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Utility of Prostate Health Index and Prostate Health Index Density in predicting detection of clinically significant prostate cancer in a cohort of patients with PSA in the grey zone and normal digital rectal examination

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Introduction & Objectives: To explore and validate the clinical utility of Prostate Health Index (PHI) and density of PHI (DPHI) in a predictive model of clinically significant Prostate Cancer (PCa) in men with PSA in the grey zone (2-10 ng/ml) and normal digital rectal examination.

Materials & Methods: A total of 162 men underwent measurement of total PSA (PSA), free PSA (fPSA), p2PSA and prostate volume before prostate biopsy in an observational and prospective study. From these measurements, PHI and PHID were calculated. Clinically significant PCa was defined as any Gleason score ≥ 7 cancer or Gleason score 6 cancer in > 2 cores or > 50% of any positive core. Clinical and analytical predictive models were created incorporating PHI and DPHI. The performance of biomarkers and models were assessed through reliability diagnosis indexes, and discrimination analysis with predictive accuracies quantifying the area under the curve (AUC). The internal validation was assessed by calibration. A scatter plot was used to assess the relationship between the predicted probabilities of the PHI model, the DPHI model and the PSA model. Multivariable logistic regression models were also performed to assess the prediction of clinically significant PCa at biopsy. Finally, we used decision curve analysis (DCA) to determine clinical utility of PHI and DPHI.

Results: Fifty-two (32%) clinically significant PCA were diagnosed. The median (interquartile range) of PHI and PHID in patients with clinically significant PCa was 88.9 (68.3-115) and 0.66 (0.41-1.02) and in patients without clinically significant PCa or without PCa was 49.4 (34.9-67.5) and 0.35 (0.24-0.54) respectively ($p<0.001$). Clinically significant PCa was identified in 3% and 73% of patients in the first and the third quartile of PHI respectively and in 10% and 72% of patients in the first and the third quartile of PHID respectively. A cut-off point of PHI around 66.88 and of PHID around 0.44 showed the best balance of sentivity and specificity (81% and 81% for PHI, and 70% and 70% for PHID). The AUC of PHI and PHID for the diagnosis of clinically significant PCa is 0.87 and 0,77 respectively. PHI showed better internal calibration that PHID. At a 25% threshold probability, decide to biopsy upon the predictive ability of PHI and PHID results in a net benefit in the diagnosis of clinically significant PCa around 21% and 15%, saving 38% and 28% of biopsies respectively. The net benefit of clinical models which incorporate PHI and PHID at a 25% threshold probability is around 26% and 22% saving 40% and 22% of biopsies respectively.

Conclusions: To include PHI into predictive models of clinically significant PCa improves the diagnosis accuracy and the clinical utility of prostate biopsy. PHID adds less clinical utility.