The PSA Dilemma: *A closer look at the uncertainty in prostate biopsy decisions*

The limitations of today's standard methods for detecting and diagnosing prostate cancer have created a medical quandary for a particular group of patients. For patients with an elevated PSA score indicating risk for prostate cancer, but a first biopsy failing to find cancer, what do you do? A lack of clear and actionable information for these patients has resulted in the PSA Dilemma.

The PSA test for prostate cancer detection was introduced over 20 years ago. However, the PSA test can be influenced by non-cancerous conditions such as prostate enlargement and infection. This limitation possibly helps explain why 75% of prostate biopsies fail to find cancer[1]. Additionally, doctors know that prostate biopsies examine only a fraction of the prostate tissue and therefore may miss up to 20-35% of cancers. In this situation, should a repeat biopsy be conducted?

The decision to repeat a biopsy is not an easy one. While a prostate biopsy is required to definitively diagnose prostate cancer, prostate biopsies are invasive and are associated with complications such as infection, bleeding and hospitalization[1, 2].

"The fear of missing cancer must also be balanced against the risks and adverse effects associated with the prostate biopsy procedure, some of which can be very serious," cautioned John Wei, MD, professor of urology at the University of Michigan. "Some studies have suggested hospitalization rates within 30 days of biopsy as high as 4%."

This situation leaves many faced with the PSA dilemma, which is a lack of clear information that increases physician and patient uncertainty on whether to proceed with or delay an additional biopsy.

"The number of patients in this dilemma population is significant," says Dr. Wei. "There is not a standard of clinical practice defining whether or when to perform a repeat biopsy, so the decision is a subjective one that depends on a number of risk factors and the physician's judgment."

In February 2012, the FDA approved the PROGENSA® PCA3 Assay, the first molecular diagnostic assay that detects the over-expression of the PCA3 gene found in 95% of prostate cancers. The specific information provided by the urine-based test—the PCA3 score—can be used in conjunction with other patient history to decide whether a repeat biopsy is necessary in men with one or more previous negative biopsies[3, 4].

True or False

PSA is specific to prostate cancer.
False. *PSA is specific to prostate volume and is influenced by non-cancerous conditions such as prostate enlargement, prostatitis, and infection.*

PCA3 is specific to prostate cancer.
True. *Prostate cancer cells express 60 to 100 times more PCA3 RNA than normal cells.*

Prostate biopsies are required to diagnose prostate cancer.
True. *Elevated PSA, a high PCA3 Score, and other risk factors may indicate likelihood of having prostate cancer, but a positive biopsy is always required for diagnosis.*

Prostate biopsies are accurate.
True and False. *Positive biopsies are accurate for diagnosing prostate cancer. However, approximately 20-35% of negative biopsies miss cancer.*

"The PROGENSA PCA3 test has a remarkable ability to predict a negative biopsy with a great deal of confidence," said Dr. Wei. "By adding the PCA3 Assay to complement PSA, we can tell patients that the likelihood of having prostate cancer that was missed on a previous biopsy is low enough that another prostate biopsy is unnecessary."

The PROGENSA PCA3 Assay is indicated for use in conjunction with other patient information to aid in the decision for repeat biopsy in men 50 years of age or older who have had one or more previous negative prostate biopsies and for whom a repeat biopsy would be recommended by a urologist based on the current standard of care, before consideration of PROGENSA PCA3 assay results.

"The healthcare implications of the test are substantial," said Dr. Wei. "In studies of the PCA3 test, nearly 50% of unnecessary biopsies could have been avoided."

Dr. John Wei was principal investigator on the PCA3 validation study, funded by the National Cancer Institute of the NIH. Dr. Wei did not receive any funding from Gen-Probe Incorporated.

BLACK BOX WARNING: The PROGENSA PCA3 Assay should not be used for men with atypical small acinar proliferation (ASAP) on their most recent biopsy. Men with ASAP on their most recent biopsy should be treated in accordance with current medical guidelines.

WARNING: The Clinical Study of the PROGENSA PCA3 assay only included men who were recommended for a repeat biopsy. Therefore, the performance of the PROGENSA PCA3 Assay has not been established in men for whom a repeat biopsy was not already recommended.

REFERENCE LIST

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