Title: Assessing the Negative Predictive Value and Accuracy of Multiparametric MRI to Predict Clinically Significant Prostate Cancer in Biopsy Naïve Men Across Racial Groups
Running Head: Accuracy of Multiparametric MRI in Biopsy Naïve Men

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Introduction / Aims: The Prostate Imaging Reporting and Data System (PIRADS) has shown promise in improving the detection of Gleason grade group (GG) 2-5 prostate cancer (PCa) and reducing the detection of indolent GG1 PCa.[1,2] However, data on the performance of PIRADS in Black and Hispanic men is sparse. We evaluated the accuracy of PIRADS version 2.0 in detecting GG2-5 PCa in White, Black, and Hispanic men. Specifically, we aimed to compare the rates of GG2-5 PCa, sensitivity, specificity, negative predictive value and positive predictive value of PIRADS for GG2-5 PCa between each race cohort. We also wanted to compare the area under the receiver operating characteristics curves for regression models for GG2-5 PCa using standard base clinical variables and PIRADS.
Methods: We performed a multicenter retrospective review of biopsy-naïve Black (n=108), White (n=108), and Hispanic (n=38) men who underwent prostate biopsy (PB) following multiparametric MRI. Sensitivity, specificity, negative predictive value (NPV), and positive predictive value (PPV) of PIRADS for GG2-5 PCa were calculated. Binary logistic regression models for GG2-5 PCa using standard clinical variables and PIRADS were used to calculate area under the receiver operating characteristics curves (AUC) and race-stratified.
Results: Rates of GG2-5 PCa were statistically similar between Blacks, Whites, and Hispanics (52.8% vs 42.6% vs 39.5% respectively, p = 0.21). Sensitivity (96.5% vs. 97.8% vs. 86.7%), specificity (21.6% vs 27.4% vs 21.7%), PPV (57.9% vs 50.0% vs 41.9%) and NPV (84.6% vs. 94.4% vs. 71.4%) were statistically similar between Blacks, Whites, and Hispanics respectively. Adding PIRADS to a base model with age, PSA and suspicious prostate exam increased its accuracy in detecting GG2-5 PCa in Whites (0.73 vs. 0.56, p=0.02). There was a borderline trend for increased AUC in Blacks (0.75 vs. 0.63, p=0.09). In Hispanics, PIRADS did not improve diagnostic accuracy (0.64 vs. 0.64, p=0.21). However, the AUCs for all PIRADS models were statistically similar between Whites, Blacks, and Hispanics and PIRADS did not interact with Race.
Discussion: Black men have been shown to have disproportionately worse prostate cancer specific health outcomes than White men, with a higher incidence (18.2% vs 13.3%) and mortality rate (4.4% vs 2.4%).[3–6] These racial disparities have been attributed to several factors including tumor biology, lifestyle (e.g. physical activity, diet, etc.), and socioeconomic factors such as differences in access to health care as well as the quality of health care received.[7-9] Given the increased risk of PCa and cancer-specific mortality that Black men have, a NPV of 84.6%, may still be too low to be able to confidently exclude these patients from PB and at least warrants ongoing PSA monitoring. A recent meta-analysis of mp-MRI showed a pooled NPV of 90.8%.[10] With limited validation data in Hispanic participants, we felt it important to provide the Hispanic data we had. Given the lower NPV in this sample, larger validation is warranted.
On ROC curve analysis, the addition of PIRADS scores to the base model improved the accuracy of detection of GG2-5 PCa by 30% in Whites and 19% in Blacks, although it had no effect on AUC for Hispanics.
The limitations of this study include its retrospective nature and small sample size. However, the study involves fellowship trained genitourinary pathologists and is the largest data set on Hispanics which is the largest ethnic minority group in the US. Despite including patients who were evaluated only based on version 2.0 of the PIRADS system, we acknowledge that like many radiologic modalities, mpMRI readings are subject to interobserver variability.
Conclusions: PIRADS improves accuracy for detection of clinically significant prostate cancer and does not seem to vary by race. There is concern that PIRADS performs poorly in Hispanics. Larger validation with version 2.1 is needed.

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