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Us TOO® PROSTATE CANCER EDUCATION & SUPPORT

HOTSHEET

April 2009

STOP PSA SCREENING IN MEN OVER 75 – BUT ONLY THOSE WITH LOW PSA, SAYS NEW STUDY

New data that support discontinuing screening for prostate cancer in men older than 75 years are reported in the April issue of The Journal of Urology (Vol. 181, pp. 1606-14, 2009).

However, the new analysis does not suggest that screening be stopped in all men older than 75 years, but only in men who have low levels of prostate-specific antigen (PSA ≤3 ng/mL).

This group is unlikely to develop aggressive prostate cancer or to die of this disease during their remaining life and, therefore, these men may represent an ideal target group for discontinuation of PSA testing," say the researchers, headed by Edward Schaeffer, MD, PhD, from the Department of Urology at Johns Hopkins University School of Medicine, in Baltimore, Maryland.

Not screening these older men would dramatically cut costs and would eliminate harm from additional evaluations and/or treatment in a population unlikely to experience benefit, they add.

The conclusions tie in with, but differ

(Continued on page 4)

RESEARCHERS IDENTIFY BIOMARKER FOR FATAL PROSTATE CANCER

Men with highest ionized serum calcium 3 times more likely to die, study finds

A newly identified biomarker for fatal prostate cancer may help guide men trying to decide whether or not to undergo treatment for the disease.

Men whose levels of ionized serum calcium are in the highest third are three times more likely to die of prostate cancer than those with the lowest levels, said researchers at Wake Forest University School of Medicine and the University of Wisconsin. They also confirmed a previous finding that men with the highest levels of total serum calcium are twice as likely to develop fatal prostate cancer.

The study, published in the February issue of the journal Cancer Epidemiology, Biomarkers & Prevention, is the first to examine the link between fatal prostate cancer risk and pre-diagnosis levels of ionized serum calcium.

The findings highlight the need for more research into the link between calcium and prostate cancer and may also help patients make treatment decisions, the researchers said.

(Continued on page 8)

COSTS FORCE SOME CANCER SURVIVORS TO PASS ON HEALTH CARE

Economic considerations are forcing an estimated 2 million cancer survivors to go without medical care, such as prescription medications, particularly survivors who are Hispanic or African American, NCI researchers report.

According to the results of a study presented last week at the American Association for Cancer Research Science of Cancer Health Disparities conference, nearly 1 in 10 cancer survivors don't get prescriptions filled, nearly 8 percent pass on what they believe to be necessary general medical care, more than 11 percent skip needed dental care, and approximately 3 percent forgo mental health services because they are too costly.

That may mean going without, or significantly delaying, such care, explained the study's lead author, Dr. Kathryn Weaver, a cancer prevention fellow in NCI's Division of Cancer Control and Population Sciences. The results were not solely explained by access to health insurance. "There are significant out-of-pocket expenses, even for those with insurance," Dr. Weaver said.

To conduct the study, the research team used 2003–2006 data from the

(Continued on page 8)

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MOLECULE'S PREVALENCE MAY AID IN DECIDING WHETHER TO TREAT PROSTATE CANCER

Scientists have made a discovery that could lead to a simple test to help determine which men who have prostate cancer require treatment and which do not. More than 180,000 men receive a diagnosis of prostate cancer each year in the US but which should receive treatment is often a tough decision.

Prostate cancers often grow very slowly, meaning many men could simply live with the disease without shortening their life span. And the treatments can cause serious complications, including incontinence and impotence. On the flip side, prostate cancer does kill more than 28,000 men each year.

In the new research, published in the 12 February 2009 issue of *Nature* (Vol.457, pp. 910-5, 2009), researchers at the University of Michigan analyzed 1,126 molecules produced by the body in 262 samples of tissue, blood or urine from men who were healthy or had early-stage prostate cancer or prostate cancer that had spread.

The researchers found that one substance, sarcosine, was particularly elevated in men with advanced prostate cancer. In fact, it appeared to be a better indicator of advancing prostate cancer than testing for PSA, which is what doctors primarily rely on at present.

Because sarcosine can be detected in urine, it could potentially be used for a simple urine test to identify men requiring treatment. In addition, tests indicate that sarcosine may play a direct role in making prostate cancer more aggressive. When the researchers added the substance to benign prostate cells in the laboratory, the cells became invasive. So drugs that block its activity could potentially be used to improve treatment.

The researchers cautioned, however, that much more research is needed to confirm the findings and determine how well it would work as a screening test. But if the initial findings hold up with further study, the substance could help save a lot of men from unnecessary treatment and alert others that they need to act upon.

HE04, 17 February 2009

GTX ANNOUNCES PHASE III CLINICAL DEVELOPMENT OF TOREMIFENE 20 MG ON COURSE FOLLOWING PLANNED SAFETY REVIEW

GTx, Inc. (Nasdaq: GTXI), today announced that following a planned safety review, an independent Data Safety Monitoring Board (DSMB) has recommended that the company continue as planned the pivotal Phase III clinical trial evaluating toremifene 20 mg for the prevention of prostate cancer in men with high grade prostatic intraepithelial neoplasia (PIN), a precancerous lesion of the prostate. The DSMB meets every six months to review unblinded safety data from the toremifene Phase III clinical trials.

"The DSMB has reviewed safety data of the nearly 3,000 men enrolled in the toremifene 80 mg and toremifene 20 mg Phase III clinical trials," said Mitchell S. Steiner, MD, Chief Executive Officer of GTx. "The accumulated safety data extend as long as two years for toremifene 80 mg and three years for toremifene 20 mg."

"We are pleased the DSMB has recommended we continue the toremifene 20 mg clinical trial as planned," Dr. Steiner continued. "A treatment to prevent prostate cancer is a critical unmet need, particularly for men with high grade PIN who are at high risk to develop prostate cancer, and we look forward to seeing the results of this clinical trial."

Nearly 1,600 patients with high grade PIN have been enrolled in the toremifene 20 mg Phase III high grade PIN clinical trial. The primary endpoint of the trial is a reduction in prostate cancer incidence. The trial is being conducted under a Special Protocol Assessment with the United States Food and Drug Administration. GTx anticipates conducting an efficacy analysis of toremifene 20 mg in the summer of 2009.

BUSINESS WIRE, 26 February 2009

PREVENTING PROSTATE CANCER: GOOD NUTRITION MAY BE THE KEY

By Jennifer Reilly, RD

In the battle against prostate cancer, men need all the ammunition they can get—and a healthy diet can help them reduce their risk. One man in six will be diagnosed with prostate cancer during his lifetime, according to the American Cancer Society, but many of these cases may be preventable with diet alone.

Scientific studies have shown that a meat-free, dairy-free diet, combined with other lifestyle changes, can help keep early-stage prostate cancer from worsening and may help prevent prostate cancer.

Dairy products are a major culprit in prostate cancer risk. In one long-term study, researchers tracked more than 20,000 male physicians for 11 years and found a moderate elevation in prostate cancer risk associated with higher intake of five dairy products, including milk, cheese, and ice cream. Milk drinking raises the amount of insulin-like growth factor (IGF-1), which is believed to play a key role in causing prostate cancer, in the blood.

Men who consume low-fat and nonfat milk also face an increased risk of prostate cancer, according to two 2007 studies in the *American Journal of Epidemiology*. One study included 82,483 men in the Multiethnic Cohort Study, 4,404 of whom developed prostate cancer over an average follow-up of eight years. Researchers found a positive association between consuming 1 cup or more per day of low-fat or nonfat milk and developing prostate cancer. The other study included 293,888 participants in the National Institutes of Health (NIH)-AARP Diet and Health Study. Consuming two or more daily servings of skim milk was associated with an increased risk of advanced prostate cancer.

British researchers report that a diet free of meat and dairy products may lower a man's risk for developing prostate cancer. An Oxford study of 696 men found that IGF-1 levels were 9 percent lower in vegan men than in meat-eating men. The study, published in the *British Journal of Cancer* in 2000, also mentions previous population studies showing that countries with low consumption of animal products had lower rates of the disease.

Some of the most impressive research on diet and prostate cancer has come from Dean Ornish, MD, best known for his groundbreaking study on the effects of diet and lifestyle factors on heart disease. Dr. Ornish's 2005 study, published in *The Journal of Urology*, showed the power of diet over prostate cancer. After one year on a low-fat vegan diet, complemented by moderate aerobic exercise and stress management, the prostate cancer survivors in the Ornish study found their prostate-specific antigen (PSA) levels decreased by 4 percent.

It is unusual for PSA levels to decrease without treatment. A control group saw its PSA levels rise by 6 percent. In addition, six of the men in the control group needed treatment during the one-year study period because their prostate cancer was progressing, but no one in the experimental group needed treatment.

Gordon Saxe, MD, MPH, PhD, an assistant professor in the Department of Family and Preventive Medicine at the University of California, San Diego, studies whether the adoption of a plant-based diet, reinforced by stress reduction, can slow the progression of recurrent prostate cancer. He's also studying the role of nutrition and genetics in cancer risk.

Dr. Saxe presented some of his research at The Cancer Project's first annual Cancer and Nutrition Symposium in 2006. The webcast of his lecture and other lectures by experts on diet and cancer can be viewed at <www.CancerProject.org/webcasts>.

Research on genetics and prostate cancer will be of great benefit, but scientific evidence already suggests that a low-fat, vegan diet may help men prevent prostate cancer or cancer recurrence. By consuming more vegetables, fruits, beans, and whole grains, and avoiding dairy products, meats, and other animal products, men can take an important step forward in safeguarding their own health.

Making the switch to a plant-based diet is easy. Many of the foods already on the dinner table can help prevent cancer. Beans, for example, are high in fiber, which helps the body rid itself of excess testosterone, and are rich in inositol pentakisphosphate, a known cancer-fighter.

Tomatoes and other lycopene-rich foods, such as watermelon and pink grapefruit, are associated with a reduced risk of prostate and other cancers. Studies from the Harvard School of Public Health have shown that men who frequently consume lycopene-rich foods cut their prostate cancer risk by one-third.

Sweet potatoes, carrots, and cantaloupe are rich in beta-carotene, which helps the immune system keep cancer at bay. Broccoli and other cruciferous vegetables, including kale and cauliflower, are rich in sulphoraphane, a cancer-fighting phytochemical that helps rid the body of excess testosterone and reduces the risk of prostate and other cancers. Soy, nut, and rice milks make an excellent and healthy alternative to cow's milk.

The Cancer Project offers a variety of resources to help men and their families make positive changes to their diets. Visit <www.CancerProject.org> and sign up for a weekly recipe or download a free copy of *The Cancer Survivor's Guide: Foods that Help You Fight Back!* at <www.CancerProject.org/Guide>. The Cancer Project also offers nutrition and cooking classes throughout the country.

Jennifer Reilly, RD, is a dietitian with The Cancer Project, coauthor of The Cancer Survivor's Guide*, and developer of The Cancer Project's Food for Life Nutrition and Cooking Classes for Cancer Prevention and Survival, held in 80 cities across the country. The Cancer Project is a collaborative effort of physicians, researchers, and nutritionists who have joined together to educate the public about the benefits of a healthy diet for cancer prevention and survival. Based in Washington, D.C., The Cancer Project is an affiliate of the Physicians Committee for Responsible Medicine.*

PERSONALIZED CALCULATOR FOR FUTURE RISK OF PROSTATE CANCER

A personalized risk calculator – a tool that combines 4 prostate cancer risk factors, 1 of which is PSA – more accurately predicts a man's future risk for prostate cancer than PSA alone. A study of the risk calculator was highlighted at a press conference at the 2009 Genitourinary Cancers Symposium, held in Orlando, FL, which is cosponsored by the American Society for Clinical Oncology, the American Society for Radiation Oncology, and the Society of Urologic Oncology.

"PSA is used to evaluate a man's current risk of prostate cancer. But what about future risk?," asked the study's lead author Monique Roobol, PhD, an epidemiologist in urologic oncology at Erasmus University Medical Center, in Rotterdam, the Netherlands.

To assess a man's future risk, the calculator uses PSA results along with 3 other common factors that predict prostate cancer risk: previous prostate biopsy results, family history of prostate cancer, and prostate size. The investigators found that an increasing PSA was the strongest single predictor of prostate cancer risk, but that the other risk factors also "significantly altered prostate cancer risk."

They found that, for any given PSA level, a family history elevated an individual's future risk, whereas a previous negative biopsy and increasing prostate volume lowered risk. For men above a certain risk threshold, more frequent screening and the use of active risk reduction strategies is warranted, said Dr. Roobol

"Clinicians [assess risk with these factors] individually on their own, but this allows for a more quantitative assessment," said Howard Sandler, MD, chair of radiation oncology at the Samuel Oschin Cancer Institute, Cedars-Sinai Medical Center, in Los Angeles, CA. Dr. Sandler moderated the press conference and was not involved with the study. "This is a well-done study. I hope that the researchers develop [a computer software application] with an easy interface for clinicians," he told Medscape Oncology.

The data for the tool were taken from more than 5176 men, aged 55 to 70 years, from the Rotterdam section of the European Randomized Study of Screening for Prostate Cancer. The role of PSA and other factors in predicting the development of prostate cancer over a 4-year period was examined. The average risk for prostate cancer in this population was calculated to determine who was at above-average risk, said Dr. Roobol.

The risk over 4 years was 5.1% at an average PSA of 1.5 ng/mL. Men with a PSA of that amount or more were at an above-average risk of developing prostate cancer in the next 4 years, she explained. Specifically, those men were 7 times more likely to develop the cancer during that period. When an individual's previous prostate biopsy results, family history of prostate cancer, and prostate size were factored in, the future risk altered according to the positive and negative impacts of the respective factors.

For instance, for a man with a previous positive biopsy, a negative family history, a prostate volume greater than 40 cm^3, and a PSA value of 4.0 ng/mL, there is a 5% future prostate cancer risk (over a 4-year interval). For a man with a similar profile but a PSA value of 7.8 ng/mL, there is a 10% risk.

"A tool such as this would allow a patient and doctor to set a threshold for handling future PSA results," said Dr. Sandler. "So, if you get a certain PSA, you are able to decide whether to ignore it or not," he added. "Essentially, they have refined risk prediction here with other variables," he summarized.

Dr. Roobol sees the tool as part of the ongoing efforts in medicine to personalize health risk assessment. "This approach is in line with the concept of personalized medicine, where screening is based on an individual's unique risk profile," she said in a statement.

2009 Genitourinary Cancers Symposium, Abstract 2, presented on 26 February 2009.

Medscape, 26 February 2009

STOPPING PSA SCREENING

(Continued from page 1)

from, the recent recommendation from the US Preventive Services Task Force (USPSTF), which advised stopping screening in all men who are 75 years or older.

However, as Dr. Schaeffer and colleagues point out, "all men older than 75 years of age may not be equal." "Indeed, in our cohort, no patient older than 75 years with a PSA of less than 3 ng/mL had high-risk prostate cancer," they write. "However, of those with a PSA greater than 3 ng/mL, there were several subsequent prostate cancer deaths."

The findings come from a new analysis of data collected in the Baltimore Longitudinal Study of Aging, in which investigators collected serial PSA measurements in 849 men, of whom 122 developed prostate cancer.

However, 2 editorial comments that accompany the new study question the conclusion about stopping screening only in older men with low PSA levels. The implication is that it may not be safe to discontinue testing if PSA is above this level," says Peter Albertsen, MD, from the University of Connecticut Health Center, in Farmington.

"While we may be able to prevent a few deaths from prostate cancer in patients older than 75 years, this comes at an enormous cost in testing and treatment," Dr. Albertsen comments. The USPSTF made similar points about men who are 75 years and older and others who have a life expectancy of 10 or fewer years. In these men, the incremental benefit from treating prostate cancer detected by screening is "small to none" and, harm outweighs benefit, it concludes.

In another editorial comment, Ruth Etzioni, PhD from the Fred Hutchinson Cancer Research Center, in Seattle, Washington, points out that the conclusions are based on observational data. In particular, the selection of the 3 ng/mL PSA cut-off level is based on a post hoc observation. "Post hoc findings may be valid but generally need to be confirmed in independent datasets," she writes.

Medscape, 20 February 2009

DONATED ITEMS SOUGHT FOR JUNE 2009 US TOO ONLINE AUCTION

Us TOO International will host our 4th Annual Online Auction June 8-23. Proceeds go to support Us TOO's patient education and support programs and services.

To donate an item, please contact Ryan Maguire at ryan@ustoo.org or by phone at 630-795-1002.

DRUG USED TO TREAT BALDNESS COULD PREVENT PROSTATE CANCER

Healthy men who get regular prostate cancer tests should consider taking a drug called finasteride, the first medication proven to help prevent the disease, experts reported this February.

Doctors stopped short of advising men to take the drug, which costs more than $1,000 a year. Finasteride is sold by Merck as Proscar® to treat swollen prostates and as Propecia® to treat male pattern baldness.

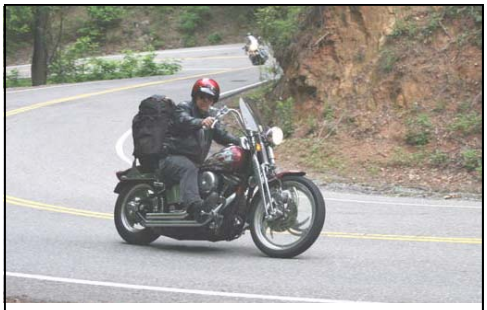
Although previous studies show it reduces the overall risk of prostate cancer by 25%, many doctors have been concerned that finasteride might increase the risk of high-grade tumors. But because more recent analyses have largely dismissed those worries, the drug's benefits now appear great enough that men should at least talk to their doctors, according to the American Society of Clinical Oncology and the American Urological Association.

Men who already take finasteride for hair loss or prostate swelling should ask about continuing the drug to prevent prostate cancer, the groups' joint statement says. Researchers are studying whether a drug that works by a similar mechanism, dutasteride, sold by GlaxoSmithKline as Avodart for swollen prostates, also prevents cancer.

(Continued on page 8)

3 STATE, 2 WEEK MOTORCYCLE RIDE FOR PROSTATE CANCER AWARENESS

After his personal experience with a prostate cancer diagnosis, Keith Colombo, an avid motorcycle enthusiast and 2-year survivor, wanted to raise awareness about the benefits of early detection opportunities for prostate cancer.



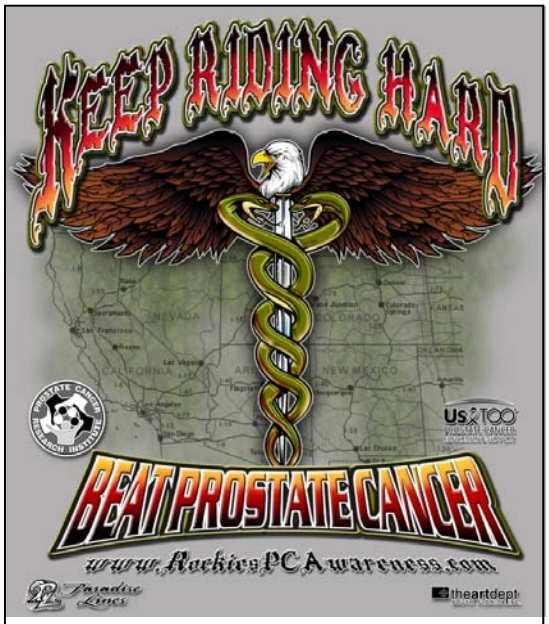
Keith Colombo, creator of "The Rocky Mountains" Prostate Cancer Awareness Ride, enjoying a ride in the Smoky Mountains on his Harley

"I was first diagnosed with prostate cancer at age 49 (two years ago). During my frantic research on prostate cancer and available treatments, I came to realize that I wasn't the only one whose life had been changed by a diagnosis of prostate cancer, and that the earlier an aggressive Prostate cancer is detected the easier it is to beat," states Colombo. "All men need to be aware of prostate cancer just as women are becoming more aware of breast cancer."

On his own, Colombo engaged Harley Davidson stores, hospitals, cancer centers and other businesses in Colorado, New Mexico, Wyoming and Florida to support his "The Rocky Mountains" Prostate Cancer Awareness Ride.

The ride will start on Fathers Day, Sunday, 21 June 2009 at the Thunderbird Harley Davidson in Albuquerque, NM, continue to the Beartooth Harley Davidson in Cody, WY on Friday, 26 June 2009, and end at the Mile High Harley - I 70 & Airport Blvd in Aurora, CO on 5 July 2009.

Those interested in supporting the cause can ride the entire event, join for one day, or make a contribution online. For a $20 donation, supporters will receive a prostate cancer awareness wristband. For a $40 donation, supporters will receive one of the gray, short sleeved, "Keep Riding Hard—Beat Prostate Cancer" event t-shirts. More t-shirts are available for an extra $20 donation.



Get great gear with your support of the Rocky Mountain PCa ride, Us TOO and PCRI! (Image as appears on back of the official event t-shirt).

All proceeds raised through donations and t-shirt sales will benefit Us TOO International, Inc. and the Prostate Cancer Research Institute (PCRI).

"If all the donations, work from all the sponsors and those that have helped with the Awareness Ride causes one man to detect his cancer early, the effort will have been successful," says Colombo. "I will thoroughly enjoy the ride through the Rocky Mountains with friends, like enthusiasts *and all of you interested in joining us. Please support the Prostate Cancer Awareness effort with a donation of any amount to the charities that have helped so many."*

To learn more about the event or to make a contribution and receive a t-shirt, visit: ***www.RockiesPCAwarenessRide.com***

HEALTHCARE FOCUS LETTER: VITAL PROSTATE CANCER STUDIES NEED FUNDING

Advances in prostate cancer research have led to dramatic decreases in the number of men who die of the disease. Still, nearly 29,000 men lost their battle in 2008.

Prostate cancer remains the leading cause of cancer among men, with 186,320 men expected to be diagnosed this year. America's men need new treatments and ways of finding the disease.

A program at the Department of Defense that helps fund my research is bringing hope through the Congressionally Directed Medical Research Programs Prostate Cancer Research Project. The second leading funder of prostate cancer research in the United States, the CDMRP has been funding innovative research since 1997. This program helped develop the lifesaving drug Herceptin for breast cancer and improved on Gleevec, a blockbuster leukemia drug.

Now, similar therapies are on the horizon for prostate cancer - targeted medicines that might replace toxic chemotherapy. But a nearly eight-year funding plateau has stretched the program to the breaking point. Inflation and increased research costs are eroding the program's research base.

On average, the CDMRP can fund approximately 20 percent of the worthy grant applications it receives, leaving potential new treatments and possibly a cure for the disease on the table. In an economy where poor business decisions have cost taxpayers billions of dollars, programs such as the CDMRP have provided consistent progress and results. Congress needs to reward efficiency, innovation and accountability with the $125 million in funding needed by this highly effective program.

http://www.mlive.com/opinion/ann-arbor/index.ssf/2009/02/healthcare_focus_letter_vital.html, 24 February 2009

THE DOCTORS NOTE

Dr. Gerald Chodak

The April issue has something for everyone; there are articles about prevention, screening and deciding on which patients need to be treated and how to treat hormone refractory disease.

The screening controversy just won't go away. A Johns Hopkins study supports NOT screening men over age 75 but only if the PSA is under 3 ng/mL. This is based on the almost zero risk of a man dying from this disease with a PSA that low. However, The editorial comment by Dr. Peter Albertson appropriately asks what is the cost and morbidity of saving a small number of men who continue screening because their PSA is over 3 ng/ml. Ultimately, will we be able to provide men with a real estimate of the risk and benefit of getting or not getting screened?

One concern regarding over-diagnosis is the potential for overtreatment. A study from Wake Forest suggests that men with a high serum level of ionized calcium are at greater risk of dying from prostate cancer. If true, it might help to identify men who do not need aggressive therapy. Unfortunately, this study's design does not prove cause and effect or that this marker is truly predictable but it does invite further study to try to determine if a real potential may exist.

Another early finding was that sarcosine might be useful for identifying men with prostate cancers that are at risk for progression. **Caution** - this preliminary finding must be validated to see if it really has a potential role and measurements cannot be recommended for counseling patients at this time.

There are 2 articles about prostate cancer prevention. The first discusses a range of dietary interventions. This article cites many studies suggesting that various foods that may be good vs. prostate cancer. However, without proper studies we cannot truly establish that anything really works. The best advice is to eat well but men should recognize that there are no proper studies that justify firm recommendations for increasing or decreasing the intake of any specific foods.

The other article about prevention cites data using finasteride which has been tested in a properly designed study and showed a significant reduction in the risk of developing prostate cancer without favoring development of more aggressive cancers. Why aren't there strong recommendations that all men take this drug? There are 3 reasons – cost, the fact that only one cancer would be prevented for every 71 men treated for several years, and that the study has not yet shown a reduction in the risk of dying from prostate cancer by taking the drug. Men who want to do as much as possible to prevent prostate cancer should discuss taking this drug with their doctor.

Lastly, encouraging data was recently presented using a new agent that is an androgen receptor antagonist. No other drugs are available with this mechanism of action. The studies found that a majority of men on MDV 3100 all of whom had failed hormone therapy, showed at least a 50% decline in PSA. More studies are needed to determine if this oral agent has a role in treating these patients.

Working with 13 of America's top prostate cancer organizations, Us TOO is supporting an effort to increase funding of the Congressionally Directed Medical Research Program (CDMRP) for Prostate Cancer at the Department of Defense (DOD). Our goal is to have $125 million appropriated for 2010. The Prostate Cancer Research Program at DOD is the only federal program that is 100% dedicated to prostate cancer research.

Please join us by writing your Congressman and Senator THIS MONTH and let them know why you want federal funding for prostate cancer research increased at the Congressionally Directed Medical Research Program at the Department of Defense (CDMRP).

Write your letter online and learn more about this effort by visiting the Fund Prostate Cancer Research Now website at <www.fundresearchnow.org>.

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

"Lifting weights may reduce fatigue after prostate cancer treatment! Wow!"

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

Bottom Line:

Lifting weights for 30-45 minutes about 3 times a week after prostate cancer treatment (or even during treatment when receiving radiation) can increase your energy levels and help you to recover faster, but first get your doctor's approval on exactly when you can start lifting weights after treatment.

Past studies found that weight lifting about 3 times a week reduced fatigue from androgen deprivation therapy (ADT) and improved quality of life in patients with advanced prostate cancer. Men with more localized or locally advanced tumors had not been evaluated adequately using a similar protocol to determine if side effects can be reduced in this group.

A total of 121 participants were placed in one of 3 groups for 24 weeks: usual care (41 men), aerobic exercise (40 men), or weight lifting (41 men). The exercise groups were asked to commit 3 days a week for approximately 45 minutes per session. This randomized controlled trial included patients receiving radiation therapy with and without ADT.[1] Approximately 60% of participants in each group were on ADT.

Results showed that aerobic exercise and weight lifting both significantly ($p=0.01$ and $p=0.004$, respectively) reduced fatigue over the short-term (12-weeks), but weight lifting had more significant ($p=0.002$) long-term effects on this endpoint. All of the following were significantly improved with weight lifting compared to usual care: quality of life, fitness, lower and upper-body strength, triglycerides, and maintaining (not increasing) body fat.

How many prescriptions are given to cancer patients that experience fatigue, weakness, and depression?! These medications carry serious side effects including some with an increased risk of a cardiovascular event. If aerobic and resistance exercise were emphasized to all patients during and after radiation therapy or even several weeks after surgery for example, I wonder what the true side effect rate of these treatments would really be under this perfect ideal scenario.

Hmmm, I bet a lot lower compared to what it is right now.

Reference

1. J Clin Oncol, Published online ahead of print on December 8, 2008

ANDROGEN RECEPTOR ANTAGONIST SHOWS RESULTS IN ADVANCED PROSTATE CANCER

More than half of patients with castration-resistant prostate cancer responded to an investigational androgen receptor antagonist by one or more criteria, according to a study reported at the 2009 Genitourinary Cancers Symposium, held from 26-28 February 2009 in Orlando, FL.[1]

A majority of patients on oral MDV3100 had at least a 50% fall in PSA values, and the proportion of patients with favorable circulating tumor cell counts increased, Howard I. Scher, MD, of Memorial Sloan-Kettering Cancer Center in New York, told attendees at the Symposium. A majority of patients with soft-tissue lesions and bone metastases had stable disease or better response to the drug, he said.

MDV3100 not only blocks the androgen receptor but inhibits androgen receptor function by preventing nuclear translocation of the receptor and DNA binding. The agent has demonstrated activity in models of bicalutamide (Casodex®)-resistant prostate cancer. Dr. Scher reported findings from a phase I-II clinical trial involving 114 patients with advanced and metastatic prostate cancer. Three fourths of the patients had received more than one hormonal therapy, and 49 had received chemotherapy.

The ongoing trial began with evaluation of MDV3100 at doses ranging from 30 to 600 mg/day in groups of three to six patients. After the drug's safety was established, enrollment continued at doses ≥60 mg/day.

PSA was measured at baseline and every four weeks while circulating tumor cells were measured at baseline, week four, and week 12. All patients had CT/MRI imaging every 12 weeks, and a subset of 16 patients had PET imaging to assess uptake of FDG and [^{18}F]-dihydrotestosterone (FDHT).

Dr. Scher reported that 37 of 65 chemotherapy-naive patients and 22 of 49 chemotherapy-experienced patients had at least a 50% decrease in serum PSA from baseline to week 12. A circulating tumor count of <5/7.5 mL of blood was defined as favorable, and higher counts were unfavorable.

Of 101 patients with data on circulating tumor counts, 56 of 61 (92%) with favorable counts at baseline maintained the favorable status at week 12. Additionally, 21 of 43 patients with unfavorable baseline cell counts converted to favorable status.

At week 12, six of 48 patients with soft-tissue lesions at baseline showed a partial response, and 30 had stable disease. Of 83 patients who had bone metastases at baseline, 52 had stable disease at week 12. PET scans revealed decreased uptake of FDHT in all 16 patients and decreased FDG uptake in 14 of 16.

In general, MDV3100 was well tolerated, Dr. Scher reported. The most commonly reported adverse event was fatigue, which led to one patient's discontinuation. Three patients receiving 360, 480 and 600 mg/day had a witnessed seizure but were taking other drugs with a known seizure risk. Dr. Scher said investigation of MDV3100 will continue at a dose of 240 mg/day.

The study was supported by Medivation Inc. and Investigators in the study included employees of Medivation.

Reference

1. 2009 Genitourinary Cancers Symposium, Abstract 151.

MedPage Today, 2 March 2009

SURVIVORS FOREGO CARE

(Continued from page 1)

CDC's National Health Interview Survey (NHIS). They identified more than 6,600 cancer survivors, the large majority of whom were white, and compared them with more than 104,000 people who had no history of cancer. Compared with non-Hispanic whites, Hispanic and African American survivors were significantly more likely to forgo dental care and prescription medications, although, after adjusting for several variables, the disparity was reduced or eliminated.

The NHIS is constructed to be representative of the U.S. population, allowing the researchers to arrive at the larger estimate of 2 million survivors who may forgo care due to cost concerns. While data are not yet available for 2008, said Dr. Weaver, the recent economic downturn will likely make things worse.

"We know that one of the strongest predictors of forgoing care was not having health insurance coverage," Dr. Weaver said. "If people lose their jobs and, as a result, their health insurance coverage, then the proportion forgoing care is likely to increase."

NCI Cancer Bulletin, 10 February 2009

FATAL CANCER MARKER

(Continued from page 1)

"Many men with this diagnosis are treated unnecessarily," said senior author Gary G. Schwartz, an associate professor of cancer biology at Wake Forest University Baptist Medical Center's School of Medicine.

"Within months of initial diagnosis of prostate cancer, many men opt to undergo either radiation or radical surgery. The problem is, we don't know who needs to be treated and who doesn't, so we treat most men, over-treating the majority," Schwartz explained. "These new findings, if confirmed, suggest that men in the lower and of the normal distribution of ionized serum calcium are three times less likely than men in the upper distribution to develop fatal disease. These men may choose to delay treatment or perhaps defer it altogether."

Schwartz noted that diet has little effect on serum calcium levels, which are controlled genetically and are stable over much of a person's life. "These results do not imply that men need to quit drinking milk or avoid calcium in their diets," he said.

HealthDay News, 13 February 2009

FINASTERIDE

(Continued from page 5)

Doctors still have important questions about finasteride, says Barnett Kramer of the National Institutes of Health, main author of the new recommendation. Doctors would have to treat 71 men for seven years to prevent one case of prostate cancer and it's not yet known if finasteride saves lives. The drug has side effects, including impotence, breast tenderness and low libido that resolve when the drug is stopped .

In addition, experts don't know whether finasteride would benefit all men, Kramer says. The most definitive study of finasteride published in 2003 only included healthy men who had regular screenings and had an initial PSA of less than 3.0 ng/mL. For that reason, experts say, their recommendations apply only to men who meet those eligibility criteria.

The American Cancer Society hasn't made any recommendations about finasteride, says chief medical officer Otis Brawley. But he agrees that regularly screened men should consider finasteride, mainly because it reduces medical problems that are common in older men, such as frequent urination.

USA Today, 24 February 2009

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