PRELIMINARY EVALUATION OF PI-RADS SCORE VERSUS ISOPSA FOR DETECTION OF HIGH GRADE PROSTATE CANCER

ERIC KLEIN, MD\textsuperscript{1}, ARNON CHAIT\textsuperscript{2}, AIMEE KESTRANEK\textsuperscript{2}, PRASAD GAWANDE\textsuperscript{2}, BORIS ZASLAVSKY\textsuperscript{2}, MARK STOVSKY, MD\textsuperscript{1,2}.

\textsuperscript{1}CLEVELAND CLINIC; \textsuperscript{2}CLEVELAND DIAGNOSTICS, INC.
INTRODUCTION: We conducted a preliminary evaluation comparing clinical performance of PI-RADS score versus IsoPSA™, a novel structure-focused plasma-based test to assess potential discrimination of high-grade (Gleason≥7) from benign or low-grade (Gleason=6) patients.

METHODS: Plasma samples (N=89) were obtained from a single clinical site, collected within 30 days prior to prostate biopsy from patients with blood PSA between 2 and 41.1 ng/ml. IsoPSA and PI-RADS score were evaluated against either mpMRI-US fusion (N=69) or 12 core TRUS (when PI-RADS had zero score, N=20) biopsy results as gold standard, and ROC curve analysis was performed for both.

RESULTS: The prevalence of GS≥7 in this cohort was 30%. ROC analysis for IsoPSA resulted in AUC=0.83 vs. AUC=0.71 for PI-RADS score using the same biopsy method for both. For 20 patients with PI-RADS zero score that underwent TRUS biopsy, 3 had GS≥7, although the same patients were correctly predicted as having high-grade disease by IsoPSA. PI-RADS>3 correctly identified 22/27 (SN=81%) actionable cases while having 26/62
false positives. Even PI-RADS>0 cutoff still missed 3/27 (SN=90%) high-grade cancers with 45/62 (SP=27%) false positives vs. IsoPSA at its usual cut-off K>8.5 resulting in 2/27
(SN=93%) false negatives and 34/62 (SP=45%) false positives. CONCLUSIONS: IsoPSA clinical performance improves with the quality of the gold standard (mpMRI-US fusion vs. TRUS). As a simple blood-based assay at significant cost differential advantage, IsoPSA also demonstrated superior clinical performance to PI-RADS score for selection of mpMRI-US fusion vs. TRUS biopsy.