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ORIGINAL ARTICLE

Comparison of multiparametric and biparametric MRI of the prostate: are gadolinium-based contrast agents needed for routine examinations?

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Abstract

Purpose To investigate, if and how omitting gadolinium-based contrast agents (GBCA) and dynamic contrast-enhanced imaging (DCE) influences diagnostic accuracy and tumor detection rates of prostate MRI.

Methods In this retrospective study, 236 patients were included. The results of biparametric (bpMRI) and multiparametric magnetic resonance imaging (mpMRI) were compared using the PI-RADS version 2 scoring system. The distribution of lesions to PIRADS score levels, tumor detection rates, diagnostic accuracy and RoC analysis were calculated and compared to the results of histopathological analysis or 5-year follow-up for benign findings.

Results Omitting DCE changed PI-RADS scores in 9.75% of patients, increasing the number of PI-RADS 3 scores by 8.89% when compared to mpMRI. No change of more than one score level was observed. BpMRI did not show significant differences in diagnostic accuracy or tumor detection rates. (AuC of 0.914 vs 0.917 in ROC analysis). Of 135 prostate carcinomas (PCa), 94.07% were scored identically, and 5.93% were downgraded only from PI-RADS 4 to PI-RADS 3 by bpMRI. All of them were low-grade PCa with Gleason Score 6 or 7a. No changes were observed for PCa ≥ 7b.

Conclusion Omitting DCE did not lead to significant differences in diagnostic accuracy or tumor detection rates when using the PI-RADS 2 scoring system. According to these data, it seems reasonable to use a biparametric approach for initial routine prostate MRI. This could decrease examination time and reduce costs without significantly lowering the diagnostic accuracy.

Keywords PI-RADS · Prostate cancer · Multiparametric MRI · Biparametric MRI · DCE · Contrast medium

Introduction

In 2012, the Prostate Imaging Reporting and Data System (PI-RADS) was introduced, providing standardization of performance, interpretation and reporting of multiparametric magnetic resonance imaging (mpMRI) of the prostate. MpMRI was defined as a combination of anatomical imaging with at least two functional modalities. Since then it included T2-weighted sequences (T2 W), diffusion-weighted imaging (DWI) and dynamic contrast-enhanced (DCE) MRI [1]. In 2015, PI-RADS was revised and version 2 (v2) was introduced. This simplified approach reduced the diagnostic relevance of DCE to a binary score, now being secondary to T2 W and DWI [2]. The authors stated that the value of DCE was not firmly established and that the added value to T2 W and DWI was modest [3].

From the very beginning the role of DCE for prostate imaging was discussed controversially: Some literature

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reported high sensitivities [4–8], stated that the addition of DCE can improve DWI scores [9], or even named DCE a cornerstone of prostatic MRI [10]. Other studies found that DCE played no, or only a minor role in the detection of prostate cancer (PCa) [11–15]. In line with that, recent studies proposed a "biparametric" MRI (bpMRI) without DCE for PI-RADS v2 [11, 12, 16–18]. Others found equal diagnostic accuracy for bpMRI and mpMRI in 542 men with PSA ≥ 3 after negative pre-biopsy [16]. Nevertheless mpMRI still is the gold standard for prostate imaging [3] and authors recently stated that further studies are necessary to assess if DCE can be omitted [17].

Besides that, the safety of gadolinium-based contrast agents (GBCA) was recently questioned, after it was shown that GBCA can form depositions in the brain [19]. Apart from safety issues, economic factors are becoming more important, as the demand for prostate MRI is rising while MRI capacities are limited and bpMRI could reduce examination time [11]. Moreover the cost of Gd-DO3A-butrol for the mpMRI of one patient with 70 kg was approximately 56 € in 2016 in Austria according to the official Austrian price list (taken from: Warenverzeichnis, Österreichische Apotheker-Verlagsgesellschaft m.b.H., Spitalgasse 31A, A-1090 Wien).

The aim of this study was to investigate, if and how omitting GBCA and DCE influences diagnostic accuracy and tumor detection rates of prostate MRI in men with cancer suspicion independent of PSA levels. We, therefore, compared the results of bpMRI and mpMRI in a cohort of 236 patients using the PI-RADS v2 scoring system.

Materials and methods

Patients

In the period of 2012–2017, 236 patients, who underwent mpMRI of the prostate because of tumor suspicion, were included in this retrospective study. Inclusion criteria were as follows: in this period at least one mpMRI had to be performed according to the technical requirements of PI-RADS v2. For verification of suspicious mpMRI results histological analysis after targeted biopsy and/or prostatectomy had to be available. In the case of benign results in mpMRI, histopathological verification after systematic re-biopsy or at least a ≥ 5-year follow-up had to be available. Examinations were selected using our institution's radiology information system and inclusion criteria were checked with our hospital information system.

Out of all 236 patients, histopathological analysis was available in 208 patients. In 159 patients, histopathology of suspicious lesions in mpMRI was obtained with MRI-ultrasound transrectal fusion biopsies consisting of 3–5 targeted cores and ten systematic biopsy cores. (Logic 9 ultrasound GPS®—GE Healthcare, Little Chalfont, UK and BiopSee® System—MedCom GmBH, Darmstadt, Germany). In 49 patients additional whole-mount step section slides after prostatectomy were available. Histopathological information about PCa grading and Gleason scores (GS) were then taken from whole-mount step section slides. Histopathological analysis was performed by a certified uropathologist. Pathology reporting and processing of specimens was performed in line with the recent European Association of Urology guidelines [20]. In 28 included patients with only benign mpMRI findings (PI-RADS scores 1 and 2) benignity could be confirmed by ≥ 5-year follow-up. Benignity was confirmed when the following criteria were fulfilled. Follow-up MRI after 5 years was available and still scored PI-RADS 1 or 2. No rise of PSA levels was observed after 5 years.

MRI examinations

MpMRI examinations were performed on either a 3-T MR scanner (Magnetom Skyra, Siemens AG, Erlangen, Germany) or a 1.5-T MR scanner (Optima MR450w, GE Healthcare, Little Chalfont, UK) using a 18-channel or a 16-channel phase-array body coil. Patients received 20 mg of Butylscopolamine (Buscopan®, Boehringer Ingelheim Pharma, Ingelheim, Germany) intravenously before the examination. All included mpMRI examinations were performed in accordance to the technical requirements of the PI-RADS v2 guidelines.

Examinations included T2 W, DWI, and DCE. T2 W turbo-spin/fast-spin echo sequences were acquired in axial plane with slice thickness 3 mm. Additionally a T2 W in coronal and sagittal plane was acquired. DWI used a single-shot spin-echo-planar sequence with 3 b-values (50, 400, 1000 s/mm^2 before 2014 and 50, 500, 1400 s/mm^2 after 2014), applying diffusion gradients in three orthogonal directions for each b-value. Apparent diffusion coefficient parameter maps were calculated using the standard mono-exponential model.

DCE was performed with a 3D volume-interpolated gradient echo sequence with temporal resolution of 7 s and duration of > 7 min. For contrast media, 0.1 ml/kg body weight of Gd-DO3A-butrol (Gadovist, Bayer Schering Pharma, Germany) was applied with a power injector (3T Tennessee, Ulrich, Germany). Perfusion curves were generated with the commercial available software TISSUE4D (Siemens AG, Erlangen, Germany) or with a GE AW-Server 3.2 (GE Healthcare, Little Chalfont, UK).

Image interpretation

Image interpretation was done by an experienced uro-radiologist, who retrospectively reviewed and classified all

MRI datasets. Initially, all MRI datasets were interpreted and classified with a biparametric diagnostic approach as a first step, therefore, only T2 W images and DWI were classified according to PI-RADS v2 whereas the DCE sequence was ignored. Only then the DCE was included and the whole mpMRI examination was re-classified according to PI-RADS v2 in a second step. These two steps were done within one session. (Rev. 2, comment 3). Using the biparametric approach lesions with DWI scores of 3 led to an overall PI-RADS 3 score when omitting DCE. Afterwards mpMRI datasets were again re-classified according to PI-RADS v1 in a second session after 1 month. Diagnostic accuracy and tumor detection rates of bpMRI and mpMRI were analyzed and compared.

Statistical analysis

The data are shown with absolute and relative numbers of distributions, the patient characteristics with means and standard deviations (SD) or median with interquartile range (IQR) as appropriate. To test for differences in dichotomized score values, Fisher's exact test was used, where two-sided values of $p < 0.05$ were considered as statistically significant. Receiver Operating Characteristic (ROC) analysis was performed to assess the discriminative value of distinguishing between benign and malignant lesions, measured with the area under the ROC curve (AUC) and the corresponding 95% confidence interval (CI). For documentation of measurements and statistical evaluation, Microsoft Excel® file (Microsoft; Redmond, WA, USA) was used. Additionally SPSS 19.0 and a web-based ROC calculator (Eng J. ROC analysis: web-based calculator for ROC curves. Baltimore: Johns Hopkins University [updated 2014 March 19]. Available from: http://www.jrocfit.org) were used for analysis.

Results

Patients

Patients' characteristics of 236 retrospectively included patients are summarized in Table 1. Histopathological analysis after MR-ultrasound fusion-targeted biopsy and prostatectomy revealed PCa in 135 (57.2%) of these patients. 46 (34.07%) of all PCa-positive lesions constituted high-grade PCa (defined as GS ≥ 7b), 89 (65.93%) low-grade PCa (defined as GS 6 or 7a). PCa could be excluded by histopathology in 73 (30.93%) patients and by follow-up for > 5 years in 28 (11.86%) patients.

Table 1 Patients' characteristics

All patients, *n*	236
Age (years), mean (SD)	67.6 (7.99)
Prostate volume (cm^3), median (IQR)	45 (15–190)
PSA (ng/mL), median (IQR)	6.4 (1.89–88.44)
Free PSA (%), median (IQR)	14 (4.2–42.3)
PCa-positive patients, *n* (%)	135 (57.20)
GS 6	43 (31.85)
GS 7a (3 + 4)	46 (34.07)
GS 7b (4 + 3)	16 (11.85)
GS 8	12 (8.89)
GS 9	18 (13.33)

PI-RADS scores of mpMRI with DCE and bpMRI without DCE

Table 2 shows the different results of all diagnostic approaches according to PI-RADS v2 with and without using DCE and according to PI-RADS v1.

Omitting DCE changed image interpretation and PI-RADS v2 scores in only 23 (9.75%) patients, when compared to mpMRI. Overall the biparametric approach without DCE led to an upgrade of score levels in 7 (2.97%) patients and to a downgrade in 16 (6.78%) patients. In detail, 6 patients were upgraded from PI-RADS 2–3, one patient was upgraded from PI-RADS 3–4 and 16 patients were downgraded from PI-RADS 4–3. No changes of 2 or more score levels were observed. Accordingly, the biparametric approach increased PI-RADS 3 scores by 8.89%.

Diagnostic accuracy

Omitting DCE did not lead to significant differences in diagnostic accuracy or tumor detection rates. It still showed a high discriminative ability of tumor detection with an AUC of 0.914 in ROC analysis, when compared to mpMRI with DCE (PI-RADS v2: AUC of 0.917, PI-RADS v1: AUC of 0.937) (Fig. 1).

The distribution of PCas on the different PI-RADS scores is shown in Table 3 for bpMRI without DCE and mpMRI with DCE: Of 135 PCas, 127 (94.07%) were scored identically. Only eight (5.93%) PCa lesions were downgraded from PI-RADS 4 to PI-RADS 3 when omitting DCE from PI-RADS v2 (Fig. 2). All of them were low-grade PCas (GS 6 or 7a) with a primary Gleason pattern of 3. No changes in PI-RADS scoring were observed for PCa with GS ≥ 7b. So when using mpMRI, 12 PCas were scored as PI-RADS 3 and 86 as PI-RADS 4 whereas with bpMRI 20 PCas were scored PI-RADS 3 and 78 as PI-RADS 4 ($p = 0.176$). The distribution of PCas regarding their GS is shown in Fig. 3.

Table 2 Distribution of all patients (*n*,%) per PI-RADS score level

Score	PI-RADS v1	%	PI-RADS v2	%	PI-RADS v2-DCE	%	Difference ∓ DCE	%
1	0	0	3	1.27	3	1.27		
2	44	18.64	44	18.64	38	16.1	− 6	− 2.54
3	64	27.12	48	20.34	69	29.24	+ 16 − 1 +6 = +21	+ 8.89
4	79	33.47	104	44.07	89	37.71	− 16 + 1 = − 15	− 6.36
5	49	20.76	37	15.68	37	15.68		
All	236	100	236	100	236	100	23	9.75

Comparison between PI-RADS version 1 (v1), PI-RADS version 2 (v2) and PI-RADS v2 without DCE

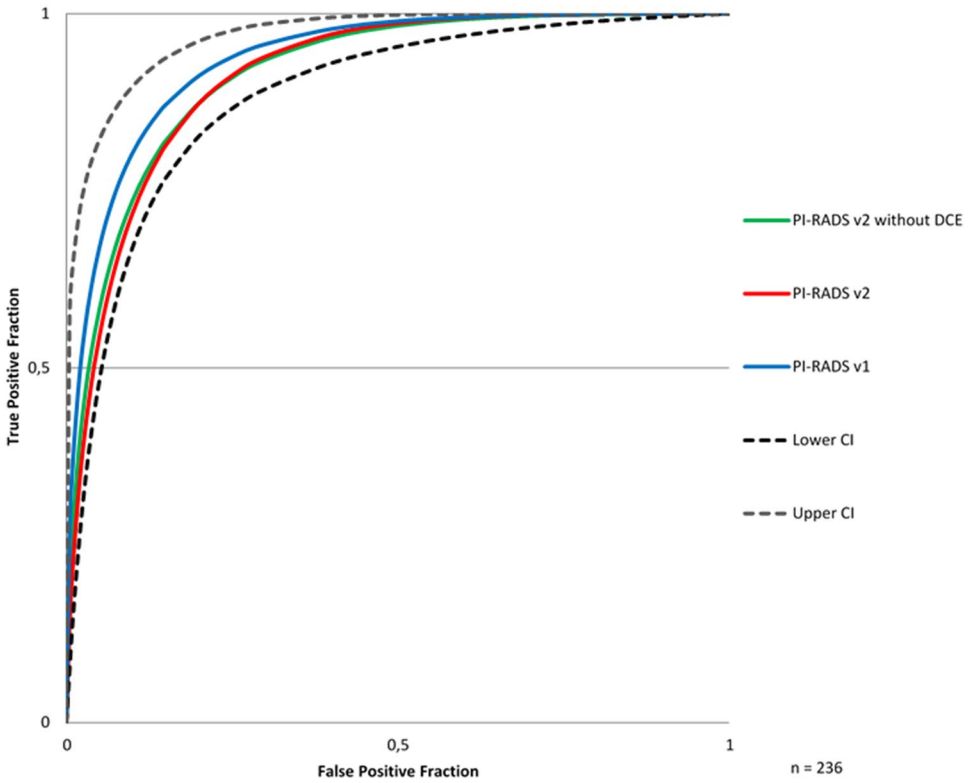

Fig. 1 ROC curves for PI-RADS version1, version 2 and PI-RADS version 2 without DCE including 95% confidence interval (CI) show no significant differences

Table 3 Distribution of all tumor lesions (*n*, %) on the different PI-RADS score levels

Score	PI-RADS v1	%	PI-RADS v2	%	PI-RADS v2-DCE	%	Difference ∓ DCE	%
1	0	0	0	0	0	0	–	
2	0	0	2	1.48	2	1.48	–	
3	22	16.30	12	8.89	20	14.81	8	5.93
4	64	47.41	86	63.70	78	57.78	– 8	– 5.93
5	49	36.30	35	25.93	35	25.93	–	
All	135	100	135	100	135	100	8	5.93

Comparison between PI-RADS version 1 (v1), PI-RADS version 2 (v2) and PI-RADS v2 without DCE

No PCa was downgraded from higher scores to score levels < 3. Therefore, no additional PCa was scored as benign or completely missed with the biparametric approach.

If a rating of PI-RADS 3-5 is considered positive for tumor suspicion, the biparametric approach without DCE showed a sensitivity of 98.5% and a specificity of 38.6%, PI-RADS v2 showed a sensitivity of 98.5% and a specificity of

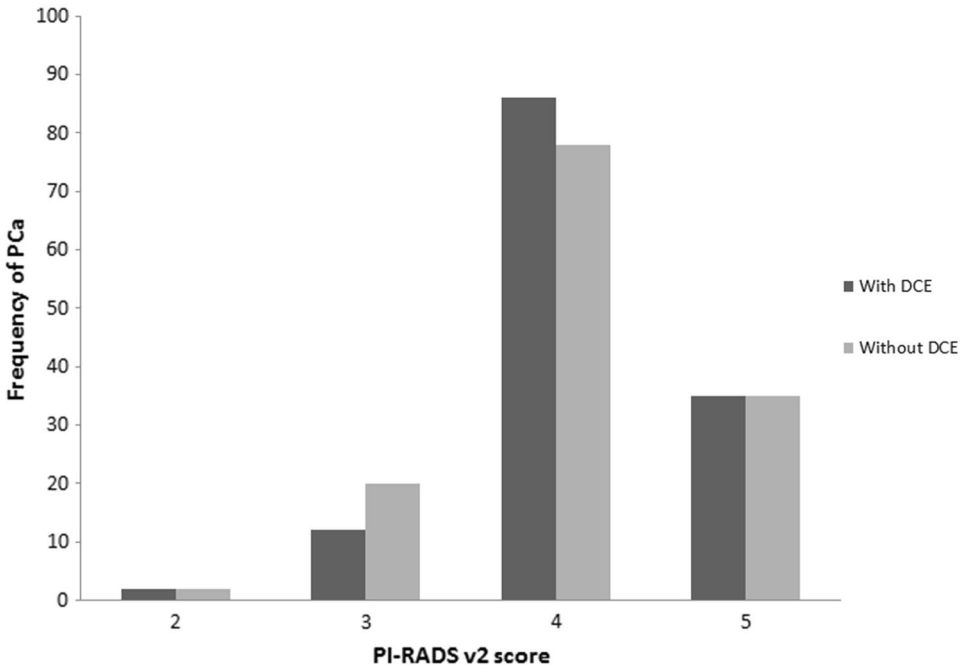

Fig. 2 Distribution of all tumor lesions per PI-RADS score level when comparing PI-RADS version 2 with and without dynamic contrast-enhanced imaging (DCE): note the downgrade of 8 prostate carcinomas (PCa) from PI-RADS 4 to PI-RADS 3 when omitting DCE

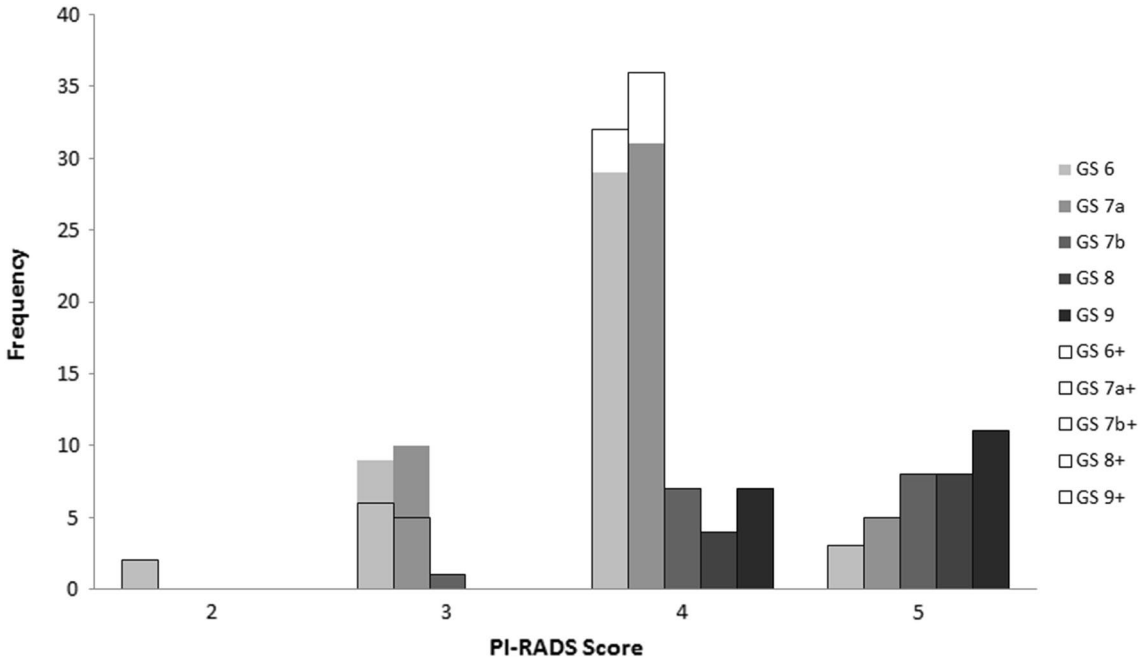

Fig. 3 Distribution of Gleason Scores (GS) per PI-RADS score level when comparing PI-RADS version 2 (v2) with dynamic contrast-enhanced imaging (empty columns, indicated by GS+) and without dynamic contrast-enhanced imaging (shaded columns): Only low-grade prostate carcinomas (PCa) are downgraded from PI-RADS 4 to PI-RADS 3

44.6% and PI-RADS v1 showed a sensitivity of 100% and a specificity of 43.6%. BpMRI led to 62 (61.4%) false-positive findings, PI-RADS v2–56 (55.4%) false-positive findings and PI-RADS v1–57 (56.4%) false-positive findings.

It is noticeable that more changes in tumor detection were observed between PI-RADS v1 and v2, than between PI-RADS v2 with DCE and PI-RADS v2 without DCE. Only PI-RADS v1 did not show any PCa in PI-RADS score levels < 3.

Irrespective of whether DCE was omitted or not, 2 PCas with GS 6 were scored benign (PI-RADS 2) and one PCa

with GS 7b was scored as indeterminate (PI-RADS 3) with PI-RADS v2.

All differences between bpMRI and mpMRI were independent of age or PSA levels.

Reduction of examination time and costs

Assuming that the marginal costs of Gd-DO3A-butrol for one mpMRI were 56 € on average (taken from: Warenverzeichnis, Österreichische Apotheker-Verlagsgesellschaft m.b.H., Spitalgasse 31A, A-1090 Wien), the variable costs for prostate imaging would have been reduced by approximately 13.216 € when omitting GBCA from mpMRI in our study population. In addition, bpMRI would have led to a time saving of approximated 12 min per patient: The acquisition time could have been reduced by approximately 7 min for DCE and approximately 5 min would have been spared for placing the peripheral venous catheter and obtaining informed and written consent. So when using bpMRI, three patients could have been examined in the time which was needed for two patients when using mpMRI according to our study protocol.

Discussion

The relevance of DCE for prostate MRI is discussed controversially. While some studies calculated sensitivities of 60–74% for DCE [4–8], or found that DCE improved the DWI scoring [9], others stated that DCE played no, or only a minor role for PCa detection [11–15, 18]. In 2011 it was published that T2 W and DWI alone had an even higher accuracy than T2 W and DCE or all three combined [21].

Recent studies focused on this biparametric approach to prostate MRI. In a study with 41 patients Scialpi et al. found no significant difference in PCa detection for bpMRI when compared to mpMRI [12]. In line with that, Stanzione et al. found a high AUC of 0.91 for bpMRI in a study group of 82 patients [11]. The main limitation of both studies was the small sample size. Another recent study with 542 patients found equal cancer detection rates for bpMRI compared with mpMRI. This is confirmed by our study. When comparing bpMRI with mpMRI, we found that 94.07% of PCa were scored identically, and only 5.93% of PCa were downgraded from PI-RADS 4 to PI-RADS 3 when omitting DCE (Fig. 4). All of these were low-grade PCa with primary Gleason Patterns of 3 (GS 6 or 7a). In other words, no high-grade PCa was downgraded or overseen by omitting DCE. In ROC curve analysis there was no significant difference regarding AUC and diagnostic accuracy.

Overall the main consequence of omitting DCE was a rising number of PI-RADS 3 scored lesions. This is due to the structure of PI-RADS v2: DCE is mainly used to further investigate inconclusive DWI results and thus can upgrade PI-RADS 3 to PI-RADS 4 [9]. This shift was also observed by a similar study by De Visschere et al. [18]. Additionally in six patients DCE helped identifying otherwise unclear calcified or fibrous tissue by their very low perfusion. Therefore, very few inconclusive results were upgraded from PI-RADS 2 to PI-RADS 3 when omitting DCE.

To deal with the risk of PCa in PI-RADS 3 scores, either follow-up MRI or initial biopsy may be appropriate [22]: Following the first approach, additional follow-up MRIs would have been performed in 5.93% of patients with low-grade tumors when omitting DCE. As to that, a previous study found no extracapsular tumor growth over a long period [23]. In the light of our results, it seems reasonable to perform such a follow-up with mpMRI in case of PI-RADS 3 at initial bpMRI. Following the second approach with initial biopsy of PI-RADS 3 lesions, the same number of biopsies would have been performed after bpMRI compared to mpMRI. To make this decision, the use of clinical parameters may improve the ability to better identify clinically significant disease among PI-RADS 3 lesions [24].

Only if PI-RADS 3 was considered a benign finding, bpMRI would lead to 5.93% false-negative results when compared to mpMRI in our study. This is in line with Scialpi et al. who reported 3.3% false-negative results [12] and Stanzione et al., who found two false-negative results in 29 patients for bpMRI when compared to mpMRI [11].

It is noticeable that in this study, most differences were found when comparing PI-RADS v1 with PI-RADS v2. This goes in line with other studies, which found that certain PCa might be missed when following the simplified decision tree of PI-RADS v2 [2, 25]. However, when following PI-RADS v2, our data show no further decrease of diagnostic accuracy when omitting DCE. This goes in line with a meta-analysis including data before 2013, which found that the biparametric approach might be sufficient for clinical practice [26].

Apart from diagnostic considerations there are other factors to be considered when deciding about the application of GBCA. The risk of immediate hypersensitivity reactions after GBCA is low [27], but placing a peripheral intravenous catheter is associated with discomfort and phlebitis rates up to 27 per 100 patients [28]. GBCA were considered to be safe until a few years ago [29], but this was recently questioned, after it was shown that GBCA can form depositions in the brain [19]. The International Society for Magnetic Resonance in Medicine (ISMRM) highlighted the incomplete understanding of this phenomenon and reminded to use caution when administering any GBCA [30]. Moreover, there are economic benefits of omitting the standard use of GBCA for prostate MRI: The price for 7 ml Gd-DO3A-butrol (70 kg patient weight) is approximately 56 € according to the official price list in Austria. Other studies published an additional cost of about 80 € for GBCA [10]. In

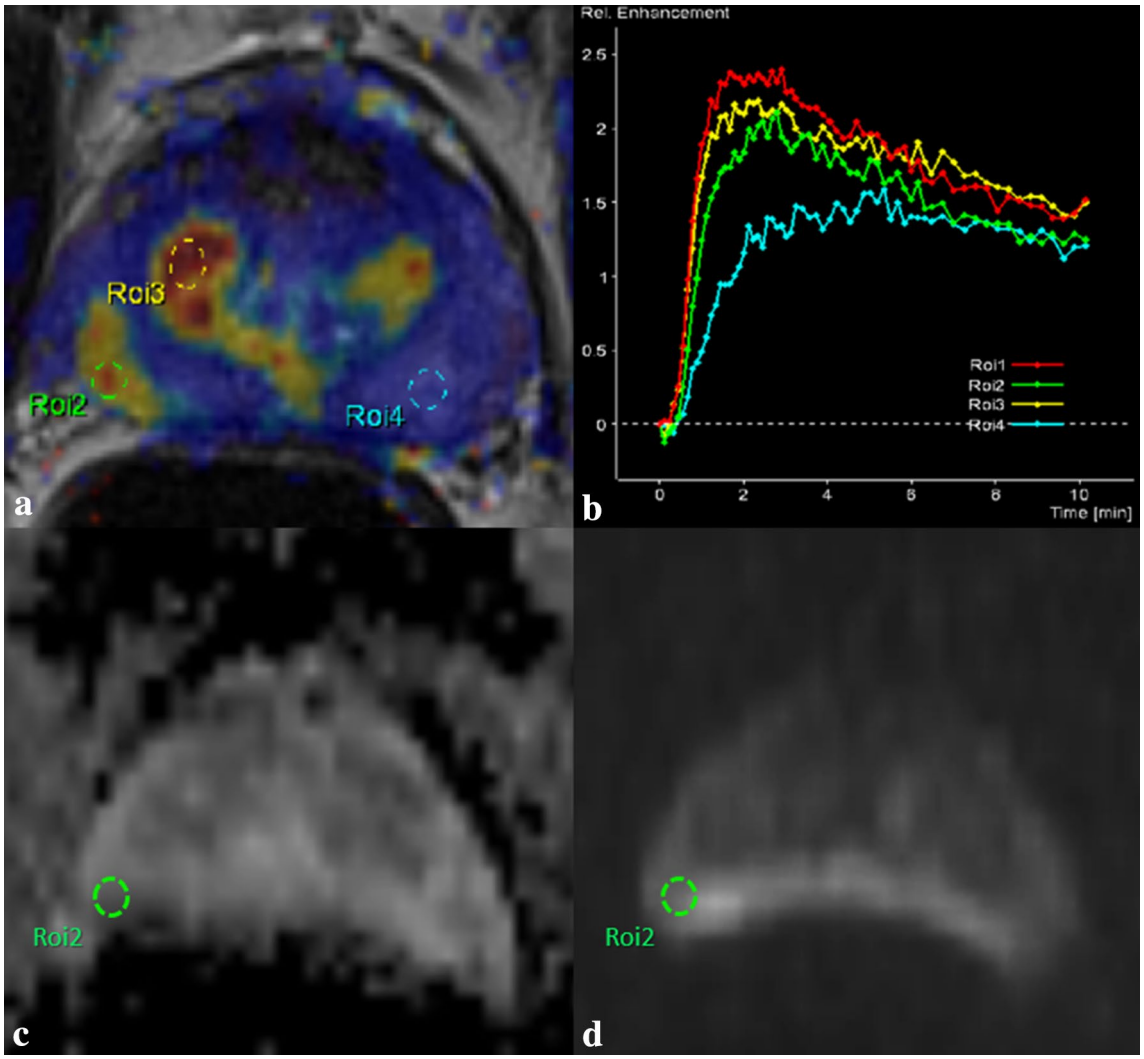

Fig. 4 Prostate Carcinoma, Gleason Score 7 (3+4) in the right peripheral zone of a 79-year-old patient: On dynamic contrast-enhanced imaging (**a**) and perfusion analysis (**b**) the carcinoma (Roi 2, green curve) is seen as a focal hyperperfusion with wash-out curve. Apparent diffusion coefficient maps (**c**) only show a slight geographical signal loss of this area and diffusion-weighted imaging (**d**) shows a diffuse hyperintensity in the whole peripheral zone. A clear focal diffusion restriction could not be diagnosed. Therefore, diffusion-weighted imaging was scored PI-RADS 3. Only with dynamic contrast-enhanced imaging, the carcinoma could be suspected (upgrade to PI-RADS 4)

view of a rising demand for prostate MRI and limited MRI capacities, examination time becomes an important factor. The acquisition time for DCE is ~ 7 min [11]; additionally about 5 min are needed for placing the peripheral venous catheter and obtaining informed and written consent for the administration of GBCA. Therefore, the total examination time of a prostate MRI could be reduced from 27 min to about 15 min by omitting DCE.

Our study has several limitations. It is a retrospective study and as such it is prone to the common types of bias which are associated with this kind of analysis. Patients with a PI-RADS score of 2 and 1 are underrepresented in this study, as they usually neither received a histologic work up nor a follow-up MRI. All patients, who were included, but did not undergo biopsy, were followed up for at least 5 years to confirm benign results. It has to be mentioned that patients were examined on 1.5 and 3.0 T scanners. We did not find any significant differences between 1.5 and 3 T examinations and all MRI protocols were performed according to PI-RADS v2 guidelines. This goes in line with a recent study showing similar diagnostic performances for 1.5 T and 3.0 T scanners [31]. Interpretation of bpMRI and mpMRI was done within one session without time gap (at first bpMRI with T2w and DWI was scored, then the DCE was additionally evaluated for mpMRI, as suggested in the ESUR guidelines PI-RADS v2).

In conclusion, omitting GBCA and DCE did not lead to significant differences in diagnostic accuracy or tumor

detection rates when using the PI-RADS 2 scoring system. According to these data, it seems reasonable to use a biparametric approach for initial routine prostate MRI. This could eliminate potential GBCA-related risks, decrease examination time and reduce costs without significantly lowering the diagnostic accuracy.

Author contributions DJ protocol and project development, data analysis, manuscript writing. FS manuscript writing and editing, data analysis. VF data collection, manuscript editing. JB data collection, data management. TT data collection, data management. FA project development, data collection. TRWH manuscript editing, interpretation of data. MR manuscript writing, critical revision of the manuscript. UN manuscript writing and editing, interpretation of data.

Compliance of ethical standards

Conflict of interest The authors declare that they have no conflict of interest, nothing to declare.

Research including human participants and ethical approval This is a retrospective study. Institutional review board approval was granted by means of a general waiver for studies with retrospective data analysis (Ethikkommission, Med. Univ. Innsbruck; 2009-02-20). All procedures performed were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent For this type of study formal consent is not required.

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