

Race and prostate imaging: implications for targeted biopsy and image-based prostate cancer interventions

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ABSTRACT

Purpose For men with an elevated prostate-specific antigen (PSA), there is a strong evidence for prostate MRI to assess the risk of clinically significant prostate cancer (CSPC) and guide targeted-biopsy interventions. Prostate MRI is assessed using the Prostate Imaging-Reporting and Data System (PI-RADS), which is scored from 1 to 5. Equivocal or suspicious findings (PI-RADS 3–5) are recommended for subsequent targeted biopsy, for which the risk of infection and sepsis is increasing. However, PI-RADS was developed primarily in men of European descent. We sought to elucidate PI-RADS and MRI-targeted biopsy outcomes in Asian men, a rapidly growing population in the USA, Europe, Australia and internationally.

Materials and methods A prospective cohort of 544 men with elevated PSA without a diagnosis of prostate cancer who underwent MRI-targeted biopsy at our institution from January 2012 to December 2018 was analyzed. We categorized the cohort by self-designated race then used a validated algorithm which uses surname lists to identify a total of 78 (14%) Asian-Americans. The primary outcome was the likelihood of diagnosing CSPC (Gleason grade group >1) in Asian-Americans versus non-Asian-Americans. Multivariable logistic regression was used to determine the association of demographic and other characteristics with CSPC.

Results Overall, MRI-targeted biopsy identified CSPC in 17% of Asian-American men versus 39% of non-Asian-American men ($p < 0.001$). Notably for PI-RADS 3, only 6% of Asian-Americans versus 15% of others were diagnosed with CSPC. In adjusted analyses, Asian-American men were less likely to be diagnosed on MRI-targeted biopsy with CSPC (OR 0.30, 95% CI 0.14 to 0.65, $p = 0.002$) and indolent prostate cancer (OR 0.37, 95% CI 0.15 to 0.91, $p = 0.030$) than other races. Regardless of race those who were biopsy naïve were more likely (OR 2.25, 95% CI 1.45 to 3.49, $p < 0.001$) to be diagnosed with CSPC.

Conclusion We found that PI-RADS underperforms in Asian-American men. For instance, only 2 of 35 (6%) Asian-American men with PI-RADS 3 were diagnosed with CSPC on MRI targeted biopsy. This has significant implications for overuse of diagnostic and image-guided interventional approaches in Asian-Americans, given the increasing risk of infectious complications from biopsy. Additional validation studies are needed to confirm our findings.

Key messages

What is already known on the subject?

► MRI aids in assessing the risk for clinically significant prostate cancer and for targeting suspicious areas seen on imaging within the prostate. The utility of prostate MRI as a biomarker for elevated PSA in Asians has not been assessed.

What are the new findings?

► This study finds that Asian men have a significantly lower risk of finding significant cancer at every risk score for prostate MRI.

How might these results affect future research or surgical practice?

► This highlights the need to assess the generalizability of biomarkers beyond the original race in which they were validated, in keeping with the IDEAL framework. We may begin to consider avoiding prostate biopsy in some Asian men if other risk factors are favorable, and our findings have significant implications for prostate MRI and targeted ablation.

INTRODUCTION

There is strong evidence supporting the use of prostate MRI for men with elevated prostate-specific antigen (PSA) to diagnose and guide treatment of prostate cancer.¹ Prostate MRI is assessed using the Prostate Imaging-Reporting and Data System (PI-RADS) which grades the likelihood of clinically significant cancer on a 1–5 scale. Men with prostate MRI assigned PI-RADS scores 3–5 are recommended for biopsy. This scoring system was developed in men of European descent.¹ In addition to risk stratification, prostate MRI aids in directing ultrasound-guided transrectal biopsy through the use of MRI-ultrasound fusion software.² Recent prospective randomized trials demonstrate better detection of clinically significant prostate cancer with MRI-targeted biopsy as compared with standard transrectal ultrasound-guided biopsy.^{2–4} Neither the PRECISION (Prostate Evaluation

for Clinically Important Disease: Sampling Using Image Guidance or Not?) nor the MRI-FIRST randomized trials report patient race, but given the predominantly European study sites, non-white patient representation is likely very low.^{4,5} This may have significant implications as MRI and targeted biopsy are disseminated worldwide.

Following the Idea, Development, Exploration, Assessment, Long-term monitoring (IDEAL) framework, which seeks to improve the quality of research in surgery and devices through staged development and analysis of procedures, we consider targeted biopsy evidence development in the long-term monitoring surveillance phase.⁶ Real-world evidence, audits and risk adjustments are required to further investigate current practices, especially in understudied populations. In this context the US Preventive Services Task Force and other professional societies have emphasized a need for research to bridge the significant evidence gap in disparities regarding prostate cancer presentation and outcomes in under-represented populations.⁷ The relationship between MRI findings and biopsy outcomes has not been thoroughly explored in Asian-Americans. The Asian-American population is the fastest growing racial group in the USA and many Western countries. The Asian-American population is projected to double from 18.3 to 36.8 million by 2060, at which time Asian-Americans will comprise the largest immigrant group.⁸ Racial disparities in prostate cancer incidence have been reported, with Asian-Americans having a prostate cancer incidence rate of 67.8 per 100 000 men as compared with 123.0 in non-Hispanic whites.⁹

With an increasing rate of infection following prostate biopsy, the diagnostic yield of prostate biopsy must be balanced against procedural harm.¹⁰⁻¹² Moreover, prostate MRI and targeted biopsy are integral to current diagnostic and therapeutic paradigms that hinge on accurate risk stratification for treatment selection and the emerging use of partial gland ablation for prostate cancer. In this study, we examine MRI-targeted biopsy outcomes for an elevated PSA in among Asian-American versus non-Asian-American men.

MATERIALS AND METHODS

We analyzed our prospective database of men with elevated PSA without a diagnosis of prostate cancer who underwent multiparametric MRI and subsequent targeted biopsy at Weill Cornell Medicine from 2012 to 2018. The MRI and biopsy protocol has been previously described.¹³ Prostate MRI was evaluated using PI-RADS version 2, and men were categorized according to their highest rated region of interest.¹⁴ MRI studies which occurred prior to the release of PI-RADS version 2 in 2015 were retrospectively recategorized by an experienced urologist (DJM). A flow diagram of the included patients is presented in figure 1.

All biopsies were performed using the Artemis MRI-ultrasound fusion-targeted biopsy platform (Eigen, Grass

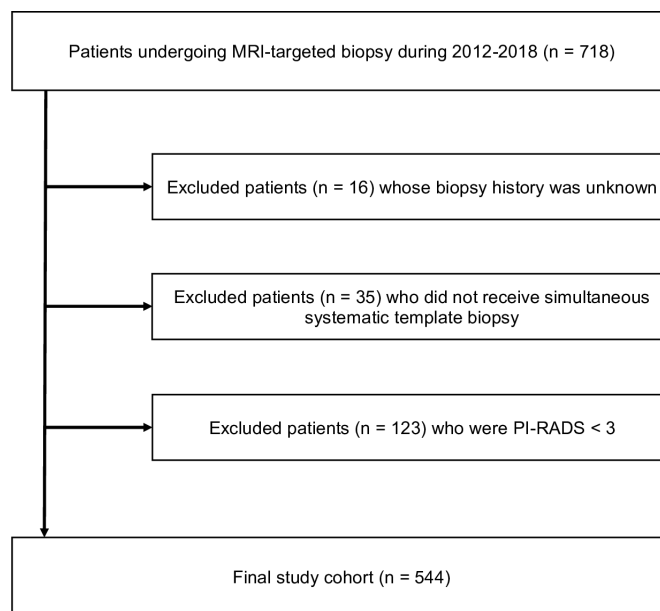


Figure 1 Patient selection and exclusion criteria.

Valley, CA, USA). We excluded all subjects with PI-RADS classification less than 3. Regardless of race, these men generally do not receive biopsy at our institution. Biopsies included at least one targeted core per lesion, as well as systematic cores. All biopsy cores were reviewed for determination of the highest pathological grade by an experienced genitourinary pathologist. Clinically significant prostate cancer was defined as Gleason grade group >1.

There was a significant number of patients who declined to self-report their race (n=108). Therefore, we relied on both self-reporting as well as surname analysis to identify Asian-Americans in the cohort. Fifty-three men self-reported as Asian-American, and given and surname analysis using a method by Lauderdale and Kestenbaum identified 25 additional Asian-Americans.¹⁵ This method used lists of names provided by the authors that are generated from Social Security Administration records, which include country of birth, and are validated against census reports with positive predictive value between 82% and 98%. Of note, 94% (50/53) who self-identified in our cohort were validated using the surname analysis.

The primary study outcome was detection of clinically significant prostate cancer. The secondary outcomes were clinically significant prostate cancer detection among PI-RADS 3–5 categories, the detection of indolent prostate cancer (Gleason grade group 1), and cancer detection by targeted versus systematic biopsy cores. Systematic cores which overlapped with a region of interest during fusion biopsy were retrospectively reclassified as targeted cores in a manner previously described.¹⁶

Patient-level variables were analyzed using Mann-Whitney U tests and χ^2 tests. Descriptive variables collected include race, age, body mass index, PSA, prostate volume by MRI, PSA density, PI-RADS category, and prior negative versus first time biopsy. When the event rate for detection of cancer was less than or equal to 5, the Fisher's exact

Table 1 Study characteristics

	Asian-American	Other	P value
Patients, n	78	466	
Median (IQR)			
Age (year)	67.1 (63–71.2)	66.7 (60.1–71.8)	0.653
Body mass index (kg/m ²)	24.9 (22.8–27)	27.0 (25–29.7)	<0.001
PSA (ng/mL)	6.9 (4.8–10.7)	6.3 (4.6–9.5)	0.368
Prostate volume (cm ³)	45.2 (33–73)	51.2 (36.6–73.1)	0.407
PSA density (ng/mL/cm ³)	0.16 (0.07–0.24)	0.12 (0.08–0.19)	0.027
Lesion diameter (cm)	1.1 (0.6–1.5)	1.1 (0.7–1.5)	0.276
n (%)			
Biopsy naïve	30 (38)	269 (58)	0.002
PI-RADS 3	35 (45)	162 (35)	0.146
PI-RADS 4	32 (41)	203 (44)	
PI-RADS 5	11 (14)	101 (22)	

PI-RADS, Prostate Imaging-Reporting and Data System; PSA, prostate-specific antigen.

test was used in lieu of the χ^2 test. Comparison of systematic and targeted biopsy yield was assessed via McNemar's test for equivalence. Multivariable logistic regression was performed to assess the association of Asian-American race on detection of clinically significant prostate cancer and indolent prostate cancer. Age and body mass index were treated as continuous variables. PI-RADS category, PSA density, and biopsy history were treated as categorical variables with respect to appropriate referents. SPSS V.25 (IBM) was used for statistical analyses.

RESULTS

Demographic and clinical characteristics are presented in [table 1](#). Of the 544 men included in this study, 78 (14%) were Asian-American, 283 (52%) Caucasian, 45 (8%) African-American, 31 (6%) Hispanic, and 107 (20%) were of unknown/other race. Asian-American men had lower body mass index compared with non-Asian-Americans (median 24.9 vs 27.0 kg/m², $p<0.001$). More Asian-Americans had undergone a prior negative biopsy (62% vs 42%, $p=0.002$). PSA density was greater in the Asian-American group (0.16 vs 0.12 ng/mL/cm³, $p=0.027$). Age, PSA and prostate volume did not vary by race. There was no significant difference in the distribution of PI-RADS categories between the two groups.

Overall, MRI-targeted biopsy detected clinically significant prostate cancer in 17% of Asian-Americans versus 39% of non-Asian-Americans ($p<0.001$). [Table 2](#) shows the biopsy results across different PI-RADS classifications. Asian-Americans with a PI-RADS 4 lesion were significantly less likely to be diagnosed with clinically significant prostate cancer compared with non-Asian-Americans (16% vs 44%, $p=0.003$). For indolent cancer, diagnoses occurred in 8% of Asian-Americans vs 21% of non-Asian-Americans ($p=0.006$). This difference was also significant for PI-RADS 3 (6% vs 22%, $p=0.031$). [Figure 2](#) depicts the

proportion of biopsy-proven cancer among Asian-Americans and non-Asian-Americans.

[Table 3](#) shows the targeted and systematic biopsy yield, after accounting for systematic cores overlapping with targeted biopsy of the region(s) of interest. In both Asian-Americans and non-Asian-Americans, targeted biopsy was superior for the detection of clinically significant prostate cancer (15% vs 6%, $p=0.0455$ and 33% vs 10%, $p<0.001$ respectively). Only one Asian-American (1%) was diagnosed with clinically significant prostate cancer on systematic biopsy where targeted biopsy identified indolent prostate cancer. In the non-Asian-American cohort, 7 (1.5%) men were diagnosed with clinically significant prostate cancer on systematic biopsy while targeted biopsy showed no cancer ($n=2$) or indolent cancer ($n=5$).

Table 2 Cancer detection by PI-RADS score and overall

	Asian-American, n (%)	Other, n (%)	P value
Clinically significant prostate cancer			
PI-RADS 3	2 (6)	25 (15)	0.177
PI-RADS 4	5 (16)	89 (44)	0.003
PI-RADS 5	6 (55)	68 (67)	0.505
Overall	13 (17)	182 (39)	<0.001
Indolent prostate cancer			
PI-RADS 3	2 (6)	36 (22)	0.031
PI-RADS 4	4 (13)	46 (23)	0.248
PI-RADS 5	0 (0)	16 (16)	0.360
Overall	6 (8)	98 (21)	0.006

PI-RADS, Prostate Imaging-Reporting and Data System.

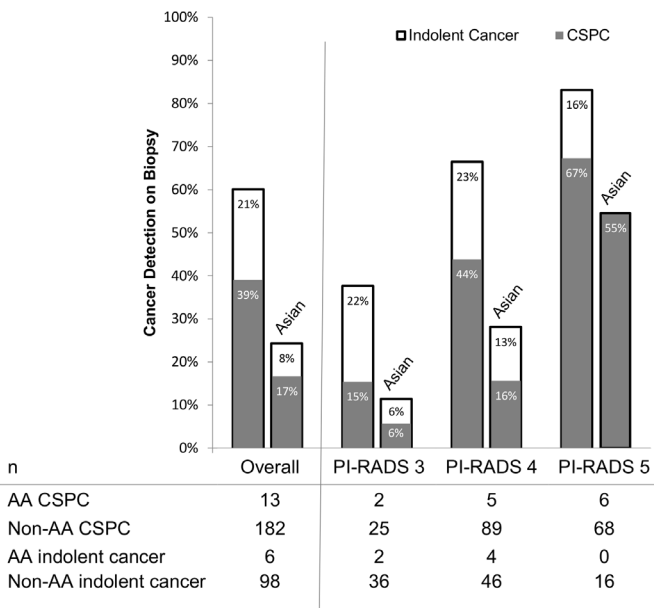


Figure 2 Prostate Imaging-Reporting and Data System (PI-RADS) and detection of prostate cancer by race. AA, Asian-American; CSPC, clinically significant prostate cancer.

In multivariable logistic regression, Asian-Americans were less likely to be diagnosed with clinically significant prostate cancer on MRI-targeted biopsy compared with non-Asian-Americans (OR 0.30, 95% CI 0.14 to 0.65, $p=0.002$). In addition, age (OR 1.07, 95% CI 1.04 to 1.11, $p<0.001$), PSA density (OR 4.02, 95% CI 2.57 to 6.29, $p<0.001$), and biopsy naïve status versus prior negative biopsy (OR 2.25, 95% CI 1.45 to 3.49, $p<0.001$) were associated with detection of clinically significant prostate cancer. The PI-RADS categories 4 (OR 3.82, 95% CI 2.27 to 6.45, $p<0.001$) and 5 (OR 7.69, 95% CI 4.14 to 14.30, $p<0.001$) had strong associations with clinically significant prostate cancer relative to PI-RADS 3 (table 4). Asian-Americans were also less likely to be diagnosed

Table 3 Comparison of biopsy result for targeted and systematic biopsy

Systematic biopsy	Targeted biopsy			Total
	No PCa n (%)	Indolent PCa n (%)	CSPC n (%)	
Asian-American				
No PCa	62 (79)	3 (4)	8 (10)	73
Indolent PCa	0 (0)	0 (0)	0 (0)	0
CSPC	0 (0)	1 (1)	4 (5)	5
Total	62	4	12	78
Other				
No PCa	239 (51)	45 (10)	101 (22)	385
Indolent PCa	12 (3)	13 (3)	8 (2)	33
CSPC	2 (0)	5 (1)	41 (9)	48
Total	253	63	150	466

CSPC, clinically significant prostate cancer; PCa, prostate cancer.

with indolent prostate cancer (OR 0.37, 95% CI 0.15 to 0.91, $p=0.030$). Older age was associated with fewer diagnoses of indolent cancer (OR 0.97, 95% CI 0.945 to 0.999, $p=0.045$).

DISCUSSION

To our knowledge, this is the first study to examine MRI-targeted biopsy performance in Asian-Americans. We demonstrate that PI-RADS underperforms in Asian-Americans versus non-Asian-Americans. In this racial group, clinically significant prostate cancer was more than two-thirds less likely to be diagnosed as compared with men of other races. This has significant implications for the potential overuse of biopsy and its harms at the population level.

Epidemiologic studies have observed a lower incidence of prostate cancer and prostate cancer-specific mortality in men of Asian-American versus non-Asian-American descent.^{17 18} These differences have been attributed to socioeconomic status and access to care. However, a prostate epidemiology study in an equal-access population demonstrated lower clinical stage and improved pathological outcomes for Asian-Americans as compared with other races.¹⁹ One may circumvent screening bias entirely by considering cases of prostate cancer found incidentally on autopsy. In this setting, Japanese immigrants to Hawaii demonstrated a significantly lower incidence of latent prostate cancer (25.6%) as compared with African-Americans (36.9%) and Caucasians (34.6%).²⁰ Both dietary and genetic factors have also been proposed to explain these trends.²¹⁻²³

Only 6% of Asian-Americans with a PI-RADS 3 region of interest were diagnosed with clinically significant prostate cancer. This is in contrast to the 15% rate observed in non-Asian-Americans which is consistent with published rates of 12%–21% for PI-RADS 3.^{3 4} Similarly, Asian-Americans also had half the incidence of indolent cancers compared with others. Our findings emphasize the importance of examining the generalizability of new medical technologies and diagnostic strategies such as PI-RADS and MRI-targeted biopsy in different populations.

Our finding that older age is associated with an increased likelihood of clinically significant prostate cancer is consistent with data from the Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE) demonstrating an association between age and high-grade disease.²⁴ A similar association has also been found in other population-based studies.^{25 26}

As expected, men with a prior negative biopsy had a lower likelihood of finding clinically significant prostate cancer.²⁷ Of note, only 6/48 (13%) of Asian-American men with a prior negative biopsy were diagnosed with clinically significant prostate cancer in contrast to 54/197 (27%) of non-Asian-Americans ($p=0.031$). Only one Asian-American man with a prior negative biopsy was diagnosed with clinically significant disease from a PI-RADS 3 region of interest, finding <5% Gleason pattern 4.

Table 4 Logistic regression for factors associated with MRI-targeted biopsy diagnosis of indolent and clinically significant prostate cancer

Covariable	Indolent cancer		Significant cancer	
	OR (95% CI)	P value	OR (95% CI)	P value
Asian-American	0.37 (0.15 to 0.91)	0.030	0.30 (0.14 to 0.65)	0.002
Biopsy naïve	1.14 (0.73 to 1.80)	0.566	2.25 (1.45 to 3.49)	<0.001
PI-RADS 3*	–	–	–	–
PI-RADS 4	1.16 (0.71 to 1.89)	0.558	3.82 (2.27 to 6.45)	<0.001
PI-RADS 5	0.77 (0.39 to 1.52)	0.450	7.69 (4.14 to 14.30)	<0.001
Age (years)	0.97 (0.95 to 0.999)	0.045	1.07 (1.04 to 1.11)	<0.001
Body mass index (kg/m ²)	0.98 (0.93 to 1.05)	0.604	1.03 (0.97 to 1.09)	0.362
PSAD (ng/mL/cm ³)	0.82 (0.52 to 1.30)	0.401	4.02 (2.57 to 6.29)	<0.001

Non-AA is the referent for AA. Prior negative biopsy is the referent for biopsy naïve.

*PI-RADS 3 as referent.

†PSAD <0.15 as referent.

AA, Asian-American; PI-RADS, Prostate Imaging-Reporting and Data System; PSAD, prostate-specific antigen density.

Our findings exemplify the significance of the ‘long-term monitoring’ IDEAL stage 4 for a commonly performed invasive intervention that has diagnostic intent for the most common solid organ tumor in Western countries.⁶ Despite strong evidence demonstrating better outcomes of a new technological innovation, real-world evidence must be gathered to assess its effectiveness beyond the population in which it was developed and validated. As use of prostate MRI has grown in recent years, estimates show its adoption as a reflex test for elevated PSA would contribute billions of healthcare dollars annually.²⁸ Our finding of low performance of PI-RADS 3 for Asian-Americans in an experienced center has significant implications for prostate cancer screening and biopsy overuse in men of Asian descent. For instance, a higher PI-RADS threshold for MRI-targeted biopsy in Asian-Americans may be more cost-effective and spare many the morbidity of biopsy, particularly with the significant increase in the infectious complications of prostate biopsy.^{10–12} MRI-targeted biopsy may be limited to Asian-American men with PI-RADS 4–5 with 16%–55% detection of clinically significant prostate cancer compared with PI-RADS 3–5 in non-Asian-Americans with 15%–67% detection of clinically significant prostate cancer. Furthermore, our results have significant implications for other settings which rely on prostate MRI, such as targeting for prostate partial gland ablation and/or surgical planning. Additional investigation into the independent effect of race on MRI-guided treatment outcomes is needed.

Our findings must be interpreted in the context of our study design. We attempted to employ a broad and inclusive categorization of Asian-American race, however East Asian-Americans comprised the majority of study subjects. We were not able to stratify by immigration history (first generation, and so on) or lifestyle such as exercise and diet. As discussed, our cohort comprised both biopsy-naïve

men and those with prior negative biopsy, but this was accounted for in adjusted analysis. Prostate MRI scoring is variable, with one study of nine radiologists reviewing the same images demonstrating significant variation in determination of PI-RADS 3, ranging from 5% to 26%.²⁹ The study benefited from an experienced urologist (DJM) interpreting MRI images. Finally, as a study in New York City with its diverse population, our results may be validated by others through future multi-institutional studies consistent with IDEAL stage 4 recommendations to include regionally or nationally representative populations.

CONCLUSIONS

Despite evolution of prostate MRI and targeted biopsy through IDEAL stage 3 *Assessment*, we demonstrate significant overestimation of PI-RADS risk assessment for prostate cancer in Asian-American men with an elevated PSA. Asian-Americans are 70% less likely to be diagnosed with clinically significant prostate cancer on MRI-targeted biopsy. Moreover, the incremental benefit of systematic biopsy in all men regardless of race was low, but markedly lower in Asian-Americans. Further, Asian-American men with a PI-RADS 3 region of interest may forego biopsy altogether. This has critical implications for other clinical settings for prostate cancer diagnosis and treatment, which is increasingly dependent on prostate MRI assessment.

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Contributors All authors have made substantial contributions to the conception or design of the work, or the acquisition, analysis or interpretation of data and have approved this manuscript.

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