Original Article

Correlation of PI-RADS Scores with TRUS-Guided Core Biopsy Findings in the Diagnosis of Prostate Cancer: A Retrospective–Prospective Observational Study

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Abstract

Background: Use of mpMRI with PI-RADS for risk assessment in the prostate cancer patient before biopsy is widely utilised. However, local clinicopathological correlation continues to remain important. The objective is to evaluate the association between PI-RADS category and TRUS-guided core-biopsy findings and assess the diagnostic performance of PI-RADS thresholds for clinically significant prostate cancer (csPCa). **Material and Methods:** This retrospective-prospective observational study was conducted in 120 male patients who underwent mpMRI followed by TRUS-guided core biopsy at ASCOMS, Sidhra, Jammu for two years. The collected data included age, PSA level, lesion size and location, PI-RADS score, biopsy findings, Gleason score, ISUP grade group, and clinically significant prostate cancer (csPCa) status. "Biopsy findings were correlated with PI-RADS categories using the chi-square test, whereas the relationship between PI-RADS categories and grade groups was analysed using Spearman rank correlation. Diagnostic parameters including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic accuracy were calculated for PI-RADS cut-offs of ≥3 and ≥4. **Results:** Mean age was 67.4 ± 6.9 years and median PSA was 9.04 ng/mL (IQR 5.38–11.76). Cancer was identified on biopsy in 103 men (85.8%), and csPCa in 67 (55.8%). PI-RADS categories 2, 3, 4, and 5 were seen in 23, 18, 37, and 42 men, respectively. PI-RADS category had a significant association with biopsy diagnosis ($P < 0.001$) and grade group (Spearman $\rho = 0.641$; $P < 0.001$). For csPCa, PI-RADS ≥4 yielded sensitivity 91.0%, specificity 66.0%, PPV 77.2%, NPV 85.4%, and accuracy 80.0%, versus 98.5% and 41.5% for ≥3". **Conclusion:** Higher PI-RADS categories were linked to malignant and clinically significant findings on biopsy. A PI-RADS threshold of ≥4 provided a more balanced diagnostic profile compared with a threshold of ≥3.

Keywords: PI-RADS; prostate carcinoma; mpMRI; TRUS-guided biopsy; ISUP grade group; diagnostic performance.

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Introduction

Prostate cancer remains a commonly diagnosed malignancy in men worldwide and continues to be a significant cause of cancer-related morbidity and mortality. Identification of clinically significant disease is essential for appropriate therapeutic decisions and for limiting unnecessary invasive procedures. Despite its widespread use, systematic transrectal ultrasound (TRUS)-guided biopsy continues to serve as a standard diagnostic approach, it is limited by sampling errors as well as procedure-related adverse events. "It could miss important lesions or incorrectly identify an indolent tumour with little clinical significance. [Z].[1,2]

Multiparametric magnetic resonance imaging (mpMRI) has improved lesion localization and pre-biopsy risk assessment, and studies have shown that MRI-targeted biopsy identifies more clinically significant cancers while limiting the detection of indolent disease compared with systematic biopsy alone.[3,4] mpMRI has become an important component of present-day diagnostic pathways and guideline recommendations.[5] The Prostate Imaging Reporting and Data System (PI-RADS) was designed to standardize image acquisition, interpretation, and reporting, advancing from the original ESUR guidelines to subsequent versions, with categories corresponding to an increasing likelihood of clinically significant prostate cancer.[6,7] Meta-analytic studies have demonstrated good overall diagnostic utility for PI-RADS,[8] and later updates culminating in version 2.1 have further refined category definitions and reporting criteria".[9,10]

Because diagnostic performance may vary across practice settings, biopsy pathways and patient populations, local

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correlation of PI-RADS findings with histopathology remains clinically important, The selection of a PI-RADS threshold involves balancing sensitivity against specificity.[11] the present study was designed to evaluate the association between PI-RADS categories and TRUS-guided biopsy findings, as well as the impact of different threshold values on diagnostic performance in a single-centre cohort.

Materials and Methods

Study design and setting: This observational study with retrospective and prospective phases was performed in the Department of Pathology at ASCOMS (Acharya Shri Chander College of Medical Sciences and Hospital, Sidhra), Jammu, over the two-year period from 14 June 2024 to 13 June 2026.

The retrospective part will include records for one year (i.e., 14th June 2024- 14th June 2025), and in the prospective part, patients will be enrolled for one year 13th June 2025 – 13th June 2026). "An observational study was conducted to evaluate the correlation between PI-RADS categories and histopathological outcomes in men undergoing prostatic biopsy.

Ethics approval and consent: The study conformed to the principles of the Declaration of Helsinki and was approved by the Institutional Ethics Committee of Acharya Shri Chander College of Medical Sciences and Hospital, Sidhra, Jammu (Approval/Reference No. ASCOMS/IEC/2025/MEETING-I/FM/09). Written informed consent was obtained from prospectively enrolled participants, while retrospective records were exempted from consent requirements".

Participants and eligibility: "Consecutive male patients with elevated serum PSA levels and/or clinical suspicion of prostate cancer undergoing mp MRI followed by TRUS-guided core biopsy were included in this study. Patients with a history of treatment for prostate cancer, contraindications to MRI, or other exclusion criteria were not included in the study". had incomplete clinical imaging and histopathology records, had benign disease, had uncorrectable bleeding disorder or abnormal coagulation profile, and who did not give sufficient tissue for evaluation.

Sample size and calculation: The researchers selected men who were 45, 46, 47 etc., and who had cancer in the past to finally derive 500 consecutive men. They proceeded with mpMRI followed by TRUS biopsy with positive mpMRI. So all men were having positive mpMRI with TRUS biopsy. Because the study's retrospective aspect dictated the sample size available, no formal sample size calculation was performed. one component drew on records already available at the time of the study and the prospective component comprised all eligible patients presenting during the recruitment period.

MRI protocol and PI-RADS assessment: "mpMRI was performed using a [1.5T/3T] scanner with or without an endorectal coil. The protocol included T2-weighted, diffusion-weighted, ADC, and dynamic contrast-enhanced sequences. Image interpretation was undertaken by a radiologist according to PI-RADS version [2/2.1], and the score of the index lesion was recorded for each patient".

TRUS-guided biopsy technique: Biopsy specimens were obtained under TRUS guidance using a 12-core systematic sampling protocol with an 18-gauge needle under local anesthesia, with antibiotic prophylaxis given before the procedure. Targeted/cognitive cores were obtained from MRI-suspicious lesions where applicable. Biopsies were performed by urology or radiology operators experienced in prostate biopsy, and all specimens were fixed in formalin and processed routinely

Histopathological evaluation: "A pathologist examined the haematoxylin and eosin-stained sections. Malignant cases were categorized into ISUP grade groups based on the modified Gleason classification. Clinically significant prostate cancer was defined as an ISUP grade group ≥2 (Gleason score ≥3+4=7).

Statistical analysis: Data analysis was carried out using SPSS version 26.0. Continuous variables were reported as mean ± standard deviation or median with interquartile range, as appropriate, whereas categorical variables were presented as frequencies and percentages. The association between PI-RADS categories and biopsy diagnosis was determined using the chi-square test, while the relationship between PI-RADS categories and grade groups was examined using Spearman rank correlation.

Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic accuracy were calculated for PI-RADS thresholds of ≥3 and ≥4. A two-sided P value of less than 0.05 was considered statistically significant.

Results

Baseline characteristics: A total of 120 men were included in the study. Their mean age was 67.4 ± 6.9 years, and the PSA level was 9.04 ng/mL (IQR 5.38–11.76). Lesions involved the peripheral zone in 81 patients (67.5%) and the transition zone in 39 patients (32.5%). Biopsy results for the occurrence of Cancer and csPCa were positive for 103 men (85.8%) and 67 men (55.8%)".

PI-RADS distribution and correlation with biopsy diagnosis

The PI-RADS distribution was 23 (19.2%) for category 2, 18 (15.0%) for category 3, 37 (30.8%) for category 4 and 42 (35.0%) for category 5. PI-RADS categories showed a significant association with biopsy diagnosis (chi-square test, $P < 0.001$). with higher PI-RADS categories showing an increasing proportion of malignant biopsies and a corresponding decline in benign findings [Table 2; Figure 1]. Furthermore, PI-RADS scores demonstrated a positive and Histopathological grade groups were significantly correlated (Spearman $\rho = 0.641$; $P < 0.001$).

Diagnostic performance by threshold: "The optimal cutoff value of the PI-RADS score for clinically significant prostate cancer was ≥3, demonstrating sensitivity of 98.5%, specificity of 41.5%, positive predictive value (PPV) of 68.0%, negative predictive value (NPV) of 95.7%, and overall accuracy (OACC) of 73.3%. When the PI-RADS cutoff was increased to ≥4, the sensitivity decreased to 91.0%", while specificity increased to 66.0%. The positive predictive value rose to 77.2%, whereas the Overall accuracy was 80.0%, whereas the negative predictive value was 85.4%. [Table 3 and Figure 2].

Thus, the higher cutoff resulted in a modest decline in sensitivity

but marked improvements in specificity and overall accuracy.

Histopathological findings: The TRUS-guided core-biopsy specimens were examined histopathologically, which revealed prostatic adenocarcinoma in 103 of the 120 men (85.8%). Sixteen specimens (13.3%) showed benign prostatic tissue and one (0.8%) atypical small acinar proliferation. The ISUP/WHO grading system based on the modified Gleason score was used to assign a Grade group to the malignant cores. It was observed that the proportion of tumours with higher grade group increased progressively With increasing PI-RADS category, the PI-RADS score showed a significant positive association with grade group (Spearman $\rho = 0.641$; $P < 0.001$).

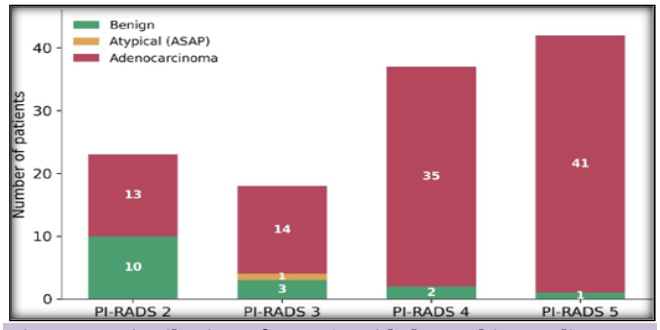

Figure 1: Distribution of TRUS-guided core-biopsy diagnoses across PI-RADS categories (n = 120). Stacked bars show the number of benign, atypical small acinar proliferation (ASAP) and adenocarcinoma cases in each PI-RADS category; the proportion of malignant biopsies increased progressively with rising PI-RADS category (chi-square test, P < 0.001).

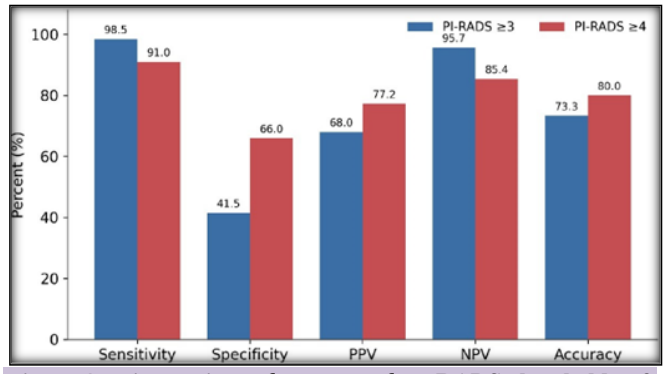

Figure 2: Diagnostic performance of PI-RADS thresholds ≥3 and ≥4 for clinically significant prostate cancer. Bars show sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and overall accuracy, expressed as percentages, for the two cut-offs.

Representative H&E–stained photomicrographs are shown in [Figure 3]. With advancing grade group there was progressive loss of glandular differentiation. Grade group 3 tumours (Gleason score 4+3=7) showed a cribriform arrangement of malignant glands, characteristic of Gleason pattern 4 [Figure 3A], corresponding on low-power examination to a core infiltrated by closely packed, irregularly arranged acini [Figure 3C]. Grade group 4 tumours (Gleason score 4+4=8) were dominated by fused and cribriform glandular architecture with only occasional discrete glands [Figure 3B]. Grade group 5 tumours (Gleason score 9–10) demonstrated solid sheets and cords of tumour cells, several with clear to pale cytoplasm, and little or no gland formation [Figure 3D]. Nuclear enlargement, conspicuous nucleoli and absence of the basal cell layer accompanied the malignant glands and became more conspicuous at higher grade groups. These morphological gradients paralleled the imaging findings, with higher PI-RADS categories showing higher-grade, architecturally more disordered tumours, consistent with the positive PI-RADS–grade group correlation observed in this cohort.

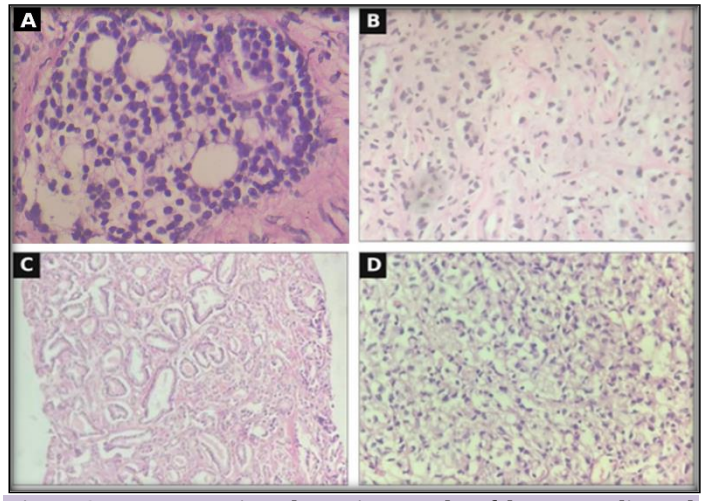

Figure 3: Representative photomicrographs of haematoxylin and eosin-stained TRUS-guided prostate needle-biopsy cores. (A) Cribriform gland arrangement, characteristic of Gleason pattern 4 (×40). (B) Fused and cribriform glandular architecture with only occasional discrete glands, corresponding to grade group 4 (Gleason score 4+4=8). (C) Low-power view of a core infiltrated by closely packed, irregularly arranged acini in a grade group 3 tumour (Gleason score 4+3=7). (D) Solid sheets and cords of tumour cells with clear to pale cytoplasm and little or no gland formation, corresponding to grade group 5 (Gleason score 9–10).

Discussion

A significant association between higher PI-RADS categories and malignant biopsy findings was observed in the present study, and PI-RADS scores were positively correlated with the ISUP grade group. With an increased PI-RADS category, a greater percentage of biopsies were malignant. The above pattern agrees with the general consensus that higher Higher PI-RADS categories correspond to an increased probability of clinically significant cancer and more aggressive histopathology.[9,10]

The threshold analysis showed that PI-RADS ≥3 achieved very high sensitivity (98.5%) at the cost of low specificity (41.5%), whereas PI-RADS ≥4 had lower sensitivity (91.0%) but substantially improved specificity (66.0%). This trade-off mirrors a recent structured review and meta-analysis of PI-RADS version 2.1, in which pooled patient-level sensitivity and specificity were 96% and 43% for a threshold of ≥3 and 89% and 66% for a threshold of ≥4, respectively—closely matching the present cohort.[11] A comparable pattern was reported by Nowier and colleagues, who observed high sensitivity but limited

specificity at a threshold of ≥3 and improved specificity at higher thresholds in biopsy-naïve men.[13]

These findings are also consistent with the Indian data In a tertiary-centre cohort of Indian men, Kubihal and colleagues found that, "for clinically significant cancer, With PI-RADS ≥3, sensitivity and specificity were 92% and 72%, respectively, whereas with PI-RADS ≥4, they were 88% and 89%. These results illustrate the gain in specificity achieved by using the higher threshold. The directional consistency of these results across diverse populations supports the external validity of stratification by PI-RADS, while variation in absolute figures highlights the impact of case mix and reference standard. An MRI-guided pathway with targeted biopsy facilitates the detection of clinically significant prostate cancer compared with systematic biopsy alone, consistent with broader systematic review evidence. The positive correlation between PI-RADS category and ISUP grade group observed in this study (Spearman $\rho = 0.641$; $P < 0.001$)". was also reported in previous studies showing a higher frequency of cancer detection and more aggressive pathologies with increasing imaging suspicion. This suggests a role for pre-biopsy mpMRI which exceeds lesion detection and extends to risk stratification.[5,11]

Clinically, these findings suggest that PI-RADS 3 lesions remain an equivocal group in which additional parameters such as PSA density may aid biopsy decisions,[16] whereas categories 4 and 5 identify men with a substantially higher probability of clinically important disease. Lowering the threshold to category 3 maximizes sensitivity but increases the number of biopsies yielding benign or indolent findings, whereas a threshold of category 4 improves specificity and may better prioritize men most likely to benefit from biopsy, in keeping with guideline-based risk stratification.[17]

Limitations: Several limitations should be considered. First, the cohort comprised men referred to a tertiary centre with elevated PSA and/or MRI-suspicious lesions who proceeded to biopsy; this referral and spectrum (selection) bias enriches the sample for malignancy and explains the high overall cancer yield (85.8%). Consequently, The positive predictive value is likely overestimated, whereas the specificity and negative predictive value are affected should be interpreted with caution; the absolute diagnostic metrics may not generalize to screening or primary-care populations. Second, the analysis is based on a single-institution dataset without external validation, formal inter-reader agreement assessment, or radical prostatectomy correlation as a reference framework, and systematic TRUS biopsy is itself susceptible to sampling error. Third, the study did not incorporate lesion-level modelling, receiver operating characteristic analysis, or multivariable adjustment for PSA density and prior biopsy status. Future work should include larger multicentre cohorts, lesion-level analysis, and multivariable models incorporating PSA density and prior biopsy status.[16]

Conclusion

Higher PI-RADS categories were associated with an increased likelihood of malignant and clinically significant findings on TRUS-guided core biopsy. In addition, PI-RADS scores exhibited a positive correlation with ISUP grade groups. A PI-RADS cutoff of ≥3 provided the highest sensitivity, whereas a cutoff of ≥4 showed improved specificity and accuracy, offering a more balanced diagnostic performance. These results further reinforce the role of PI-RADS in supporting biopsy decision-making and clinicopathological assessment in men with suspected prostate cancer, considering the increased cancer detection rate in this biopsy-referred population.

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Conflicts of interest

There are no conflicts of interest.

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