New blood test greatly reduces false-positives in prostate cancer screening

May 28 2009

ORLANDO, Fla.--A new blood test used in combination with a conventional prostate-specific antigen (PSA) screening sharply increases the accuracy of prostate cancer diagnosis, and could eliminate tens of thousands of unneeded, painful, and costly prostate biopsies annually, according to a study led by researchers at Dana-Farber Cancer Institute.

At the annual meeting of the American Society of Clinical Oncology in Orlando, Fla., William K. Oh, M.D., and Robert W. Ross, M.D., will report that the six-gene molecular diagnostic test, when combined with a PSA test, accurately detected prostate cancer more than 90 percent of the time. Earlier studies suggest that the conventional PSA test is 60-70 percent accurate in detecting cancer.

Men who are found to have elevated levels of PSA in routine screening tests are often referred for a biopsy of the gland to check for tumors. Nearly two-thirds of biopsies performed -- a painful procedure with some risk of complications -- do not find any cancerous cells. This high rate of "false positive" PSA test results underscores the need for a more accurate method for detecting prostate cancer, said Oh, who is the clinical director of the Lank Center for Genitourinary Oncology at Dana-Farber.

The two-year study involved 484 participants. The group comprised 204 men with known prostate cancer, 110 men with benign prostatic hypertrophy (BPH), and 170 healthy men in a control group. (BPH can elevate PSA levels in the blood, which often leads to a biopsy to rule out

prostate cancer.) These groups were split into age-matched training and validation sets.

The researchers sought to measure the accuracy of a six-gene whole blood RNA transcript-based diagnostic test developed by Source MDx in Boulder, Colo., both in terms of its sensitivity (the ability to detect prostate cancer) and specificity (the ability to identify people who don't have prostate cancer).

Source MDx researchers developed the test after initially working with a set of 174 candidate genes whose activity was compared in the different study groups. They narrowed the pool down to just six genes that, as a group, were highly sensitive in predicting which patients had prostate cancer and which were normal.

The study found that "the six-gene model was more accurate than PSA alone at predicting cancer if you had it and no cancer if you didn't," said Oh. The test's accuracy improved even more when PSA measurements were added. Combined, the two tests achieved a diagnostic accuracy of more than 90 percent in specificity and sensitivity and eliminated most of the false-positives yielded by the PSA test.

Based on these findings, the researchers are planning to conduct a larger, multicenter clinical trial involving approximately 1,000 men to determine if the findings remain valid.

"These findings are very encouraging and suggest that this new test could spare tens of thousands of men from undergoing an unnecessary biopsy," Oh said. "However, until we can verify our findings, it is important to recognize that the PSA test, despite its limitations, is still the best test available for diagnosing prostate cancer at this time."

Source: Dana-Farber Cancer Institute