Prostate Health Index (phi) using [-2]proPSA improves detection of prostate cancer preferentially identifying aggressive cancers

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Objectives

The benefit of screening for prostate cancer (PCa) using total prostate-specific antigen (PSA) as the biochemical marker is a matter of intense debate, due to the relatively low clinical specificity of PSA leading to serious drawbacks such as overdiagnosis and overtreatment. New biomarkers that could improve the specificity for PCa detection are highly desirable. Previous studies showed that a molecular isomer of PSA ([-2]proPSA) could improve the clinical specificity for the detection of PCa compared to PSA and free PSA (fPSA) [1,2]. Beckman Coulter recently developed an innovative "Prostate Health Index" or "phi" which combines PSA, pPSA, and [-2]proPSA results [3]. This four center study was set up to confirm previously demonstrated clinical performance of phi for the detection of PCa [3]. The results of an interim analysis are presented in this poster.

Material and Methods

A total of 902 patients with PSA values between 1.6 – 8.0 ng/mL (WHO-calibrated), 446 with and 456 without PCa, underwent 210 core biopsies in four different sites were enrolled in the study. A PSA range of 1.6 – 8.0 ng/mL, with a WHO-calibrated PSA Access assay corresponds to a range of 2 – 10 ng/mL with a Hybteck-calibrated PSA Access assay. Similarly, the classical decision point of 4.0ng/mL in a Hybteck-calibrated assay corresponds to 3.1 ng/mL with a WHO-calibrated assay. Serum samples were prepared from blood drawn prior to DRE. Serum samples from the enrolled patients were prepared within 3 hours of the blood draw then stored frozen at -20°C or -80°C [4]. The serum concentrations of PSA, pPSA and [-2]proPSA were measured using Beckman Coulter Access immunoassays on an Access® or UniCel Dxi 800 instrument. The Prostate Health Index was calculated using the following formula: [p2PSA/PSA]/[psa/PSA]. ROC curves were plotted to compare the clinical performances of PSA, %fPSA and phi for the detection of PCa. The relationship with PCa aggressiveness was performed on 352 patients for which the Prostate Health Index score information was available. Based on this information, the patients were grouped as "aggressive PCA" patients with biopsy Gleason score of 7 and above (GS ≥ 7) or "less aggressive" PCa patients with phi Gleason score 6 (GS < 7).

Results.

• Detection of PCa for patients with PSA > 1.6 and < 8.0 ng/mL

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Conclusions.

The results of this multicenter study indicate that phi has superior clinical performance in detecting PCa in the PSA range of 1.6 – 8.0 ng/mL (WHO calibration) compared to PSA or %fPSA. The phi index was the best predictor of prostate cancer compared to PSA and %fPSA, phi tends to preferentially detect aggressive PCa. At high sensitivity, phi PSA are missed are mainly Gleason <7. These data confirmed previously published observation on the benefit of phi for the detection of PCa [3]. The results of an interim analysis are presented in this poster.

References.

2 Nikolajczyk et al. Prostate-Specific Forms of Prostate-Specific Antigen in Serum Improve the Detection of Prostate Cancer. Clinical Chemistry 2004; 50:1027-16
3 Jansen et al. Prostate-Specific Antigen (PSA) isomar [-2PSA] in Combination with Total PSA and Free PSA Improves Diagnostic Accuracy in Prostate Cancer Detection. European Urology 2010; 57:921-27