

IMPLEMENTATION OF PI-RADS IN PROSTATE CANCER WITH 3 TESLA MRI- A PILOT STUDY

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ABSTRACT**BACKGROUND**

For standardising of multiparametric magnetic resonance (MR) imaging of the prostate, the European Society of Urogenital Radiology published Prostate Imaging Reporting and Data System (PI-RADS) in 2012.^{1,2} Later it was validated and the PI-RADS sum score for summation of the single score for the three different pulse sequences (T2-weighted imaging, diffusion-weighted imaging [DWI] and dynamic contrast material-enhanced [DCE]) was being used. MRI has an emerging role in facilitating the diagnosis of prostatic malignancy.

The purpose of the present study was to correlate the results of TRUS-guided targeted prostate biopsy with the PI-RADS scoring (Version 2) on MP-MRI in patients, wherein prostatic malignancy has been suspected.

MATERIALS AND METHODS

This was a descriptive study done at Yenepoya Medical College, Deralakatte, Mangalore over a period of 6 months after obtaining ethical clearance. 30 patients were included in the study.

Inclusion Criteria being-

- Patients with PSA > 4 ng/dL.
- Patients with palpable lesion on digital rectal examination.

The data so obtained was tabulated in Excel Sheet and analysed for sensitivity, specificity and other statistical tests for individual parameters.

RESULTS

30 patients underwent MRI and TRUS-guided biopsy. Mean age of patients was 64 years, ranging from 52 - 79 years. All these patients had increased PSA levels. All these patients who underwent MP-MRI had a documented PI-RAD score. 4 of them had PI-RAD I, 5 of them had PI-RAD III, 9 of them had PI-RAD IV and 12 of them had PI-RAD V. 21 patients with PI-RAD IV and PI-RAD V on imaging showed positive for malignancy on HPE showing significant association on Chi-square test with $\chi^2 = 18.122$ and $p < 0.001$ (statistically significant).

CONCLUSION

In our study, we found that a very good correlation with positivity of prostate cancer on HPE with higher PI-RADS (IV and V). PI-RAD overall score was sensitivity (90%) compared to its component alone (DWI- 69%, T2- hypointensity- 68%). This was similar to previous observation done by Junker et al. PI-RAD scoring is better done on 3 Tesla than 1.5 Tesla.

KEYWORDS

Multiparametric MRI (MP-MRI), Prostate Specific Antigen (PSA), Dynamic Contrast Enhancement (DCE), PI-RADS (Prostate Imaging Reporting and Data System).

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BACKGROUND

For standardising of multiparametric magnetic resonance (MR) imaging of the prostate, the European Society of Urogenital Radiology published Prostate Imaging Reporting and Data System (PI-RADS) in 2012.^{1,2} Later, it was validated and the PI-RADS sum score for summation of the single score for the three different pulse sequences (T2-weighted

imaging, diffusion-weighted imaging [DWI] and dynamic contrast material-enhanced [DCE]) was being used). After many years of practice, there was a modification of the same with single score system (on a scale of 1 - 5), similar to this Breast Imaging Reporting and Data System was thought of.³

Baur et al reported that assigning a PI-RADS score on the basis of DWI for PZ lesions and a PI-RADS score on the basis of T2-weighted imaging for TZ lesions was enough for patient workup and management,⁴ and this is why PI-RADS steering committee of the American College of Radiology developed PI-RADS version 2.0.⁵

Clinical suspicion of prostate cancer is typically based on Digital Rectal Examination (DRE) and the finding of elevated prostate-specific antigen.⁶ Cancer may still be detected after initial negative biopsy with repeat TRUS biopsy, but the cancer detection rate falls with each repeat biopsy episode.⁷

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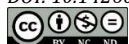
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MRI has an emerging role in facilitating the diagnosis of prostatic malignancy.^{8,9,10} Techniques typically involve MRI with morphological imaging, primarily high resolution T2-weighted (T2W) imaging combined with one or more functional MRI techniques (Diffusion-Weighted Imaging [DWI], Dynamic Contrast-Enhanced imaging [DCE], Magnetic Resonance Spectroscopy [MRS]).^{8,9,10}

The purpose of the present study was to correlate the results of the present study was to correlate the results of TRUS-guided targeted prostate biopsy with the PI-RADS scoring (version 2) on MP-MRI in patients, wherein prostatic malignancy has been suspected.

MATERIALS AND METHODS

Patient Selection

This was a descriptive study conducted at Yenepoya Medical College, Deralakatte, Mangalore, over a period of 6 months. Institutional Ethical Committee approval was obtained. Sample size was taken conveniently.

Inclusion Criteria

- Patient with PSA > 4 ng/dL.
- Patient with palpable lesion on digital rectal examination.

Exclusion Criteria

Patient with history of prostatic biopsy in past 6 weeks.

Methodology

After obtaining informed written consent, 30 patients who were suspected for prostatic cancer were subjected to multiparametric MRI followed by USG-guided 12 core biopsy. HPE result obtained was correlated with PI-RADS score.

Multiparametric MRI Protocol

All MRI imaging was done using phase array body coil on GE SIGNA Pioneer 3 Tesla. Parameter and sequence used are mentioned below.

Sl. No.	Parameter	T2	DWI (b-800)	Enhancement
1	FOV	28X28 cm	24x12 cm	28x28 cm
2	Matrix	320x256	160x80	320x256
3	TR in msec	5329	5040	590
4	Section thickness	3 mm	3 mm	3 mm
5	Time for acquisition	3 mins 17 sec	4 mins 57 sec	2 mins 43 sec
6	Spacing	1 mm	1 mm	1 mm

TRUS Guided 12 Core Biopsy

Before the procedure, the patients were given broad spectrum antibiotics to protect them against infection. They were also given rectal enema to empty the rectal canal before the procedure to obtain clear images. Intrarectal instillation of 20 mL of local anaesthetic gel (Lidocaine 2%) was used to alleviate pain and discomfort during the procedure.

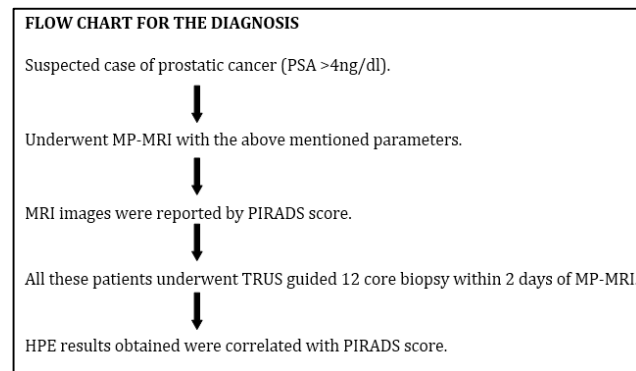
A transrectal ultrasound probe (6 - 12 MHz range) with a combination of end-viewing and side-viewing transducer attached to GE Voluson E8 ultrasound machine was used. Local anaesthetic gel (lidocaine 2%) was applied over a latex condom applied onto the probe. A full urinary bladder was ensured to help in better visualisation of the gland prior to

the procedure. All patients were examined and biopsied in the left lateral decubitus position and it was well tolerated.

The prostate was imaged in both axial and sagittal planes with assessment of volume, echogenicity, surface, calcification and the presence of nodules.

Each nodule was assessed for size, location in the gland, morphology, echogenicity, margin and extent.

MR image of Prostate finalised were analysed by radiologist with 2-year experience and PI-RADS score were documented. HPE result was collected within 7 days to minimise error and was correlated with PI-RADS score.



Statistical Analysis

The data obtained were analysed using Statistical Package for Social Sciences (SPSS) version 21. Histopathological findings were considered as the standard of reference and sensitivity, specificity, positive predictive value and negative predictive value were calculated for parameters DWI and T2 intensity. Comparative analysis of the quantitative data was done for categorical variables using chi-square test. All tests with p-value < 0.05 were considered as statistically significant.

RESULTS

Evaluation of Diagnostic Test

30 patients underwent MRI and TRUS-guided biopsy. Mean age of patients was 64 years ranging from 52 - 79 years. All these patients had increased PSA levels.

All these patients who underwent MP-MRI had a documented PI-RAD score.

4 of them had PI-RAD I, 5 of them had PI-RAD III, 9 of them had PI-RAD IV and 12 of them had PI-RAD V.

21 patients with PI-RAD IV and PI-RAD V on imaging showed positive for malignancy on HPE showing significant association on Chi-square test with $\chi^2 = 18.122$ and $p = < 0.001$ (statistically significant).

T2 Hypointensity

Out of 30 patients who underwent MRI, 25 patients showed T2 hypointensity. 18 out of 25 patients showed positive on HPE with sensitivity of 68%, specificity of 100% indicating that 18 patients with positive HPE had T2 hypointense lesion in the peripheral zone.

DWI

23 patients showed diffusion positivity, out of which 18 patients were positive on HPE which was statistically significant with 'p' value of 0.010.

DCE Curve

21 patients out of 30 had a dynamic enhancement curve of B and C (B= 4, C= 17). Out of 21 patients, 18 patients were positive on HPE.

Overall PI-RADS Score

Results were analysed using overall PI-RADS score. 90% sensitivity with positive predictive value of 65.38% was documented and negative predictive value of 100% was documented.

Overall PI-RADS Score	Radiological Given (n= 30)	HPE Malignant Positive (n= 18)	Biopsy Negative (n= 12)	Chi-Square value	P value
1	4	-	4	18.122	<0.001
2	-	-	-		
3	5	-	5		
4	8	6	2		
5	13	12	1		
DWI					
1	3	-	4	6.679	0.010
2	1	-	-		
3	6	-	5		
4	7	6	2		
5	13	12	1		
T2					
1	2	-	1	7.846	0.005
2	2	-	4		
3	5	-	-		
4	6	6	5		
5	15	12	2		
DCE					
A	9	0	9	15.181	0.002
B	4	3	1		
C	17	15	2		

Table 1. Association between the Radiologically reported Grading of CA Prostate and HPE Results

Parameters of Imaging	Sensitivity (%) N (CI)	Specificity	Positive Predictive value	Negative Predictive value	Accuracy	Prevalence of the Disease
PI-RADS Score	100 (80.49-100.00)	30.77 (9.09-61.43)	65.38 (46.2-80.6)	100 (50.01-99.99)	70 (50.60-85.27)	56.67 (37.43-74.54)
DWI	94.12 (71.87-99.01)	46.15 (30.11-63.04)	69.57 (47.08-86.79)	85.71 (42.13-99.64)	73.33 (54.11-87.72)	76.67 (57.72-90.07)
T2 Intensity	100	38.46 (26.09-52.53)	68 (46.6-85.05)	100 (47.82-100.00)	73.33 (54.11-87.72)	83.33 (65.28-94.36)

Table 2. Validity of the Parameters of Imaging

Parameter of Imaging	HPE		Total
	Positive	Negative	
PI-RADS			
Positive	17	9	26
Negative	0	4	4
Total	17	13	30
DWI			
Positive	16	7	23
Negative	1	6	7
Total	17	13	30
T2 intensity			
Hypointense	17	8	25
Hyperintense	0	5	5
Total	17	13	30

Table 3. Parameter of Imaging

DISCUSSION

In our study, we found a very good correlation with positivity of prostate cancer on HPE with higher PI-RADS (IV and V). The study conducted by Kuru TH et al and five other studies observed positive correlation with prostate cancer detection and higher PI-RADS score.^{11,12,13,14}

In our study, it was also found that patients with overall PI-RADS < 3 had reduced incidence of prostate cancer when correlated with HPE. As a result, we can infer that multiparametric MRI with PI-RADS scoring reduces the need for biopsy in men with PI-RADS < 3, while at the same time improving the overall rate of detection of intermediate/ high-risk prostate cancer.

Pokorny MR et al also observed that MP-MRI reduces need of biopsy in patients with lower overall PI-RADS score.¹⁵

Overall, PI-RAD scoring in our study showed 90% sensitivity compared to that of its individual components alone (DWI- 69%, T2- hypointensity- 68%), which was similar to previous observation done by Junker et al.¹⁶

We have detected clinically significant disease and other studies have shown that MRI reduces the need for biopsies and increases the detection of intermediate/ high-grade cancer.¹⁷

CONCLUSION

Multiparametric MRI of prostate has shown great promise for early detection of prostate cancer. PI-RADS version 2 is an improvement of the older version and it is a reliable tool for better communication between radiologists and clinicians in patients evaluated for prostate cancer. In addition to that, PI-RADS version 2 scoring has significantly improved decision making with regard to need and guidance for biopsy.

Limitation of Study

- Sample volume of the study was small.
- PI-RADS scoring was done by single radiologist with multiple radiologists reviewing the same could have better scoring.
- Imaging protocol had only T2, DWI and DCE. The scoring would have been much better with MRS being done for all the cases.

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