

REVIEW ARTICLE

Structured reporting for magnetic resonance imaging of the prostate using PI-RADS 2.1

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ABSTRACT

Clinical/methodological problem: The identification of clinically significant prostate carcinomas while avoiding overdiagnosis of low-malignant tumors is a challenge in routine clinical practice. **Standard radiologic procedures:** Multiparametric magnetic resonance imaging (MRI) of the prostate acquired and interpreted according to PI-RADS (Prostate Imaging Reporting and Data System Guidelines) is accepted as a clinical standard among urologists and radiologists. **Methodological innovations:** The PI-RADS guidelines have been newly updated to version 2.1 and, in addition to more precise technical requirements, include individual changes in lesion assessment. **Performance:** The PI-RADS guidelines have become crucial in the standardization of multiparametric MRI of the prostate and provide templates for structured reporting, facilitating communication with the referring physician. **Evaluation:** The guidelines, now updated to version 2.1, represent a refinement of the widely used version 2.0. Many aspects of reporting have been clarified, but some previously known limitations remain and require further improvement of the guidelines in future versions.

Keywords: Prostate Carcinoma; Multiparametric Magnetic Resonance Imaging; Prostate Aspecific Antigen; Transitional Zone; Scoring System

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1. Introduction

In recent years, multiparametric magnetic resonance imaging (mpMRI) of the prostate for the detection of suspicious foci has become the clinical standard in the evaluation of patients with suspected prostate cancer^[1]. The previously valid guideline PI-RADS 2.0^[2] was revised in 2019 to eliminate ambiguities that had become known in the meantime. The resulting PI-RADS guideline version 2.1 presented here thus represents the currently valid basis for the reporting of mpMRI^[3].

2. Origin and significance of PI-RADS

In prostate diagnostics, the focus is on the detection of clinically significant tumors, i.e., prostate carcinomas that show an ISUP grade ≥ 2 according to PI-RADS 2.0, a tumor size ≥ 0.5 ml, and/or extraprostatic spread and that can be expected to have an influence on the patient's further survival^[2]. Several large prospective clinical studies have demonstrated the value of prebioptic MRI. This can represent a higher detection rate of clinically significant tumors without, however, the number of low-malignant tumors increasing detected. In addition, prebioptic mpMRI of the prostate leads to a lower number of necessary biopsy punctures^[4-6]. These advantages of targeted prostate biopsy,

for which the visualization of suspicious lesions by mpMRI is a necessary condition. So, prostate mpMRI therefore has been included in German, European, and American urology guidelines^[7-9].

The PI-RADS acquisition, interpretation, and reporting guidelines was introduced in 2012 and revised in 2015 and 2019, which contributed significantly to the acceptance and success of prostate MRI and have been validated by both radiological and urological experts^[10].

The last iteration of the guidelines took place in 2019 with the update of the version PI-RADS 2.0^[2] published in 2016 to version 2.1^[3]. In addition to clarifying individual technical requirements for the examination technique, the new version was primarily intended to reduce inconsistencies in the assignment of scores and thus to improve the reproducibility of the findings. At the same time, it should reduce the number of clinically difficult indeterminate lesions^[11].

This article presents the most important changes made by PIRADS 2.1 and the literature published to date on the validation of this scoring system and highlights other issues and problems. For information on the basic reporting of multiparametric prostate MRI, please refer to reviews previously published in this journal^[12,13].

3. PI-RADS 2.1 guidelines

Compared to the changes associated with the change from version 1.0 to version 2.0, the adaptations in version 2.1 are significantly smaller and, in addition to individual changes regarding recommendations for technical implementation, primarily concern clarifications in the characterization of individual lesions, particularly in the transitional zone (TZ), the central zone (CZ) and in the anterior fibromuscular stroma (AFMS). The basic procedure for reporting an mpMRI remains unchanged, and the sequence considered dominant for the respective zone is also retained. Currently, mpMRI with T2-weighted, diffusion-weighted (DWI) and dynamic contrast-enhanced (DCE) sequences continues to be recommended. Although due to the increasing number of examinations, a bi-parametric approach without contrast is gaining popularity, at least in specialized centers, especially under active

surveillance.

4. Technical adjustments in image acquisition

In PI-RADS 2.1, individual clarifications and modifications of the recommended minimum technical requirements for the examination procedure were made.

Typically, high-resolution T2-weighted turbo spinecho sequences are acquired in axial (either tilted along the longitudinal axis of the prostate or strictly axial), coronal and sagittal slices to examine the prostate. In version 2.1, it was specified that at least one axial and one additional sagittal or coronal sequence must be acquired. However, the acquisition of T2-weighted sequences in all 3 planes is still recommended, especially for the evaluation of lesions in the transitional zone.

In PI-RADS 2.0, the use of a low b value >0 s/mm² (e.g., 50–100 s/mm²) was preferred for acquisition of DWI sequences to minimize the influence of perfusion effects at low b values. In version 2.1, this has been taken further, and acquisition of a low b value of 0–100 s/mm² and an intermediate b value of 800–1,000 s/mm² is now recommended. The high b-value ($\geq 1,400$ s/mm²), which is important for the evaluation, should either be acquired separately or calculated from the previous values via linear interpolation (so-called calculated or virtual high b-value).

With regard to DCE sequences, the technical requirements have been reduced in PIRADS 2.1, and a temporal resolution ≤ 15 s (previously ≤ 10 s, preferably < 7 s) and the use of 3D gradient echo sequences are now preferred—both of which allow higher local resolution and thus better delineation of lesions. The DCE sequence should cover a period of at least 2 min after contrast administration.

5. Changes in the diagnostic criteria for focal lesions

In order to improve the reproducibility between different diagnosticians, individual formulations have been made more precise in the new version of the PI-RADS guideline. At the same time, lesions of the central zone and the anterior fibro-

muscular stroma are included for the first time, although without specific evaluation criteria.

In the transitional zone, all focal lesions that show either direct criteria of malignancy or a signal behavior that clearly deviates from the surrounding area should receive a score. Here, all typical nodules of benign prostatic hyperplasia (BPH) have recently been assigned to PI-RADS category 1 (formerly 2) and should no longer be reported separately. A typical BPH nodules with a PI-RADS score of 2 now include an almost completely sharp-bordered nodule, a homo-generic circumscribed nodule without a sharp T2w hypointense border, and a homogeneous low-grade T2w hypointense area between 2 nodules (**Figure 1**). These lesions can now receive a PI-RADS score of 3 with clear Diffusion restriction (DWI score ≥ 4). The potential upgrade of PI-RADS-3 lesions (on T2-weighted sequences) in the transitional zone at a DWI score of 5 to a total score of 4 remains unchanged.

In the assessment of lesions in diffusion imag-

ing in both the peripheral zone (PZ) and the TZ, individual ambiguities were also resolved: linear or wedge-shaped lesions that are hypointense in the ADC and/or hyperintense in the high b-value image receive a score of 2 (**Figure 2**). Focal hypointensities in the ADC and/or focal hyperintensities in the high b-value image (as long as they are not yet assessed as “markedly diffusion-restricted”), as well as lesions that are markedly hypointense in the ADC or markedly hyperintense in the high b-value image (**Figure 3**), are all assigned a DWI score of 3.

Regarding the assessment of DCE sequences, the statement on negative contrast uptake has been added. All lesions that show either no early contrast uptake or a diffuse multifocal contrast uptake that does not correspond to a focal lesion on the other sequences are now designated as negative.

The CZ extends symmetrically on both sides from the vas deferens at the base of the prostate to the verumontanum and is best delineated on coronary T2-weighted sequences. Tumors of the CZ are

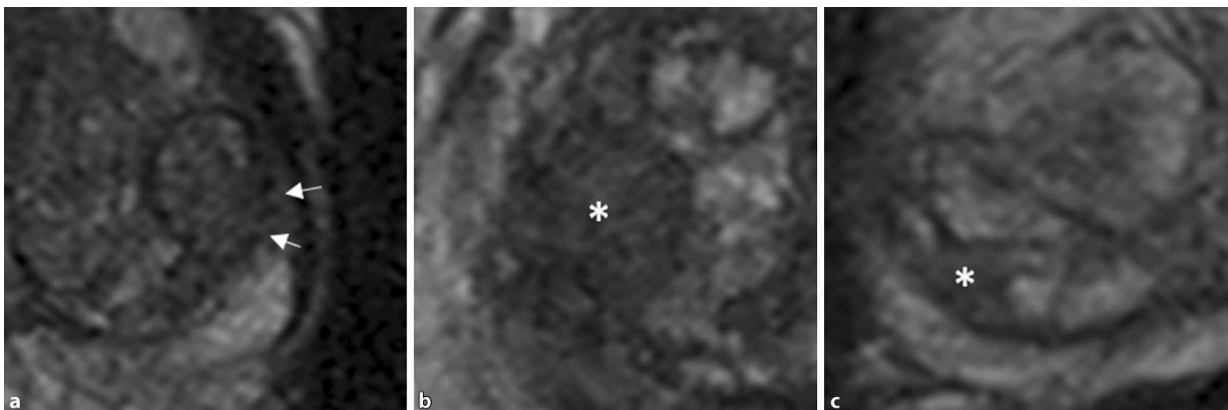


Figure 1. A typical nodules of benign prostatic hyperplasia (BPH) with a PI-RADS score of 2. **a.** Fast complete (arrow) sharp bordered nodules. **b.** Homogeneously rewritten nodules (asterisk) without sharp, T2w-hypointenseborder. **c.** T2w-hypointense area (asterisk) between 2 BPH nodules.

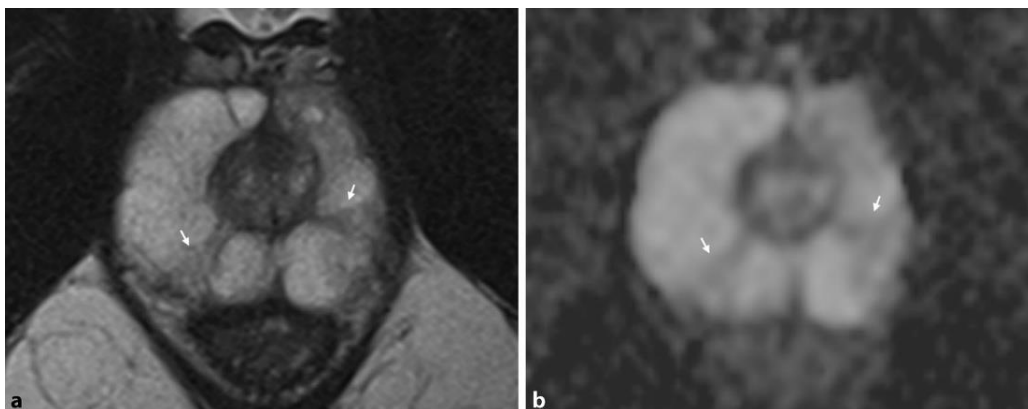


Figure 2. Linear and wedge-shaped lesions with hypoin intensity on the T2-weighted sequences (**a**) and in ADC (**b**) and a PI-RADS score of 2 according to version 2.1.

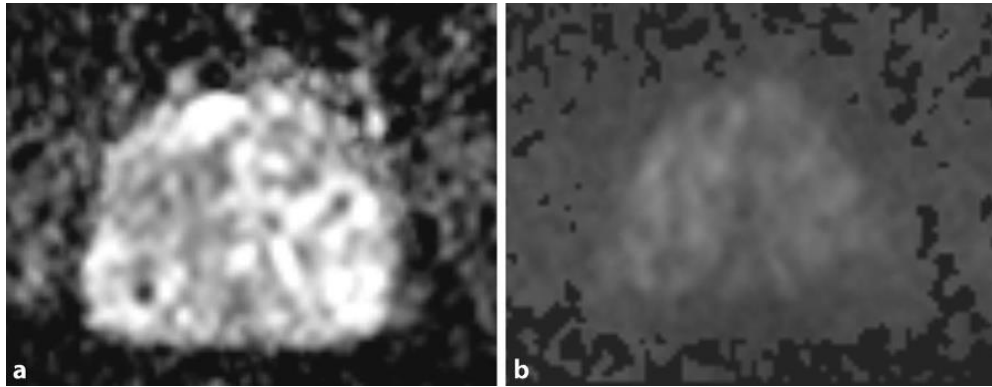


Figure 3. Diffusion-weighted (DWI) score of 3 according to PIRADS 2.1. Pronounced hypointense lesion in ADC (a) at near iso-intensity in high b-value image (b), calculated b-value: 1,400 s/mm².

very rare—most often, infiltration of the central zone occurs from tumors that have arisen in adjacent tissue. However, because the tissue signal of the CZ is hypointense in T2w and ADC even in healthy individuals, tumors in this area are often difficult to detect. Asymmetry in T2-weighted sequences, in diffusion imaging, or after contrast administration is considered a diagnostic criterion. However, there are also norm variants with asymmetry to one side, which complicates the diagnosis.

The anterior fibromuscular stroma may also be infiltrated by adjacent tumors, particularly in the transitional zone—the rule here is to base findings on the zone of presumed origin of the tumor.

Regarding the calculation of prostate volume, it was specified that anterior-posterior and longitudinal extent should be determined on a sagittal T2-weighted sequence, and transverse extent on an axial T2-weighted sequence.

On the sector map, which previously contained 36 zones for the prostate, two for the seminal vesicles, and one for the membranous urethra, two new zones were added in the basal medial prostate.

6. Structured reporting

Structured reporting of prostate MRI is one of the most important ways of improving consistency and comparability of findings and facilitates communication with referring physicians^[14,15]. Version 2.1 of the PI-RADS Guidelines^[3] contains a structured report template in appendix, and most centres use this form or a slightly modified form. The following points are of particular importance and should be part of the structured report:

Clinical information and indication: Last PSA

value, previous biopsies or therapies (radiation, androgen deprivation therapy), digital rectal examination due, etc.

Technique: statement on PI-RADS compatibility, field strength, coil selection, contrast agent administration, and sequence selection.

Prostate:

- Size (L × W × H) and volume, PSA density
- Image quality statement
- Hemorrhagic prostatic lesions

Lesions: Each lesion separately (max. 4 lesions), starting with the lesion with the highest PI-RADS score.

- Location (sector card and serial/image number, if applicable)
- Size of the lesion
- Signal behavior in T2w, DWI and DCE
- Contact to the prostate rim

Staging/overlying pelvis:

- Extraprostatic spread
- Distance to or infiltration of the neurovascular bundle (for PI-RADS 4/5).
- Infiltration of the seminal vesicles
- Lymph node or bone metastases

Overall assessment: for the remaining free text fields, the PI-RADS 2.1 guidelines offer a separate index, so that the variability between individual diagnosticians should also be kept as low as possible. The sector map of the prostate according to version 2.1 is also integrated into many report templates—the marking of the lesions facilitates the correct identification of the described lesions for the biopsy colleagues (**Figure 4**). Several software products from different manufacturers are now available to support the preparation of reports, facilitating the simple and graphically appealing crea-

tion of a structured report.

7. Validation of changes through PI-RADS 2.1 to date

The results of studies to date on the impact of changes in PI-RADS 2.1 compared with 2.0 on the accuracy of detection of clinically significant carcinomas and reproducibility between different investigators are partly contradictory. While some studies report slightly increased accuracy or slightly improved reproducibility at least for transitional zone lesions^[16-21], other studies show virtually no difference in tumor detectability between the two scoring systems^[22-25]. This is presumably due to the small number of transitional zone lesions that

have been upgraded in clinical routine by version 2.1—whereas the overwhelming majority, especially of lesions with clinically significant carcinomas, were already correctly categorized in version 2.0. Therefore, the impact of the new version 2.1 on the clinical management of patients is considered to be low^[24], and only larger prospective studies will probably allow a definitive statement to be made in this regard. Also, the changes made to classify lesions in the peripheral zone (e.g., the definition of linear diffusion restrictions as PI-RADS 2) seem to result in a downgrading from PI-RADS 3 to PI-RADS 2 only very rarely^[24]. The estimation of prostate volume seems to be slightly more accurate in PI-RADS 2.0 than in version 2.1^[26].

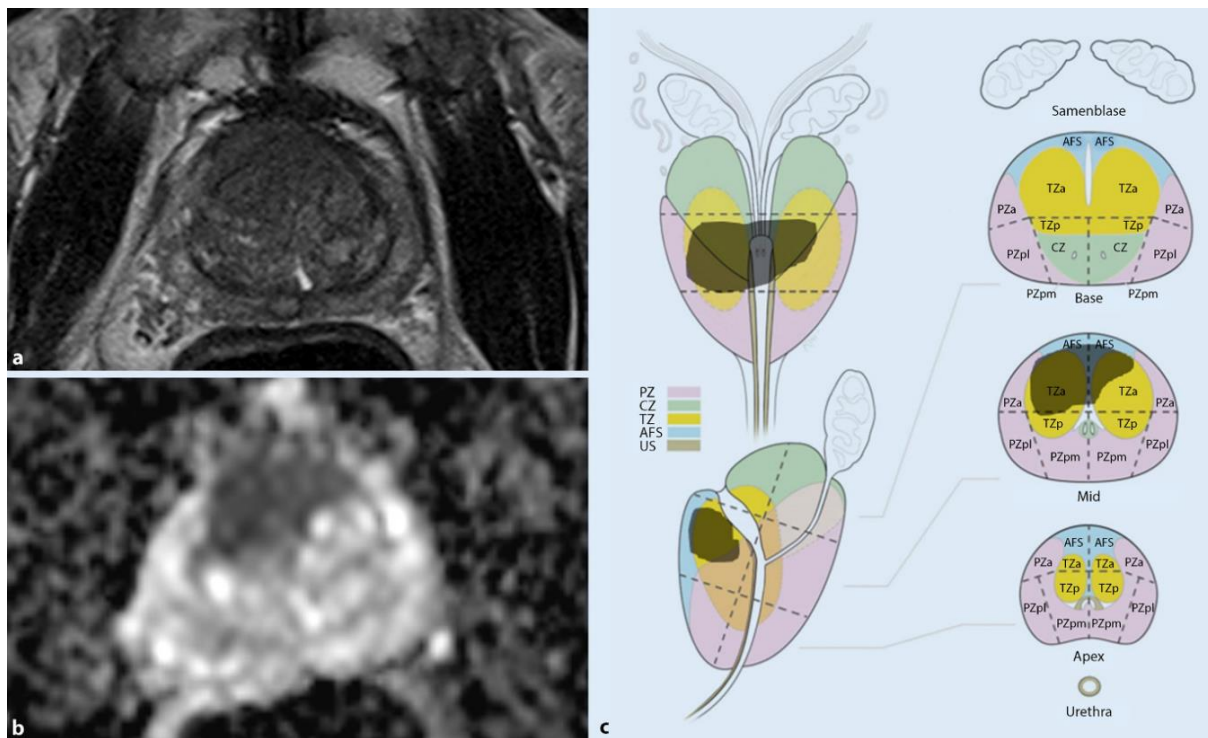


Figure 4. Example of structured findings of a prostate carcinoma (Gleason 4 + 4). Tumor-susceptible lesion in the anterior transitional zone on the T2-weighted sequence (a) and ADC map (b) and on the sector map included in the PI-RADS2.1 guidelines (c). PZ peripheral zone, CZ central zone, TZ transitional zone, US urethral sphincter, AFS anterior fibromuscular stroma.

8. Limitations of the current PI RADS guidelines

Version 2.1 of the PI-RADS guidelines is a refinement of the existing guidelines in version 2.0. The changes made are therefore comparatively minor, and individual points of criticism and inconsistencies of previous versions have been addressed, but known limitations of PI-RADS still remain.

Although the structured reporting template requires the last PSA value and, if applicable, the PSA density, clinical information currently has no influence on the reporting or the assignment of scores to lesions. However, some publications report that the inclusion of PSA density can improve accuracy^[27,28] or personalize decisions regarding the need for biopsy^[29]. The PI-RADS guidelines do not yet contain any recommendations for the further therapy or diagnosis of patients (in contrast, for example, to the

guidelines for breast diagnostics, BI-RADS). However, proposals of the PI-RADS Steering Committee for the implementation of MRI in the evaluation of patients with suspected prostate cancer have already been published^[30], so that an incorporation in future versions is likely.

In most centers, not only PI-RADS 4 or 5 lesions but also in-determined lesions with a score of 3 are biopsied in order not to miss a clinically significant carcinoma. This is also due to the difficulty in assessing these PI-RADS 3 lesions, where the changes in PI-RADS 2.1, especially for lesions in the transitional zone, do not show a large effect on clinical management according to studies to date^[24]. In principle, the inclusion of quantitative parameters (e.g., the ADC value) could be helpful here and, in addition to better detection of higher-grade tumors, also enable a reduction in the variability between the individual investigators. For this, however, standardization of measurements between different institutions and devices is essential^[31,32]. For the threshold of 1.5 cm between a lesion with a score of 4 vs 5, only few data are available. This decision could also be improved by additional quantitative parameters^[33]. The potential added value of new sequences or analytical methods such as MR fingerprinting or radiomics has not yet been sufficiently clarified and is therefore not yet included in the current version of the guidelines.

Serial monitoring of progression as part of an active surveillance strategy will become increasingly important in the future, although the evaluation criteria have not yet been precisely defined. For example, the detection of tumor progression could be based on a size measurement on T2w sequences or possibly also on a decrease in the ADC value during progression (as an indication of a higher Gleason score)^[34]. Similar limits also exist for the assessment of recurrence after local therapy, and initial recommendations have recently been published^[35].

The image quality of the MRI sequences and the häufigen, mostly (post) inflammatory changes in the peripheral zone also have a major Einfluss on the detection of lesions^[36,37]-here, at the same, the current guidelines still lack an assessment that is as objective and reproducible as possible.

8.1 Conclusion for practice

The PI-RADS guidelines have been instrumental in the standardization and thus the dissemination and acceptance of multiparametric MRI of the prostate.

The guidelines, which have now been updated to version 2.1, represent an evolutionary refinement of the existing version 2.0, which is intended primarily to address technical requirements and reduce ambiguities and inaccuracies in the scoring system.

In addition to structured reporting and a standardized keyword index, these specifications should contribute to improved comparability between investigators and centers.

However, some limitations already known from version 2.0 remain and should be addressed in future versions.

Conflict of interest

The authors declared no conflict of interest.

Abbreviations

ADC: Apparent Diffusion Coefficient.

AFMS: Anterior fibromuscular stroma.

CZ: Central Zone.

DCE: Dynamic contrast-enhanced.

DWI: Diffusion weighted imaging.

ISUP: International Society of Urological Pathology.

mpMRT: Multiparametric MRT.

PZ: Peripheral zone.

PSA: Prostate specific antigen.

PI-RADS: Prostate Imaging Reporting and Data System.

TZ: Transitional zone.

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