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[-2]proPSA improves prediction of repeat prostate biopsy results

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OBJECTIVES

The use of prostate specific antigen (tPSA) for the detection of prostate cancer (PCa) is being criticized because of a relatively low specificity. In repeat prostate biopsies the predictive value of tPSA is very low. The clinical performance of a molecular isoform of free PSA (fPSA), [-2]proPSA, for the detection of PCa in initial versus repeat prostate biopsies was evaluated.

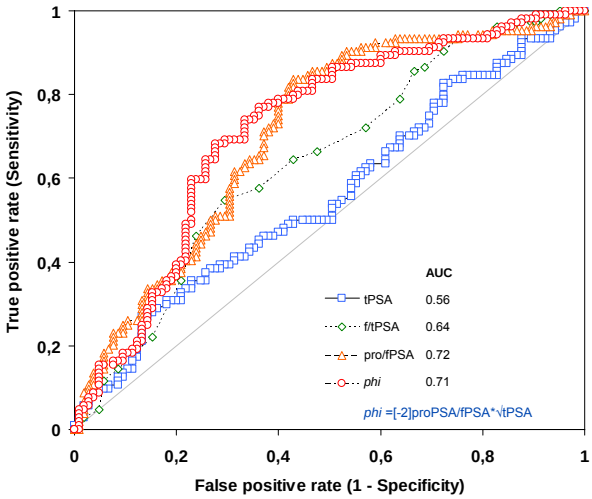
METHODS

A total of 377 patients with tPSA values between 1.6 – 8.0 ng/mL (median 5.07, mean 5.01 ng/ml WHO-calibrated Hybritech Access) underwent ≥10 core biopsies. 209 pts. underwent their first biopsy session (tPSA 1.6 - 8.0 ng/mL, median 5.0, mean 5.1), 191 pts. underwent repeat biopsies (tPSA 1.6 - 8.0 ng/mL, median 5.48 mean 5.32). Prior to biopsy, serum samples were prepared within 3 hours from blood draw and frozen at -75°C immediately [Semjonow et al. Clin Biochem 2010]. The serum concentrations of tPSA, fPSA, and [-2]proPSA were measured with the automated Beckman Coulter immunoassays on the Access2 instrument.

ROC-CURVES

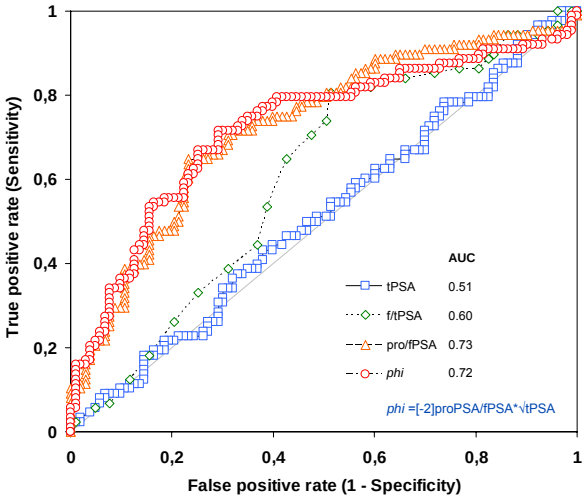
First Biopsies

n= 209, tPSA 1.6-8.0 ng/mL, WHO-calibrated



Repeat-Biopsies

n= 191, tPSA 1.6-8.0 ng/mL, WHO-calibrated



RESULTS

Evaluation of the two cohorts using area under ROC curve (AUC) analysis showed the following results:

First biopsy cohort: [-2]proPSA/fPSA (AUC=0.72) provided significantly ($p<0.005$) better clinical performance relative to tPSA (AUC=0.56) but was not significantly better than f/tPSA (AUC=0.66) in predicting PCa.

Repeat biopsy cohort: [-2]proPSA/fPSA (AUC=0.73) provided significantly better prediction of biopsy outcome relative to f/tPSA (AUC= 0.60) or tPSA (AUC 0.51), differences between AUCs $p<0.001$. Difference between f/tPSA and tPSA $p<0.03$.

The diagnostic accuracy of [-2]proPSA/fPSA improves with increasing prostate volume.

CONCLUSIONS

[-2]proPSA/fPSA shows a superior clinical performance in detecting PCa in the tPSA range of 1.6 - 8.0 ng/mL (i.e. 2 – 10 ng/mL in traditional calibration) as compared to tPSA or f/tPSA. In pts. undergoing repeat prostate biopsy, [-2]proPSA/fPSA shows the highest AUC outperforming all other parameters investigated statistically significant. Performance of [-2]proPSA/fPSA increases with increasing prostate volume, thus possibly providing important information for the group of pts. in which a decision concerning repeat biopsies is most difficult.

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