ORIGINAL ARTICLE

DIAGNOSTIC ACCURACY OF PI-RADS FOR PROSTATIC MALIGNANCY; NON-INVASIVE ASSESSMENT OF THE PROSTATE GLAND

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Background: The use of multi-parametric (MP) MRI for the detection and characterization of prostate lesions has evolved over the last decade. This study was conducted to determine the diagnostic accuracy of Prostate Imaging Reporting and Data System (PI-RADS) in diagnosing prostatic malignancy, taking histopathology as gold standard. **Methods:** A cross-sectional validation study was conducted in Dept. of Radiology, Benazir Bhutto Hospital Rawalpindi from March 10th to June 10th 2024. Total 120 patients with suspected prostate malignancy (50–80 years' age) were included. Patients with known allergy to Gadolinium based MRI contrast agent, Impaired renal function (GFR<30 ml/min) and claustrophobia were excluded. The MRI examinations were done in all cases on 1.5 Tesla MRI unit with body coil coupled to endorectal coil in the supine position. The PI-RADS findings were interpreted by consultant radiologist for prostatic malignancy. All patients were undergone biopsy in the concerned ward and tissue was sent to institutional laboratory for histopathology. Histopathology report was compared with PI-RADS findings. **Results:** The Sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy of PI-RADS in diagnosing prostatic malignancy, taking histopathology as gold standard was 85.51%, 84.31%, 88.06%, 81.13% and 85.0% respectively. **Conclusion:** This study concluded that PI-RADS is the non-invasive modality of choice with high diagnostic accuracy in detecting prostate cancer, and has dramatically improved our diagnostic and prognostic ability.

Keywords: Prostate Cancer; Prostate Imaging Reporting and Data System. PI-RADS. Sensitivity

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INTRODUCTION

Prostate cancer (PCa) ranks as the second most common malignancy in male population with 5.8% overall reported prevalence in Pakistan. PCa has been the second leading cause of cancer-related mortality in Western men.[1] Though the high morbidity and mortality exist, advancements in the early diagnosis attribute much to the improvement of life expectancy. Different Protocols and screening tests are being used worldwide for its early detection.[2] Studies have shown that early detection through Prostate Specific Antigen (PSA) screening can alter the natural history of the disease and reduce mortality.[3] However, this benefit is associated with diagnosing many indolent tumours, for which radical treatment leads to an adverse impact on quality of life without altering survival.[4]

The most commonly accepted protocol being practiced is clinical diagnosis based on Digital Rectal Examination, screening by serum PSA and Transrectal Ultrasonography (TRUS).[3,5,6] Imaging studies can be a valuable part of pretreatment staging of prostate cancer, helping to differentiate clinically localized disease, which is generally amenable to local therapy, from more advanced disease that may require multimodal therapy. Ultrasound (US) and magnetic resonance imaging (MRI) are the two main imaging methods used for prostate cancer detection.[7] Urologists use TRUS during prostate biopsy and can sometimes see a hypoechoic area (tissues or structures that reflect relatively less of the ultrasound waves directed at them). But US has poor tissue resolution and thus, is generally not clinically used.[8]

The use of multiparametric (mp) MRI for the detection and characterization of prostate lesions has evolved over the last 10 years. mp-MRI protocols combining information of morphology with high spatial resolution (T2-weighted turbo spin echo imaging = T2 TSE), cell density (diffusion weighted imaging = DWI) and vascularization (dynamic contrast-enhanced imaging=DCE) provide high diagnostic accuracy for the detection of clinically significant PCa.[4,5] In addition, MRI is increasingly used for targeted prostate biopsy, which leads to improved detection of significant PCa.[6] The European

Society of Urogenital Radiology (ESUR) has called a panel of experts and published a guideline providing recommendations for the performance of mp-MRI investigations and a structured reporting scheme named PI-RADS in February 2012.[7] In a study, the prevalence of prostate cancer was found to be 69.09% and sensitivity and specificity of Prostate Imaging Reporting and Data System (PI-RADS) in diagnosing prostate cancer as 92.11% and 94.12% respectively.[8] Alistair et al. results showed that the sensitivity is 97.0% and specificity is 60.0%.[9]

Pakistan being a developing country, faces challenges to meet the costs of healthcare. The purpose of this study was to establish the diagnostic accuracy of PI-RADS as a screening and diagnostic test for prostate cancer. The prostate biopsy is time consuming, needs anaesthesia and finances as well. No such previous study has been done in Pakistan. Hence, PI-RADS may prove to be a better option, being-non-invasive and cost effective. The use of PI-RADS in early detection of prostate cancer may improve the quality of patient's life by guiding the therapeutic management in our area as

MATERIAL AND METHODS

The cross-sectional validation study was conducted in Dept. of Radiology, Benazir Bhutto Hospital Rawalpindi over a period of four months from March 10th 2024 to June 10th 2024 after the institutional ethical review committee approval (ERB#4827/RTH/RWP, dated 7th march 2024). Cases were selected by non-probability, consecutive sampling. Sample size of 120 cases was calculated with 95% confidence level, taking prevalence of prostate cancer as 69.09%, precision 8% for sensitivity and 6% for specificity of PI-RADS as 92.11% and 94.12% respectively.[8]

Total 120 adult patients with suspected prostate malignancy between 50–80 years of age were included. Suspected prostate malignancy was defined as enlarged prostate with hard consistency, irregular surface, immobile rectal mucosa, nodule on Digital Rectal Examination and S/PSA > 4 ng/ml. Patients with known allergic reaction to Gadolinium based MRI contrast agent, impaired renal function with GFR<30 ml/min and claustrophobia were excluded. The biodata and clinical history were taken from all the patients. Investigations were reviewed. Preliminary ultrasound KUB was performed under guidance of consultant radiologist.

In all the patients, MRI examinations were done on 1.5 Tesla MRI unit with body coil coupled to endorectal coil in the supine position. The protocol of MRI was as follows: T2WI and T1WI Axial and coronal, (TR, 5029, TE,100) and (TR500, TE, 15), FOV, 350, slice thickness 3 mm and interval, 0.3 mm. DCE-MRI Gad DETPA (gadolinium-Diethylenetriamine Penta-acetic acid) dose of 0.2 mmol/kg (maximum dose 15 mmol) injected IV at a rate of 3 mL/s and Post Gad study was taken at the early and delayed phases (after 2 min to assess enhancement pattern and delayed after 5 min to assess washout). DWI with ADC values measurements: – DW images obtained at b0, 500, 1000 s/mm2 gradients. (TR, 1570 ms; TE, 75, FOV 160 mm and slice thickness 3 mm); the region of interests (ROI), were placed on lesion to measure ADC values. ADC maps were obtained from DW images at b0, b500 and b1000 s/mm2 gradients.

The PI-RADS findings were interpreted by consultant radiologist (with >5 years of post-fellowship experience) for presence or absence of prostatic malignancy. Each tumour within the prostate gland was identified and graded as per PI-RADS v2 to report likelihood of PCa (1: highly unlikely, 2: unlikely, 3: equivocal, 4: likely, and 5: highly likely). Therefore, the present study will consider PI-RADS ≥ 3 as prostate cancer.

All patients were undergone biopsy in the concerned ward and tissue was sent to institutional laboratory for histopathology. Infiltrative small glands or cribriform glands, loss of basal cells, cellular atypia, and mitotic figures was considered as malignant lesion. The histopathology report was compared with PI-RADS findings.

The data was recorded on a specially designed *proforma* and analyzed through SPSS 25.0. Age and size of prostate were presented as mean and SD. Prostatic malignancy on PI-RADS and histopathology (yes/no) were presented as frequencies and percentages. The 2×2 contingency table was used to calculate the sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy of PI-RADS in diagnosing prostatic malignancy. Stratification was done for age and size of prostate. Post-stratification sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy were also calculated.

Table-1: Demonstrating the concept of true and false positive/negative cases based on MRI based Pi-RADS and Histopathological diagnosis of carcinoma prostate

Prostate Imaging		Prostatic malignancy on Histopathology	
		Yes	No
Reporting and Data System (PI-RADS)	Yes	True Positive (a)	False Positive (b)
	No	False Negative (c)	True negative (d)

*Sensitivity: a/a+c x 100; Specificity: d/b+d x100; PPV: a/a+b x 100; NPPV: d/c+d x 100; Diagnostic accuracy: a+d/a+b+c+d x100.

RESULTS

Amongst the 120 selected cases, the mean age was 61.75±6.53 years (range 50–80 years). Majority of the patients 95 (79.17%) were between 50–65 years 95 (79.17%), while there were 25 (20.87%) cases from

66–80 years' age. The mean weight of prostate was 55.58±13.36 grams, 43 (35.83%) had prostate weight ≤50 gm and 77 (64.17%) has >50 gm weight.

Amongst 120 cases, 67 (55.8%) had PI-RADS ≥3. In 67 PI-RADS positive patients, 59 (True Positive) had prostate cancer and 08 (False Positive) had no prostate cancer on histopathology. Among, 53 PI-RADS negative patients, 10 (False Negative) had prostate cancer on histopathology whereas 43 (True Negative) had no prostate cancer on histopathology Table-2.

The overall sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy of PI-RADS in diagnosing prostatic malignancy was 85.51%, 84.31%, 88.06%, 81.13% and 85.0% respectively (table-2). The stratification of diagnostic accuracy with respect to age groups and weight is shown in table 3.

Table-2: Diagnostic accuracy of PI-RADS in diagnosing prostatic malignancy, taking histopathology as gold standard (n=120).

Reporting in all 120 cases	Positive on Histopathology	Negative on Histopathology	*p*-value
Positive on PI-RADS	59 **(TP)**	08 **(FP)**	**0.0001**
Negative on PI-RADS	10 **(FN)**	43 **(TN)**	
Sensitivity 85.5%; Specificity 84.3%; PPV 88.1%; NPV 81%; diagnostic Accuracy 85%			

Table 3: Stratification of diagnostic accuracy with respect to age groups and weight of prostate gland (n=130)

	Reporting	Positive on Histopathology	Negative on Histopathology	*p*-Value
Age group 50-65 years (n=95)	**Positive on PI-RADS**	46 (TP)	06 (FP)	**0.001**
	Negative on PI-RADS	07 (FN)	36 (TN)	
	Sensitivity 86.8%; Specificity 85.7%; PPV 88.5%; NPV 83.7%, diagnostic accuracy 86.3%.			
Age group 66-80 years (n=25)	**Positive on PI-RADS**	13 (TP)	02 (FP)	**0.001**
	Negative on PI-RADS	03 (FN)	07 (TN)	
	Sensitivity 81.3%; Specificity 77.8%; PPV 86.7%; NPV 70%; diagnostic accuracy 80%.			
Weight of prostate≤50g (n=43)	**Positive on PI-RADS**	22 (TP)	03 (FP)	**0.001**
	Negative on PI-RADS	04 (FN)	14 (TN)	
	Sensitivity 84.6%; Specificity 82.3%: PPV 88%; NPV 77.8%, diagnostic accuracy 83.7%.			
Weight of prostate>50 g (n=77).	**Positive on PI-RADS**	37 (TP)	05 (FP)	**0.001**
	Negative on PI-RADS	06 (FN)	29 (TN)	
	Sensitivity 86%; Specificity 85.3%; PPV 88%; NPV 82.8%; diagnostic accuracy 85.7%.			

DISCUSSION

The increased availability of magnetic resonance imaging (MRI) of prostate, its morphologic and different functional imaging modalities along with its greater standardization has enhanced its performance in detecting, localizing and staging the PCa.[10] In 2012, the European Society of Urogenital Radiology (ESUR) published clinical guidelines for multi-parametric MRI (mp-MRI) along with a structured reporting system called the PIRADS.[11,12] During the later years, ESUR developed an updated version of PIRADS, known as PIRADS version 2.0.[11] The PIRADS assesses the probability of finding Clinically significant prostate cancer (csPCa) on a five-point Likert scale for each lesion.[13,14] A considerable number of studies have commented on high negative predictive value (NPV) of mp-MRI for detecting csPCa using 12-core biopsy, saturation or radical prostatectomy specimen as reference tests. Certain studies have reported low specificity and low positive predictive value (PPV) of PIRADS score.[15]

In our study, sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy of PI-RADS was 85.51%, 84.31%, 88.06%, 81.13% and 85.0% respectively. El-Kareem et al in his study found the prevalence of prostate cancer to be 69.09%, while the sensitivity and specificity of PI-RADS in diagnosing prostate cancer was 92.11% and 94.12% respectively.[8] However, Alistair *et al.* found comparatively high sensitivity of 97.0% and lower specificity 60.0%.[9]

Ahmed *et al* reported that sensitivity of PIRADS score for detecting csPCa in patients with PSA up to 15 ng/mL was 93% with NPV of 89%, specificity of 41% and with PPV of 51%.[16] Another study reported an AUC of 0.89, and the NPV of PIRADS score of ≤2 was 98%. However, PPV of 49% raises a doubt about the PIRADS score being not able to predict the outcome. In addition, a few patients with a PIRADS score of ≤2 had csPCa.[17] Thompson and colleagues (2016) found that when PIRADS score was used for predicting csPCa, mp-MRI had sensitivity, specificity, PPV and NPV of 96%, 36%, 52% and 92%, respectively.[18] A very recent study revealed that in patients with PSA between 4 and 10 ng/mL, a PIRADS score ≥4 was the cut-off for predicting csPCa.[19] Engelhard *et al's* study has evaluated the impact of PIRADS 3 score in differentiating equivocal lesions as malignant or benign and found that PIRADS 3 lesions revealed only benign conditions. Hence, PIRADS 3 score could not be confirmed as an absolute marker in patient clinical management care. Another study which evaluated the significance of PIRADS score ≥4 in identifying csPCa showed that the sensitivity and specificity of PIRADS scoring were 77.0% and 73.8%

for reader 1 and 77.3% and 71.4% for reader 2, respectively.[20] These observations corroborate with the results of previous studies which indicated increased specificity of PIRADS score to identify csPCa when PIRADS ≥4 (criterion 4) were used.[17]

A meta-analysis by Zhang *et al*[21] analyzed 13 studies (2049 total patients) for overall diagnostic accuracy of PI-RADS v2 in diagnosing prostate cancer. This analysis estimated a pooled sensitivity of 0.85 (0.78–0.91), pooled specificity of 0.71 (0.60–0.80), PPV from 0.54–0.97, and NPV from 0.26–0.92. The results of this meta-analysis showed significant heterogeneity among the studies. Inter-reader agreement was reported good to excellent for studies in which 2 or more readers provided separate results of MRI interpretations. A study by Seo *et al*[22] included patients with biopsy proven GS ≥ 6 PCa who underwent MRI and radical prostatectomy. csPCa was surgically defined as GS ≥7 or a tumour volume of ≥0.5 cm3, or tumour category ≥T3. For the experienced readers, the proportions of csPCa were significantly higher in a group with PS ≥4 than in a group with a PS <4 (<0.001). For inexperienced reader, PI-RADS v2 scores were predictive of GS ≥7 and category ≥T3, but not of tumour volume ≥0.5 cm3 or presence of csPCa. Although the individual sequences are useful, T2WI in combination with two functional sequences has been shown to provide better characterization of tumour in the prostate.[23] In a diagnostic meta-analysis of seven studies, de Rooij *et al*. revealed a high overall sensitivity and specificity on accuracy of mp-MRI using T2WI, DWI and DCE MRI. Pooled sensitivity and specificity were 0.74 and 0.88, respectively, with negative predictive value (NPV) ranging from 0.65–0.94.[24]

In another study, mp-MRI showed good performance at detecting and ruling out clinically significant cancer, following at least one previous biopsy, with a NPV of 95% using trans perineal template systemic biopsy as the gold standard.[25] The authors concluded that mp-MRI can therefore be used as a triage test following a negative biopsy and thereby identify patients who can avoid further biopsies. A recently published study reported clinical NPV of mp-MRI at 89.6% for significant cancer over a longitudinal follow-up period of 5 years.[26] Shakir *et al*. demonstrated that the benefit of MRI and targeted biopsy increases with increasing PSA levels and that the diagnostic usefulness and upgrading to clinically significant disease on biopsy occurred above a PSA threshold of 5.2 ng/mL.[27]

While several studies have shown the benefit of functional imaging in detection of prostate cancer in the peripheral zone,[28] functional imaging may have a limited role in evaluating cancers in the transition zone on mp-MRI because of the heterogenous appearance and enhancement secondary to benign prostatic hyperplasia. Hoeks *et al*[29] reported that DCE-MRI in particular did not show any additional benefit over T2WI for detection of cancer in the transition zone. In their study, accuracy of mp-MRI for detecting Gleason grades 4 and 5 in the transitional zone was 79% for T2WI and 72% when combined with DWI and DCE MRI. For low-risk disease, the accuracy levels were 66% for T2WI and 62% when combined with functional imaging. In another study, the authors reported that adding DWI to T2WI improved the accuracy of detecting prostate cancer in the transition zone.[30]

Tumour volume is a documented prognostic factor for prostate cancer outcome, and is its correct estimation is mandatory for success of focal therapy,[31] the new organ-sparing treatment technique that aims to selectively ablate locally confined, clinically significant index lesions, while sparing the rest of the prostate gland and the surrounding structures. Histologic architecture of the tumour affects quantitative MRI findings and is known to be a major predictor of tumour visibility on mp-MRI.[32] Sparse or infiltrative tumour mixed with normal tissue may be present at the periphery of the MRI-visible "dense" tumour. Studies have shown that the greatest tumour volume on mp-MRI determined from images on any of the individual sequences provided a fairly accurate estimation of the tumour volume on whole-mount histology, although estimation was more accurate for larger tumours over 10 mm and >0.5 cc in volume than for small tumours.[31]

CONCLUSION

This study concludes that PI-RADS is the non-invasive modality of choice with high diagnostic accuracy in detecting prostate cancer. We suggest that PI-RADS scoring should be done routinely in all suspected cases of prostate cancer for accurate pre-operative assessment. This may guide to proper surgical approach and reduce the burden of pure diagnostic biopsies in prostate cancer which ultimately may reduce the morbidity and mortality of these patients.

AUTHORS' CONTRIBUTION

All the authors contributed equally.

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