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ORIGINAL ARTICLE

Comparison of Diagnostic Performance of PI-RADS V2 and V2.1 and Interobserver Agreement in Both Versions

PI-RADS V2 ve V2.1'in Tanısal Performansının ve Her İki Sürümdeki Gözlemciler Arası Uyumun Karşılaştırılması

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ABSTRACT

Objective: To compare the diagnostic performance for the detection of clinically significant prostate cancers and interobserver agreement between PI-RADS v2 and v2.1
Material and Method: The mpMRI images of 258 patients and 394 nodüles included in this retrospective study were obtained on 3T MR and evaluated by two radiologists according to PI-RADS v2 and v2.1. Sensitivity and specificity between v2 and v2.1 were compared. Detection rates for clinically significant prostate cancers were evaluated. Interobserver agreement was evaluated using κ statistics.
Results: PI-RADS v2.1 and v2 had higher sensitivity and lower specificity (100%, 52.38%) in the peripheral zone, and showed higher sensitivity and specificity (92.86%, 98.79%) in the transition zone for category ≥4 lesions to estimate csPCa, but no remarkable difference was found between the two versions. Interobserver agreement was statistically significant and very weak in the transition zone (κ=0.383, κ=0.279, respectively), very strong in the peripheral zone (κ=0.869) according to both classifications and they were similar.
Conclusion: The diagnostic performance of PI-RADS v2 and v2.1 were found similar in the determination of clinically significant cancers and all cancers in both zones. The clinically significant cancer detection rate in category 2+1 lesions in the transition zone was higher than in category 2 lesions but it was not statistically significant. Interobserver agreement was low in the transition zone and very strong in the peripheral zone in both versions.

Keywords: PI-RADS V2.1, clinically significant prostate cancer, interobserver agreement

ÖZ

Amaç: PI-RADS v2 ile v2.1 'nin klinik olarak anlamlı prostat kanserlerinin saptanmasına yönelik tanısal performansı ve gözlemciler arası uyumunu karşılaştırmak.
Gereç ve Yöntem: Bu retrospektif çalışmaya dahil edilen 258 hasta ve 394 nodülün mpMRI görüntüleri 3T MR'da elde edilmiş ve iki radyolog tarafından PI-RADS v2 ve v2.1'e göre değerlendirildi. V2 ve v2.1 arasındaki duyarlılık ve özgüllük karşılaştırıldı. V2'den v2.1'in kullanımında yükseltilmiş ve indirgenmiş lezyonlarda klinik olarak anlamlı prostat kanserlerinin tespit oranları değerlendirildi. Gözlemciler arası uyum κ istatistikleri kullanılarak değerlendirildi.
Bulgular: PI-RADS v2.1 ve v2, csPCA tespitinde kategori ≥4 lezyonlar için periferik zonda yüksek duyarlılık ve düşük özgüllük (%100, %52,38) ve transizyonel zonda yüksek duyarlılık ve özgüllük (%92,86, %98,79) gösterdi, iki versiyon arasında anlamlı bir fark bulunamadı. Her iki sınıflandırmaya göre de gözlemciler arası uyum istatistiksel olarak anlamlı ve transizyonel zonda çok zayıf (sırasıyla κ=0,383, κ=0,279), periferik zonda çok güçlü (κ=0,869) ve benzerdi.
Sonuç: PI-RADS v2 ve v2.1'in tanısal performansı, klinik olarak anlamlı kanserlerin ve her iki bölgedeki tüm kanserlerin tespitinde benzer bulundu. Geçiş bölgesindeki kategori 2+1 lezyonlarda klinik olarak anlamlı kanser tespit oranı, kategori 2 lezyonlara göre daha yüksekti ancak istatistiksel olarak anlamlı değildi. Her iki versiyonda da gözlemciler arası uyum transizyonel zonda düşük, periferik zonda ise çok güçlüydü.

Anahtar Kelimeler: PI-RADS V2.1, klinik olarak anlamlı prostat kanseri, gözlemciler arası uyum

Introduction

The main purpose of multiparametric prostate magnetic resonance imaging (mpMRI) is to identify and situate abnormalities corresponding to clinically significant prostate cancer (csPCa) (1,2). PI-RADS is a guideline created to advance the identification, localization, qualification, and risk classification of PC and to provide international standardization in the acquirement, explication and evaluation of mpMRI examinations (3). In order to determine the minimum and optimal parameters for early diagnosis, staging, and LN/bone evaluation of PC, a guideline containing T1WI, T2WI, DWI, DCI, and MRSI examinations was published and defined as PI-RADS v1 in 2012, by the ESUR (4,5). In 2015, an advanced version of PI-RADS v2 was defined by AJR, ESUR, and AdMeTech Foundation (6). Although PI-RADS v2 is widely supported by many clinical studies, due to a lack of experience in scoring and differences among readers, without changing the general scope or principles of version 2, it has been made with a few minor adjustments to simplify and standardized evaluation and reduce interobserver agreement, the v2.1 version has been created (7). T2WI imaging also maintains the dominant sequence position in the current version, especially in the evaluation of TZ lesions and tumor staging. BPH nodules, which are very common in TZ, especially in

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old age, and are mixed with PC, are detailed in the T2WI in the new version. In the new version, normal-appearing (rare) or round encapsulated nodules on T2W images in TZ are classified as "typical nodules" in the score 1 category. Generally, encapsulated nodules or non-encapsulated homogeneous nodules with smooth borders are defined as "atypical nodules" and evaluated in the score 2 category. Nodules in category 2 in TZ and with a DWI score of ≥ 4 are considered as category 3 in the new classification. In addition, homogeneous slightly hypointense areas between the nodules were also included in the score 2 category. In PZ, the diffusion score of linear-wedge-shaped focal diffusion restricting areas in DWI is reported as 2 (8).

In this retrospective study, lesions at risk of PC according to two versions were compared with their histopathological findings after cognitive fusion biopsy and/or radical prostatectomy (RP). The purpose of the study is the comparison of diagnostic performances of both versions by calculating sensitivity, specificity, PPV, NPV, and diagnostic accuracy parameters. In addition, the interobserver agreement was appraised in two versions.

Material And Methods

Patient selection

In our study, 326 patients with mpMRI, cognitive fusion biopsy, and/or RP in the radiology clinic with the suspicion of PC between June 2018 and May 2021 were evaluated. 68 patients were excluded from the study due to criteria, the rest 258 patients and their 394 nodules were analyzed. More than 1 nodule was present in 102 patients. The study population flowchart is shown in Figure 1.

Imaging Protocol

The mpMRI images included in the study were obtained on 3T Siemens MR (Skyra, Siemens Healthcare, Erlangen, Germany) devices with 24-channel pelvic phase array coils in such a way that all prostate glands and seminal vesicles (SV) enter the imaging field. Routine antispasmodic and antiperistaltic agents were not used in patients who were recommended bowel cleaning before the examination. High-resolution T2WI was taken in three plans corresponding to the position of the prostate gland. Moreover, the axial DWI was obtained with 3 different b values (b: 50, 1000, and 1500 sec/mm2), and ADC maps were created. When artifactual DWI was obtained due to gas distension in the rectum, the examination was terminated and repeated after being given antispasmodic and antiperistaltic agents. In addition, before, during, and after IV administration of contrast agent (with a concentration of 0.1–0.2 mmol/kg and an injection rate of 2-4 mL/sec) appropriate for the weight of the patients, axial fat-suppressed T1WI of the entire prostate gland was taken 3 times in 7 seconds for 240-300 seconds with a slice thickness of 0.5 mm. For the determination of pelvic metastases and lymph nodes, the area from the bifurcation of the aorta level to the pubic tubercules was evaluated on T1WI with wide FOV.

Imaging analysis

Before the start of the image analysis, significant changes in PI-RADS v2 and v2.1 were discussed with self-learning materials and representative cases between two readers. A more experienced reader (15 years of experience with>500 prostate MRIs a year) marked both zones' lesions on the PACS workstations with the basis of a PI-RADS sector map. Marked lesions were then scored by the more experienced reader and by the second reader (5 years of experience with>250 prostate MRIs a year) at different times according to both versions of PIRADS. T2WI was used about the morphological and signal characteristics of the lesions in PI-RADS category 1 lesions (downgrade 2-1) and category 2 lesions (downgrade 3-1) with PI-RADS v2.1. For PI-RADS 3 lesions in both versions and PI-RADS 2 lesions in PI-RADS v2.1, the DWI was used to figure out the final score. PI-RADS category 2 + 1 or 3 + 1 lesions enhanced to the final category proportional to the DWI criteria. In PIRADS 4 and above lesions, action was taken according to the size, extension and diffusion signal characteristics according to the guideline. Then final scores of two readers in both versions were compared with histopathological results. In this way, both the diagnostic performance and the interobserver agreement in both versions were evaluated. In addition, sensitivity, specificity, PPV, NPV and accuracy values between the two versions were compared.

Histopathologic analysis for reference standard

Specimens were prepared according to the International Society of Urological Pathology Consensus (9). A radiologist signed all suspicious lesions with a urologic pathologist to mate the pathologic outcomes. More than one nodule was detected in 102 patients. Benign prostatic hyperplasia (BPH) nodules, calcifications, and anatomic landmarks such as verumontanum and urethra were used to compare images and specimens. Cancers with a Gleason score of 7 and above and/or tumor volume of 0.5 cc and above and/or extraprostatic extension were considered clinically significant while tumors with a Gleason score of 6 were considered to be in the benign group, including non-tumor pathologies covering clinically insignificant cancer and precancerous lesions.

Statistical analysis

Analysis of the data was performed in the IBM SPSS Statistics 21.0 package program (IBM Corporation, Armonk, NY, USA). Figurative statistics were presented as mean ± standard deviation or median (width between quarters) for continuous numerical variables while categorical variables were shown as number of cases and symbol (%).

Age, PSA, free PSA, prostate volume, and PSA density in terms of the difference in importance were examined with students' t-tests in binary groups.

In PI-RADS v2 and PI-RADS v2.1, the levels of interobserver agreement were analyzed by ascertaining the Kappa coefficient. A Kappa coefficient in the range of 0.00-0.20 indicates that there is no agreement among the observers, the range of 0.21-0.39 is a very weak agreement between the observers, the range of 0.40-0.59 is poor agreement between the observers, the range of 0.60-0.79 is a moderate agreement, the range 0.80-0.90 is strong agreement and above 0.90 indicates a very strong agreement. The statistical significance of PI-RADS v2.0 and PI-RADS v2.1 in detecting clinically significant prostate cancer was investigated by calculating the area under the ROC curve and with 95% confidence intervals. Diagnostic performance indicators for different threshold values of two versions were evaluated by calculating sensitivity, specificity, PPV, NPV, and diagnostic accuracy rates.

Unless otherwise stated, results for $p<0.05$ were noted as statistically significant.

Results

The study included 258 patients who underwent cognitive fusion biopsy or radical prostatectomy. The mean ± standard deviation values of age, PSA, free PSA, prostate volume and PSA densities of all patients are presented in Table 1. Mean age, PSA, free PSA and PSA density values were statistically significantly higher, and volume was lower in clinically significant prostate cancer ($p<0.05$). Sixty-one (18.7%) of the lesions were in the PZ; 262 (80.4%) were located in the TZ.

Forty PZ lesions (65.5%) were defined as clinically significant prostate cancer and 21 lesions (34.5%) were defined as clinically insignificant prostate cancer or benign. No scoring difference was found between the two PI-RADS versions in both readers in PZ lesions. 14 of TZ lesions (5.3%) were diagnosed as clinically significant prostate cancer and 248 lesions (94.7%) were diagnosed as clinically insignificant prostate cancer or benign. According to the first reader, there were no diagnostic differences between both versions in clinically significant cancer detection. According to the second reader, only 1 lesion reported as PI-RADS 2+1 was identified as clinically significant cancer. 39 lesions defined as PI-RADS 2 according to v2 by both readers were evaluated as PI-RADS1 according to v2.1 due to their total encapsulation appearance and all were benign. In addition, clinically significant cancer was not detected between 16 lesions evaluated as 2+1 in PIRADS v2 by radiologist 1 and 30 lesions evaluated by radiologist 2 as 2+1 in PI-RADS v2 (Table 3). All of the lesions that we classified as category 2 (downgrade 3-1) about v2.1 were benign (Figure 2).

Both versions showed the same diagnostic effectiveness in the recognition of clinically significant prostate cancers and all cancers in PZ. The diagnostic effectiveness of the two versions was similar in TZ (Figure 3, Table 3).

In our study, when the cut off ≥3 was taken due to 16 lesions according to the 1st reader and 30 according to the 2nd user, a decrease in the specificity, PPD and accuracy rates was noted. When cut-off ≥4 was taken, no difference was found between the two versions in other parameters. According to the second reader, the sensitivity and NPV increased in PI-RADS v2.1 when the cut-off ≥3 was taken in the recognition of clinically significant cancer in TZ, while the specificity, PPV, NPV, and accuracy rates increased when the cut-off was ≥4. When all cancers in the TZ were evaluated and the cut off ≥3 was taken, sensitivity and NPV values increased in PI-RADS v2.1 compared to the first reader, and sensitivity, NPV, and PPV values increased compared to the second reader. When the cut off ≥4 was taken, no significant difference was found between the parameters specified in both versions in both readers.

Interobserver agreement was statistically significant and very strong according to the two classification systems in the PZ. The interobserver agreement was statistically significant and very weak according to the two classification systems in the TZ (Table 4).

Table 1. Comparison of age, PSA value, prostate volume, and PSA density values according to clinical significance and frequency distributions of pathology, ISUP grade, and Gleason scores according to lesion location in patients

	csPCa (n = 54)	ciPCa (n=272)	p*
	Value	Value	
Age*	68.44 ±8.98	64.08±7.32	0.001
PSA*	17.44±16.77	11.56±12.23	0.017
Free PSA*	3.35±3.45	2.53±2.65	0.05
Prostate Volume*	60.05±39.44	84.80±53.59	0.001
PSA density*	0.37±0.44	0.15±0.16	<0.001
	PZ (n=61)	TZ (n=262)	
Pathology Groups**			
Benign	14 (23)	223 (85.1)	
csPCa	7 (11.5)	25 (9.5)	
ciPCa	40 (65.6)	14 (5.3)	
ISUP grade or Gleason score**			
ISUP 1 or ≤ 6	7 (14.9)	25 (64.1)	
ISUP 2 or 3+4 = 7	13 (27.6)	8 (20.5)	
ISUP 3 or 4+3 = 7	12 (25.5)	4 (10.2)	
ISUP 4 or 4+4 = 8	7 (14.9)	-	
ISUP 5 or 9-10	8 (17)	2 (5.1)	
Pathology**			
Prostatitis	3 (4.9)	79 (30.2)	
Adenomatous hyperplasia	4 (6.5)	118 (45)	
HGPIN	1 (1.6)	4 (1.5)	
PIN	1 (1.6)	3 (1.1)	
ASAP	2 (3.3)	18 (6.9)	
Adenocancer	46 (75.4)	39 (14.9)	
Intraductal cancer	4 (6.5)	-	
Insitu cancer	-	1 (0.4)	

*Data values are presented as a mean ± standard deviation. **Data values are presented as a count and percentages. ISUP = International Society of Urological Pathology; PZ= Peripheral zone, TZ = Transition zone, csPCa = Clinically significant prostate cancer, ciPCa = Clinically insignificant prostate cancer and benign.

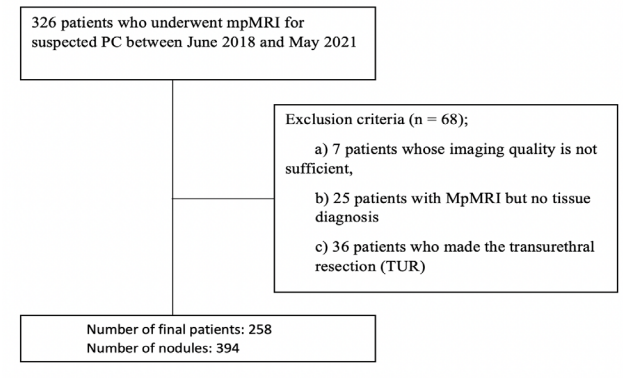

Figure 1. Study population flowchart.

Table 2. Distribution of lesions located in the PZ and TZ according to PI-RADS 2 and PI-RADS 2.1

	Reader 1		Reader 2	
	csPCa	ciPCa	csPCa	ciPCa
PZ				
PI-RADS v2				
PI-RADS 1	-	-	-	-
PI-RADS 2	-	-	-	-
PI-RADS 3	-	11 (52.4)	1 (2.5)	9 (42.9)
PI-RADS 4	17 (42.5)	8 (38.1)	16 (40)	10 (47.6)
PI-RADS 5	23 (57.5)	2 (9.5)	23 (57.5)	2 (9.5)
PI-RADS v2.1				
PI-RADS 1	-	-	-	-
PI-RADS 2	-	-	-	-
PI-RADS 3	-	11 (52.4)	1 (2.5)	9 (42.9)
PI-RADS 4	17 (42.5)	8 (38.1)	16 (40)	10 (47.6)
PI-RADS 5	23 (57.5)	2 (9.5)	23 (57.5)	2 (9.5)
TZ				
PI-RADS v2				
PI-RADS 1	-	-	-	-
PI-RADS 2	-	215 (86.7)	1 (7.1)	127 (51.2)
PI-RADS 3	1 (7.1)	30 (12.1)	4 (28.6)	88 (35.5)
PI-RADS 4	10 (71.4)	3 (1.2)	6 (42.9)	32 (12.5)
PI-RADS 5	3 (21.4)	-	3 (21.4)	1 (0.4)
PI-RADS v2.1				
PI-RADS 1	-	39 (15.7)	-	39 (15.7)
PI-RADS 2	-	160 (64.5)	-	58 (23.4)
PI-RADS 3	1 (7.1)	46 (18.5)	5 (35.7)	118 (47.6)
PI-RADS 4	10 (71.4)	3 (1.2)	6 (42.9)	32 (12.9)
PI-RADS 5	3 (21.4)	-	3 (21.4)	1 (0.4)

Data in parentheses are percentages. PI-RADS = Prostate Imaging Reporting and Data System; csPCa = clinically significant prostate cancer, ciPCa = clinically insignificant prostate cancer, PZ = Peripheral zone, TZ = Transition zone

Table 3. Diagnostic performance of PI-RADS v2 and v2. 1 in PZ and TZ cancers

	p-value	Cut-off	PI-RADS V2	PI-RADS V2.1
Peripheral zone				
csPCa				
Sensitivity (%)	<0.001	≥4	100 (91.19-100)	100 (91.19-100)
Specificity (%)	<0.001	≥4	52.38 (29.78-74.29)	52.38 (29.78-74.29)
PPV (%)	<0.001	≥4	80 (71.86-86.23)	80 (71.86-86.23)
NPV (%)	<0.001	≥4	100	100
Accuracy (%)	<0.001	≥4	83.61 (71.91-91.85)	83.61 (71.91-91.85)
AUC (%95 GA)	-	-	0.851 (0.744-0.959)	0.851 (0.744-0.959)
All Cancers				
Sensitivity (%)	<0.001	≥4	95.74 (85.46-99.48)	95.74 (85.46-99.48)
Specificity (%)	<0.001	≥4	64.29 (35.14-87.24)	64.29 (35.14-87.24)
PPV (%)	<0.001	≥4	90 (81.64-94.8)	90 (81.64-94.8)
NPV (%)	<0.001	≥4	81.82 (52.32-94.86)	81.82 (52.32-94.86)
Accuracy (%)	<0.001	≥4	88.52 (77.7-95.3)	88.52 (77.7-95.3)
AUC (%95 GA)	-	-	0.819 (0,671-0.968)	0.819 (0,671-0.968)
Transition zone				
csPCa				
Sensitivity (%)	<0.001	≥4	92.86 (66.13-99.82)	92.86 (66.13-99.82)
Specificity (%)	<0.001	≥4	98.79 (96.51-99.75)	98.79 (96.51-99.75)
PPV (%)	<0.001	≥4	81.25 (58.23-93.09)	81.25 (58.23-93.09)
NPV (%)	<0.001	≥4	99.59 (97.37-99.94)	99.59 (97.37-99.94)
Accuracy (%)	<0.001	≥4	98.47 (96.14-99.58)	98.47 (96.14-99.58)
AUC (%95 GA)	-	-	0.988 (0.971-1.00)	0.988 (0.971-1.00)
All Cancers				
Sensitivity (%)	<0.001	≥4	38.46 (23.36-55.38)	38.46 (23.36-55.38)
Specificity (%)	<0.001	≥4	99.55 (97.53-99.99)	99.55 (97.53-99.99)
PPV (%)	<0.001	≥4	93.75 (67.1-99.1)	93.75 (67.1-99.1)
NPV (%)	<0.001	≥4	90.24 (87.83-92.22)	90.24 (87.83-92.22)
Accuracy (%)	<0.001	≥4	90.46 (86.24-93.73)	90.46 (86.24-93.73)
AUC (%95 GA)	-	-	0.690 (0.583-0.797)	0.690 (0.583-0.797)

Data are percentages, with the 95% confidence interval shown in parentheses. PI-RADS = Prostate Imaging Reporting and Data System. PZ= Peripheral zone, TZ = Transition zone. PPV= Positive predictive value, NPV= Negative predictive value, csPCa= clinically significant prostate cancer

Table 4. Interobserver agreement scores according to PI-RADS v2.0 and v2.1 classifications for the PZ and TZ.

PI-RADS category	Zone	Kappa coefficient	p-value
PI-RADS V2	PZ	0.869	<0.001
PI-RADS V2	TZ	0.279	<0.001
PI-RADS V2.1	PZ	0.869	<0.001
PI-RADS V2.1	TZ	0.400	<0.001

The levels of interobserver agreement were evaluated by calculating the Kappa coefficient.

PI-RADS = Prostate Imaging Reporting and Data System, PZ= Peripheral zone, TZ = Transition zone.

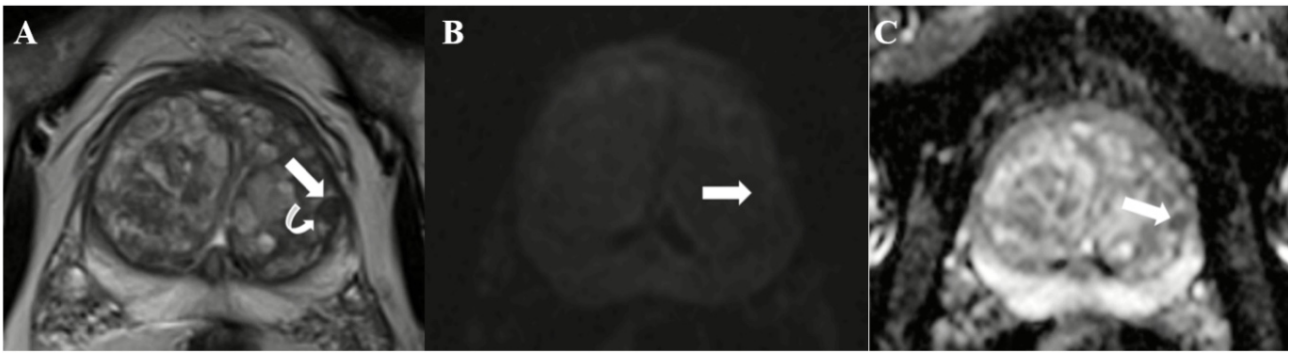

Figure 2. Multiparametric MRI of a 68-year-old patient with PSA 14,82 who underwent radical prostatectomy. Axial T2-weighted image (A) showed a mostly encapsulated nodule (arrow) with a slightly obscured margin (curved arrow) in the left TZ, which was categorized as category 3 by PI-RADS v2 but downgraded to category 2 by v2.1. A focal mildly hyperintense nodule was evident on DWI (B) and mildly hypointensity was observed on an ADC map (C), which was a DWI score of 3. The histopathology of the lesion was reported as benign tissue.

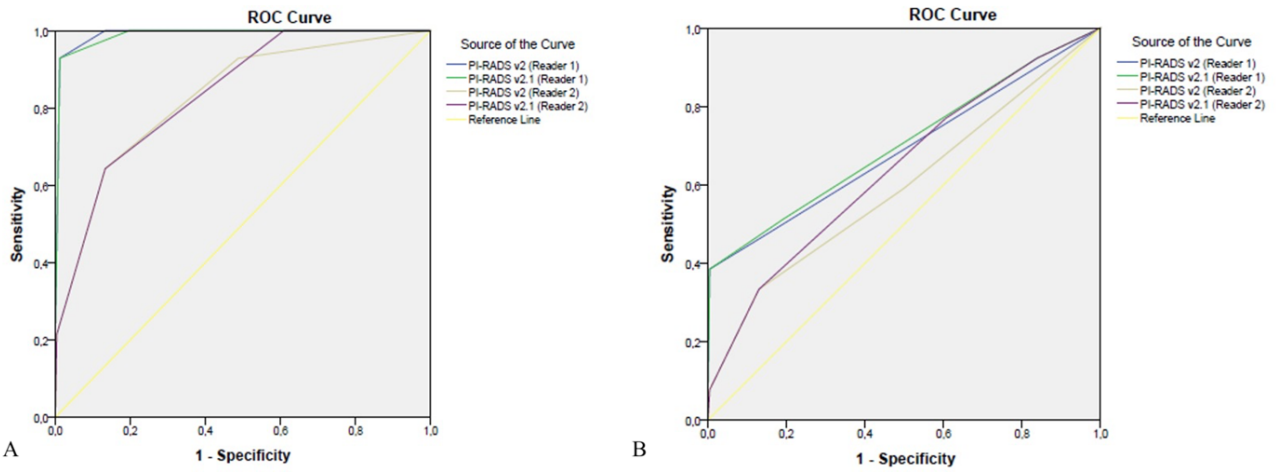

Figure 3. Curves of PI-RADS v2 and v2.1 relative to both readers in the PZ (A) and TZ (B).

Discussion

In this study, the diagnostic effectiveness of PI-RADS v2 and PI-RADS v2.1 and the interobserver agreement in both versions were compared using mpMRI in both PZ and TZ cancers. In our analyses, we identified that the diagnostic performance of PI-RADS v2 and v2.1 was similar in both csPCa and all cancers in PZ and TZ.

Moreira et al. have stated that the most important difference between the two versions is that the lesions, which were classified in category 2 in the previous version due to the typical benign prostatic hyperplasia nodules in TZ, are in category 1 in the current version (9, 10). The results of our study were similar to this study. Chao-gang Wei et al. published a study reporting that sensitivity, specificity, and accuracy in the evaluation of TZ lesions were lower in PIRADS v2.1 than in PIRADS V1 among all readers. In the same study, they argued that PI-RADS v2.1 had a better interobserver agreement than PI-RADS v2 for analyzing TZ lesions (11). Jieun Byun et al. reported that the sensitivity and specificity of v2.1 (94.5% and 60.9%) was higher than v2 (91.8% and 56.3%) for category ≥3 lesions in the detection of csPCa in TZ, although not significantly (12).

The targeted biopsy is frequently performed for ≥3 lesions with PI-RADS v2 because of its high specificity (2,13,14). However, in the presence of high PSA values and supportive clinical findings, some urologists may request a targeted biopsy for PIRADS <3 lesions. Clinically significant cancer detection rates in category ≥3 lesions vary between 3.8-30% in studies (15-17). It is thought that this difference arises from definitions such as "ambiguity of borders" or "moderate hypointensity" defined in PI-RADS v2, which may cause different interpretations from reader to reader (18,19,20). In this context, there are also studies stating that the cut-off value should be ≥4, especially in TZ lesions, to increase the specificity in targeted biopsies (21,22,23).

As a result of the clear and understandable definitions of the 'atypical nodule' concept that came with the current version in TWI, all of the lesions that we classified as category 2 (downgrade 3-1) were benign. This enhanced the sensitivity and specificity of category ≥3 lesions to determine csPCa. One of the major changes that came with PIRADS v2.1 is the definition of 'typical nodule', downgrading category 2 lesions to category 1. In our study, there was no clinically significant cancer in any of the total encapsulated lesions defined as

"typical BPH nodules" downgraded from category 2 to 1 according to v2.1. In previous studies, clinically insignificant cancers with low volume and Gleason score ≤ 6 have been detected in some category 1 lesions. (12). However, this can be ignored because the most important target of PI-RADS classification is to detect csPCa.

Many studies have been done about the importance of DWI in v2 before (24). One of the most important changes in PIRADS v2.1 is that the DWI score of ≥4 in atypical nodules in the TZ upgrades the lesion from category 2 to category 3. According to PI-RADS v2.1, clinically significant cancer was detected in only 1 case whose DWI score was ≥4 in TZ and upgraded from category 2 to 3. In our study, the detection level of csPCa and all cancers in category 2+1 lesions was higher in the current version, but it was not significant. Also, we understood that especially in PI-RADS 3 lesions, which are frequently confused with BPH nodules in TZ, increasing the agreement interobserver and preventing unnecessary biopsies is the main purpose of v2.1. However, in our study, the number of lesions that were upgraded (2+1) due to DWI score in TZ compared to v2.1 was higher than the number of lesions downgraded with the definition of ''atypical nodule'' (3-1=2), and there was an increase contrary to the decrease in the number of targeted biopsies.

In our analyses; the interobserver agreement was statistically significant and very strong according to the PI-RADS v2.0 and v2.1 classifications in the PZ and very weak according to the two classifications in the TZ. Rajesh Bhayana et al. claimed that agreement between interobservers enhanced using PI-RADS v2.1 in the PZ but there were no similar findings in TZ (25). This study yielded similar results to our study. Jieun Byun et al. stated that interreader agreement at category ≥3 lesions in the TZ, v2.1 showed better performance than v2 (12). Hotker AM et al. found that the diagnostic performance and inter-reader agreement of v2.1 were higher than v2.0 but the changes in the new version applied to a small group of patients (26).

In our study, there were some limitations the first of which was a single-center retrospective study. Non-targeted systematic biopsy in MR-negative patients was a limitation. The low number of PI-RADS category 2+1 lesions was another limitation and reduced the effect of statistical analysis. In addition, the fact that not all pathological results were obtained from RP material, radiologists, and urologists who did not have sufficient experience in targeted fusion biopsies, was another limitation.

Conclusion

PI-RADS v2.1 and v2 showed higher sensitivity and lower specificity in PZ and showed higher sensitivity and specificity in TZ in the detection of csPCa, and there was no significant difference between the two versions. On the other hand, in our study; the interobserver agreement was statistically significant and very weak according to the two classifications in the TZ and very strong according to the two classifications in the PZ. PI-RADS category 2 + 1 lesions upgraded by DWI from category 2 identified on T2WI showed a higher detection rate of csPCa than category 2 lesions, but it was not significant. Although clinically significant cancer was detected in only one of the lesions whose category was evaluated as 2+1 according to PI-RADS v2.1 in our study, the rate of csPCa detection can increase in 2+1 category lesions compared to category 2 lesions in larger and multicenter studies. Although there was no statistically significant difference in csPCa detection between the two versions, it can be determined that v2.1 is superior to v2.0, especially in the diagnostic performance of TZ cancers, in studies with a larger number of patients. With the updated versions, more detailed descriptions of especially difficult to score TZ lesions can make the difference in lesion character clearer and the agreement of evaluation among readers can be increased. With each updated version of the MpMRI and PI-RADS scoring system, it has made progress in creating a common interpretation language and strengthens its place in the diagnosis and follow-up of PC day by day.

Abbreviation: PI-RADS = Prostate Imaging Reporting and Data System, ISUP = International Society of Urological Pathology; PZ= Peripheral zone, TZ = Transition zone, csPCa = Clinically significant prostate cancer, ciPCa = Clinically insignificant prostate cancer, PPV= Positive predictive value, NPV= Negative predictive value, RP = Radical prostatectomy, ESUR = European Association of Urogenital Radiology, AJR = American Journal of Roentgenology

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Authors' contributions: Ahmet Baytok manuscript writing/editing. Mustafa Koplay: manuscript writing/ editing. Halil Özer: statistical analysis. Ömer Faruk Topaloğlu: manuscript editing. Mehmet Kaynar: collecting data. Serdar Göktaş: collecting data. Ali Furkan Batur: contributed to data interpretation.

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