

DIAGNOSTIC ACCURACY OF MRI PI-RADS TO DIAGNOSE PROSTATE CANCER, KEEPING HISTOPATHOLOGY AS GOLD STANDARD

Muneeb Ur Rahman¹, Ghazala Wahid², Hafiza Ayesha Jawaid¹, Adnan Sajid¹, Mehreen Khan¹, Gohar Ali¹, Mahnoor Rehman Khan²

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¹Trainee Medical Officer, Department of Radiology, Hayatabad Medical Complex, Peshawar

²Associate Professor, Department of Radiology Hayatabad Medical Complex, Peshawar

Correspondence

Ghazala Wahid, Associate Professor, Department of Radiology, Hayatabad Medical Complex, Peshawar

☎: +92-336-5249949

✉: ghazalawahid3@gmail.com

ABSTRACT**OBJECTIVES**

This study aimed to evaluate the diagnostic accuracy of mpMRI using PI-RADS v2 in a prospective study, with histopathology as the reference standard.

METHODOLOGY

This prospective single-centre diagnostic accuracy study was conducted between January 2022 and June 2023 in the Department of Radiology, Hayatabad Medical Complex, Peshawar, Pakistan, in accordance with STARD guidelines. A total of 127 men (aged 40-85 years) with elevated prostate-specific antigen (PSA >4 ng/dL) and abnormal digital rectal examination findings were enrolled by a consecutive sampling method. The study was conducted at the Department of Diagnostic Radiology, Hayatabad Medical Complex, Peshawar, over a period of 6 months. All participants underwent mpMRI with PI-RADS scoring followed by systematic prostate biopsy. Clinically significant prostate cancer was defined as a Gleason score ≥ 7 . Diagnostic accuracy metrics, including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy, were calculated.

RESULTS

Prostate cancer was histopathologically confirmed in 58.3% (74/127) of patients. Using a predefined diagnostic threshold of PI-RADS ≥ 4 versus < 4 , mpMRI demonstrated a sensitivity of 89.2%, specificity of 81.1%, PPV of 86.8%, NPV of 84.3%, and overall accuracy of 85.8%. Performance was superior in patients with PSA >10 ng/dL (92.5% sensitivity) and for PI-RADS 5 lesions (94.7% concordance with high-grade cancer). False negatives were predominantly anterior zone tumors (75%), while false positives were primarily due to prostatitis. Inter-reader agreement was substantial ($\kappa = 0.72$).

CONCLUSION

In this study, mpMRI using PI-RADS v2 showed good diagnostic performance and reproducibility for detecting csPCa in a Pakistani cohort. Limitations persist in anterior zone assessment, and inflammatory mimics were observed, underscoring the need for careful interpretation and optimized biopsy strategies.

KEYWORDS: Prostate Cancer, PI-RADS, Multiparametric MRI, Diagnostic Accuracy, Gleason Score, Prostate Biopsy

INTRODUCTION

Prostate cancer remains a significant health concern globally, ranking as the second most common cancer in men and a major contributor to cancer-related morbidity and mortality.¹ In Pakistan, prostate cancer incidence is rising, yet local diagnostic performance data for mpMRI remain limited.² Although PI-RADS has been extensively validated in Western populations, data from South Asian and other low- and middle-income countries are comparatively scarce. Despite histopathology being the definitive method for diagnosing prostate cancer, its invasive nature poses

various risks, such as infection, bleeding, and discomfort for the patient.³ Consequently, noninvasive imaging methods, especially multiparametric magnetic resonance imaging (mpMRI) using the Prostate Imaging-Reporting and Data System (PI-RADS), have become increasingly important for identifying and assessing prostate cancer risk.⁴ The PI-RADS system standardizes the interpretation of MRI, enhancing consistency in diagnosis and assisting in the detection of clinically significant prostate cancer (Gleason score ≥ 7).⁵ Multiparametric MRI has become integral to prostate cancer diagnosis by improving the detection of clinically significant disease while reducing

unnecessary biopsies. The Prostate Imaging-Reporting and Data System (PI-RADS) standardizes MRI acquisition, interpretation, and reporting, facilitating consistent risk stratification. However, reported diagnostic accuracy varies across institutions due to differences in patient spectrum, MRI protocols, and reader experience. The results have the potential to improve patient care by minimizing unnecessary biopsies and enabling the quick identification of significant, high-risk prostate cancer. The integration of MRI-based PI-RADS into standard clinical practice has greatly improved prostate cancer diagnosis by enhancing the detection of clinically important tumors while also lowering the rates of diagnosing indolent or low-risk conditions.⁶ However, variations in radiologist experience, MRI scanner protocols, and patient populations can influence diagnostic performance, leading to discrepancies in reported sensitivity and specificity across different institutions.⁷ This variability necessitates localized validation studies to ensure that PI-RADS maintains high diagnostic accuracy in diverse healthcare settings, including resource-limited environments where access to advanced imaging may be constrained. Despite its advantages, the widespread adoption of MRI PI-RADS faces challenges, including cost, accessibility, and interobserver variability in interpretation.⁸ Recent advancements in artificial intelligence (AI) and machine learning show promise in augmenting PI-RADS assessments by improving lesion detection and risk stratification.⁹ However, further research is needed to standardize imaging protocols, optimize radiologist training, and validate PI-RADS in underrepresented populations, including Asian and Middle Eastern cohorts, where prostate cancer profiles may differ from Western populations.¹⁰ To address this local evidence gap, the present study was designed as a prospective diagnostic accuracy and inter-reader reliability study of PI-RADS v2 in a Pakistani population, with additional PSA-stratified performance analysis. This framing emphasizes external validation rather than methodological novelty.

METHODOLOGY

This prospective diagnostic accuracy study was conducted at the Department of Radiology, Hayatabad Medical Complex, Peshawar, from January 2022 to June 2023, and was reported in accordance with STARD recommendations. Ethical approval was obtained from the Institute bearing Ref. No. HMC-QAD-F00/1670, Dated: 26-12-2023 and CPSP No -787 Men aged 40-85 years presenting with a prostate-specific antigen (PSA) level greater than 4 ng/dL and abnormal digital rectal examination findings were enrolled. Patients with a history of prior prostate biopsy or surgery, use of 5- α -reductase inhibitors within the

preceding six months, recent treatment for prostatitis, or contraindications to magnetic resonance imaging were excluded. All included participants were biopsy-naïve. Multiparametric magnetic resonance imaging (mpMRI) of the prostate was performed using a 1.5-Tesla scanner with a phased-array pelvic coil. Imaging followed Prostate Imaging-Reporting and Data System (PI-RADS) version 2 recommendations and included axial, sagittal, and coronal T2-weighted sequences (slice thickness 3 mm), diffusion-weighted imaging with b-values of 0, 800, and 1400 s/mm² along with apparent diffusion coefficient maps, and dynamic contrast-enhanced imaging using a gadolinium-based contrast agent. MRI examinations were independently interpreted by three radiologists with 6-12 years of experience in prostate MRI, who were blinded to histopathological findings but aware of PSA levels and digital rectal examination status. Prior to study initiation, readers underwent calibration using standard PI-RADS v2 training cases. Discrepancies in scoring were resolved by consensus, and the final PI-RADS score was used for analysis. For the primary diagnostic analysis, a PI-RADS score of ≥ 4 was considered positive for clinically significant prostate cancer, while PI-RADS 3 lesions were analyzed descriptively but classified as negative in the primary 2 $\times$ 2 analysis. All patients subsequently underwent systematic 12-core transrectal ultrasound-guided prostate biopsy without MRI-targeted sampling. Histopathological examination served as the reference standard, with clinically significant prostate cancer defined as a Gleason score of ≥ 7 . Diagnostic performance was assessed by calculating sensitivity, specificity, positive predictive value, negative predictive value, overall accuracy, and area under the receiver operating characteristic curve, along with 95% confidence intervals. Comparisons between PSA subgroups were performed using chi-square tests for proportions, and subgroup analyses were pre-specified. Inter-reader agreement was evaluated using Fleiss' kappa for both ordinal PI-RADS scores and dichotomized categories.

RESULTS

A total of 127 male patients aged 40-85 years were included in the study. The mean age was 65.4 ± 8.2 years, with a median PSA level of 9.6 ng/dL (IQR: 6.2-14.1). Histopathological examination confirmed prostate cancer in 74 patients (58.3%), all of whom had clinically significant disease (Gleason score ≥ 7). The most frequent Gleason score was 7 (3+4), followed by 7 (4+3), while high-grade disease (Gleason ≥ 8) was identified in 17 patients (23.0%). Using a PI-RADS threshold of ≥ 4 , multiparametric MRI demonstrated good diagnostic performance for clinically significant prostate cancer, with a sensitivity of 89.2% and

specificity of 81.1%. Diagnostic accuracy was higher in patients with PSA levels >10 ng/dL than in those with PSA levels 4-10 ng/dL. Cancer detection increased progressively with higher PI-RADS categories, reaching the highest yield in PI-RADS 5 lesions. Inter-reader agreement among radiologists was substantial, supporting the reproducibility of PI-RADS scoring in this cohort.

Table 1: Baseline Clinical Characteristics of Study Participants (n = 127)

Variable	Value
Age (years), mean $\pm$ SD	65.4 $\pm$ 8.2
PSA (ng/dL), median (IQR)	9.6 (6.2-14.1)
Prostate volume (g), mean $\pm$ SD	52.3 $\pm$ 18.7
Prostate cancer on histopathology	74 (58.3%)
Clinically significant cancer (GS $\geq$ 7)	74 (58.3%)

Table 2: Diagnostic Performance of PI-RADS v2 (Threshold $\geq$ 4) for Clinically Significant Prostate Cancer

Parameter	Value (95% CI)
Sensitivity	89.2% (83.1-93.6)
Specificity	81.1% (74.3-86.7)
Positive predictive value	86.8% (80.9-91.3)
Negative predictive value	84.3% (77.8-89.4)
Overall diagnostic accuracy	85.8% (81.2-89.6)
Area under the ROC curve	0.87 (0.82-0.92)

Table 3: Cancer Detection Rate According to PI-RADS Category and PSA Level

Variable	csPCa Detected n (%)
PI-RADS 3 (n = 24)	2 (8.3%)
PI-RADS 4 (n = 38)	30 (78.9%)
PI-RADS 5 (n = 38)	36 (94.7%)
PSA 4-10 ng/dL (n = 59)	Sensitivity 84.6%
PSA >10 ng/dL (n = 68)	Sensitivity 92.5%*

DISCUSSION

This prospective diagnostic accuracy study supports the clinical utility of mpMRI using PI-RADS v2 for detecting csPCa in a Pakistani cohort. Our findings are consistent with international literature while highlighting region-specific performance characteristics. The observed sensitivity of 89.2% (95% CI: 83.1-93.6%) and specificity of 81.1% (95% CI: 74.3-86.7%) position our results within the spectrum of recent multicenter validation studies.⁶ While our sensitivity exceeds that reported by Bangash et al. (84.85%), it remains more conservative than Almolla et al.'s findings (94.2%).¹¹ These variations likely reflect differences in MRI field strength (1.5T vs 3T), with mounting evidence suggesting 3T scanners provide superior lesion characterization.¹² The substantial inter-reader agreement (Fleiss' $\kappa=0.72$) reinforces PI-RADS v2's reliability as a standardized reporting system,¹³ though the lower agreement for transition zone lesions ($\kappa=0.65$) highlights persistent interpretation challenges in this anatomically complex region.⁹ These findings are particularly relevant given

the increasing adoption of PI-RADS v2.1, which specifically refines transition zone evaluation criteria.⁸ Our detailed analysis of diagnostic errors revealed important patterns. The false-negative rate (10.8%) was dominated by anterior zone tumors (6/8 cases), confirming this region as a persistent diagnostic blind spot.⁴ Recent technical advances, including specialized anterior coil placement and transperineal biopsy approaches, show promise in addressing this limitation.¹⁸ Among false positives (18.9%), inflammatory conditions accounted for the majority of cases, underscoring the need for advanced imaging biomarkers to differentiate malignancy from prostatitis.¹⁴ Emerging techniques like restriction spectrum imaging and quantitative perfusion analysis demonstrate particular promise in this regard.¹⁵ The strong PSA-dependent performance gradient (84.6% vs 92.5% sensitivity for PSA 4-10 vs >10 ng/dL) suggests MRI may be most effectively deployed after initial PSA triage.¹⁶ This aligns with recent cost-effectiveness analyses favoring MRI after PSA exceeds 10 ng/dL.¹⁷ Our finding that age and prostate volume minimally affected accuracy supports MRI's broad applicability across diverse patient demographics, though emerging data suggest that adjusted PI-RADS thresholds may benefit patients with very large prostates (>80).^{18,19} The near-perfect concordance (94.7%) between PI-RADS 5 lesions and high-grade cancer on histopathology supports growing interest in biopsy-free diagnostic pathways for unequivocal cases. However, the lower PPV for PI-RADS 4 (78.9%) reinforces the need for histologic confirmation in these indeterminate cases.²⁰ Recent technical advances in MRI-guided biopsy, particularly the combination of cognitive and software fusion approaches, may further optimize targeted sampling.²¹ The optimal biopsy strategy continues to evolve, with evidence supporting combined systematic and targeted approaches for comprehensive assessment.²²

LIMITATIONS

The study includes a single-center design, the absence of MRI-targeted biopsy, potential spectrum bias due to the inclusion of PSA/DRE-positive patients only, and a lack of PI-RADS v2.1 comparison. These factors limit generalizability to screening populations.

CONCLUSIONS

In this diagnostic accuracy study, mpMRI using PI-RADS v2 demonstrated good diagnostic performance and substantial inter-reader agreement for detecting clinically significant prostate cancer in a Pakistani population. The findings support its use in similar clinical settings, while caution is advised, particularly

for anterior zone lesions and inflammatory conditions.

CONFLICT OF INTEREST: None

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AUTHORS CONTRIBUTION

Muneeb Ur Rahman - Concept & Design; Data Acquisition; Drafting Manuscript; Critical Revision; Final Approval

Ghazala Wahid - Concept & Design; Data Acquisition; Data Analysis/Interpretation; Drafting Manuscript; Critical Revision; Final Approval

Haftiza Ayesha Jawaaid - Concept & Design; Data Acquisition; Drafting Manuscript; Critical Revision; Final Approval

Adnan Sajid - Concept & Design; Data Acquisition; Data Analysis/Interpretation; Drafting Manuscript; Final Approval

Mehreen Khan - Concept & Design; Data Acquisition; Data Analysis/Interpretation; Drafting Manuscript; Final Approval

Gohar Ali - Concept & Design; Data Acquisition; Data Analysis/Interpretation; Drafting Manuscript; Final Approval

Mahnoor Rehman Khan - Concept & Design; Data Acquisition; Drafting Manuscript; Final Approval

The authors accept responsibility for all aspects of the work and will ensure that any concerns regarding the accuracy or integrity of any part are properly investigated and resolved.



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