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Whether p2PSA, %p2PSA and Prostate Health Index improves clinically significant prostate cancer detection in men with PSA range 2-10 ng/ml

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Introduction & Objectives: Prostate cancer screening programs based on total PSA (tPSA) test, which has a characteristic of low specificity when PSA value is less, than 10 ng/ml, lead to many unnecessary prostate biopsies and over-diagnosis and over-treatment of clinically non-significant disease. In order to improve the specificity of prostate cancer serum biomarkers, a premature forms of PSA, called proPSA, have been described. Studies have shown that prostate cancer diagnosis is more accurate when using a new indices based on [-2]proPSA (p2PSA), such as p2PSA/fPSA ratio (%p2PSA) and prostate health index (PHI).
The objectives of our study were to evaluate whether p2PSA, %p2PSA and PHI improves the detection of clinically significant prostate cancer in comparison to tPSA.

Materials & Methods: 210 men scheduled for initial or repeat prostate biopsy with tPSA levels ranged between 2 and 10 ng/ml and normal digital rectal examination were enrolled in prospective observational study. tPSA, fPSA, and p2PSA (Beckman Coulter Access) were determined from blood serum before 12-core prostate biopsy for every patient. PHI was calculated according to the formula $(p2PSA/fPSA)x\sqrt{tPSA}$. Clinically significant prostate cancer definition was based on the Epstein criteria and Gleason ≥7 score on biopsy. The data was analysed using the statistical SAS 9.2 software. Logistic regressions have been concluded to assess the diagnostic accuracy of serum biomarkers.

Results: Prostate cancer has been diagnosed in 112 (53.3%) patients. Epstein significant and Gleason ≥7 score prostate cancer have been identified in 81 (72.3%) and 40 (35.7%) patients, respectively. Based on ROC analysis PHI showed the greatest AUC for Epstein significant and Gleason ≥7 score prostate cancer of 0.7725 and 0.7669, respectively ($p<0.05$). PHI with a cut-off of 44.47 for Epstein significant prostate cancer and 44.71 for Gleason ≥7 score prostate cancer have showed the best balance between sensitivity and specificity of 69.1% and 81.4%, and 75.0% and 72.4%, respectively.

Conclusions: In patients with normal digital rectal examination and PSA range of 2-10 ng/ml, PHI is the most accurate predictive tool for clinically significant prostate cancer detection and can help to reduce unnecessary prostate biopsies and prostate cancer over-diagnosis.