US TOO® PROSTATE CANCER EDUCATION & SUPPORT

HOTSHEET

JANUARY 2013

FDA EXPANDS ZYTIGA'S USE FOR LATE-STAGE PROSTATE CANCER

The US Food and Drug Administration expanded the approved use of Zytiga® (abiraterone acetate) to treat men with late-stage (metastatic) castration-resistant prostate cancer (CRPC) prior to receiving chemotherapy.

The FDA initially approved Zytiga in April 2011 for use in patients whose prostate cancer progressed after treatment with docetaxel chemotherapy. Zytiga decreases the production of male sex hormone testosterone. Some men have CRPC, meaning the cancer cells continue to grow even with low levels of testosterone.

"This approval demonstrates the benefit of further evaluating a drug in an earlier disease setting and provides patients and health care providers the option of using Zytiga earlier in the course of treatment," said Richard Pazdur, MD, director of the Office of Oncology Drug Products in the FDA's Center for Drug Evaluation and Research.

FDA reviewed Zytiga's application for this new indication under the agency's priority review program. The program provides for an expedited six-month review for drugs that may offer major advances in treatment or provide a treatment when no adequate therapy exists.

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ADDING TESTOSTERONE TO SILDENAFIL OFFERS NO BENEFIT

Testosterone added to sildenafil (Viagra®) is no better than placebo in improving erectile dysfunction (ED) or sexual satisfaction, according to a study published online November 19 in the *Annals of Internal Medicine*.

Many men with ED also have low testosterone. Matthew Spitzer, MD, from the Boston University School of Medicine in Massachusetts and colleagues hypothesized that adding testosterone to phosphodiesterase type 5 (PDE5) inhibitors, such as sildenafil, could increase the effect of the drug. Association of the hormone in humans with sexual desire and response supports the hypothesis.

In a parallel, randomized, placebo-controlled, double-blinded trial, the current study compared testosterone plus sildenafil to placebo plus sildenafil in middle-aged to older men with low testosterone levels and ED.

Primary outcome was improved ED response. Secondary outcomes were other aspects of the response, such as sexual desire, ejaculation, and orgasm; frequency, quality, and satisfaction with intercourse and intimacy with a partner.

Participants were between age 40 and 70 years, scored less than 25 points on the EF domain (EFD) of the International Index of Erectile Function, and had total testosterone levels lower than 11.45

(Continued on page 4)

AEROBIC EXERCISE EASES FATIGUE IN PATIENTS WITH BREAST AND PROSTATE CANCER

Aerobic exercise can help relieve fatigue related to breast and prostate cancer, both during and after treatment, according to an updated review published online November 14 in the Cochrane Database of Systematic Reviews.

The findings suggest that aerobic exercise should "be considered as one component of a management strategy for fatigue that may include a range of other interventions and education," write review authors Fiona Cramp, PhD, and James Byron-Daniel, PhD, from the University of West England in Bristol, UK.

In the past, cancer patients were often encouraged to manage fatigue with rest. Currently, this approach is considered counterproductive because "inactivity leads to muscle wasting and loss of cardiorespiratory fitness, leading to increased fatigue," the authors write. They also point out that the American College of Sports Medicine takes no definitive stand on exercise for cancer-related fatigue.

This updated review involved 28 studies from their original 2008 review and 28 from an updated literature search, and provided data on 1461 patients receiving an exercise intervention and 1187 control subjects. Although the participants had various cancer diagnoses, many were from studies of breast cancer.

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DIAGNOSTIC PERFORMANCE OF PCA3 TO DETECT PROSTATE CANCER IN MEN WITH INCREASED PROSTATE SPECIFIC ANTIGEN: A PROSPECTIVE STUDY OF 1,962 CASES

Crawford ED, Rove KO, Trabulsi EJ, et al

J Urol 188: 1726-31, 2012

Purpose: The detection of prostate cancer relies primarily on abnormal digital rectal examination or increased serum prostate specific antigen concentration. However, low positive predictive values result in many men with increased prostate specific antigen and/or suspicious digital rectal examination having a negative biopsy. We investigated the value of the PCA3 (prostate cancer gene 3) urine test in predicting the likelihood of diagnosis of cancer before biopsy.

Materials and Methods: We performed a prospective, community based clinical trial to evaluate PCA3 score before any biopsy. This trial was conducted at 50 urology practices in the United States. Samples were obtained from 1,962 men with increased serum prostate specific antigen (greater than 2.5 ng/ml) and/or abnormal digital rectal examination before transrectal prostate needle biopsy. Study samples (urinary PCA3 and biopsies) were processed and analyzed by a central laboratory. Sensitivity-specificity analyses were conducted.

Results: A total of 1,913 urine samples (97.5%) were adequate for PCA3 testing. Of 802 cases diagnosed with prostate cancer 222 had high grade prostatic intraepithelial neoplasia or atypical small acinar proliferation and were suspicious for cancer, whereas 889 cases were benign. The traditional PCA3 cutoff of 35 reduced the number of false-positives from 1,089 to 249, a 77.1% reduction. However, false-negatives (missed cancers) increased significantly from 17 to 413, an increase of more than 2,300%. Lowering the PCA3 cutoff to 10 reduced the number of false-positives 35.4% and false-negatives only increased 5.6%.

Conclusions: Urinary PCA3 testing in conjunction with prostate specific antigen has the potential to significantly decrease the number of unnecessary prostate biopsies.

CABOZANTINIB IN MEN WITH ADVANCED PROSTATE CANCER: RESULTS OF A PHASE II RANDOMIZED DISCONTINUATION TRIAL

Smith, DC, Smith MR, Sweeney C, et al

J Clin Oncol 19 Nov 2012; Epub

Purpose: Cabozantinib (XL184) is an orally bioavailable tyrosine kinase inhibitor with activity against MET and vascular endothelial growth factor receptor 2. We evaluated the activity of cabozantinib in patients with castration-resistant prostate cancer (CRPC) in a phase II randomized discontinuation trial with an expansion cohort.

Patients and Methods: Patients received 100 mg of cabozantinib daily. Those with stable disease per RECIST at 12 weeks were randomly assigned to cabozantinib or placebo. Primary end points were objective response rate at 12 weeks and progression-free survival (PFS) after random assignment.

Results: One hundred seventy-one men with CRPC were enrolled. Random assignment was halted early based on the observed activity of cabozantinib. Seventy-two percent of patients had regression in soft tissue lesions, whereas 68% of evaluable patients had improvement on bone scan, including complete resolution in 12%. The objective response rate at 12 weeks was 5%, with stable disease in 75% of patients. Thirty-one patients with stable disease at week 12 were randomly assigned. Median PFS was 23.9 weeks (95% CI, 10.7 to 62.4 weeks) with cabozantinib and 5.9 weeks (95% CI, 5.4 to 6.6 weeks) with placebo (hazard ratio, 0.12; $P < .001$). Serum total alkaline phosphatase and plasma cross-linked C-terminal telopeptide of type I collagen were reduced by $\geq 50\%$ in 57% of evaluable patients. On retrospective review, bone pain improved in 67% of evaluable patients, with a decrease in narcotic use in 56%. The most common grade 3 adverse events were fatigue (16%), hypertension (12%), and hand-foot syndrome (8%).

Conclusion: Cabozantinib has clinical activity in men with CRPC, including reduction of soft tissue lesions, improvement in PFS, resolution of bone scans, and reductions in bone turnover markers, pain, and narcotic use.

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

"Holiday quiz time…What has about 150 calories per serving and is one of the biggest reasons why Santa Claus can't lose weight?! "

Mark A. Moyad, MD, MPH, Univ. of Michigan Medical Center, Department 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: The average American adult gets about 100 calories a day (men consume 150 calories and women 50 calories) on average consuming beer, wine or liquor. To put things in perspective 1 alcoholic drink is 150 calories, 1 soda is 150 calories and 1 fruit juice drink is a little less or more than 150 calories. So, enjoy the holidays and remember how easy it is to get calories from a variety of alcoholic and non-alcoholic drinks.

A new study from participants around the US has found a surprising number of calories in women and especially men are coming from alcoholic beverages.[1] Now, everyone knows that I love beer almost as much as life itself (oh and I also love college football and reality television shows where people fight a lot-reminds me of growing up with 2 brothers), but I have a rule that if I have 1 or 2 beers when I go out I have to add another 300 calories of exercise burning time to my daily routine! Now, that does not sound like fun and I am NOT trying to promote alcoholism but better caloric awareness.

It is crazy that we spend so much time picking on just sugary soda at 150 calories per can when most alcoholic beverages and fruit juices today are 150 calories per bottle, can, cup, or glass. An apple has about 70 calories, more than 3 grams of fiber and 14 grams of sugar, but just an 8-ounce glass of apple juice can have 120 calories, virtually no fiber and almost 30 grams of sugar! A whole orange has less than 50 calories and over 2 grams of fiber and 9 grams of sugar, but just 8 ounces of orange juice has about 120 calories and no fiber and over 21 grams of sugar! A cup of grapes are 60 calories and a cup of grape juice has over 150 calories. Compare pomegranate or any other juice (all about 150 calories per 8 ounces) and the problem is all these calories just never end.

Weight gain reduces testosterone, reduces sexual health, increases cholesterol, blood pressure, blood sugar, artificially lowers PSA, and who would have thought that alcohol and fruit juice in adults are such large contributors to a large waist line!

Whether or not you believe in Santa Claus is not the issue (I believe in Santa Claus and UFOs and Big Foot and that Elvis is alive and is living somewhere near the Us TOO home office and he goes by the fake last name of Kirk), but I do not understand how anyone today in America can begin to lose weight without reducing intakes of alcohol, fruit juices and sugary (not diet) soda. Additionally, there was a fabulous study in 2009 that never received attention showing that heavy drinking (4 or more per day) may increase the risk of aggressive prostate cancer and may even reduce the effectiveness of the drug finasteride to prevent prostate cancer![2]

Happy Holidays and sorry to be so depressing so I will end on a positive note…1 cup of eggnog is 350 calories! Okay, sorry about that but I just wanted to reinforce my holiday message! Pass me a light beer and whole orange (not juice) and turn on the Michigan game and I will be happy (especially if they win the Outlook Bowl)!

Reference:

1. Nielsen SJ, Kit BK, Fakhouri T, Ogden CL. Calories consumed from alcoholic beverages by U.S. adults, 2007–2010. NCHS data brief, no. 110, November 2012.
2. Gong Z, Kristal AR, Schenk JM, et al. Alcohol consumption, finasteride, and prostate cancer risk: results from the Prostate Cancer Prevention Trial. Cancer 2009; 115:3661-9.

ASK DOCTOR SNUFFY MYERS

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With increasing emphasis on active surveillance, prostate cancer survivors are understandably concerned about disease progression. Can untreated Gleason grade 3 (G3) cells in a tumor progress to grade 4 or 5 or does the grade of the tumor cells remain in their original classification? I am referring to the cancer cells that are classified as G3, not the total Gleason score of x+x.

First, the whole point of active surveillance is to identify those cancers that are progressing. It is extremely important to understand that active surveillance is done with curative intent. The goal is to identify those who need to be cured and getting them to curative treatment.

A portion of Gleason 3+3=6 cancers do progress. As I look at the published series, that number varies from center to center for reasons that are not very clear. Our own experience is that progression to surgery or radiation probably approaches 10%, but then we do more than just active surveillance. I think our results arise from several factors. First, we extensively characterize patients at the start. I think the use of color Doppler ultrasound has been important as it identifies highly vascular tumors. A portion of Gleason 3+3=6 lesions will be highly vascular and these are at high risk for progression. It looks as if MRI techniques that assess vascular permeability may offer similar insights into the biology of the cancer. As a result, we do a pretty good job of identifying cancers likely to progress and refer these patients for curative treatment.

Behind your question, I think you are concerned the cancer might have progressed so that cure is not possible? Published literature suggests that risk is low.

TESTOSTERONE + SILDENAFIL

(Continued from page 1)

nmol/L or free testosterone levels lower than 173.35 pmoL/L.

Half of the 140 subjects received sildenafil plus daily 1% transdermal T-gel, and the other half received the drug plus placebo gel. Researchers adjusted testosterone doses to achieve the desired levels. Candidates were excluded if they did not have sexual partners or had prostate or breast cancer, penile abnormalities, untreated sleep apnea, major psychiatric diseases, recent myocardial infarction or stroke, or elevated hematocrit, creatinine, PSA, hemoglobin A1c, or blood pressure levels.

Researchers predicted that the sample sizes were sufficient to show that adding placebo gel to sildenafil would add 2 points to the EFD score, and adding testosterone gel would add 6 or more points. However, the anticipated boost with testosterone did not happen.

"The primary analysis indicated that 14-week change in EFD score after randomization...did not differ significantly between the testosterone and placebo groups (difference between mean changes, 2.2 [(confidence interval), −0.8 to 5.1]; P = 0.150)," researchers conclude.

Frequency of attempts at sex, vaginal penetration, ejaculation, satisfaction, and percentage of successful encounters improved similarly in both groups, indicating that sildenafil was responsible for the improvements, and not testosterone supplementation. Frequency of adverse events also did not differ between groups.

A limitation of the study is that it did not examine whether testosterone improves ED without sildenafil or whether adding the hormone has other benefits, such as improving body composition, muscle strength, cognition, and metabolism.

"The bottom line is that addition of testosterone to PDE5 only helps men who have very low testosterone levels" stated H. Ballentine Carter, MD, professor of urology and oncology at Johns Hopkins Medicine in Baltimore, MD who was not involved in the study. He pointed to a study finding a similar lack of effect of supplementary testosterone in men taking tadalafil (Cialis®).

Medscape Medical News, 19 November 2012

AEROBIC EXERCISES RELIEVE CANCER FATIGUE

(Continued from page 1)

Exercise interventions occurred both during and after cancer treatment. The aerobic activity included resistance training, or flexibility exercises. Delivery of interventions varied widely in duration, frequency and intensity. Self-pacing to regimens involved the monitoring of heart rate and oxygen uptake.

For the outcome of fatigue, which was assessed using a wide range of outcome measures across studies, aerobic exercise such as walking and cycling had a statistically significant benefit over no exercise (P = 0.03).

The results of the review should not be considered in isolation, the authors note. A range of nonpharmacologic interventions can also be considered beneficial, they point out. "Interventions that may be delivered in conjunction with an exercise program include, but are not limited to, psychosocial therapies, stress management, nutrition therapy, and sleep therapy."

"The findings support exercise to help reduce symptoms of fatigue in survivors of the 2 most common forms of cancer: breast cancer and prostate cancer," noted Margaret McNeely, PhD, an expert in cancer rehabilitation and exercise and assistant professor in the Department of Physical Therapy at the University of Alberta and in the Department of Oncology and the Rehabilitation Medicine Department at the Cross Cancer Institute in Edmonton, Alberta, Canada.

"Further work is necessary to determine the most effective parameters of exercise for fatigue management, including multimodal exercise (combined aerobic and resistance), frequency and length of each exercise session, and exercise intensity," Drs. Cramp and Byron-Daniel write.

Medscape Medical News, 14 November 2012

PROTONS FOR PROSTATE CANCER: FLEETING QOL BENEFIT

Men with prostate cancer treated with proton-beam therapy (PBT) had better quality-of-life (QoL) in the first few months after treatment than those treated with 2 more common radiotherapy (RT) modalities, according to new research.

However, over time, QoL scores of men treated with PBT were similar to those treated with 3D conformal (3D-CRT) or intensity-modulated RT (IMRT), according to the study presented at the American Society for Radiation Oncology (ASTRO) 54th Annual Meeting.

The study looked at QoL scores for patient-reported bowel and urinary function. The authors, led by Phillip J. Gray, MD, from the Harvard radiation oncology program in Boston, MA, used data from 3 different patient cohorts because there has been no direct comparison of PBT, 3D-CRT, and IMRT.

Dr. Gray and colleagues reviewed the outcomes of 370 patients: 94 treated with PBT at Massachusetts General Hospital in Boston; 123 treated with 3D-CRT at hospitals affiliated with Harvard University; and 153 treated with IMRT who were part of the Prostate Cancer Outcomes and Satisfaction with Treatment Quality Assessment consortium.

Median ages in the PBT, 3D-CRT and IMRT groups were 64, 70 and 69 years, respectively. RT dose ranged from 74.0 to 82.0 Gy relative biologic effectiveness in the PBT group, from 66.4 to 79.2 Gy in the 3D-CRT group, and from 75.6 to 79.2 Gy in the IMRT group.

Men treated with IMRT and PBT were assessed using the Expanded Prostate Cancer Index Composite (EPIC) instrument. Men treated with 3D-CRT were assessed using the Prostate Cancer Symptoms Index (PCSI); these scores were converted to match those of the EPIC scale. Clinically meaningful differences in QoL scores were defined as those exceeding half the standard deviation of the mean baseline score.

At 2- to 3-month follow-up, men treated with PBT reported minimal decline in bowel function, whereas those treated with 3D-CRT or IMRT reported modest but "clinically meaningful changes" in bowel function, Dr. Gray reported. But, at 1 and 2 years, men in all 3 groups reported a clinically meaningful decline in bowel function. The decline just took longer to develop in the PBT group.

At 2- to 3-month follow-up, urinary QoL scores were lower than they were at baseline in all 3 groups; however,

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

Editor: 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 More good news is available for men failing hormone therapy! Abiraterone acetate (Zytiga®) combined with prednisone was FDA approved in 2011 for men who have failed docetaxel chemotherapy. Now, this combination is also approved for men with metastatic disease who are progressing on hormone therapy before docetaxel. A randomized study in over 1,000 men showed that Zytiga delayed X-ray progression of the disease and also prolonged overall survival like it does if given after chemotherapy. These results supported FDA's decision to expand the indications for use for this drug in this patient subgroup.

The Bottom Line: Positive results show a benefit to men receiving abiraterone plus prednisone before they receive chemotherapy and hopefully this will become available in the near future for men in the US.

a2p1c2 Another study provides some information for men with erectile dysfunction but do not have prostate cancer. Supplementing sildenafil with testosterone was tested in a randomized study to see if the combination would offer greater benefit than sildenafil alone. Unfortunately, this did not help unless the men definitely had a low testosterone. This study has one consolation for those men who do have erectile dysfunction following localized treatment for prostate cancer. At present, many doctors are reluctant to offer testosterone to these men to improve their erections. The findings from this study mean that these men are not missing an opportunity to be helped. However, suppose a man does have a low testosterone and erectile function after his cancer therapy. We need to ask whether it is wrong to give him this drug in cases where we think the cancer has been eliminated. If there are no cancer cells alive in the body of a man with low testosterone, then why not see if the testosterone will help him. This would be reasonable to discuss with your doctor.

The Bottom Line: For men who have problems with their erections and normal levels of testosterone, there is no benefit from adding testosterone to a PDE5 inhibitor such as sildenafil.

a3p1c3 The article from the Cochrane database on aerobic exercise addresses an underappreciated problem with our treatments for prostate cancer; many men develop fatigue, particularly those on hormone therapy. In conversations with urologists around the United States, I have found that few of them offer or suggest any exercise programs during treatment. One problem or limitation is that the types of studies needed for counseling patients have been lacking. However, this updated review provides useful support for having men engage in aerobic exercise during their treatment. Unfortunately, not enough patient information is provided in this report about either the cancer treatments given or the exercise programs followed. Consequently, there are many questions that would need answering to fully inform men what they should do. But this is certainly a start and the idea that men should rest and avoid strenuous activity during their therapy would seem to be the wrong thing to tell them. Hopefully this finding will stimulate comparative studies aimed at showing which combination and duration of exercises would be best.

The Bottom Line: Men should be encouraged to do aerobic exercise while being treated for their prostate cancer as it will overcome some fatigue and should improve their overall well-being.

a4p2c2 One of the ongoing problems for men without prostate cancer who get a PSA is the high percentage of men with a negative biopsy. A test to help avoid unnecessary biopsies would be very helpful. The PCA3 urine test has been approved for men with a negative biopsy to see if another biopsy is warranted. Now Crawford and co-workers used this test to see if some men could avoid an unnecessary biopsy. A challenge with all tests is deciding what defines a normal and abnormal value. This is always a trade-off; to make a test more specific, the sensitivity will go down. In this study, using a cutoff of 10 for the PCA3 test resulted in a large reduction in the percentage of men without cancer undergoing a biopsy while only about 6% of those with cancer being missed. Is this acceptable? It might be. What we do not know from this study is enough information about the cancers being detected and those being missed. A review of the full paper does not give us this information. If the cancers being missed were low risk, then that would not be bad. But, if higher grade or more dangerous cancers were missed then that would be a problem. Hopefully that information will be forthcoming.

The Bottom Line: PCA3 may offer an opportunity to reduce the number of unnecessary biopsies in men with a PSA above 2.5 ng/ml but more information is needed to make this determination.

a5p2c3 Encouraging news for all men with advanced prostate cancer is provided by the study of cabozantinib, a tyrosine kinase inhibitor that acts by interfering with chemicals produced by tumors that help them grow. Smith and Sweeney conducted a phase II study and results were impressive. Compared to placebo, a significant percentage of the men taking cabozantinib experienced a reduction in soft tissue lesions, bone metastases, pain and narcotics requirements. We can expect that a phase III randomized study will be forthcoming or may have already started. A few words of caution are needed, however. The randomized study included only a small number of men and the design only included those men not progressing during the first phase of the study. This means we can expect less robust results with lower benefit when the next study is performed. Even so, this may potentially offer yet another way to treat men with advanced prostate cancer.

The Bottom Line: Cabozantinib shows very encouraging results in a Phase II study and a phase III study will be conducted to see if this drug can be added to the growing list of options for men with progressive metastatic disease.

a10p4c2 Proton Beam treatment (PBT) is the most expensive form of RT for men with prostate cancer. Advertisements promote it as having fewer side

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INDEX OF MEDICAL ARTICLES PUBLISHED IN US TOO'S *HOTSHEET* DURING 2012

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ZYTIGA APPROVED PRE-CHEMO

(Continued from page 1)

Safety and effectiveness for expanded use were established in a clinical study of 1,088 chemotherapy-naive men with late -stage, CRPC. Participants received either Zytiga or a placebo combined with prednisone. The study endpoints were overall survival (OS) and radiographic progression-free survival (rPFS).

The median OS with Zytiga was 35.3 months vs. 30.1 months with placebo. Zytiga also improved rPFS; the median rPFS was 8.3 months in the placebo group and had not yet been reached in the Zytiga group at the time of analysis.

The most common side effects reported with Zytiga include fatigue, joint swelling or discomfort, fluid retention, hot flush, diarrhea, vomiting, cough, high blood pressure, shortness of breath, urinary tract infection, and bruising.

The most common laboratory abnormalities included anemia, and elevated levels of alkaline phosphatase, fatty acids, sugar, and liver enzymes in the blood; and low levels of lymphocytes, phosphorous and potassium in the blood.

FDA News Release, 10 December 2012

FLEETING QOL WITH PROTONS

(Continued from page 4)

these changes were only clinically meaningful in the IMRT group. At 12 months, there was also a clinically meaningful decline in urinary QoL in the PBT group. Again, the adverse event took longer to develop in the PBT group. At 2 years, the QoL scores had returned to near-baseline levels in all 3 groups, leaving a minimal – and not clinically meaningful – loss of function.

The 3 modalities have "distinct patterns of toxicity," Dr. Gray noted about this mishmash of data.

These are "exactly the kind of data we need," said press conference moderator Colleen Lawton, MD, from the Medical College of Wisconsin in Milwaukee, about the comparison of the radiation methods. "We certainly know [that PBT is] more costly," she noted.

"Our study provides a unique addition to existing research in this field and suggests that patients undergoing proton-beam therapy for prostate cancer may experience fewer immediate side effects," said Dr. Gray.

Medscape Medical News, 9 November 2012

THE BOTTOM LINE

(Continued from page 5)

effects even though no studies support that claim. So far there is limited information about cancer control and no ten-year survival data. Now, Gray and co-workers report quality of life results for an uncontrolled comparison of PBT, 3D-CRT and IMRT. Results showed that shortly after treatment was completed, PBT resulted in fewer side effects for bowel and urinary function. Unfortunately, at 2 years those differences were no longer present. In other words, PBT offered no real long-term advantage over the other methods, which is what really matters most. One should not over-interpret these results because there may be many differences between the men in each group. We do know that the PBT group was younger, which could partially account for the better short-term results. Hopefully, the planned randomized study will provide more reliable results.

The Bottom Line: For now, benefits of PBT are not supported by good clinical data. For that reason, men considering PBT should be made aware that there is no proven benefit vs. less expensive and more convenient forms of RT.

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