East Lancashire Prostate Cancer Support Group Newsletter

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What's Inside

"New prostate cancer test shows promise"

"Thousands of lives could be saved by a new cancer test," the *Daily Express* reported today. It said that the new test for prostate cancer "detects twice as many cases as the current method".

This story is based on a study in 288 men with and without prostate cancer, which assessed whether a urine test that measures levels of a protein called EN2 could detect the disease. Cases of prostate cancer had been confirmed through biopsy. The study found that testing for the protein could accurately identify 66% of men with prostate cancer, and correctly rule out the disease in almost 90% of men without the disease.

This study has identified a potential new marker for prostate cancer. The results are promising, but the research is at an early stage, and much further study is needed. The performance of the test will need to be confirmed in larger samples of men from the general population. After this, studies would need to examine how the test affects outcomes such as the numbers of men dying from prostate cancer, and those having unnecessary biopsies. Newspaper estimates that the test will be ready within months are probably overly optimistic.

Where did the story come from?

The study was carried out by researchers froY-our health, your choicesm the University of Surrey and other research centres in the UK. It was funded by Cancer Research UK and the Prostate Project Foundation. The authors were also supported by The University of Cambridge, Hutchison Whampoa Limited, the NIHR Cambridge Biomedical Research Center, the Department of Health, and the Medical Research Council.

The study was published in the peer-reviewed medical journal *Clinical Cancer Research*.

The *Daily Express*, *Daily Mail*, *Mirror*, and *The Daily Telegraph* covered this research. The papers vary in their predictions of how soon the test might be available. The *Mail* suggests it could be in general use within months, while the *Telegraph* claims "within 18 months". The *Express* suggests that the test could cost less than £100. However, the test's performance is still being assessed in the laboratory. It is too early to say if it is reliable and accurate enough to be put

What kind of research was this?

This laboratory research investigated whether testing for a protein called engrailed-2 (EN2) might detect prostate cancer. This protein belongs to a family of proteins that are usually produced in cells in the embryo but are also switched back on in cancerous cells. The researchers wanted to test whether this protein was produced by prostate cancer cells, and whether it might be a good marker for prostate cancer.

Currently, prostate cancer is detected by measuring the levels of prostate specific antigen (PSA) in the blood. PSA levels are also used to monitor the effects of treatment. PSA is made by normal prostate cells as well as cancerous prostate cells, and men vary in their natural levels of PSA. Raised PSA levels may indicate the presence of prostate cancer, but can also occur in men with non-cancerous enlargement of the prostate. This means that the PSA test misses some cancers (false negatives), and it may suggest that cancer is present in some men who do not have the disease (false positives). The performance of the test depends on the level of PSA selected as the "threshold" for indicating the possible presence of cancer. It also depends on the population tested. Different studies have reported that the PSA test detects between 15% and 44% of prostate cancers.

Therefore, researchers are looking into whether they can develop a better test for prostate cancer. This study aimed to test the diagnostic accuracy of the EN2 urine test (its sensitivity and specificity) and to define a useful threshold for the test, i.e. what a 'normal' and 'abnormal' level for the protein might be.

What did the research involve?

The researchers first tested whether the EN2 protein was produced by prostate cancer cells and non-cancerous prostate cells grown in the laboratory. They also tested for EN2 in normal and cancerous prostate tissue samples from men with prostate cancers. Prostate tissue samples from men with the non-cancerous condition "benign prostatic hyperplasia" were also tested, as were tissue samples from men with the pre-cancerous condition "high-grade prostatic intraepithelial neoplasia".

In the next part of their study, the researchers compared the levels of EN2 in urine samples from 82 men with biopsy-confirmed prostate cancer, with the levels in 102 men without the disease.

Some of the urine samples were collected from men who had been referred to their specialist oro-oncology clinic. These men were referred because they had urinary symptoms that could be a sign of prostate cancer, or had no symptoms but were concerned that they might have prostate cancer (due to a family history of prostate cancer, for example) or had an abnormal PSA test. These men had been referred for testing to determine whether they did or did not have prostate cancer. Of these men, 82 had prostate cancer confirmed on biopsy. Fifty-eight had negative biopsies and were included in the control group of men without prostate cancer.

The researchers also collected urine samples from additional control men aged over 40, who had normal levels of PSA (below 2.5 nanogrammes per mL). These men either had blood in their urine but had no malignancies in their urinary system (urothelial malignancy) detected on testing (17 men), or they had no symptoms or family history of prostate cancer (27 men). The researchers also had urine samples from 10 men with the pre-cancerous condition "high grade prostatic intraepithelial neoplasia".

Men already being treated for known prostate cancer, or with any known cancer in the past 10 years, or with a urinary tract infection, were not eligible to take part in the study. Urine samples were collected from the first passage of urine of the day. They were taken before any biopsies were performed or any hormone therapy received, and at least 24 hours after any digital rectal examination.

The researchers testing the urine samples did not know which men had cancer. Blood samples for PSA testing were also collected before the urine samples were collected. The researchers looked at whether the levels of EN2 in a man's urine were related to the levels of PSA in his blood.

To confirm their results, another research centre tested urine from a further 81 patients with prostate cancer and 13 men without prostate cancer.

What were the basic results?

The researchers found that the EN2 protein was being made and secreted by prostate cancer cells grown in the laboratory, but not in normal prostate cells.

They also found EN2 protein in 92% of 184 prostate cancer tissue samples, but in none of the 20 normal prostate tissue samples. The EN2 protein was not detected in prostate tissue samples from men with "benign prostatic hyperplasia", nor in prostate tissue samples from men with "high grade prostatic intraepithelial neoplasia".

The urine tests showed that 66% of the men with prostate cancer had EN2 protein in their urine. About 12% of men without prostate cancer had EN2 protein in their urine. The researchers report that using a cut-off value of 42.5 ng/mL of EN2 protein in the urine appeared to be optimal, giving a sensitivity of 66% and specificity of almost 90%. This suggests that in combination with other tests it may be useful at ruling out disease in normal men and confirming disease in those with cancer.

On average, levels of EN2 protein in the urine of men with prostate cancer were 10.4 times higher than those in men without prostate cancer. Independent testing of urine samples from another 94 men at another laboratory found that 58% of the prostate cancer patients in this sample had EN protein in their urine, compared with 15% of control men without the disease.

Of the 10 men with the pre-cancerous condition "high grade prostatic intraepithelial neoplasia", three had EN2 protein in their urine. A second biopsy taken within six months of the first found that two of these three men had prostate cancer.

The level of EN2 in the

How did the researchers interpret the results?

The researchers concluded that EN2 protein in the urine is a good candidate marker for the presence of prostate cancer. They say that a larger study across multiple centres "to further evaluate the diagnostic potential of EN2 is justified".

Conclusion

This study has identified a potential new marker for prostate cancer. This research is at an early stage, and much further research is needed. The test's accuracy will need to be confirmed in larger samples of men from non-specialist settings to show how effective it is at screening for prostate cancer in the general population. After this, studies would need to examine how the test affects outcomes such as the numbers of men dying from prostate cancer, and those having unnecessary biopsies.

Though promising, these findings also need to be considered with some pragmatism. Even if the EN2 test performs well in larger scale testing, the test would not necessarily replace PSA testing. The authors suggest that the tests could be used together in prostate cancer diagnosis. Also, if the combined tests did indicate that cancer might be present, the results would still need confirmation by prostate biopsy.

There is a need for improved prostate cancer tests, particularly those that can detect early prostate cancer accurately. There is a lot of ongoing research in this area. More research is needed to see how well these newer tests perform when compared with current tests, and which of them performs the best

http://www.nhs.uk/news/2011/03March/Pages/new-prostate-cancer-test-studied.aspx

From Left to Right Hazel Goulding (Treasurer) Leon D Wright (IT Admin) Stuart Marshall (Secretary) Steve Laird (Vice Chairman) Dave Riley (Chairman)

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We are a group of local people who know about prostate cancer. We are a friendly organisation dedicated to offering support to men who have had or who are experiencing the effects of this potentially life threatening disease.

The East Lanc's Prostate Cancer Support Group offers a place for free exchange of information and help for local men and their supporters (family and friends) who may be affected by this increasingly common form of male cancer.

At each meeting we strive to be a happy, supportive and upbeat group of people; encouraging open discussion on what can be a very difficult and perhaps for some an embarrassing subject. We have lively, informative, interactive, sharing and above all supportive meetings.

"£50,000 Appeal to Buy New Prostate Cancer Scanner for Burnley"

Chair of East Lancs Prostrate Cancer Support Group Dave Riley, Stuart Marshall (secretary), Burnley MP Gordon Birtwistle, Tracy Cooke (clinical nurse specialist neurology) and Mr Mohan Pillai (consultant neurologist) with the old scanner.

Published on 30/04/2013 10:47

Burnley MP Gordon Birtwistle is leading a £50,000 fund-raising charge to replace a prostate cancer scanner he helped fund a decade ago.

The scanner, which has saved countless lives during its residency at Burnley General Hospital, has become outdated and Mr Birtwistle has called upon the Burnley Express and the town's residents to get behind this latest campaign.

"This machine has scanned thousands upon thousands of patients, it's been invaluable to the hospital and the people of the area," he said. "Like anything though, it's 10 years old now and there is better technology out there. We want to raise £50,000 to replace this scanner but we don't want to stop there. Anything else we raise will go towards buying portable scanners to use within the community.

"It doesn't just detect prostate cancer but also bladder, kidney and testicular cancer. It has saved hundreds of lives and a new one would continue to do the same."

Mr Birtwistle, along with the efforts of his wife Kathleen, managed to raise £60,000 during their year as the borough's Mayor and Mayoress in 2002/2003.

The appeal was inspired by his father, who died from prostrate cancer.

"After my dad died from prostate cancer I went to the urology department and asked them what we could do to help.

"They said they wanted a new scanner but didn't have enough money to buy it so that is when we started the appeal. At the time it was the most advanced scanner of its kind in the world.

"We're going to be raising funds for 15 months so I'm sure we can reach the target."

Anyone who can help the campaign or companies willing to hold fund-raising events can contact the Burnley Express or email gordon.birtwistle.mp@parliament.uk.

Related Articles

Mayor's Fund Gift Aids Cancer Fight

A REVOLUTIONARY piece of equipment which will help in the diagnosis of prostate and bladder cancer has been presented to consultants at Burnley General Hospital.

We've smashed 25,000 target!

Mayors Scanner Appeal to continue until next May!

SCANNER APPEAL - 50,000 reasons to say thanks

WEVE done it! With just days to spare, weve reached, doubled and surpassed all our expectations and raised more than 50,000 to buy a life-saving scanner to detect prostate and testicular cancer.

(Article from pendletoday.co.uk)

ELPCSG

Promoting & Collecting for the Prostae Scanner Appeal in the Blackburn Shopping Precinct on Friday 24th May 2013 From Left to Right Stuart Marshall, John Goulding, Moira & Eddie Griffiths & Graham Pountain.

FDA approves new drug for advanced prostate cancer

Xofigo approved three months ahead of schedule under priority review program

The U.S. Food and Drug Administration today approved Xofigo (radium Ra 223 dichloride) to treat men with symptomatic late-stage (metastatic) castration-resistant prostate cancer that has spread to bones but not to other organs. It is intended for men whose cancer has spread after receiving medical or surgical therapy to lower testosterone.

Prostate cancer forms in a gland in the male reproductive system found below the bladder and in front of the rectum. The male sex hormone testosterone stimulates the prostate tumors to grow. According to the National Cancer Institute, an estimated 238,590 men will be diagnosed with prostate cancer and 29,720 will die from the disease in 2013.

Xofigo is being approved more than three months ahead of the product's prescription drug user fee goal date of Aug. 14, 2013, the date the agency was scheduled to complete review of the drug application. The FDA reviewed Xofigo under the agency's priority review program, which provides for an expedited review of drugs that appear to provide safe and effective therapy when no satisfactory alternative therapy exists, or offer significant improvement compared to marketed products.

"Xofigo binds with minerals in the bone to deliver radiation directly to bone tumors, limiting the damage to the surrounding normal tissues," said Richard Pazdur, M.D., director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research. "Xofigo is the second prostate cancer drug approved by the FDA in the past year that demonstrates an ability to extend the survival of men with metastatic prostate cancer."

In August 2012, the FDA approved Xtandi to treat men with metastatic castration-resistant prostate cancer that has spread or recurred, even with medical or surgical therapy to minimize testosterone. Xtandi is approved for patients who have previously been treated the chemotherapy drug docetaxel.

Xofigo's safety and effectiveness were evaluated in a single clinical trial of 809 men with symptomatic castration-resistant prostate cancer that spread to bones but not to other organs. Patients were randomly assigned to receive Xofigo or a placebo plus best standard of care[2].

The study was designed to measure overall survival. Results from a pre-planned interim analysis showed men receiving Xofigo lived a median of 14 months compared to a median of 11.2 months for men receiving placebo. An exploratory updated analysis conducted later in the trial confirmed Xofigo's ability to ex-

tend overall survival.

The most common side effects reported during clinical trials in men receiving Xofigo were nausea, diarrhea, vomiting and swelling of the leg, ankle or foot. The most common abnormalities detected during blood testing included low levels of red blood cells (anemia), lymphocytes (lymphocytopenia), white blood cells (leukopenia), platelets (thrombocytopenia) and infection-fighting white blood cells (neutropenia).

Xofigo is marketed by Wayne, N.J.-based Bayer Pharmaceuticals. Xtandi is co-marketed by Astellas Pharma U.S., Inc. of Northbrook, Ill., and Medivation, Inc. of San Francisco, Calif.

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