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mp-MRI of prostate gland with PI-RADS v2.1 assessment: correlation with fusion biopsy results

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ABSTRACT

Aims: The aim of our study is to evaluate the correlation of patients reported as 3, 4 and 5 according to 'prostate imaging reporting data system' (PI-RADS v2.1) on 1.5 and 3 Tesla (T) multiparametric prostate magnetic resonance imaging (mp-MRI) with fusion biopsy results and to find out the effectiveness of mp-MRI in directing to fusion biopsy.

Methods: Between 2017 and 2020, a total of 73 patients who underwent targeted fusion biopsy were retrospectively included in the study. The patients had biopsy from a total of 116 lesions reported as PI-RADS 3, 4 and 5 on the mp-MRI examinations. In our department, only one MRI device has been utilized for prostate imaging. Before June 2018, a 1.5T MRI was used; after this date, a 3T MRI has been in operation. MRI images were re-examined independently by two radiologists. Both radiologists used PI-RADS v2.1 criteria for lesion scoring, since all the images were evaluated retrospectively.

Results: When the diagnosis of significant and insignificant cancers were considered together; with MRI, observer 1's sensitivity 93.10%, specificity 58.62%, positive predictive value (PPV) 42.85% and negative predictive value (NPV) 96.22%, observer 2's sensitivity 89.65%, specificity 68,96%, PPV 49% and NPV 95.25% was calculated. When only clinically significant cancers were considered; observer 1's sensitivity 87.5%, specificity 69.11%, PPV 66.66% and NPV 88.67%, observer 2's sensitivity 83.33%, specificity 80.88%, PPV 75.47% and NPV 87.30% was calculated. In the kappa test which was performed to calculate interobserver agreement between the two observers; k=0.801 was calculated and found to be substantial agreement ($p<0.01$).

Conclusion: The high rate of malignant lesions scored as PI-RADS 4 and 5 in prostate MRI reveals that these patients should be directed to biopsy. Focus-oriented biopsy using MRI guidance increases the PPV and prevents unnecessary systemic biopsies and complications.

Keywords: Prostate cancer, PI-RADS, multiparametric MRI, fusion biopsy

INTRODUCTION

We need more accurate diagnostic methods to reduce the overdiagnosis and overtreatment of clinically insignificant prostate cancer, improve detection of clinically significant prostate cancer, and reduce the number of unnecessary biopsy procedures.[1] Multiparametric prostate magnetic resonance imaging (mp-MRI) has an important role in noninvasive imaging, localization and staging of suspicious lesions in the prostate gland.[2,3]

With widespread use of mp-MRI and its better standardization, the ability to detect and rule out clinically significant cancer has improved in recent years.[4-6] Studies have shown that MRI-targeted biopsies detect high-grade cancers at a higher rate than systematic biopsy.[7-10]

mp-MRI before biopsy or MRI-targeted biopsy is an alternative to standard transrectal ultrasonography (TRUS) guided biopsy in men with suspected prostate cancer.[11,12] mp-MRI can be used to avoid a biopsy if its results are negative and it can also be used to target abnormal areas in the prostate during biopsy.[4,13,14]

In our clinic, mp MRI is performed in all patients with suspected prostate cancer, and if a suspicious lesion is detected, transperineal fusion biopsy is performed.

The aim of our study is to evaluate the correlation of patients reported as prostate imaging reporting data system (PI-RADS v2.1) 3,4 and 5 on 1.5 and 3 tesla (T) mp-MRI with fusion

biopsy results and to find out the effectiveness of mp-MRI in directing to fusion biopsy.

METHODS

The study was conducted with the permission of TOBB-ETU Faculty of Medicine Clinical Researches Ethics Committee (Date: 26.06.2020, Decision No: KAEK-118/087). All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki. This retrospective study is approved by our institutional review board (26.06.2020/KAEK-118/087) and the requirement for informed consent from patients was waived.

Study Population

Between 2017-2020, 73 patients with high prostate-specific antigen (PSA) values, rapid PSA elevation, abnormal digital rectal exam findings, family history or benign findings from prior TRUS biopsy underwent mp-MRI and targeted biopsy at our institution.

A total of 116 lesions previously reported as PI-RADS 3, 4 and 5 on the mp-MRI examinations were biopsied. The mean age of the patients was 62.43±7.8, with a median PSA value was 10.34 ng/ml (range: 1.0-100 ng/ml), and a median prostate volume of 51.25 cm^3 (range: 20-150 cm^3).

The exclusion criteria in our study was the patients whose biopsies or mp-MRI were performed in other institutions. We also excluded patients for whom we could not perform fusion biopsy due to the inability to administer anesthesia.

mp-MRI Protocol and Image Analysis

All mp-MRI examinations included anatomic T2-weighted and T1-weighted imaging, diffusion-weighted imaging (DWI) and dynamic contrast enhanced imaging (DCE). In our department, only one MRI device has been utilized for prostate imaging. Before June 2018, a 1.5T (Symphony, Siemens, Germany) MRI was used; after this date, a 3T (Ingenia, Philips Medical Systems, Netherlands) MRI has been in operation. The difference in MRI field strengths did not create any diagnostic challenges, as the imaging protocols were optimized for both systems to ensure consistency in lesion evaluation. When the patient population was divided into 1.5T and 3T groups, the number of patients was statistically insufficient, and therefore, a comparision could not be performed. The imaging difference between 1.5T and 3T MRI did not affect the biopsy protocol. 27 patients were examined with 1.5T, 46 patients were examined with 3T. T2-weighted images were obtained on axial, sagittal and coronal planes, DWI and DCE images were obtained on the axial plane. For the 1.5T device, the "b" values for DWI were 50, 750, 1500 s/mm^2. On 3T device, DWI were obtained with "b" values 0, 1500 s/mm^2, but on 3T device ADC maps were created from 0, 200,1000 s/mm^2 b values to reduce the effect of kurtosis. For DCE imaging, all patients were injected intravenously 0.2ml/kg gadoterate meglumine (Dotarem; Guerbet, Roissy, France) with an injection rate of 3ml/s. In the 3T device, 44-channel spine coil and 32-channel phased array body coils; in 1.5T device, 32-channel spine coil and 8-channel phased array body coils were used.

DWI and axial T2 images were obtained with a 3-mm section thickness for fusion combining. Axial sections were taken without inclination for compatibility with fusion biopsy images. The temporal resolution was determined as 15s for 1.5T and 3T imaging.

MRI images were re-examined independently by two radiologists. One of the radiologists had 15 years of experience and the other had 6 years of experience in abdominal imaging. Radiologists were unaware of patients' pathology reports and only knew how many patients underwent fusion biopsy and how many lesions were biopsied. Both radiologists used PI-RADS v2.1 criteria for lesion scoring, since all the images were evaluated retrospectively. PI-RADS v2.1 scoring was performed by evaluating the localization of suspected lesions on peripheral and transitional zones and evaluating T2-weighted, DWI and DCE images.

PI-RADS scores 4 and 5 were considered as high probability for malignancy and compared with the biopsy finding diagnosed as clinically insignificant (Gleason 3+3) and clinically significant cancers (Gleason≥3+4).

Transperineal Fusion Biopsy Technique

Patients underwent a transperineal biopsy in a day surgery unit. We carried out the procedure under general anesthesia and in the lithotomy position. All patients were administered cephazolin parenterally for pre-procedural prophylaxis. Scrotum was lifted up by firm dressing after perineal cleaning for better visualization of perineum. The prostate was imaged after insertion of real-time transrectal ultrasound view which was fused with pre-procedural drawn MRI scenes by Biojet (Barum, Germany) MRI-US fusion biopsy software. A biopsy template grid fixed to a cradle was placed near the perineum. An 18G biopsy needle was directed through the biopsy grid under transrectal US probe and minimum of three pieces were taken from each suspected area and also from random areas. All patients were discharged on same day after a short follow-up. There was no serious complications noted after the procedure.

Histopathological Analysis

Hematoxylin and eosin stained slides of all biopsy materials that were suspicious for prostatic adenocarcinoma were examined microscopically. Some of biopsy slides also had immunostainings of antibodies against HMWCK and p63. Prostatic adenocarcinoma was diagnosed and graded according to Gleason score.

Statistical Analysis

If normality assumption is provided for numerical variables as descriptive statistics in our study, the mean±std. deviation; if it is not provided, the median (min-max) is given. The agreement between observer 1 and observer 2 was evaluated with kappa method. Sensitivity, specificity, negative predictive value (NPV), positive predictive value (PPV) were calculated according to the results of the observers. Type I error probability was determined as 0.05 in all analyses. All the statistical calculations of the study were done using IBM SPSS V22 program (IBM, SPSS Corp.; Armonk, NY, USA).

RESULTS

In our study, the observer 1 reported 23 lesions as PI-RADS 2, 32 lesions as PI-RADS 3, 50 lesions as PI-RADS 4, and 11 lesions as PI-RADS 5. The observer 2 reported 25 lesions as PI-

RADS 2, 41 lesions as PI-RADS 3, 38 lesions as PI-RADS 4 and 12 lesions as PI-RADS 5. A total of 48 pathologically positive lesions were diagnosed from the biopsy specimens. Pathology scores are as follows: 19 with Gleason score 3+3 (**Figure 1**); 20 with Gleason score 3+4 (**Figure 2**); 3 with Gleason score 4+3 (**Figure 3**); 2 with Gleason score 4+4; 2 with Gleason score 4+5; 1 with Gleason score 5+4; 1 with Gleason score 5+5. We reported 82 of the lesions in the peripheral zone and 34 in the transitional zone.

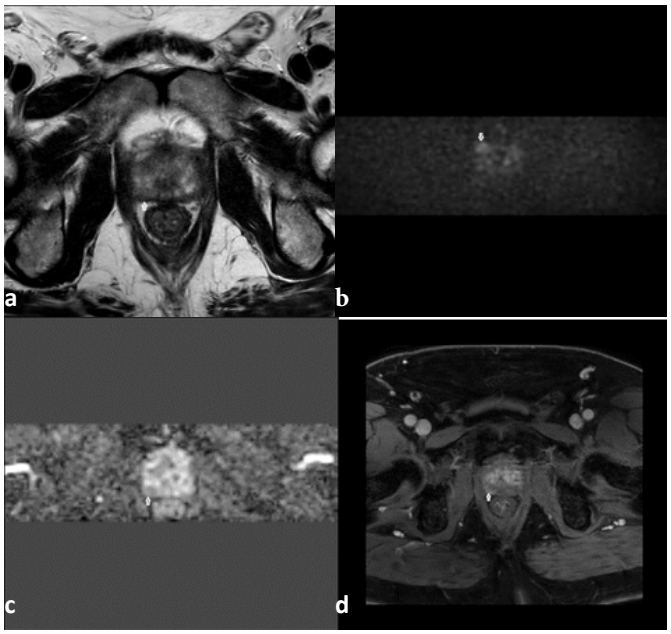

Figure 1. 55-year-old patient with PSA 6.53 ng/ml, right peripheral zone hypointense area on T2 (**a**), minimal hyperintense focal area on DWI (**b**), hypointense focal area on ADC (**c**) and there is early arterial phase contrast enhancement in dynamic contrast images (**d**) PIRADS 4 lesion. Fusion biopsy result was compatible with Gleason score 3+3

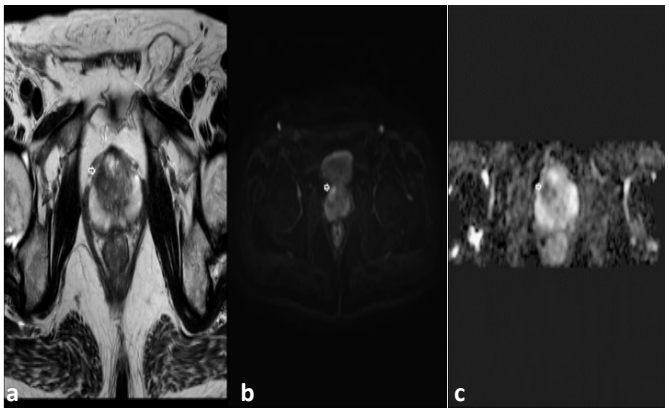

Figure 2. 68-year- old patient with PSA 6.8 ng/ml, right transitional zone hypointense area on T2 (**a**), hyperintense on DWI (**b**), hypointense on ADC (**c**) PIRADS 5 lesion. Fusion biopsy result was compatible with Gleason score 3+4

Of the lesions reported as PIRADS 3 and 4 and biopsied in the period before the PIRADS v2.1 criteria began to be used; the observer 1 reported 23 lesions and the observer 2 reported 25 lesions as PI-RADS 2 in this evaluation (**Figure 4**).

When ≥Gleason 3+3 lesions are evaluated; observer 1's sensitivity was calculated as 93.10%, specificity 58.62%, PPV 42.85% and NPV 96.22%, observer 2's sensitivity was calculated as 89.65%, specificity 68,96%, PPV 49% and NPV 95.25%. When ≥ Gleason 3+4 lesions are evaluated; observer 1's sensitivity was calculated as 87.5%, specificity 69.11%,

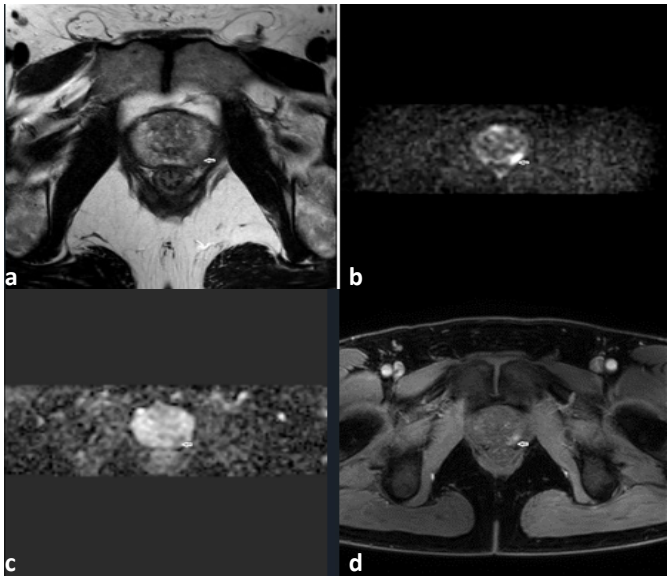

Figure 3. 55-year-old patient with PSA 5.63 ng/ml, left peripheral zone hypointense area on T2 (**a**), hyperintense on DWI (**b**), hypointense on ADC (**c**), early arterial phase contrast enhancement in dynamic contrast images (**d**) PIRADS 4 lesion. Fusion biopsy result was compatible with Gleason score 4+3

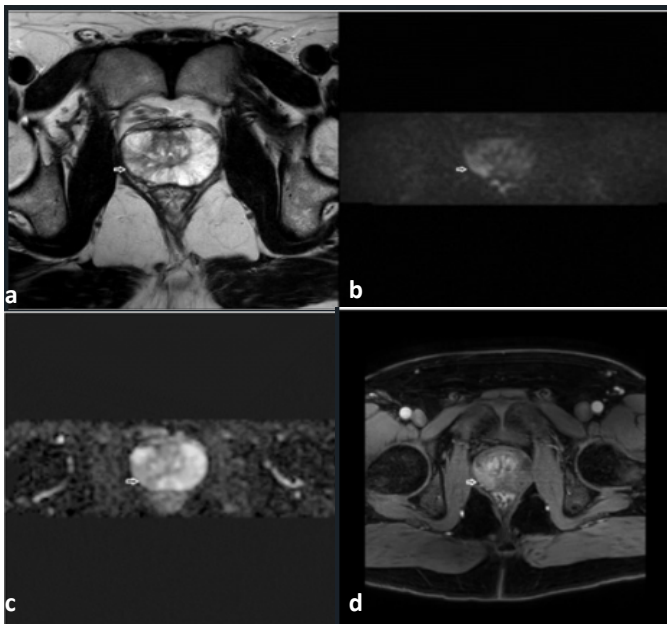

Figure 4. 52-year-old patient with PSA 9.4 ng/ml, right peripheral zone hypointense area on T2 (**a**), hyperintense on DWI (**b**), hypointense on ADC (**c**) , early arterial phase contrast enhancement in dynamic contrast images (**d**) PIRADS 2 lesion. Fusion biopsy result was compatible with prostatitis

PPV 66.66% and NPV 88.67%, observer 2's sensitivity was calculated as 83.33%, specificity 80.88%, PPV 75.47% and NPV 87.30% (**Table 1 and 2**).

In the kappa test which was performed to calculate interobserver agreement between the two observers; k=0.801 was calculated and found to be substantial agreement (p<0.01).

Table 1. Overall sensitivity, specificity, PPV, NPV for clinically significant and insignificant cancers

Clinically significant and nonsignificant	OBSERVER 1	OBSERVER 2
Sensitivity (%)	93.10	89.65
Specificity (%)	58.62	68.96
PPV (%)	42.85	49
NPV (%)	96.22	95.25

PPV: Positive predictive value, NPV: Negative predictive value

Table 2. Sensitivity, specificity, PPV, NPV for clinically significant cancer

Clinically significant	OBSERVER 1	OBSERVER 2
Sensitivity (%)	87.5	83.33
Specificity (%)	69.11	80.88
PPV (%)	66.66	75.47
NPV (%)	88.67	87.30

PPV: Positive predictive value, NPV: Negative predictive value

DISCUSSION

In our clinic, transperineal fusion biopsy is performed on all patients in order to reduce side effects of transrectal biopsy and to detect clinically significant cancers at a high rate, thus preventing unnecessary biopsy and treatment. Therefore, mp-MRI is performed in all patients with suspected cancer before making a biopsy decision.

In a randomized prospective study, Panebianco et al.[15] have shown the advantages of MRI- based diagnostic pathway over TRUS guided biopsy. They found a higher rate of clinically significant cancer in the group that underwent mp-MRI/biopsy compared to TRUS biopsy. Also found that mp-MRI is a very reliable method to identify patients to schedule in active surveillance.

Hoeks et al.[16] reported a 25% cancer detection rate in patients with at least once a negative biopsy history for increased PSA and then with mp-MRI and MRI-guided bore biopsy, and 87% of these cancers were clinically significant. The PPV of this study was 41%.

Following the first negative biopsy, Sonn et al.[17] detected cancer in 34% of patients using MRI-US fusion biopsy and the PPV of mp-MRI for only high or very high suspicious (grade 4 and 5) lesions was 50%.

Siddiqui et al.[7] found that targeted MRI/ultrasound fusion biopsy increased the detection of high-risk prostate cancer and decreased low-risk prostate cancer detection compared to standard biopsy. The sensitivity of the targeted biopsy was 77%.

In a multicenter randomized controlled study, it was shown that mp-MRI before biopsy and MRI targeted biopsy were diagnostically superior to TRUS biopsy.[11] In a cochrane systemic review and meta-analysis, it was concluded that the MRI pathway is a more useful diagnostic test than systemic biopsy in men with clinically significant cancer suspicion. Therefore, any pre-biopsy mp-MRI examination should be included in the diagnostic study.[12]

Unlike these studies, systemic biopsy comparison was not performed in our study. In our institution, we use the fusion biopsy method in order to reduce complications, provide more accurate diagnosis and make it more comfortable for the patient. Our aim was to investigate the efficacy of mp-MRI in directing fusion biopsy for the detection of cancer. Compared to other studies, sensitivity and specificity yielded similar value ranges, but PPV of mp-MRI was higher than other studies. The difference of our study from these studies is to perform mp-MRI to all patients before biopsy and take it from the suspicious lesion directly by transperineal fusion biopsy. We think that this approach increased our PPV.

4 lesions Gleason 3+3, 1 lesion Gleason 3+4, was reported as PI-RADS 3 by observer 1, 5 lesions Gleason 3+3, 2 lesions Gleason 3+4, 1 lesion Gleason 4+3 was reported as PI-RADS 3 by observer 2. We thought that the reason why observer 2 reported more clinical significant cancers in lesions reported as PI-RADS 3 compared to observer 1 was due to observer 2 had less experience in reporting mp-MRI compared to observer 1. From these results, we think that PI-RADS 3 lesions reported by radiologists experienced in mp-MRI can be followed-up without biopsy.

In most of the other studies, only clinically significant cancers were included in the study. In our study, we evaluated both clinically significant and clinically insignificant cancers together and only clinically significant cancers. The reason we evaluated the two separately is because Gleason score 3+3 patients all require close follow-up and some of these patients who do not want to be followed for a long time are included in the treatment protocol. These patients are good candidates for targeted therapy before the lesion's dimensions are increased. That's why we think that these patients should also be diagnosed and followed accordingly. In the evaluation made, our PPV and specificity increase and our NPV and sensitivity decrease when only clinical significant cancers are included. However, we need a higher number of patients to understand the reason for this.

Active and chronic prostatitis and atypical small acinar proliferation (ASAP) are the main causes of false positive findings in our patients. In one of our patients, first MRI examination was evaluated as acute prostatitis but follow-up MRI showed localized more rounded T2 hypointense area with positive DWI findings and then the patient was directed to fusion-biopsy.

A good inter-observer agreement of MRI findings was found for cancer-positive lesions proven at biopsy. The reason for the high inter-observer agreement is that we used the standardized v2.1 criteria in the evaluation.

Limitations

Our trial has limitations. The most important limitation of our study is the small number of patients. Second, we can't compare our results with standard biopsy since only transperineal fusion biopsy was performed in our clinic.

CONCLUSION

In conclusion the high rate of malignant lesions scored as PI-RADS 4 and 5 in prostate MRI reveals that these patients should be directed to biopsy. Focus-oriented biopsy with US-MRI fusion biopsy techniques increases the PPV and prevents unnecessary systemic biopsies and complications. When appropriate sequences were used in 1,5T and 3T prostate mp-MRI, the detection rate of non-malignant lesions was also high. In this way, complications that may occur secondary to the patients' exposure to unnecessary invasive procedures are prevented.

ETHICAL DECLARATIONS

Ethics Committee Approval

The study was conducted with the permission of TOBB-ETU Faculty of Medicine Clinical Researches Ethic Committee (Date: 26.06.2020, Decision No: KAEK-118/087).

Informed Consent

Because the study was designed retrospectively, no written informed consent form was obtained from patients.

Referee Evaluation Process

Externally peer-reviewed.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Financial Disclosure

The authors declared that this study has received no financial support.

Author Contributions

All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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