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HOPKINS RESEARCHERS FIND A BETTER BLOOD TEST FOR PROSTATE CANCER

- EPCA-2 testing curtails unnecessary biopsies and can differentiate disease that has spread outside the prostate from cancer within the prostate, Hopkins team says

New studies of a blood protein recently identified at Johns Hopkins, early prostate cancer antigen-2 (EPCA-2), may change the way men are screened for prostate cancer - a disease that kills tens of thousands of men every year.

Current standards of screening and testing for prostate cancer focus on the blood protein prostate-specific antigen (PSA) along with a digital rectal examination. Men who have more than 2.5 nanograms per milliliter of PSA are considered at risk for prostate cancer. However, PSA testing often erroneously highlights noncancerous conditions (false positives) and can miss some cases of cancer (false negatives), according to Robert H. Getzenberg, Ph.D., professor of urology and director of research at the James Buchanan Brady Urological Institute at The Johns Hopkins University School of Medicine.

Due to elevated PSA levels, approximately 1.6 million men undergo prostatic biopsies in the United States annually, and roughly 80 percent of these men have negative results, according to Getzenberg, lead author of the study. He says that of the entire population of men in the United States who have been tested for PSA, an estimated 25 million have elevated PSA levels and a biopsy of the prostate that did not reveal any prostate cancer. Conversely, roughly 15 percent of men with prostate cancer go undetected because their PSA levels are below the cutoff level, according to Getzenberg.

In a study published in the April issue of the journal *Urology*, Getzenberg and a team of Hopkins researchers introduce evidence in support of EPCA-2 testing as a more accurate way to identify cancer in the prostate.

“A blood test based on EPCA-2 may greatly improve our ability to accurately detect prostate cancer early and minimize the number of false positives, therefore lowering the number of unnecessary biopsies,” says Getzenberg. “In addition, this is the first time we have a test that effectively distinguishes between men with cancer confined to the prostate and those whose disease has spread outside of the gland.”

Getzenberg and his team measured EPCA-2 levels in the blood of 330 Hopkins patients separated into several groups: men with normal PSA levels and no evidence of disease; men with elevated PSA levels but who had negative biopsies, men with a common noncancerous prostate condition known as benign prostatic hypertrophy (BPH) who did not receive biopsies for prostate cancer, men with prostate cancer but with normal PSA levels, men with prostate cancer confined to the prostate, men with prostate cancer that had invaded outside of the gland at the time of surgery, and a diverse group of patients with benign conditions of other organs as well as individuals with other cancer types.

Patients with an EPCA-2 cutoff level of 30 nanograms per milliliters or higher were considered to be at risk for prostate cancer. This cutoff was based on a pilot study of 30 blood samples, which was then applied throughout the larger study.

Results showed that the EPCA-2 test was negative in 97 percent of the patients who did not have prostate cancer. Men with no evidence of disease (regardless of their PSA levels), as well as the control group of patients with other cancer types and benign conditions, all had EPCA-2 levels below the cutoff.

In contrast, in a multi-institutional study published in 2003 in the Journal of Urology, PSA levels between 4 and 10 nanograms per milliliter were shown to be accurate in identifying patients without prostate cancer only 19 percent of the time.

In addition, 77 percent of the BPH patients had a level of EPCA-2 lower than the cutoff point. Getzenberg says this is well within the likely percentage range of BPH patients who are prostate-cancer free. He says this result was encouraging since BPH is often associated with elevated PSA levels, leading to misdiagnosis and unnecessary biopsies.

When it came to correctly identifying patients with prostate cancer, EPCA-2 levels at or above the cutoff were detected in 90 percent of the men with organ-confined prostate cancer and in 98 percent of the men with disease outside the prostate. Overall, in this study, the EPCA-2 test detected 94 percent of the men with prostate cancer.

Results of the study also revealed that EPCA-2 levels were significantly higher in patients whose cancers had spread outside the prostate compared to those with disease confided to the gland. EPCA-2 was dramatically better at separating these groups than were PSA levels, according to Getzenberg.

“This is important, since cancer that has spread outside the prostate is more deadly, which makes it even more crucial to have a tool that detects it early,” says Getzenberg.

An optimized version of the assay, evaluated in a separate set of 55 patients, supported the earlier findings. Finally, the EPCA-2 test identified 78 percent of the men with prostate cancer in the group with PSA levels below the accepted cutoff level of 2.5 nanograms per milliliter. According to their PSA levels, these were all “healthy men,” but EPCA-2 was able to show that they had prostate cancer.

EPCA-2 is the second prostate-cancer marker identified by Getzenberg and his team that has outperformed PSA. Last year, they discovered an unrelated, tissue-based test, EPCA-1, that also proved effective at identifying prostate cancer. The only commonality between these markers is that they were discovered using the same approach. Getzenberg says the efficacy of EPCA-1 as a test of biopsy samples is currently being evaluated.

Prostate cancer is the most common type of cancer found in American men. The American Cancer Society estimates that there will be approximately 218,890 new cases of prostate cancer in the United States in 2007, and 27,050 men will die of this disease.

Getzenberg says larger clinical trials for EPCA-2 are planned that could make this test available to the public in approximately 18 months.

Funding for the study was provided by the National Cancer Institute of the National Institutes of Health, and Onconome Inc.

Under a licensing agreement between Onconome Inc. and the University of Pittsburgh, Getzenberg is entitled to a share of royalty received by the University on sales of products described in this manuscript. Getzenberg also is a paid consultant to Onconome Inc., which has a licensing agreement with The Johns Hopkins University covering EPCA-2 and related technologies. The terms of this arrangement are being managed by The Johns Hopkins University in accordance with its conflict of interest policies.

Other researchers from the Brady Urology Institute at Johns Hopkins who contributed to this study are Eddy S. Leman, Ph.D.; Department of Urology Chairman Alan W. Partin, M.D., Ph.D.; Daniel W. Chan, Ph.D.; Bruce J. Trock, Ph. D.; Lori J. Sokoll, Ph.D.; Leslie Mangold, and Grant W. Cannon.

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