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Prostate Cancer Urine Test Predicts Biopsy Test Results

March 8, 2010 — A urine test that detects prostate cancer cells can help predict whether a prostate biopsy will reveal cancer, according to research presented at the 2010 Genitourinary Cancer Symposium (GUCS) in San Francisco, California.

The urine test, known as the PCA3 (prostate cancer gene 3) assay, measures a gene that is overexpressed in prostate cancer. It is approved in Europe and marketed as *Progensia*. Its uses include guiding biopsy decisions in men who have an elevated prostate-specific antigen (PSA) level but who also have one or more prior negative biopsy results, despite the PSA results. The assay has not yet been submitted for Food and Drug Administration approval in the United States.

In the new study of 1072 men, those who had higher PCA3 scores were more likely to have a positive biopsy result and thus prostate cancer, said Jack Groskopf, PhD, at a meeting press conference. He is director of research and development in cancer diagnostics at Gen-Probe Incorporated, the manufacturer of the PCA3 test. "PCA3 provides direct detection of prostate cancer cells," said Dr Groskopf.

"PCA3 is overexpressed in more than 90% of prostate cancers," said Dr. Groskopf. Unlike PSA, it is not expressed in other prostate disorders, such as prostatitis or benign prostatic hyperplasia, he added.

Results from the new study also indicated that higher PCA3 scores were associated with a higher biopsy Gleason score (>7), Dr. Groskopf added. "This is evidence that PCA3 may help identify aggressive cancers," he commented. "Most prostate biopsies are negative," pointed out Dr. Groskopf. However, in men who have a continuously elevated PSA level, there may be a need to undergo repeat biopsies. The PCA3 test might have a role to play in the management of these men, including selecting men for active surveillance, said Dr. Groskopf. "The authority of this test is potentially helpful," said Nicholas J. Vogelzang, MD, chair and medical director of the Developmental Therapeutics Committee of US Oncology, who moderated the GUCS press conference.

Study Results

The men in the new study come from REDUCE (REduction by DUasteride of prostate Cancer Events), a large, multinational chemoprevention trial evaluating dutasteride (*Avodart*, GlaxoSmithKline) in healthy men to see if it reduces the risk of prostate cancer.

The new study was performed on men in the placebo arm of the REDUCE trial because all participants undergo regular 10-core biopsies at 2 and 4 years into the study. The men all had previous negative biopsy results and serum PSA levels between 2.5 and 10 ng/mL. Urine specimens were collected and stored before year 2 and year 4 biopsies and then subsequently analyzed with the PCA3 assay. In the placebo arm, 18% of 1072 men had positive biopsy results at year 2.

Of those men with prostate cancer, the researchers found that the PCA3 score was correlated with a positive prostate biopsy result. Specifically, cancer was diagnosed in only 6% of men with a PCA3 score below 5 but in 57% of men with a PCA3 score over 100, reported Dr. Groskopf. Among the men with negative biopsy results at year 2, the PCA3 test also predicted the likelihood of having prostate cancer diagnosed at the year 4 biopsy.

Specifically, men with elevated PCA3 scores (>35) and a negative biopsy result at year 2 were twice as likely as men with lower PCA3 scores to have cancer detected through biopsy at year 4.

The investigators also looked at PSA values at 2 and 4 years in these same men. "Serum PSA and percentage of free PSA had no correlation with future biopsy outcome," said Dr. Groskopf.

GUCS is cosponsored by the American Society for Clinical Oncology, the American Society for Radiation Oncology, and the Society of Urologic Oncology.

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