FDA APPROVES URINE TEST FOR REPEAT PROSTATE BIOPSIES

The US Food and Drug Administration (FDA) has approved a urine-based molecular assay (Progensa, Gen-Probe) that helps determine the need for repeat prostate biopsies in men who have had a previous negative biopsy.

The test, which is already approved and marketed in Europe and Canada, detects levels of prostate cancer gene 3 (PCA3), which is overexpressed in “virtually all prostate carcinoma specimens,” according to an independent review published last year (Nat Rev Urol 8:123-124, 2011). The PCA3 assay is indicated for helping to decide whether men 50 years or older who have had 1 or more previous negative prostate biopsy, and “for whom a repeat biopsy would be recommended by a urologist based on the current standard of care,” should undergo a repeat biopsy, according to the company.

Such men have been described as having a “PSA dilemma” – that is, an elevated PSA score but negative biopsies. FDA approval of the PCA3 assay was based on a clinical study that enrolled 495 eligible men at 14 clinical sites. In the study, the PCA3 assay had a negative predictive value of 90%, meaning that a negative result predicted a negative prostate biopsy 90% of the time, according to the company.

(Continued on page 8)
ADVERSE EFFECTS OF ROBOTIC-ASSISTED LAPAROSCOPIC VersUS OPEN RETROPUBIC RADICAL PROSTATECTOMY AMONG A NATIONALWIDE RANDOM SAMPLE OF MEDICARE-AGE MEN

Barry MJ, Gallagher PM, Skinner JS, Fowler FJ


Purpose: Robotic-assisted laparoscopic radical prostatectomy is eclipsing open radical prostatectomy among men with clinically localized prostate cancer. The objective of this study was to compare the risks of problems with continence and sexual function following these procedures among Medicare-age men.

Patients and Methods: A population-based random sample was drawn from the 20% Medicare claims files for August 1, 2008, through December 31, 2008. Participants had hospital and physician claims for radical prostatectomy and diagnostic codes for prostate cancer and reported undergoing either a robotic or open surgery. They received a mail survey that included self-ratings of problems with continence and sexual function a median of 14 months postoperatively.

Results: Completed surveys were obtained from 685 (86%) of 797 eligible participants, and 406 and 220 patients reported having had robotic or open surgery, respectively. Overall, 189 (31.1%; 95% CI, 27.5% to 34.8%) of 607 men reported having a moderate or big problem with continence, and 522 (88.0%; 95% CI, 85.4% to 90.6%) of 593 men reported having a moderate or big problem with sexual function. In logistic regression models predicting the log odds of a moderate or big problem with postoperative continence and adjusting for age and educational level, robotic prostatectomy was associated with a nonsignificant trend toward greater problems with continence (odds ratio [OR] 1.41; 95% CI, 0.97 to 2.05). Robotic prostatectomy was not associated with greater problems with sexual function (OR, 0.87; 95% CI, 0.51 to 1.49).

Conclusion: Risks of problems with continence and sexual function are high after both procedures. Medicare-age men should not expect fewer adverse effects following robotic prostatectomy.

FINASTERIDE AND DUTASTERIDE DO NOT CONTROL LOW RISK PROSTATE CANCER

Neither finasteride nor dutasteride significantly reduced progression of low-risk prostate cancer in a retrospective study reported by Maryland-based researchers.

The two 5-alpha reductase inhibitors (5-ARIs) are used to treat lower urinary tract symptoms (LUTS) in men with benign prostatic hyperplasia.

But the researchers also cite evidence, in a 30 January 2012 online paper in BJU International, that the drugs might prevent prostate cancer. On the other hand, they point to evidence that the drugs can increase the risk of more aggressive high-grade disease.

To examine what effect 5-ARIs might have on cancer reclassification during active surveillance (AS), Dr. Edward M. Schaeffer and colleagues at Johns Hopkins Medical Institutions in Baltimore, MD retrospectively studied 587 men with low-risk prostate cancer.

None were taking 5-ARIs initially. Eventually, 47 did take the drugs, largely for LUTS, starting at a mean of 2.4 years (range up to 10 years) after enrollment. Mean exposure was for 2.4 years.

These men had larger prostate and PSA levels at diagnosis. PSA decreased by a mean of 47% and prostate volume fell by 11% during treatment. Median values increased in patients not taking 5-ARIs.

The 5-ARI users had a mean of 2.5 surveillance biopsies while on their drug. 5-ARI use “had a protective but nonsignificant effect on biopsy reclassification during AS,” the authors report.

They note that these findings contradict those of a similar study that suggested a more positive role for 5-ARIs, but that earlier study did not allow for the variable time between enrollment in AS and initiation of 5-ARI use.

The researchers suggest that “the use of 5-ARIs in carefully followed men with LUTS and very-low risk prostate cancer is oncologically safe.” But, they add, the findings do “not support a role for 5-ARI use in the secondary prevention of clinically significant prostate cancer.”
DUTASTERIDE IN LOCALISED PROSTATE CANCER MANAGEMENT: THE REDEEM RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL

Fleischer NE, Lucia MS, Egerdie B, et al

The Lancet, Epub 24 January 2012

Background: We aimed to investigate the safety and efficacy of dutasteride, a 5α-reductase inhibitor, on prostate cancer progression in men with low-risk disease who chose to be followed up with active surveillance.

Methods: In our 3 year, randomised, double-blind, placebo-controlled study, undertaken at 65 academic medical centres or outpatient clinics in North America, we enrolled men aged 48-82 years who had low-volume, Gleason score 5-6 prostate cancer and had chosen to be followed up with active surveillance. We randomly allocated participants in a one-to-one ratio, stratified by site and in block sizes of four, to receive once-daily dutasteride 0.5 mg or matching placebo. Participants were followed up for 3 years, with 12-core prostate biopsy samples obtained after 18 months and 3 years. The primary endpoint was time to prostate cancer progression, defined as the number of days between the start of study treatment and the earlier of either pathological progression (in patients with ≥1 biopsy assessment after baseline) or therapeutic progression (start of medical therapy). This trial is registered with ClinicalTrials.gov, number NCT00363311.

Findings: Between August 10, 2006, and March 26, 2007, we randomly allocated 302 participants, of whom 289 (96%) had at least one biopsy procedure after baseline and were included in the primary analysis. By 3 years, 54 (38%) of 144 men in the dutasteride group and 70 (48%) of 145 controls had prostate cancer progression (pathological or therapeutic; hazard ratio 0.62, 95% CI 0.43-0.89; P = 0.009).

Incidence of adverse events was much the same between treatment groups. 35 (24%) men in the dutasteride group and 23 (15%) controls had sexual adverse events or breast enlargement or tenderness. Eight (5%) men in the dutasteride group and seven (5%) controls had cardiovascular adverse events, but there were no prostate cancer-related deaths or instances of metastatic disease.

Interpretation: Dutasteride could provide a beneficial adjunct to AS for men with low-risk prostate cancer.

However, she explained that there are concerns about screening leading to false-positive PSA tests, adverse effects from biopsies (such as infections), and overtreatment because of overdiagnosis. These issues all affect the risk/benefit ratio for screening in individual patients. Dr. Loeb added that in the US, the majority of men receive active treatment, but in Europe, a greater proportion of men undergo active surveillance.

“It’s very important to determine the true value of screening. Specifically, we needed to evaluate the true effects of treatment for men diagnosed through screening,” she remarked.

Dr. Loeb’s team randomized 42,376 men during the first round of ERSPC Rotterdam (1993 to 1999). There were 1151 prostate cancers diagnosed in the screening group and 210 in the control group. More cases were diagnosed and there were more RPs in the screening group than in the control group (420 vs. 50), Dr. Loeb reported. Fewer men in the control group underwent RP, probably because a proportionately larger number of men with advanced disease.

The researchers compared progression-free survival, metastasis-free survival, and cancer-specific survival in the 2 groups after RP. Patients in the screening group had significantly better progression-free, metastasis-free, and cancer-specific survival. “This means that men whose cancer was detected through screening were less likely to die from prostate cancer after surgery,” Dr. Loeb said.

The researchers also looked at PSA level, tumor stage, Gleason score, and age to help predict prognosis after surgery. Even after accounting for all these factors, screening status was found to provide better progression-free and metastasis-free survival, she noted.

One finding surprised the investigators and provided useful insight into factors affecting prognosis. “Everything changed with the tumor volume of the RP specimen. After accounting for this, screening status was no longer significant,” Dr. Loeb reported. “It seems [that] screening led to diagnosis at a time when tumor volume was significantly less. A lower burden of disease at diagnosis made the men more likely to be helped by surgery,” she said.

She emphasized the importance of selecting the right men for the wide-scale implementation of a screening program. “If we do not select who is screened carefully, then we may cause more harm than benefit.”

Commenting on the study, Patrick Walsh, MD, from the Department of Urology, Johns Hopkins School of Medicine, Baltimore, MD, said “this is a very important study because it provides further evidence that PSA testing is valuable.” Having practiced in the pre-PSA era, I’ve seen too many men who missed the window of curability. This study demonstrates...[that] it doesn’t help to remove the prostate in men who are not curable, and provides further evidence that PSA saves lives.”

Medscape Medical News, 2 March 2012
Us TOO Advocacy Issues

Draft Letter Regarding FY13 Funding for Congressionally Directed Medical Research Programs (CDMRP)

Note: This letter will be sent during the week of March 19th. It is directed to the leaders of the House appropriations committee subcommittee on Defense and seeks support for CDMRP, which includes funding for prostate cancer research. Us TOO will be signing this letter to show support for the PCRP, one of Us TOO’s highest advocacy priorities.

The Honorable C.W. Bill Young The Honorable Norm Dicks
Chairman, Subcommittee on Defense Ranking Member, Subcommittee on Defense
Committee on Appropriations Committee on Appropriations
H-307 Capitol Building 1016 Longworth House Office
Washington, DC 20515 Washington, DC 20515

DRAFT

ATTENTION: DoD Appropriations Staff
February, 2012

Dear Chairman Young and Ranking Member Dicks:

As you begin work on the Fiscal Year 2013 (FY13) Defense Appropriations bill, we write to request your continued support for the critical and highly successful medical research initiatives conducted within the Department of Defense (DOD) Congressionally Directed Medical Research Programs (CDMRP). We deeply appreciate your support in a challenging fiscal environment for these programs during the FY12 budget process. Although many of these programs experienced an unfortunate reduction in funding, we were grateful to see them funded through the end of FY12. We are hopeful that for FY13, programs can be restored to at least their FY11 funding levels.

While other federal agencies support medical research, the programs within the CDMRP are innovative and even unique in many aspects.

First, the medical research programs within the CDMRP directly impact the health and lives of the US military, their families and the public. This disease-specific approach includes important medical research programs related to several forms of cancer (breast, blood, colorectal, melanoma, pediatric, brain, lung, ovarian, and prostate) and other disorders (like neurofibromatosis, tuberous sclerosis complex and bone marrow failure) that have lead to breakthroughs on nerve regeneration and traumatic brain injury – key developments favorably impacting our newest wounded warriors. Other programs within the CDMRP provide groundbreaking research on psychological health (including TBI and PTSD), Gulf War Illness, spinal cord injury, and hearing and vision loss (which comprise a significant portion of current battlefield injuries). Others diseases and conditions in the CDMRP include Multiple Sclerosis (MS), Scleroderma, ALS, and Autism.

Second, while Congress allocates funding through the CDMRP to specific medical conditions; it does not direct the programs’ dollars to specific researchers, making this program very different from an “earmark.” The CDMRP utilizes an efficient multi-tiered process that includes multiple stages of peer review, including two levels of formal peer review of final proposals. Proposals are scored and ranked in a number of key areas, providing a robust comparative basis for helping accomplish CDMRP’s mission of finding and funding the best research related to Congressionally directed medical conditions.

Third, the CDMRP funds highly innovative proposals – funding which may not otherwise be available. For example, programmatically related Department of Veterans Affairs (VA) research funding is only available to VA employees (at least 0.625 full-time equivalents). CDMRP funds the best-qualified proposals, from top research universities and medical centers to individual investigators. Continued funding for CDMRP programs helps ensure funding for invaluable medical research that would otherwise not be possible.

Fourth, the unique, Congressionally-directed nature of these programs makes them unusually agile and adaptable. Each of the separate programs is guided by a specific vision and mission statements, which in addition to incorporating Congressional direction, are adapted yearly to accommodate rapid change in knowledge, address research gaps and prevent overlaps. Annual funding prevents out-year budget commitments, which in turn further enhances programmatic flexibility.

Fifth, CDMRP-funded medical research is non-duplicative by design through careful programmatic balance. CDMRP grants neither duplicate nor supplant National Institutes of Health (NIH), VA, or other DOD research efforts, but rather enhance those efforts.

Sixth, many CDMRP programs find (or even work to develop) and fund collaborative and consortia research, helping to bring unique, interdisciplinary, inter-institutional collaborative efforts to bear on complex medical research issues unlikely to be solved though the inherent limits of individual researchers.

Finally, all CDMRP programs incorporate the full and equal participation of consumer reviewers at every stage of the multi-tiered review process – a state-of-the-art practice in medical research funding. Consumers – people actually affected by the disease or medical condition – help ensure CDMRP’s funded research will have the greatest impact on those who are affected. Consumer reviewers also help inform and educate their disease advocacy community and others.

(Continued on page 5)
In short, the well-executed and efficient programs within the CDMRP demonstrate responsible government stewardship of taxpayer dollars and benefit current and former military servicemembers, the general patient population, and our nation’s economy:

- **Military/Veterans** – programs target diseases that have a disproportionate and service-related impact. As one example, the ALS CDMRP is specifically designed to find treatments for this fatal neurological disease that inexplicably affects those who have served in the US military at twice the rate of those who have not served.

- **American People** – cutting-edge biomedical research into the treatment and cures of diseases serves patients and the general population. For example, CDMRP research on the prevention of epilepsy after Traumatic Brain Injury (TBI) demonstrated that administering an antiepileptic drug immediately after TBI reduces early seizures, diminishes the development of late epilepsy, and facilitates recovery.

- **Economy** – research activities promote job growth and encourage long-term economic development through innovation. It has been estimated that for every dollar awarded in biomedical research grants, more than $2 of additional business activity is created. CDMRP research grants are awarded to universities and institutes in every state in the country.

Perhaps most importantly, the CDMRP’s innovative approaches to funding biomedical research has led to a number of significant breakthroughs and achievements, contributing to national security and the health and welfare of US Armed Forces personnel and their dependents. Enclosed is a short white paper providing several examples. Continued federal funding will only build on these successes.

The undersigned respectfully request your support for FY 2013 funding of all programs within the CDMRP, restored to at least their FY11 funding levels.

Sincerely,

Enclosure

cc: Members, House Appropriations Committee

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**TARGETED ANTIMICROBIAL PROPHYLAXIS USING RECTAL SWAB CULTURES IN MEN UNDERGOING TRANSRECTAL ULTRASOUND GUIDED PROSTATE BIOPSY IS ASSOCIATED WITH REDUCED INCIDENCE OF POSTOPERATIVE INFECTIOUS COMPLICATIONS AND COST OF CARE**

Taylor AK, Zembower TR, Nadler RB, et al

*J Urol, 15 February 2012; Epub ahead of print*

**Purpose:** We evaluated targeted antimicrobial prophylaxis in men undergoing transrectal ultrasound guided prostate biopsy based on rectal swab culture results.

**Materials and methods:** From July 2010 to March 2011 we studied differences in infectious complications in men who received targeted vs. standard empirical ciprofloxacin prophylaxis before transrectal ultrasound guided prostate biopsy. Targeted prophylaxis used rectal swab cultures plated on selective media containing ciprofloxacin to identify fluoroquinolone resistant bacteria. Patients with fluoroquinolone susceptible organisms received ciprofloxacin while those with fluoroquinolone resistant organisms received directed antimicrobial prophylaxis. We identified men with infectious complications within 30 days after transrectal ultrasound guided prostate biopsy using the electronic medical record.

**Results:** A total of 457 men underwent transrectal ultrasound guided prostate biopsy, and of these men 112 (24.5%) had rectal swab obtained while 345 (75.5%) did not. Among those who received targeted prophylaxis 22 (19.6%) men had fluoroquinolone resistant organisms. There were no infectious complications in the 112 men who received targeted antimicrobial prophylaxis, while there were 9 cases (including 1 of sepsis) among the 345 on empirical therapy (p = 0.12). Fluoroquinolone resistant organisms caused 7 of these infections. The total cost of managing infectious complications in patients in the empirical group was $13,219. The calculated cost of targeted vs. empirical prophylaxis per 100 men undergoing transrectal ultrasound guided prostate biopsy was $1,346 vs. $5,598, respectively. Cost-effectiveness analysis revealed that targeted prophylaxis yielded a cost savings of $4,499 per post-transrectal ultrasound guided prostate biopsy infectious complication averted. Per estimation, 38 men would need to undergo rectal swab before transrectal ultrasound guided prostate biopsy to prevent 1 infectious complication.

**Conclusions:** Targeted antimicrobial prophylaxis was associated with a notable decrease in the incidence of infectious complications after transrectal ultrasound guided prostate biopsy caused by fluoroquinolone resistant organisms as well as a decrease in the overall cost of care.

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**RANDOMIZED, DOUBLE-BLIND, PHASE 3 TRIAL TO COMPARE THE EFFICACY OF IPILIMUMAB VS. PLACEBO IN ASYMPTOMATIC OR MINIMALLY SYMPTOMATIC PATIENTS WITH METASTATIC CHEMOTHERAPY-NAÏVE CASTRATION RESISTANT PROSTATE CANCER**

The purpose of this study is to determine if patients with metastatic prostate cancer who have not received chemotherapy live longer when treated with ipilimumab than those treated with a placebo. This is an NCI-sponsored clinical trial (NCT01057810).

**Inclusion criteria:**
- Metastatic prostate cancer
- Asymptomatic or minimally symptomatic disease
- Progression during hormonal therapy
- ECOG Performance Status 0-1

**Exclusion criteria:**
- Liver, lung or brain metastases
- Prior immunotherapy or chemotherapy for metastatic prostate cancer
- Autoimmune disease
- HIV, or Hepatitis B or C infection

**Gender:** Male

**Ages:** 18 Years and older

**Contact:** For more information and to find the locations of study sites go to: http://clinicaltrials.gov/ct2/show/study/NCT01057810?term=CA184-095&rank=1
**ASK DOCTOR SNUFFY MYERS**

*Editors’ note: This column contains opinions and thoughts of its author and are not necessarily those of Us TOO International.*

**Q:** I have had a year and a half of Taxotere chemotherapy. The last six months were in combination with Carboplatin. I developed tingling and a tightness in my feet. I have been off chemo for almost a year and the discomfort in my feet seems to gradually be getting worse. Question: Are there treatments that address this condition?

**A:** There are several things that can be done. Two supplements seem to help. One is Jarrow Alpha Lipoic Acid Sustain 300 mg two twice a day. The other is Jarrow Glutamine powder one teaspoon mixed with fruit juice with each meal and at bedtime. This usually lessens the severity as long as you take it, but the benefit disappears within 1-3 days after you stop. Neurontin and Lyrica can both lessen symptoms. Low dose Effexor helps some patients.

Taxotere neuropathy normally improves gradually off the drug. I worry that something else might be going on. As a prostate cancer patient who has been on hormonal therapy, you would be at risk for diabetes. Diabetes is one of the more common causes of these symptoms of peripheral neuropathy and would be expected to worsen off Taxotere. You should at least have a fasting blood sugar test. It would even be better to have a hemoglobin A1c as that shows your average blood sugar over the previous 90 days. If that proves not to be the case, you should consult a neurologist and get worked up for other causes of peripheral neuropathy.

**DOC MOYAD’S WHAT WORKS & WHAT IS WORTHLESS COLUMN – ALSO KNOWN AS “NO BOGUS SCIENCE” COLUMN**

“Okay, is it time for Moyad to buy some stock in Starbucks® and/or at least start drinking coffee?! Maybe, but I want to know the secret!”

Mark A. Moyad, MD, MPH, University of Michigan Medical Center, Dept. of Urology

*Editors’ note: This column contains opinions and thoughts of its author and are not necessarily those of Us TOO International.*

**Bottom Line:** Coffee continues to garner attention as an overall healthy and disease preventing beverage. Who would have believed this years ago when so many bone headed health “experts” told me coffee was the devil’s liquid!

I never liked coffee and never really drank coffee (Diet Mountain Dew is my Achilles heel folks and the direct source of my daily caffeine...aka “addiction”) except once in a while when I want to talk really fast, and act as hyper as an 18-year-old kid at prom with a new cellular phone I have a cup of coffee. I digress...another very large epidemiologic study has just shown that daily coffee (caffeinated or decaffeinated) consumption does not seem to increase or decrease the risk of cancer and heart disease, but appears to lower the risk of type 2 diabetes. And, last year was that large study that showed a lower risk of depression in coffee drinkers, and then that Harvard study that showed that coffee (caffeinated or decaffeinated-6 or more cups per day compared to non-drinkers) could have a lower risk of lethal prostate cancer.

Wow! In reality, I am not so sure I buy into all this stuff. I do believe that coffee is not really harmful and may have healthy benefits for many folks. However, I also believe that coffee drinkers in Europe and some in the US and Canada that consume a good deal of coffee (like my wife) also tend to follow some kind of healthy behavior that we cannot pick up in a questionnaire or interview. For example, in the US coffee study, men that drank more coffee were actually more likely to have been smokers, less likely to be involved in “vigorous” physical activity, consumed more calories, alcohol and processed meat!!! This is crazy stuff that not many folks that reported the story last year picked up on! Are coffee drinkers more likely to go to the doctor, take their medications that they need, happier and more social (this describes my wife – happiest person I have ever met but she also loves to eat right and exercise daily and drink her coffee every darn morning...makes me sick to admit this)?? What the heck is it that gives the coffee drinker some kind of health edge that researchers are dumbfounded by in many cases?

Some would have you believe it is the variety of healthy compounds in coffee, but I again am not so sure. Regardless, here is to life in moderation and all those coffee drinkers...the next time you have a cup, think of me and please tell me what your secret is...please! Does Starbucks give you free statins or aspirin or a cute puppy with each purchase...what is it? I need to know the secret!!! Tell me! “I’m as mad as hell, and I’m not going to take this anymore!!!” I need to know the secret! Please tell me!

**References:**


a1p1c1 Many men subjected to a prostate biopsy that is found to be negative are faced with having repeat biopsies over the ensuing years. That is because no optimal method has been found to tell who does NOT need a biopsy. The recent approval of the PCA3 test is intended to help fill that gap. The test is done on a urine sample collected after a prostate massage yields a number reflecting the amount of this marker. It does not give a yes or no result. The lower the number, the lower the chance of cancer, but even at the very lowest levels, about 10-14% of men still have cancer. That means if the test shows a low level, that individuals cannot be assured cancer is absent. All the test provides is the odds that having cancer are low. Men with low results will have to decide if they want to accept the low risk to avoid another biopsy.

THE BOTTOM LINE: PCA3 is a new tumor marker that may help men decide if they should undergo a repeat prostate biopsy if the first one is negative but it does not guarantee a man is free from cancer even if the test result is very low.

a2p1c2 The article on men in the European screening study who underwent radical prostatectomy (RP) takes an interesting spin on the study. It suggests that RP in men with screen-detected cancer yielded better overall survival in men having RP with cancer not detected by screening. Unfortunately, there are several reasons why the results need to be interpreted cautiously. The real message here may be that RP for men who have a high likelihood of not having localized disease is not a good idea. One criticism of the European study is that treatment was not standardized. Men in the control group may have been treated less aggressively, which may partly explain a survival difference. Until this study is published, a complete evaluation is not really possible.

THE BOTTOM LINE: Men not diagnosed by screening may have a worse outcome if treated by RP vs. men diagnosed by screening meaning that other options might be more appropriate.

a3p1c3 The study about proton therapy raises important concerns about how men are being counseled and it also suggests that profit is a driving force in how men get treated. Proton therapy has been discussed in the HotSheet before. Men should realize that NO study has demonstrated either better results or lower morbidity for this treatment compared to other options. Also, NO survival results have yet been reported so men do not know if they have the same, better, or inferior survival to other options. Despite these shortcomings, new machines appear around the US. Based on this study, one can expect the costs for treating prostate cancer to continue increase without evidence that men are benefitting. A strong argument could be made NOT to pay for this more expensive treatment UNTIL there is clear evidence it is worth the added cost. If a man can get the same survival and quality of life with a treatment at one-fifth the cost WHY have the more expensive and time-consuming treatment? This is a question that truly needs answering.

THE BOTTOM LINE: Men living near a Proton Beam Center should ask more questions about their options otherwise they are more likely to receive a more expensive treatment that has no proven advantage over less costly options.

a4p2c2 In yet another example where publicity trumps science, the study on robotic RP addresses the question whether this method delivers better results than an open RP. Men were randomly selected to receive a written validated survey of their outcomes and a high percentage complied. In contrast to the hype about better results, this study found that men undergoing robotic RP were as likely to have problems with urinary incontinence and sexual function as those having an open RP. This is an important study because it looks at a cross section across the US rather than results at high volume specialty centers.

THE BOTTOM LINE: Robotic RP is not routinely providing better urinary control or sexual function than open RP meaning men should spend more time choosing their surgeon rather than worrying about how the operation is done.

a5p2c3 & a6p3c1 The role of 5-ARI’s in prostate cancer continues to be debated. Randomized studies show it may reduce the chance of finding prostate cancer and uncontrolled reports are using them in combination with medical castration to treat progressive disease. If indeed they will be helpful for prostate cancer patients, then one ideal place to study them is in men on active surveillance (AS). Two studies in this issue address this approach, one retrospectively and the other prospectively and randomized. The REDEEM study found that men randomized to receive the 5-ARI showed less evidence of pathological progression on biopsy and were less likely to show progressive disease. One major weakness, however, is that men could chose to stop the study and no information is provided to know how often that occurred. Another shortcoming is that without knowing the long-term impact on survival, the real benefit cannot be defined. In the retrospective study, some men on AS were given the 5-ARI to treat symptomatic BPH and their repeat biopsies results were compared to repeat biopsies results of men who did not receive the 5-ARI. This study did not find a reduced risk of developing tumor progression on biopsies. Based on the study design of the two studies, the REDEEM study is more likely to be the correct result but longer follow-up is really needed to know if this is a helpful approach for these men.

THE BOTTOM LINE: The role of 5-ARI’s in men on AS remains unclear and more studies with longer follow-up are needed to see if they prolong survival.

a8p5c2 In the past several months, published studied reported an increased risk of infectious complications associated with transrectal prostate biopsy despite prophylactic antibiotics. This suggests that the infections are caused by resistant bacteria. This interesting study looked at
non-Hispanic white men were also slightly more likely to receive proton beam treatment, according to the study.

While most insurers cover proton beam therapy, it comes at a hefty price. Previous studies have estimated that therapy costs twice as much as intensity-modulated RT, another form of external RT and about 5 times more than radioactive seed implants (brachytherapy).

And side-by-side comparisons of proton beam therapy and other prostate cancer treatments have not been done, according to Dr. Leonard Lichtenfeld, Deputy Chief Medical Officer for the American Cancer Society. So, despite the added costs, there’s no evidence to suggest that proton beam therapy delivers better outcomes than other forms of prostate cancer treatment, including other forms of RT, surgery or hormone therapy.

Touted as a technological advancement over other forms of RT, proton beam therapy allows radiated particles to more tightly target and destroy tumor cells, leaving more of the surrounding tissue intact. Although it has been shown to be superior in targeting tumors of the brain, eye and spine, those cancers are rare.

Institutions with proton beam facilities often look to pad their numbers by treating prostate cancer, according to Dr. Anthony Zietman, a radiation oncologist at Massachusetts General Hospital in Boston who was not involved in the study.

Dr. Aaronson added, “People often think that technology is synonymous with ‘better,’ but in some cases, it’s not. With the healthcare crisis looming and multiple treatment options available, newer, more expensive procedures for prostate cancer should be validated before they are implemented.”

 Reuters Health, 17 February 2012

PCA3 Urine Test Approved
(Continued from page 1)

The pivotal clinical study of the assay only looked at men recommended to have a repeat biopsy. Performance has not been established in cases where a repeat biopsy has not been recommended.

“Unlike PSA, it is not expressed in other prostate disorders, such as prostatitis or benign prostatic hyperplasia, he said at a press conference that covered a study of the assay presented at the meeting.

 Reuters Health, 17 February 2012

The Bottom Line
(Continued from page 7)

the effect of performing rectal swab before the biopsy and tailoring the antibiotic prophylaxis against any organisms resistant to ciprofloxacin. Although details are not provided, the authors found that cultures lowered the infection rate and the cost of managing this infection.

THE BOTTOM LINE: Using targeted antibiotic prophylaxis may be both cost-effective and safer than the method of using the same antibiotic in everyone.

a9p5c3 A long-standing challenge in treating men with metastatic disease is what to do when the PSA rises but there is no other evidence of cancer progression? At this time, many questions remain and studies are needed. A recent study of Abiraterone has shown positive results but it is not yet approved for that indication. More studies are in progress including the one using Ipilimumab. A good reason for men eligible to participate is the opportunity to get a new drug before it is widely available and the possibility of delaying chemotherapy.

THE BOTTOM LINE: When the optimal treatment for your prostate cancer is not clear, participating in a clinical trial