the drainage tube is periodically blocked by the stone trying to make its way out. As the stone moves fur-



ther down the tube, the pain experienced moves down the body. Other symptoms common during a stone episode include seeing blood in the urine, nausea & vomiting, and feeling the urge to urinate. Once a stone is passed and makes it way out of the ureter tube and into the bladder, most patients describe a sensation of instant relief as the blockage and pressure is relieved. However, stones can take from days to weeks to pass.

Most doctors feel that kidney stones only cause pain if they are blocking the ureter and trying to pass down towards the bladder. Stones that are not obstructing, such as those lo-

cated in the kidney’s calyces, are generally thought to be non-painful. This explains why some patients can have extremely large stones filling up their entire kidney with no or minimal pain.



*Dr. Lipika R. McCauley M.D.*

**Pain from kidney stones can vary from waves of excruciating amount of pain to relief in minutes to hours**

Winter 2011



## Valley Urologic Associates

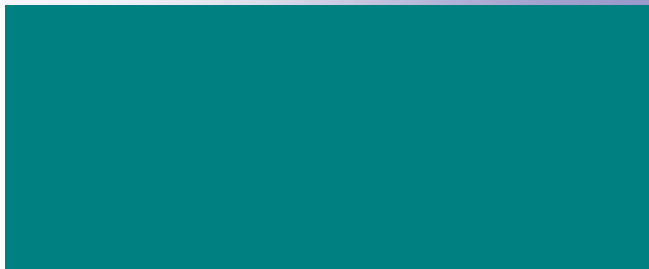
*State of the Art with Compassion and Sensitivity*

Valley Urologic Associates  
A Division of ACHO, PLC  
13555 W. McDowell Rd. Suite 304  
Goodyear, AZ 85395  
Phone: 623-935-5522  
Fax: 623-935-3220  
[www.vuaurology.com](http://www.vuaurology.com)

Shawn D. Blick, M.D.  
Jonathan Agins, M.D.  
Lynn W. Blunt, M.D.  
Ben O. Donovan, M.D.  
Vi Hua, M.D.  
Torre Rhoades, M.D.  
Rahul Thaly, M.D.  
Lipika McCauley, M.D.  
Timothy Coyne, PA-C  
Beth Dean, PA-C

Valley Urologic Associates provides excellent service in **ALL AREAS OF UROLOGY**. The members of VUA are all experienced general urologists with different sub-specialties. Uniquely, this allows specific docs to treat specific problems, providing the highest level of urologic care for patients in the Phoenix Metro Area.

**POSTMASTER: PLEASE MAIL TO**



Visit us on the Web!

<http://www.vuaurology.com>



### *Valley Urologic Continues on with New Research Trials*

VUA physicians have been tasked by several industry sponsors in partnership with Precision trials to conduct several new trials involving **prostate cancer, bladder cancer, and BPH**.

Precision Trials is a physician owned and physician-led network of Practicing Physicians Research Groups (PPRG) who have dedicated themselves to integrating the highest quality of patient care with state-of-the-art Clinical Research to offer a continuum of health services and resources to benefit General Health.

Recruiting subjects from existing Doctor/Patient relation-

ship is a powerful tool. The selection process associated with this continuum enables Precision Trials to launch new trials efficiently and expeditiously. These relationships provide our pharmaceutical and industry sponsors with consistent subject enrollment, comprehensive regulatory oversight, precision and accurate data, and a very high retention rate.

VUA has been enrolling patients in several research trials in conjunction with Precision Trials. One of these uses a novel agent to achieve hormone therapy using a selective estrogen receptor modulator

minimizing the side effects of low libido, osteoporosis, and hot flashes.

There are several locations throughout the valley. Ask your physician if you qualify as a candidate and your care and time may be reimbursed. VUA commits to bringing the state of the art care to our patients by incorporating the latest, cutting-edge products or pharmaceuticals before they arrive to Market. See our web page for more details or visit <http://www.precisiontrials.com>