



## Head-to-head comparison of PI-RADS v2 and PI-RADS v1

Stephan Polanec<sup>a</sup>, Thomas H. Helbich<sup>a,b</sup>, Hubert Bickel<sup>a</sup>, Katja Pinker-Domenig<sup>a</sup>,  
Dietmar Georg<sup>b,c</sup>, Shahrokh F. Shariat<sup>d</sup>, Wolfgang Aulitzky<sup>e</sup>, Martin Susani<sup>f</sup>,  
Pascal A. Baltzer<sup>a,b,\*</sup>

<sup>a</sup> Department of Biomedical Imaging and Image-guided Therapy, Division of Molecular and Gender Imaging, Medical University of Vienna (AKH), Waehringer-Guertel 18-20, A-1090 Wien, Austria

<sup>b</sup> Christian Doppler Laboratory for Medical Radiation Research for Radiation Oncology, Medical University Vienna (AKH), Waehringer-Guertel 18-20, A-1090 Wien, Austria

<sup>c</sup> Department of Radiation Oncology, Division of Medical Radiation Physics, Medical University of Vienna (AKH), Waehringer-Guertel 18-20, A-1090 Wien, Austria

<sup>d</sup> Department of Urology, Medical University of Vienna (AKH), Waehringer-Guertel 18-20, A-1090 Wien, Austria

<sup>e</sup> Department of Urology, Confraternität Vienna, Skodagasse 32, A-1080 Wien, Austria

<sup>f</sup> Clinical Institute of Pathology, Medical University of Vienna (AKH), Waehringer-Guertel 18-20, A-1090 Wien, Austria

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### ABSTRACT

**Purpose:** To compare the reproducibility and diagnostic performance of PI-RADS version 2 (v2) and version 1 (v1) for the diagnosis of prostate cancer (PCa) on multiparametric MRI.

**Methods:** This IRB-approved retrospective study included 65 consecutive biopsy-naïve or biopsy-negative patients suspicious for PCa (mean age: 65 years, mean PSA: 10.8 ng/ml) who were undergoing MR-guided biopsy after multiparametric 3T prostate MRI (T2w, DWI, DCE). Two independent readers ( $R_1$ ;  $R_2$ ) scored the prostate lesions according to the v2 score and the v1 sum score. Diagnostic measures (sensitivity, specificity, and area under the ROC-curve) were compared for all cases and stratified by location (transitional zone, TZ, peripheral zone, PZ). Inter-reader agreement was assessed by kappa statistics.

**Results:** Inter reader agreement for v2 and v1 was substantial to almost perfect (kappa v2: 0.71, v1: 0.81). Overall, sensitivity between both readers and methods did not differ ( $p > 0.05$ ). Overall specificity was higher using v1 compared to v2 ( $R_1$ :  $p = 0.0078$ ,  $R_2$ :  $p = 0.0313$ ). In the TZ, v2 showed a higher AUC (0.81–0.84) compared to v1 (AUC 0.77–0.78). Here, the sensitivity of v2 (87.5–100%) was higher than that of v1 (75%) while v2 specificity (50%–56.3%) was lower than that of v1 (68.8–75%). In the PZ, AUCs were higher using v1 (AUC 0.82–0.83) compared to v2 (AUC 0.61–0.63). The specificity for v1 was higher (43.8–62.3%) than that for v2 (12.5–18.8%) while both v2 and v1 achieved 100% sensitivity.

**Conclusion:** PI-RADS v2 and v1 inter-reader agreement is excellent, but their diagnostic performance differs. While v2 appears to be the preferable method for the evaluation of TZ lesions, v1 performs better in the PZ.

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## 1. Introduction

With the rapid dissemination and establishment of multiparametric magnetic resonance imaging (MP-MRI) as the modality of choice for clinical staging of localized prostate cancer (PCa), the imaging community has recognized the need for a standardized way to report and assess lesion characteristics on MRI. In 2012,

the European Society of Urogenital Radiology (ESUR) published the first version of the Prostate Imaging Reporting and Data System (PI-RADS v1) as a guideline to standardize the evaluation and reporting of MP-MRI comprising T2-weighted (T2w), diffusion-weighted (DWI), and dynamic contrast-enhanced (DCE) sequences [1,2]. The PI-RADS v1 system was based on a five-point Likert scale that assigned an individual score to each of the MRI sequences. Several research groups have shown that a sum score from these three MRI sequences (v1) is a robust, valid, and reliable method with which to predict the presence of PCa on histopathology [3–7]. In 2015, the PI-RADS steering committee developed an updated version (PI-RADS v2) to overcome some of the limitations of PI-RADS v1 [8]. Essentially, this updated version takes the location

\* Corresponding author at: Department of Biomedical Imaging and Image-guided Therapy, Division of Molecular and Gender Imaging, Medical University of Vienna, General Hospital Vienna, Waehringer Gürtel, A-1090 Wien, Austria.

E-mail address: [pascal.baltzer@meduniwien.ac.at](mailto:pascal.baltzer@meduniwien.ac.at) (P.A. Baltzer).

and size of a lesion into consideration and offers a decision process that results in a final five-point score (v2). Empirical data on the diagnostic performance and assumed superiority of the PI-RADS v2 compared to PI-RADS v1 in the diagnosis of prostate cancer on MP-MRI is still quite limited. Consequently, the aim of our study was to compare the reproducibility and diagnostic performance of PI-RADS v2 and v1 for the diagnosis of PCa on MP-MRI.

## 2. Materials and methods

This retrospective, single-center, cross-sectional study was approved by the ethics committee of our university.

### 2.1. Patient selection

All biopsy-naïve patients and those with a prior negative transrectal ultrasound-guided biopsy of the prostate, with a clinical suspicion for PCa, and who were referred for MP-MRI between June 2011 and September 2015 at our institution, were considered eligible for this study. Patients with at least one PCa-suspicious lesion on MP-MRI were further evaluated with MR-guided biopsy (MRGB). To ensure an accurate reference standard for every evaluated lesion, the following exclusion criteria were applied: those with (i) a negative MP-MRI; (ii) those who underwent no MRGB for histopathological diagnosis (e.g., ultrasound-guided biopsy); and (iii) those who were lost to follow-up were excluded from the analysis. The algorithm of patient selection is displayed in Fig. 1.

### 2.2. MR imaging

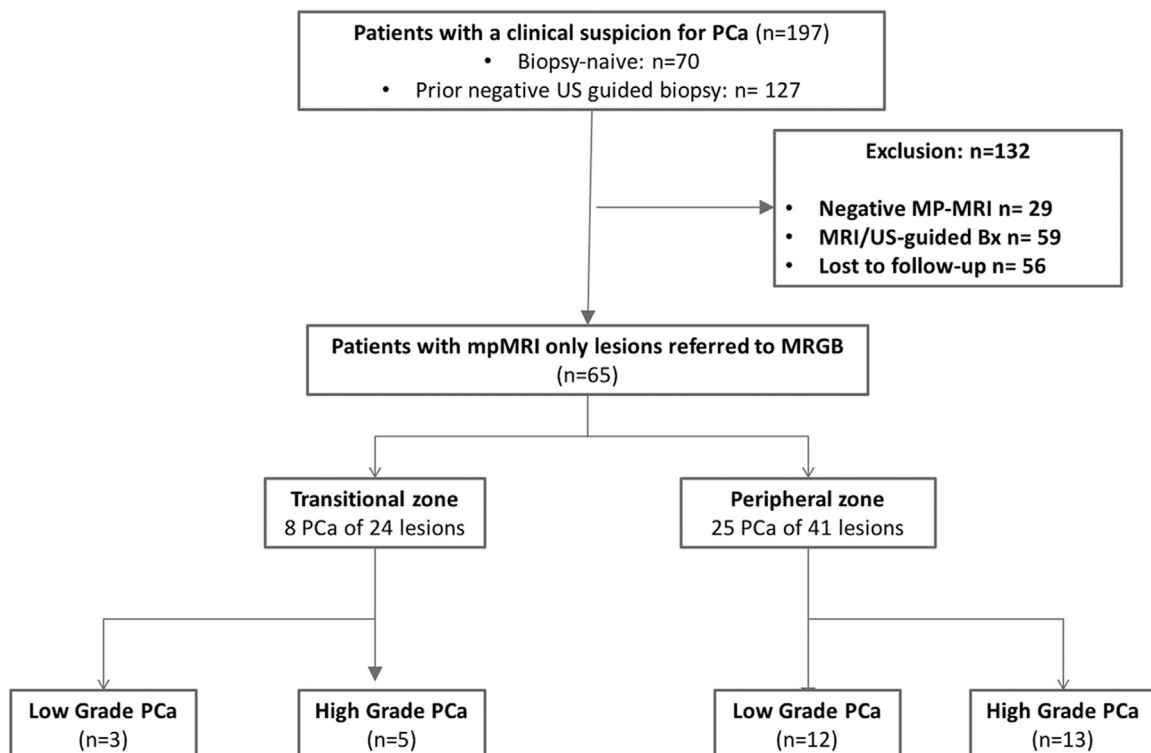
All MP-MRI examinations were performed using a vendor-supplied, combined spine array coil and a body array receive-only coil on a 3T MRI system (Tim Trio, Siemens Healthcare, Erlangen, Germany). No endorectal coil was used. After emptying the bladder,

the patients were positioned in a feet-first supine position. An anti-peristaltic agent (10 mg hyoscine butyl-bromide, Buscopan®, Boehringer Ingelheim GmbH, Germany) was injected i.m., and the rectum were filled with ultrasound gel (Ultraschall Gel, Gello GmbH, Germany).

The MP-MRI protocol included the following sequences:

- Anatomical T2w turbo spin echo in all three planes (TR/TE/TI 4000/101/230 ms; field of view (FOV) 200 mm; 20 slices at 3.0 mm; matrix 320; flip angle 150°; TA ≤ 4: 10 per plane, GRAPPA factor 2).
- Diffusion-weighted, single-shot, echo-planar imaging with inversion recovery fat suppression (DWI, TR/TE 3300/60 ms; spectrally adiabatic inversion recovery (SPAIR) fat suppression; FOV 260 mm; 20 slices at 3.6 mm; matrix 160; eight averages; b-values of 0, 100, 400 and 800 s/mm<sup>2</sup>; TA 4:34 min, GRAPPA factor 2).
- Contrast-Enhanced (DCE) MRI was acquired using a view-sharing, three-dimensional, T1-weighted gradient echo sequence (TWIST) (TR/TE 3.85/1.42; flip angle 12°; GRAPPA factor 2; 70 repetitions; TWIST k-space subsampling with central region A 30% and sampling density 25%, resulting in a temporal resolution of 4.22 s; FOV 260 mm; matrix 160). Gadoterate-meglumine (Gd-DOTA, Dotarem®, Guerbet, France) was injected intravenously after three baseline-scans as a bolus (0.2 ml/kg body weight) using a power injector at a flow rate of 4 ml/s, followed by a flush of 20 ml of saline solution.

In clinical routine reading, the diagnostic MP-MRI was interpreted in consensus by two of four radiologists using standard criteria [2,3,8–12] (cf. Fig. 2).



**Fig. 1.** Algorithm of patient selection.

Note: PCa—Prostate cancer; Bx—Biopsy; MP-MRI—multiparametric Magnet Resonance Imaging; MRGB—Magnetic resonance-guided biopsy; TRUS—Transrectal ultrasound.

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