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Us TOO® PROSTATE CANCER EDUCATION & SUPPORT

HOTSHEET

DECEMBER 2010

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DRUG EXTENDS SURVIVAL IN PROSTATE CANCER

Patients with metastatic, castration-resistant prostate cancer (CRPC) appeared to benefit from an experimental drug that counteracts the tumor's ability to create growth-sustaining hormones, researchers presenting at the European Society for Medical Oncology (ESMO) meeting. Treatment with abiraterone acetate led to a 35% reduction in the risk of death (HR=0.65; 95% CL: 0.54-0.77; P <0.0001), while those on the combination of abiraterone and steroids achieved a median 14.8 month survival, 36% longer than the 10.9 months for patients receiving steroids and placebo. In addition to meeting the primary endpoint of overall survival, the time to disease progression was 10.2 months among those on abiraterone and 6.6 months for the placebo patients (P <0.0001).

The randomized, double-blind, placebo-controlled phase III study included recruitment through 147 centers in 13 countries, and enrolled 1,195 men with advanced CRPC that was refractory taxane-containing chemotherapy. Lead investigator Johann de Bono, MD, PhD, of the Institute of Cancer Research at Royal Marsden Hospital in London, said 787 patients were randomized to receive abiraterone 1,000 mg once a day by mouth plus a steroid (prednisone or prednisolone 5 mg twice daily). The

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COST SHOULD ENTER EFFECTIVENESS EQUATION, RESEARCHERS SAY

Although the healthcare reform law forbids it, using cost factors in comparative effectiveness research could save billions of dollars and put Medicare on a more secure financial footing, researchers argued.

Writing in the online October issue of Health Affairs, authors Steven Pearson, MD, MPH, and Peter Bach, MD criticized the current payment model, in which Medicare covers any treatment that is deemed "reasonable and necessary," regardless of how it stacks up in cost or efficacy against other comparable treatments. Pearson is president of the Institute for Clinical and Economic Review at Massachusetts General Hospital's Institute for Technology Assessment. Bach is an attending physician at Memorial Sloan-Kettering Cancer Center in New York City and former adviser to the CMS Administrator.

"Medicare's processes for determining coverage and setting reimbursement rates are like computer programs that date all the way back to the 1960s," Pearson and Bach wrote. "They demonstrate the arcane complexity of decades of ad-hoc updates with no fundamental redesign."

The reimbursement-plus-profit model currently used by Medicare is often

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ATYPICAL PROSTATE BIOPSY SHOULD BE REPEATED

When needle biopsy shows atypical prostate glands suspicious but not diagnostic of carcinoma (ATYP), patients should have repeat biopsies within six months, according to a September 17th online paper in *The Journal of Urology*.

About 5% of prostate needle biopsies return a diagnosis of ATYP, and this diagnosis is associated with a roughly 40% risk of prostate cancer on the next biopsy, according to the article.

Lead author Dr. Ying-bei Chen and colleagues from Johns Hopkins Hospital, Baltimore, MD, studied 169 men with an initial ATYP diagnosis who had prostate cancer diagnosed on repeat biopsy. The median time between the ATYP biopsy and the repeat biopsy showing cancer was 6.1 months. Cancer was diagnosed in 92% of these cases (156/169) on the first repeat biopsy.

"This finding is consistent with the general recommendation of re-biopsy within three to six months after an ATYP diagnosis to detect cancer in a timely fashion," the authors note.

All of the men had radical prostatectomy (RP), and during a median follow-up of four years only four (2%) had biochemical progression. These four men each had at least one adverse feature present at RP.

Seminal vesicle involvement was uncommon (2/169 cases, 1.2%), and none of the men had metastases to the pelvic lymph nodes.

On multivariate analysis, an ATYP biopsy was a significant independent predictor of organ-confined disease at RP, but this factor lost significance when tumor volume on needle biopsy was included in the analysis. Maximum percentage of cancer independently predicted non-organ confined disease.

"As a significant minority of cases after an initial ATYP diagnosis has a higher Gleason score and extra-prostatic extension, our findings emphasize the importance of follow-up biopsy within three to six months of an ATYP diagnosis on needle biopsy," the authors conclude.

Reuters Health, 8 October 2010

CALYPSO MEDICAL RECEIVES FDA 510(K) CLEARANCE FOR DYNAMIC EDGE GATING TECHNOLOGY

Calypso Medical Technologies, Inc., a developer of real-time localization technology used for the precise tracking of tumors, announced it has received 510 (k) clearance from the US FDA to market the Calypso® System with Dynamic Edge™ Gating Technology.

The Calypso System, with its GPS for the Body® technology, utilizes miniature implanted Beacon® transponders to provide precise, continuous information on the location of the tumor during external beam radiation therapy (EBRT). The real-time position information provided by the Calypso System allows physicians to deliver maximum RT directly to the tumor while sparing the surrounding healthy tissues and organs from exposure.

The new gating technology allows therapists to set motion thresholds which automatically signal RT delivery to be stopped each time the targeted tissue moves outside the preset threshold. This technology may enable a further decrease in RT-associated side effects, such as bowel and bladder incontinence and sexual dysfunction.

"The automatic response of the Calypso System to organ motion results in benefits to both the patient and the department," said Lorraine Marshall Wright, chief marketing officer and vice president of Calypso Medical. "Holding the radiation beam when the target is outside of clinician-defined limits results in a safer, more uniform approach to radiation delivery, which may lead to a decrease in the side effects of prostate RT."

Side effects result when the tumor moves outside of the radiation field in response to normal physiologic processes such as digestion, coughing and breathing, as well as small movements by the patient, while RT is being delivered. As a result, healthy tissue receives the intended RT, and at the same time, the tumor fails to receive the fully prescribed RT dose thereby compromising effectiveness of the therapy. While some side effects may resolve over time,

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PSA TEST REDUCES RISK OF SPREAD IF PROSTATE CANCER STRIKES

Study found screening showed benefit, despite debate about its usefulness

Having a PSA test to screen for prostate cancer reduces the risk that if cancer develops it will spread to other parts of the body, new research indicates. The finding adds to the ongoing debate on whether PSA screenings actually improve survival rates or, by contrast, lead to unnecessary treatment.

"Our study shows that routine screening not only improves the patient's quality of life by stopping metastatic disease, but it also decreases the burden of care for this advanced disease that must be provided by the health-care system," study author Chandana Reddy, a senior biostatistician at the Cleveland Clinic in Ohio, said in a news release from the American Society for Radiation Oncology.

"This demonstrates that the PSA test is extremely valuable in catching the disease earlier and allowing men to live more productive lives after treatment," Reddy said. Reddy and his colleagues reported their findings last month at the American Society for Radiation Oncology annual meeting, in San Diego.

PSA tests measure levels of the prostate-specific antigen protein produced by the prostate; high levels are thought to be an indication of prostate cancer. However, critics have cautioned that some patients diagnosed with early prostate cancer are subjected to aggressive treatments – and their unwelcome side effects, such as incontinence and erectile dysfunction –

(Continued on page 5)

DON'T FORGET!

Share your inspirational story by Jan 21 on the **My Prostate Cancer Roadmap** website, and you will be entered to win a copy of the *Blue Ribbon Recipes for Prostate Health* cookbook.

My Prostate Cancer Roadmap (www.myprostatecancerroadmap.com) is an educational program that provides resources and information specific to advanced prostate cancer patients and those who love them.

THE DEPARTMENT OF VETERANS AFFAIRS BEGINS PAYING BENEFITS FOR NEW AGENT ORANGE CLAIMS

VA Encourages Affected Vietnam Veterans to File Claims

The VA has begun distributing disability benefits to Vietnam Veterans who qualify for compensation under recently liberalized rules for Agent Orange exposure.

"These initiatives show VA's ongoing resolve to modernize its processes for handling claims through automation and improvements in doing business, providing Veterans with faster and more accurate decisions on their applications for benefits"

"The joint efforts of Congress and VA demonstrate a commitment to provide Vietnam Veterans with treatment and compensation for the long-term health effects of herbicide exposure," said Secretary of Veterans Affairs Eric K. Shinseki. Up to 200,000 Vietnam Veterans are potentially eligible to receive VA disability compensation for medical conditions recently associated with Agent Orange. The expansion of coverage involves B-cell (or hairy-cell) leukemia, Parkinson's disease and ischemic heart disease.

Shinseki said VA has launched a variety of initiatives – both technological and involving better business practices – to tackle an anticipated upsurge in Agent Orange-related claims.

"These initiatives show VA's ongoing resolve to modernize its processes for handling claims through automation and improvements in doing business, providing Veterans with faster and more accurate decisions on their applications for benefits," Shinseki said.

Providing initial payments – or increases to existing payments – to the 200,000 Veterans who now qualify for disability compensation for these three conditions is expected to take several months, but VA officials encourage all Vietnam Veterans who were exposed to Agent Orange and suffer from one of the three diseases to make sure their applications have been submitted.

VA has offered Veterans exposed to Agent Orange special access to health care since 1978, and priority medical care since 1981. VA has been providing disability compensation to Veterans with medical problems related to Agent Orange since 1985.

In practical terms, Veterans who served in Vietnam during the war and who have a "presumed" illness do not have to prove an association between their illnesses and their military service. This "presumption" simplifies and speeds up the application process for benefits.

The three new illnesses – B-cell (or hairy-cell) leukemia, Parkinson's disease and ischemic heart disease – are added to the list of presumed illnesses previously recognized by VA.

Other recognized illnesses under VA's Agent Orange "presumption" rule are:

- **Prostate Cancer**
- Acute and Subacute Transient Peripheral Neuropathy
- Chloracne
- Chronic Lymphocytic Leukemia
- Diabetes Mellitus (Type 2)
- Hodgkin's Disease
- Multiple Myeloma
- Non-Hodgkin's Lymphoma
- Porphyria Cutanea Tarda
- Respiratory Cancers
- Soft Tissue Sarcoma (other than Osteosarcoma, Chondrosarcoma, Kaposi's sarcoma, or Mesothelioma)
- Amyloidosis

Veterans interested in applying for disability compensation under one of the three new Agent Orange presumptives should go to www.fasttrack.va.gov or call 1-800-827-1000.

BUSINESS WIRE, 1 November 2010

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COST EFFECTIVENESS EQUATION *(Continued from page 1)*

criticized by policy experts who argue that the doctors who stand to gain the most under Medicare are the ones who provide the most expensive procedures.

Under the model proposed by Pearson and Bach, Medicare would still use its "reasonable and necessary" standard, but would also use comparative effectiveness research to assign each treatment to one of three categories -- "evidence of superior comparative clinical effectiveness; evidence of comparable comparative clinical effectiveness; or insufficient evidence to determine comparative clinical effectiveness."

Payment for treatments in the "superior" bucket would be set according to current Medicare formulas. For treatments in the "comparable" bucket, Medicare would examine the rates paid for those comparable alternatives and pay at the lowest price.

If a new service or treatment lacked evidence of comparative effectiveness, Medicare would set up a temporary payment schedule while comparative research is conducted. If, over time, evidence fails to show a new modality is superior to an existing one, Medicare would likely drop reimbursement rates for the service.

"The time is ripe for Medicare to use comparative effectiveness research to reach a new paradigm, which would include equal payments for services that provide equivalent results," wrote. The authors list a number of barriers to using costs to set payment policies, and partisan politics is near the top of the list.

Pearon S, Bach P "How Medicare could use comparative effectiveness research in deciding on new coverage and reimbursement" Health Aff 2010; 29; Epub ahead of print

MedPage Today, 5 October 2010

FDA ADDS NEW WARNINGS ON PROSTATE CANCER DRUGS

The FDA has called for new warnings on the labels of widely used hormonal prostate cancer drugs because of evidence of a slight increased risk of heart disease and diabetes in the men who take them. They first announced in May that it was reviewing the prostate cancer drugs known as gonadotropin-releasing hormone (GnRH) agonists, citing this possible increased risk. These medications indirectly suppress production of testosterone, a hormone that can spur prostate cancer growth. Drugs include Eligard®, Lupron®, Synarel®, Trelstar®, Vantas®, Viadur®, Zoladex® and several generic products.

Hormone-based therapy is not a cure for prostate cancer, because tumors can eventually become resistant to therapy. However, therapy can extend survival.

So, should the new label warnings deter men from enrolling on hormone-based treatment? Experts say the cardiovascular risk is something to consider, but the therapy does have real benefits. "Clearly these drugs are needed for the treatment of prostate cancer," Dr. Mark Soloway, chair of urology at the University of Miami Miller School of Medicine, stressed in May. "Lowering the male hormone is by far the most effective treatment," he said, but at the same time "there should be more judgment in prescribing GnRH agonists."

Soloway believes that any increased risk for heart disease and diabetes would be due to a lowering of testosterone. "At this point, it makes sense to use hormone therapy (HT) when necessary, but not for everyone that has prostate cancer," he said. Another expert, Dr. Nelson Neal Stone, a clinical professor of urology and radiation oncology at Mount Sinai School of Medicine in New York City, agreed that, "there is evidence that low testosterone can induce metabolic syndrome," which in turn raises men's risk for diabetes and heart attack.

Speaking after the FDA's announcement earlier this spring, Stone said studies have shown that men with advanced prostate cancer who take HT face a two-fold increased risk of developing metabolic syndrome, a cluster of symptoms tied to the development of heart disease. "When I speak to patients who have to go on these agents, I counsel them about the risks of increased weight gain and I tell them they need to monitor their carbohydrate intake and increase their amount of exercise, and they can decrease the risk of developing metabolic syndrome," he said.

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ABIRATERONE

(Continued from page 1)

remaining 398 patients were assigned to placebo and the same steroid dose.

About 38% of the abiraterone patients experienced a treatment response that favorably affects PSA levels compared with 10% of the patients on placebo plus steroids. Adverse drug effects included fluid retention and hypokalemia.

"The patients in this study represent the sickest of the sick patients – the CRPC [patients]," said Fortunato Ciardiello, MD, professor of Second University in Naples, Italy, who moderated a press briefing where trial results were presented. "What we see here is that one of three of these patients who have no treatment options can be helped by this drug," he said.

"This has been a remarkable year for prostate cancer patients," de Bono said, noting the approval in the US of cabazitaxel (Jevtana®) and sipuleucel-T (Provenge®). "If abiraterone is approved I can see it and the other new drugs being used sequentially to try and make advanced prostate cancer more of a chronic disease."

In a statement, drugmaker Janssen Pharmaceutical said that it plans to file marketing applications for abiraterone in the US and Europe by the end of the year.

De Bono has received honoraria and consulting fees from Merck, Pfizer, AstraZeneca, Johnson & Johnson, Medivation and Genentech. Other co-authors have disclosed financial relationships with other companies and several of them are employees of Ortho Biotech Oncology Research and Development.

MedPage Today, 11 October 2010

CMS petition deadline extended!
Continue collecting signatures! Go to the Us TOO website and click on this button to make your voice heard!

www.ustoo.org

THANK YOU!

PSA SCREENING

(Continued from page 3)

for a disease that can be slow-moving and not diminsh survival if left untreated among older patients who are likely to die of other, unrelated causes.

However, the researchers pointed out that prostate cancer is not curable when it is caught late and has spread (or metastasized) to other parts of the body. They suggested that assessing to what degree a PSA diagnosis might reduce the risk of metastasis could be the best way to determine the value of the test. To that end, Reddy and his team analyzed data on more than 1,700 prostate cancer patients who between 1986 and 1996 had been treated with either radiation therapy or surgery to take out their prostate gland and the surrounding tissue.

Noting that in the first half of the study period, PSA tests were not yet available, the authors compared the spread of the disease over the course of 10 years among those who had been diagnosed with a PSA test and those who had not.

Over the 10-year period, metastatic disease took hold among 13 percent of all the patients. However the researchers found that regardless of whether patients were categorized as having high-, medium-, or low-risk disease, those who had been diagnosed as a result of a PSA screening were significantly less likely than those who weren't to have seen their cancer spread during the decade following their original treatment.

Dr. Lionel L. Banez, an assistant professor of urologic surgery at Duke University Medical Center, said that the current study leans toward the relative benefits of prostate cancer screening.

"There is compelling evidence that PSA testing saves lives, especially when performed in an optimized strategy," he said. "For example, getting an initial PSA measurement at age 40 to properly assess baseline prostate cancer risk has been proven to be quite beneficial.

Nevertheless, Banez acknowledged that doctors need to interpret test results judiciously. "The challenge," he stressed, "lies in ensuring that the risks for overdiagnosis and over-treatment, as well as potential decline in quality of life, are minimized or avoided."

HealthDay News, 25 October 2010

FDA ISSUES NEW WARNING

(Continued from page 4)

Prostate cancer patients typically have some treatment choices. After initial treatment for prostate cancer, whether by surgery or radiation, doctors usually track blood levels of disease-linked PSA over time. Based on that, one can initiate HT, Soloway said, or simply wait and monitor the patient.

"There is further evidence that you should not begin HT until such time when there is more compelling reason than just a slight rise in PSA," Soloway said. "There are hundreds and hundreds of thousands of such patients." Soloway believes that many men across the US are unnecessarily taking HT for prostate tumors that have not yet spread. "I think HT can be delayed for months to years in some of these men," he said.

For men with more advanced metastatic prostate cancer, HT can be used for several months until the PSA goes down, at which point the therapy can be stopped, Soloway said. "If you stop it for the time it takes for the PSA to rise again, that could be many months to a couple or more years," he said.

Men taking HT need to understand that, as with any drug treatment, there are some risks, Soloway said. But heart disease is largely preventable, and he believes that GnRH agonists might boost heart risks because they cause men to pile on extra pounds. So, "you want to do what you can to decrease your chance of diabetes, cardiovascular disease. This has to do with diet, keeping your weight down," Soloway said.

For Stone, the toughest part is striking a balance between cancer risk and risks from the number one killer of men, heart disease. "It doesn't make much sense to try and treat their prostate cancer and prevent them from dying from prostate cancer if we are going to increase their risk of then dying from heart disease," he reasoned. Once patients understand that, Stone hopes they will be motivated to watch their diet and exercise.

In the meantime, men should not stop taking their HT, but do everything they can to reduce their risk of developing cardiovascular disease and diabetes with lifestyle changes, he said.

HealthDay News, 20 October 2010

ASPIRIN USE ASSOCIATED WITH LOWER RISK OF CANCER DEATH FOR MEN WITH PROSTATE CANCER

Men with prostate cancer who take anticoagulants like aspirin in addition to radiation therapy or surgery may be able to cut their risk of dying of the disease by more than half, according to a large study presented on November 3, 2010, at the 52nd Annual Meeting of the American Society for Radiation Oncology (ASTRO) in San Diego. The study involved more than 5,000 men with localized cancer whose disease had not spread beyond the prostate gland.

"Evidence has shown that anticoagulants may interfere with cancer growth and spread," Kevin Choe, M.D., Ph.D., lead author of the study and a radiation oncologist at University of Texas South-

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Editors' note: In the spirit of information sharing, we have invited certain physicians and others to provide comments and opinions for Us TOO's *HotSheet.* It is our desire to enrich the content of the *HotSheet* to empower the reader. The columns by Drs. Chodak, Moyad and Myers contain the opinions and thoughts of its author and is not necessarily those of Us TOO International.

ASK DOCTOR SNUFFY MYERS

"Which is better for prostate cancer patients: farm raised or wild salmon?"

For prostate cancer, we advocate consumption of fish, especially cold water fish, as they are a great source of omega three fatty acids. These omega three fats play an important role in slowing the spread of prostate cancer. They also counter the inflammatory and cancer stimulating actions of omega 6 fatty acids, which are often present in large amounts in the American diet. Generally speaking farm-raised and wild salmon are roughly equivalent in terms of omega three fats.

The larger problem with salmon is that this fish can easily become contaminated with polychlorinated biphenols (PCB) and dioxin. At high doses PCBs cause liver damage. At lower levels, they can cause skin and eye lesions. They can interfere with sex hormone action and have been reported to interfere with women's menstrual cycle.

They also can suppress the immune system. Exposure in childhood has been reported to result in poor cognitive development. In humans, PCB exposure has been linked to liver, bladder and bile tract cancers. They can act like estrogens and stimulate the development and growth of breast cancer, but the human link is less convincing. Prostate cancer does not appear to be associated with PCB exposure.

There are now multiple reports of PCB contamination in farm-raised salmon. Furthermore, I found one report that salmon farms were responsible for contaminating nearby wild fish populations. PCBs and other contaminants can be found in wild salmon as well as these chemicals are used in many industrial and farming applications.

When I survey the literature, salmon caught off the Pacific Northwest of the USA and Alaska have fared best in testing. Fortunately, much of the canned salmon available in grocery stores comes from these waters.

We recently reviewed the issue of smoked fish for our newsletter and found that smoking also coated fish with cancer causing chemicals. Hot smoke was worse than cold smoking. So, the worst possible outcome would be to have contaminated farm raised salmon hot smoked!

For all of these reasons, I limit myself to wild caught Alaskan salmon if I am going to have this fish. Of course, I eat far more sardines than salmon as they are more economical and commonly test out free of contamination.

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

"Happy Holidays! Also, the Moyad strike is over! Oh and by the way – what do mega-dose vitamins and bladder cancer have to do with prostate cancer?"

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

Bottom Line:

Mega-dose supplements added to conventional treatment for bladder cancer did not help, and this should be kept in mind the next time someone tries to convince you that more is better along with your prostate cancer treatment.

What is worse than the Michigan football team's record against Big Ten teams over the past 3 years…not much! If we lose to Ohio State again I am going to do something really insane like order a large fries at McDonalds instead of a small one! Anyway on to today's lesson.

Since 1994, there has been a suggestion that taking a mega-dose vitamins and minerals along with your conventional immune therapy for bladder cancer can reduce the risk of the disease coming back. However, this was a small study and a much larger study was needed to confirm these unique findings.

So, the large study happened and individuals either received a daily multivitamin pill or a mega-dose of supplements that included 36,000 IU of vitamin A, 100 mg of vitamin B6, 2000 mg of vitamin C, 1600 IU of vitamin D3, 1.6 mg of folate, 400 IU of vitamin E, and 30 mg of zinc! However, after 2 years the risk of cancer returning was actually non-significantly greater in the conventional treatment + mega-dose supplements compared to the conventional treatment + multivitamin group. In other words, more was not better along with one of the most popular treatments ever given for bladder cancer treatment.

This is simply the best holiday message I can send to you today. There are always those that will try to convince you that more is better with cancer treatment, but outside of prostate cancer the evidence is suggesting that this is not the case. Reduce cholesterol, weight, waist, blood pressure, blood sugar, heart rate…did ya ever notice that less is more, and more does not appear to be more! Happy Holidays and hope your egg nog is loaded with Viagra and beer (in moderation of course)!

Reference

Nepple KG, Lightfoot AJ, Rosevear HM, et al. *J Urol* 184:1915-9, 2010

DOCTOR CHODAK'S BOTTOM LINE

Abiraterone acetate significantly increased survival in men by 4 months without causing many severe side effects. Based on the results, the study has stopped and all men are being offered the drug while the company submits to the FDA for approval.

One important point not contained in the HotSheet article is that all men had to first receive docetaxel chemotherapy and then progress before being eligible for this treatment. That would probably mean that if approved, Medicare and other payers might not cover the cost if given to men who had not already received the chemotherapy. The company is very likely to do another study in men with less advanced disease but that will take a number of years to complete.

The Bottom Line: Abiraterone is likely to be another valuable treatment to help many men whose cancer is progressing despite chemotherapy.

An important article worth noting is deals with Atypia on a prostate biopsy. Several years before doctors started doing 12 core biopsies, a finding of high grade PIN was thought to warrant a repeat biopsy within a few weeks or months because of a suspected likelihood that cancer was also present. When a higher number of samples were taken, however, doctors realized that the risk was no higher than in men having a repeat biopsy without PIN.

Now a concern is being raised about a biopsy that shows atypical glands, also known as ASAP. This finding occurs in a small fraction of men but a repeat biopsy will find cancer in about 40% of them. The problem is that pathologists do not see enough abnormal cells to warrant a man getting treated and they would rather have the biopsy repeated than see someone treated unnecessarily.

The Bottom Line: Each person should ask to see a copy of his biopsy to make sure he is getting the right recommendation. A repeat biopsy is needed if atypia is found.

Yet another potential marker for prostate cancer seems to be on the horizon. British scientists found that MSMB is a protein that can be found in urine of men most at risk for prostate cancer. This is a potentially exciting finding but caution is needed before men start requesting this test be done. First, it is unclear how it would do in helping to find cancer in men with no symptoms and how accurate would be the results. Although urinary MSMB was a better predictor of cancer than urinary PSA, it was far inferior to serum PSA in finding cancer. For that reason, its potential usefulness would be unclear.

The Bottom Line: Although this may not be the test that improves the weaknesses of PSA, it is an interesting finding and further studies may find it could play a role in this disease.

The article about comparative effectiveness is a timely, and in my opinion, a most important issue that needs to be addressed. There are 14 treatment options for localized prostate cancer with a wide range of cost and NOT ONE study proving that one of them is better than another. The only valid comparison was done outside the US, which compared watchful waiting to radical prostatectomy. Patients need to be concerned about the possibility of receiving biased information when IMRT may net the doctor/institution more than $30,000 compared to only a small fraction of that amount for conservative therapy.

An excellent example is ProstRcision, which is very costly and contains misleading information about its effectiveness. The marketing is being driven in part by the large profit it generates rather than true advantages for men with the disease.

The Bottom Line: When buying a car, you pay more for a Mercedes than a Volkswagen because it offers several advantages. Why should you or the government pay a much higher price for one treatment than another that is less costly when there is no proof more expensive one is worth the money? Would men benefit by having a standard payment to doctors that takes out the financial incentive to perform certain treatments unless or until there is proof it delivers better results? Paying for effectiveness is in the best interest of patients and it may stimulate proper studies being done.

Here we go again! Two new uncontrolled studies trying to prove something is good for you. In the first one, the topic is aspirin use and other blood thinners, which suggested that aspirin reduced the death rate from this disease. The study used the CaPSURE database, a self selected group of men with localized disease. By now, most HotSheet readers are well acquainted with all the reasons why no conclusions can be made from these types of analyses.

The Bottom Line: The only way to find out if aspirin or similar agents are beneficial in men with prostate cancer is to test it properly with a prospective randomized study. Until then, men with prostate cancer should not start taking aspirin unless their doctor prescribes it for other health reasons.

The second similar type of study used the Calypso tracking system, which has now received approval for marketing. One paper was recently published claiming that side effects might be lowered using this method. Unfortunately, the paper was not a valid comparison meaning there is no way yet to tell if it truly benefits men getting radiation treatment.

The Bottom Line: The Calypso system is yet another example of technology getting approved before knowing whether it really is better for men or not. Before running out to find out where to get this treatment, men need to be aware that without results for at least 10 years, there is uncertainty about how this compares to other options.

Before closing this month, I have been given the opportunity to make you aware of a new prostate cancer book I have written that will be published in December. The title is WINNING THE BATTLE AGAINST PROSTATE CANCER. It is very balanced and covers every aspect of this disease, containing the most up-to-date information available from good scientific studies. Anyone interested can find it at <www.Amazon.com>.

DYNAMIC EDGE GATING

(Continued from page 2)

many do not, leaving the patient with a significant impact to their quality of life.

In May 2010, , a scientific peer-reviewed journal, a new study published in the journal *Urology* demonstrated that patients whose RT delivery was guided by the Calypso System experienced a significant decrease in the side effects associated with prostate RT. The study compared Calypso prostate RT to conventional RT. Study results showed that physicians were able to decrease the margin of healthy tissue that surrounds the tumor target to just a few millimeters. Irradiating less healthy tissue resulted in fewer side effects.

In contrast to other guidance techniques, Calypso's electromagnetic technology is the only non-ionizing guidance solution to keep the treatment precisely focused on the target without adding unnecessary RT. The Calypso System is the only commercially available real-time tracking system for radiation therapy shown to improve patient outcomes for prostate cancer.

Medical News Today, 12 October 2010

ASPIRIN MAY LOWER RISK OF PROSTATE CANCER DEATH

(Continued from page 5)

western Medical School in Dallas, said. "If the major effect of anticoagulants is preventing metastasis (the ability of cancer cells to spread to other parts of the body), this may be why previous clinical trials with anticoagulation medications produced mixed results, since most patients in these trials already had metastasis. If the cancer has already metastasized, then anticoagulants may not be as beneficial."

Researchers evaluated data from the Cancer of the Prostate Strategic Urological Research Endeavor (CaPSURE) database to investigate the effect of anticoagulation medications (aspirin, warfarin, clopidogrel and/or enoxaparin) on the risk of dying from prostate cancer among men whose cancer has not metastasized.

The study involved 5,275 men whose cancer had not spread beyond the prostate gland (localized prostate cancer) and were treated with surgery or radiation, two of the most common treatment modalities for prostate cancer. Of these patients, 1,982 were taking anticoagulants. Patients were classified as having high-, intermediate- or low-risk disease.

Results of the study show that the use of anticoagulants among prostate cancer patients treated with either surgery or radiation reduced the risk of dying from the disease from 10 percent to 4 percent at 10 years. The risk of developing bone metastasis was also reduced. In addition, findings reveal that the benefit appeared even greater among patients diagnosed with high-risk prostate cancer. This is exciting news as patients with high-risk disease have the most aggressive cancer, with a high likelihood of dying from the disease, and the treatment options are currently limited.

The study also found that the benefit was most prominent with aspirin, compared to other anticoagulants.

Choe said, "Findings from this study are promising, however, further studies are necessary before the addition of aspirin to prostate cancer therapy becomes standard treatment."

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