A new study from Harvard School of Public Health (HSPH) and Brigham and Women’s Hospital researchers has found a strong association between the common sexually transmitted infection, *Trichomonas vaginalis*, and risk of advanced and lethal prostate cancer in men. The study was published online ahead of print on 9 September 2009 in the *Journal of the National Cancer Institute*. Website.

“Prostate cancer is the most common cancer among men in western countries, and the second leading cause of cancer-specific mortality. Identifying modifiable risk factors for the lethal form of prostate cancer offers the greatest opportunity to reduce suffering from this disease,” said Jennifer Stark, an HSPH researcher and lead author of the study.

One potential risk factor is inflammation, which appears to play an important role in the development and progression of prostate cancer, but the source of inflammation of the prostate is not clear. *Trichomonas vaginalis*, which infects an estimated 174 million people globally each year and is the most common non-viral sexually trans-
SOY PILLS FAIL TO PREVENT BONE LOSS

Soy protein extracts showed no evidence of preventing bone loss in postmenopausal women in two placebo-controlled trials, researchers reported here at the American Society for Bone and Mineral Research (ASBMR) meeting (Abstract SA0412).

In one trial with 224 participants, very similar declines in lumbar spine and hip bone mineral density (BMD) were seen after three years in women taking the soy pills and those taking placebo. The other study found that levels of a biomarker of bone resorption were virtually identical after two years of high-dose soy extracts versus placebo.

Previous studies had yielded conflicting results as to whether the isoflavones in soybeans prevented bone loss. A retrospective Chinese study reported in 2005 had found a strong preventive effect in women who had consumed large quantities of soy foods.

“I think we can close the door on this issue,” declared the first study’s leader, D. Lee Alekel, PhD, of Iowa State University in Ames, IA. Alekel said an earlier study in her own lab had found a modest benefit in peri-menopausal women. But other studies had either failed to find any benefit for the soy extracts or were marred by small numbers of participants or other limitations.

Alekel’s study randomized 224 healthy postmenopausal women, mean age 54, to take placebo or 80 or 120 mg of soy isoflavones in pill form for three years. They also received daily supplements of 500 mg of calcium and 600 IU of vitamin D. The researchers ran multivariate analyses of BMD changes that included age, treatments, whole body fat mass, and the CTX biomarker of bone resorption, at three standard sites: lumbar spine, proximal femur, and femoral neck.

Alekel said the analyses showed that the 120-mg dose of soy was modestly protective at the femoral neck, relative to placebo (parameter estimate -1.223, P=0.024) in women who took at least 80% of their assigned medications on schedule. But no significant benefit was found for the soy pills in any other measure. Whole body fat mass, age, and CTX levels were much more predictive of BMD loss, she said.

The other study, led by Silvina Levis, MD, of the University of Miami, found no effect on a biomarker of bone resorption after two years of treatment with placebo or 200 mg/day of soy isoflavone pills (Abstract MO0374).

Participants were 248 postmenopausal women, average 53 years old, about two-thirds of whom were Hispanic whites. Levis and colleagues reported that levels of urinary N-telopeptide of type I bone collagen (NTx) -- like CTX a measure of bone resorption -- did not differ between treatment groups after one and two years of treatment. The study -- called SPARE (Soy Phytoestrogen As Replacement Estrogen) -- also included measurements of lumbar spine and hip BMD, but those data were not reported here.

Peter Burckhardt, MD, who studied nutrition and endocrinology at the University Hospital of Lausanne in Switzerland until his recent retirement, said the studies’ findings did not surprise him. “The overall evidence in the literature is negative,” he said. Burckhardt said one of the earlier studies purported to find a benefit was misleading.

“[It] was published in a high-ranking journal with an attractive title that it worked. But when you go into the data you discover that it worked only in a subgroup and only with a special [bone measurement],” he said. Referring to the Iowa State study of BMD, Burckhardt said, “It looks solid.”

Alekel emphasized that the negative results apply only to the soy extracts used in the studies. She said soy foods, consumed over a lifetime, could well help women limit bone loss and fractures, just because such foods may be less fattening and have other health benefits.
Research published online ahead of print in the Journal of the American Medical Association (JAMA), by a team at The Cancer Institute of New Jersey (CINJ), showed that men diagnosed with prostate cancer in the early 1990’s had significantly improved survival outcomes compared with patients whose cancers were diagnosed in prior decades.

The study, Outcomes of Localized Prostate Cancer Following Conservative Management, examined 14,516 men aged 66 or older who were diagnosed with prostate cancer from 1992 through 2002 and did not receive surgery or radiation within six months of diagnosis. The researchers utilized information from the Surveillance, Epidemiology and End Results (SEER) cancer registries and healthcare encounter data collected by Medicare.

The study found that the risk of dying from prostate cancer over a ten-year period following diagnosis declined by more than 60 percent compared with patients diagnosed in the 1970s and 1980s. For example, among patients with intermediate-risk cancer, men aged 66 to 74 had between a two and six percent chance of dying from prostate cancer within ten years compared to 15 to 23 percent in the earlier period. The JAMA research also showed that men aged 66 and older with low- to intermediate-risk cancer without initial surgery or radiation had a low risk of needing palliative therapy. Only four to eleven percent of men in this group used palliative surgery, radiation, or chemotherapy to alleviate pain or cancer symptoms over a ten-year period following diagnosis. It also was determined that between 56 and 60 percent of men in the study (depending on tumor grade) had a risk of dying of causes other than prostate cancer within ten years following diagnosis.

The authors say improvement in survival rates since the 1990’s could relate to such factors as earlier diagnosis due to the increased use of the PSA test, changes in how disease is classified, and advances in medical care. The improved survival reported in JAMA is in line with findings of another study published by some of the same authors online ahead of print in the Journal of the National Cancer Institute (JNCI), which documents significant changes in the contemporary risk profile of prostate cancer patients.

(Continued on page 7)

**GETTING CLOSER TO THE ORIGINS OF PROSTATE CANCER**

In a study reported online ahead of print in the journal Nature, researchers describe a previously unknown form of prostate stem cell that can become cancerous if genetic controls go haywire. The prostate consists of several layers of cells, with the lowest, the basal layer, playing a supporting role and the luminal layer, just above it, doing the actual work of the gland.

The discovery was made in mice. The mouse work showed that the newly described stem cells can give rise to cancers if the action of a tumor-suppressing gene is lost. That gene is frequently mutated in human prostate cancers. The next step is to show that the same kind of stem cells exist in humans. “But this work partially explains how you can have a prostate cancer that is luminal,” explained study co-author Cory Abate-Shen, a professor of urology, pathology and cell biology at Columbia University’s Herbert Irving Comprehensive Cancer Center, in New York City.

“Up until our paper, it was thought that all the stem cells in the prostate reside in the basal layer,” Abate-Shen said. “We have found a second stem cell population that is luminal rather than basal.” The research group already is looking for similar stem cells in human prostate glands. “If we can identify them in humans, we can analyze them molecularly,” Abate-Shen said. “That would give us a tool to study where and how prostate cancer originates – we want to do battle with these stem cells” he added.

HealthDay News, 9 September 2009
**PROTEIN TIED WITH AGGRESSIVE PROSTATE CANCER**

In the largest study of its kind, an international team of pathologists studied an initial 4,000 prostate cancer patients over a period of 15 years to understand the natural progression of the disease and how it should be managed. The research, published online in the *British Journal of Cancer*, could be used to develop a blood test to distinguish between aggressive and non-aggressive forms of prostate cancer.

Studies have shown that men with non-aggressive prostate cancer can live with the disease untreated for many years, but aggressive cancer requires immediate treatment.

Prof. Chris Foster, Head of the University’s Division of Pathology, explains, “The protein we’ve identified (HSP-27) provides a signal that the disease will continue to progress. We know that at the point this marker is expressed, medics need to administer treatment to kill the cancer cells. We have shown that in the majority of cases, however, this marker is not expressed and therefore patients do not necessarily need to go through treatment to lead a normal life.”

The protein normally has a positive function in the body, helping healthy cells survive when they are placed under ‘stressful’ conditions. If the protein is expressed in cancer, however, it can prevent the diseased cells from dying, allowing the cancer to progress.

The team, supported by Cancer Research UK (CRUK) and in collaboration with scientists in London and New York, found that the protein can be used to predict how the disease will behave and could help doctors advise patients on how the disease could affect their daily lives.

“By studying the disease in a large number of men throughout the UK and over a long period of time, we have been able to get a more complete picture of how to manage the disease successfully, whilst limiting the negative impact it can have on a patient’s life,” added Prof. Foster.

The study also demonstrates the role of modern Pathology, not only in establishing diagnoses but in determining if the subsequent management of individual patients is biologically appropriate for their particular condition.

*Lab News Daily, 23 September 2009*

---

**SEA BLUE PROSTATE CANCER WALK DELIVERS FUN, FUNDS AND SUN**

A sunny, warm day welcomed the 973 walkers who came to celebrate and honor the men and families who have dealt with a prostate cancer diagnosis, and to encourage other men to learn about their risk for the disease and the resources available to them should they be needed.

Previously known as the Greater Chicago Prostate Cancer Run, Walk ‘n Roll, the new SEA Blue Prostate Cancer Walk was held on September 13, 2009 in Lincoln Park, Chicago, IL. This 5th annual event was a collaboration between Us TOO International and Wellness Place – two cancer organizations which offer programs and services at no cost for prostate cancer survivors and their families.

Highlights included performances by Jesse White Tumblers, led by founder and Illinois Secretary of State, Jesse White, and blues band Phil Guy’s Chicago Machine, (Buddy Guy’s brother, Phil, recently passed away from prostate cancer and his band played in his honor). Robert Jordan, WGN-TV9 news co-anchor and prostate cancer survivor, served again as event emcee, and Damon T. Arnold, MD, MPH, Director of the Illinois Department of Public Health, and Commander of the Army National Guard Joint Task Force Medical Command in Springfield, gave a moving, motivational presentation to the crowd, sharing his personal prostate cancer story.

Greg Bielawski, Treasurer for the Us TOO Int’l Board of Directors and re-

(Continued on page 7)
SUCCESSFUL PROSTATE CANCER AWARENESS & FUNDRAISING EVENT:
5th Annual Chicago SEA Blue Prostate Cancer Walk —September 13, 2009

Abbott Team shows their support for Us TOO

New record: PSA tests for 101 men

Great volunteers!!! Thank you!!!

A proud survivor walks

IL Sec. of State Jesse White (left) with emcee & survivor, Robert Jordan, WGN-TV News

Us TOO Co-Founder Ed Kaps (center) walked with his family & Us TOO President/CEO Tom Kirk (at Ed’s left)

Survivors IL Dept of Health Director Dr. Damon Arnold (left) with event co-chair James Branch

After last year’s rainout, the sunny, 80 degree day was enjoyed by all!

Honoring the special ones no longer with us

Survivors group photo, total of 118 participated
Doc Moyad’s What Works & What is Worthless Column, also known as “No Bogus Science” Column

“Prescription drugs (dutasteride, finasteride...) for prostate enlargement or benign prostatic hyperplasia (BPH) are better than the dietary supplements recommended for BPH by some alternative medicine experts for 10 reasons!”

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

Bottom Line: Dutasteride (Avodart®) and finasteride (Proscar® & generic version) are better than dietary supplements for prostate enlargement because these drugs may prevent prostate cancer and prevent the need for the treatment of non-life-threatening prostate tumors. Oh yeah, and they also may stop hair loss on the head.

Saw palmetto, Pygeum africatum, zinc … they are all over the place for sale to improve urinary flow and some commercials advertise that they may actually reduce the risk of prostate cancer. B.S. my friends! I believe these products may help a little but the truth is that the prescription drugs for non-cancerous enlargement of the prostate have become so good that many people need to put away their pharma bias and accept this truth. Let’s review why these prescription medications have become so good by themselves.

First, both drugs are proven to prevent prostate cancer, especially the most commonly diagnosed forms of prostate cancer or the well-differentiated and non-aggressive forms of prostate cancer. Second, both drugs now have some minimal evidence that they may treat some very tiny non-aggressive tumors already in the prostate. Third, we know that these drugs should reduce your PSA by half or 50% within 6 months and if they do not they may provide some further and even better insight into how to treat your condition. Fourth, these drugs should shrink your prostate by an average of 25% or a little more or a little less so you can urinate better. Fifth, these drugs make the PSA test more accurate. Sixth, both drugs should reduce anxiety in men on active surveillance or watchful waiting (the less politically correct term for active surveillance so it is not used as often) by reducing their PSA and perhaps by offering more of a treatment option compared to just doing nothing or making dietary changes. Seventh, these drugs reduce hair loss on the head and promote hair growth and not that this should matter at all, but it is an eye-opening or hair-raising side effect (pun intended). Eighth, the price of these drugs should drop in time because finasteride is also available as a generic, which should also help to reduce the price of dutasteride over time. Ninth, the newer drug, dutasteride or Avodart has a 5-week half-life, which basically means if you forget to take your daily pill a few times a week this is no big deal because it will continue to work fine over time. Tenth, well there is no tenth but I wish there were a tenth reason to complete my compelling argument. Actually, a tenth reason is that research will continue on these products so every year we will learn more and more about them.

What is the catch? Well, cost is always a catch and a small percentage of men have an increased risk of erectile dysfunction and may have a lower sex drive when taking these pills. Also, the ejaculation volume during orgasm decreases with these drugs and younger men and even older men these days that still want to have a baby or a mid-life crisis will have a more difficult time getting their part-

New Us TOO Resources

In addition to the new Us TOO / Inspire discussion community, Us TOO is also announcing the availability of two new wiki resources related to Prostate Cancer & Intimacy (PCAI) and Radical Prostatectomy & Post Surgical Issues (RP-Help). Both house a collection of articles focused on intimacy and sexuality in the context of prostate cancer. What is a wiki? Learn more at <www.ustoo.org/Wiki.asp>.

Using new, innovative technology for networking

Us TOO was founded on the model of peer-to-peer support, so these safe, secure online communities and wiki resources are a way to extend reach and support for those who may not have a support group chapter nearby. We are adopting new social networking technology to simplify and encourage your interactions with others with the added benefit of increasing your privacy and security controls.

Nowadays, we can all be virtual neighbors in the prostate cancer patient and survivor community. Many of you have great initiative and passion, and your willingness to engage others in conversation about these important subjects will help not only you, but MANY couples in finding options and solutions as you each navigate your personal prostate cancer journeys.

We hope you will find these communities a private, respectful place for open dialogue among people from all backgrounds and relationships.
The Doctors Note – Gerald Chodak, MD

The optimal management for men with prostate cancer continues to be a challenge because so many men are being diagnosed and treated while only a percentage of them actually are in danger. Currently, we are faced either with treating most men diagnosed at the risk of over-treating many or avoiding over-treatment at the risk of failing to help some men who really need it. Further evidence that many men are being over-treated is provided in the article by Lu-Yao and published in JAMA. The authors found that men aged 65-74 who were diagnosed with a Gleason score 5, 6 or 7 cancer and treated conservatively only had a 6% chance of dying from prostate cancer in the next ten years versus approximately a ten fold higher chance of dying from some other cause. Although these findings do not tell us what to expect for younger men, they are important for the large number of men over 65 who may not truly understand why conservative therapy is a very reasonable option for them.

What we really need is a way to figure out which of the men are in danger. Help soon may be forthcoming, however, as evidenced by the very exciting article on hsp27. It is a heat shock protein that normally helps protect damaged non-cancerous cells. The researchers found evidence that the presence of hsp27 in prostate cancer cells may be a predictor of aggressive, potentially lethal cancers. If confirmed, this finding is huge because it may be the marker everyone is looking for to decide which prostate cancers do need treatment and which ones do not. We will all wait anxiously while this work develops.

Other exciting treatment news involves MDV3100, a potentially new treatment for advanced prostate cancer. AFFIRM is the name of a very important phase III study for men with hormone refractory disease previously treated with chemotherapy. In earlier studies this drug appears to provide good results and this study is critical to determine if it will improve survival. Anyone who is no longer responding to chemotherapy should strongly consider participating in this study.

It seems that this column is incomplete unless it addresses some study of an herb or other supplement that is thought to be helpful. This month it involves soy pills to prevent osteoporosis in women but we might think the same would also be true for men, especially those on androgen suppression. The study failed to show a benefit. Readers are probably getting tired of hearing me say that without good science the claims about supplements remain unfounded but each time a good study is done it fails to meet expectations. “Let the buyer beware!”

Survival Outcomes

(Continued from page 3)

The time period studied is an era when methods of diagnosing, classifying and treating prostate cancer underwent significant changes. The investigators say their finding may prompt a reassessment of treatment options for localized prostate cancer. CINJ is a Center of Excellence of UMDNJ-Robert Wood Johnson Medical School.

Grace Lu-Yao, PhD, MPH, cancer epidemiologist at CINJ and associate professor of medicine at UMDNJ-Robert Wood Johnson Medical School.

JAMA (Continued from page 3)

Want to learn more about local prostate cancer support group activities? Read the CHAPTER NEWS! at www.ustoo.org!
MEDIVATION ANNOUNCES INITIATION OF PHASE 3 CLINICAL TRIAL OF MDV3100 IN ADVANCED PROSTATE CANCER

In September, Medivation, Inc. announced treatment of the first patient in a Phase 3 clinical trial of the investigational drug MDV3100 in advanced prostate cancer. Known as AFFIRM, the trial will evaluate the novel androgen receptor antagonist MDV3100 in men with castration-resistant prostate cancer who were previously treated with docetaxel-based chemotherapy.

“Late stage prostate cancer remains an obvious and large unmet clinical need,” said David Hung, MD, president and chief executive officer of Medivation. Our ultimate goal is to develop MDV3100 for the broadest possible spectrum of prostate cancer disease states. The first step is to develop this product candidate for patients with the most advanced disease and in greatest need.”

The randomized, placebo-controlled, double-blind, multi-national AFFIRM trial is expected to enroll approximately 1,200 patients at sites in the US, Canada, Europe, South America, Australia and South Africa. The primary endpoint of the trial is overall survival; secondary endpoints include progression-free survival, safety and tolerability. This trial will evaluate MDV3100 at a dose of 160 mg taken orally once daily versus placebo.

Information about patient eligibility and enrollment can be obtained by calling the AFFIRM study hotline toll-free at +1 888 782-3256.

PRNewswire-FirstCall, 23 September 2009

LETTER TO THE EDITOR

In the Sept. 2009 Special Issues Supplement of Us TOO HotSheet, there is an article by Charles Myers, MD, “The Prostate Cancer Screening Controversy,” in which he writes on page 3: “Pomegranate had a dramatic impact on prostate cancer progression in a well-designed Phase II trial. A randomized controlled trial is underway.”

Question:
Was the impact good or bad? Reason for my inquiry – I drink a lot of pomegranate juice.

Thank You in advance, R.J. Irvine

From the Editorial Team:
Mr. Irvine, we forwarded your question to Dr. Myers, and he provided the following response:
“Pomegranate slows the growth of prostate cancer recurrent after surgery or radiation. The juice is high in sugar and if you take more than 8 oz a day, the sugar load may become a problem. If you are diabetic or have other reasons to limit your sugar intake, pomegranate capsules can be used.”

If you have questions or want to comment on any articles published in the Us TOO HotSheet, please forward them to Tom Kirk at tom@ustoo.org.

DOC MOYAD
(Continued from page 6)

In September, Medivation, Inc. announced treatment of the first patient in a Phase 3 clinical trial of the investigational drug MDV3100 in advanced prostate cancer. Known as AFFIRM, the trial will evaluate the novel androgen receptor antagonist MDV3100 in men with castration-resistant prostate cancer who were previously treated with docetaxel-based chemotherapy.

“Late stage prostate cancer remains an obvious and large unmet clinical need,” said David Hung, MD, president and chief executive officer of Medivation. Our ultimate goal is to develop MDV3100 for the broadest possible spectrum of prostate cancer disease states. The first step is to develop this product candidate for patients with the most advanced disease and in greatest need.”

The randomized, placebo-controlled, double-blind, multi-national AFFIRM trial is expected to enroll approximately 1,200 patients at sites in the US, Canada, Europe, South America, Australia and South Africa. The primary endpoint of the trial is overall survival; secondary endpoints include progression-free survival, safety and tolerability. This trial will evaluate MDV3100 at a dose of 160 mg taken orally once daily versus placebo.

Information about patient eligibility and enrollment can be obtained by calling the AFFIRM study hotline toll-free at +1 888 782-3256.

PRNewswire-FirstCall, 23 September 2009

DOC MOYAD
(Continued from page 6)

In September, Medivation, Inc. announced treatment of the first patient in a Phase 3 clinical trial of the investigational drug MDV3100 in advanced prostate cancer. Known as AFFIRM, the trial will evaluate the novel androgen receptor antagonist MDV3100 in men with castration-resistant prostate cancer who were previously treated with docetaxel-based chemotherapy.

“Late stage prostate cancer remains an obvious and large unmet clinical need,” said David Hung, MD, president and chief executive officer of Medivation. Our ultimate goal is to develop MDV3100 for the broadest possible spectrum of prostate cancer disease states. The first step is to develop this product candidate for patients with the most advanced disease and in greatest need.”

The randomized, placebo-controlled, double-blind, multi-national AFFIRM trial is expected to enroll approximately 1,200 patients at sites in the US, Canada, Europe, South America, Australia and South Africa. The primary endpoint of the trial is overall survival; secondary endpoints include progression-free survival, safety and tolerability. This trial will evaluate MDV3100 at a dose of 160 mg taken orally once daily versus placebo.

Information about patient eligibility and enrollment can be obtained by calling the AFFIRM study hotline toll-free at +1 888 782-3256.

PRNewswire-FirstCall, 23 September 2009

LETTER TO THE EDITOR

In the Sept. 2009 Special Issues Supplement of Us TOO HotSheet, there is an article by Charles Myers, MD, “The Prostate Cancer Screening Controversy,” in which he writes on page 3: “Pomegranate had a dramatic impact on prostate cancer progression in a well-designed Phase II trial. A randomized controlled trial is underway.”

Question:
Was the impact good or bad? Reason for my inquiry – I drink a lot of pomegranate juice.

Thank You in advance, R.J. Irvine

From the Editorial Team:
Mr. Irvine, we forwarded your question to Dr. Myers, and he provided the following response:
“Pomegranate slows the growth of prostate cancer recurrent after surgery or radiation. The juice is high in sugar and if you take more than 8 oz a day, the sugar load may become a problem. If you are diabetic or have other reasons to limit your sugar intake, pomegranate capsules can be used.”

If you have questions or want to comment on any articles published in the Us TOO HotSheet, please forward them to Tom Kirk at tom@ustoo.org.

DOC MOYAD
(Continued from page 6)