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Us TOO® PROSTATE CANCER EDUCATION & SUPPORT

HOTSHEET

OCTOBER 2013

INSURERS NIX PAYMENT FOR PROSTATE CANCER PROTON THERAPY

Proton-beam radiotherapy (PBRT), which is used primarily in the US, is a controversial alternative to conventional RT for cancer patients. Proponents argue that it is safer and causes fewer complications and less damage to healthy tissue, but opponents say that, in most cases, the supporting evidence just isn't there, especially considering the exorbitant cost.

The controversy has now reached another level. According to a report in the *Wall Street Journal*, insurers are now balking at the cost. Two major insurance companies, Blue Shield of California and Aetna, have announced that they no will longer pick up the tab for PBRT to treat early-stage prostate cancer. A third, Cigna, has joined the fray, saying it will be reviewing its policy later this year.

Blue Shield of California notified 300 radiation oncology and urology practices in the state that, as of the end of October, it will no longer cover PBRT for prostate cancer. Ironically, this decision comes just as Scripps Health in San Diego is preparing to open its new PBRT center, which will be the second in California and the twelfth in the country.

These are not the first insurers to discontinue coverage. Three years ago,

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CHEMOPREVENTION FOR PROSTATE CANCER: NEW DATA

Long-term data confirm the finding that finasteride reduces the risk for prostate cancer by about a third, but they also show no effect on overall survival (OS) or on survival after a diagnosis of prostate cancer (CSS). The new data, from an 18-year follow-up of men taking part in the Prostate Cancer Prevention Trial (PCPT), were published in the August 15 issue of the *New England Journal of Medicine*.

The PCTP was a 7-year study conducted in 18,880 healthy men (median age, 63.2 years) who were randomly assigned to receive either finasteride or placebo. Prostate cancer was diagnosed in 10.5% of the men in the finasteride group (989 of 9423 men) and in 14.9% of the men in the placebo group (P <0.001), a reduction in risk of 30%. However, there was also a significant increase in the percentage of tumors that were high grade among the men who took finasteride (3.5% vs 3% in the placebo group, P=0.05).

The main explanation for this finding of an increase in high-grade prostate cancer has been detection bias, in which the drug's effect of shrinking the prostate gland makes detection of high-grade cancer more likely. However, there was a lingering concern that these high-grade cancers detected in men receiving finasteride would be clinically more

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LOW-GRADE PROSTATE CANCERS MAY NOT BECOME AGGRESSIVE WITH TIME – ADDS SUPPORT FOR 'WATCH AND WAIT' APPROACH

Prostate cancer aggressiveness may be established when the tumor is formed and not alter with time, according to a study published online in *Cancer Research.* Investigators found that after the introduction of PSA screening, the proportion of men diagnosed with advanced -stage cancers dropped by more than six -fold in 22 years, but the proportion diagnosed with high Gleason grade cancers did not change substantially.

Cancer stage refers to the extent or spread of disease, and Gleason grade for prostate cancer refers to the aggressiveness of the disease.

Lead author Kathryn Penney, ScD and colleagues used data from 420 men recruited to the Physicians' Health Study and 787 men recruited to the ongoing Health Professionals Follow-up Study. All men were diagnosed with prostate cancer between 1982 and 2004, and treated with surgery. Researchers reanalyzed prostate tissue collected from these patients to assess Gleason grade.

They divided the data into 4 time periods based on when the men received a diagnosis and treatment: 1982-1993, 1993-1996, 1996-2000, and 2000-2004,

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TESTOSTERONE THERAPY DOES NOT RAISE PROSTATE CANCER RECURRENCE RISK

Testosterone replacement therapy (TRT) does not appear to increase the risk of prostate cancer (PCa) recurrence in men following radical prostatectomy (RP), researchers concluded in a paper reported in the *Journal of Urology* (Vol. 190, pp. 639-644, 2013).

Alexander W. Pastuszak, MD, PhD, of the Baylor College of Medicine in Houston, and colleagues reviewed data from 103 hypogonadal PCa patients treated with testosterone after RP (treatment group) and 49 PCa patients who underwent RP but were not hypogonadal (reference group). After a median follow-up of 27.5 months, researchers observed a significant increase in testosterone level in the treatment group. The treatment group also experienced a significant rise in PSA level, whereas the reference group did not. Overall, biochemical recurrence (BCR) occurred at a lower rate in the treatment group: four patients (3.8%) versus eight patients (16%). All recurrences in both groups were in patients with high-risk PCa.

Overall, 15% of the high-risk patients in the treatment group had BCR, which is lower than the 18% to 32% recurrence rate found in previous studies for patients not receiving TRT after radical prostatectomy during a comparable follow-up period.

To better understand whether the observed increase in PSA reflected PCa growth, the investigators calculated the PSA velocity (PSAV) for each group. The median PSAV for all patients in the treatment and reference groups was 0.002 and 0.0002 ng/mL per year, respectively, a nonsignificant difference between the groups.

Furthermore, the researchers found no significant difference in PSAV between the high-risk and non-high-risk subgroups in the treatment and reference groups, indicating that neither group had PSA increases at a rate suggestive of BCR, according to the researchers.

Renal & Urology News, 23 July 2013

EFFECT OF REPEATED PROSTATE BIOPSIES ON ERECTILE FUNCTION IN MEN UNDER ACTIVE SURVEILLANCE FOR PROSTATE CANCER

Braun K, Ahallal Y, Sjoberg DD, et al

J Urol, 22 August 2013; Epub

Purpose: Active surveillance (AS) is becoming an increasingly common management strategy for low-grade prostate cancer and involves repeated prostate biopsies over time. It has been hypothesized that serial biopsies can lead to reduced erectile function (EF) in patients on AS. We explored this hypothesis in a longitudinally followed cohort.

Materials and Methods: We identified 342 men on AS whose first biopsy occurred between 2000 and 2009. We investigated EF using patient-reported outcomes, namely the six EF questions from the International Index of Erectile Function (IIEF-6). We estimated the change in EF over time using locally-weighted scatterplot smoothing.

Results: The median age in this cohort was 64 (IQR 58-68) years. Median follow-up on AS was 3.5 years (IQR 2.3-5.0), and the median number of biopsies was 5 (IQR 3-6). Over the first 4 years on AS, EF declined 1.0 points/year (95% confidence interval [CI], 0.2, 1.7) on the IIEF-6 (scale 1-30). When stratified by comorbidities or number of biopsies, we see an almost identical drop in EF over time. The use of Phosphodiesterase-5 inhibitors increased from 5% to 27% from baseline to year 5 on AS.

Conclusion: In this longitudinally followed AS cohort we observed a small decline of EF and an increased use of phosphodiesterase-5 inhibitors over time. While we cannot separate out the effect of multiple biopsies from that of the natural aging process on EF in this observational study, our data suggests AS-related biopsies do not have a large impact on EF

MORTALITY AFTER PROSTATE CANCER TREATMENT WITH RADICAL PROSTATECTOMY, EXTERNAL-BEAM RADIATION THERAPY, OR BRACHYTHERAPY IN MEN WITHOUT COMORBIDITY

Nepple K, Stephenson A, Kallogjeri D, et al

Eur Urol 64: 372-378, 2013

Background: Medical comorbidity is a confounding factor in prostate cancer (PCa) treatment selection and mortality. Large-scale comparative evaluation of PCa mortality (PCM) and overall mortality (OM) restricted to men without comorbidity at the time of treatment has not been performed.

Objective: To evaluate PCM and OM in men with no recorded comorbidity treated with radical prostatectomy (RP), external-beam radiation therapy (EBRT), or brachytherapy (BT).

Design, setting, and participants: Data from 10,361 men with localized PCa treated from 1995 to 2007 at two academic centers in the United States were prospectively obtained at diagnosis and retrospectively reviewed. We identified 6692 men with no recorded comorbidity on a validated comorbidity index. Median follow-up after treatment was 7.2 yr.

Intervention: Treatment with RP in 4459 men, EBRT in 1261 men, or BT in 972 men.

Outcome measurements and statistical analysis: Univariate and multivariate Cox proportional hazards regression analysis, including propensity score adjustment, compared PCM and OM for EBRT and BT relative to RP as reference treatment category. PCM was also evaluated by competing risks analysis.

Results and limitations: Using Cox analysis, EBRT was associated with an increase in PCM compared with RP (hazard ratio [HR]: 1.66; 95% confidence interval [CI], 1.05-2.63), while there was no statistically significant increase with BT (HR: 1.83; 95% CI, 0.88-3.82). Using competing risks analysis, the benefit of RP remained but was no longer statistically significant for EBRT (HR: 1.55; 95% CI, 0.92-2.60) or BT (HR: 1.66; 95% CI, 0.79-3.46). In comparison with RP, both EBRT (HR:

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LOW-GRADE CANCERS

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to represent the pre-PSA and PSA eras. They found that the proportion of men who had PSA screening increased from 42% in 1994 to 81% in 2000. In addition, the proportion of late-stage cancers decreased from 19.9% in the 1982-1993 group to just 3% in the 2000-2004 group – an 85% decline. However, there was only a moderate decrease in high Gleason grade cancers, from 25.3% in the 1982-1993 group to 17.6% in the 2000-2004 group, reflecting a 30% drop.

With further analyses, the researchers found that the moderate drop in high Gleason grade cancers was not because progression to more aggressive disease was prevented through screening, but because of an increased diagnosis of low-grade disease that would not have been detected without PSA screening.

"Over time, because of PSA screening, men have been more likely to be diagnosed with prostate cancer at an earlier stage, before the disease has had an opportunity to grow and spread. If Gleason grade also progressed over time, we would expect a similar decrease in high Gleason grade disease over time," said Kathryn Penney, Sc.D., instructor in medicine at the Harvard Medical School and associate epidemiologist at the Channing Division of Network Medicine at Brigham and Women's Hospital in Boston, Mass. "We were surprised by just how constant the incidence of high-grade disease has been over time."

Results of this study suggest that low-grade prostate cancers do not progress to higher grade over time. This adds more evidence to the argument that men diagnosed with low-grade prostate cancers can opt for an active surveillance, or "watch and wait" approach instead of getting treated right away.

"Radical prostatectomy or radiation therapy, the usual treatments for prostate cancer, can have negative side effects such as impotence and incontinence; choosing active surveillance could prevent this decline in quality of life," said Penney. "Men with low-grade disease at diagnosis should seriously consider talking with their doctors about active surveillance."

Science Daily, 14 August 2013

AMERICAN CANCER SOCIETY DISCONTINUES MAN TO MAN PROGRAM

As a follow-up to the initial rumors about the demise of the American Cancer Society (ACS) Man to Man (M2M) support groups, Us TOO initiated a discussion with ACS to discuss how Us TOO can be of assistance to prostate cancer patients and caregivers who previously participated in M2M support groups.

Us TOO is here to help in the transition and Chapter Services Manager Terri Gibbons Likowski has already received calls from about two dozen former members of M2M prostate cancer support groups. Subsequent to our conversation with ACS, they provided us with the following statement about their decision and where they are headed.

The ACS has been forced to make some difficult decisions to better enable the organization to finish the fight against cancer. Achieving that vision will require the Society to narrow its focus and put all its energy and resources into strategies that help the most people, end the most suffering and save the most lives. Among the programs the Society will no longer be offering is the ACS' Man To Man® Prostate Cancer Education and Support Program. While ACS M2M offered a wonderful service, today's cancer patients have many options for ongoing patient support groups, including more programs offered by health care facilities and online. As a result, fewer prostate cancer survivors are utilizing ACS M2M as they have identified alternative programs.

The ACS will continue to support all cancer patients, including those battling prostate cancer. Prostate cancer patients can always find information and resources at cancer.org/prostatecancer or by calling the ACS 24 hours a day, seven days a week at 1-800-227-2345. The Society's toll free information line can help patients find support and resources including Us Too International chapters in their community. Additional links to online and community patient education and support can be found at cancer.org/aboutus/howwehelpyou/contactus/index

The Society will continue to invest in research to find the causes of and cures for prostate cancer, and advocate for

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2013 SEA BLUE PROSTATE CANCER WALK/RUN

The rain didn't dampen the spirits of participants and supporters who attended the 2013 SEA Blue Prostate Cancer Walk/Run at Chicago's Lincoln Park on Sunday, September 15! Thank you and congratulations to all participants who braved the weather to ensure that the event was a success. And thank you to all of our event sponsors, with a special shout out to our premier supporters -- Bayer Healthcare, Novartis, Abbvie, Dendreon and Medivation/Astellas!

VIPs in attendance included:

- Prostate cancer survivors who sported dark blue prostate cancer warrior shirts
- Kevin Coster wearing number 888 from Oak Forest, IL -- the first prostate cancer survivor to cross the finish line of the 5K race with a time of 25:38.7
- Hundreds of members of the 83 SEA Blue teams that each carried a team flag in the Celebration Walk
- Steve Sanders, our returning honorary event emcee, news anchor at WGN-TV Channel 9, and prostate cancer survivor
- Amy Gregorio, wearing the crown as Mrs. International and sharing her experience of being a SEA Blue walker for the past few years in memory and support of family members impacted by prostate cancer
- Michele Smith, Chicago Lincoln Park alderman of the 43rd Ward, presenting a resolution proclaiming September as Prostate Cancer Awareness Month in Chicago

INSURERS NIX PAYMENT

(Continued from page 1)

Regence, a BlueCross Blue Shield insurer that operates in 4 states, stopped its coverage for this indication, and Highmark Inc., Pittsburgh, and Blue Cross and Blue Shield of Kansas City do not cover it. Although many experts agree that some patients are good candidates for PBRT – most notably children with central nervous system tumors – its use in prostate cancer is highly controversial.

The major issue with PBRT is the cost of the treatment as well as the treatment facility. PBRT has a much higher price tag. Some data show that for prostate cancer, the median Medicare reimbursement for PBRT is $32,428 and for intensity-modulated RT (IMRT) is $18,575.

The cost to equip and construct a suitable PBRT center can range from $25 to $150 million. The acquisition cost for IMRT systems is far less pricey, ranging from $1.8 to $5.4 million, according to a 2009 report by the Institute for Clinical and Economic Review on management options for low-risk prostate cancer.

"I think you've been spending money on something that, at the moment, doesn't deliver. It may deliver in the future, but that will probably be after my retirement," Frank H. Saran, MD, from the Royal Marsden NHS Foundation Trust in the United Kingdom, told the mainly American audience at the 2013 AUA meeting. "Proton radiotherapy sells hope, but there is no clear measurable benefit that we can actually translate and explain to a patient" he added.

Even though PBRT is supposed to focus the beams more tightly and thereby reduce complication rates, there is no real evidence for this, explained Gerald Chodak, MD, director of the Midwest Prostate and Urology Health Center in Michiana Shores, Indiana, in an earlier *Medscape* videoblog. And, although some centers have been using this technology for a substantial period of time, "we have yet to see a single report talking about long-term mortality," Dr. Chodak added.

But not all insurers are throwing in the

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

"Is the dietary supplement resveratrol a waste of money? Lets just say I would rather have you use your money to contribute to the Moyad Beer Fund right now!"

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: New research suggests that if you are a rat or test tube this anti-aging supplement sold in many medical offices and on-line might help, but in humans the results have not been impressive thus far. I would not spend your money on this dietary supplement and it is not invited at the Moyad table until it proves it can really do something heart healthy, or it has real consistent anti-cancer activity in humans. The claims on this supplement have been incredible! Anti-aging, extends telomeres, you can live longer, beat cancer, and even get the cable company to answer your phone call and they will send a technician out the same day (okay, I embellished that last one for fun). However, I have sat on the sidelines for the past 5 years watching the public purchase resveratrol and have witnessed some doctors or medical offices selling it and espousing benefits of this product.

The problem is that although this product looked good in some animal studies and made the cover of some magazines there were not enough human studies conducted for me to jump up and down with excitement. Over the past year the supplement has failed to show any heart healthy benefits (lower cholesterol, blood pressure, reduce weight gain….) in a variety of human studies.[1,2] And, when used in some cancer patients it failed to show activity[3] and in another recent study it appeared to reduce the benefits of exercise.[4] If that isn't enough for you another recent laboratory study suggested it does not have anti-prostate cancer effects and may in fact encourage tumor growth[5] (keep in mind this was a laboratory study). In reality, I don't think resveratrol helps or harms cancer cells and I hope I am wrong and it is found to do something good in the near future. In the meantime, in order to be invited to the Moyad dietary supplement table for dinner you have to prove your supplement is heart healthy and you have to have some consistent evidence that you work in humans and not just in test tubes and in rats. So, in the meantime I would save your money and donate it either to prostate cancer research or the Moyad beer fund (funding and supplies are running unusually low this year).

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LAPAROSCOPIC AND ROBOTIC RADICAL PROSTATECTOMY OUTCOMES IN OBESE AND EXTREMELY OBESE MEN

Sundi D, Reese AC, Mettee LZ, Trock, BJ, Pavlovich CP

Urology, 15 July 2013; Epub ahead of print

Objective: To evaluate the operative and pathologic outcomes of laparoscopic radical prostatectomy and robot-assisted radical prostatectomy in men with progressive changes in body mass index (BMI) category.

Materials and methods: A single-surgeon series of 1,023 laparoscopic radical prostatectomy and robot-assisted radical prostatectomy (mostly extraperitoneal) patients was considered. Of these patients, 987 were evaluable. Results were stratified by the World Health Organization BMI category. Multivariate linear and logistic regression analysis was used to model the operating time, length of stay, positive surgical margins, and non-curable cancer.

Results: Of the 987 patients, 563 (57%) were overweight and 193 (19.6%) were obese. Of the 193 obese patients, 152 (15.4%) had a BMI of 30 to <35 kg/m^2 (class I obesity), 28 (2.8%) a BMI of 35 to <40 kg/m^2 (class II), and 13 (1.3%) a BMI of ≥40 kg/m^2 (class III). No differences were found in the estimated blood loss, complications, PSM, pathologic stage, or biochemical recurrence across the BMI categories (6-month median follow-up). However, pelvic lymph node dissection was more commonly omitted and the nerve-sparing score was inferior in the obese men. On multivariate analysis, a higher BMI was a significant predictor of a longer operating time.

Conclusion: Obese men can safely undergo laparoscopic radical prostatectomy or robot-assisted radical prostatectomy, although the ability to perform excellent nerve sparing appears to decrease with increasing obesity. Nevertheless, obese men can expect perioperative and early oncologic outcomes comparable to those of normal weight men without an increased risk of perioperative complications.

LONG-TERM FOLLOWUP DATA FROM THE PCPT *(Continued from page 1)*

aggressive and thus more lethal, the authors comment.

The new analysis, with follow-up data of up to 18 years, was headed by Ian Thompson Jr, MD, director of the Cancer Therapy and Research Center at the University of Texas Health Science Center at San Antonio, and was done specifically to look at whether there was an increased risk for death with finasteride.

The new analysis shows no increase in mortality. The 15-year survival rate was 78% for finasteride and 78.2% for placebo. Additionally, the authors report 10 -year survival data for the 2 different grades of cancer. Men who were diagnosed with low-grade prostate cancer had 10-year survival rates of 83% on finasteride and 80.9% on placebo, whereas men diagnosed with high-grade prostate cancer had 10-year survival rates of 73% on finasteride and 73.6% on placebo.

A major stumbling block to the use of finasteride (and also the similar drug dutasteride) in healthy men for preventing prostate cancer was a finding that emerged from the prevention clinical trials. Although both drugs significantly reduced the risk of being diagnosed with prostate cancer, paradoxically, they also increased the risk of being diagnosed with a high-grade prostate cancer (Gleason score 7-10). It was this finding that scuttled the chances of these drugs being used for chemoprevention. A US Food and Drug Administration (FDA) advisory committee meeting recommended against approval of this indication (both drugs are already marketed for benign prostatic hyperplasia and male-pattern baldness). The FDA also mandated that the finding of an increased risk of being diagnosed with high-risk prostate cancer was highlighted in a black box warning in the product labeling.

The new data should reopen the debate about using finasteride for the prevention of prostate cancer, says Eric Klein, MD, from the Cleveland Clinic, in Ohio, who was not involved in the study. "I think this was an over-reaction [by FDA]," Dr. Klein said. He said the black box warning was sensationalist… suggesting that it put men's lives at risk," whereas there was no evidence at the time that men were harmed, he said.

The new long-term data from the PCTP trial shows that there was no difference in overall survival between the 2 arms of the trial. "This is indisputable evidence that it's safe to take these drugs and they don't make people die," Dr. Klein said in an interview.

"So what's the point of going on that therapy?" asks another prostate cancer expert. Discussing the new survival data from PCTP in a recent Medscape Medical News videoblog, Gerald Chodak, MD, director at the Midwest Prostate and Urology Health Center, Michiana Shores, IN, pointed out that men who took finasteride were less likely to be diagnosed with prostate cancer, but they lived just as long as men who did not take the drug. "The bottom line here is that with the more mature data, it is difficult to make a strong recommendation for the use of finasteride to prevent prostate cancer," he said.

Dr. Klein disagrees; he hopes that the new survival data will allay previous concerns and will reignite enthusiasm for chemoprevention for prostate cancer. "This is the only intervention we have that has shown in a high-quality clinical trial to reduce a man's likelihood of getting prostate cancer," he said. He suggested that it is an intervention that would be appropriate for men with a high risk for prostate cancer, for example, because of family history or ethnicity (African American race).

Dr. Thompson suggests that chemoprevention could save thousands of men from undergoing unnecessary treatment.

Medscape Medical News, 14 August 2013

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

Gerald Chodak, MD 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 Considerable controversy is now occurring over the use of Proton Beam radiation for men with localized prostate cancer. For many years, Loma Linda Hospital in California, the first center to offer this treatment, has been promoting Proton therapy with the following information taken directly from their website:

- *The treatment is capable of delivering precise, high doses of radiation to accurately target cancer cells without causing damage to healthy tissue surrounding the prostate.*
- *It is more accurate than other kinds of radiation*
- *It poses minimal risk of impotency*
- *The treatment has lower risk of side effects compared with conventional treatment*

These claims have been made WITHOUT ANY valid scientific evidence to support them. In fact, there has never been a study to show that it is as effective as or safer than other forms of therapy for localized disease. And yet, insurers for years have been paying the significantly higher bill. Now we are hearing that some companies are withdrawing their coverage. No doubt, many men who have had this treatment and those desiring it will be upset. But shouldn't men be more upset about being charged more for a treatment that has not been shown to be worth the higher cost? It is no surprise that our medical costs are skyrocketing when we pay for treatments that are more expensive without clearly delivering better results. To paraphrase a line from the movie "Jerry Macquire", SHOW ME THE DATA!

The Bottom Line: Scientific studies rather than theory or hype should be the basis for deciding if a treatment for prostate cancer is worth the expense.

a2p1c2 The updated results from the prostate cancer prevention trial are likely to heat up the debate about using a 5-alpha reductase inhibitor to prevent prostate cancer. After two additional years of follow-up, Thompson and coworkers found no difference in survival for men taking finasteride compared to placebo despite the higher incidence of high-grade tumors in those taking the drug. Some experts are making the case that since active surveillance (AS) is difficult to accept for many men, avoiding a diagnosis of low-grade disease by taking this drug will spare them the anxiety of conservative therapy or the side effects of a treatment they did not need.

This argument has several problems. First, in this study, 14.9% of men on placebo were diagnosed with cancer compared to about 10.5% of those on finasteride. However, in men subjected to normal screening, the overall cancer detection rate is only about 7.5%. This means that the entire study found nearly twice as many cancers as would be found from normal screening. While finasteride reduced this rate, even in that group, more cancers were found than would be expected in a screened population. So, the drug is mainly reducing the diagnosis of non-life threatening disease that never would have been detected anyway while having no impact on reducing the death rate.

Furthermore, based on two studies that compared watchful waiting to radical prostatectomy (RP), surgery offered no survival benefit to men over 65. The study by Thompson ideally would have looked at the survival in men with high-grade disease who were diagnosed under age 65 to show if the finasteride was causing any harm but there were not enough cases to allow for that analysis.

The Bottom Line: At this time, it is still hard to make a strong enough case for taking finasteride to justify its widespread use for preventing prostate cancer.

a3p1c3 Among the many questions surrounding prostate cancer screening is whether finding cancer earlier and treating it will enable men to avoid developing a more aggressive cancer if their cancer is not diagnosed until several years later. The study by Penney and coworkers attempts to provide an answer and their finding may partly explain why screening for this disease has not resulted in a much greater benefit than observed in randomized studies. Their results suggest that bad cancers are bad from the beginning, and the not-so-dangerous ones, those found so often with screening, do not appear to change over time to a more aggressive cancer. This is a VERY important observation because it means that more men with Gleason 3+3=6 might benefit initially from AS rather than aggressive treatment for their management.

In the largest ongoing study of conservative therapy, Klotz found that only about 25% of those switching to aggressive therapy did so because their tumor grade increased. Dr. Carter from John Hopkins has reported that the 15 year risk of dying from a low risk cancer with or without treatment is only about 3%. An argument can be made that they may have been higher grade from the start but those cancer cells were missed on the initial biopsy. Perhaps every man with Gleason 3+3=6 disease should have a repeat biopsy and then delay aggressive therapy unless higher-grade disease is detected. This study also suggests that many of the men who abandon AS for reasons other than a change in Gleason score may be doing so unnecessarily.

The Bottom Line: These data provide additional support for AS in men who truly have only Gleason 3+3 disease.

a4p2c2 Can impotent men treated for prostate cancer safely be given testosterone? Pastuszak and colleagues addressed this important question in a small cohort study. They compared two groups followed for a median of 28 months after RP and found that the odds of a biochemical recurrence were not higher in treated men compared to men not getting testosterone. Other small studies have had similar findings but caution is still needed because the study design used is not sufficient for proving it is absolutely safe. That would require prospective studies with much longer follow-up in which either metastases or

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THE BOTTOM LINE

(Continued from page 7)

survival was the real outcome measured.

The Bottom Line: Data is accumulating that men with prostate cancer suffering from impotence due to low testosterone may be able to safely take medication to improve their erectile dysfunction but better data still are needed to be sure.

a5p3c1 The study by Nepple and co-workers attempts to compare radical prostatectomy, external radiation and brachytherapy for men with localized disease by focusing on men without other co-morbidity. The reason for this analysis is that less healthy men often choose some form of radiation compared to RP, which is a major surgery, making a comparison of treatments more difficult. The authors found that overall mortality was greater with either form of radiation than with surgery. Unfortunately, the study design precludes any conclusions about the relative merits of the different treatments.

The Bottom Line: Retrospective studies cannot tell us which therapy is best for localized prostate cancer.

INSURERS NIX PAYMENT

(Continued from page 5)

towel. Notably, the federally funded Medicare program is continuing to pay for proton therapy for prostate cancer, and they have not announced any changes in that coverage. However, Medicare reduced the average payment for proton therapy from $1549 in 2012 to $682 in 2013. This means a 32% drop in revenue, from an average of $35,917 per patient to a projected average of $24,565 per patient.

WellPoint, the second-largest insurance company in the US, will also continue to cover the procedure, but is negotiating the cost down. Kristin Binns, a spokesperson for WellPoint quoted in the *Wall Street Journal* report, said that WellPoint considers proton therapy to be "medically necessary" in certain situations. Blue Shield, like WellPoint, believes PBRT has advantages for certain patients, and it will continue to cover it when clinical evidence supports its use, such as in children with certain tumors.

Medscape Medical News, 30 August 2013

MAN TO MAN PROGRAM

(Continued from page 3)

federal funding for cancer research and improved quality of life through its non-profit, nonpartisan advocacy affiliate the ACS Cancer Action Network.

Debbie Kirkland | Director,
Cancer Prevention and Early Detection
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Phone: 404.329.7624
cancer.org | 1.800.227.2345

RP, EBRT OR BT MOTALITY

(Continued from page 3)

1.71; 95% CI, 1.40-2.08) and BT (HR: 1.78; 95% CI, 1.37-2.31) were associated with increased OM.

Conclusions: In a large multicenter series of men without recorded comorbidity, both forms of radiation therapy were associated with an increase in OM compared with surgery, but there were no differences in PCM when evaluated by competing risks analysis. These findings may result from an imbalance of confounders or differences in mortality

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