European Journal of Radiology 116 (2019) 180–185

Contents lists available at ScienceDirect

European Journal of Radiology

journal homepage: www.elsevier.com/locate/ejrad

Research article

Comparison of PI-RADS v1 and v2 for multiparametric MRI detection of prostate cancer with whole-mount histological workup as reference standard

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ARTICLE INFO

Keywords:
Multiparametric MRI
Prostate cancer
PI-RADS

ABSTRACT

Purpose: The aim of this study was to compare Prostate Imaging Reporting and Data System (PI-RADS) versions v1 and v2 for the detection of prostate cancer (PCa) in multiparametric MRI (mpMRI) using whole-mount histological workup as reference standard.

Material and methods: MRI data of 40 patients with positive transrectal ultrasound-guided biopsy were analyzed retrospectively by two blinded readers (5 and 4 years' experience) with PI-RADS v1 and v2 for cancer-suspicious lesions. Prior to radical prostatectomy, patients had undergone IRB-approved mpMRI at 3 T according to PI-RADS recommendations: T2-weighted (T2w), diffusion-weighted (DWI) and dynamic contrast-enhanced (DCE) imaging. The reference standard was provided by whole-mount sections of the prostatectomy specimens. Versions v1 and v2 were compared with respect to sensitivity and positive predictive value (PPV) per lesion. Subgroups stratified by tumor location (peripheral vs. transition zone) and aggressiveness (high vs. low grade) were also analyzed. We also evaluated the concordance of the dominant MRI sequence in v2 (DWI or T2w) and the highest individual score under v1. Interobserver agreement for PI-RADS v1 and v2 was assessed by Cohen's kappa statistics.

Results: Reader 1 (R1) described 66 and Reader 2 (R2) 72 MRI lesions. The average Gleason score of 58 PCa lesions was 6.5 (range: 6 = 3 + 3 to 8 = 4 + 4), most of them (65.5%) located in the peripheral zone. PI-RADS v2 showed a trend towards lower sensitivities, but differences were not significant for both readers: R1 72.4% (v1) vs. 63.8% (v2) (P = 0.426) and R2 77.6% (v1) vs. 69.0% (v2) (P = 0.402). The trends were more pronounced in the transition zone and for low-grade cancers but remained insignificant (p-values from 0.313 to 0.691). Likewise, the apparent PPV differences, overall as well as in each zone, were not significant. Agreement between high-score v1 and dominant v2 sequence was 48% for R1 and 53% for R2. Cohen's κ of PCa detection for two readers was 0.48 for both v1 and v2.

Conclusion: Our findings indicate that the simplified, zone-specific approach of PI-RADS v2 (2015) for MRI assessment of prostate cancer may not necessarily be better than the original v1 criteria (2012). In specific cases, a strict interpretation of v2 criteria may even lead to false-negative findings. Therefore, the current PI-RADS criteria should be reconsidered, despite the low statistical evidence here.

Abbreviations: Bx, biopsy; DCE, dynamic contrast-enhanced; DWI, diffusion-weighted; ESUR, European Society of Urogenital Radiology; FA, flip angle; FOV, field of view; hg, high grade; IRB, Internal Review Board; IPR, in-plane resolution; lg, low grade; mpMRI, multiparametric Magnetic Resonance Imaging; PCa, prostate carcinoma; PSA, prostate-specific antigen; PZ, peripheral zone; PI, RADS-Prostate Imaging Reporting and Data System; PPV, positive predictive value; SG, slice gap; SS, EPI-single-shot echo planar imaging; ST, slice thickness; TE, time of echo; TR, time of repetition; TRUS, transrectal ultrasound; TSE, turbo spin echo T2w-T2-weighted; TZ, transition zone; TZa, anterior transition zone; R, reader; v, version

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https://doi.org/10.1016/j.ejrad.2019.04.012
Received 10 January 2019; Received in revised form 11 March 2019; Accepted 20 April 2019

1. Introduction

Multiparametric MRI (mpMRI) has substantially improved the detection of clinically significant prostate cancer (PCa) and the confidence in characterizing benign and insignificant findings [1,2]. The initial version (v1) of the Prostate Imaging Reporting and Data System (PI-RADS) guideline was issued in 2012 with the aim to reduce the variability of MRI techniques and acquisition parameters and to standardize the MRI assessment [3].

In 2015, version v2 replaced the sum of individual parameter scores (1–15 or 1–20) with a zone-specific, dominant MRI sequence (DWI in the peripheral zone PZ and T2w in the transition zone TZ) and final scores of 1–5 only [4]. Several studies have deliberately compared the diagnostic accuracy of both PI-RADS versions for PCa detection with results being largely inconsistent [5–13]. Some studies have found the diagnostic accuracy to be comparable for both [7–11,13] while others favor either v1 or v2 [5,6,12]. One reason for this discrepancy might be the different reference standard used for PCa diagnosis. Most studies used the histological results of in-bore MRI biopsies as a reference, which are prone to sampling errors and undergrading.

Only one of these direct comparisons has deliberately used whole-mount step sections as pathological reference, which are generally more reliable despite some variation in reading and correlation with MRI findings. That study, however, might be limited by a reader bias because each radiologist interpreted the findings for one specific PIRADS version only [5]. Therefore, the aims of our study were to compare the accuracy of PI-RADS v1 and v2 for PCa detection for two blinded readers applying both PI-RADS versions each and using whole-mount histological workup as reference standard and to assess the agreement between both readers.

2. Material and methods

2.1. Patient characteristics

Forty-three consecutive patients who had undergone radical prostatectomy at the Urology Department of our institution between 10/2010 and 02/2013 were included in this retrospective analysis. Patients initially presented with a history of elevated serum prostatespecific antigen (PSA) levels and positive findings from standard biopsies (guided by transrectal ultrasound, TRUS) suggesting surgical treatment. Prior to surgery, all patients had an IRB-approved, multiparametric MRI (mpMRI) of the prostate. MRI data were correlated with whole-mount histology slides of prostatectomy specimens. Exclusion criteria were patients with general contraindications to either MRI (e. g. pacemaker) or gadolinium-based contrast agents as well as patients with prostate biopsies performed less than 3 weeks before MRI to minimize chances of hemorrhage-related image artifacts. Two patients with effective lesion diameters under 3 mm and one patient with incomplete histopathological workup were also excluded from analysis.

2.2. Magnetic resonance imaging

Presurgical mpMRI was performed in a 3 T MRI system (Magnetom Trio, Siemens Healthcare, Erlangen, Germany) following ESUR guidelines [3,14]. Signals were acquired with pelvic and spine array coils combined with an endorectal coil (eCoil, Medrad, Pittsburg, PA). The endorectal coil was filled with 30–40 ml of perfluorocarbon solution (perfluorooctyl bromide, ABCR GmbH, Karlsruhe, Germany) to minimize susceptibility artifacts. All patients received an intravenous injection of either 40 mg butylscopolamine (Buscopan, Boehringer Ingelheim, Germany) or 1 mg glucagon (Glucagen, Nordisk, Gentofte, Denmark) to reduce bowel peristalsis. The MRI protocol included T2-weighted imaging (T2w), diffusion-weighted imaging (DWI) and dynamic contrast-enhanced imaging (DCE) following bolus injection of 15–20 ml of contrast agent (Gadovist, Bayer Healthcare, Berlin, Germany). Perfusion curves were analyzed with a standard application (Mean Curve, Siemens Healthcare, Erlangen, Germany). An overview of the main imaging parameters is given in Table 1.

2.3. Histopathological work up

Prostatectomy specimens were processed immediately after radical resection and fixed in 10% neutral buffered formalin for about a week. The seminal vesicles were separated, and the prostate was sliced into 4 to 5-mm thick step sections, perpendicular to the posterior, rectal surface of the gland. After paraffin embedding and hematoxylin-eosin staining, histology slices (typically 10 per prostate) were evaluated by a senior pathologist (15 years of experience in urogenital pathology), who was blinded to MRI. Tumor foci were outlined on the microscopy slides. Lesions were annotated and characterized according to the Gleason grading system [15]. Low-grade and high-grade PCa were defined as Gleason scores $\leq$ 7a = 3 + 4 and $\geq$ 7b = 4 + 3, respectively. All specimens were staged according to the TNM classification [16]. Only tumors with diameters of at least 3 mm were considered for further evaluation. Findings like nodular prostatic hyperplasia, prostatitis and normal prostate tissue were summarized as benign findings.

2.4. MRI assessment

Two radiologists, reader R1 with 5 years' and reader R2 with 4 years' experience in prostate mpMRI independently reviewed the MRI data with a standard application (Syngo Plaza, Siemens Healthcare). Both were blinded to clinical and histopathological findings and were allowed to define up to four prostate lesions per patient. Lesion locations were reported using a 16-region PI-RADS v1 scheme [3]. Lesion diameters were measured in three orthogonal views and an effective diameter was computed as geometric mean. Each reader applied both v1 and v2 in random order with at least 10 days between readings to minimize the chance of remembering findings. All lesions with an overall PI-RADS scores $\geq$ 4 were considered to be suspicious for PCa.

PI-RADS v1 assessment involved scores from 1 to 5 (highly likely to be benign or malignant, respectively) for each modality (T2w, DWI and DCE). The DCE score rates the presence of focal or asymmetric contrast enhancement and the shape of the signal intensity-time curve. Individual scores were added and converted to an overall PI-RADS score between 1 and 5, as published elsewhere [17]. Two patients had incomplete DCE data and, therefore, PI-RADS scores 1–5 were assigned for sum scores of 2, 3–4, 5–6, 7–8 and 9–10, respectively.

PI-RADS v2 assessment followed a zone-specific model with

Table 1
Imaging parameters of multiparametric prostate MRI.

	Sequence	Slices	ST/SG (mm)	IPR (mm)	TR (ms)	TE (ms)	FOV (mm)	FA (°)
T2w (tra, cor, sag)	TSE	19-22	3/0.6	0.57 × 0.57	4000–4600	126	110 × 110	120–135
DWI (tra)	SS-EPI	19-22	3/0.6	0.98 × 0.98	3000	85	250 × 250	90
T1w DCE (tra)	3D-SPGR	19-22	3/0.6	0.57 × 0.57	4.7	1.7	110 × 110	14

Note: DWI-diffusion weighted imaging; DCE-dynamic contrast enhanced; TSE-turbo spin echo; SS-EPI-single-shot echo planar imaging; SPGR-spoiled gradient echo; ST-slice thickness; SG-slice gap; IPR-in-plane resolution; TR-repetition time; TE-echo time; FOV-field of view; FA-flip angle.

dominant sequences for TZ (T2w) and PZ (DWI) [4]. DCE was analyzed for PZ lesions in case of a DWI score of 3. Lesions were assigned to a single zone only if the respective cancer volume (3D) exceeded 70%.

2.5. Radiologic-pathologic correlation

Section slides were digitized for radiologic-pathologic correlation. After MRI reading, findings were matched with histopathological lesions by two readers in consensus using the following features: Morphological T2w appearance of TZ and PZ, allocation to specific prostate segment (out of 16 for PI-RADS v1) [3] and anatomical landmarks like cysts, calcifications, seminal vesicle insertion or apical urethra. Radiologic-pathologic correlation was considered positive if the tumor focus marked on the whole-mount step section was within the same segment (position and side) and within 5 mm of the respective MRI focus. Histopathologically proven PCa lesions not seen on MRI with a diameter of at least 3 mm were given a PI-RADS score of 1.

2.6. Analysis and statistics

The value of PI-RADS scores for the prediction of PCa was analyzed per suspected lesion and per patient. Results were distinguished between different parts of the prostate (PZ, TZ and whole gland) as well as tumor aggressiveness (high and low-grade cancer). Differences in sensitivity and PPV between both PI-RADS versions were analyzed with Fisher's exact test (two-sided, 0.05 significance level). Correspondence between the parameter with the highest individual v1 score and the so-called dominant sequence in v2 (DWI or T2w) was reported as percentage of cases. Agreement between PI-RADS versions as well as between observers for each version were determined using Cohen's kappa statistics and roughly classified as excellent ($\kappa > 0.80$), good ($\kappa = 0.61-0.80$), moderate ($\kappa = 0.41-0.60$), fair ($\kappa = 0.20-0.40$) or poor ($\kappa < 0.20$). Data were analyzed with SPSS version 24.

3. Results

Characteristics of the patients and the histopathology of the lesions are summarized in Table 2. Five of 40 patients (12.5%) had locally advanced disease (stage pT3). The pathologist identified a total of 58 PCa lesions, the majority was located in the PZ (65.5%). The mean Gleason score was 6.5 and nine of the lesions were high-grade tumors (15%; Gleason score ≥7b).

Table 2
Patient and lesion characteristics.

Parameter	Value
Number of patients	40
Age [years]	63 (48–74)
PSA [ng/ml]	11.7 (0.6–56.0)
Time between TRUS-Bx and MRI [days]	49 (28–202)
Time between MRI and surgery [days]	3 (1–83)
T-Stage	
2a	4 (10.0%)
2b	2 (5.0%)
2c	29 (72.5%)
3a	2 (5.0%)
3b	3 (7.5%)
Number of PCa lesions	58
Localization	
Peripheral zone	38 (65.5%)
Transition zone	18 (31.0%)
Seminal vesicles	1 (1.7%)
Anterior stroma	1 (1.7%)
Gleason score	
6 = 3 + 3	26 (44.8%)
7a = 3 + 4	23 (39.7%)
7b = 4 + 3	5 (8.6%)
8 = 4 + 4	4 (6.9%)

Values are given as mean (range) or number (percentage).
Note: TRUS-transrectal ultrasound; Bx-Biopsy; PCa-prostate cancer.

Readers R1 and R2 described 66 and 72 lesions in MRI, respectively. The average MRI lesion size was 11.9 (5–44.8) mm for R1 and 12.7 (5–26.8) mm for R2. An overview of the distribution of PI-RADS scores for both readers is given in Fig. 1. Six histopathologically proven PCa foci were missed on MRI by both R1 and R2, all of low grade (four Gleason 6 and two 7a).

Considering PI-RADS scores ≥4 as suspicious for PCa, sensitivities per lesion were 72.4% with v1 and 63.8% with v2 (P = 0.426) for R1. The respective sensitivities for R2 were 77.6% (v1) and 69.0% (v2) (P = 0.402). Similarly, PPV per lesion appeared slightly higher with v2 for R1 (v1: 85.7% vs. v2: 88.1%; P = 0.767) and R2 (v1: 78.9% vs. v2: 80.0%; P = 1.000) (Fig. 2 and Table 3). Agreement between dominant (v2) and high-score (v1) sequence was 47.7% for R1 and 52.8% for R2. Fig. 3 shows an example for a mismatch between dominant and high-score sequence.

Zone-specific analysis also suggested differences in sensitivity and PPV, but again without statistical significance (see Table 3). Fig. 4 illustrates a sample case where a malignant lesion was classified differently between v1 and v2.

Considering high-grade cancers (Gleason score > 7a = 3 + 4) only, PI-RADS v1 showed a high sensitivity of 88.9% for R1 and R2. Both readers wrongly considered an 8-mm wide Gleason 8 = 4 + 4 cancer in the PZ to be unsuspicious. Under PI-RADS v2, sensitivities were 77.8% for R1 (missing one additional tumor) and 88.9% for R2–with differences insignificant. Similar results were obtained for low-grade cancers (Gleason score ≤ 7a = 3 + 4) (Table 3, P = 0.525 for R1 and P = 0.376 for R2).

Interobserver reliability for cancer detection was moderate for PI-RADS v1 and v2 (both $\kappa = 0.48$). The agreement between PI-RADS versions is classified as moderate for R1 ($\kappa = 0.56$) and substantial for R2 ($\kappa = 0.73$).

4. Discussion

Several individual studies as well as recent meta-analyses have generally shown a high diagnostic accuracy of PI-RADS v2 [18–21] in the detection of PCa. Various studies have also performed a direct comparison between PI-RADS v1 and v2 [5–13]. Whole-gland assessments have so far been inconsistent with the majority reporting a similar diagnostic accuracy for both versions [7,8,10,11] and others finding either v1 or v2 to be superior [5,6,9]. The pooled sensitivity of six individual studies was significantly higher for v2 [19]. Our study showed the diagnostic performances of PI-RADS v2 and v1 to be equivalent. In comparison, sensitivities of PI-RADS v2 for the whole gland appeared systematically lower, but differences were insignificant. The heterogeneity observed in the current literature can be explained by the differences in the respective incidence of PCa, in magnetic field strength and particularly in the reference standard. Only Auer et al. have deliberately used whole-mount histological workup for their comparison of PI-RADS versions [5]. Their readers, however, strictly applied only one PI-RADS version. In contrast with our findings, their AUC analysis of tumor detection in the whole gland showed v1 to be superior over v2.

In our zone-dependent subgroup analysis and in line with the results of Auer et al., sensitivities of PI-RADS v2 vs. v1 were seemingly lower in the TZ, but not significantly [5]. Both observations are in contrast to four other studies that have used MR-guided (3x) or TRUS guided biopsy (1x) as reference standard [6,9,11,12]. The respective authors instead highlight the diagnostic value of v2 in the TZ for the differentiation between PCa and benign lesions like, for example, stromal nodules. In our study, sensitivities in the PZ were similar for v1 and v2, in line with most other studies [5,6,9–11]. Only Polanec et al. and Auer

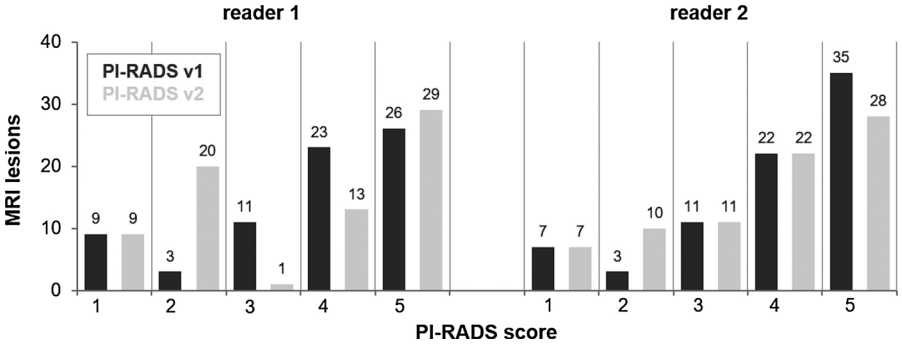

Fig. 1. Distribution of PI-RADS scores for both readers. Plot shows the number of PI-RADS scores for both PI-RADS v1 (black bars) and v2 (gray bars). R1 and R2 described 66 and 72 total lesions, respectively. Histologically confirmed PCa lesions missed on MRI but larger than 3 mm were included as virtual PI-RADS 1 lesions (six for each reader).

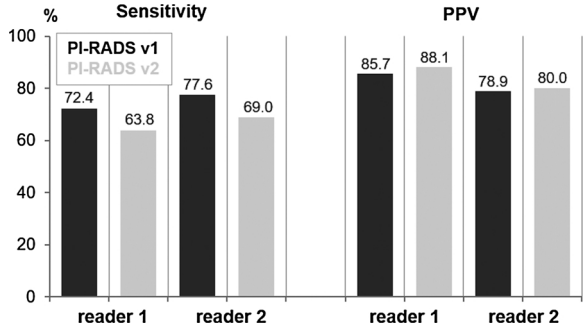

Fig. 2. Differences in sensitivity (left) and PPV (right) between PI-RADS v1 (black bars) and v2 (gray bars) for all prostate lesions and both readers. Analysis comprised 72 lesions for reader 1 and 78 lesions for reader 2. Percentages are statistically not different.

et al. have reported a significantly better PCa detection in the PZ with v1 [5,11].

The key sequence of PI-RADS v2 (T2w in TZ and DWI in PZ) matched the one with the highest v1 score in about half of the cases. This suggests that the other, "inferior" sequence may still have an impact on image interpretation and that the preference of a single sequence based on zonal location alone might be too simplistic.

An independent explanation for our ambivalent results might be the high percentage of low-grade cancers (85%) in our cohort, also when compared with other studies (33–57%) [9,11]. In that subgroup, sensitivities showed the largest, still non-significant differences between v2 and v1. In TZ whenever T2w findings were not conclusive for malignancy, for example, for mildly hypointense lesions with partially interrupted pseudo capsules, PI-RADS v2 ignored the potential of DWI. In our cohort, some low-grade TZ tumors appeared suspicious on DWI, but were missed due to an indifferent T2w appearance. A stronger weighting of DWI will likely refine the assessment of TZ findings but also needs to clarify the clinical impact of a discrimination between benign lesions and low-grade cancers.

Assessment of high-grade PCa lesions was generally consistent for both PI-RADS versions, in line with previous results [5,6]. Similar to the study of Auer et al., however, one reader missed one additional high-grade (Gleason 7b = 4 + 3) PCa lesion with PI-RADS v2 in PZ, where a focus with low ADC but isointensity on high-b-value DWI was scored as 2 in PI-RADS v2, but 4 in v1. This observation underlines the impact of

Table 3
Sensitivity and Positive Predictive Value (PPV) of PI-RADS v1 and v2 for two readers.

Lesions	reader 1			reader 2		
	PI-RADS v1	PI-RADS v2	P	PI-RADS v1	PI-RADS v2	P
All	72			78		
PIRADS ≥4	49 (68.1%)	42 (58.0%)		57 (73.1%)	50 (64.1%)	
Sensitivity	72.4%	63.8%	0.426	77.6%	69.0%	0.402
PPV	85.7%	88.1%	0.767	78.9%	80.0%	1.0
Zonal						
Peripheral zone	42 (58.3%)			45 (57.7%)		
PIRADS ≥4	30 (71.4%)	30 (71.4%)		30 (66.7%)	28 (62.2%)	
Sensitivity	71.1%	68.4%	1.0	73.7%	68.4%	0.801
PPV	90.0%	86.7%	1.0	93.3%	92.9%	1.0
Transition zone	25 (34.7 %)			31 (39.7%)		
PIRADS ≥4	17 (68.0%)	10 (40.0%)		24 (80.0%)	21 (70.0%)	
Sensitivity	73.7%	52.6%	0.313	83.3%	72.2%	0.691
PPV	82.4%	100.0%	0.274	62.5%	61.9%	1.0
Histopathological			58			
hgPCA			9 (15.5%)			
Sensitivity	88.9%	77.8%	1.0	88.9%	88.9%	1.0
lgPCA			49 (84.5%)			
Sensitivity	69.4%	61.2%	0.525	75.5%	65.3%	0.376
Peripheral zone			31 (63.3 %)			
Sensitivity	67.7%	67.7%	1.0	71.0%	64.5%	0.786
Transition zone			16 (32.7 %)			
Sensitivity	75.0%	50.0%	0.273	81.3%	68.8%	0.685

Results are reported for all cancer-suspicious lesions with PI-RADS ≥ 4 and differentiated for zonal location (whole gland, PZ and TZ) and grade type (low and high). Sub-group analyses into PZ and TZ were only feasible (sufficient number of lesions) for low-grade cancers and sensitivity. Percentages refer to the sum of all MRI-detected lesions of any size and all MRI-missed, histologically confirmed ones larger than 3 mm for each reader (66 + 6 for R1 and 72 + 6 for R2). Not listed are two lesions in the seminal vesicles and one in the anterior stroma for both readers. P-values (P) are given as a measure of statistical significance for the difference between sensitivity and PPV values for both readers.

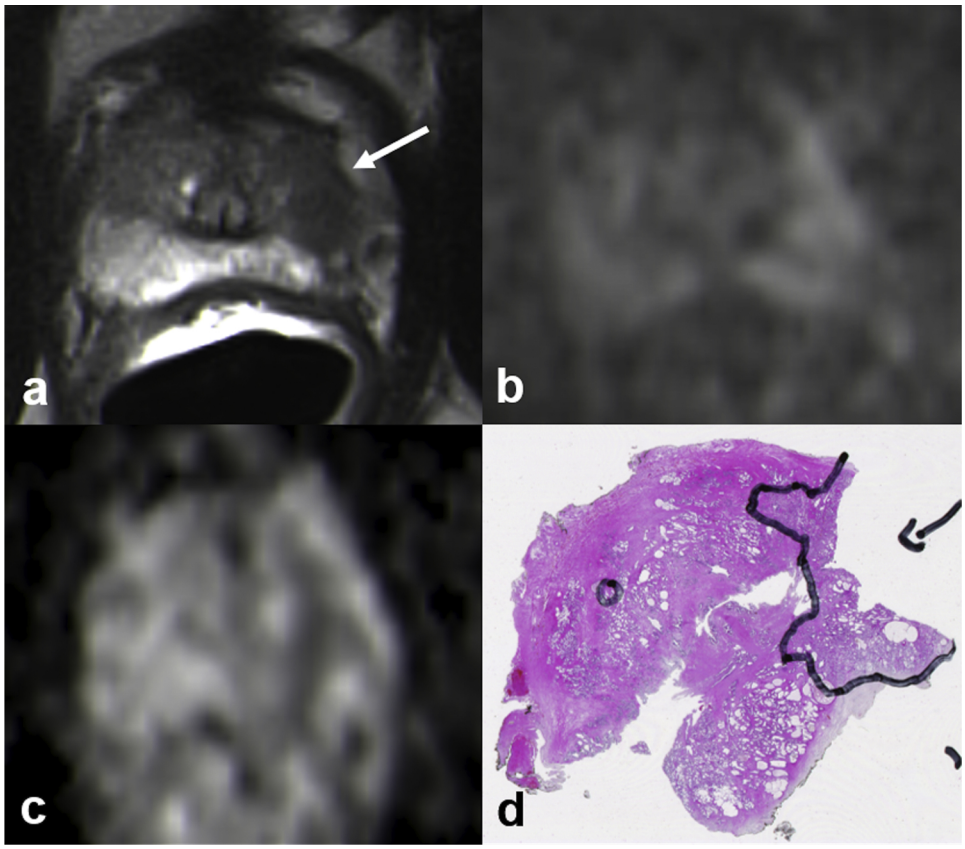

Fig. 3. Multiparametric MRI of a 66-year-old patient with Gleason score 7a = 3 + 4 PCa in the left PZ. (a) T2-weighted image shows homogeneous, hypointense lesion in the apical, anterior PZ (white arrow) with partially blurred margins, highly suspicious for PCa. Transverse (b) DW images at b = 1500 s/mm^2 and (c) the corresponding ADC map fail to show a clear, focal diffusion restriction (instead, only diffuse hyperintensity on DWI and no focal signal loss on ADC). This results in an underestimation of the tumor outlined in the step section of the prostatectomy specimen (d, hematoxylin-eosin staining). Consideration of T2w information might have helped to raise PCa suspicion.

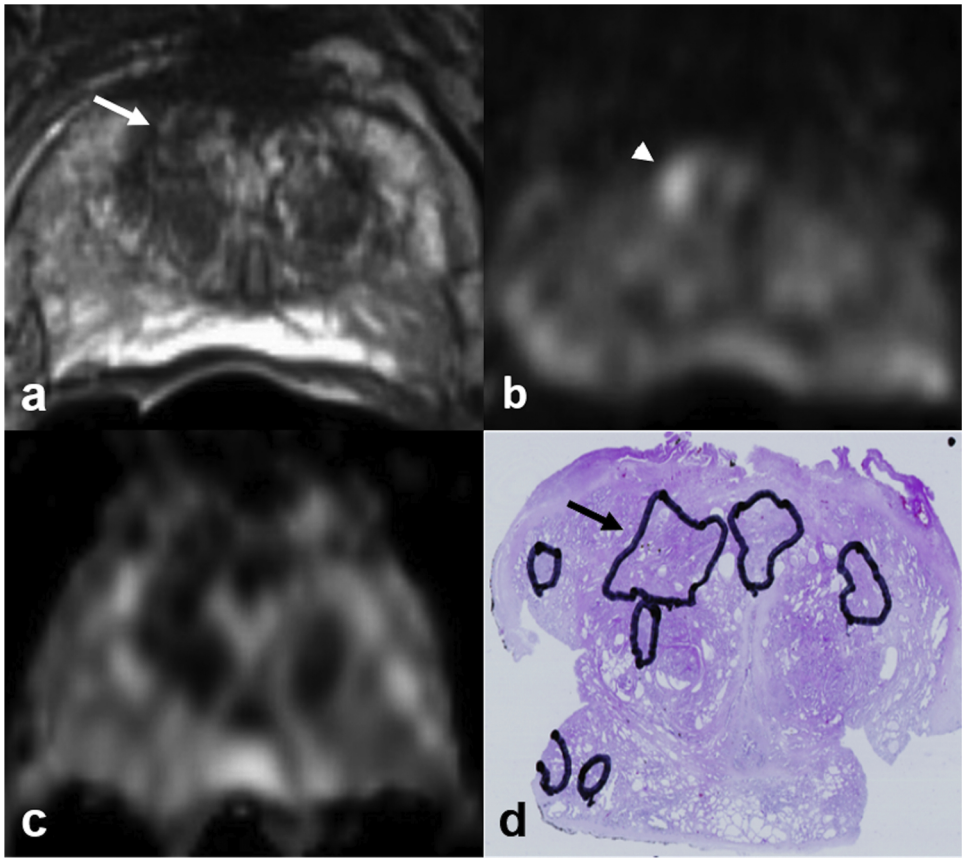

Fig. 4. MR images of a 64-year-old patient with Gleason score 6 = 3 + 3 PCa in the TZ (segment 3a/TZa). (a) Transverse T2-weighted image shows heterogeneous, encapsulated hypointensity in right anterior TZ (white arrow). Transverse (b) high-b-value DWI with focal hyperintensity (arrowhead) and (c) low values on the corresponding ADC map. Ratings with v1 were 2 for T2w, 5 for DWI and 5 overall. PI-RADS ratings with v2 were 2 for T2w, 4 for DWI and 2 overall due to T2w dominating overall PI-RADS assignment in the TZ. (d) Corresponding histopathological step section with tumor foci outlined (arrow marks cancer-suspicious MRI focus).

the exact DWI criteria on overall assessment.

Interobserver agreement for cancer detection has typically been good in previous studies, for example 0.71 per quadrant by Becker et al. [8], but was only moderate here (κ = 0.48 for both versions). This might be explained by our study design, which is characterized by a free definition of potential foci, similar to routine diagnostics, rather than the assessment of preselected lesions.

Our study is primarily limited by the retrospective design and the moderate number of PCa lesions. In some cases, the time gap between biopsy and MRI was small due to surgical scheduling. Still, hemorrhage was only apparent in one case and was not considered to negatively affect image quality. The deliberate use of PCa-positive cases only (blinded) restricts statistical analysis to sensitivity and positive predictive value.

It is widely accepted that mpMRI misses a considerable amount of prostate cancers, especially of small size [22]. In comparison with other studies [23] our cutoff diameter of 3 mm belongs to the smaller ones and may have affected overall sensitivity. Furthermore, many other studies with MR or TRUS biopsies as a reference might be partially biased towards a higher sensitivity because these biopsies are typically performed in lesions that were already identified by MRI. Although the analysis of whole-mount sections is generally considered to be more reliable than that of biopsy samples, radiological-pathological correlation is sometimes complicated by mechanical slicing or chemical fixation issues [24]. Moreover, pathological reading is also known to be slightly subjective [25].

5. Conclusions

Our findings indicate that the simplified, zone-specific approach of PI-RADS v2 (2015) for MRI assessment of prostate cancer is equally sensitive as the original v1 (2012). The apparent systematic trend towards lower sensitivities with v2, particularly for low-grade cancers and in the TZ, however, was not statistically significant. The leading v2 sequence had the highest v1 score in about half of the cases only. Although this finding might be specific to our analysis, there seems to be a need to reconsider some of the PI-RADS v2 criteria to further improve its already high performance.

Conflict of interest

H.B. has received a speaker honorarium from Siemens Healthcare. All other authors of this manuscript declare no relevant conflicts of interest, and no relationships with any companies, whose products or services may be related to the subject matter of the article.

Funding/disclosures

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Acknowledgement

None.

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