

Beaumont Health

Beaumont Health Scholarly Works and Archives

Website/Multimedia Contributions

Urology

8-28-2022

ISOPSA: Clinical Performance of a Single Parameter, Structure Based Test for High Grade Prostate Cancer Unaffected by 5-ARI and A-Blocker Medications

Eric Klein

Alan Partin

Yair Lotan

Jack Baniel

Martin Dineen

See next page for additional authors

Follow this and additional works at: https://scholarlyworks.beaumont.org/urology_websitemedia



Part of the [Urology Commons](#)

Authors

Eric Klein, Alan Partin, Yair Lotan, Jack Baniel, Martin Dineen, Jason Hafron, Kannan Manickam, Marc Pliskin, Matthew Wagnet, and AO Zhang

Conclusion: In a preliminary direct comparison, the EPI biomarker assay provides superior sensitivity and negative predictive value for assessing the risk of clinically significant cancer prior to biopsy.

Classifier	Sensitivity	Specificity	NPV	PPV
EPI >= 11.6	0.98	0.21	0.96	0.30
PSAD >= 0.1	0.76	0.51	0.70	0.38
PSAD >= 0.11	0.71	0.66	0.80	0.34
PSAD >= 0.13	0.62	0.70	0.79	0.37
PSAD >= 0.12	0.71	0.67	0.79	0.42

Funding: Exosome Diagnostics, Waltham, MA, USA

Poster #19

ISOPSA: CLINICAL PERFORMANCE OF A SINGLE PARAMETER, STRUCTURE BASED TEST FOR HIGH GRADE PROSTATE CANCER UNAFFECTED BY 5-ARI AND A-BLOCKER MEDICATIONS

Eric Klein¹, Alan Partin², Yair Lotan³, Jack Baniel⁴, Martin Dineen⁵, Jason Hafron⁶, Kannan Manickam⁷, Marc Pliskin⁸, Matthew Wagner⁹, Ao Zhang¹, Aimee Kestranek¹⁰, Mark Stovsky¹⁰
¹Cleveland Clinic Glickman Urological and Kidney Institute, Cleveland, OH, ²Johns Hopkins Brady Urological Institute, Baltimore, MD, ³University of Texas Southwestern Medical Center Department of Urology, Dallas, TX, ⁴Rabin Medical Center, Petah Tikvah, Israel, ⁵Advanced Urology Institute, Daytona Beach, FL, ⁶Michigan Institute of Urology, St. Clair Shores, MI, ⁷Chesapeake Urology Associates, Baltimore, MD, ⁸The Urology Group, Cincinnati, OH, ⁹Kaiser Permanente Northwest, Clackamas, OR, ¹⁰Cleveland Diagnostics, Cleveland, OH
 Presented By: Ao Zhang, MD, PhD

Introduction: We present cumulative results describing the clinical performance of IsoPSA, a blood-based, structure-focused assay for high grade prostate cancer (PCa), in patients taking 5-ARI and α -blocker medications for BPH.

Methods: In this validation study (N = 1093), blood samples were obtained from multiple clinical sites, collected within 30 days prior to prostate biopsy from patients with serum PSA between 4 and 100 ng/ml on α -blocker (N=270) and 5-ARI (N=46). IsoPSA was evaluated against TRUS and/or MRI Fusion biopsy results. The prevalence of high-grade PCa in the study group was 35.3%. The test parameter (IsoPSA Index) was evaluated by ROC analysis.

Results: For patients on α -blockers, ROC analysis resulted in AUC=0.795, SN=83.1%, SP=61.3%, NPV=91.0% and PPV=43.4% at the established cutoff (IsoPSA Index \leq 6.0) to identify patients at low risk for high-grade PCa. For patients on 5-ARI, ROC analysis resulted in AUC=0.789, SN=94.1%, SP=41.4%, NPV=92.3% and PPV=48.5% to identify patients at low risk for high-grade PCa. IsoPSA results were relatively unaffected by the use of BPH medications compared to the study group as a whole. IsoPSA in patients on α -blockers showed higher specificity and NPV than the aggregate study group. IsoPSA in patients on 5-ARIs showed higher sensitivity and NPV than the aggregate study group.

Conclusions: IsoPSA displays robust diagnostic accuracy in patients on α -blockers and 5-ARIs for BPH. IsoPSA diagnostic accuracy is relatively unaffected by these medications. This data suggests that IsoPSA could be a useful adjunct to prostate cancer early detection methodologies in this challenging diagnostic cohort.

Funding: Cleveland Diagnostics, Inc

Poster #20

DEVELOPMENT OF HIGH GRADE PROSTATE CANCER IN PATIENTS WITH INITIAL “FALSE POSITIVE” ISOPSA

Ao Zhang, Eric Klein
 Cleveland Clinic Glickman Urological and Kidney Institute, Cleveland, OH
 Presented By: Ao Zhang, MD, PhD

Introduction: IsoPSA is a novel structure-based serum assay with high sensitivity and specificity for high grade prostate cancer (PCa, Gleason score 7 or greater). We aimed to assess if patients with “false positive” IsoPSA subsequently develop high grade PCa.