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Variability of the Positive Predictive Value of PI-RADS for Prostate MRI across 26 Centers: Experience of the Society of Abdominal Radiology Prostate Cancer Disease-focused Panel

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Conflicts of interest are listed at the end of this article.

See also the editorial by Milot in this issue.

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Background: Prostate MRI is used widely in clinical care for guiding tissue sampling, active surveillance, and staging. The Prostate Imaging Reporting and Data System (PI-RADS) helps provide a standardized probabilistic approach for identifying clinically significant prostate cancer. Despite widespread use, the variability in performance of prostate MRI across practices remains unknown.

Purpose: To estimate the positive predictive value (PPV) of PI-RADS for the detection of high-grade prostate cancer across imaging centers.

Materials and Methods: This retrospective cross-sectional study was compliant with the HIPAA. Twenty-six centers with members in the Society of Abdominal Radiology Prostate Cancer Disease-focused Panel submitted data from men with suspected or biopsy-proven untreated prostate cancer. MRI scans were obtained between January 2015 and April 2018. This was followed with targeted biopsy. Only men with at least one MRI lesion assigned a PI-RADS score of 2–5 were included. Outcome was prostate cancer with Gleason score (GS) greater than or equal to 3+4 (International Society of Urological Pathology grade group ≥2). A mixed-model logistic regression with institution and individuals as random effects was used to estimate overall PPVs. The variability of observed PPV of PI-RADS across imaging centers was described by using the median and interquartile range.

Results: The authors evaluated 3449 men (mean age, 65 years ± 8 [standard deviation]) with 5082 lesions. Biopsy results showed 1698 cancers with GS greater than or equal to 3+4 (International Society of Urological Pathology grade group ≥2) in 2082 men. Across all centers, the estimated PPV was 35% (95% confidence interval [CI]: 27%, 43%) for a PI-RADS score greater than or equal to 3 and 49% (95% CI: 40%, 58%) for a PI-RADS score greater than or equal to 4. The interquartile ranges of PPV at these same PI-RADS score thresholds were 27%–44% and 27%–48%, respectively.

Conclusion: The positive predictive value of the Prostate Imaging and Reporting Data System was low and varied widely across centers.

Online supplemental material is available for this article.

Prostate MRI with MRI-targeted biopsy has been among the most impactful recent technologies for prostate cancer detection and risk stratification. Overdiagnosis and overtreatment of prostate cancer, as well as underdetection of disease, are well recognized health care problems that MRI may help mitigate. According to the PRECISION trial (Prostate Evaluation for Clinically Important Disease: Sampling Using Image Guidance or Not?), prostate MRI with

Abbreviations

CI = confidence interval, DFP = disease-focused panel, GS = Gleason score, IQR = interquartile range, ISUP = International Society of Urological Pathology, PI-RADS = Prostate Imaging Reporting and Data System, PPV = positive predictive value

Summary

Wide variation in prostate cancer detection is seen across all Prostate Imaging Reporting and Data System scores for men with suspected or biopsy-proven untreated prostate cancer who undergo MRI.

Key Result

- In a multicenter cross-sectional study of the Prostate Imaging Reporting and Data System (PI-RADS) in men with suspected or biopsy-proven untreated prostate cancer, the detection rate of Gleason score 3+4 or higher was low (estimated PI-RADS ≥3; positive predictive value = 35%) and varied widely across imaging centers (interquartile range of positive predictive value for PI-RADS ≥3 = 27%–48%).

MRI-targeted biopsy helps detect more clinically significant cancer and fewer clinically insignificant prostate cancers compared with standard systematic biopsy (1). In 2016, the American Urological Association and the Society of Abdominal Radiology published in 2016 a consensus statement supporting the use of prostate MRI and MRI-targeted biopsy in patients with a prior negative prostate biopsy (2). The European Urology Association states that multiparametric MRI should be performed before biopsy and that biopsy should combine targeted and systematic sampling (3). Finally, Medicare utilization databases demonstrate the rapidly growing adoption of MRI-targeted prostate biopsy across the nation (4).

The Prostate Imaging Reporting and Data System (PI-RADS) version 2 international consensus recommendations were developed to standardize the acquisition, interpretation, and reporting of prostate MRI (5). Published data support the overall use of PI-RADS for prostate cancer detection, and this system has undergone rapid incorporation into widespread clinical practice. However, single-center studies have called into question the system's reliability (6–8). It has been suggested that PI-RADS may be challenging to translate to smaller or community centers, lowering its performance relative to expert centers (9). Such concerns regarding the variability in performance of prostate MRI, including that of PI-RADS, continue to pose barriers to broader incorporation of prostate MRI into clinical practice. Nonetheless, the extent of variability in the diagnostic performance of prostate MRI remains incompletely investigated. Such knowledge would be useful to not only better understand the expected performance of prostate MRI across practice settings, but also to guide the establishment of minimum performance benchmarks and implementation of quality improvement initiatives at individual centers.

Accordingly, we conducted this study to estimate the positive predictive value (PPV) of PI-RADS for the detection of high-grade prostate cancer across imaging centers.

Materials and Methods

Study Design

This investigator-initiated pragmatic retrospective multicenter cross-sectional study of PI-RADS was compliant with the Health Insurance Portability and Accountability Act. The study protocol was approved by each participating institution's committee on human research, and the requirement to obtain written informed consent was waived. Four authors reported potential conflicts of interest (listed at the end of the article). This project was supported by a seed grant from the Department of Radiology and Biomedical Imaging, University of California, San Francisco, and the Clinical and Translational Science Institute, University of California, San Francisco. The funders had no influence on the design or conduct of the study and were not involved in data collection or analysis, in the writing of the manuscript, or in the decision to submit it for publication. No industry support was received for this project.

Study Participants

The Society of Abdominal Radiology Prostate Cancer Disease-focused Panel (DFP) is an international panel of experts in prostate MRI. The lead investigators (DFP members A.C.W. and A.B.R., with 17 and 12 years of experience, respectively) invited all members of the DFP to submit retrospective consecutive-patient data regarding the results of MRI-targeted prostate biopsy from their individual institutions. Confirmation of sampling method at individual centers is not available, and the sample should be considered a convenience sample. Only one DFP member did not participate in the study because of a potential conflict with a concurrent project at the member's institution. All participating institutions had one DFP member, except for two centers that each had two DFP members.

Figure 1 shows the general outline of the study. Participating centers submitted data for all eligible patients at their institution within the study period. Eligible patients comprised adult men (≥18 years) with suspected prostate cancer (elevated prostate-specific antigen level or abnormal digital rectal examination) or untreated biopsy-proven prostate cancer who underwent prostate MRI between January 2015 and April 2018. MRI scans were acquired and interpreted according to the PI-RADS recommendations, followed by MRI-targeted biopsy. Information regarding institutions' individual imaging protocols is available in Table E1 (online). Prostate MRI was performed at 1.5 T or 3 T. Only men with at least one MRI lesion assigned a PI-RADS score of 2–5 were included, given that a PI-RADS score of 1 indicates an absence of an MRI-reported lesion, thereby precluding MRI-targeted biopsy. Representative sample images are shown in Figures 2 and 3. Scans were interpreted as part of standard clinical care at the individual centers. Accordingly, the actual interpreting radiologists were not all expert members of the Society of Abdominal Radiology Prostate Cancer DFP, and the interpreting radiologists' experience varied across centers. The DFP members did not review or reinterpret MRI scans prior to data submission. No requirements were placed on participating centers regarding magnetic field strength, scanner vendor, use of an endorectal coil, biopsy targeting method, or acquisition of systematic cores. MRI-targeted biopsy was required to be performed within 180 days after prostate MRI. Only images from a single examination per patient could be included. When multiple scans were available, the initial one was submitted.

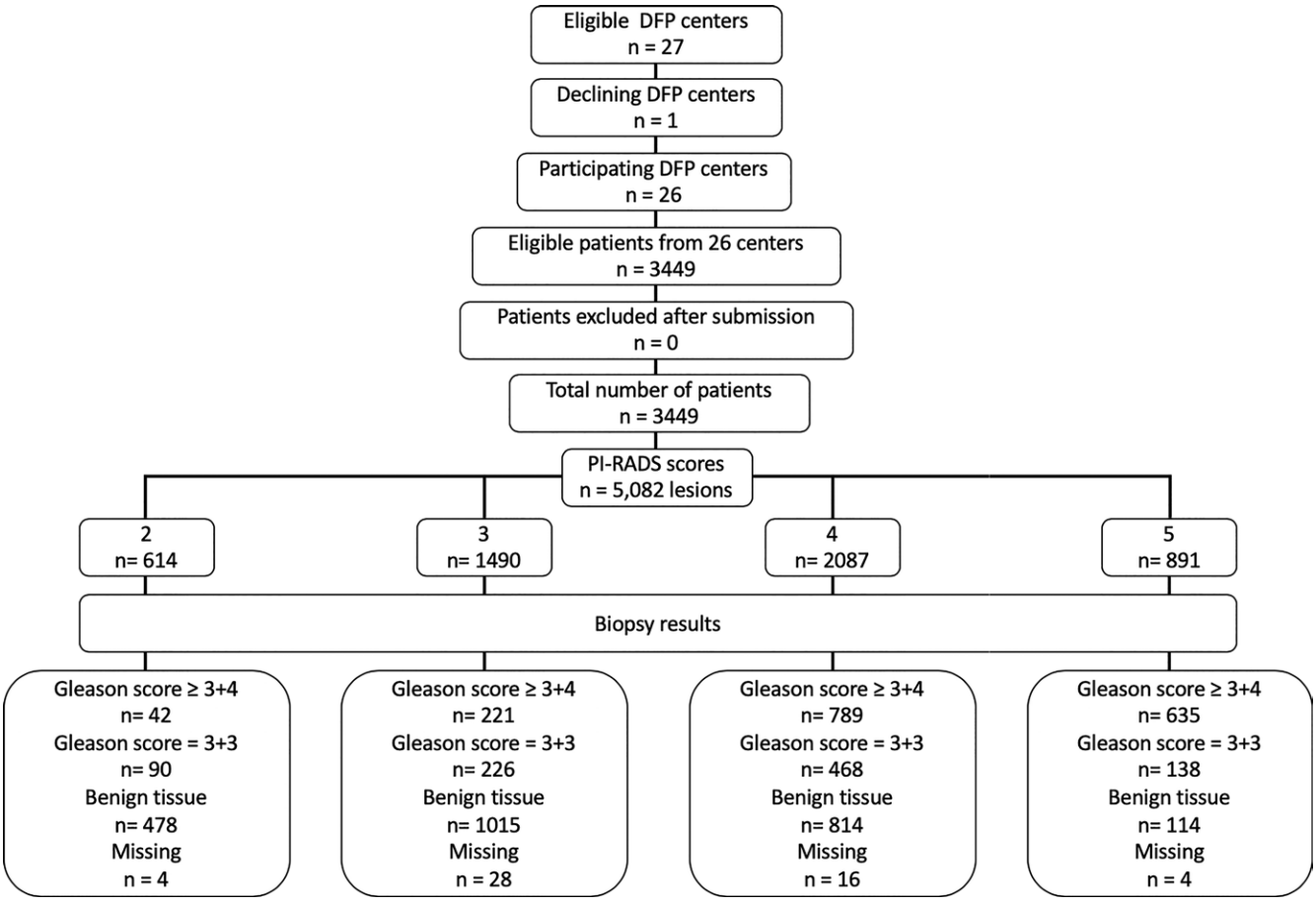

Figure 1: Flowchart shows the number of participating imaging centers and patients, as well as MRI and biopsy results. DFP = disease-focused panel, PI-RADS = Prostate Imaging Reporting and Data System.

Targeted biopsies were performed as part of standard clinical care at the individual institutions. Accordingly, the expertise of the physicians performing the biopsies also varied across centers. Cognitive and transrectal US–guided MRI fusion biopsies were performed by urologists or radiologists, while in-bore biopsies were performed by radiologists. Table E1 (online) summarizes the characteristics of all imaging centers.

Patients who had previously undergone therapy for prostate cancer were not included, given that PI-RADS states that the scoring should not be applied to assess for recurrent cancer. Patients with hip replacement were not eligible for inclusion given extensive susceptibility to artifact and image distortion resulting on MRI from hip replacement, thus precluding reliable assignment of PI-RADS categories.

Data Collection

All study data were anonymized and collected using a standardized web-based form created using Research Electronic Data Capture, or REDCap (10), electronic data capture tools hosted at the University of California, San Francisco (Appendix E1 [online]). Research Electronic Data Capture is a secure, web-based application designed to support data capture for research studies. It provides *(a)* an intuitive interface for validated data entry, *(b)* audit trails for tracking data manipulation and export procedures, *(c)* automated export procedures for data downloads to common statistical packages, and *(d)* procedures for importing data from external sources.

The requested information submitted for each patient included *(a)* demographic information (age, race, and/or ethnicity), *(b)* family history of prostate cancer, *(c)* presence and results of any prior prostate biopsy (including Gleason score [GS] if positive), *(d)* baseline prostate-specific antigen level, *(e)* presence of palpable nodule at rectal examination, *(f)* MRI technique (magnet strength, vendor, and coil type), *(g)* MRI characteristics (location, size, and PI-RADS scores) of up to four MRI-defined lesions, *(h)* prostate volume estimated with MRI, *(i)* biopsy approach (transrectal or transperineal), *(j)* targeting technique (cognitive, transrectal US–guided MRI fusion, or in-bore), *(k)* biopsy results for each MRI-targeted lesion, and *(m)* and concurrent systematic procedure (lesion GS).

Statistical Analysis

The goal of this study was to estimate the variability of high-grade prostate cancer detection rate with PI-RADS. PPV is defined as the rate at which the outcome of interest is correctly detected. Accordingly, the term *PPV* is used to refer to the detection rate of high-grade prostate cancer with PI-RADS. The outcome for statistical analyses was the detection of clinically significant prostate cancer, defined as GS greater than or equal to 3+4 (International Society of Urological Pathology

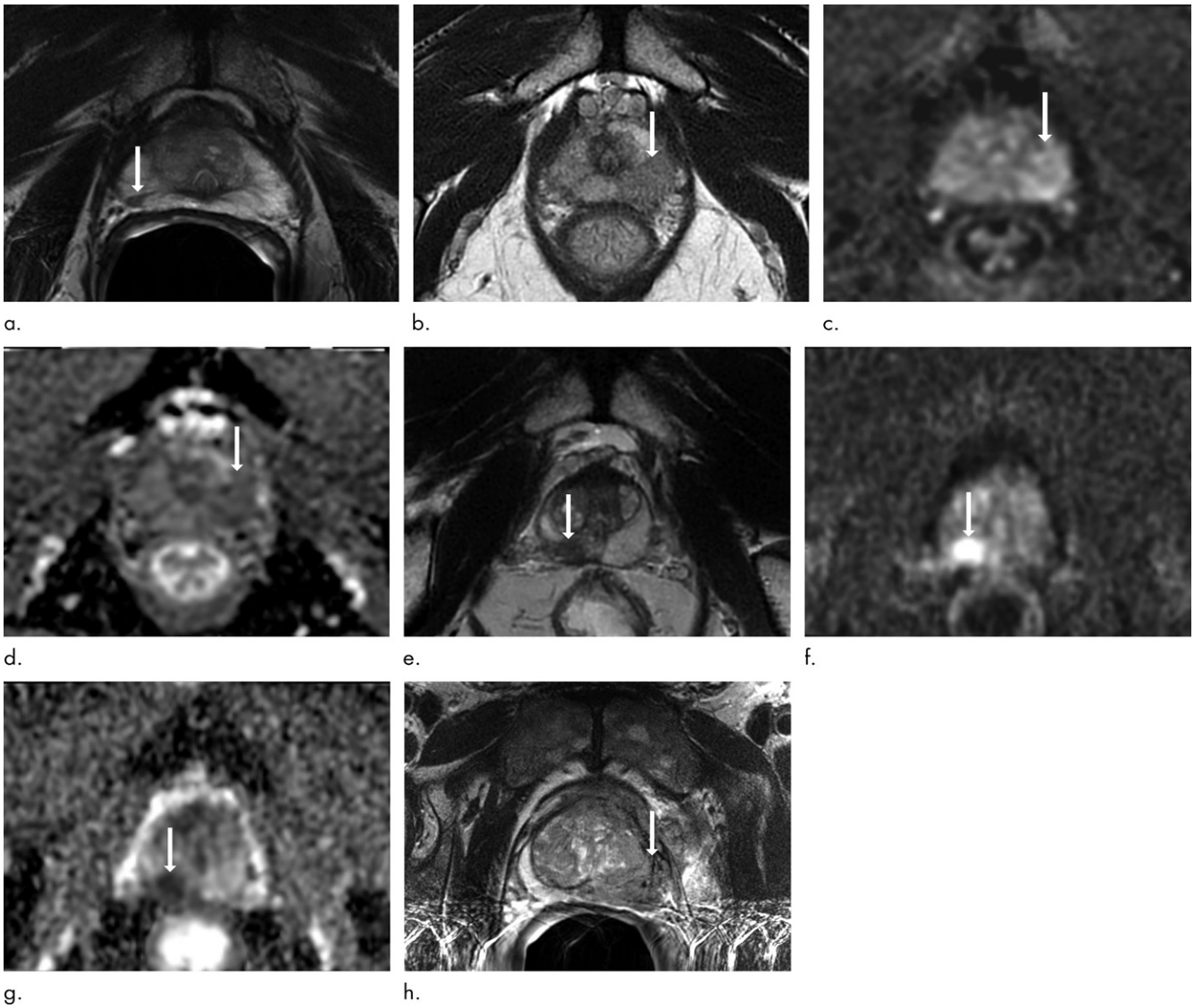

Figure 2: Images show representative peripheral zone lesions (arrow). **(a)** Prostate Imaging Reporting and Data System (PI-RADS) score 2. T2-weighted MRI scan shows triangular lesion with low T2 signal intensity in right midgland. **(b–d)** PI-RADS score 3. T2-weighted MRI scan (**b**), diffusion-weighted MRI scan obtained with high *b* value (**c**), and apparent diffusion coefficient (ADC) map (**d**) show focal lesion in left apex. Lesion has mildly low signal intensity on ADC map and mildly high signal intensity on diffusion-weighted image. No enhancement was seen on dynamic contrast material–enhanced image (not shown). **(e–g)** PI-RADS score 4. T2-weighted MRI scan (**e**), diffusion-weighted MRI scan obtained with high *b* value (**f**), and ADC map (**g**) show 1.0-cm focal lesion in right midgland. Lesion has markedly low signal intensity on ADC map and markedly high signal intensity on diffusion-weighted MRI scan. **(h)** PI-RADS score 5. T2-weighted MRI scan shows large left midgland lesion associated with extraprostatic extension.

[ISUP] grade group ≥2), as stated in PI-RADS. The other two definitions of histologically and clinically significant disease mentioned by PI-RADS (tumor volume ≥0.5 cm^3 and extraprostatic extension) were not considered as they are determined according to results of radical prostatectomy rather than with biopsy.

To assess the PPV across centers, we conducted two types of analyses: *(a)* model-based estimates of the overall PPV that account for differences across centers (eg, different sample size and prevalence of clinically significant disease) and the possibility of more than one lesion per patient and *(b)* simple descriptive statistics of the observed PPV across centers, quantified by the median and interquartile range (IQR) (due to nonnormality).

The first analysis was achieved by fitting a mixed-model logistic regression with a positive value as the outcome, with institution and patient as random effects to accommodate clustering at both of these levels, and no predictors. We used the same modeling strategy to test for differences in PPV according to various characteristics (eg, coil type and magnet strength) by including them as predictors in the model. Two-sided $P \leq .05$ was considered to indicate a statistically significant difference. Analyses were performed with a commercially available statistical software package (Stata, version 15.1; StataCorp, College Station, Tex). One author (C.E.M.), a biostatistician with 38 years of experience, performed or supervised all analyses.

Results

Participating Centers

Twenty-six centers participated in the study. These centers were located in the United States (n = 21), Canada (n = 2), Brazil

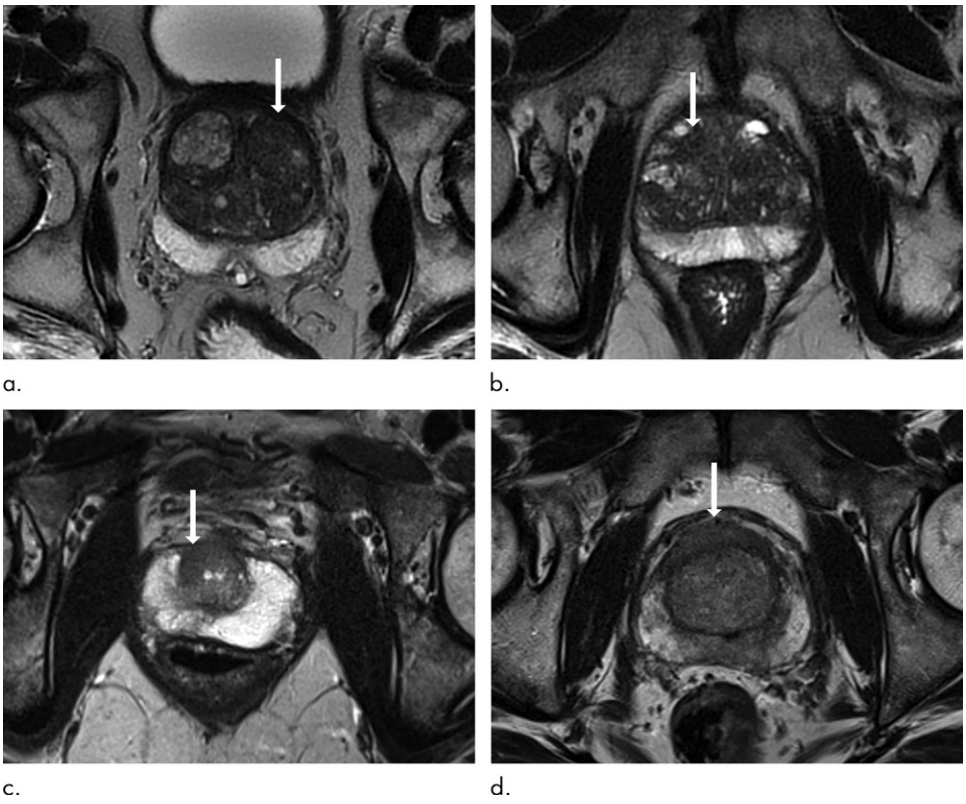

Figure 3: T2-weighted MRI scans show representative transition zone lesions (arrow). **(a)** Prostate Imaging Reporting and Data System (PI-RADS) score 2. Image shows encapsulated, mildly heterogeneous nodule in left midgland to base with predominantly low signal intensity. **(b)** PI-RADS score 3. Image shows heterogeneous signal intensity with ill-defined margins in right midgland. **(c)** PI-RADS score 4. Image shows small, noncircumscribed lesion with homogeneous and moderately low signal intensity at right apex to midgland level. **(d)** PI-RADS score 5. Image shows bilateral midgland, large lenticular lesion in midgland with homogeneous and moderately low signal intensity that extends into the anterior fibromuscular stroma.

(*n* = 1), Netherlands (*n* = 1), and South Korea (*n* = 1). The median number of patients submitted by the centers was 166 (IQR: 100–253; range, 13–675).

Between one and 10 different radiologists interpreted the scans at the individual centers (median, four radiologists; IQR: 3–7). Urologists, radiologists, or both performed all biopsies in 15, six, and five institutions, respectively. Between one and seven different physicians performed the biopsies at the individual centers (median, two physicians; IQR: 2–4).

Baseline Characteristics of Patients

A total of 3449 men were included, with a mean age of 65 years ± 8 (standard deviation) and median baseline prostate-specific antigen level of 6.6 ng/mL (IQR: 4.8–9.8 ng/mL). The median number of patients submitted by the centers was 166 (IQR: 100–253; range, 13–675).

Patients at eight centers were predominantly (ie, ≥50%) biopsy naive. Patients with previous negative biopsy results and those with prior positive biopsy results represented the majority of patients in four and three institutions, respectively. In the other 11 centers, none of these subsets represented more than 50% of the center's sample.

Nine hundred forty-three men had previously undergone biopsy (1059 lesions were benign, 675 were GS 3+3 [ISUP grade group 1], and 123 were GS 3+4 or higher [ISUP grade group 2]). The biopsy history was unknown in 193 men. The GS of a prior positive biopsy was unknown in 88 men. The baseline characteristics of the men are listed in Table 1. The distributions of all baseline characteristics were statistically different across imaging centers ($P < .05$; detailed information is provided in Table E2 [online]).

Imaging and Biopsy Results

Prostate MRI was performed using 1.5-T (*n* = 451, 13.1%) or 3-T (*n* = 2981, 86.4%) magnets. The field strength was not reported for 17 of the 3449 patients (0.5%). An endorectal coil was used in 249 of the 451 men (57%) imaged with a 1.5-T scanner and 674 of the 2981 men (23%) imaged with a 3-T scanner.

The mean MRI-based prostate volume was 54.3 cm^3 ± 32.9. Five thousand eighty-two lesions were identified with MRI (PI-RADS score 2 = 614, 12.1%; 3 = 1490, 29.3%; 4 = 2087, 41.1%; and 5 = 891, 17.5%). The median number of lesions detected per patient was two (IQR: 2–2; range, 1–4). Of the 5042 lesions, 3567 (70.7%) were located in the peripheral zone. The MRI lesion location was missing in 0.8% of lesions (40 of 5082).

Transrectal US–guided MRI fusion biopsy was performed in 3106 of the 3449 patients (90%), in-bore targeted biopsy in 181 (5%), and cognitive targeted biopsy in 129 (4%). The targeting technique was not reported in 33 biopsies. A concomitant systematic biopsy was performed in 3159 of the 3449 men (92%).

Targeted biopsy helped detect 2623 cancers (GS 3+3 [ISUP grade group 1] = 925; GS 3+4 [ISUP grade group 2] = 950; GS 4+3 [ISUP grade group 3] = 393; GS 8 [ISUP grade group 4] = 206; GS 9–10 [ISUP grade group 5] = 149; GS and ISUP grade missing = 42) in 2082 of the 3449 patients (60%). In 652 of these 2082 patients (31%), the highest GS at targeted biopsy was 3+3 (ISUP grade group 1). In the remaining 1430 patients (69%), MRI targets helped detect a cancer with a GS greater than or equal to 3+4 (ISUP grade group 2).

Clinically significant prostate cancer (ie, GS ≥3+4 or ISUP grade group ≥2) was diagnosed in 1247 of the 3567 lesions in the peripheral zone (35.0%) and 435 of the 1475 lesions in the transition zone (29.5%). The location of 16 of these tumors was missing.

Systematic biopsy helped detect prostate cancer in 1862 of 3159 men (59%), with 814 of the 1862 men (44%) having a

Table 1: Baseline Characteristics of All 3449 Men across All 26 Expert Centers

Characteristic	Value
Mean age (y)*	65 (7.8)
Race and/or ethnicity†	
American Indian or Alaska Native	1 (0.03)
Asian	320 (9.3)
Black or African American	185 (5.4)
Hispanic or Latino	58 (1.7)
Native Hawaiian or other Pacific Islander	6 (0.17)
White	1437 (41.7)
Other	58 (1.7)
Unknown	1384 (40.1)
Family history of prostate cancer	
Yes	431 (12.5)
No	1636 (47.4)
Unknown	1382 (40.1)
Median baseline PSA level (ng/mL)†	6.6 (4.8–9.8)
Presence of palpable nodule†	
Yes	212 (6.2)
No	1947 (56.5)
Unknown	1290 (37.4)
Prior biopsy results	
Benign	1059 (30.7)
Gleason score 3+3 (ISUP grade group 1)	675 (19.6)
Gleason score 3+4 (ISUP grade group 2)	107 (3.1)
Gleason score 4+3 (ISUP grade group 3)	11 (0.3)
Gleason score 4+4 (ISUP grade group 4)	5 (0.1)
Unknown Gleason score	88 (2.6)
Unknown biopsy status	193 (5.6)
No previous biopsy	1311 (38.0)
Mean prostate volume (cm^3)*	54.3 (32.9)

Note.—Except where indicated, data are numbers of men with percentages in parentheses. ISUP = International Society of Urological Pathology, PSA = prostate-specific antigen.

* Number in parentheses is the standard deviation.

† Numbers in parentheses are the interquartile range.

GS3+3 cancer (ISUP grade group 1) and 1048 (56%) having a higher grade cancer. The GSs from systematic biopsies are available in Table E3 (online).

The median rate of GS greater than or equal to 3+4 (ISUP grade group ≥2) prostate cancer across sites was 45.1% (IQR: 43.4%–52.4%).

Of 1430 men in whom MRI-targeted biopsy helped detect GS greater than or equal to 3+4 (ISUP grade group 2) cancer, 634 (44%) had a systematic biopsy showing only benign tissue or GS 3+3 (ISUP grade group 1) cancer. Conversely, of the 1048 men with GS greater than or equal to 3+4 (ISUP grade group 2) prostate cancer at systematic biopsy, 252 (24%) had low-grade cancer or benign tissue identified on the MRI-targeted samples.

PPV of PI-RADS

After accounting for differences across centers (eg, sample size and prevalence of disease) and clustering within patients (ie, the possibility of more than one lesion), the estimated overall PPV was 31% (95% confidence interval [CI]: 24%, 40%) for PI-RADS score greater than or equal to 2, 35% (95% CI: 27%, 43%) for PI-RADS score greater than or equal to 3, and 49% (95% CI: 40%, 58%) for PI-RADS score greater than or equal to 4. The estimated overall PPV stratified according to PI-RADS scores was as follows: score 2 = 5% (95% CI: 3%, 7%), score 3 = 15% (95% CI: 11%, 19%), score 4 = 39% (95% CI: 34%, 45%), and score 5 = 72% (95% CI: 67%, 77%).

Table 2: PPVs of PI-RADS

PI-RADS version 2 Score	Estimated Overall PPV (%)	Confidence Interval (%)*	Interquartile Range (%)†
≥2 (*n* = 5030)	31	24, 39	27–44
≥3 (*n* = 4420)	35	27, 43	27–48
≥4 (*n* = 2958)	49	40, 58	34–65
2 (*n* = 610)	5	3, 7	0–14
3 (*n* = 1462)	15	11, 19	10–26
4 (*n* = 2071)	39	34, 45	25–55
5 (*n* = 887)	72	66, 77	61–82

Note.—Numbers in parentheses are numbers of lesions. PI-RADS = Prostate Imaging Reporting and Data System, PPV = positive predictive value.

* Estimated using logistic regression to account for differences across imaging centers and the possibility of more than one lesion per patient.

† Raw (collected) data.

The IQR of the PPV was 27%–44% for PI-RADS score greater than or equal to 2, 27%–48% for PI-RADS score greater than or equal to 3, and 34%–65% for PI-RADS score greater than or equal to 4. The IQR of PPV stratified according to PI-RADS score was as follows: score 2 = 0%–14%, score 3 = 10%–26%, score 4 = 25%–55%, and score 5 = 61%–82%. These results are shown in Table 2 and summarized in Figure 4. Further analysis stratified by biopsy status, that is, no prior biopsy, prior negative biopsy result, or prior positive biopsy result, suggest that low PPV and wide variability persist across these groups (Table E4 [online]). Table E5 (online) describes the impact of coil type, magnet strength, and lesion location on the PPV of PI-RADS score greater than or equal to 3.

Discussion

The results of this study of 3349 men from 26 different centers undergoing prostate MRI and MRI-targeted biopsy demonstrate wide variation and an overall low positive predictive value of the Prostate Imaging Reporting and Data System.

PI-RADS must be reliable to guide the diagnostic process, assist with management decisions, and improve patient outcomes. Therefore, the wide variability in PPV could hinder managing physician confidence in the system, affecting the broader acceptance and use of PI-RADS. Wide variation in outcomes may also hinder the ability to assess radiologist or institutional performances in PI-RADS according to benchmarks, in turn

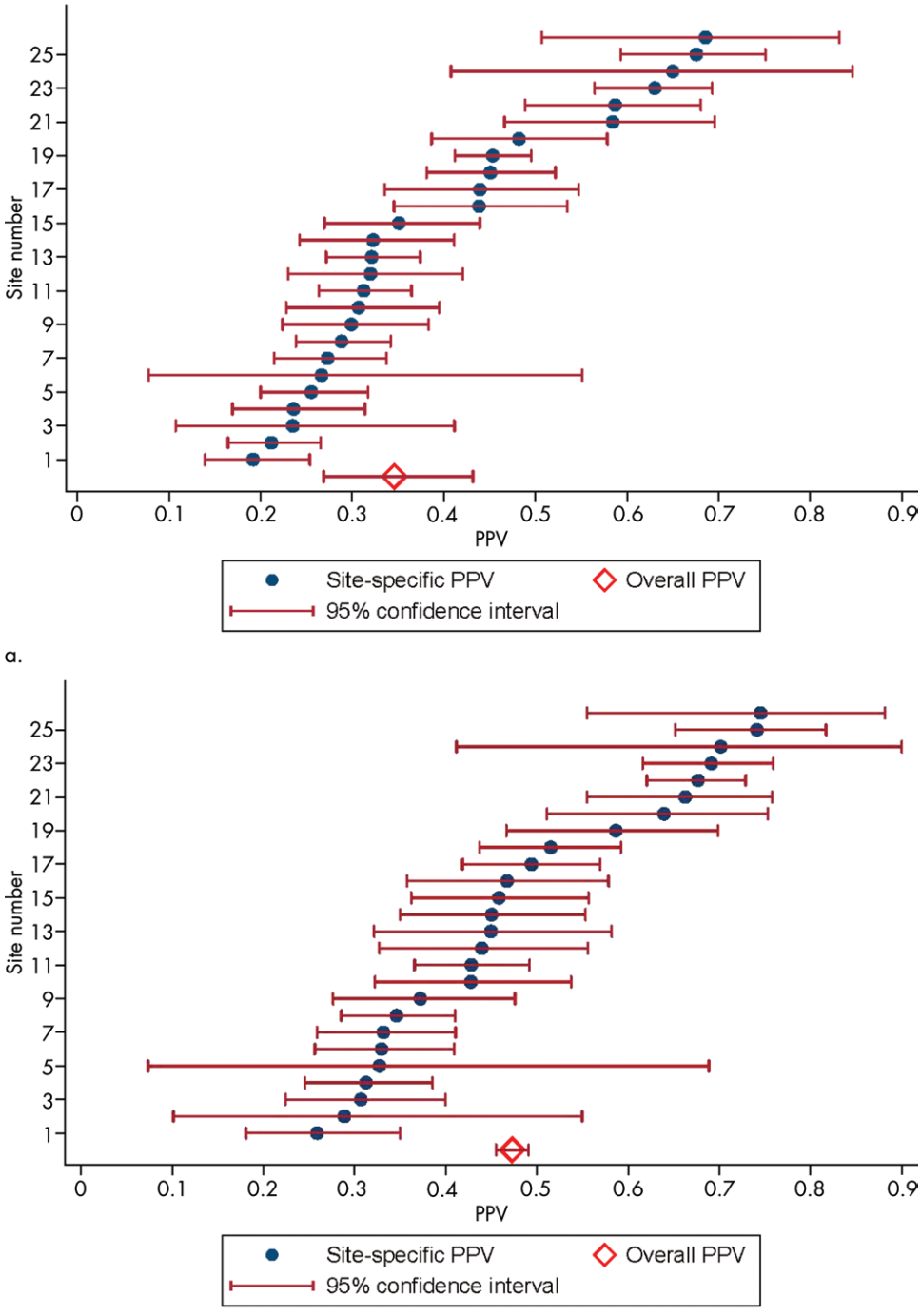

Figure 4: Forest plots show site-specific median positive predictive values (PPVs) of **(a)** Prostate Imaging Reporting and Data System (PI-RADS) score greater than or equal to 3 and **(b)** PI-RADS score greater than or equal to 4. The overall estimated PPV for all sites is also shown.

potentially reducing payers' and other policymakers' support of prostate MRI. The variation in PPV may create particular challenges in patients undergoing serial MRI examinations, in terms of understanding the clinical significance of any changes across the studies.

The low PPV in our study is in line with the results of a recent meta-analysis performed by Barkovich et al (11), in which 6%, 12%, 48%, and 72% of lesions assigned PI-RADS scores of 2, 3, 4, and 5, respectively, represented high-grade cancer. Yet, Barkovich et al did not quantify or attempt to identify causes of the variability in PPV across the various studies. While low reproducibility of PI-RADS scoring may partially explain this finding, prior studies observed reasonable interreader agreement, for example, 79.2% for PI-RADS score greater than or equal to 3 among expert readers (12). The disparity could result from inaccurate targeting of MRI lesions and mischaracterization of cancer grade. However, the rate of undergrading with fusion biopsy relative to prostatectomy has been low in prior studies (13). Variation in PPV may also relate to differences in prevalence of disease across centers. However, it is difficult, if not impossible, to know the true prevalence of high-grade prostate cancer in each of the individual centers. Because that information was not available, as a proxy for adjusting for prevalence, we adjusted the analysis for baseline characteristics that are or may be associated with the prevalence of high-grade cancer (eg, patient age, race and/or ethnicity, and baseline biopsy status). Ultimately, the variation in PPV is likely multifactorial, related to these and other considerations (eg, mimics of cancer or number of samples obtained from each target), and our study is unable to fully explain it.

The pretest probability of high-grade prostate cancer depends on the patient's prior biopsy status. For example, men with known cancer under active surveillance are generally more likely to have high-grade cancer than men who have never undergone biopsy. Accordingly, we hypothesized that the PPV and its variation would also differ across these strata. Yet, our analyses show that the low PPV and the broad variation in PPV persisted even after stratification according to pre-MRI biopsy history.

Detection and characterization of transition zone lesions is challenging given the varied appearances of benign prostatic

hyperplasia and stromal tissue in this zone (14–16), which may mimic prostate cancer and lead to false-positive results. In our study, the PPV was indeed higher in the peripheral zone than in the transition zone. In addition to challenges relating to benign prostatic hyperplasia and stromal tissue, another possible explanation for the difference is better calibration of PI-RADS criteria to the detection of lesions in the peripheral zone. As approximately 30% of cancers occur in the transition zone, it is important that further research efforts focus on the detection and characterization of these lesions.

Although the use of 3-T magnets is expanding and has been endorsed (17) and the value of endorectal coils remains a matter of debate, the PPV of PI-RADS scores assigned using 1.5-T magnets did not differ significantly from those obtained with a 3-T scanner, with or without the endorectal coil. As hardware configuration is largely determined by the given institution and influenced by factors not considered herein (eg, costs, examination complexity, and workflow), we caution against making definitive conclusions in favor or against a particular magnet strength or coil until more data are available.

The results may be criticized as not representative of the general community because of the selection of participating imaging centers according to membership in the Society of Abdominal Radiology Prostate Cancer DFP, which comprises experts dedicated to prostate cancer imaging. However, the number of readers across centers ranged from one to 13, and the DFP member was the sole reader of the prostate MRI scans in only three participating centers. On the other hand, even for the centers with multiple readers beyond the center's DFP representative, these readers generally were all subspecialized abdominal radiologists. This fact may also be viewed as an important strength of the study. In the general population of radiologists, one should expect to find even more variation than identified herein, underscoring the need for further improvements in PI-RADS, greater dedication to training, and development of quality assurance programs.

Our study had limitations. Patients without visible lesions at MRI, that is, a PI-RADS score of 1, were not included, and a minority of lesions were assigned a score of 2. Therefore, we could not determine the overall diagnostic accuracy of PI-RADS. The use of biopsy specimens, instead of prostatectomy specimens, as the standard of reference can be debated. Yet, while cancer may be missed at either MRI-targeted biopsy or systematic biopsy, their combination (as in our cohort) has a high detection rate (18). Furthermore, using prostatectomy specimens as the standard of reference would have introduced other biases. Our sample did not include men who had a lesion visible at MRI but who did not undergo targeted biopsy of the lesion. The influence of such lesions on our results is unpredictable and depends on the size of that particular patient cohort and their prevalence of clinically significant prostate cancer. Furthermore, we were unable to distinguish the PPV of peripheral zone lesions that are upgraded to a final PI-RADS score of 4 from an initial diffusion-weighted imaging score of 3 based on a positive score at dynamic contrast material–enhanced imaging. Some data suggest that the likelihood of clinically significant cancer is higher when the score of 4 is originally assigned at diffusion-weighted imaging (19).

In conclusion, the positive predictive value of the Prostate Imaging Data and Reporting System (PI-RADS) was low and varied widely across centers. This variation was multifactorial, persisting after data were adjusted for an array of baseline characteristics. We hope these results will motivate discussion and will lead to further research, educational initiatives, quality assurance efforts, and, perhaps, PI-RADS updates that may address this issue.

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