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Diagnostic Accuracy of Multiparametric 3Tesla Magnetic Resonance Imaging of Prostate in Patients with Elevated Prostate Specific Antigen

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ABSTRACT
Objective: *To evaluate the diagnostic accuracy of multiparametric magnetic resonance imaging (mpMRI) of prostate in patients with raised prostate specific antigen (PSA).* ***Design and Methods:*** *The studyconducted on 31 patients in Department of Radiodiagnosis in collaboration with Urology department, Regional Institute of Medical Sciences (RIMS), Imphal, Manipur from January 2021 to December 2022 and analysed for sensitivity and specificity of the test (mpMRI) was calculated to find out its accuracy.* ***Conclusion:****Multi-parametric MRI PIRADS scoring in patients with raised PSA levels is an invaluable, non-invasive and feasible option to detect carcinoma prostate with a high sensitivity and specificity besides high predictive values and can help in identifying patients in need of biopsy and also helps in targeted biopsy and characterizing the extent and aggressiveness of the prostate cancer.*

KEYWORDS: *multiparametric magnetic resonance imaging (mpMRI), prostate specific antigen (PSA), Multi-parametric MRI,PIRADS scoring*

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I. INTRODUCTION

Prostate cancer is the most prevalent non-cutaneous malignancy as well as the third leading cause of death in male worldwide.[1] In India, the projected new case load in 2020 is expected to be 41,532 with Age adjusted Rate (AAR) incidence of 5.2 per 100000 population.[2] Prostate specific antigen (PSA) and digital rectal examination (DRE) are commonly used for the initial evaluation of prostate cancer, while systematic transrectal ultrasound (TRUS) – guided prostate biopsy remains the common means of prostate cancer diagnosis. In the current era with the widespread use of PSA, many patients undergo systematic TRUS- guided biopsy (SB), resulting in the detection of the clinically insignificant cancers,[3] while about 25-35% of cancers are missed on the first SB.[4,5] Sensitivity and specificity of the PSA assay levels in correlation with prostatic carcinoma is low while DRE is a crude technique having high inter observer variability with a low positive predictive value. It is imperative from many studies that TRUS guided biopsy do miss upto 20% of prostate cancers, mainly due to under sampling of anterior, apex and midline prostate resulting in high false negativity.[6]Complete multiparametric magnetic resonance imaging (mpMRI) includes a series of key pulse sequences, including T2 weighted images that are used to assess the anatomic size of the lesion as well as the relationship of the lesion to important landmarks such as the prostate capsule and seminal vesicles,[7] diffusion weighted images (DWI) that provide information regarding the cellular density/potential aggressiveness of a site of prostate cancer by examining the degree of diffusion restriction of water molecules in tissue,[8] and a T1 weighted dynamic contrast-enhanced (DCE) acquisition that generates a wash-out of the vascularity of the prostate lesion. Generally, the less T2 signal, the more diffusion restriction, the more vascularity these lesions exhibit, the more likely it is that a clinically significant will be found histologically. MR spectroscopy may also be used in supplement to evaluate the ratio of the metabolites choline and citrate in a given voxel within the prostate as prostate cancers have increased choline and decreased citrate levels. As the ratio of choline to citrate increases, the potential aggressiveness for a detected prostate cancer also increases.[9,10] The combination of these imaging features has

been standardized using the Prostate Imaging Reporting and Data System (PI-RADS) lexicon, and lesions can be risk stratified based on their PI-RADS scores, with higher scores indicating a greater likelihood of the presence of high-grade prostate carcinoma.[11,12]

II. MATERIALS AND METHODS

The cross- sectional study conducted on 31 participants with prostate enlargement and elevated serum PSA at Regional Institute of Medical Sciences, Imphal following convenient sampling with following criteria:

Inclusion criteria:

1. Patients presenting with elevated PSA (>4ng/ml) in the department of Urology, Regional Institute of Medical Sciences, Imphal
2. Age between 50 and 80 years

Exclusion criteria:

1. Patients with MRI incompatible implants
2. Patients suffering from claustrophobia
3. Patients suffering from urinary tract infection

Study tools:

The machine used in this study was SIEMENS 3.0 Tesla MRI (Skyra, Erlangen Germany) with phased array body coil. Multi-parametric MR imaging protocol included 2D T2w-MRI, DW-MRI, DCE-MRI and MRSI. High resolution Axial, Sagittal and coronal T2WI using T2w turbo spin echo sequence was taken in three orthogonal planes. The signal intensities of prostate gland involving transition zone, peripheral and central zone were analysed.

PI-RADS SCORING SYSTEM (PIRADS V 2.1)

The prostate imaging- reporting and data system (PI-RADS) was followed in the study. The PI-RADS scoring is based on the European Society for Urogenital Radiology (ESUR) guidelines for uniform structured scoring system for components of multi -parametric MRI. PI-RADs V2.1 assessment uses a 5 point scale based on likelihood (probability) that a combination of mpMRI findings on T2W, DWI, and DCE correlates with the presence of a clinically significant cancer for each lesion in the prostate gland.

PI- RADS Assessment for T2W

Score	Criteria
A1	T2WI for peripheral Zone
1	Uniform hyperintense signal intensity (normal)
2	Linear or wedge- shaped hypointensity or diffuse mild hypointensity, usually indistinct margin.
3	Heterogeneous signal intensity or non- circumscribed, rounded, moderate hypointensity Includes others that do not qualify as 2, 4, or 5
4	Circumscribed, homogenous moderate hypointense focus/mass confined to prostate and <1.5 cm in greatest dimension.
5	Same as 4 but ≥1.5cm in greatest dimension or definite extraprostatic extension/invasive behaviour.

Score	Criteria
A2	T2WI for Transition Zone
1	Normal appearing TZ (rare) or a round, completely encapsulated nodule. (“typical nodule”)
2	A mostly encapsulated nodule OR a homogenous circumscribed nodule without nodule. “atypical nodule” OR a homogenous mildly hypointense area between nodules
3	Heterogeneous signal intensity with obscured margins Includes others that do not qualify as 2, 4, or 5
4	Lenticular or non- circumscribed, homogeneous, moderately hypointense, and <1.5 cm in greatest dimension.
5	Same as 4, but ≥1.5cm in greatest dimension or definite extraprostatic extension/invasive behaviour.

PI- RADS Assessment of DWI

Score	Criteria
B	Peripheral Zone (PZ) or Transition Zone (TZ)
1	No abnormality (i.e., normal) on ADC and high b- value DWI
2	Linear/wedge shaped hypointense on ADC and/or linear/wedge shaped hyperintense on high b-value DWI
3	Focal (discrete and different from the background) hypointense on ADC and/or focal hyperintense on high b- value DWI; may be markedly hypointense on a ADC or markedly hyperintense on high b-value DWI, but not both
4	Focal markedly hypointense on ADC and markedly hyperintense on high b- value DWI; <1.5cm in greatest dimension
5	Same as 4 but ≥1.5cm in greatest dimension or definite extra-prostatic extension/invasive behaviour

PI- RADS Assessment for DCE

Score	Criteria
C	Peripheral Zone (PZ) or Transition Zone (TZ)

(–)	no early or contemporaneous enhancement, or diffuse multifocal enhancement NOT corresponding to a focal finding on T2W and/or DWI or focal enhancement corresponding to a lesion demonstrating features of BPH on T2WI (including features of extruded BPH in the PZ)
(+)	focal, and; earlier than or contemporaneously with enhancement of adjacent normal prostatic tissues, and; corresponds to suspicious finding on T2W and/or DWI

A major objective of a prostate MRI exam is to identify and localize abnormalities that correspond to clinically significant prostate cancer, and mpMRI is able to detect intermediate to high grade cancers with volumes ≥0.5cc, depending on the location and background tissue within the prostate gland. However, there is no universal agreement of the definition of clinically significant prostate cancer. In PI- RADS v2.1, the definition of clinically significant cancer is intended to standardize reporting of mpMRI exams and correlation with pathology for clinical and research applications. Based on the current uses and capabilities of mpMRI and MRI- targeted procedures, for PI- RADS v2.1 clinically significant cancer is defined on pathology/histology as Gleason score ≥7 (including 3+4 with prominent but not predominant Gleason 4 component), and/or volume ≥0.5cc, and/or extra prostatic extension (EPE).

PI- RADS v2.1 Assessment Categories
PIRADS 1 – Very low (clinically significant cancer is highly unlikely to be present)
PIRADS 2 – Low (clinically significant cancer is unlikely to be present)
PIRADS 3 – Intermediate (the presence of clinically significant cancer is equivocal)
PIRADS 4 – High (clinically significant cancer is likely to be present)
PIRADS 5 – Very high (clinically significant cancer is highly likely to be present
TRUS SCAN AND TRUS GUIDED BIOPSY

All the patients were subjected for TRUS scan with sonolace X6 medison or Samsung HS 70A or canon esaote machine with rectal probe in left lateral position. Complete zonal anatomy of prostate was studied and systematic 12 core biopsy was taken. Targeted biopsy of the suspicious area was also be taken whenever feasible. Each biopsy specimen was specifically labelled according to the orientation of biopsy site and sent for histopathological examination. One dose of ciprofloxacin 500 mg half an hour prior to TRUS biopsy was given to all participants. Low rectal enema prior to biopsy was also done.

HISTOPATHOLOGICAL ANALYSIS

Gleason‘s score was obtained by histopathologic analysis of the TRUS guided biopsy specimens. The tumors were then divided into three groups based on Gleason‘s score. Tumors with Gleason‘s score <6 were categorized as low grade tumors, score equal to 7 as intermediate grade tumors and those with score >7 as high grade tumors. Tumor were considered clinically significant if the Gleason’s score is ≥ 7(4+3,3+4).[13]

III. RESULT

Total 31 patients with elevated prostate specific antigen participated in the study with the mean age of 67.13 ± 6.28 years and ranges from 54 to 80 years. Majority of participants were of age group of 60-70 years [17 out of 31 (54.6%)]; and minority of participants were of age group less than 60 years [5 out of 31 participants (16.1%)] and more than 70 years [9 out of 31 (29.1%)]. The mean serum PSA level was 10.80 ng/dl ± 5.11 ng/dl. 54.8% of participants had serum PSA level of less than 10.8 ng/dl and 45.2% had serum PSA level of more than 10.8 ng /dl. The mean prostate volume was 58.28 cm^3 ± 21.57 cm3 and ranged from 32.90 to 110 cm.

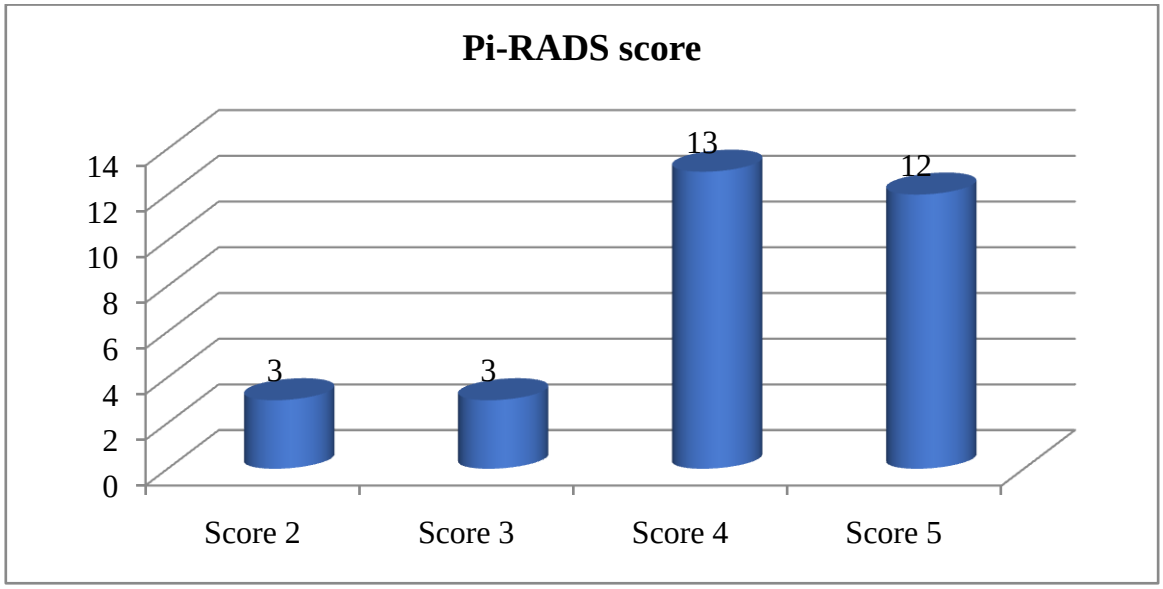


Figure 1: Bar chart showing distribution of Pi-RADS score (N=31)

The Pi-RADS score of 4 - 41.9% (13 out of 31), score 5 – 38.7% (12 out of 31) and score 2 and score 3 was 9.7 % and 9.7% respectively. The Pi-RADS Score 2, 3, 4 & 5 were categorized as low (9.7%), intermediate (9.7%), high (41.9%) and very high (38.7%), respectively. The Pi-RADS score of 2 and 3 were levelled as less significant clinically (19.4%) and score of 4 & 5 were levelled as clinically significant which was 80.6% i.e 25 out of 31 participants.

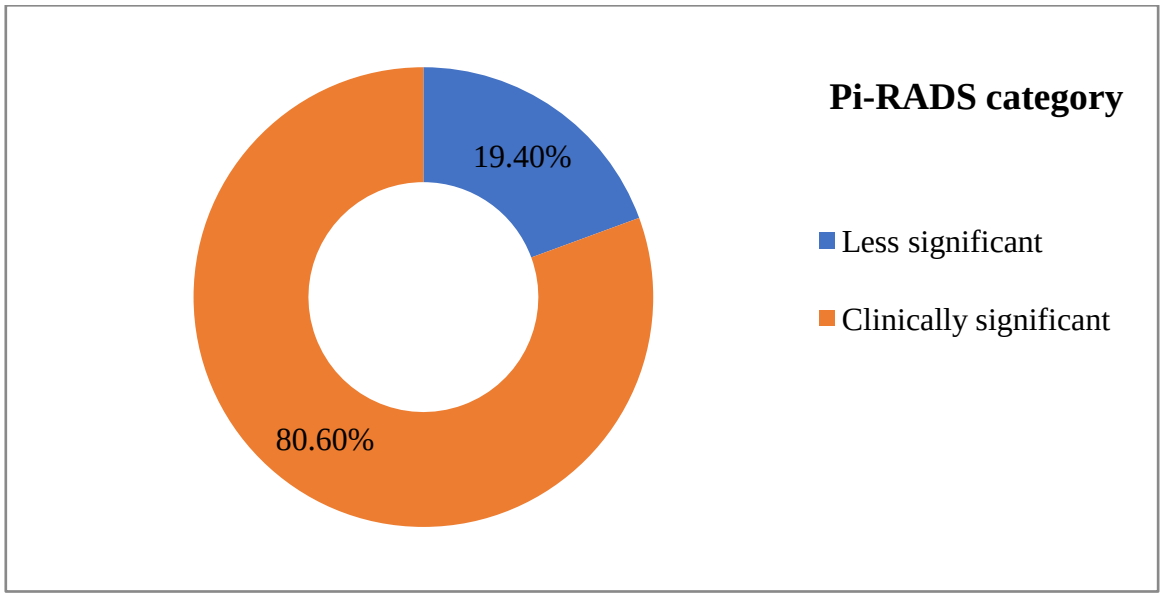


Figure 2: Pie chart showing distribution of Pi-RADS category (N=31)

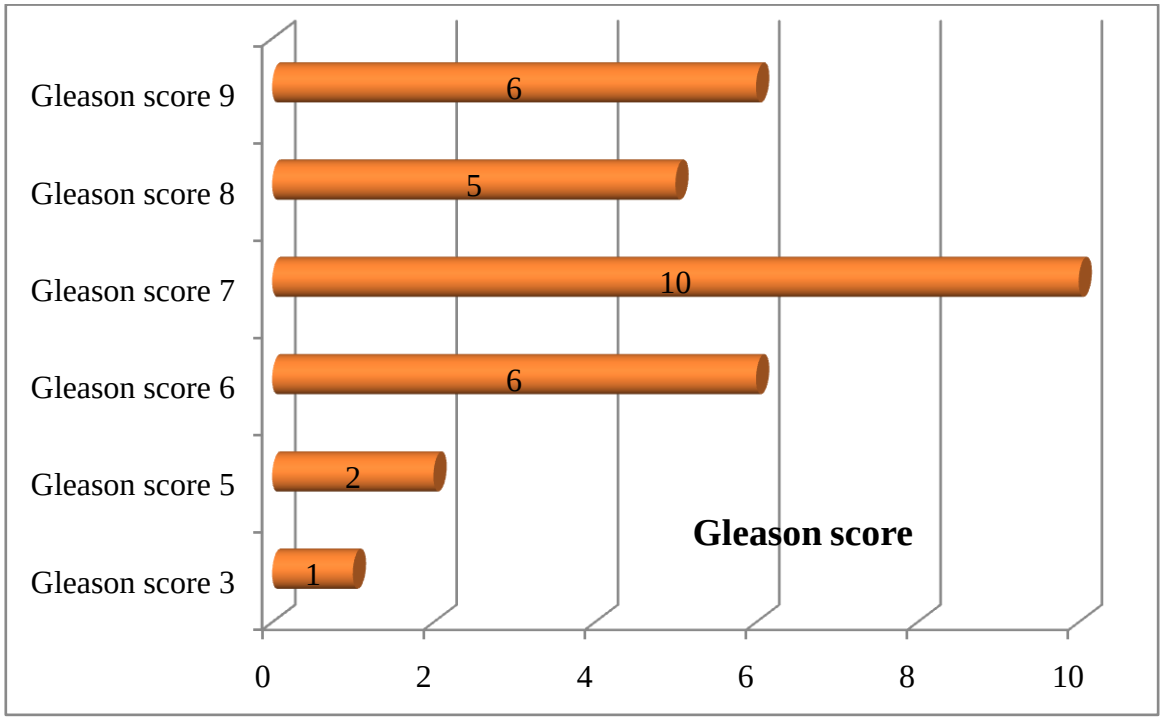


Figure 3: Bar chart showing distribution of Gleason score (N=31)

Majority of participants had Gleason score of 7 [10 out of 31 (32.3%)]. The lowest gleason score of was 3 [1 out 31 participants (3.2%)].

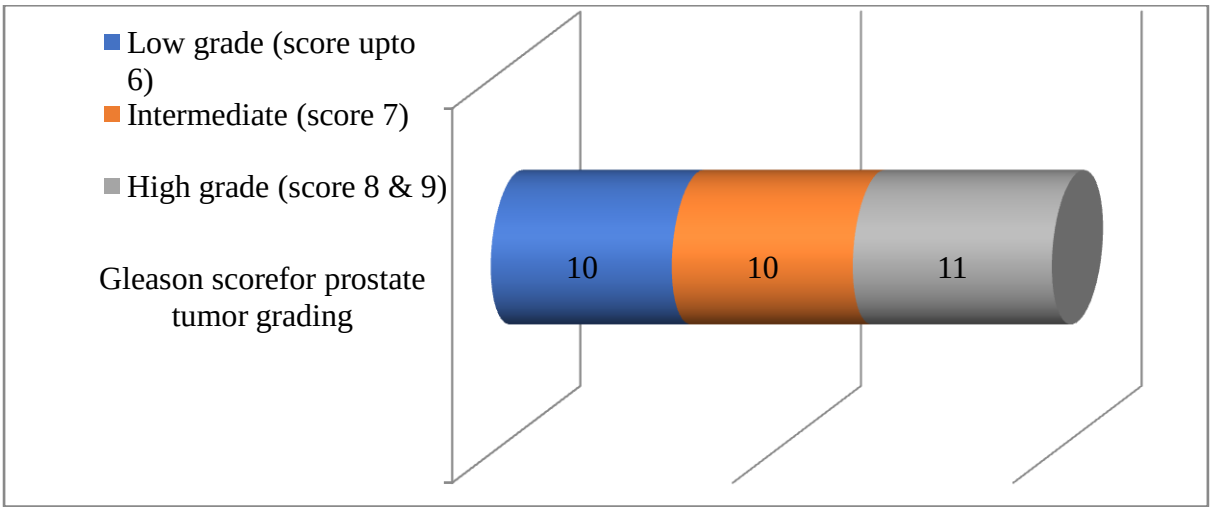


Figure 4: Grading of prostate tumor as per Gleason score (N=31)

The above figure depicts that the high-grade tumor was slightly higher in number (11 out of 31 participants) while low and intermediate grades were 10 each in number among the participants.

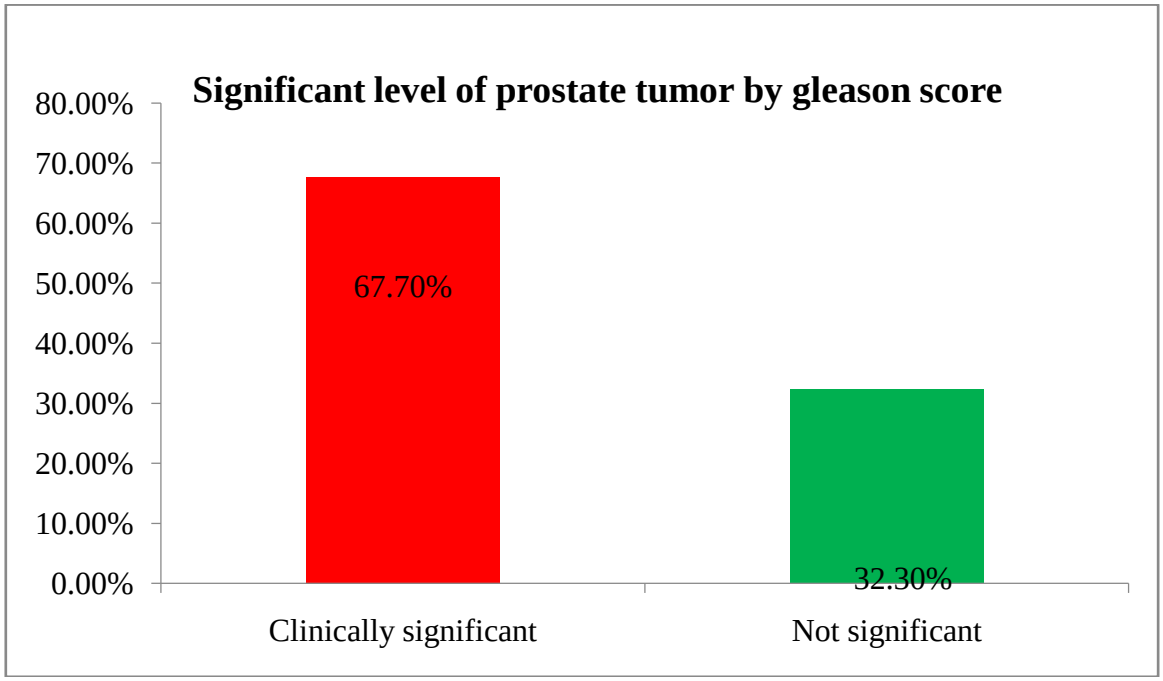


Figure 5: Bar chart showing tumor significant by Gleason score (N=31)

Above figure shows that 67.7 % (21 out of 31) of participants had clinically significant tumor (Gleason score ≥7) and 32.3% (10 out of 31) of the participants had clinically insignificant prostate tumor (Gleason score <7). The mean apparent diffusion coefficient (ADC) value was 942.54 ± 148.42 s mm^{-2} and ranges from 654 to1164 s mm^{-2}.

Table 1: Summary of sensitivity, specificity, positive predictive value, negative predictive value for PI-RADS score Vs Gleason's sum score.

Sensitivity (%)	Specificity (%)	positive predictive value (PPV) %	negative predictive value (NPV) %
95.2%	50%	80%	83.3%

Above table depicts the diagnostic accuracy of PI-RADS score when compared with Gleason's sum score for diagnosing PCa.

Table 2: Relationship between Pi-RADS score and Gleason score (N=31)

PiRADS Category		Gleason score	
		Clinically not significant	Clinically Significant
Less Significant	Count	5	1
	% within Gleason score	50.0%	4.8%
Significant clinically	Count	7	21
	% within Gleason score	50.0%	95.2%

Table 2 shows association between Gleason score and PI-RADS score where both significant clinically are found to be in 95.2% of the cases.

Table 3: Correlation between Pi-RADS score and Gleason Score

Correlations		Pi-RADS Score	Gleason Score
Pi-RADS Score	Pearson Correlation	1	0.720**
	Sig. (2-tailed)		0.000
	N	31	31
Gleason Score	Pearson Correlation	0.720**	1
	Sig. (2-tailed)	0.000	
	N	31	31
**. Correlation is significant at the 0.01 level (2-tailed).			

Table 3 depicts that there is strong correlation where one unit change in PI-RADS score there will be change or increase of 0.720 of Gleason score and this finding is statistically significant with a p value of 0.000.

Table 4: Relationship between Pi-RADS score and ADC value

Pi-RADS Category	ADC value for Prostate Ca	
	Benign lesion	Malignant lesion
Less Significant	0	6
	0.0%	100.0%
	0.0%	46.2%
Significant clinically	18	7
	72.0%	28.0%
	100.0%	53.8%

Table 5: Correlation between Pi-RADS score and ADC value

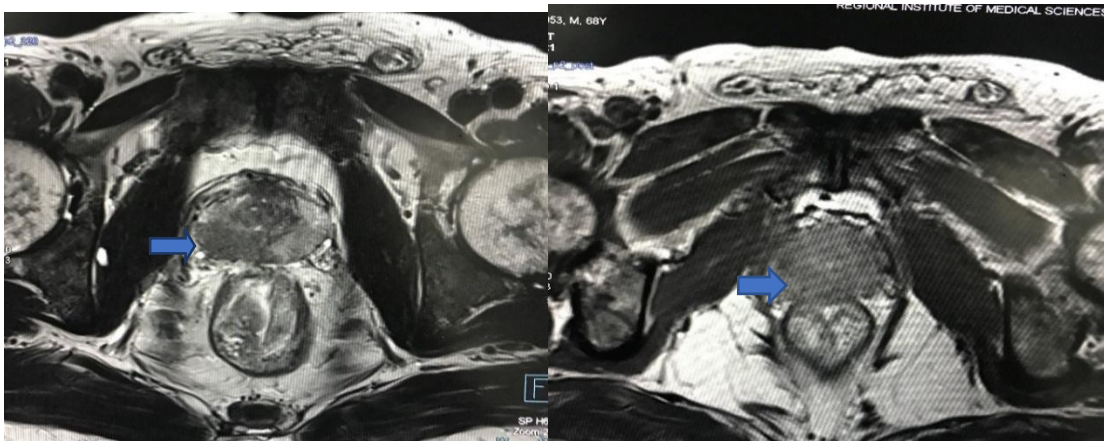
Correlation		Pi-RADS Score	ADC value in sq mm/sec
Pi-RADS Score	Pearson Correlation	1	-.604**
	Sig. (2-tailed)		.000
	N	31	31
ADC value in sq mm/sec	Pearson Correlation	-.604**	1
	Sig. (2-tailed)	.000	
	N	31	31
**. Correlation is significant at the 0.01 level (2-tailed).			

Table 5 depicts that there is negative correlation where one unit change in PI-RADS score there will be change or decrease of 0.604 of ADC value and this finding is statistically significant with a p value of 0.000.

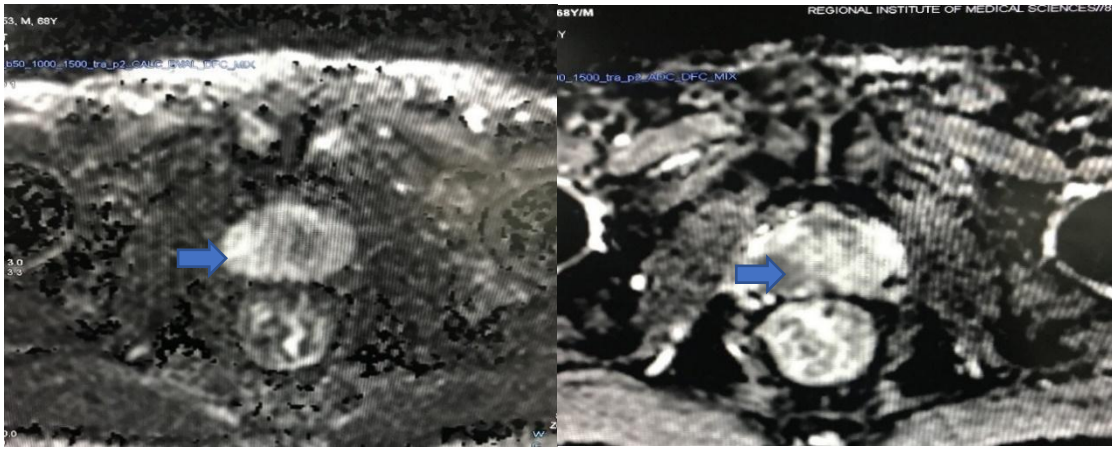
Table 6: Correlation between Gleason score and ADC value

Correlation		ADC value in sq mm/sec	Gleason Score
ADC value in sq mm/sec	Pearson Correlation	1	-.638**
	Sig. (2-tailed)		0.000
	N	31	31
Gleason Score	Pearson Correlation	-.638**	1
	Sig. (2-tailed)	0.000	
	N	31	31
**. Correlation is significant at the 0.01 level (2-tailed).			

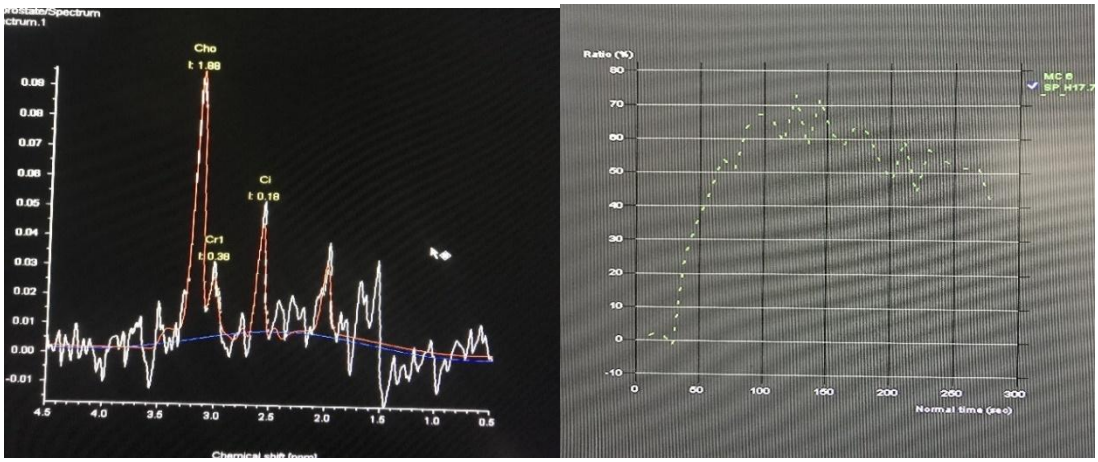
Table 6 depicts that there is negative correlation where one unit change in ADC values, there will be change or decrease of 0.638 of Gleason score and this finding is statistically significant with a p value of 0.000.



A B



C D



E F

A: T2 weighted image showing a homogenous, moderately hypointense lesion in mid right posterolateral and posteromedial peripheral zone measuring less than 1.5 cm in greatest diameter, B:T1 weighted post contrast image showing enhancing lesion, C: Diffusion weighted image showing markedly hyperintense lesion on high b-value ,D: ADC weighted image showing focal markedly hypointense lesion(Mean ADC value 854 s mm^{-2}), E:MR spectroscopy image showing increased choline/creatine peak and decreased citrate peak , and F: Time intensity curve showing type 3 curve.

IV. DISCUSSION

The results were similar to data from published research trials and support the proposed patient benefits of the use of mpMRI in initial investigations as more csPCa was detected in patients assigned PI-RADS 4 and 5.[14,15,16] Zhen et al[15]reported the sensitivity and specificity for mpMRI at 0.87 [95%CI, 0.81–0.91] and 0.68 [95%CI,0.56–0.79], respectively. The present study shows diagnostic accuracy with sensitivity 95.2% and specificity 50% when PI-RADS score and Gleason score were taken into consideration. Hauth E et al[16] demonstrated that Sensitivity of mpMRI in patients was 97.7% and specificity was 11.8%.The association between Gleason score and PI-RADS score where both were significant clinically are seen in 21 out of 31 (67.7%) of the cases. This finding is similar to previous literatures. As per Otti VC et al[17]overall detection rate of csPCa in 67.7 of cases is in keeping with the published literature in routine clinical settings which is similar to the present findings. The higher the PI-RADS score, the more clinically significant the PCa detected through histology.Dominguez C[18]studiedon patients with clinically localized PCa and found that Sensitivity, specificity, accuracy, positive predictive value (PPV), and negative predictive value (NPV) of mp-MRI for ECE were 54.9%, 90.9%, 76%, 81% and 74.1% respectively which is incorporated with the present finding. Sonn et al[19] also detected cancer in 34% (36/105) of patients using MRI-TRUS fusion following initial negative biopsy, with 72% of these being clinically significant. The positive predictive value of mp-MRI for highly suspicious lesions (PI-RAD scores of 4 and 5) was 50% (24/48 patients). The present study supports these findings.

V. CONCLUSION

The mean serum PSA level was 10.80 ng/dl ± 5.11 ng/dl. The Pi-RADS Score 2, 3, 4 & 5 were categorized as low (9.7%), intermediate (9.7%), high (41.9%) and very high (38.7%) respectively. The Pi-RADS score of 2 and 3 were levelled as less significant clinically (19.4%) and score of 4 & 5 were levelled as clinically significant which is 80.6%. 32.3% participants had Gleason score of 7. The lowest Gleason score of was 3 (3.2%). High-grade tumor was seen in 11 out of 31 participants (35.4%), intermediate in 10 out of 31 participants (32.2%) and low grade in 10 out of 31 participants (32.2%). The Gleason score of ≥ 7 (clinically significant) was seen in 21 out of 31 participants (67.7%). The mean apparent diffusion coefficient (ADC) value was 942.54 ± 148.42 s mm^{-2}. 58.1% (18 out 31 participants) participants have malignant lesion as predicted by high ADC value < 1000 s mm^{-2} and 41.9% (13 out of 31) have benign lesions.

Multi-parametric MRI PIRADS scoring in patients with raised PSA levels is an invaluable, non-invasive and feasible option to detect carcinoma prostate with a high sensitivity and specificity besides high predictive values and can help in identifying patients in need of biopsy and also helps in targeted biopsy and characterizing the extent and aggressiveness of the prostate cancer.

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