Variation in Magnetic Resonance Imaging-Ultrasound Fusion Targeted Biopsy Outcomes in Asian American Men: A Multicenter Study

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Abbreviations and Acronyms

CSPC = clinically significant prostate cancer

GG = Grade Group

MRI = magnetic resonance imaging

PI-RADS™ = Prostate Imaging-Reporting and Data System

PSA = prostate specific antigen

ROI = region of interest

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Purpose: Asian American men have distinctly different prostate cancer epidemiology than other men. To our knowledge the role of multiparametric magnetic resonance imaging and targeted biopsy for elevated prostate specific antigen in this population has not been assessed. We sought to define imaging and targeted biopsy outcomes in Asian American men compared to other men.

Materials and Methods: We accrued a multicenter, prospective cohort of men who underwent magnetic resonance imaging targeted and systematic biopsy for elevated prostate specific antigen. The outcome of interest was a diagnosis of clinically significant prostate cancer (Gleason Grade Group 2 or greater) stratified by the PI-RADS™ (Prostate Imaging-Reporting and Data System) score and a history of negative biopsy. Multivariable logistic regression was used to assess the effect of Asian American race on cancer detection.

Results: Of the 2,571 men 275 (11%) were Asian American. Clinically significant prostate cancer was detected in 37% of Asian American men compared to 48% of men of other races ($p < 0.001$). Asian American men were also less likely to be diagnosed with Grade Group 1 cancer (12% vs 18%, $p = 0.007$). Additionally, there was significantly lower detection of significant cancer using PI-RADS 3 in Asian American men vs men of other races (12% vs 21%, $p = 0.032$). On adjusted analysis Asian American men were less likely to be diagnosed with significant cancer (OR 0.57, 95% CI 0.42–0.79, $p < 0.001$) and Grade Group 1 cancer (OR 0.57, 95% CI 0.38–0.84, $p = 0.005$) than nonAsian men.

Conclusions: Asian American men are less likely to be diagnosed with clinically significant prostate cancer on targeted biopsy, illustrating the different performance of PI-RADS in this population. Conventional risk assessment tools should be modified when selecting Asian American men for biopsy.

Key Words: prostatic neoplasms, Asian continental ancestry group, image-guided biopsy, magnetic resonance imaging, risk assessment

The EAU (European Association of Urology) 2019 Prostate Cancer Guidelines endorse multiparametric MRI prior to prostate biopsy for elevated PSA.[1] Prostate MRI is assessed by PI-RADS™, version 2.0. This risk assessment was primarily developed in European men with a low Asian representation.[2] Randomized trials have supported the benefit of MRI targeted biopsy to detect prostate cancer.[3–5] However, these trials

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enrolled predominantly Caucasian men in North American and European centers.[4,5]

Defining the usefulness of prostate cancer diagnostic modalities in underrepresented populations is a priority.[6] Furthermore, the IDEAL (Idea, Development, Exploration, Assessment and Long-Term Study) Collaboration to improve the quality of research in surgery emphasizes the need for continued investigation and evaluation of novel technologies in subpopulations.[7] This is particularly important in the Asian population, given recent immigration trends in Western countries and the known difference in prostate cancer epidemiology.[8] In the United States Asian Americans are the fastest growing population.[9] Similarly, in the United Kingdom the Asian population is expected to quadruple by 2056.[10]

Asian men have a lower incidence of prostate cancer at 56.0/100,000 compared to 101.7/100,000 in nonHispanic Caucasian men.[8] Differences in the predictive ability of prostate cancer biomarkers have been demonstrated in European vs Asian populations.[11] However, to our knowledge the accuracy of PI-RADS and targeted biopsy outcomes has not been assessed in Asian American men. Therefore, we sought to assess MRI targeted prostate biopsy outcomes to detect CSPC in Asian American men.

MATERIALS AND METHODS

Study Population

We pooled and retrospectively analyzed MRI targeted biopsy data prospectively collected during 2010 to 2018 from 4 institutions, including Weill Cornell Medicine-New York Presbyterian Hospital, UCLA, Stanford University and New York Presbyterian-Queens Hospital. Data collection was approved by Institutional Review Boards at each institution (IRB No. 1509016548). We excluded men on active surveillance who underwent MRI targeted biopsy. Additionally, men with a PI-RADS classification less than 3 were excluded as criteria for biopsy in these men differed among institutions (fig. 1).

Magnetic Resonance Imaging and Fusion Biopsy

Subjects underwent contrast enhanced, multiparametric 3 Tesla MRI without an endorectal coil. Studies were performed with T1-weighted and T2-weighted imaging, dynamic contrast enhanced imaging and diffusion-weighted imaging. Regions of interest were categorized using PI-RADS version 2 by experienced uroradiologists. MRI studies done prior to the release of PI-RADS version 2 in 2015 were retrospectively recategorized using reported imaging features, including zone, size, borders and signal characteristics. All scans, including those acquired before 2015, were acquired in accordance with PI-RADS version 2 technical specifications.

All biopsies were performed using the Artemis™ MRI-ultrasound fusion targeted biopsy platform in the outpatient setting with the patient under local anesthesia.

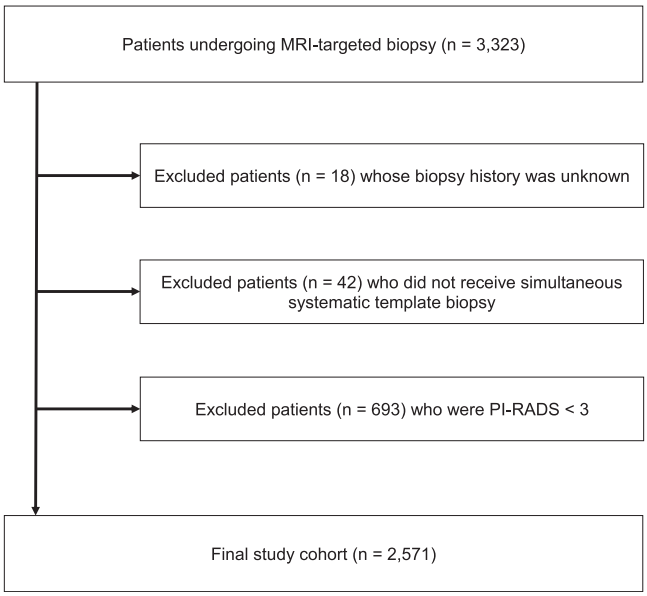


Figure 1. Patient selection and exclusion criteria

Biopsies included targeted sampling and standardized systematic cores with a minimum of 12 systematic cores as generated by the Artemis template. All biopsy specimens were reviewed by an experienced genitourinary pathologist. CSPC was defined as Gleason GG 2 or greater.

Identification of Asian American Men

Race was ascertained from medical records when it was recorded. In cases in which race was unknown, as at Weill Cornell and New York Presbyterian-Queens, we applied standardized surname analysis to classify additional Asian men.[12] This method used lists of names provided by the authors generated from SSA (Social Security Administration) records including country of birth and are validated against census reports with 82% to 98% positive predictive value. Notably, race in 78 of the 88 men (89%) who self-identified as Asian in the study was validated using this surname analysis.

Study Outcomes and Statistical Analysis

The primary study outcome was CSPC detection. Secondary outcomes included CSPC detection stratified by PI-RADS category, biopsy status (biopsy naïve or prior negative biopsy), detection of indolent prostate cancer (GG 1) and cancer detected by targeted vs systematic biopsy.

Collected baseline characteristics included race, age, prebiopsy PSA, prostate volume on MRI, PSA density greater than 0.15 ng/ml/cm^3, PI-RADS category and prior negative vs first time biopsy. Continuous and categorical data were analyzed by the Mann-Whitney U and chi-square tests, and the Fisher exact test, respectively. Systematic and targeted biopsy yields were compared by the McNemar test of equivalence. Multivariable logistic regression was done to assess the association of Asian American race with prostate cancer detection.

All tests were considered statistically significant at $\alpha = 0.05$. Analysis was performed with SAS®, version 9.4.

Table 1. *Study population baseline characteristics*

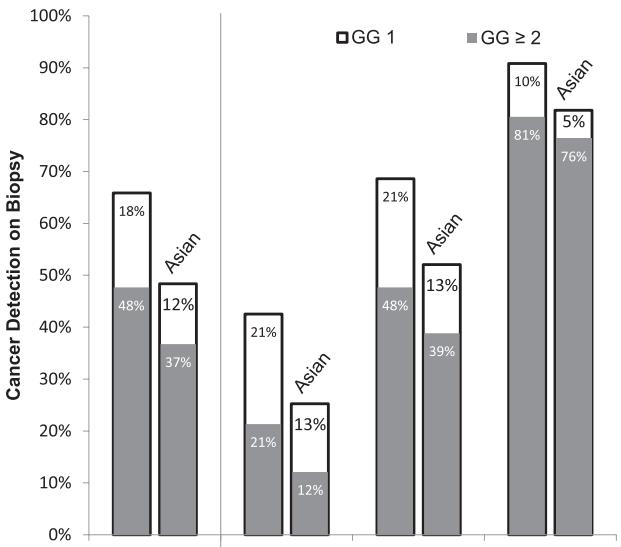
	Asian American	Other	p Value
No. pts	275	2,296	—
Median age (IQR)	67 (62–72)	67 (62–72)	0.461
Median ng/ml PSA (IQR)	7.6 (5.2–12.2)	6.9 (4.9–10.3)	0.060
Median cm^3 prostate vol (IQR)	43.0 (33–67)	49.1 (36–69)	0.009
Median ng/ml/cm^3 PSA density (IQR)	0.17 (0.11–0.25)	0.14 (0.09–0.22)	<0.001
Median cm ROI diameter (IQR)	1.1 (0.6–1.5)	1.1 (0.7–1.5)	0.809
No. biopsy naïve (%)	141 (51.3)	1,277 (55.6)	0.171
No. PI-RADS (%):			
3	99 (36.0)	764 (33.3)	0.061
4	121 (44.0)	921 (40.1)	
5	55 (20.0)	611 (26.6)	
No. center (%):			
Queens	41 (14.9)	91 (4.0)	<0.001
Stanford	71 (25.8)	541 (23.6)	
UCLA	85 (30.9)	1,198 (52.2)	
Weill Cornell	78 (28.4)	466 (20.3)	

RESULTS

Table 1 shows baseline demographic and clinical characteristics. Of the 2,571 men included in study 275 (11%) were Asian American, 1,564 (61%) were Caucasian, 152 (6%) were African American, 145 (6%) were Hispanic and 435 (17%) were of unknown or other race. Asian American men had a smaller prostate than the others (43.0 vs 49.1 cm^3, p=0.009). PSA density was significantly higher in Asian American men (0.17 vs 0.14 ng/ml/cm^3, p <0.001). Age at biopsy, ROI diameter on MRI and the distribution of PI-RADS categories did not differ between Asian American men and men of other races (all p≥0.05).

CSPC was detected in 37% of Asian American men vs 48% of other men (p <0.001, supplementary table, https://www.jurology.com). Asian American men were also less likely to be diagnosed with indolent cancer (12% vs 18%, p=0.007). Of men with PI-RADS category 3 ROIs only the Asian American men were less likely to be diagnosed with CSPC on biopsy compared to other men (12% vs 21%, p=0.032, fig. 2). Of men with a prior negative biopsy CSPC was diagnosed less often in Asian American men (27% vs 40%, p=0.003).

Targeted biopsy was equivalent to concurrent systematic biopsy for detecting CSPC in Asian American men (29.1% vs 26.5%, p=0.317). However, targeted



n	Overall	PI-RADS 3	PI-RADS 4	PI-RADS 5
Asian American GG ≥ 2	101	12	47	42
Non-Asian American GG ≥ 2	1094	163	439	492
Asian American GG 1	32	13	16	3
Non-Asian American GG 1	418	162	193	63

Figure 2. PI-RADS and prostate cancer detection by race

Table 2. *Targeted and systematic biopsy results*

	No. Targeted Biopsy (%)			
Systematic Biopsy	No Prostate Ca	GG 1	GG 2 or Greater	Total No.
Asian American:	166	29	80	275
No prostate Ca	145 (52.7)	8 (2.9)	22 (8.0)	175
GG 1	8 (2.9)	13 (4.7)	6 (2.2)	27
GG 2 or Greater	13 (4.7)	8 (2.9)	52 (18.9)	73
Other races:	1,049	307	940	2,296
No prostate Ca	837 (36.5)	99 (4.3)	235 (10.2)	1,171
GG 1	139 (6.1)	152 (6.6)	157 (6.8)	448
GG 2 or Greater	73 (3.2)	56 (2.4)	548 (23.9)	677

biopsy was superior to detect CSPC in other men (40.9% vs 29.5%, p <0.001). Table 2 shows the concordance between targeted and systematic biopsies. In Asian American men targeted biopsy failed to detect 7.6% of CSPC while systematic biopsy missed 10.2%. In men of other races targeted biopsy failed to detect 5.6% of CSPC while systematic biopsy missed 17.1%. Compared to Asian American men systematic biopsy was less likely to detect CSPC in men of other races (p=0.003) while targeted biopsy detection did not significantly differ (p=0.177).

On multivariable logistic regression analysis Asian American men were less likely to be diagnosed with CSPC on MRI targeted biopsy compared to other men (OR 0.57, 95% CI 0.42–0.79). Age (OR 1.05, 95% CI 1.04–1.06), PSA density (OR 3.75, 95% CI 3.10–4.54) and first time biopsy status vs prior negative biopsy (OR 1.78, 95% CI 1.46–2.15, all p <0.001) were associated with CSPC detection. PI-RADS categories 4 and 5 (vs PI-RADS 3) were associated with higher detection of CSPC (OR 3.29, 95% CI 2.63–4.10 and OR 11.75, 95% CI 8.99–15.37, respectively, each p <0.001, table 3). Asian American men were less likely to be diagnosed with indolent cancer (OR 0.57, 95% CI 0.38–0.84, p=0.005). Older age, higher PSA density and a PI-RADS 5 ROI were associated with lower odds of indolent cancer detection (OR 0.98, 95% CI 0.96–0.99; OR 0.67, 95% CI 0.54–0.83; and OR 0.50, 95% CI 0.37–0.69, respectively, all p <0.001).

DISCUSSION

In a multicenter cohort we found that PI-RADS and MRI targeted biopsy outcomes distinctly differed in Asian American men compared to men of other races. After adjusting for potential confounders Asian American men were 50% less likely to harbor CSPC. Historically, Asian men have a lower prostate cancer incidence relative to other men in the United States and the United Kingdom.[8,13] Prostate cancer incidence is also much lower in Asian countries than in the United States and European countries, although this is thought to be due in part to differences in screening.[14] Additional biological and lifestyle factors are also thought to contribute to these epidemiological differences.[15–17]

For PI-RADS 3 ROIs the biopsy yield of CPSC and indolent cancer in Asian American men was also half that observed in other men. The low 12% CSPC detection rate in Asian American men is similar to that in studies performed in Japan and Singapore.[18,19] The 21% rate of CSPC detection in all other men with PI-RADS 3 ROIs was consistent with the 21% rate reported in the PROMIS (Patient-Reported Outcome Measurement Information System) trial.[3]

This study illustrates the pitfalls of applying biomarker classifications derived in men of European descent to Asian American men. For example, the ERSPC (European Randomized Study of Screening for Prostate Cancer) PSA based screening trial showed a 9.76% prostate cancer incidence while a universal screening program in Japan resulted in a

Table 3. *Logistic regression of factors associated with MRI targeted biopsy diagnosis of GG 2 or greater and GG 1 prostate cancer*

	GG 1		GG 2 or Greater	
	OR (95% CI)	p Value	OR (95% CI)	p Value
Asian American*	0.57 (0.38–0.84)	0.005	0.57 (0.42–0.79)	<0.001
Biopsy naïve†	1.12 (0.91–1.39)	0.290	1.78 (1.46–2.15)	<0.001
PI-RADS score:				
3	Referent	—	Referent	—
4	1.00 (0.80–1.26)	0.984	3.29 (2.63–4.10)	<0.001
5	0.50 (0.37–0.69)	<0.001	11.75 (8.99–15.37)	<0.001
Age	0.98 (0.96–0.99)	<0.001	1.05 (1.04–1.06)	<0.001
PSAD (ng/ml/cc):				
Less than 0.15 (referent)	Referent	—	Referent	—
0.15 or Greater	0.67 (0.54–0.83)	<0.001	3.75 (3.10–4.54)	<0.001
Center:				
Weill Cornell	Referent	—	Referent	—
Queens	0.87 (0.52–1.46)	0.606	1.43 (0.91–2.25)	0.118
Stanford	1.05 (0.77–1.42)	0.770	1.65 (1.25–2.20)	<0.001
UCLA	0.88 (0.68–1.15)	0.360	1.50 (1.17–1.92)	0.001

* Referent is nonAsian American.
† Referent is prior negative biopsy.

0.76% cancer detection rate.[20,21] Neither the PRECISION (Prostate Evaluation for Clinically Important Disease: Sampling Using Image-guidance or Not?) trial nor the MRI-FIRST (Assessment of Prostate MRI Before Prostate Biopsies) trial describes racial breakdown but they were performed in mostly North American and European centers.[4,5] Moreover, European derived risk assessment calculators such as the ERSPC have been shown to under perform in Korean men relative to the Seoul National University Prostate Cancer Risk Calculator.[22] Our findings highlight the need for additional studies to improve risk stratification in racially distinct populations in which critical genetic variations have historically been missed in large-scale studies.[23]

We found that increased age and first biopsy were associated with increased odds of cancer detection, consistent with prior studies.[24–26] Contrary to recent results from the MRI-FIRST trial, we found that targeted biopsy alone was superior for detecting CSPC in men who underwent initial biopsy compared to systematic biopsy ($p < 0.001$).[5] However, this difference was not present in Asian American men. While optimal cancer detection was achieved by combining systematic and targeted biopsy, the incremental benefit of MRI targeted biopsy appeared to be lower in Asian American men. Moreover, in the prior negative biopsy setting a third less CSPC was detected in Asian American men than in other men. For instance, only 1 of 52 Asian American men (2%) who underwent repeat biopsy with a PI-RADS 3 ROI was diagnosed with CSPC (GG 3 disease). At a 4% incidence CSPC detection was double in the 394 men of other races who underwent repeat biopsy with a PI-RADS 3 ROI, including 10 (3%) with GG 3, 3 (1%) with GG 4 and 2 (1%) with GG 5.

Our results suggest that PI-RADS 3 ROIs may not require biopsy in Asian American men, avoiding the well documented procedural morbidity.[27,28] In our study only 12% of CSPC overall was diagnosed in Asian American men with a PI-RADS 3 ROI. Using PI-RADS 4 as a biopsy threshold in these patients would have resulted in an MRI negative predictive value of 0.88 (95% CI 0.81–0.93), sparing 36% of Asian American men from biopsy. It is possible that supplementing with other biomarkers may improve risk stratification to avoid biopsy in Asian men with a PI-RADS 3 ROI.[11]

Our findings must be interpreted in the context of the study design. We could not assess immigration history (eg native vs foreign born), diet or other lifestyle factors in this multicenter study. Furthermore, we could not adjust for different Asian ethnicities, including South, Central, Southeast, Middle Eastern and Far East groups. However, subgroup analysis suggested that at least 90% of the men were of Far East Asian descent. We also recognize that the diverse ethnicities comprising Asian American race may result in significant differences in MRI targeted biopsy outcomes.

The surname analysis used to identify additional Asian American men is a potential source of bias. However, these men represented only 12% of our final cohort and 89% who self-identified confirmed that they used this method.

The study is limited by the retrospective use of PI-RADS version 2 but this reflects a reality of evolving clinical practice. Site specific differences in cancer detection were observed, which is not uncommon in multicenter studies (supplementary figure, https://www.jurology.com). This may be secondary to differences in cancer prevalence, biopsy decision making, PI-RADS scoring or targeted biopsy learning curves.[29,30]

CONCLUSIONS

In a large multicenter cohort we found that Asian American men were half as likely to be diagnosed with CSPC on MRI targeted biopsy. In particular, Asian American men should be counseled that the risk of CSPC is significantly lower in those with PI-RADS 3 ROIs and longitudinal PSA monitoring may be offered. Moreover, we report that the diagnostic yield of targeted and systematic biopsies is similar in Asian American men while the targeted biopsy yield is superior in men of other races. Finally, our findings exemplify the need to validate biomarker accuracy in races beyond developmental populations.

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EDITORIAL COMMENT

Should MRI of the prostate be read while blinded to clinical information? This question is most interesting as the consensus of the PI-RADS committee has been to assess the PI-RADS score in the absence of any clinical information.[1]

Yet the current study provides some insight on how this vision could be questioned. The study reveals that the likelihood of significant cancer on MRI targeted biopsy was significantly lower in patients from an Asian heritage, especially those with a PI-RADS 3 lesion. This suggests that a similar finding on MRI could have different meanings depending on the background of the patient. In fact, it shines a new light on how to integrate MRI results in practice. The score is a probability of cancer based on imaging features and just that. This last sentence is sometimes overlooked and radiologists and referring clinicians may put too much emphasis on the MRI results in isolation. This score is only one of many factors to integrate into the evaluation of patients at risk for cancer. Clinical factors should be used not only to decide when to perform MRI but also to interpret the MRI result itself.

So, should MRI of the prostate be read while unblinded from clinical information? The debate remains open and it is worth more research.[2] However, the current study gives a compelling argument on why the PI-RADS score should have a disclaimer next to it: these results should be interpreted in light of all clinical information available… including ethnicity!

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REPLY BY AUTHORS

Biopsy practices surrounding the MRI result are relatively standard and yet race remains an under studied and underused component of risk assessment which we have only just begun to address in this study. MRI represents but a piece of the puzzle. It is most effective to predict the presence or absence of significant cancer when combined with PSA density and other measures. Moreover, PSA density has been proposed as a means to avoid biopsy in cases of some PI-RADS 3 lesions.[1]

We do not advocate that radiologists should begin to consider clinical factors in PI-RADS grading. In fact, it has been demonstrated that adding a randomly assigned clinical history does not significantly bias the reader (reference 2 in comment). Rather, the future of the diagnostic pathway is sure to involve such personalized measures as race in concert with advanced biomarkers and imaging.

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