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US TOO® PROSTATE CANCER EDUCATION & SUPPORT

HOTSHEET

NOVEMBER 2013

IN INTERMEDIATE RISK PROSTATE CANCER, FEWER WEEKS OF HORMONE THERAPY BEFORE RADIATION REDUCES SIDE EFFECTS

A shorter course of total androgen suppression (TAS) prior to radiation therapy (RT), compared to a longer course of TAS, yields favorable outcomes and fewer adverse effects for men with intermediate-risk prostate cancer (PCa), according to research presented at the 2013 American Society for Radiation Oncology's (ASTRO) Annual Meeting. The study confirmed a disease-specific-survival (DSS) rate of 95% when men received fewer weeks of neoadjuvant (NEO) TAS.

The multi-institutional phase III trial, Radiation Therapy Oncology Group (RTOG) 9910, evaluated 1,490 men with intermediate-risk (PCa) from 152 institutions in the US and Canada. Men were accrued from 2000 to 2004 and followed for an average of 9 years, and the average age was 71 at the time of accrual. The men were stratified and randomized into two groups – Group 1 consisted of 752 men who received eight weeks of NEO TAS, and Group 2 consisted of 738 men who received 28 weeks of NEO TAS. Both groups then received eight weeks of external beam RT (EBRT) and concurrent TAS.

Cumulative incidence was used to estimate and analyze the efficacy for DSS,

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PSA SCREENING DOES MORE HARM THAN GOOD

To the ongoing debate over whether routine screening for prostate cancer reduces prostate cancer (PCa) mortality comes a new analysis that suggests that it does more harm than good.

The total harms that men experience in terms of impotence, incontinence, and other side effects from PCa treatment can severely affect their quality of life, lead author Mathieu Boniol, MD, said at the European Cancer Conference 2013 (ECCO-ESMO-ESTRO).

Dr. Boniol and colleagues conducted a systematic literature review for data on results of PSA testing, biopsy rates, and mortality/associated side effects from radical prostatectomy, as well as hospitalization rates associated with biopsy. They also used data from the European Randomized Study of Screening for Prostate Cancer, which is the study showing the most favorable outcomes for PSA screening. Dr. Boniol is research director at the International Prevention Research Institute (IPRI) and a professor at Strathclyde Institute for Global Public Health at IPRI, Lyon, France.

Researchers estimated the total harm men would endure if exposed to PSA testing by applying different side-effect estimates to a virtual population of 1000 men aged 55 to 69 years. They also included a group of 1000 unscreened men as a control group.

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NO ADDITIONAL BENEFIT OF VENLAFAXINE OR SOY PROTEIN VS PLACEBO ON HOT FLASHES IN MEN WITH PROSTATE CANCER

Hot flashes occur in approximately 80% of androgen-deprived men. In a randomized study reported in the Journal of Clinical Oncology by Mara Z. Vitolins, DrPH, MPH, RD, of Wake Forest School of Medicine, and colleagues, neither venlafaxine nor soy protein – both of which have been used to treat menopausal symptoms in women – improved hot flashes in men with prostate cancer more than placebo. Soy protein vs no soy protein was found to have a beneficial impact on quality of life.

In the study, 120 androgen-deprived men were randomly assigned to one of four daily regimens for 12 weeks in a 2×2 factorial design: milk protein powder (20 g, one packet per day) and placebo pill (n = 30), venlafaxine (75 mg once daily in the morning) and milk protein powder (n = 30), soy protein powder (20 g with 160-mg isoflavones, one packet per day) and placebo (n = 30), or venlafaxine and soy protein powder (n = 30). The primary endpoint was hot flash symptom severity score. Patients recorded the total number of hot flashes or night sweats daily and averaged their severity (1 = mild, 2 = moderate, 3 = severe). Daily hot flash symptom severity score was calculated as the number of hot flashes times the severity ratings, and a weekly

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ANALYSIS OF HERBAL PRODUCTS SHOWS CONTAMINATION IS COMMON

Most herbal products, available to buy as alternative medicines, may be contaminated. Reporting in BioMed Central's open access journal BMC Medicine researchers demonstrate the presence of contamination and substitution of plant species in a selection of herbal products using DNA barcoding.

There is currently no best practice for identifying plant species in herbal products. Traditionally plants are identified through the appearance of the whole plant. This method is not useful though when analyzing processed plant material. DNA barcoding analyzes a short genetic sequence from the plant's genome and identifies small differences that allows species identification. In this new study the researchers used barcoding to examine the plant species found in a sample of herbal plant products.

The results showed that 59% of the products contained plant species not listed on the labels. Over two thirds of the products tested had plant species present which were a substitution for the plants listed on the label and a third of products also contained other species that may be a filler or contamination.

According to the World Health Organization, the adulteration of herbal products is a threat to consumer safety. In this current analysis the researchers detected plant species that could pose serious health risks when consumed. Results detected the presence of toxic plant species with known side effects and/or adverse interactions with other herbs, supplements, or medications..

Authors concluded that the contamination and substitution dilute the effectiveness of otherwise useful remedies, lowering the perceived value of all related products because of a lack of consumer confidence in them. "We suggest that the herbal industry should embrace molecular diagnostic tools such as DNA barcoding for authenticating herbal products through testing of raw materials used in manufacturing products. This would be a minor cost to industry with a limited amount of bulk product testing, which would certify a high quality, authentic product," said Dr. Steven Newmaster of the University of Guelph and lead author of the paper.

Science Daily, 14 October 2013

BIOCHEMICAL AND OBJECTIVE RESPONSE TO ABIRATERONE ACETATE WITHDRAWAL: INCIDENCE AND CLINICAL RELEVANCE OF A NEW SCENARIO FOR CASTRATION-RESISTANT PROSTATE CANCER

Caffo O, Palermo A, Veccia A, et al

Urology 31 August 2013
Epub ahead of print

Objective: To describe the incidence and clinical relevance of biochemical and objective responses to abiraterone acetate (AA) withdrawal (AAWD) in patients with castration-resistant prostate cancer (CRPC).

Materials and Methods: Twenty-six patients with progressive CRPC treated with first-line docetaxel-based chemotherapy were administered with AA at the standard dose of 1000 mg/day in combination with prednisone until progression. The patients were regularly followed up during treatment and after AAWD.

Results: Nineteen of the 26 patients discontinued AA because of progression. Three of the patients undergoing AAWD experienced a biochemical response, which was accompanied by a metabolic and radiological response as revealed by C-11 choline positron emission tomography (PET) in 2 cases.

Conclusion: Regardless of the underlying molecular bases, AAWD response does not occur rarely. It is sometimes long-lasting and accompanied by a metabolic and radiographic improvement. AAWD response should be taken into account when further therapeutic strategies are planned in patients with CRPC with progressive disease during abiraterone therapy.

DISABILITY BENEFITS AND PROSTATE CANCER

By Molly Clark, writer, Social Security Disability Help blog

Receiving a diagnosis of prostate cancer can be overwhelming and confusing. Patients must consider the emotional, physical, and even the financial impact that the condition may have on their lives. Individuals with more advanced prostate cancer may find that the effects of their treatment make it impossible for them to continue working. The resulting loss of income can become a source of significant financial distress.

If you find yourself facing similar circumstances, you may be eligible to receive financial assistance from one of the federal disability benefit programs. These programs are operated by the Social Security Administration (SSA) and include Social Security Disability Insurance (SSDI) and Supplemental Security Income (SSI). The benefits that each program provides can be used to help support you while you receive treatment for your prostate cancer.

The following article will provide you with a general understanding of Social Security Disability benefits and contains the information needed to begin the application process.

Defining Disability

In order to qualify for Social Security Disability benefits, all applicants must be disabled. While this comes as no shock, it isn't always clear what the term "disability" means. For this reason, the SSA has established an official definition of the word "disability". This definition is made up of the following criteria:

- An adult is disabled if he or she cannot do the work they did prior to becoming disabled; and
- He or she has a physical or mental condition that prevents them from learning to do a different type of work; and
- His or her condition has lasted, or is expected to last, at least 12 months or result in death.

If you do not meet the criteria set forth in this definition, the SSA will not consider you to be disabled and you will not qualify for disability benefits. Because of this, individuals with less advanced forms of prostate cancer may have a difficult time qualifying.

Those who do meet these requirements will then be evaluated based on certain technical and medical requirements. These are explained in the following sections.

SSDI vs. SSI

As previously mentioned, the SSA administers two separate types of benefits – SSDI and SSI. Each of these programs has its own technical eligibility requirements and is intended to help different groups of people.

- SSDI is intended to provide financial assistance to disabled workers and their eligible family members. This is an insurance-type program that workers pay into throughout their careers. For this reason, eligibility for SSDI is dependent on an applicant's employment history and tax contributions. Individuals who have not worked or paid Social Security taxes will not be eligible for SSDI benefits. For a deeper look into SSDI technical requirements, visit the following page: http://www.disability-benefits-help.org/ssdi/qualify-for-ssdi.
- SSI, on the other hand, is intended to provide financial assistance to disabled individuals of all ages who earn very little income and who have few financial resources. Technical eligibility for SSI is solely dependent on an applicant's income. Learn more about the financial limits for SSI, here: http://www.socialsecurity.gov/ssi/text-eligibility-ussi.htm

It is important to note that individuals who have limited work history and who fall within SSI financial limits may be eligible to receive benefits from both programs. Also of importance – SSDI recipients become eligible for Medicare after a two year waiting period and SSI recipients automatically become eligible to receive Medicaid.

Medical Eligibility and SSA's Blue Book

In addition to each program's technical requirements, disability applicants must also meet very specific medical requirements. These can be found in the SSA's official handbook of disabling conditions—more commonly referred to as the Blue Book. The Blue Book is broken up into sections, each dedicated to a particular condition. Under each condition you will find the specific medical requirements that you must meet in order to receive benefits.

Individuals applying with prostate cancer must meet the requirements listed under Blue Book section 13.24. This listing requires that applicants provide medical evidence of the following:

- Applicant's cancer is progressive or recurrent despite initial hormonal intervention; or
- Applicant's cancer has metastasized to internal organs.

To prove that you meet the above-mentioned criteria, you must include extensive medical documentation in your application. This may be in the form of MRIs, CT scans, and biopsy reports.

Other Ways to Qualify

If you have been diagnosed with small cell prostate cancer, you will be eligible for Compassionate Allowance processing. The Compassionate Allowance program allows individuals with inherently disabling conditions to be approved in as little as ten days. To secure Compassionate Allowance processing you will not need to fill out additional paperwork. Simply fill out the application paperwork and the SSA will evaluate your claim and expedite it accordingly. Learn about the Compassionate Allowance listing for small cell prostate cancer, here:

https://secure.ssa.gov/apps10/poms.nsf/lnx/0423022310.

If an applicant does not meet a Blue Book listing or the Compassionate Allowance listing, he may still be able to qualify for disability benefits under a medical vocational allowance. This means that the SSA will evaluate your age, job training, physical limitations, and mental limitations to determine whether or not you can do any type of work. If it is determined that you cannot be expected to work, you may qualify for disability benefits.

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COMMERCIAL URINE TEST FOR PROSTATE CANCER AVAILABLE

A new urine test for prostate cancer (PCa) that measures minute fragments of RNA is now commercially available from the University of Michigan Department of Pathology MLabs. The new test – Mi-Prostate Score (MiPS) – improves the utility of the PSA blood test by increasing physicians' ability to discriminate between high- and low-risk PCa, to help avoid unnecessary biopsies.

The MiPS test incorporates blood PSA levels and two molecular RNA markers specific for PCa in one final score that provides men and their doctors with a personalized PCa risk assessment.

For decades the PSA test has been used as a marker for the presence of PCa – high or rising levels in blood may indicate the presence of a prostate tumor. However, the PSA test is a non-specific test for PCa. And even when levels rise above what has been considered a trigger level (4.1 ng/mL) for a prostate biopsy, less than half of those biopsies find cancerous cells. In addition, up to 44 percent of PSA-triggered biopsies find PCa cells that are non-lethal, indolent PCa cells, highly unlikely to shorten a man's life.

The unreliability of the PSA test has led to sharp disagreement over the use of PSA as a routine health screening test. What everyone does agree upon is the need for better markers of PCa. To date there are no perfect biomarkers that identify only high-risk PCa. But each year progress is made toward such a goal. Today, the University of Michigan's MLabs will begin offering the MiPS urine test that is ultra-specific for prostate cancer. The MiPS test scans urine samples for two RNA markers that are distinct to PCa. One marker is PCA3 that is overactive in 95% of all PCa tumors. The second marker is RNA that is made only when two genes (TMPRSS2 and ERG) abnormally fuse. The presence of this fusion RNA in a man's urine is ultra-specific for PCa.

The PROGENSA PCA3 test, developed and marketed by Gen-Probe, gained FDA approval in 2012 for use in men who are considering repeat biopsy after an initially negative result. While a welcome development, research shows that MLabs' new urine test should improve a doctor's ability to stratify men suspected of having PCa. In a study published in Science Translational Medicine, Scott Tomlins, MD, PhD and colleagues found the highest rates of cancer in men with the highest levels of TMPRSS2:ERG and PCA3 in their urine. Dr. Tomlins is an assistant professor of pathology and urology at the University of Michigan and co-discovered what is now known as the TMPRSS2:ERG fusion.

Study results showed that men stratified as having low, intermediate and high levels of TMPRSS2:ERG and PCA3 in their urine had PCa diagnosed in 21%, 43%, and 69% of men, respectively. Men with a Gleason score >6, also occurred at different frequencies in the three groups with 7%, 20%, and 40% diagnosed in each group respectively.

Medical News Today, 30 September 2013

DISABILITY BENEFITS

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Application Process

The initial application is made up of several forms. To fill these out you can visit the SSA's website or schedule an appointment to apply in person at your local Social Security office. Prior to submitting your application, review the Adult Disability Interview Checklist. This will provide you with a list of the documents and records needed to apply.

(http://www.socialsecurity.gov/disability/Documents/Checklist%20-%20Adult.pdf)

After initially submitting an application, it may be several months before you receive a decision. While you wait, you should continue with any prescribed medical treatments and continue to collect all updated medical records. This will prepare you for the appeals processes in the event that your application is denied.

If your application does get denied, do not panic and do not give up. You will have 60 days in which to appeal the SSA's decision. Although facing the appeals process may seem discouraging, it is often a necessary step toward being awarded benefits. In fact, statistics have shown that more applicants are approved during the appeals processes than during the initial application.

For more information, visit this page:

http://www.disability-benefits-help.org/disabling-conditions/prostate-cancer.

PATHOLOGICAL AND ONCOLOGIC OUTCOMES FOR MEN WITH POSITIVE LYMPH NODES AT RADICAL PROSTATECTOMY: THE JOHNS HOPKINS HOSPITAL 30-YEAR EXPERIENCE

Pierorazio PM, Gorin MA, Ross AE, et al

Prostate 73: 1673-1680, 2013

Background: We report the 30-year institutional experience of radical prostatectomy (RP) for men with clinically localized prostate cancer (PC) found to have lymph node (LN) metastases at the time of surgery.

Methods: The Johns Hopkins RP Database (1982-2011) was queried for 505 (2.5%) men with node-positive (N1) PC. Survival analysis was completed using the Kaplan-Meier method and proportional hazard regression models.

Results: The proportion of men with N1PC was 8.3%, 3.5%, and 1.4% in the pre- (1982-1990), early- (1991-2000), and contemporary-PSA eras (2001-2011), respectively. A trend toward decreasing PSA, less palpable disease but more advanced Gleason sum was noted in the most contemporary era. Median total and positive nodes were 13.2 (1-41) and 1.7 (1-12), respectively. Of 135 patients with a unilateral tumor, 80 (59.3%), 28 (20.7%), and 15 (11.1%) had ipsilateral, contralateral, and bilateral positive LN. 15-year biochemical-recurrence free, metastases-free and cancer-specific survival was 7.1%, 41.5%, and 57.5%, respectively. Predictors of biochemical-recurrence, metastases and death from PC in multivariate analysis included Gleason sum at RP, the number and percent of positive LN; notably total number of LN dissected did not predict outcome.

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PSA SCREENING

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In a group of 1000 men, the authors estimated that there will be 116 biopsies and 60 cases of PCa. Overall, there will be 119 deaths in this population, of which 5.17 would be as a result of PCa. In the population exposed to screening, there would be 270 biopsies performed and 96 PCa tumors diagnosed.

Mortality would be similar, with 191 deaths overall and 4.1 from PCa. For 1 cancer death to be prevented among 1000 men, there would have to be an additional 154 biopsies, of which 9 would require hospitalization for severe adverse events; another 0.2 deaths would result from biopsy complications.

There would be 35 additional PCa diagnoses primarily in low-risk men . These would be associated with 12 additional cases of impotence, 2 cases of incontinence, and 1 case of fecal incontinence.

The authors note that a high percentage of PCa–related surgery (18%) was performed on men who were older than 70 years. In addition, 183 deaths (0.15%) occurred 60 days after surgery. The overall risk of dying was 0.11% for men aged 40 to 69 years, and this number jumped to 0.36% for those 70 years or older 60 days after surgery.

Overall, they found that the harms outweigh the benefits on a population level. This should further discourage the use of routine PSA testing for PCa in the general population, Dr. Boniol said. He did acknowledge, however, that there are high-risk groups, such as men with a family history of aggressive disease, who can benefit from PSA testing.

Dr. Boniol explained that in the 1980s, before the advent of testing, the incidence of PCa in France was 5%, and disease-specific mortality was 2%. But in the era of testing, he explained, incidence is now 14%. "But the risk of dying did not go up, it is still 2%."

Jack Cuzick, PhD, professor of epidemiology at the Wolfson Institute of Preventive Medicine at Queen Mary University of London, UK noted that a large, currently ongoing trial "may be the tiebreaker." The UKCAP/PROTECT trial includes 450,000 men and is expected to report its findings in 2016.

Medscape Medical News, 29 September 2013

DOC MOYAD'S WHAT WORKS & WHAT IS WORTHLESS COLUMN, ALSO KNOWN AS "NO BOGUS SCIENCE" COLUMN

"Please remember that the recommended daily allowance (RDA) for potassium is 4700 mg per day! 4700 mg per day! So, those taking Zytiga and/or prednisone should especially pay close attention !"

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

Editors' note: Us TOO has invited certain physicians and others to provide information and commentary for the *HotSheet* to enrich its content to empower the reader. This column contains the opinions and thoughts of its author and is not necessarily those of Us TOO International.

Bottom Line: Potassium is the forgotten nutrient especially in most individuals and those taking Zytiga! And, the recommended daily allowance (RDA) is very high or 4700 mg per day. A banana only has about 400-450 mg so you still have to get over 4000 mg from other sources everyday (say hello to a little coconut water my friends)! Since Zytiga can result in lower blood potassium levels in men taking this drug , it's a good idea to paste a list of food sources high in potassium on their refrigerator (think heart healthy foods).

Low potassium or not getting enough potassium is a big ,big problem for many men and women reading this column right now (yes, that means you my friend). Why? Few people realize that the recommended daily allowance (RDA) is a mind blowing and large 4700 mg per day! This is how much is needed to keep the body functioning normally. Say you eat a banana every day, but that only gives you 450 mg or less so where are you going to get another 4000+ milligrams during your day? Eight or more bananas? Nope! How about taking a potassium dietary supplement? Nice try but you can only buy tablets with 99 mg or less in them so taking a ton of pills makes no sense (and cents) here! Plain yogurt, beans, fish, fruits, veggies, and even coconut water can contain almost as much potassium as a banana or more! So, the key to really getting more potassium is simply eating a heart healthy diet! How about spinach? One cup has almost twice the amount of potassium compared to a banana (Popeye was the man!) and so does one cup of avocado! A total of 17% of men experienced low potassium blood counts with Zytiga in their phase-3 trial of the drug when used before chemotherapy AND in the phase-3 trial after chemotherapy (prednisone can cause low potassium also)! What can happen when your potassium is very low? Abnormal heart rhythms, fatigue, constipation, muscle problems such as weakness/spasms/damage, and paralysis (especially of the lungs) are some of the not-so-fun things that can happen…. YIKES! So, the word of the day to all of those reading my column this month is…. P-O-T-A-S-S-I-U-M! Perhaps this is why the Michigan Football team has not been playing with consistency and are driving me crazy this year?! They need more potassium right now! Oh, and can someone remove the potassium from the Ohio State football cafeteria before they play Michigan this year….thank you!

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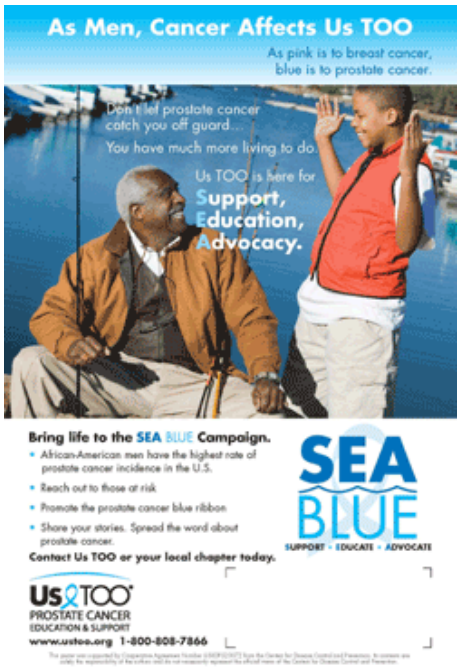
2. de Bono JS, Logothetis CJ, Molina A, et al. Abiraterone and increased survival in metastatic prostate cancer. N Engl J Med 2011;364:1995-2005



MELBOURNE CONSENSUS STATEMENT CLARIFIES CONFUSION AROUND PSA TESTING

Reid Graves, MD

In August of 2013, prostate cancer (PCa) experts from around the word met in Melbourne, Australia at the Prostate Cancer World Congress to discuss the much debated role of PSA testing for the detection of early PCa. The panel, consisting of leaders in urology, radiation oncology, medical oncology, epidemiology, general practice and allied health, released the Melbourne Consensus Statement in an attempt to quell the shared confusion and frustration many healthcare providers face regarding PSA testing. The document, composed of 5 consensus statements, aims to provide a practical, evidence based summary of the use of PSA testing for the early detection of PCa. Broadly speaking, the Melbourne Statement has been warmly welcomed by many as providing some realistic and relevant advice for primary care physicians and others who find this area challenging and confusing.

While specific age ranges are identified as benefitting most from PSA testing, 50 -69, the opportunity to test patients in their 40's and those over 70 is not ignored. The real focus of the consensus statement is on a shifting paradigm in which the goal should not to be to treat all men diagnosed with PCa but to diagnose all men with potentially lethal PCa and to avoid over treatment in men diagnosed with low risk PCa. The authors stress the importance of a multivariable approach to early PCa detection, admitting the shortcoming of the PSA test as a generalized population-based screening tool but not disregarding the role it has played in the last 30 years in decreasing PCa mortality and the incidence of metastatic PCa. In the wake of the USPTF Grade D recommendation on PCa screening, the Melbourne Consensus Statement gives healthcare providers a

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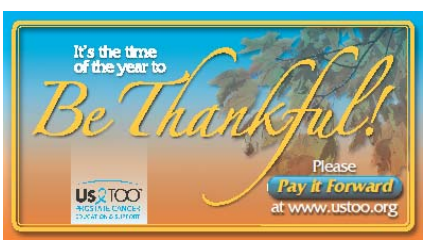

NO RELIEF OF HOT FLASHES IN MEN *(Continued from page 1)*

mean score was calculated. Quality of life (QoL) was assessed using the Functional Assessment of Cancer Therapy-Prostate (FACT-P) and FACT-General (FACT-G) scales; the FACT-P scale consists of the FACT-G scale plus a prostate-specific subscale.

Patient groups were generally well matched for age, body mass index (80% –90% overweight or obese), race/ethnicity, stratification by disease stage/hot flash severity (e.g., metastatic/severe in 3%–10%, nonmetastatic/moderate in 50%–57%), Eastern Cooperative Oncology Group performance status (0 in 70% –97%), and treatments (e.g., luteinizing hormone-releasing hormone agonists (LHRH-A) in 77%–87%).

Overall, significant decreases (all P < .001) were observed in mean number of hot flashes in all groups (from 8.8–10.0 to 4.1–5.9), mean severity in all groups (from 2.1–2.4 to 1.6–1.8), and mean hot flash symptom severity score in all groups (from 21.3–22.9 to 9.2–13.6) at 12 weeks with no significant differences among groups. At week 12, hot flash symptom severity score was reduced by 28% in the venlafaxine plus soy group, 35% in the venlafaxine group, 31% in the soy group, and 55% in the placebo group.

There were no significant differences among groups in number of hot flashes at any time point, although patients who received venlafaxine tended to have fewer hot flashes during the initial 2 weeks. There were no significant differences in severity between the soy and placebo groups at any time point, with the venlafaxine group tending to have lower scores at weeks 1 to 4. With regard to hot flash symptom severity score, although the placebo group initially did poorly, that group had the greatest percentage decline from baseline to 12 weeks, resulting in early termination of the trial by the Data Safety Monitoring Board due to lack of effect.

An interaction between venlafaxine and number of followup visits was significant (P = 0.014), with an initial greater effect of venlafaxine being lost over time. Hot flash symptom severity score was decreased by 28% at week 2 in patients receiving venlafaxine compared with 2% in those not receiving venlafaxine (P = 0.005); by week 12, the decreases were 29% vs 36% (P = 0.723).

Quality-of-life results according to whether patients did or did not receive venlafaxine or soy showed no significant effect of venlafaxine vs no venlafaxine on subscales or total FACT-P or FACT-G scores. Compared with patients not receiving soy protein, those receiving soy protein had significant improvements in emotional (P = 0.029) and functional (P = 0.041) subscales and in total FACT-G (P = 0.025) and FACT-P scores (P = 0.048). Toxicity was minimal and did not differ among groups.

Investigators concluded, "In androgen-deprived men, neither venlafaxine nor soy proved effective in reducing hot flashes. Interventions that appear effective for decreasing hot flashes in women may not always be effective in men."

The ASCO Post, 11 October 2013

WINNING THE BATTLE AGAINST PROSTATE CANCER , 2ND EDITION

The second edition of Dr. Gerald Chodak's book "Winning the Battle Against Prostate Cancer" is now available online at Amazon.com. Unlike the first edition, which provided information about prevention and detection of prostate cancer, this edition is primarily intended for men who have already been diagnosed with the disease. Doctors rarely agree on the means of managing prostate cancer and often promote one treatment over another without good scientific evidence. This book makes you aware of these possible biases, so you can avoid getting a treatment that may not be the right one for you. This book avoids potential biases because it strictly follows the principles of evidence-based medicine or EBM. It means that a therapy will be recommended only when high quality scientific studies have demonstrated it is the best option. If such studies do not exist, this book will help you understand the pros and cons and risks and benefits of all the treatments available without a bias toward any one of them.

The key is to be adequately informed so you can work with your doctor to find the treatment that is right for you. To play an active role in this decision, you need to know what you need to know, which means asking the right questions.

DOCTOR CHODAK'S BOTTOM LINE *(Ref Key: article #, page #, column #)*

Gerald Chodak, MD Author, Winning the Battle Against Prostate Cancer , Second Edition www.prostatevideos.com

Editors' note: Us TOO has invited certain physicians and others to provide information and commentary for the *HotSheet* to enrich its content to empower the reader. This column contains the opinions and thoughts of its author and is not necessarily those of Us TOO International.

a1p1c1 Important progress has occurred in understanding the benefit of combining Androgen Suppression Therapy (ADT) with external radiation in men with prostate cancer. For those with high-risk disease, three years is thought to be optimal although preliminary results now suggest that 18 months may be just as effective. One randomized study has shown that giving six months of ADT along with the radiation significantly improved survival for men with intermediate risk disease. Now, another study reported at the recent ASTRO meeting compared a total of 16 weeks of ADT (8 weeks before and 8 weeks during radiation) to a total of 36 weeks of therapy and found a similar survival with a lower incidence of side effects. Without doing another study to find out if there is any difference between using four and six months of ADT, four months is a reasonable approach for men with intermediate risk disease who will receive external radiation.

The Bottom Line: Men with intermediate risk prostate cancer receiving external radiation should be informed that using ADT for eight weeks before and eight to 16 weeks during radiation offers the best survival.

a2p1c2 Another study has attempted to assess the benefits and harms of screening large groups of men for prostate cancer. Boniol and associates did a mathematical analysis based on published data that included the side effects from biopsies and radical prostatectomy. They concluded that for every cancer death prevented, an additional 154 biopsies would be performed, 35 men would be diagnosed with prostate cancer of which 12 would become impotent and 2 would be incontinent. Unfortunately, they did not look at the impact of external radiation or brachytherapy, which would have had a somewhat lower negative impact. Nevertheless, their findings add to the growing concern that screening does more harm than good in society. The challenge remains, however, that SOME men will benefit from undergoing screening and early treatment and this paradox will remain until we find ways to distinguish those men who definitely need treatment from those who do not.

The Bottom Line: Until better tools to gauge cancer aggressiveness are developed, the overall harms of widespread screening appears to outweigh the benefits, though some lives are saved.

a5p2c3 One of the many important developments in the past few years has been the approval of abiraterone acetate for men with progressive metastatic prostate cancer. This novel drug is an androgen synthesis inhibitor and ketoconazole (Nizoral®), but is much more potent. The study by Caffo and coworkers provides an important observation that some men improve simply by stopping the abiraterone when disease progression occurs. They found that 16% of men who stopped the drug had an improvement in their PSA, although it is unclear how long that response lasted. This finding needs to be confirmed in other reports.

The Bottom Line: This study suggests that for men who have disease progression on abiraterone, the drug should be stopped and the PSA rechecked before starting another therapy.

a7p4c1 Most experts now acknowledge the limitations of screening for prostate cancer using PSA and many efforts are underway to stratify men into groups that might avoid a biopsy or avoid treatment should cancer be detected. The University of Michigan has developed a new test based on two molecular markers that may provide helpful information. I have reviewed one of their papers (Sci Transl Med 3 August 2011) and it is a positive step toward helping men but its actual value to individuals is still unclear. For example, in men with low levels of these markers, there still is a 20% chance of having cancer, which many men may feel is too high to risk not undergoing a biopsy. In those men with high levels of these markers, there is a 40% chance that their cancer might not be that dangerous and therefore may not need immediate treatment. For the intermediate group, the uncertainties are even greater.

The Bottom Line: The use of two molecular markers (PCA3 and TMPRSS2:ERG) improves the accuracy of PSA for identifying cancer and high risk cancer, but for individuals so far it still does not provide yes or no answers that make it possible to safely decide what to do. It may, however, suggest which men considering active surveillance should have more extensive biopsies or those with a negative biopsy who should have a repeat biopsy.

a8p4c4 Among the many debates in prostate cancer is the question of what to do with the pelvic lymph nodes at the time of a prostatectomy; remove them or leave them alone? Because removing normal lymph nodes offers no patient benefit, the vast majority of men diagnosed today do not need them removed. However, in those individuals at higher risk for lymph node metastases (PSA above 10 or 20 ng/mL, a T2c or T3a cancer and a Gleason score of 8-10), the uncertainty is whether a limited or extended lymph node dissection should be done. The more extensive operation is more time consuming and has a higher risk for complications. The trade-off, however, is it can identify more patients with cancer in the lymph nodes. The paper from Johns Hopkins looked at the results for men who had a limited or extensive dissection and found better survival, a lower incidence of metastases and a lower biochemical recurrence rate. What is surprising about the results is the patients in both groups had a similar rate of positive nodes so the question is why the better outcome? The most likely reason, which is not discussed in the abstract, is that the men with positive lymph nodes were given early androgen deprivation therapy, which has been shown to improve survival compared to delayed treatment.

The Bottom Line: For those men needing a lymph node dissection, this study suggests that a more extensive dissection can lead to better outcomes.

CONSENSUS STATEMENT

(Continued from page 6)

pragmatic approach to counseling their patients on the early detection of prostate cancer as well as limiting the side of effects of treatment for those men diagnosed with prostate cancer by perhaps not treating them at all.

The five consensus statements are:

1. For men aged 50-69, level 1 evidence demonstrates that PSA testing reduces PCa-specific mortality and the incidence of metastatic PCa.
2. PCa diagnosis must be uncoupled from PCa intervention.
3. PSA testing should not be considered on its own, but rather as part of a multivariable approach to early PCa detection.
4. Baseline PSA testing for men in their 40's is useful for predicting the future risk of PCa.
5. Older men in good health with over ten year life expectancy should not be denied PSA testing on the basis of their age.

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SHORTER NEO TAS COURSE

(Continued from page 1)

PSA failure (PSAF), locoregional tumor progression and distant metastasis. Overall survival (OS) was estimated via the Kaplan-Meier method and efficacy was tested with the log rank test.

There were 30 PCa deaths in Group 1, for a 10-year DSS rate of 95%; and 24 PCa deaths in Group 2, for a 10-year DSS rate of 96% (no statistical difference). There were 200 additional deaths not attributable to PCa in Group 1 for a 10-year OS rate of 66%, and 196 such deaths in Group 2, for a 10-year OS rate of 67%. By 10 years, 27% of men had a PSAF (using the RTOG-ASTRO definition), 5% had locoregional PCa recurrence and 6% had distant metastasis. Hot flashes and erectile dysfunction were more common in Group 2.

"Sometimes, preliminary research leads us to assume that more treatment is better, but this study serves as a strong cautionary note to put the promising treatment to the test," said Thomas Pisansky, MD, lead author of the study and professor of radiation oncology at the Mayo Clinic in Rochester, MN."

POSITIVE LYMPH NODES AT RP

(Continued from page 4)

Conclusions: In this highly-selected RP cohort, men found to have N1PC disease at RP can experience a durable long-term metastases-free and cancer-specific survival. Predictors of survival include Gleason sum, number, and percentage of positive LN. While total number of LN dissected was not predictive, approximately 30% of men with N1PC will have positive LN contralateral to the primary prostatic lesion highlighting the importance of a thorough, bilateral pelvic LN dissection

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