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ORIGINAL ARTICLE

Assessment of the accuracy of multi-parametric MRI with PI-RADS 2.0 scoring system in the discrimination of suspicious prostatic focal lesions

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KEYWORDS

Mp-MRI prostate;
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Abstract *Objectives:* Assessing the value of Mp-MRI with PI-RAD2.0 in distinguishing between malignant and benign prostatic lesions.
Patients & methods: 55 patients with suspicious prostatic lesions underwent PR examination, PSA tests, TRU/S, and Mp-MRI prostate. Mean age was 62 years and imaging data were correlated with histopathological data.
Results: Histopathology results revealed 38 malignant lesions and 17 were benign. DWI showed significant restriction with low ADC value, 0.89 ± 0.24 μm^2/ms in 30 PZ lesions that diagnosed to be likely malignant, (3–5 score) and 7 benign lesions showed no diffusion abnormality with ADC values, 1.34 ± 0.21 μm^2/ms which were statistically significantly higher than those of malignant lesions ($P < 0.001$). Of the 18 TZ lesions, T2 WI diagnosed 7 to be likely malignant (score 3–5) and 11 were benign (1–2 score). DCE-MRI revealed positive results in 28 PZ and 8 TZ lesions. Adding DCE-MRI to DWI and T2WI score in equivocal lesions raises its score from 3 to 4 in 6/9 lesions that aid in malignant lesions diagnosis. Negative enhancement was noted in 9 PZ and 10 TZ benign lesions (−ve).
Conclusion: Multi-parametric MRI with PI-RAD V2 scoring system was proved to be non invasive and accurate tool for distinguishing between malignant and benign prostatic lesions.

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1. Introduction

Prostate cancer is the 3rd leading cause of death and is the most common genitourinary malignancy in men (1). Advances in MRI show promise for improved detection and characterization of prostate cancer, using a multiparametric approach, which combines anatomical and functional data (2). The multiparametric (Mp-MRI) approach using three different techniques, T2-weighted (T2W) MRI, diffusion-weighted imaging (DWI), and dynamic contrast-enhanced MRI (DCE-MRI)) can improve the diagnostic accuracy (3). 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 Prostate Imaging Reporting and Data System (PI-RADS) in February 2012 (4). The Major goals of PI-RADS are to allow comparison of inter-observer interpretation variability; to enhance communication with clinicians in a uniform way; to facilitate quality assurance and research; and to improve patient outcome (5). The PI-RADS scoring committee of the American College of Radiology (ACR) and the European Society of Urogenital Radiology (ESUR) prostate MRI working group have diligently developed a revised version called PIRADS 2.0 which was made public in early 2015. PI-RADS 2.0 provides extensive information on how to acquire, interpret, and report Mp-MRI of the prostate (6). The specific aims of PI-RADS 2.0 were to establish guidelines for minimum acceptable technical parameters for prostate Mp-MRI, to simplify and standardize the terminology and content of Mp-MRI reports, and to develop assessment categories that summarize the levels of suspicion or risk of having significant prostatic cancer. PI-RADS 2.0 is intended to be a "living" document that evolves as clinical experience and scientific validation data accrue (7).

This study aimed to assess the value of Mp-MRI with PI-RAD 2.0 scoring system in differentiation between malignant and benign prostatic lesions.

1.1. Patients and methods

During the period from May 2014 to October 2015, 55 patients referred to radiodiagnosis department from urology Department and their ages ranged between 51 and 79 years (Mean = ±62 years). The patient's clinical diagnosis was suspicious prostatic nodule that felt during digital rectal examination. All patients underwent, PR examination, PSA tests, MRI examination of the prostate with PI-RAD 2.0 scoring system and TRU/S examination with biopsy. Written informed consent was obtained from each patient and this work was approved by local research ethics committee of our hospitals.

Table 1 Analysis of the final diagnosis of the 55 patients according to the histopathologic results.

Histopathology	No of lesions	Percentage (%)
Adenocarcinoma	38	69.1
Benign prostate hypertrophy	11	20
Focal adenoma	4	7.2
Prostatitis	2	3.6
Total	55	100

1.2. Exclusion criteria

Twelve patients were excluded from this study: – Five patients had contraindications for MRI examination and contrast-medium injections (3 with renal impairment, 1 claustrophobic and 1 with cardiac pacemakers). Two patients rejected MR examination and 3 refused to undergo the biopsy, also 2 patients with previous prostatic surgery were excluded from this work.

1.3. MRI techniques

MRI examinations were done on 1.5 Tesla MRI (Gyroscan, Philips, Netherland) unit with body coil coupled to endorectal coil in the supine position, and the protocol 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-Diethy lenetriaminepenta-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 were 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/mm^2 gradients. (TR, 1570 ms; TE, 75, FOV 160 mm and slice thickness 3 mm); the region of interests (ROI), was placed on lesion to measure ADC values. ADC maps obtained from DW images at b0, b500 and b1000 s/mm^2 gradients.

Lesions were assessed by using ESUR/PI-RADS criteria for DWI, T2WI, DCE-MRI, and by using the sum of these scores. Zonal dominant parameters corresponding to the score of

Table 2 Gleason score at biopsy for 38 malignant lesions.

Tumor Gleason score at biopsy*	No. of lesions (%)
6	13 (34.2%)
7	12 (31.5%)
8	8 (21%)
9	3 (7.8%)
10	2 (5.2%)

* TRUS Biopsy.

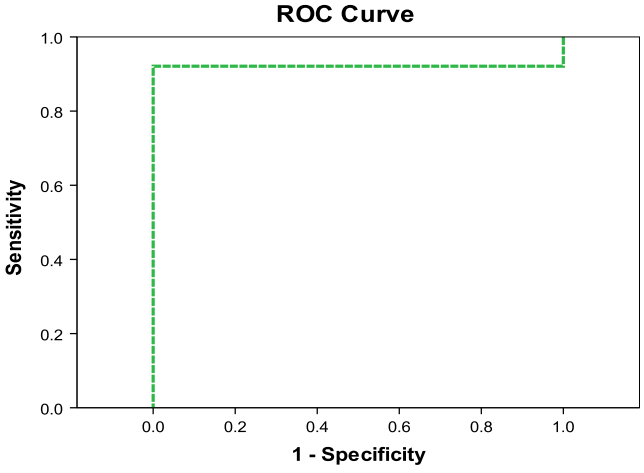

Fig. 1 ROC curve for the sensitivity and specificity of Mp-MRI with PI-RAD2.0 scoring system.

Table 3 DWI with ADC values in 37 PZ lesions and T2WI in 18TZ lesions with DCEMRI findings and PI-RAD2 scoring system.

PI-RAD score	DW PZ finding	No & %	T2 TZ finding	No & %
1	No abnormality	4 (10,8)	No abnormality	6 (33.3)
2	Indistinct area on ADC map	3 (8.1)	Well defined hypo-intense/heterogonous	5 (27.7)
3	Moderate diffusion restriction	6 (16.3)	Heterogonous with obscured margin	3 (16.7)
4	Marked diffusion restriction	16 (43.2)	Non circumscribed hypo-heterogeneous	1 (5.6)
5	> 1.5 cm with marked RD or invasive behavior	8 (21.6)	> 1.5 cm non circumscribed or invasive behavior	3 (16.7)
ADC	Malignant	(0.89 ± 0.24 μm^2/m 30 (81)		30 (81)
P < 0.001	Benign	(1.34 ± 0.21 μm^2/ms)		7 (19)
DCEMRI				
Positive	Malignant	28 PZ	8 TZ	65.5%
Negative	Benign	9 PZ	10	34.5%

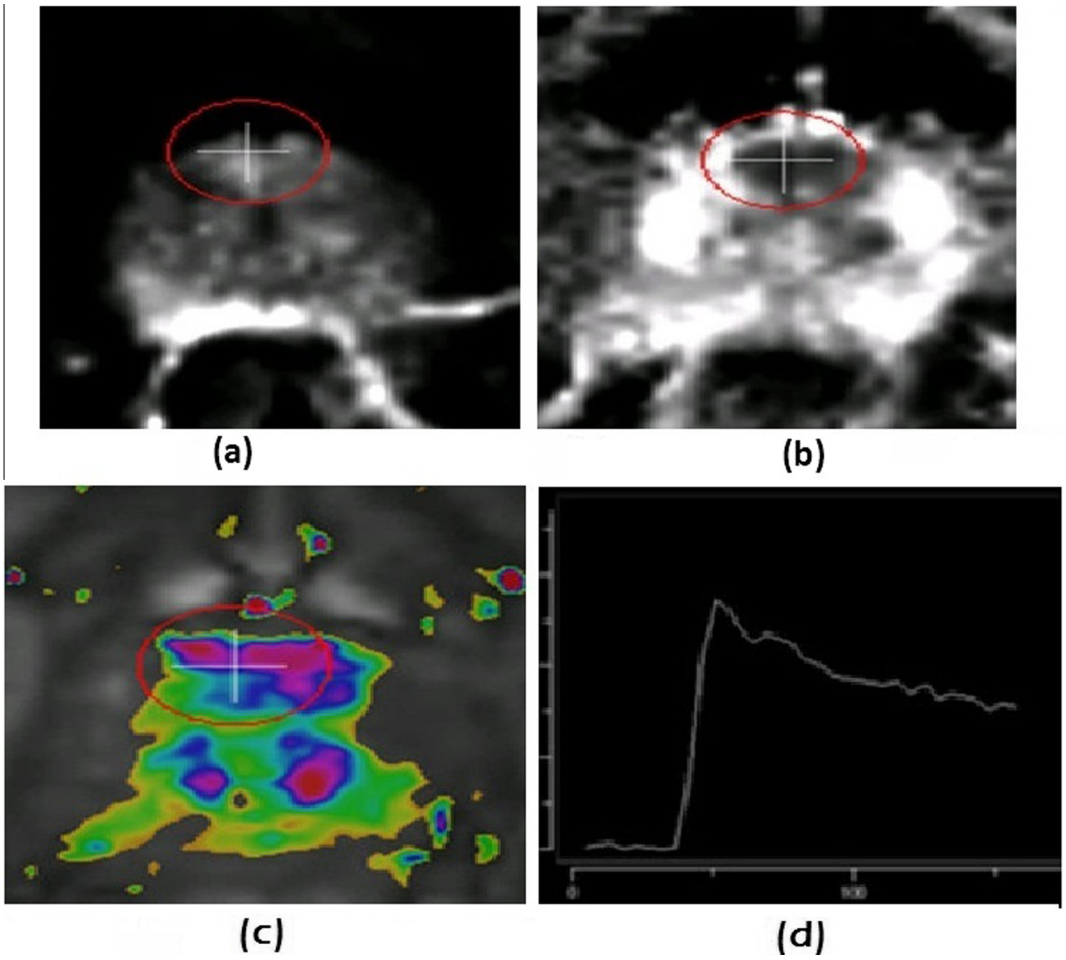

Fig. 2 62yrs old patient, with felt P/R hard suspicious prostate nodule, (a and b) DWI and ADC map revealed nodular lesion at the anterior aspect of PZ with significant diffusion restitution, ADC value measuring "0.8763", (c and d) DCE-MRI revealed moderate enhancement with type III enhancement curve). PI-RADS 2.0, score = 4. All MP-MRI findings are collectively diagnostic of Malignant lesion. Histo-pathology: Adeno-Ca. *(Gleason score 8)*.

DWI for PZ lesions and to T2WI for TZ lesions were calculated. PI-RAD V2 classification was used to define the total summation of the different Mp-MRI findings (DWI, T2, CDE) for differentiation between malignant and benign prostatic lesions (8).

1.4. Lesion assessment

All the lesions were evaluated by two radiologists; all patients underwent TR U/S biopsy from the detected MRI focal lesion, shortly after the MRI examination (at a period ranging from

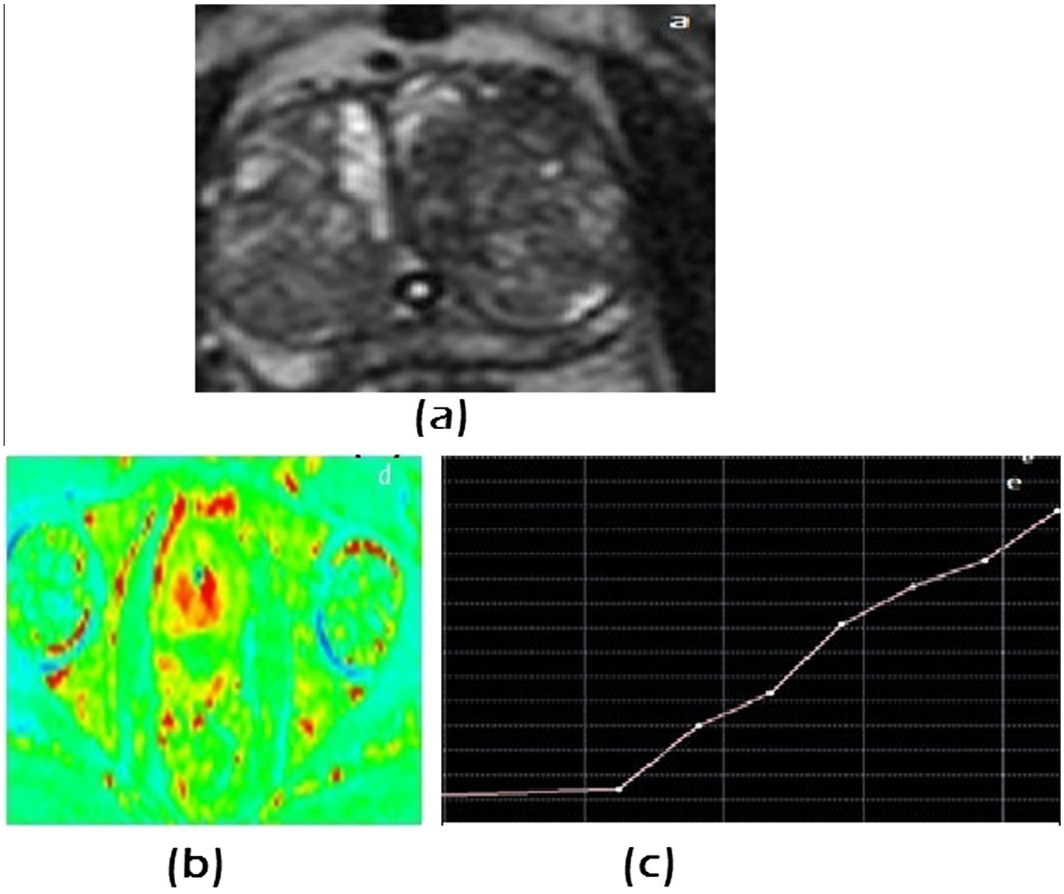

Fig. 3 73 yrs old patient, C/O: enlarged prostate with suspicious nodular gland felt by P/R (a) T2WI, showed non-homogenous texture with no definite well defined focal lesion, (b and c) DCE-MRI revealed gradual enhancement with persistent rising type I enhancement curve. All MP-MRI findings are diagnostic of Benign prostatic lesion: PI-RADS 2.0 score = 1, Histo-pathology: Benign prostate hypertrophy, no malignancy.

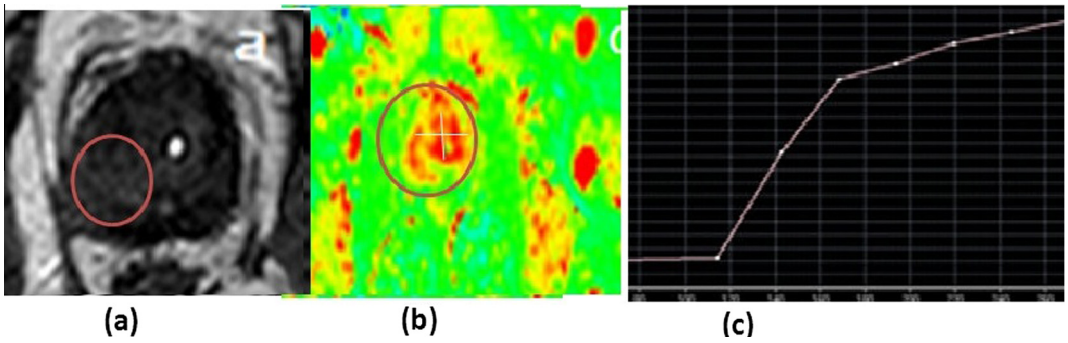

Fig. 4 57 yrs old patient, with hard suspicious Rt. prostatic nodule felt by at P/R examination. (a) T2WI, showed a non-homogenous poorly defined focal area at the Rt. sided TZ lesion (red circle). (b and c) DCE-MRI revealed early enhancement with type II enhancement curve. PI-RADS 2.0, score = 4 All MP-MRI findings are collectively diagnostic of Malignant lesion, Histo-pathology: Adeno-Ca. *(Gleason score 7)*.

few days to a maximum 2 weeks). All sequences were reviewed during a single session. The prostate was divided into 18 regions for purposes of review, 12 in the PZ and 6 in the TZ. First, the readers assigned a PI-RADS 2.0 score to each region. Briefly, this system entails assignment of a separate score from 1 to 5 to each region for each of the DW imaging, T2-weighted imaging, and DCE MRI sequences. For DCE MR images, a binary scale was used (0 = no focal early enhancement; 1 = presence of early focal enhancement). In addition, the overall score consisted of the score for the dominant sequence

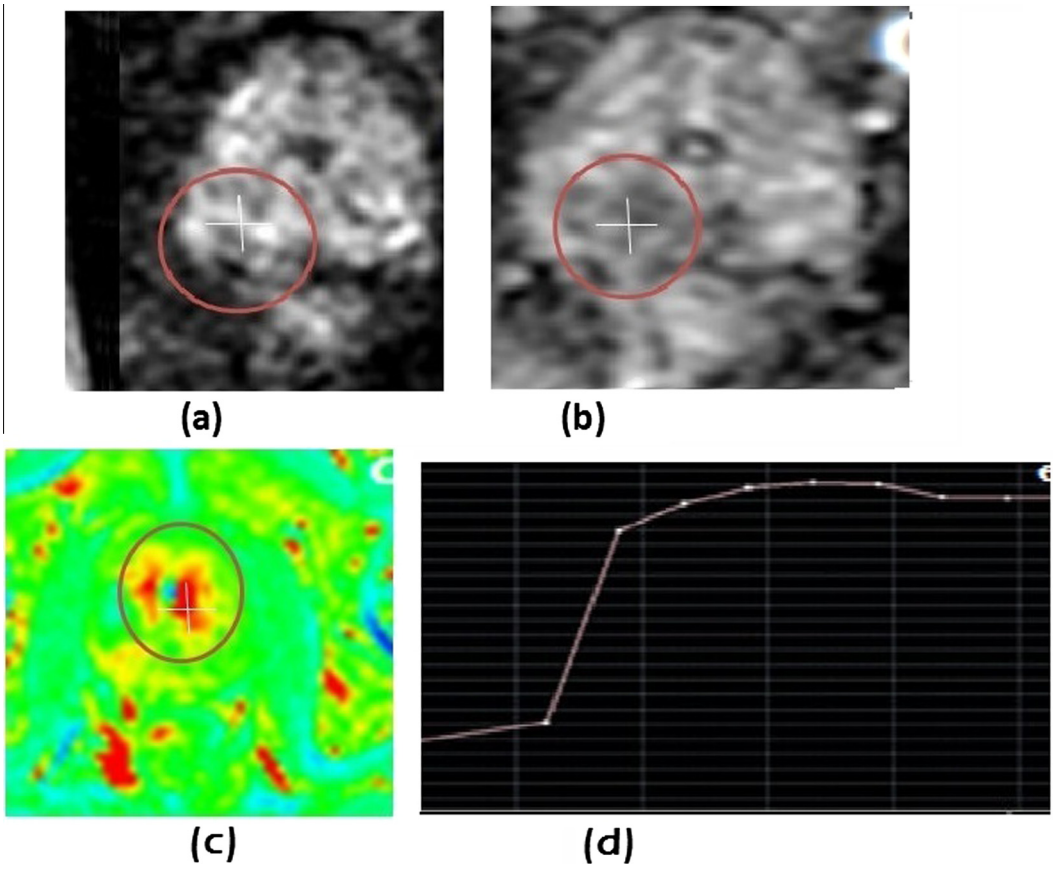

Fig. 5 71 yrs old patient, with hard suspicious Rt. prostatic nodule felt by P/R (a and b) DWI and ADC map revealed moderate diffusion restriction at Rt. side peripheral zone lesion (red circle), ADC value "0.958.93", (c and d) DCE-MRI revealed mild enhancement with type II enhancement curve. PI-RADS 2.0 score = 3. All MP-MRI findings are collectively diagnostic of mostly Malignant lesion. Histo-pathology: Adeno-Ca. *(Gleason score* 8*)*.

(DWI for PZ lesions and T2-weighted for TZ lesions) plus one point added to the overall score for DCE MR imaging results that were positive for cancer, but only if the addition of the one point converted the PI-RADS 2.0 score from 3 to 4 (8).

1.5. Histopathologic examination

The prostatic biopsy was fixed in 4% buffered formaldehyde for approximately 48 h and was handled according to local clinical histopathologic routines for diagnostic purposes. A pathologist with more than 13 years of experience who was blinded to the imaging results examined the hematoxylin-eosin and saffron–stained slides, outlined cancer foci and described cancer location, and determined the cancer grade according to the Gleason grading system; Higher grade prostate cancer was defined as lesions showing a primary Gleason score pattern of 4 or higher (9) (Tables 1 and 2).

1.6. Statistical analysis

Data entry and analysis were done using the program Statistical Package for the Social Sciences (SPSS). Quantitative data were presented by mean and standard deviation, while qualitative data were presented by frequency distribution. The ADC values between malignant and benign groups were compared using Mann–Whitney test. $P < 0.05$ was considered statistically significant. The sensitivity, specificity, negative and positive predictive values (PPV) were assessed. Also, the ROC curve analysis was performed.

2. Results

Out of the 55 lesions included in this study, 38 lesions proved to be malignant: 30 lesions in the PZ and 8 in the TZ (Histo-path: Adenocarcinoma), while 17 lesions proved to be benign prostatic lesions; 7 in the PZ and 10 in the TZ (Histo-path; 11 benign prostate hypertrophy, 4 adenoma and 2 prostatitis) (Tables 1 and 2).

Mp-MRI (DWI with ADC value measurements for PZ lesions (37)) followed by Post Gad dynamic MRI findings and PI-RAD2 scoring of the included prostatic suspicious lesions:-

I- **DWI:-**it showed focal moderate-marked diffusion restriction (scores 3 and 4) in 22 (6 and 16) lesions while score 5 was given to 8 lesions more than 1.5 cm or with invasive behavior; Mean ADC value was $0.89 \pm 0.24\ \mu m^2/ms$ for the lesions that proved to be malignant (see Fig. 1).

No abnormality/hypo-intense areas at ADC map were noted in 7 benign lesions. The ADC values of benign prostatic lesions were $1.34 \pm 0.21\ \mu m^2/ms$ which were statistically

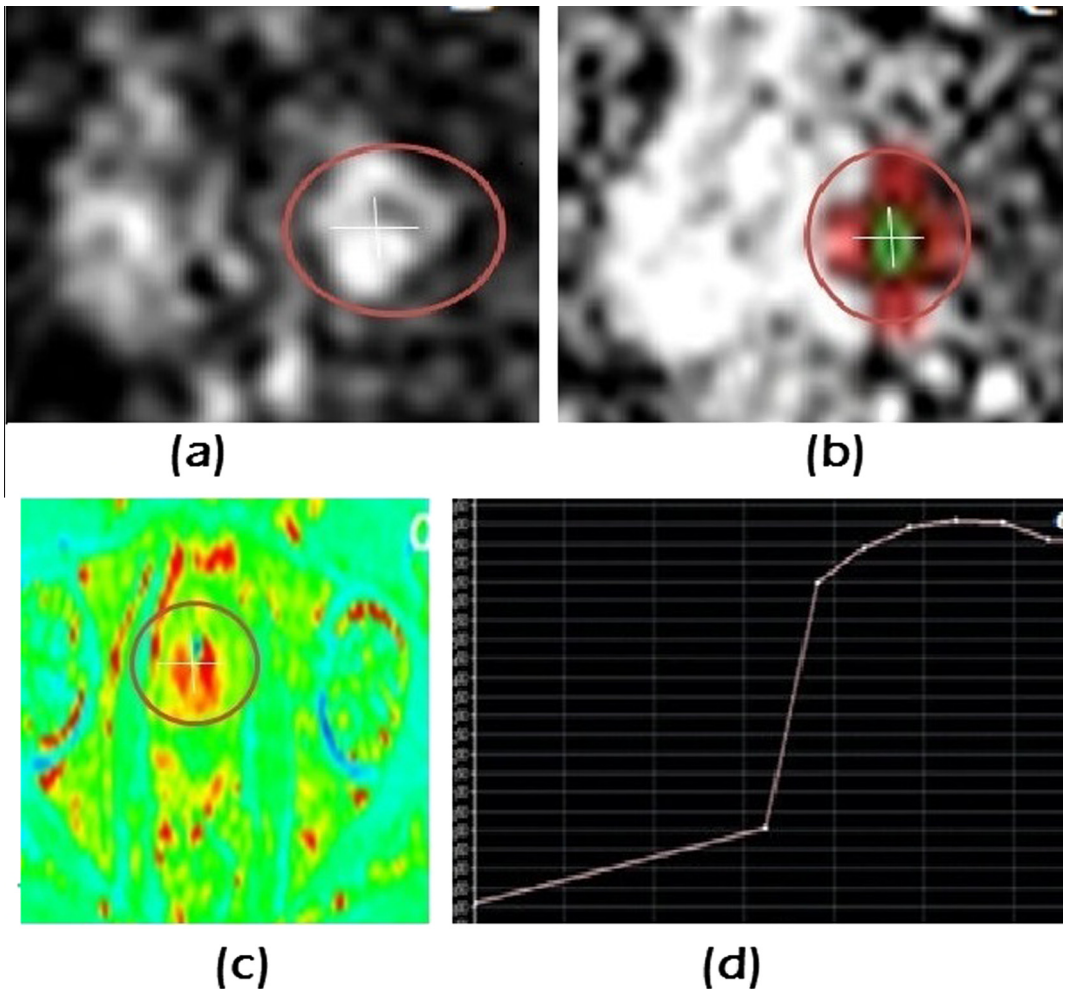

Fig. 6 66 yrs old patient with hard suspicious Lt. prostatic nodule at P/R examination. (a) DWI showed a moderate diffusion restriction of the lesion (red circle), (b) ADC map revealed, ADC value "0.641", (c and d) DCE-MRI revealed early moderate enhancement (red circle),with type II enhancement curve). The total PI-RADS 2.0 score given to this lesion, was = 4. All Mp-MRI findings are collectively diagnostic of Malignant lesion. Histo-pathology: Adeno-Ca. *(Gleason score* 8*)*.

significantly higher than those of malignant lesion ($P < 0.001$) (Table 3).

II-DCE-MRI, revealed focal enhancing lesion that showed early enhancement and early washout (+ve) in 28 lesions. Adding DCE MRI to DWI score in the 6 lesions with score 3 in lesions raises it to score 4 in 4/6 lesions that aid in the diagnosis of malignant lesions.

No enhancement/gradual rising enhancement pattern (−ve) was noted in 9 (7 benign and 2 indeterminate) lesions (Table 3, Figs. 2, 5 and 6).

Mp-MRI (T2 for TZ lesions) (10) followed by Post Gad dynamic MRI findings and PI-RAD2 scoring of the included prostatic suspicious lesions:-

I-T2WI of the TZ lesions detected 3 lesions that appeared as ill-defined heterogeneous signal intensity area (score 3) and non-circumscribed hypo-heterogeneous area (score 4) in 1 lesion while lesions > 1.5 cm or with invasive behavior diagnosed in 3 lesions.

Eleven lesions with benign score (1–2) that appeared as normal or well defined hypo-intense/heterogeneous 6/5 lesions were detected in T2 WI (Table 3).

II-DCEMRI, revealed focal enhancing lesion that showed early enhancement and early washout (+ve), in 8 lesions. Adding DCE MRI to T2WI score in score 3 in lesions raises it to score 4 in 2/3 lesions that aid in the diagnosis of malignant lesions.

No enhancement/gradual enhancement pattern (-ve) was noted in 10 lesions (Table 3, Figs. 3 and 4).

– **The total PI-RAD 2.0 score** of Mp-MRI for the 55 suspicious prostatic lesions revealed 36 malignant lesions (scores, 4–5) and 16 benign lesions (scores 1–2) while indeterminate lesions were 3 (score 3) that pathologically proved to be 2 malignant and 1 benign lesions.

Table 4 Sensitivity, specificity and accuracy of Mp-MRI with PI-RADS 2.0 in diagnosis of prostatic focal lesions.

Sensitivity	92.11%
Specificity	94.12%
+ve predictive value	97.22%
Accuracy	92.727%

– The sensitivity, specificity and accuracy of MP-MRI in diagnosis of prostatic focal lesions using new PI-RADS score were 92.11%, 94.12% and 92.7% respectively (Table 4).

3. Discussion

Prostate MR imaging provides the potential to assist clinical management of prostate cancer. Most recently, PI-RADS standardized interpretation scheme that facilitates greater clinical use of prostate MR imaging (11).

The histopathologic results were the gold slandered for this work, it revealed 38 malignant "adenocarcinoma" and 17 benign lesions and the multi-parametric MRI examination of the prostate was the selected technique for lesion evaluation. This was concealed with Schlemmer et al. and Franiel who stated that the procedure of choice for diagnosing prostate cancer is the multi-parametric MRI (12,13).

This work used Mp-MRI findings with PI-RAD score V2 to differentiate malignant from benign lesions of the prostatic. For the PZ we considered DWI to be the primary determining sequence (dominant technique), while for the TZ, T2W is the primary determining sequence. This was in agreement with Leonardo et al. who introduced the concept of a zonal dominant parameter in an attempt to incorporate to ESUR/PI-RADS criteria the performance of different techniques applied to peripheral and transitional zone lesions (14). Also, 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 sufficient for stratification of patients for further diagnostic workup (15).

For the 37 lesions located in PZ we considered DWI that categorized 6 lesions with score 3, 16 lesions with score 4 and 8 lesions were given score 5; Mean ADC value was 0.89 $\pm$ 0.24 μm^2/ms for the lesions that proved to be malignant. However, no abnormality/hypo-intense areas at ADC map were noted in 7 benign lesions. The ADC values of benign prostatic lesions were 1.34 $\pm$ 0.21 μm^2/ms which were statistically significantly higher than that of malignant lesion ($P < 0.001$).

These results were in concordance with Zelhof et al. who stated that on DWI, tumors appear hyperintense compared to background due to the restricted water diffusion (16) and with Koo et al. results that revealed significant difference between ADC values of normal prostate parenchyma and prostate cancer (17). Noha et al. concluded that the addition of the ADC map provides significantly more accurate results for prostate cancer detection and staging (18) and Meltem et al., found that Mean ADC value of prostate cancer group was significantly lower than normal group ($P = 0.001$) (10). Sato et al. found that ADC values of prostate cancer in both peripheral and transition zones were significantly lower than those of benign tissue (19).

This study yielded that T2 WI of the detected 18 lesions in the TZ, diagnosed 9 lesions to be likely malignant, 3 lesions with score 3 while 4 lesions were given score 4 and 2 lesions were given score 5. However, 9 lesions were likely benign with 1–2 score that was in agreement with Akin et al. who stated that prostate cancer typically manifests as a round or ill-defined, T2 WI low signal intensity focus in the peripheral zone (20) and with Sandeep et al. who concluded that T2W MRI is critical in suggesting the location and extent of cancer which is generally seen as low signal foci on the T2W MRI (21).

DCE-MRI, revealed enhancing focal lesion that showed positive results in 28 PZ lesions and 8 TZ lesions with curve type 2–3 (+ve). Adding DCE MRI to DWI score in equivocal PZ lesions raises it from score 3 to 4 in 4/6 lesions and to T2 score in equivocal TZ lesions raises its score from 3 to score 4 in 2/3 lesions that aid in the diagnosis of malignancy.

No enhancement/gradual rising enhancement pattern (−ve) was noted in 9 PZ lesions (7 benign and 2 indeterminate) and in 10 TZ lesions (9 benign and 1 indeterminate).

These results matched with those of Meltem et al., who found that the prostate cancers manifested with intense enhancement at arterial phase and exhibited washout at late phase on DCE MR images (10) and with Alonzi et al. and Sciarra et al. who reported that early, rapid, and strong enhancement with quick washout of contrast material is highly suggestive of prostate cancer (22,23). Hara et al. showed that DCE MRI is able to detect clinically important prostate cancer in 93% of cases (24).

The total PI-RAD score V2 of Mp-MRI for the 55 suspicious prostatic lesions revealed 36 malignant lesions (scores, 4–5) and 16 benign lesions (scores 1–2) while indeterminate lesions were 3 (score 3) that pathologically proved to be 2 malignant and 1 benign lesions.

This matched results of other studies regarding the PI-RADS classification system which suggests high reliability for Mp-MRI interpretation and its sum-score shows a strong relation to tumor incidence and malignancy in the routine setting for prostate cancer diagnosis (25,26). Sciarra et al. said that: At present, Mp-MRI is the most sensitive and specific imaging technique for localizing prostate cancer (27).

The statistical results of this study revealed that, Sensitivity, Specificity and Accuracy of MP-MRI in diagnosis of prostatic focal lesions using new PI-RAD2.0 score were, 92.11%, 94.12% and 92.7% respectively. This was in concordance with results of Daniel who found that the sum PI-RAD score is reliable for cancer detection (sensitivity 90%, specificity 62%) (28) and Alistair et al. found that 2 out of 88 men with Pi-RAD score of 1 or 2 had significant prostate cancer, giving a sensitivity of 97% and a specificity of 60% at this threshold (29) while Portalez et al. results showed that the sensitivity is 73.5%; specificity is 81.5%; and accuracy is 95.2% (26).

4. Conclusion

PI-RAD V2 scoring of the Multi-parametric MRI, including DWI with ADC measurements, T2WI added to DCE-MRI, was proved to be a sensitive, non invasive and accurate tool for characterization of prostatic focal lesions and distinguishing between malignant and benign lesions.

Conflict of interest

All authors state that no conflict of interests in the manuscript, including financial, consultant, institutional and other relationships that might lead to bias or a conflict of interest.

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