Hello, Friends. For 21 years, Us TOO International and hundreds of our volunteers have been carrying out peer-to-peer education and support activities for those in need. Maybe you or one of your loved ones have benefitted from our brotherhood and resources. Unfortunately, we still often hear “I wish I had known about your organization six months ago when my husband/brother/father was diagnosed.” We don’t want to be a best-kept secret! We want the best for these men and their families, and know we can give so many the hope they seek through our education, support and advocacy resources.

This year’s annual fundraiser appeal – which we are calling the Hope Campaign – is very important to our ability to serve you and the ever-growing stream of men and their families confronted by prostate cancer decisions. We are wrapping up another year and looking forward to a bright future, but we need your help.

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**SHARE HOPE AND DONATE TO US TOO**

The experimental oral agent for metastatic castration-resistant prostate cancer (CRPC), MDV3100, improved survival by 4.8 months compared with placebo, in a phase 3 trial. A planned interim analysis of the AFFIRM trial revealed that estimated median survival was 18.4 months for men treated with MDV3100, compared with 13.6 months for men treated with placebo (P < 0.0001). This translates into a 37% reduction in the risk for death with MDV3100 (hazard ratio, 0.631). As a result, the trial’s Independent Data Monitoring Committee recommended that AFFIRM be stopped early and that men who were receiving placebo be offered MDV3100. The recommendation was based on the fact that the study’s prespecified interim efficacy stopping criteria were successfully met. The committee also examined the safety profile to date and determined that MDV3100 demonstrated a risk/benefit ratio that was favorable enough to stop the study, according to a company press statement.

“MDV3100 was rationally designed to target androgen-receptor signaling, a key driver of prostate cancer growth,” said Howard I. Scher, MD, co-principal investigator of the AFFIRM study, in a press

(Continued on page 3)

**PROSTATE CANCER TRIAL STOPPED AS MDV3100 IMPROVES SURVIVAL**

**SURVEY OF TOP DOCTORS FINDS WIDESPREAD SUPPORT FOR PSA SCREENING IN THE US**

Most Top Doctors disagree with a government task force that has proposed ending routine use of a prostate-cancer screening test, according to exclusive survey results released today by US News Media Group. US News polled urologists and internal-medicine specialists listed at US News Top Doctors. Nearly all Top Urologists and most Top Internists endorsed the use of PSA to diagnose prostate cancer in men 50 and older, despite the draft recommendation against the test issued this month by the US Preventive Services Task Force.

Today’s survey is the first ever conducted among US News Top Doctors. “Many of the doctors responding to our survey expressed dismay at the thought that millions of men may stop receiving the PSA test,” said Steve Sternberg, US News Deputy Editor of Health Rankings, who wrote today’s exclusive report on the survey’s results. “On the other hand, nearly 40 percent of internists, who are often the doctors who order the test for their patients, expressed concern that the uncertainty inherent in the test may expose some men to unnecessary and potentially harmful treatment.”

(Continued on page 4)
Brachytherapy Doesn’t Boost Extra Prostate Cancer Risk

Treating prostate cancer with brachytherapy instead of prostatectomy doesn’t increase the risk of a second primary cancer, according to a new paper by Dutch investigators.

In their study of nearly 2,000 men followed for a median of 7.5 years, the rate of second primary cancers was 11% in the brachytherapy group and 12% in the prostatectomy group – and there was no increased tumor risk compared to the general population.

However, the risk for bladder cancer was significantly increased after brachytherapy for men age 60 years or younger, with a standardized incidence rate (SIR) of 5.84. The risk of bladder cancer was also significantly increased in the first four years of follow-up (SIR 2.14).

In their report, published online in the Journal of Clinical Oncology on 24 October 2011, lead author Dr. Karel A. Hinnen of the Netherlands Cancer Institute in Amsterdam and colleagues say they think the bladder cancer findings are probably due to lead time or screening bias, not radiation, “because the latency period between brachytherapy and bladder cancer development is expected to be longer.”

They point out that the SIR for bladder cancer overall was numerically lower in the brachytherapy group (1.69 vs. 1.82), as was the SIR for all malignancies (0.94 vs. 1.04).

The authors also point out that whether treated with brachytherapy or prostatectomy, “approximately one in eight patients would be diagnosed with any type of second primary cancer in the 10-year period after treatment.”

“Both prostatectomy and brachytherapy have been shown in literature to be equally effective in treating locally confined prostate cancer,” Dr. Hinnen told Reuters Health in an email.

The study, he added, shows that the most serious potential side-effect of brachytherapy – radiation induced secondary effects of brachytherapy – radiation induced secondary effects is not significantly increased in daily clinical practice.

Antibiotic Change Before Prostate Biopsy Increases Postsurgery Infections

Changing antibiotic regimens in an effort to reduce Clostridium difficile infections at a UK hospital paradoxically led to higher overall infection rates after prostate biopsy according to a study published in the November issue of BJU Int (Vol. 108, pp. 1597-1602, 2011).

After an audit of 709 records of prostate biopsies, more than 5 times as many postsurgery infections developed in 255 patients given the new antibiotic regimen (co-amoxiclav and gentamicin) compared with 454 patients given the previously ciprofloxacin regimen (P < 0.001). Almost 13% of patients given co-amoxiclav and gentamicin developed infections vs. 2.4% given ciprofloxacin. Twelve patients were readmitted with sepsis, one with septic shock.

“This is the first study to compare the use of co-amoxiclav and gentamicin with the use of ciprofloxacin for [ultrasound-guided prostate biopsy],” senior author David Neal, FMedSci, FRCS, professor of surgical oncology at Addenbrooke Hospital in Cambridge, UK said in a statement.

“This audit study supports the use of locally determined prophylactic regimes for this procedure.”

Rising Clostridium difficile rates in the UK, were thought to be the result of widespread use of broad-spectrum antibiotics such as ciprofloxacin. “The new regime was introduced on the provision that both the hospital-acquired infection rates and postoperative infection rates would be closely monitored,” Dr. Neal said. “Given that there were no cases of Clostridium difficile recorded in our study, but postoperative infection rates increased significantly, the decision was taken to revert back to the original regime.” Once that was done the overall infection rate went back down to 3.8%.

Researchers write that no national guidelines on the use of antibiotics exist, and local protocols vary widely. They recommended that any change in antibiotic use should be based on local Clostridium difficile rates and on strong clinical evidence to avert risk of ill health.
Approximately 10-20 percent of prostate cancer patients have a family history of the disease. There are three major factors that are used to evaluate the extent and aggressiveness of prostate cancer, help make treatment decisions, and estimate prognosis: the PSA, Gleason score (GS) from the biopsy, and the digital rectal exam (DRE) findings. However, men with a family history of prostate cancer have often been feared to have a more aggressive form of the disease not otherwise represented by these three factors and therefore are sometimes urged to undergo more aggressive treatment.

Now, Mark Buuyounouski, MD, MS, a radiation oncologist at Fox Chase, reports that men with a family history of prostate cancer should expect equally good outcomes following radiotherapy (RT) for prostate cancer as patients without a family history. Buuyounouski introduced the new data at the 53rd annual meeting of the American Society of Radiation Oncology.

In the study, Buuyounouski and his team of collaborators examined 1,711 men who received three-dimensional conformal RT or intensity modulated RT between 1989 and 2007 at Fox Chase Cancer Center in Philadelphia. A positive family history was defined as any prostate cancer in one or more first-degree relatives. Twenty-eight percent of the patients had a positive family history for prostate cancer. The median follow-up from completion of treatment was 71 months.

“What we learned was that whether the men had a history of prostate cancer or not, all had equivalent PSA controls, freedom from metastasis, recurrence-free survival, and overall survival,” says Buuyounouski. “Patients should feel comfortable knowing that when they receive RT having a history of prostate cancer in the family doesn’t compromise the results. This is important because patients, especially those with a family history, might assume that RT might not work as well and opt for surgery when it may not be necessary.”

Interestingly, Buuyounouski and his colleagues also learned that men with a family history of prostate cancer were more likely to be younger, have a lower PSA, and non-palpable disease.

“This study shows that patients with a family history are being screened and diagnosed with prostate cancer earlier. Careful screening may have contributed to the good results we observed.”

Medical News Today, 07 Oct 2011

MDV3100 statement. He is chief of the genitourinary oncology service at the Memorial-Sloan Kettering Cancer Center in New York City. “If approved, MDV3100 will be a welcome option for men with prostate cancers who have progressed on hormones and after initial chemotherapy.”

The randomized, double-blind, multinational trial compared MDV3100 (160 mg/day) with placebo in 1199 men with advanced prostate cancer previously treated with docetaxel chemotherapy. Enrollment was completed in November 2010, and the interim analysis was triggered at 520 events. If approved by the US Food and Drug Administration, MDV3100 will move into an increasingly crowded marketplace of products for the treatment of CRPC.

In phase 3 clinical trials in this setting, the immunotherapy sipuleucel-T (Provenge®) has demonstrated a 4.1-month median survival benefit, and abiraterone (Zytiga®) showed a 3.9-month benefit. In addition, the chemotherapy cabazitaxel (Jevtana®) demonstrated a 2.4-month overall survival advantage over standard therapy.

MDV3100 is more potent and more specific than the older antiandrogens, such as bicalutamide (Casodex), which have been and are still being used in prostate cancer, usually with LHRH agonists/antagonists, such as goserelin (Zoladex®) and abarelix (Plenaxis®), said Dr. Scher in an earlier interview. These older antiandrogen compounds also have some agonist activity, and have been found to stimulate prostate cancer growth in some men, Dr. Scher explained. This has not been seen with MDV3100, he noted at the time.

The mechanism of action of MDV3100 is very different from abiraterone, which is an inhibitor of androgen synthesis but does not block androgen binding. Dr. Scher said. Because they act in different ways, there might be benefits from using the drugs together, he added.

Medscape Medical News, 3 November 2011

Men with a Family History of Prostate Cancer Do Not Need More Aggressive Treatment

(Continued from page 1)

Approximately 10-20 percent of prostate cancer patients have a family history of the disease. There are three major factors that are used to evaluate the extent and aggressiveness of prostate cancer, help make treatment decisions, and estimate prognosis: the PSA, Gleason score (GS) from the biopsy, and the digital rectal exam (DRE) findings. However, men with a family history of prostate cancer have often been feared to have a more aggressive form of the disease not otherwise represented by these three factors and therefore are sometimes urged to undergo more aggressive treatment.

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“This study shows that patients with a family history are being screened and diagnosed with prostate cancer earlier. Careful screening may have contributed to the good results we observed.”

Medical News Today, 07 Oct 2011

Share Hope and Donate

(Continued from page 1)

could use your help to reach a wider audience of men and those who care about them. We appreciate any assistance you can provide in helping support our outreach, programs and services for men and their families battling prostate cancer.

Please share the hope and make a donation to Us TOO this holiday season. Our goal is to raise $30,000 by December 31, 2011. As of this publication date, we have only received $1,135, so we have a ways to go.

Funds raised will be directed to help the Us TOO home office’s ability to work better and more closely with all the local support group chapters, who in turn, better support local community members with or concerned about prostate cancer. Please help us continue these important and vital services so they can be available for those wrestling with this disease.

Donate at www.ustoo.org/DonateHope, or you can mail us a check using the donation form on page 8 of this issue. Thank you.

Sincerely,

Thomas Kirk
President & CEO
Us TOO International
tom@ustoo.org

There is Hope
You are invited to help Us... help them TOO!
www.ustoo/DonateHope
DURATION OF SHORT-COURSE ANDRrogen Suppression Therapy and the Risk of Death As a Result of Prostate Cancer

D’Amico AV, Chen M-H, Crook J, et al
J Clin Oncol 31 October 2011; E-pub

Purpose: We evaluated whether the duration of androgen suppression therapy (AST) had an impact on the risk of prostate cancer–specific mortality (PCSM) in men with unfavorable-risk prostate cancer (PC) within established Gleason score (GS) categories.

Patients and Methods: Between February 2, 1996, and December 27, 2001, 761 men with unfavorable-risk PC were treated in Australia, New Zealand, Ireland, or the United States in a randomized trial with radiotherapy and 3, 4, or 6 months of AST (the study cohort). Competing risks regression was used to evaluate whether the duration of AST interacted with GS and was significantly associated with the risk of PCSM, adjusting for age, trial site, and PC prognostic factors.

Results: After a median follow-up of 10.9 years, 263 men died, 111 (42%) from PC. For all men, 6 versus 3 or 4 months of AST was associated with a reduced risk of PCSM (adjusted hazard ratio [AHR], 0.55; 95% CI, 0.36 to 0.82; P=0.004). AHRs evaluating the impact of the duration of AST on the risk of PCSM were 0.67 (95% CI, 0.29 to 1.56; P=0.35), 0.47 (95% CI, 0.25 to 0.85; P=0.01), and 0.59 (95% CI, 0.30 to 1.19; P=0.14) for men with GS ≤6, 7, and 8 to 10 PC, respectively. Therefore, the strongest evidence for this benefit was in men with GS 7 PC.

Conclusion: AST durations of no less than 6 months should be considered when treating GS 7 PC with conventional dose RT.

NEW NCI STUDY IN CASTRATE-RESISTANT PROSTATE CANCER PATIENTS FAILING DOCETAXEL

NCI’s Center for Cancer Research (CCR) in Bethesda, Maryland, is conducting a Phase 2.5 study for patients with androgen-insensitive prostate cancer (AIPC) who have two or more bone lesions consistent with progressive disease on or following a docetaxel based-regime. The goal of the study is to determine if treatment with PSA/TRICOM vaccine (PROSTVAC®) combined with 125I Sm-EDTMP radiation (Quadramet®) can delay the progression of prostate cancer better than radiation alone. For additional study information, please click on the link below.

A Randomized Phase 2.5 Study of [153] Sm-EDTMP (Quadramet) With or Without a PSA TRICOM Vaccine in Men With Androgen-Insensitive Metastatic Prostate Cancer (NCI-07-C-0106, NCT00450619)

Key eligibility criteria:
- Histologically confirmed androgen-insensitive metastatic prostate cancer with at least 2 bone lesions
- Prior treatment with docetaxel based-regime OR unable to tolerate docetaxel
- No medical condition that would preclude study participation
- ECOG performance status 0–1

Support of clinical research from patient referrals is vital to our efforts to find new and better ways to treat patients with prostate cancer. That’s why we’re committed to keeping physicians informed of the clinical research taking place within our branch. As part of our commitment, we promise to keep the referring physician informed of the patient’s progress, study developments, and updates. We look forward to working with referring physicians, and we welcome the opportunity to discuss treatment options for their patients or answer any questions about our study. To learn more about this study, please contact the protocol nurse coordinators, Laura Otten, RN, ottenl@mail.nih.gov at (301) 451-1228 or Mary Pazdur, pazdurm@mail.nih.gov at (301) 496-7870.

Patients are not charged for the medical care they receive as participants in an NCI clinical trial. Once enrolled, they also receive support for travel costs associated with study-related visits; however, patients will be responsible for travel costs for their initial screening visits. It will also be important for them to maintain their current insurance plan to cover all medical care that is provided away from the NIH Clinical Center.

SURVEY OF TOP DOCTORS (Continued from page 1)

“America is grappling with many healthcare challenges, and the voices of the country’s best doctors deserve to be heard on these crucial issues,” said US News & World Report Editor and Chief Content Officer Brian Kelly. “As a news organization, and as publisher of US News Top Doctors, we’re well positioned to report on their views.”

“The overwhelmingly negative response to this new recommendation, coming from physicians who are among the nation’s best, suggests that further study and debate on the issue is warranted,” said Dr. John Connolly, President and CEO of Castle Connolly Medical Ltd., publisher of America’s Top Doctors® and other Top Doctors and consumer health guides. The US News Top Doctors directory draws from Castle Connolly’s database of Top Doctors, all recommended for their clinical skills by other doctors and individually vetted by Castle Connolly’s physician-led research team.

Ninety-five percent of Top Urologists responding to the survey disagreed with the government task force, and 97 percent said they themselves would get the PSA test. Among Top Internists, 62 percent felt that men over the age of 50 should be advised to get a PSA test.

To read the exclusive report, go to: Survey of Top Doctors Finds Widespread Support for PSA Test

Want to learn more about local prostate cancer support group activities? Read the CHAPTER NEWS! at www.ustoo.org!

Get connected to other men and family members dealing with a prostate cancer diagnosis at: http://ustoo.inspire.com
**QUANTERIX PSA TEST FOUND TO BE A RELIABLE PREDICTOR OF PROSTATE CANCER RECURRENCE FOLLOWING SURGERY**

Quanterix Corporation, a company enabling a new generation of molecular diagnostic tests based on its revolutionary Single Molecule Array (SiMoA™) technology, announced results from a clinical evaluation of its Prostate Specific Antigen (PSA) test, a fifth-generation digital immunoassay, demonstrating that the assay is a reliable predictor of five-year biochemical recurrence (BCR)-free survival following radical prostatectomy (RP). The pilot study was published online by BJU International.

“These results have important implications for the way prostatectomy patients will be managed in the future,” states Dr. Herbert Lepor, prostate cancer expert and Chairman of the Department of Urology at NYU School of Medicine. “Not only will physicians be able to reassure patients who are at low risk of recurrence following radical prostatectomy, but the identification of a reliable predictor of recurrence soon after surgery has important implications for the frequency of PSA testing and selection of candidates for adjuvant therapy. In addition to providing patients with peace of mind, implementation of this test could lead to a reduction in healthcare costs.”

To determine the ability of this test to predict five-year BCR-free survival following RP, researchers utilized frozen serum specimens, provided by NYU Langone Medical Center and the Johns Hopkins University School of Medicine, from men who had undergone RP and who had no evidence of BCR using conventional PSA measurement methods.

The SiMoA test has an analytical sensitivity 1000-fold lower than conventional ultrasensitive PSA assays, and was capable of accurately measuring PSA levels in all men following surgery. Researchers found that the PSA nadir (lowest level of PSA following RP) was a significant predictor of BCR. Kaplan Meir analysis showed that 100% of men with low PSA nadir values did not develop BCR, while 63% with higher PSA values.

(Continued on page 8)

**ASK DOCTOR SNUFFY MYERS**

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

I have been diagnosed with low grade PC and am at this time treating the PC by active surveillance. In an issue of the Us TOO HotSheet last year, you cited a Johns Hopkins study that investigated the hypothesis that repeated biopsies correlates with the appearance of circulating PC cells in the blood. This is, of course, of the utmost concern for those of us on active surveillance. Is there any update on the study or any other information available related to the relationship of biopsies to circulating PC cells?

Every few months, we get a version of this question sent to us. And at least once a year, we answer this question as best as we can. The answer is one that many patients find unsettling. The plain fact is that I have never been able to find any evidence that cancer cells released by biopsy have caused the cancer to spread.

For nearly all clinically significant prostate cancers, the cancer cells have already escaped the gland prior to diagnosis and can be found in the blood and bone marrow if sufficiently sensitive techniques are used. Yet, despite this fact, many, if not most of these patients, are cured by radical prostatectomy or radiation therapy. After definitive treatment like this, the cancer cells gradually disappear from the bone marrow. The obvious conclusion is of the cancer cells released prior to diagnosis, an overwhelming majority lacks the capacity to grow and cause metastatic disease.

How can this be? In the laboratory, prostate cancers can be found to contain a range of different cell types. The most common type is a PSA producing cell. These are the cells shed during biopsy and that are found to have reached the bone marrow prior to diagnosis. These cells appear to have no or very limited capacity to grow and seem to be unable to establish metastases.

There is a less common cell type that does not produce PSA and is capable of rapid growth, but only for a relatively short time. This cell type also appears unable to establish metastasis and therefore cannot spread. Finally, there exist a small proportion of cells able to spread and establish distant metastases. These have been called cancer stem cells. One factor that determines the aggressiveness of a cancer is the proportion of cells in the cancer that exhibit this stem cell-like capacity. Based on our current understanding, prostate cancers limited aggressiveness is the result of either a limited number of cells with stem-cell like activity or limited capacity for harm in those that do exist.

I think the most dramatic example of this limited aggression in prostate cancer may be seen in men who have recurrent disease after radical prostatectomy. We used to think that these patients had widespread micrometastatic disease and if we waited long enough, the cancer would be found at multiple bone and lymph node sites. We now know that widespread metastatic disease is relatively uncommon. In fact, using first the Combidx scan and now the Feraheme MRI and F18 PET bone scan, we know that 70-80% of men with recurrent prostate cancer have disease limited to a few lymph nodes or fewer than 5 bone lesions. Many of these patients can be put into a durable complete remission by radiation to these sites of recurrent disease.

So, my final response is that yes biopsies lead to the release of cancer cells into the blood but I can find no evidence that this leads to any spread of the cancer. It is my impression that a vast majority of experts in prostate cancer agree with me. When I was diagnosed, I never spent a moment worrying about this issue. If my cancer returns, I plan to have it biopsied and tested. I will not lose any sleep over this decision.

**US TOO WANTS TO ANSWER YOUR QUESTIONS!**

Dr. Myers would love to provide direct answers to questions posed by Us TOO members. Instead of printing questions answered in the Prostate Forum, we’d rather provide readers who subscribe to both publications with fresh content. Questions about imaging, active surveillance, and biochemical relapse would be particularly appreciated right now.

If you have questions, please send them to <Jackie@ustoo.org> or call the Helpline at 800-808-7866.
**USE OF [11C]CHOLINE PET-CT AS A NONINVASIVE METHOD FOR DETECTING PELVIC LYMPH NODE STATUS FROM PROSTATE CANCER AND RELATIONSHIP WITH CHOLINE KINASE EXPRESSION**

Contractor KB, Challapalli A, Barwick T, et al

Clin Cancer Res, 28 Oct 2011, E-pub

**Purpose:** To evaluate the accuracy and biological basis for [11C] choline-PET-CT in the nodal staging of high risk localised prostate cancer patients.

**Experimental Design:** Twenty eight patients underwent dynamic [11C] choline-PET-CT of the pelvis and lower abdomen prior to extended laparoscopic pelvic lymph node dissection (eLPL). The sensitivity and specificity of [11C] choline PET, [11C]choline PET-CT and MRI for nodal detection were calculated. Average and maximal standardized Uptake Values (SUVave, SUVmax) were compared with choline kinase alpha (CHKα) and Ki67 immunohistochemistry scores.

**Results:** 406 lymph nodes, in 26 patients, were assessable. 27 (6.7%) involved pelvic nodes at eLPL were detected in 9 patients. 17 out of the 27 involved nodes were sub-centimetre. The sensitivity and specificity on a per nodal basis were 18.5 % and 98.7%, 40.7% and 98.4%, and 51.9% and 98.4% for MRI, [11C]choline PET and [11C]choline PET-CT, respectively. Sensitivity was higher for [11C]choline PET-CT compared with MRI (p=0.007). A higher nodal detection rate, including sub-centimetre nodes, was seen with [11C]choline PET-CT than MRI. Malignant lesions showed CHKα expression in both cytoplasm and nucleus. SUVave and SUVmax strongly correlated with CHKα staining intensity (r=0.68, p<0.0001 and r=0.63, p=0.0004, respectively). In contrast, Ki67 expression was generally low in all tumors.

**Conclusions:** This study establishes the relationship between [11C]choline PET-CT uptake with choline kinase expression in prostate cancer and allows it to be used as a non-invasive means of staging pelvic lymph nodes, being highly specific and more sensitive than MRI including the detection of sub-centimetre disease.

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

“Metformin and lifestyle changes = WOW! Another Moyad Approved Heart Healthy Medication is getting a lot of fabulous attention!”

Mark A. Moyad, MD, MPH

University of Michigan Medical Center, Department of Urology

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

**Bottom Line:** Metformin and lifestyle changes may be one of the best and cheapest interventions to fight weight gain side effects of androgen deprivation therapy (ADT) for prostate cancer. Metformin may safely reduce weight, waist circumference (WC), BMI, blood pressure and control blood sugar.

Wow! And, what if I say “wow” spelled backwards. I find it so interesting that cholesterol lowering is heart healthy and prostate healthy, and so is low-dose aspirin, but there is a new kid in town folks! Actually, it is another old heart healthy medication that has found its way into the Moyad HEART HEALTHY = PROSTATE HEALTHY crazy world that I live in right now!

There is a generic and cheap drug known as metformin that has been helping men and women control their blood sugar and lose weight for decades (it is still arguably one of the safest and best medications for type 2 diabetes). This drug was also really derived from an herbal product. Cool stuff dudes! Now, keep in mind that metformin is incredibly safe but healthy liver, kidney and heart function makes it more likely that your doctor will prescribe this to you, and if you are receiving anything that could compromise your kidney function (like a dye to improve an imaging test for example) then you should not be on this drug during this time.

Back to my story…researchers decided to compare the impact of daily metformin (850 mg every day for 2 weeks and then 850 mg twice a day thereafter), a low glycemic index diet (aka reduced calorie diet) and exercise versus standard of care in patients on 6-months of ADT.

After 6 months, the metformin group experienced significant reductions in waist size, weight, BMI, and systolic blood pressure compared to the control arm. In the metformin group men were more likely to control their blood sugar over 6 months. No side effects were reported, and no subjects reported stopping metformin during the 6-month clinical trial. This drug and these lifestyle changes need to be tested for a lot of different prostate cancer situations right now!

I find it interesting that as researchers and others spend millions of dollars on new preventive medications and treatments for side effects from cancer treatments that arguably some of the most promising recommendations and medications are heart healthy and generic.

In other words, if you are NOT convinced by now that heart healthy = prostate healthy then please call me ASAP, because I am willing to tell you where your Big Foot and Loch Ness Monster are hiding, and where aliens from Mars are living in the US right now as long as you pay me a million dollars up front.

**Reference:**


PS: If Michigan does not beat Ohio State this year I am going to lose it folks!!!

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**Thank you Military and Federal Employees for your CFC contributions!**

**Us TOO International**

Providing education & support services to prostate cancer patients & their families

**Us TOO CFC# 11614**
Editors’ note: This column contains opinions and thoughts of its author and is not necessarily those of US TOO International.

a2p1c2 Men with advanced prostate cancer received more good news with the announcement that MDV3100 showed a significant improvement in survival in men who failed docetaxel chemotherapy. The randomized study has been stopped and patients can expect a likely FDA approval during the coming months. When that occurs, a new challenge will occur; deciding which therapy men should receive first after chemotherapy fails. Abiraterone (Zytiga®) and cabazitaxel (Jevtana®) are also approved for this stage of disease and it is unlikely that a head-to-head study will ever be conducted. All three drugs have delivered similar improvements in survival. Both abiraterone and MDV3100 are administered as a pill, which might make either of them more attractive than cabazitaxel and abiraterone is given with prednisone, which sometimes causes side effects. Another question is whether combining two of these drugs will deliver even better results than using one until it fails and then switching to another one.

The Bottom Line: MDV3100 will provide additional help to men failing chemotherapy and patients can look forward to the results of studies assessing its role prior to chemotherapy.

a3p1c3 The US Preventive Safety Task force report remains in the news with a survey of doctors showing strong disagreement with the latest recommendations. This story is not yet complete but regardless of the final recommendation that is made by the task force, perhaps all the debate will increase the odds that men will get more accurate information about the pros and cons of the test so each person can make an informed choice whether the test should be done.

a4p2c1 Does radiation (RT) or brachytherapy (BT) increase the risk of developing a secondary cancer in the pelvis? This is partly addressed in the article by Hinnen, et al that looked at men who received BT. Although they found more men developed bladder cancer, this occurred so early that they do not believe it was a result of RT. However, a very large US study did find an increased risk of secondary pelvic cancers but that occurred at 10-15 years, whereas this new study has a much shorter follow-up.

The Bottom Line: Uncertainty remains about the long-term effect of RT in causing secondary cancers in the pelvis but fortunately, if there is an added risk, that risk is very small. For now, men with a long life expectancy should be aware of this uncertainty if they decide to undergo this therapy.

a5p2c3 Recently, growing concerns have been raised about the complications associated with prostate biopsy. One problem is that added resistance is occurring to standard antibiotics. Another concern is the development of hard to treat infections. A new study from England looked at the effect of using amoxicillin and gentamicin instead of ciprofloxacin for the biopsy and the results were alarming; more men developed infections after prostatectomy.

The Bottom Line: Until more information is available, the optimal approach to antibiotics for the prostate biopsy will remain unclear but using more potent antibiotics is not appropriate.

a6p3c2 Do men with a family history of prostate cancer have worse outcomes after radiation than men with no family history? That question was partly addressed in the study by Buyyounouski and co-workers and their results found no difference. Unfortunately, there are weaknesses, which create uncertainty in their findings. First, half the men were followed less than 6 years, secondly, PSA alone may not predict long-term survival and thirdly, the authors did not explore whether having a family member who was diagnosed at a younger age compared to those diagnosed at an older age affected the results.

The Bottom Line: More information is needed to be able to tell whether having a family history of prostate cancer puts a newly diagnosed patient at greater risk from the disease.

a9p5c1 Preliminary results with another more sensitive PSA test were recently published suggesting it might be a better predictor of developing a rising PSA. However, it is entirely unclear whether this will be a more worthwhile test than either conventional or ultrasensitive PSA. Only 31 men were included in the study of which only 11 developed a PSA recurrence, they did not compare the results with conventional PSA and they only looked at 5-year biochemical free results which is not long enough to know if it predicts long-term outcome.

The Bottom Line: Much more information is needed to know if an ultra-ultra sensitive PSA test adds additional useful information.

a11p6c1 An important question for men with high-risk disease is whether or not cancer has spread to the lymph nodes. The study by Contractor and co-workers compare MRI with Choline-PET and Choline-PET-CT and found higher sensitivity with the latter vs. MRI. Does this prove the test is worth doing? Unfortunately, much more information is needed beyond this study. The real questions are how many men need to be tested to find one with cancer in the lymph nodes and how often does the test give a false-positive and false negative result?

The Bottom Line: For now, the results do not justify the use of either Choline-PET-CT or MRI for assessing nodal status in men with high-risk disease.

a14p8c1 Ongoing questions about managing locally advanced disease have been properly studied over the last 8 years. First, studies proved that adding hormone therapy (HT) to radiation (RT) improved survival. Some questioned if RT was necessary and HT alone would be just as effective. Now another study by Warde, et al has addressed that question by comparing RT plus life-long HT to HT alone. The results again were better survival. Based on the results, for every 12 men getting the combined treatment, 1 less death occurred in seven years. Must men take HT forever to get a benefit? Fortunately, other well-done studies have found that 36 months of HT improved survival in nearly one out of every 5 men taking the treatment. The good news is that men can increase their chances for survival while avoiding long-term side effects that occur with life-long HT.

(Continued on page 8)
RT PLUS HORMONES EXTENDS LIFE IN HIGH-RISK PROSTATE CANCER

A combination of radiation (RT) and hormone therapy (HT) prolongs survival in men whose cancer has spread beyond the prostate, Canadian and UK researchers reported online in The Lancet.

Up to 25% of men with prostate cancer have high-risk, or locally advanced disease. While HT alone is often used, “In patients with locally advanced prostate cancer, combining RT + HT gives much better results than HT alone,” said lead author Dr. Padraig Warde, deputy head of the Princess Margaret Hospital Cancer Program and a professor of radiation oncology at the University of Toronto.

In the study, >1,200 men with high-risk prostate cancer were randomly assigned to HT alone or HT and RT. After 7 years, 66% of men who had HT alone were still alive, vs. 74% who received both HT and RT. In the group of men who had HT alone, 26% died from prostate cancer, vs. 10% who had combination therapy, the researchers found.

Warde noted that while men had the predicted HT side effects of, such as impotence, hot flashes, etc., the addition of RT did not affect overall quality of life 3 years after treatment.

When the study began in 1995, HT was given for life, and RT was given in lower doses and less precisely as it is today, Warde said. Currently, HT is shorter, usually 2-3 years, and higher doses of RT is given and better targeted to the tumor. “There is reason to think that with modern RT approaches that the results would be much better,” he said.

Prostate cancer expert Dr. Anthony D’Amico, chief of radiation oncology at Brigham and Women’s Hospital in Boston, said that “this doesn’t change practice, because we already do this, but it’s a validation that you cannot leave out one or the other treatment when treating someone with locally advanced disease.”

Dr. Matthew R. Cooperberg, an assistant professor of urology at UC San Francisco, and author of an accompanying journal editorial, said that “high-risk disease needs to be treated aggressively.” However, “There are studies showing that the best treatment for high-risk disease starts with surgery and then RT and HT as necessary. Whether the approach should be surgery possibly followed by RT, is still the big open question that we need to answer.”

HealthDay News, 2 November 2011

THE BOTTOM LINE

The Bottom Line: Men with locally advanced prostate cancer benefit from HT + RT, but 3 years is as effective as life-long therapy. Although some physicians believe surgery, followed by RT + HT is a reasonable alternative, no good studies compare these options and without them, men may question why they should endure the added side effects of also having surgery without clear proof it is as good as or better than RT + HT.

QUANTERIX PSA TEST

(Continued from page 5)

eventually recurred. The sensitivity, specificity, positive predictive and negative predictive values of the test were 100%, 75%, 69% and 100% respectively.

“We are encouraged by these results, which further supports the value of our SiMoA platform,” said Martin Madaus, PhD, Executive Chairman of Quanterix. “We are actively validating assays important in oncology and several other applications while working towards our goal of automating the SiMoA system to offer a menu of assays to the life sciences and in vitro diagnostics markets.”

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