PROSTATE CANCER LINKED TO MOTHERS’ GENES

Female genetic material may predispose male offspring to disease

Can men inherit risk for a uniquely male disease from their moms?

New research raises that possibility. Scientists think they have found a gene that predisposes men to prostate cancer in parts of a cell that come exclusively from mothers, who obviously don’t have prostates.

The find gives scientists a different place to look for cancer genes, and it could help biologists better understand what causes prostate cancer, the most common type of tumor in America.

The work was reported at an American Association for Cancer Research meeting in Anaheim, CA in April.

Inherited risk

More than 99% of our genes are contained in the nucleus, but a very small number are in tiny structures containing mother’s genetic material.

(Continued on page 2)

VITAMIN D MAY HELP IN PROSTATE CANCER

Men dying from prostate cancer may be able to extend their lives, thanks to a potent form of vitamin D developed at Oregon Health & Science University.

A new study considered men who had advanced tumors growing despite surgery or radiation and subsequent drug treatment. Doctors now give such patients the chemotherapy docetaxel (Taxotere®), which lets them live for about 16 months, on average.

Adding the experimental vitamin pill DN-101 to that chemotherapy increased the average expectancy to roughly two years. A two-year survival “is the highest ever seen in a randomized study,” said Dr. Bruce Montgomery, a Seattle Cancer Care Alliance prostate cancer expert who was not involved in the research. "It clearly is a big step forward."

Although researchers know DN-101...

(Continued on page 3)

LONGER SCREENING INTERVALS DELAY PROSTATE CANCER DETECTION

Extending the prostate cancer screening interval to 2 or 4 years would substantially delay the detection of advanced prostate cancers, according to a report in the April issue of The Journal of Urology (Vol. 173, pp. 1116-20, 2005).

"Even though a relatively small percentage of men have rapidly rising PSA levels, they are the ones with life-threatening prostate cancer," Dr. William J. Catalona from Northwestern University, Chicago, told Reuters Health. "The widespread use of infrequent screening intervals could lead to delays in the detection of these potentially lethal cancers until the opportunity for cure is missed."

Dr. Catalona and colleagues used data from more than 18,000 men screened for prostate cancer at 6-month to 1-year intervals to deter...

(Continued on page 3)
In addition to the HotSheet, Us TOO offers a FREE e-mail based service called NEWS You Can Use sponsored by Sanofi-Aventis, providing updates on the latest prostate cancer related news. To subscribe or link to the archives, simply visit the Us TOO website www.ustoo.org.

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PHONE: (630) 795-1002 / FAX: (630) 795-1602
WEBSITE: WWW.USTOO.ORG

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US TOO EXHIBITS AT THE 2005 AUA MEETING

Jim Kiefert, Us TOO Chairman of the Board, (left) and Tom Kirk, Us TOO President & CEO, greet physicians and other visitors at the Us TOO booth at the American Urological Association (AUA) Annual Meeting, held in San Antonio, Texas on May 22 – 25, 2005.
**DELAY IN DETECTION**  
*(Continued from page 1)*

mine the potential delay in detection that could result from 2- and 4-year PSA screening intervals. A total of 377 (2.0%) of the subjects had prostate cancer diagnosed over 8 years of follow-up. Only 24% of the 1569 men who underwent biopsy were found to have cancer. 

PSA level at the time of prostate cancer detection was less than 2.6 ng/mL in 21% of men, 2.6 to 4.0 ng/mL in 57% of men, and over 4.0 ng/mL in only 20% of men, the authors report. 

Increasing the screening interval from 1 year to 2 years would have resulted in at least a 4-month delay in prostate cancer detection in 62% of the men, the researchers note. More than three quarters of the men (77%) would have experienced a mean delay of detection of 12 months with a 4-year interval. 

"Many of these diagnosed tumors had potentially aggressive histological phenotypes," the investigators write. "Infrequent screening may also delay the detection of prostate cancer in men with rapidly increasing PSA, who most likely would benefit from early diagnosis."

"Further careful study is indicated before recommending screening intervals longer than 1 year," Dr. Catalona concluded. 

*Reuters Health, 28 April 2005*

**BREAST CANCER DRUG COULD BENEFIT PROSTATE**

A new study gives encouraging signs that a hormonal drug used to fight breast cancer might help prevent abnormal prostate growths from turning into cancers. 

Men who took low doses of the drug for a year cut their chances of developing prostate cancer roughly in half, doctors reported at meeting of the American Society of Clinical Oncology (ASCO) in April. 

As many as 50,000 men each year are diagnosed with such growths, and then suffer constant worry and frequent biopsies to see whether cancer has developed. 

The drug is toremifene, sold as Acapodene for treating advanced breast cancer. It selectively blocks some of the effects of estrogen, a hormone men have but in much smaller quantities than women. 

For decades, prostate cancer prevention and treatment has focused on blocking the male hormone, testosterone. Targeting estrogen "opens up a new area," said the cancer society's medical director, Dr. Harmon Eyre. 

Men who have abnormal growths called prostatic intraepithelial neoplasia, or PIN, have about a 30% chance of developing prostate cancer within a year and about a 65% chance within two years. 

The study involved 514 men with the growths at 64 sites across the country who were given either fake pills or 20, 40 or 60 milligrams of toremifene for a year. Biopsies were done at six months and a year after treatment started. 

Cancer rates were similar among the groups at 6 months, possibly because initial biopsies missed some cases found on second biopsy. 

But after a year, 24.4% of those on the drug had developed cancer versus 31% of those on fake pills. 

That means that for every 100 patients who took the drug for a year, seven cancers were prevented, Price said. The benefit was greatest for those who took the lowest dose for a full year. Their cancer risk was 48% lower than men who didn't get the drug. 

Side effects were similar for those on the drug and those given fake pills: 1 to 4% reported headaches, hot flashes, fatigue, nausea, dry eye or problems with sex. 

A larger study testing the lowest dose is enrolling 1,500 men now. If it confirms that the drug can prevent prostate cancer, it would be "an important step" because there's little agreement now about how to treat the disease once it's found, said Dr. Peter Greenwald, director of cancer prevention at the National Cancer Institute. 

*The Associated Press, 14 May 2005*

**VITAMIN D MAY HELP**  
*(Continued from page 1)*

101 added at least seven months to the average survival, they can't yet calculate the new median life expectancy, because half the men who took DN-101 in the study are still alive. The treatment "has a lot of guys I see every day getting a meaningful chunk of extra time, without any extra side effect," said Dr. Tomasz Beer, the OHSU Cancer Institute scientist who helped develop the drug. 

The study followed 250 men, randomly assigned to receive either docetaxel alone or with DN-101. 

Among the 125 men who used the chemo drug alone, the median survival was 16.4 months. The median survival among men who also took DN-101 is an additional 7.1 months, and counting. The 250-patient study indicates that the pills extend life, but a larger study with about 600 men is needed to prove DN-101 is ready for market, Beer said. 

When a larger study might start is unclear. Officials with DN-101's manufacturer, Novacea Inc., want to meet with the FDA before deciding how to proceed, CEO Brad Goodwin said. Montgomery said the DN-101 study is part of a push to find safe drugs that make cancers more susceptible chemotherapy. 

If DN-101 makes it to market, OHSU stands to profit. They licensed the drug to Novacea in 2002, getting payments including stock in the privately held company and royalties on any sales of the drug. 

*The Associated Press, 17 May 2005*
RESEARCHERS IDENTIFY 'DEATH FROM CANCER' GENES

A set of 11 genes -- dubbed the "death from cancer signature" -- can identify people at the highest risk of dying from cancer, according to research presented at the 2005 meeting of the American Association for Cancer Research (AACR) held in Anaheim, CA this April.

The genes are associated with cell multiplication and renewal in both stem cells and 10 different types of cancer, according to a study by a team from the Sidney Kimmel Cancer Center in San Diego, CA.

The 11 genes will alert physicians to those patients who are at much higher risk for metastatic complications and more severe cancer, said Dr. Gennadi Glinksy, associate professor at the cancer center.

The gene panel can also identify patients least likely to respond to conventional cancer therapies. Identifying these patients earlier can direct them to more aggressive, customized treatments or experimental clinical trials, Glinksy said.

Science – Reuters, 19 April 2005

STUDY BACKS PROSTATE CANCER SURGERY BEFORE AGE 65

A landmark study of one of the most agonizing decisions faced by men with early prostate cancer -- Should I have surgery? Or should I wait and see if it spreads? -- found that for those under 65, operating clearly saves lives, cutting the death rate by more than half.

About 9.5% of those who got surgery and 15% of those in the WW group died within 10 years of diagnosis. But all the benefit appeared to be among men under 65, where the WW group had more than double the death rate of the surgery group.

The study's lead author, Dr. Anna Bill-Axelson of University Hospital in Uppsala, Sweden, said urologists who favor surgery over WW will now be able to say that, in younger men, "there is finally proof it saves lives."

About 60,000 Americans undergo prostate cancer surgery each year. A man's age, his overall health, how advanced the cancer is and how aggressive it appears under the microscope are among the factors that doctors use in deciding whether to recommend surgery.

But recent research has shown that even slow-growing tumors can become more lethal after 15 years.

The latest study began in 1989. Researchers at 14 hospitals in Sweden, Finland and Iceland studied 695 men, most with localized tumors and were considered moderately aggressive. Their age averaged just under 65 years. Half got surgery; the other half had WW.

Brooks said longer-term research is needed to determine how the results apply in this country.

The Associated Press, 12 May 2005

STUDY FINDS PROSTATE CANCER IN 25% OF HIGH-RISK MEN WITH 'NORMAL' PSA LEVELS

Men at high risk of developing prostate cancer should undergo aggressive screening for the disease. That is the recommendation following a Fox Chase Cancer Center study of 520 men at high-risk of developing prostate cancer in which 25% were diagnosed with the disease despite having a low PSA. The findings were presented at the American Society of Clinical Oncology 41st Annual Meeting held in Orlando, FL in May 2005.

"This study demonstrates that we can find cancer earlier in high-risk men if we use more aggressive screening criteria," said Andre Konski, M.D., clinical director of the Prostate Cancer Risk Assessment Program at Fox Chase and lead investigator of the study. "Men at high risk of prostate cancer are more likely to develop the disease at a younger age. Catching the cancer early before it has spread is critical to curative treatment."

This report detailed the results of a study involving the first 520 men enrolled in Fox Chase's Prostate Cancer Risk Assessment Program between 1996 and 2004 (200 Caucasians, 315 African-Americans and five others). African-American men and men with a family history of prostate cancer who are between the ages of 35 and 69 are eligible to enroll in the Prostate Cancer Risk Assessment Program. Caucasian men testing positive for the BRAC1 gene are also eligible.

"Our study criteria dictated that men with an abnormal digital rectal exam and a PSA level between 2 and 4 would receive a biopsy," explained Konski. "While an abnormal digital rectal exam could trigger a physician's concern about the possible presence of cancer, the
HIGH-RISK MEN
(Continued from page 4)

low PSA level would not usually raise suspicions. A PSA level between 2 and 4 would not warrant a biopsy according to traditional screening guidelines." Of the 520 men, a total of 75 men (44 African-American and 31 Caucasian) underwent 101 biopsies. The median age at biopsy was 56 (37 to 73). The median PSA at biopsy was 3.5 (0.4-53.6 ng/ml).

"We found prostate cancers in 45 percent of these men," said Kon-ski. "Twenty-six percent of these men had a Gleason score of seven or higher, indicating aggressive cancers. What's more surprising is that 25 percent of the men who were diagnosed had a PSA of 2.5 or lower." This PSA level falls below the new guidelines adopted last year by the National Comprehensive Cancer Network and the American Urological Association, suggesting biopsy when PSA levels exceed 2.5.

Men's Health News, 15 May 2005

LOVE BATTLES PROSTATE CANCER

Having a supportive partner greatly improves quality of life (QOL) for men with prostate cancer, a new study finds.

Researchers at the University of California, Los Angeles, tracked the ongoing health of 291 prostate cancer patients and found that those in a partnered relationship reported much better psychosocial and spiritual health and fewer prostate cancer and general cancer-related problems than single men. Men in relationships were also better able to tolerate their disease- and treatment-related symptoms, according to the study, which is scheduled to appear in the July 1, 2005 issue of Cancer.

Previous research has shown that a cancer patient's QOL can affect survival and that improved QOL may actually extend survival. The study authors noted that only 13% of prostate cancer patients attend support groups, perhaps because personal relationships serve as an alternative.

In light of the apparent positive impact that a close relationship can have on QOL, "clinicians caring for prostate cancer patients need to address coping and social support mechanisms in order to encourage the beneficial aspects of partnership and overcome the detrimental effects of being single," the study authors wrote.

Health Day News, 25 May 2005

GLEASON PATTERN HELPS GRADE PROSTATE CANCER

Following radical prostatectomy, the use of the combined percentage of Gleason patterns 4 and 5 appears to be the best predictor of cancer progression, according to Indianapolis-based researchers.

Dr. Cheng and colleagues at Indiana University School of Medicine examined specimens from 364 patients who had undergone radical prostatectomy. None had received preoperative androgen therapy.

Analyzing the percentages of Gleason patterns 4 and 5, Gleason score, preoperative PSA and other factors, the team found that the combined percentages of Gleason patterns 4 and 5 and total tumor volume were significant predictors of PSA recurrence (p < 0.0001).

Presence of high-grade elements may dictate the biologic behavior of tumors, the investigators note in the May 1st issue of the Journal of Clinical Oncology (Vol. 23, pp. 2911-17, 2005). Dr. Cheng noted, "the worst cancer grade is most closely linked to the biological aggressiveness of prostate cancer."

Investigators established that the combined percentages of Gleason patterns 4 and 5 are superior to conventional Gleason score in identifying patients at increased risk.

They recommend, "The amount of high-grade cancer in a prostatectomy specimen should be taken into account in therapeutic decision making and assessment of patient prognosis."

Reuters Health, 3 June 2005

TESTOSTERONE STAYS LOW AFTER STOPPING HORMONE THERAPY

In prostate cancer patients found to be osteoporotic while receiving luteinizing hormone-releasing hormone analogues (LHRH-A), stopping therapy does not lead to a rapid recovery of testosterone levels, according to UK researchers.

Lead investigator Dr. Robin Weston explained, "our study demonstrates prolonged testosterone suppression after discontinuing LHRH-A in osteoporotic patients with prostate cancer."

In the April issue of BJU International (Vol. 95, pp. 776-9, 2005), Dr. Weston and colleagues at Arrowe Park Hospital, Liverpool, report their findings in 15 such patients shown to be osteoporotic after a year or more of LHRH-A therapy. After cessation of LHRH-A, the time to initial testosterone detection ranged from 6 to 22 months. Six patients achieved normal testosterone after a mean of 17.5 months.

In the year after stopping the therapy, mean bone mineral density (BMD) fell by 7.2%.

"We recognize that LH-RH analogues and other androgen ablative techniques are very effective in controlling prostate cancer," concluded Dr. Weston. "However, we would advocate the monitoring of BMD, which is not currently standard urological practice, to avoid the morbidity and mortality associated with osteoporotic fractures."

Reuters Health, 19 May 2005
Salvage surgery should be considered in well-selected patients who have persistent prostate cancer after undergoing definitive radiotherapy, investigators contend in a report in the April issue of The Journal of Urology (Vol. 174, pp. 1156-60).

Salvage surgery for prostate cancer that recurs after radiotherapy.

"We have long disagreed with the reluctant use of salvage surgery in well-selected patients," write Dr. John F. Ward from the Naval Medical Center in Portsmouth, Virginia and colleagues.

They report contemporary outcomes with salvage surgery in 199 patients with biopsy proven prostate cancer following definitive radiotherapy, including 138 who underwent retropubic prostatectomy and 61 who underwent cystoprostatectomy (CP).

Overall 10-year cancer-specific survival for all patients was 65%, they report. The mean progression-free and cancer-specific survival in all patients following surgery was 7.8 and 12.2 years, respectively.

Patients who underwent retropubic prostatectomy fared better overall than those who underwent CP. The 10-year cancer-specific survival was 77% for retropubic prostatectomy versus 38% for CP, and median progression-free survival was 8.7 years versus 4.4 years, respectively.

Gleason score, tumor ploidy, and pathological stage of the excised tumor were significant predictors of progression-free survival and cancer-specific survival. The preoperative serum PSA, on the other hand, has "little prognostic value" and, in some cases, "may be counterintuitive," they found.

The data also show that morbidity rates, including continence, "moderately improved with time." Urinary continence, defined as needing 0 pads, improved from 43% to 56% following salvage surgery, "with an additional 20% requiring 1 or fewer pads daily," the researchers report.

The most common complications -- urinary extravasation and bladder neck contracture -- occurred in 15% and 22% of patients, respectively.

Salvage surgery following initial treatment of localized prostate cancer with radiotherapy is "a feasible and viable option for a growing number of young healthy men," they conclude.

Men with life expectancy of 10 years or more and localized tumors receptive to retropubic prostatectomy are most likely to benefit from salvage surgery, they say. This series of patients, the authors add, could serve as a contemporary benchmark against which newer treatments can be compared.

Reuter Health, 5 May 2005

Drug Giants Fail to Name Compounds in Trial Database

Critics charge that negative results are deliberately obscured.

An international group of medical editors is challenging several leading pharmaceutical companies, saying that their reporting of clinical trials is deliberately incomplete.

The International Committee of Medical Journal Editors made their complaint in an editorial in The New England Journal of Medicine, published online on May 23, 2005. They argue that leading pharmaceutical companies are obeying the letter but not the spirit of a 1997 law that requires the public registration of ongoing trials involving serious or life-threatening illnesses.

The government-maintained registry, www.clinicaltrials.gov, is intended to help patients find information about clinical trials. But the editors say that drug firms are inserting a "meaningless phrase" instead of the names of drugs, so patients aren't getting the full picture.

The New England journal's editor-in-chief, Jeffrey Drazen, says that Merck, GlaxoSmithKline (GSK) and Pfizer in particular "didn't meet the sniff test" in a review conducted early this month by Deborah Zarin, the database's director. Zarin found that specific drug names were missing in scores of trials, which used the phrase "investigational drug" to describe their products. Drugs weren't named in 36% of 75 Pfizer studies reviewed, in 53% of 55 GSK trials, and in 90% of 132 Merck trials.

The drug companies insist that they are trying to make the reporting as transparent as possible. They claim they are complying with the law, which does not explicitly require companies to name drugs, but asks them to describe the "intervention" used. "We think we've made big strides in improving the transparency of clinical data. And we will continue to do so," says GSK spokesman Rick Koenig.

Pfizer's spokeswoman Betsy Raymond says her company withholds the names of certain drugs for competitive reasons. Merck did not return a call seeking comment.

The editors' committee wants to see trials being publicly registered in a meaningful way, partly so that negative results about particular drugs can be accessed. They have defined a list of minimum criteria that companies must provide. And this summer, the editors will start refusing to publish trials that do not register this information. The editorial "is a message that we are paying close attention," says Drazen.

Drug_Discovery@Nature.com
3 June 2005
US TOO Featured Resources

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   - **Circles of Love Music CD** – This original collection of upbeat and inspirational songs was written to celebrate the love and support between the patient and his companions and family members. Contributing artists include Soozie Tyrell of the E Street Band, Alan Glass (who has written hits for Aretha Franklin, Earth, Wind and Fire, Kenny G and others), Jerry Peters (who has written for Luther Vandross and others), country artist Deborah Allen, and folk artist Kat Eggleston. 12 songs including pop, R&B, soul, country, folk and dance. Also available separately for $15.00 includes S+H.
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   - **What You Need to Know About Prostate Cancer**
   - **“Life after Cancer Treatment” Resource and Referral Guide** – excerpt from NCI

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   - **Know Your Options** – from Us TOO and the National Cancer Institute (NCI)
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**Drug Helps Target Prostate Biopsies**

It may spare men repeat procedures, researchers say.

The drug dutasteride, currently used to treat enlarged prostate, may improve the accuracy of prostate biopsies, researchers report. It may even help doctors reduce the number of biopsies needed for diagnosis in patients suspected of having prostate cancer.

"If cancer is there and we find it on the first biopsy, these men can be diagnosed sooner and be spared from having to undergo a repeat biopsy," said study lead author Dr. Elizabeth Ives, a research fellow at Thomas Jefferson University Hospital in Philadelphia, PA.

The study involved 11 patients who took dutasteride before undergoing ultrasound-guided prostate biopsy.

The drug works to suppress blood flow in benign tissue in the prostate. This enables radiologists using ultrasound to more accurately map out potentially malignant tissues.

Based on blood flow reduction, one patient had a biopsy a week after taking the drug, eight patients had biopsies two weeks after taking the drug, and two patients had biopsies three weeks after taking the drug.

Up to four targeted biopsies, as well as six standard biopsies, were performed on each patient.

The researchers report that the targeted biopsies detected prostate cancer in four of the men, while standard biopsy detected three of the four cancers.

"If we can reduce the benign blood flow, we're better able to see where the cancer tissue is located, and detect cancer if it is present," Ives said.

She noted that, currently, about 10 percent of men who have a prostate biopsy require a subsequent biopsy.

The study was presented at the annual meeting of the American Roentgen Ray Society in May.

*HealthDay News*, 19 May 2005

**Active Surveillance Obviates Treatment for Some Men With Prostate Cancer**

Active surveillance is a feasible approach to managing favorable, early prostate cancer, British researchers report. Active surveillance differs from "watchful waiting" by applying radical treatment for biochemical progression, rather than palliation for symptomatic progression.

Dr. Chris C. Parker and colleagues suggest in the May issue of BJU International (Vol. 95, pp. 956-60) that "the challenge of managing early prostate cancer is to distinguish patients with clinically relevant cancers from those whose 'disease' is destined merely to be an incidental histological phenomenon."

Dr. Parker's group followed 80 patients with early prostate cancer (clinical stage T1-T2, initial PSA 20 ng/mL or less and Gleason score of 7 or less; median age 70.5 years). Surveillance included serial PSA testing and digital rectal exams (DRE). After a median follow-up of 42 months, 64 men were still being followed by active surveillance, while 11 underwent radical treatment and 5 had died. None of the deaths were due to prostate cancer and there was no evidence of metastatic disease.

The investigators note that median PSA doubling time was 12 years, which "suggests an indolent course of disease in most patients."

"While the long-term prostate cancer mortality associated with (active surveillance) in young, fit men with favorable-risk early prostate cancer is unknown, in the worst possible case it will be as good as that associated with (watchful waiting) in such patients," Dr. Parker's group maintains.

*Reuters Health*, 30 May 2005

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