Prostate Health Index (phi), A More Precise Blood Test, Outperforms Traditional PSA Screening In Predicting Clinically Significant Prostate Cancer

San Diego, CA – The Prostate Health Index (phi), a blood test used to evaluate the probability of prostate cancer diagnosis, outperformed commonly used prostate-specific antigen (PSA) and free/total prostate-specific antigen (%fPSA) tests in predicting the presence of clinically significant prostate cancer and in improving prostate cancer detection, according to a new study. Findings from the study will be presented to reporters at the 108th Annual Scientific Meeting of the American Urological Association (AUA) during a press conference at the San Diego Convention Center, San Diego, CA on May 7 at 11:30 a.m. PDT.

The phi combines measurements of %fPSA(percent of protein-attached and protein-free PSA circulating in the bloodstream) and a subcategory of free PSA called pro-PSA, and is estimated to be 2.5 times more specific in detecting prostate cancer in patients than a PSA screening. The phi was approved by the US Food and Drug Administration (FDA) in June 2012 and has been available since late 2012.[1]The study also found using a specific phi benchmark level may help identify biopsy candidates and reduce over-detection of indolent (slow-growing) prostate cancer.

"The phi can play a valuable role in determining whether an elevated PSA is likely due to prostate cancer or benign changes," said Brant Thrasher, MD, chair of Urology, University of Kansas Medical Center, Kansas City, KS. "This option may prevent patients from potentially undergoing unnecessary biopsies."

Study Details

Researchers at several leading institutions in the United States and the Netherlands, including Harvard Medical School and Johns Hopkins University, investigated whether the use of phi, as compared to total PSA and %fPSA, can reduce unnecessary biopsy and over-detection of indolent prostate cancer, while improving the detection of aggressive prostate cancer.

The study consisted of 658 participants who were 50 years of age or older with a biopsy-confirmed prostate cancer diagnosis, a final PSA between 4-10 ng/mL and a benign rectal examination. Study investigators evaluated prediction of clinically significant cancer (aggressive histopathology per Epstein criteria or Gleason 7+) based on pre-biopsy measures of pro-PSA, total PSA, fPSA, %fPSA and phi and evaluated prospects for eliminating unnecessary biopsies based on results of phi prior to biopsy.

The researchers found:

- At 90 percent sensitivity, the specificity of phi was 31.1 percent, compared to 19.8 percent for %fPSA (p=0.024) and 10.8 percent for PSA (p<0.001).
- At a moderate to high phi range of 27 to 55, the probability of cancer varied from 9.8 to 50.1 percent and the probability of clinically significant cancer extended from 3.9 to 28.9 percent.
- At a phi level of 27, which is the 90 percent sensitivity cut-point, 18.8 percent of men could have been spared from undergoing prostate biopsy or over-diagnosis of non-aggressive disease.

Study investigators concluded phi outperformed PSA and %fPSA in predicting the presence of clinically significant prostate cancer and for improving prostate cancer detection. Additionally, using a phi level of 27 for selecting men for prostate cancer biopsy, when total PSA is 4 to 10 ng/mL, can decrease unnecessary biopsies and reduce over-detection of indolent prostate cancer.

NOTE TO REPORTERS: Experts are available to discuss this study outside normal briefing times. To arrange an interview with an expert, please contact the AUA Communications Office at the number above or e-mail Communications@AUAnet.org.

***About the American Urological Association**: Founded in 1902 and headquartered near Baltimore, Maryland, the American Urological Association is a leading advocate for the specialty of urology, and has more than 19,000 members throughout the world. The AUA is a premier urologic association, providing invaluable support to the urologic community as it pursues its mission of fostering the highest standards of urologic care through education, research and the formulation of health policy.*

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[1]Beckman Coulter, Inc. (2012.) FDA Approves New Blood Test to Improve Prostate Cancer Detection [Press release]. Retrieved from https://www.beckmancoulter.com/wsrportal/wsrportal.portal?_nfpb=true&_windowLabel=UCM_RENDERER&_urlType=render&wlpUCM_RENDERER_page=newsDetail&wlpUCM_RENDERER_id=GLB_BCI_152527

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http://auanet.mediaroom.com/2013-05-07-Prostate-Health-Index-phi-A-More-Precise-Blood-Test-Outperforms-Traditional-PSA-Screening-In-Predicting-Clinically-Significant-Prostate-Cancer