Dismissing Reduced Abiraterone Dose is Absolutely Wrong

A debate has intensified about cutting the dose — and hence the cost — of the oral prostate cancer drug abiraterone acetate (Zytiga) by taking it with food. A prominent figure in the prostate cancer world has entered the discussion and added withering words for those opposing the idea.

Ian Tannock, MD, PhD, DSc, from Princess Margaret Hospital, Toronto, Ontario, endorses taking one daily pill of abiraterone with a low-fat breakfast (250 mg) instead of the standard four pills on an empty stomach (1,000 mg) for the treatment of castrate-resistant prostate cancer (CRPC). And he said critics who dismissed the take-with-food approach as being “of small consequence” were “absolutely wrong.”

The lower dose and reduced cost would make the efficacious drug available to many more men, especially in poor and middle-income countries, and thus is a matter of “enormous consequence,” Tannock writes in a letter to the editor published online September 6 in the Journal of Clinical Oncology (JCO).

Tannock was provoked to write the letter after reading an editorial published May in JCO that accompanied publication of the randomized, 72-patient phase 2 study upon which the dose-reduction concept is based. The editorialists said the evidence of noninferiority of the low-dose was “non-compelling” and use of the primary outcome was “clinically questionable.” They also concluded that the low-fat abiraterone food effect was “minimal at best” and of “little consequence.”

Can Aspirin Help Treat Cancer?

Can aspirin (ASA) help treat cancer? A new review investigates. Peter Elwood, of the Cochrane Institute of Primary Care and Public Health at Cardiff University in the U.K. is the lead and corresponding author of the new analysis, which was published in the journal PLOS One.

Their paper is entitled “Systematic review update of observational studies further supports aspirin role in cancer treatment: time to share evidence and decision-making with patients?”

Elwood explains the motivation for the research, saying, “The use of low-dose ASA as a preventive in heart disease, stroke, and cancer is well established, but evidence is now emerging that the drug may have a valuable role as an additional treatment for cancer, too.”

The authors looked at data from the National Cancer Institute’s Surveillance, Epidemiology, and End Results (SEER) program on more than 49,000 men diagnosed with prostate cancer, 42% of whom had a Gleason score of 6 or lower. Thirty-four percent had a score of 7 and 18% had a score of 8-10.

(Continued on page 5)
Bladder Cancer Risk Higher With Radiation Therapy for Prostate Cancer

External beam radiation therapy (EBRT) for prostate cancer is associated with a greater risk of a bladder cancer compared with radical prostatectomy (RP), according to a new study. In a study of 84,397 men older than 65 years with localized prostate cancer (PCa) treated either with EBRT or RP from 1988 to 2009, investigators examined the risk of a secondary pelvic cancer (bladder and/or rectal cancer). The 5- and 10-year cumulative incidence rates of a primary bladder cancer were 1.26% and 2.34%, respectively, for EBRT recipients compared with 0.75% and 1.63%, respectively, for RP patients.

"In multivariable competing-risk analyses, EBRT was associated with a significant 35% increased risk of bladder cancer compared with RP," a team led by Marco Moschini, MD, PhD, of Luzerner Kantonssspital, Lucerne, Switzerland, reported online ahead of print in the journal *European Urology*.

"This information should be discussed during the counseling of clinically localized PCa patients during the decision making regarding RP versus EBRT," Dr. Moschini and his colleagues concluded.

The study found no significant difference in the risk of rectal cancer between the treatment modalities. The investigators identified their study population using the Surveillance, Epidemiology and End Results (SEER)-Medicare database. Of the 84,397 patients, 51,145 and 33,252 underwent EBRT and RP, respectively. The EBRT group was older than the RP group (median 74 vs. 69 years). The median follow-up was 69 months, during which 1,236 primary bladder cancers and 432 primary rectal cancers were diagnosed.
Doc Moyad’s What Works & What is Worthless Column — Also Known as “No Bogus Science” Column

“Low-Dose Aspirin Could be Dangerous? Yup!”

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

Editor’s Note: Us TOO invites certain physicians and others to provide information and commentary for the Hot SHEET to enrich its content to empower the reader. This column contains the opinions and thoughts of its author and are not necessarily those of Us TOO International.

Just when you thought it was safe to go to the drug store and purchase baby/low-dose aspirin (ASA) along comes the ASPREE trial to frighten you around the time of Halloween1–3 Boo! Yikes! In a series of three studies published in the September 16, 2018 issue of the “wicked awesome” New England Journal of Medicine, the results of this randomized trial conducted in the U.S. and Australia scared a lot of folks, and especially elderly folks. (Still, I do not like the term “elderly” but rather “seasoned” or “overwhelmingly experienced.”) Participants in this study were very healthy (please remember this) and seasoned (median age of 74 years of age), did NOT have cardiovascular disease, dementia, or disability (very healthy) and were randomly assigned to 100 mg of daily enteric-coated ASA (n=9525) or placebo (n=9589). After a median 4.7 years of follow-up there was a significantly greater risk of major bleeding events with ASA vs. placebo without a reduction in cardiovascular disease events and cancer! In fact, there appeared to be a higher risk of death from some cancers such as those of the gastrointestinal tract (not prostate).

“What? Moyad, you were so excited about aspirin?! So, what is your opinion now?” I am glad I asked myself this question and the answer is that my opinion has not only NOT changed but strengthened! “What? Are you drinking some wacky Ohio State is number 1 in football juice?” No! I have stated countless times in the Us TOO newsletter that I love aspirin for the people that QUALIFY FOR ASPIRIN based on their CARDIOVASCULAR risk. One way to determine if you qualify is going to the web-site cvriskcalculator.com from the American College of Cardiology (ACC) and American Heart Association (AHA). This is the website I have pushed over the last five years since it was released! And, when doing the calculations, many healthy seasoned persons in their 70s and 80s would NOT qualify for aspirin because the risk of bleeding would be greater than the benefit! So, this trial should further force (hopefully) people to make decisions on low-dose aspirin therapy using more information than just guesswork, which is why I like part of the message of this trial! I hate the fact that countless people are taking regular or even low-dose aspirin that are perfectly healthy simply because some “expert” said they should take it! It is about doing a lot of homework before taking any pill in your life. Do the pros exceed the cons or cons exceed the pros? This takes time, analysis and some opinions. Still, the most incredible finding from this trial received minimal attention and that is the fact that the chances of dying from any medical condition (including cancer) in the seasoned individuals in the aspirin and placebo groups were dramatically lower in the participants of this trial than what normally occurs in the general population of similarly-aged elderly people!

What? Yes, far more elderly people succumb to countless diseases over time than what occurred in this trial? Why? It is because this was already a group of healthy elderly people! Most were not obese, did not smoke and did not have diabetes. So, the greatest message from this trial was the fact that, as you get older, if you have or keep taking care of yourself (woman or man), then the probability that you will live longer goes up dramatically! This should not have been a story about pills, but instead a story about lifestyle and knowledge empowerment! So, the next time your doctor or someone else tells you that you are healthy, and elderly, then tell her or him “thank you but I would rather be known as seasoned” and you do not want to take ANY pill unless the positives exceed the negatives after we do some rigorous analysis! Man, I love this stuff and I like being “semi-seasoned” right now!

References:

Profile of Apalutamide in the Treatment of Metastatic Castration-Resistant Prostate Cancer: Evidence to Date

Chong JT, Oh WK, Liaw BC

Onco Targets Ther 11: 2141–2147, 2018

Abstract

Advances in therapies have led to the approval of six therapeutic agents since 2004, each demonstrating overall survival benefit in randomized studies, and these have significantly improved the outlook for men facing metastatic castration-resistant prostate cancer (CRPC). More recently, efforts have been directed at trying to effect change at earlier phases of the disease. Apalutamide (ARN-509), a second-generation androgen receptor antagonist, recently received approval in the non-metastatic (M0) CRPC space. Similar to enzalutamide, apalutamide inhibits the binding of androgen to androgen receptor (AR), nuclear translocation of the androgen–AR complex, and binding of AR transcription complex to DNA-binding sites and transcription elements. Phase I and II trial experience demonstrates the safety and tolerability of apalutamide, as well as its efficacy in effecting prostate-specific antigen response and radiographic-free survival in CRPC. US Food and Drug Administration approval in M0 CRPC was granted following positive results from the phase III SPARTAN study, where apalutamide demonstrated significant improvements in metastasis-free survival and time to symptomatic progression as compared to placebo.
**Immunotherapy Could Offer Hope for Some Men with Aggressive Prostate Cancers**

A group of men with especially aggressive prostate cancer (PCa) may respond unusually well to immunotherapy, a major new study reports. The research offers the possibility of effective treatment for men with PCa who currently die from their disease much more rapidly than other men—with clinical trials already starting.

An international team led by scientists at The Institute of Cancer Research (ICR), London, and the Dana-Farber Cancer Institute in the U.S. showed why some men with advanced PCa have much worse survival rate than others.

Their research found that men with PCa who have specific faults in their tumours that make their DNA error-prone and unstable survive only half as long as other men with advanced disease. And the findings have exciting implications for treatment—with the researchers showing that these unstable tumours are more likely to stimulate an immune response than other cancers. That should make men with these aggressive PCa particularly good candidates for immunotherapy.

The new study, published in the *Journal of Clinical Investigation*, looked at 127 tumour biopsies from 124 men and genomic information from a further 254 men acquired by the Prostate Cancer Foundation (PCF)/Stand Up to Cancer International Prostate Cancer Dream Team. The research was funded by the PCF, Movember Foundation, Prostate Cancer UK, Stand Up to Cancer, V Foundation, the Stewart J. Rahr Foundation, Cancer Research UK, the Experimental Cancer Medicine Centre and NIHR Biomedical Research Centre at The Royal Marsden NHS Foundation Trust and ICR.

The team found that 8.1% of men with advanced PCa had evidence of mismatch repair mutations in their tumours. These men survived only 3.8 years after beginning PCa treatment, vs. 7.0 years for men with advanced disease with no detectable mismatch repair defects.

Cancers with ‘mismatch repair’ gene mutations can’t correct single-letter mistakes in their DNA code properly and so are genetically unstable. They acquire more and more mutations as they grow and rapidly evolve drug resistance—which is why new treatment approaches are so badly needed.

But researchers suspected these ultra-mutant cancer cells might be particularly easy for the immune system to recognize, since they look different from healthy cells. They looked at the levels of a protein called PD-L1 on the surface of cancer cells as a way of indicating the likely response to checkpoint inhibitor immunotherapy. Targeting PD-L1 activity with an immune checkpoint inhibitor takes the ‘brakes’ off the immune system, setting it free to attack cancer cells.

The researchers found that half of tumours with mismatch repair mutations had high levels of PD-L1, compared with only 9.8% without these mutations—making men with these tumours much more likely to benefit from a checkpoint inhibitor. They also found that over half of tumours with mismatch repair mutations had been invaded by T cells from...

(Continued on page 6)

**Surgery and Radiation for Advanced Prostate Cancer Offers Better Survival**

Primary treatment of locally or regionally advanced prostate cancer (PCa) with radical prostatectomy (RP) and adjuvant radiotherapy (RT) is associated with a lower risk of cancer-specific death and improved overall survival compared with primary treatment consisting of RT plus androgen deprivation therapy (ADT), new study findings suggest, published online in the journal *Cancer*.

RP and adjuvant RT, however, is associated with a greater risk of erectile dysfunction (ED) and urinary incontinence (UI). In an observational study using Surveillance, Epidemiology and End Results (SEER) Medicare data, Thomas L. Jang, MD, MPH, of Rutgers Cancer Institute of NJ, and colleagues compared survival outcomes associated with the two treatments among 13,856 men aged 65 years or older diagnosed with locally or regionally advanced PCa.

“At a median follow-up of 14.6 years, 2,189 deaths occurred. Of these, 702 were PCa-related. Regardless of tumor stage or Gleason score, the adjusted 10-year PCa-specific survival and 10-year overall survival (OS) rates were significantly higher with RP plus RT compared with RT plus ADT,” Dr. Jang’s team reported. For example, among men with T3a-bN0-XM0 cancer (positive surgical margin at surgery), the adjusted 10-year PCa-specific survival was 88.9% in the RP-RT group compared with 74.2% in the RT-ADT group. The adjusted 10-year OS rates were 64.2% and 48.3%, respectively.

The RP-RT group had a significantly higher rate of ED (28% vs. 20%) and UI (49% vs. 19%). The investigators stated that their findings should be interpreted within the limitations of an observational study design.

“Because our patients were not randomized, the two groups may have differed in measured and unmeasured ways that are associated with differences in survival despite our best efforts to rigorously adjust for confounders,” they noted.

“Another limitation was reliance on administrative claims for billing purposes,” they explained. Key information that may influence outcomes, such as RT dosage or whether nerve-sparing was performed during RP is not captured precisely.

*Renal & Urology News* – 26 September 2018

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**Resources Address Anxiety, Depression and Prostate Cancer**

Many men who are diagnosed with prostate cancer, or are managing the disease, experience some level of anxiety and/or depression. Caregivers may also be affected. The psychosocial challenges surrounding treatment choices and side effect management can have a negative impact on the prostate cancer journey.

Anxiety and depression aren’t always effectively treated, in part because the symptoms may not be recognized. We encourage you to visit the US TOO web page for important information on recognizing and managing anxiety, depression and prostate cancer.

[www.ustoo.org/anxiety-and-depression](http://www.ustoo.org/anxiety-and-depression)
from other causes among people in the aspirin-taking group. The researchers then compared these data with those of approximately 400,000 people who did not take the drug.

Of the studies included in the analysis, 29 examined cases of colorectal cancer. In addition, the researchers focused on breast cancer, which featured in 14 studies, and prostate cancer, which was the subject of 16 studies. Overall, the analysis revealed that the chances of surviving a cancer diagnosis were 20-30% greater among people who took aspirin compared with those who did not. This was true at any given point after receiving the diagnosis.

Elwood and colleagues also note that evidence suggests aspirin may benefit different cancers to varying extents, “Aspirin seems to reduce the risk of dying from colon cancer by 25 percent, the risk of breast cancer mortality by 20%, and the risk of dying of prostate cancer by 15%.”

Zooming in on colon cancer, for example, one of the studies analyzed revealed that the outlook of an otherwise healthy, 65-year-old man who receives a diagnosis of colon cancer and starts to take aspirin is similar to that of a 60-year-old man who is in the same situation but does not take aspirin.

The authors concede some limitations to their review. For instance, they write that the studies reviewed are purely observational and some of them did not find any benefits to taking aspirin. However, Elwood and colleagues conclude that the findings “merit wide discussion regarding whether or not it is adequate to justify the recommendation of low-dose therapeutic aspirin” in the treatment of cancer.

“Evidence from further studies is urgently required, and patients should be strongly encouraged to participate in appropriate research studies,” says the study’s lead author. He added, “All patients should consult their [physician] before starting new medication.”

Medical News Today
3 October 2018

High Mutation Load Seen in the High-Risk Prostate Tumors of African Men

African men with high-risk prostate cancer had an elevated tumor mutational burden (TMB) compared with European men, according to a study published in the journal Cancer Research.

Whole-genome sequencing (WGS) revealed a nearly two-fold increase in TMB in prostate tumors derived from African patients compared with the mutations found in the prostate tumors of European patients.

The small study included 15 previously untreated subjects with high-risk prostate tumors. WGS was performed on these tumors; these data were compared with the data from tumors derived from European subjects.

When these tumors from European and African patients were compared, the analysis confirmed a 1.8-fold increase in TMB in the tumor samples extracted from African men. The researchers excluded one hypermutated tumor from the analysis that had 55 mutations per megabase. Excluding that hypermutated tumor, there was an approximately four-fold increase in the burden of small somatic variants than had previously been reported for individuals at high risk of prostate cancer. This translated into a 7.7-fold increase when the researchers considered published TMB data from men at low or intermediate risk of prostate cancer.

Also, tumors from African subjects had an increase in oncogenic driver mutations compared with tumors in European participants. Roughly 30% of affected genes were novel to prostate cancer, and 79% of recurrent driver mutations appeared early in tumorigenesis.

Investigators determined that the risk alleles applicable to European patients were “unlikely to be risk-predicting” for patients of African ancestry. Tumors from African men lacked ERG fusions and PIK3CA mutations, and PTEN loss was less frequent.

However, CCND1 and MYC mutations were frequently gained. And, in African patients, the genes that regulate calcium ion-ATPase signal transduction were disrupted.

“Given the significant increase in burden of small somatic mutations among African-derived tumors... one may speculate that higher TMB would predict for responsiveness to immunotherapy within African men with higher-risk prostate cancer, as seen for diverse cancer types,” the researchers wrote.

Cancer Therapy Advisor
27 September 2018
Dismissing Reduced Abiraterone Dose is Absolutely Wrong (Continued from page 1)

The phase 2 study findings on the two doses were first reported last year by Medscape Medical News, when they were presented at the 2017 Genitourinary Cancer Symposium. At that time, lead author Russell Szmulowitz, MD, from the University of Chicago, IL, said that it was well-known that abiraterone is more efficiently absorbed with food. However, abiraterone, like many cancer drugs, was tested at fasting levels in clinical trials. “In cancer, there’s a belief that fasting will give you better and more predictable drug levels with patients,” Szmulowitz stated.

In his letter to the editor, Tannock acknowledges that a larger phase 3 trial to support the lower dose instead of the higher dose would be ideal, but the current phase 2 study design was wise. “The authors sensibly chose a widely used proximal end-point of PSA response and progression-free survival (PFS),” he writes. The study also investigated reduction in the androgen dehydroepiandrosterone sulfate (DHEA-S), which is an “important pharmacodynamic (PD) marker of abiraterone activity,” Tannock notes.

“Within reasonable limits of error, the authors showed similar PSA response and PFS, and similar PD effects to reduce DHEA-S between the arms, with a quarter of the recommended dose, despite higher trough levels of abiraterone in the standard arm,” he summarizes.

However, in their JCO editorial that accompanied publication of the phase 2 results, Jill Kolesar, PharmD, University of Kentucky, Lexington, and Glenn Liu, MD, University of Wisconsin-Madison, focused on pharmacokinetics data and largely dismissed the trial and concept.

The editorialists are blinded by their methodological purity, Tannock suggests: “They are emphasizing small residual uncertainties and ignoring the global value of the reduced-dose treatment.” In his letter, Tannock suggests that this one-pill-a-day strategy should be used when men cannot afford the full dose. “Currently, many men will be denied abiraterone in developed countries as well as poor and middle-income countries,” he says. “Abiraterone has huge potential to improve the duration and quality of survival of millions of men with metastatic prostate cancer worldwide,” he writes.

What Janssen Said
When the study was published in May 2018, the authors concluded that “these data warrant consideration by prescribers, payers, and patients.” They called for further studies to assess the long-term efficacy of the long-dose with food approach.

At that time, Janssen issued a statement that said abiraterone should be taken, in accordance with the prescribing information, “on an empty stomach.” The company warned that taking abiraterone with food “may cause more of the medicine to be absorbed by the body than is needed and this may cause side effects.” Further, Janssen noted that “the use of food as a way to increase bioavailability in patients with cancer could present problems and risks.

“Given the variation in the content and composition of meals, the recommendation is to take [abiraterone] exactly as described in the prescribing information,” the company added.

Medscape Medical News
17 September 2018

Immunotherapy Could Offer Hope for Some Men with Aggressive Prostate Cancers (Continued from page 4)

the patient’s immune system, another indicator that immunotherapy may well be effective.

Researchers are now developing tests to identify men with mismatch repair mutations in their tumours. Based on these results, new clinical trials led by the ICR and the Royal Marsden are testing the effectiveness of checkpoint inhibitor immunotherapies in this group of patients. Study leader Professor Johann de Bono, Regius Professor of Cancer Research at ICR, London, and Consultant Oncologist at the Royal Marsden NHS Foundation Trust, said, “Our study found that some men with advanced PCas have genomic mutations in their tumours that make the disease unstable, aggressive and resistant to standard therapies. Men with mismatch repair mutations only live about half as long as others who also have advanced PCa but whose tumours don’t carry such mutations.

“We discovered that tumours with mismatch repair mutations have key hallmarks which make them particularly likely to respond to checkpoint inhibitor immunotherapy. We are now developing tests that could pick out patients with these mutations, and we’re running new clinical trials to see if immunotherapy can offer new hope for these men.” Professor Paul Workman, Chief Executive of ICR, London, said, “We are seeing a revolution in cancer treatment as immunotherapy becomes an important option for many types of the disease.

“Immunotherapy is an unusual treatment in working best in cancers that have a lot of mutations. Prostate cancers normally tend to have fewer mutations than other types, which may be why immunotherapy has so far only been successful in a small minority of patients.

“This new study is exciting in providing a way to pick out those men with PCa who have the most aggressive, unstable disease and the worst survival – but who conversely might be the best responders to immunotherapy. It will be fascinating to see whether we can translate the theory into practice in the new clinical trials to test out immunotherapy in men with genetically unstable tumours.”

Howard Soule, Ph.D., executive vice president and chief science officer of the Prostate Cancer Foundation, said, “This important study informs identification of prostate cancer patients whose disease is likely to respond to treatment with immune checkpoint inhibitors. We applaud the achievement of this international research team which has been funded by the Prostate Cancer Foundation, the V Foundation, and the Stewart J. Rahr Foundation.”

Institute of Cancer Research
5 September 2018

US TOO INTERNATIONAL PROSTATE CANCER EDUCATION & SUPPORT
P1, PCa Detection in Men...
Is the government spending too much money on older men with prostate cancer? According to an analysis of SEER data, Chen and co-workers found it cost about $1.2 billion every three years to diagnose the disease in men over 70. Costs of treating them are also quite high. Although a significant percentage of them are treated conservatively, many men who have co-morbid disease still end up getting screened and receive subsequent therapy. We can speculate on potential cost saving efforts. If a man has a certain co-morbidity index where his chances of benefit are very low, would it be reasonable to not allow screening to occur? As you can imagine, few people would accept that restriction, but one day we may have to make decisions in which some limitations on health care must be made.

The Bottom Line: The cost of screening men over 70 years of age results in a substantial outlay of health care dollars with only a small fraction benefitting. Setting some limitations based on poor health may be a reasonable consideration.

P1, Dismissing Reduced...
An interesting and provocative editorial by Ian Tannock regarding using a lower dose of abiraterone if taken in conjunction with food raises important issues. First, the editorial is in response to a small randomized study comparing low and standard dosing. The authors claimed on the basis of only 72 patients that PSA responses were similar and the lower dose was non-inferior. Dr. Tannock argues that this finding should not be dismissed because it could make it possible for many more men in other countries to be able to afford the treatment. I am not a statistician, but I would seriously worry about translating these findings in such a small sample, even though randomized, to its impact on survival. PSA is still not a reliable predictor of survival and without establishing its non-inferiority in a larger study with survival as the outcome, it could result in many men thinking they are being helped and still spending a lot of money without really knowing its potential impact. It might be reasonable to offer the lower dose while another larger randomized study is conducted with a survival outcome, but without doing so I believe this could do more harm than good.

The Bottom Line: More information is needed before routinely recommending a lower dose of abiraterone, if taken with food.

P1, Can Aspirin Help...?
Is aspirin good for men with prostate cancer? That is the question partly addressed by Elwood and colleagues who reviewed 71 uncontrolled studies and concluded that taking aspirin helped improve survival. Prostate cancer was not the main focus of the paper. Caution is needed in applying these findings to men with prostate cancer. The study was observational potentially leading to many variables having an effect. At best, this report might justify a prospective, randomized study, but it is insufficient for guiding therapy at this time, particularly for men who do not have good medical indication for taking the aspirin. It can cause problems, which is why it is not advised for all aging men.

The Bottom Line: The value of taking aspirin to improve survival of men with prostate cancer is not established on the basis of this study and a prospective, randomized study would be needed to make that assessment.

P2, “Simple Clinical...”
Can we better predict the outcome of men with non-metastatic disease using simple parameters such as co-morbidity, PSA doubling time and age? That is the basis of the report by Daskivich et al. who retrospectively reviewed men diagnosed with nmCRPC between 2000 and 2015. Not surprisingly, having significant co-morbidity, as measured by the Charlson co-morbidity index, resulted in a much greater likelihood of dying of other causes than prostate cancer. Also, having a shorter doubling time of less than nine months predicted a greater likelihood of dying from prostate cancer. Unfortunately, the paper has significant limitations making it potentially misleading information. First, it was retrospective and, as the authors acknowledge, a definitive study would be needed to prove this finding and those studies are underway. On the basis of this study, it does not clearly show that this combination is the best option and the study did find a higher rate of complications.

The Bottom Line: This retrospective study suggests that surgery plus radiation offers a better survival compared to radiation plus ADT, however, without a randomized study it should not be used to guide therapy.
Study Private Payer Coverage of Prostate MRI Lagging

Prostate magnetic resonance imaging (MRI) has become increasingly important in diagnosing and managing prostate cancer (PCa), but private payer coverage of prostate MRI varies widely and frequently does not reflect current clinical practice, investigators found. Coverage policies fail to recognize major clinical scenarios and is overly restrictive, they concluded.

“This creates challenges for patients and referring physicians seeking to obtain ready access to prostate MRI services,” Michael T. Booker, MD, MBA, of the University of California, San Diego, and colleagues concluded in a paper published online ahead of print in the Journal of the American College of Radiology.

Dr. Booker’s team used the Policy Reporter database to evaluate private payer coverage related to prostate MRI for 81 plans covering 149 million people in the United States. Overall, 11% of payers cover prostate MRI in biopsy-naïve patients with suspected prostate cancer (PCa), with the remaining 88.9% requiring a prior negative biopsy. Nearly all payers require either a rising PSA or abnormal rectal examination. “Rarely, a planned future MRI-targeted biopsy serves as a basis for MRI coverage,” they wrote.

Most payers cover initial staging, although typically with stringent indications, such as a PSA level of 20 ng/mL or higher, Gleason score of 7 or 8, stage T3 or T4 and a 20% or greater risk of nodal metastases (to lymph nodes).

The authors noted that prostate MRI has been included in various recent PCa position statements issued by professional organizations. For example, an American Urological Association (AUA)–Society of Abdominal Radiology collaborative statement supports prostate MRI following a negative prostate biopsy, and an AUA policy statement supports a role for prostate MRI in some biopsy-naïve patients.

“Despite the growth of prostate MRI, it is unclear if insurance coverage has kept pace with evolving clinical practice,” Dr Booker’s team wrote. “This is largely because the payer landscape is highly variable, with multiple private payers, radiology benefit managers, and associated government policies all creating unique requirements.”

Renal and Urology News
28 September 2018
Between the Sheets...

This column provides the platform for experts in the field to help men and women by providing answers to questions about sexual health and intimacy challenges that can result from prostate cancer treatment.

Information provided was compiled with the help of Dr. Anne Katz, Certified Sexuality Counselor and Clinical Nurse Specialist at CancerCare Manitoba. She has educated thousands of healthcare providers and cancer survivors about cancer, sexuality and survivorship. She is the editor of the Oncology Nursing Forum, an avid blogger for ASCO Connections, and the author of 13 books on the topics of illness, sexuality and cancer survivorship. (www.drannekatz.com)

QUESTION FROM PROSTATE CANCER SURVIVOR:
Ever since my surgery (laparoscopic prostatectomy with the DaVinci robot) I leak urine during sexual activity/oral sex. This is NOT sexy and I don’t know what to do about it. I need help!

RESPONSE FROM DR. ANNE KATZ:
This is not an uncommon occurrence and most men find it very distressing. The sphincter, which is the valve that keeps the bladder closed, is damaged or destroyed when the prostate gland is surgically removed. The muscles of the pelvic floor have to take over that function during sexual activity. Especially during orgasm, the muscles of the pelvic floor ‘let go’ or contract, which can cause leakage or outright gushing. While a towel under you and/or your partner is an obvious band-aid solution, it doesn’t get to the root of the problem; and, of course, a towel is not going to help much if you are leaking during oral sex.

Although urine is sterile and cannot harm you or your partner, loss of urine during sexual activity can be embarrassing and can have a major negative impact on sexual satisfaction and quality of life. There’s no need to suffer in silence. A visit to a knowledgeable pelvic floor physical therapist, or physiotherapist, can be very helpful. The American Physical Therapy Association is the official organization for physiotherapists in the U.S. Search for a physical therapist on their website at https://bit.ly/2mwByW6. But be sure to confirm that any physical therapist you are considering has expertise in pelvic floor physiotherapy, as this is not included in basic training programs.

Do you have a question about sexual health or intimacy? If so, we invite you to submit it for possible inclusion in future Between the Sheets columns.

Please email your question to: ustooBTS@ustoo.org

Or mail your letter to:
Us TOO International
Between the Sheets
2720 S. River Road, Suite 112
Des Plaines, IL 0018
Let Us Help You Plan Your Path
Through Every Step of Your Journey...

Prostate Cancer Pathways for Patients and Caregivers is a new educational event and webcast series from Us TOO International. The Chicago area Pathways event is the last of three regional events planned for 2018.

Each Pathways event provides valuable content including:
- An educational overview of prostate health and prostate cancer awareness
- Presentations with relevant content for newly diagnosed, recurring, and advanced patients
- Content to help Us TOO support group leaders maximize their impact on the local prostate cancer community

This event will feature a special presentation on erectile dysfunction and incontinence after prostate cancer treatment. In-person attendees will receive a free copy of Dr. Albaugh’s book, Reclaiming Sex & Intimacy After Prostate Cancer – A Guide for Men and Their Partners (both the first edition and brand new second edition will be available).

Presenters for the Chicago Event:
- Dr. Jeffrey Albaugh, Board Certified Advanced Practice Urology Clinical Nurse Specialist, Board Certified Sexuality Counselor, Director of Sexual Health at NorthShore University HealthSystem and at Jesse Brown VA Medical Center, and member of the Us TOO Board of Directors
- Dr. Brian T. Helfand, Chief, Division of Urology and Director, Program for Personalized Cancer Care at NorthShore University HealthSystem
- Dr. Benjamin H. Lowentritt, Director, Minimally Invasive Surgery and Robotics, Chesapeake Urology Associates Director, Prostate Cancer Care Program, Chesapeake Urology Associates Past President, Baltimore City Medical Society
- Heather L. Moky, PT, DPT, University of Illinois Hospital and Health Sciences System/UIC Health Pelvic Health Physical Therapy Program

All sessions will be webcast live and videotaped.

Us TOO Presents:
Prostate Cancer Pathways for Patients & Caregivers

Free Educational Event and Webcast Series

Saturday, November 3

NorthShore University HealthSystem
Skokie Hospital
9600 Gross Point Road
Sharfstein/SH Rooms A, B and C
Skokie, IL 60076
10:00 am - 3:00 pm

Attend in person or watch the online webcast with live video and audio from the event.

To register, visit www.ustoo.org and click on the banner, or contact Terri at 877-978-7866 or terril@ustoo.org.

Please note that on-site space is limited. We will attempt to accommodate those registering in person on the day of the event, but we cannot guarantee a seat or a free lunch.