Effect of PIRADSv2 instead of PIRADSv1 in the analysis of multiparametric prostate MRI at 310 prostatic lesions proven by MR-guided biopsy at 3T vs 1.5T

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Purpose

Introduction

Prostate cancer (PCa) is the third most common cancer in the total population representing approximately 11% of all cancer diagnosis. After the lung and bronchial cancer, prostate cancer is the second most common malignancy diagnosed in men, with an incidence of approximately 130 per 100,000 men per year, which is translated to 180,890 estimated new cases in the U.S. in 2016 and an overall lifetime risk of 1 to 7 men according to the SEER database [15]. Similar data have been reported in the U.K. with one to 8 lifetime prevalence and 46.690 new cases per anno in 2014 [13]. Prostate cancer affects by 55-60% men aged above 65 and has an excellent overall survival rate of 94% in the 1st year, 85% in 5 years and 84% in 10 years according to UK databases [14]. According to the SEER database the relative survival rate reaches 100% in the first 5 years and 95% in 15 years [15], provided that the cancer will be diagnosed at the local (stage I, II) or the regional stage (stage III), as occurs with more than 80% of the cases [15]. The 5-year survival rate at stage IV (distant disease) 28-30% renders the importance of early stage clinical diagnosis indisputable [14, 15] (Fig. 1).

In the current clinical practice, clinical examination including digital rectal examination (DRE) and the prostate-specific antigen (PSA) assay remain, despite the debated outcome, the most popular screening methods as recommended by the American Cancer Society (ACS) [4, 5, 9, 12]. Upon clinical suspicion and/or PSA elevation beyond 4ng/mL, an ultrasound-guided prostate biopsy is the next recommended step [12]. For patients with still elevated PSA and negative ultrasound-biopsy, magnetic resonance imaging (MRI) is a useful screening adjunct to allocate suspect lesions [1, 3, 7, 8, 10]. MRI is superior for providing information about the size, localization and spread of the disease. Furthermore, the available multiparametric MRI sequence battery (mpMRI) including high resolution T2-weighted sequences (T2w), diffusion weighted imaging (DWI) with apparent diffusion coefficient (ADC) maps, dynamic contrast-enhanced (DCE) sequences and, albeit with debated diagnostic value, magnetic resonance spectroscopy (MRS), allow for precise allocation and detailed anatomical and functional description of prostate lesions (Fig. 2).

The diagnostic mpMRI outcome is decisive for the patient treatment with a targeted biopsy or active surveillance. The first organized attempt to construct a structured reporting system was the publication of Prostate Imaging Reporting And Data System version 1 (PI-RADS™ v1) in 2012 by the European Society of Urogenital Radiology (ESUR) [1]. PI-RADS is a structured, unifying reporting system that created an mpMRI-based score for malignancy prediction. According to PI-RADS v1, T2w images, DWI with ADC maps, DCE and optionally MRS are evaluated with a score 1 to 5. The final summation product, ranging from 3 to 15 (without MRS) or 4-20 (with MRS), is classified in the PI-RADS scale from 1 to 5. PI-RADS 1 and 2 recommends active surveillance and
PI-RADS 4 and 5 a targeted biopsy. Lesions scored as PI-RADS 3 are potential biopsy candidates, the decision being dependent on the global patient's profile.

PI-RADS™ v1 was evaluated by a metaanalysis summarizing 14 studies (1785 patients) [3], which reported a polled sensitivity of 0.78 (95%CI, 0.70-0.84) and specificity 0.79 (95%CI, 0.68-0.86). Major withdrawals of PI-RADS v1 were the moderate to good interobserver agreement, the relatively diminished usage of MRS and restricted usability of the DCE as reported by various users. Based on these results, the PI-RADS Steering ESUR committee in combination with the American College of Radiology (ACR) have published a new, revised version PI-RADS™ v2 in 2015 [11, 16] in order to simplify reporting and reducing the interobserver gap. The core changes in PI-RADS™ v2 versus v1 are summarized as follows [2] (Fig. 3):

- The 15-20 point system is abandoned. Instead of a symmetrically balanced score of all sequences in v1, PI-RADS v2 defines dominant sequences for each prostate region such as the DWI for the peripheral zone and the T2w for the transitional zone. The dominant sequence determines in the vast majority of cases the final PI-RADS score as it can be only minimally affected by other sequences (Fig. 2).
- DCE in PI-RADS v2 is dichotomous, evaluated as "focal", "earlier" and "contemporaneous" rather than based on kinetic curve types. Its role has been drastically restricted only between PI-RADS 3 and 4 in the peripheral zone.
- MRS is no longer included in the scoring system.
- The graphical map has been adapted and improved.

Aims and Objectives

To verify the diagnostic potential of PI-RADS™ v2 in predicting prostate cancer and reducing unnecessary prostate biopsies at different field strengths (3.0T and 1.5T).
Fig. 1: Figure 1. Prostate cancer statistics and survival. The 5-year survival rate at stage IV (distant disease) 28-30% renders the importance of early stage clinical diagnosis indisputable. Modified from [14, 15]. Localized = confined to primary site, Regional = spread to regional lymph nodes, Distant = distant metastasis, Unknown = unknown stage by diagnosis.

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Methods and Materials

The study was retrospective for 354 lesions from 232 patients aged 65.12±7.14 years (mean/#), scanned in our department between 4/2010 and 8/2016. All patients were examined with suspicion for prostate cancer based on elevated PSA assay on basis of an inconclusive ultrasound biopsy and had an MR-guided biopsy within 3 months post-diagnosis. A total of 51 patients (97 lesions) were examined at 1.5T and 181 patients (257 lesions) at 3.0T field strength. The lesion sample is well balanced between different prostate zones with 169 lesions (47.74%) in the transitional and 185 lesions (52.26%) in the peripheral zone. The following mpMRI dataset has been applied as standard of diagnosis with an average duration of 35 - 40 min (3T and 1.5T, respectively):

- (i) T2w tse HR paracoronal, paraaxial and parasaggital in 2mm resolution
- (ii) Diffusion weighted Echo Planar Imaging (DWI EPI) at 5 different b-values (b0-100-500-800-1000 s/mm²)
- (iii) T1 weighted Fast Field Echo (T1-FFE) with dynamic contrast enhancement (DCE) in 25 repetitions with 13.35 s temporal resolution and 7 s delay. A body weight-adjusted bolus of gadoteridol 0.1mmol/kg was injected at 3 ml/s flow rate.

All lesions were graded by 2 radiologists; one with intermediate experience and a board-certified radiologist according to PI-RADS™ v1 and -v2.

Ethical statement: All patient data derived from the prostate database of the Suedharz Hospital Nordhausen. Data were analyzed retrospectively, fully anonymized, in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its amendments as well as with the guidelines of the Ethical Committee for clinical studies of the University of Jena. Due to the retrospective character of the study, the ethical committee has waived the mandate from obtaining a legally effective informed consent from the included subjects.
Images for this section:

**Fig. 2:** Figure 2. Multiparametric magnetic resonance imaging (mpMRI). (a) transitional zone lesion (b) peripheral zone lesion (I) T2w (ii) ADC map (iii) DCE and (iv) kinetic curve.

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Results

From n/N (lesions/patients) 97/51 scanned at 1.5T field strength, 33 (34.02%) lesions were malignant (prostate cancer, PCa) and 64 (65.97%) benign. The histological outcome for n/N 257/181 scanned in 3.0T field strength was 119 (46.30%) PCa and 138 (53.69%) benign (Fig. 4). The proportion of benign lesions (false positives) was for 1.5T/3.0T: n(%) prostatitis 26(40.64)/40(28.99), benign prostate hyperplasia (BPH) 14(21.88)/40(28.99), prostate tissue without pathology 12(18.75)/30(21.78), ASAP 9(14.06)/27(19.57) and surrounding periprostatic tissue 4(6.25)/2(1.45), respectively (Fig. 4). The distribution of Gleason score amongst PCa lesions was for 1.5T/3T: n(%) Gleason 6 4(12.12)/34(28.57), Gleason 7 17(51.52)/59(49.58), Gleason 8 4(12.12)/10(3.40), Gleason 9 1(3.0)/8(6.72), Gleason 10 0/2(1.68) respectively (Fig. 4).

Upon re-scoring all lesions for PI-RADS v2, n(%) 15(15)/22(9) lesions at 1.5T/3.0T, respectively, were upgraded. From the upgraded lesions, 4(4)/8(3) were PCa and the remaining benign. Additionally, a total of 32(33)/75(29) lesions were downgraded, from which 10(10)/31(12) were PCa. The PPV of PI-RADS v2 at rescoring was rather poor for both field strengths (%) 55.32/53.60.

Post-hoc assignment of lesion identity to the PI-RADS diagnostic score is summarized in Figure 5. Overall, the percent of malignant (PCa) lesions in PI-RADS 4 class was for 1.5T/3.0T (%) 24.2/29.2 when applying -v1 and 37.3/40.1 with v2. Within the PI-RADS 5 class PCa occurred (%) 62.07/65.85 with v1 and 46.43/70.89 with v2 for 1.5T/3.0T, respectively. The PPV of PI-RADS v2, especially for PI-RADS 4 and 5 lesions is slightly higher compared to - v1 for both field strengths (Fig. 5).

The receiver operative characteristic (ROC) curve analysis (Fig. 6) for 1.5T images reveals a moderate prognostic value for PI-RADS v1 with AUC±SEM 0.71±0.05, P 0.0008. Youden statistics suggest an optimal cut-off value of 4.5 with sensitivity/specificity (%) 54.55/82.81. The performance of PI-RADS v2 at 1.5T was slightly worse with rather poor AUC±SEM 0.65±0.05, P 0.015. The difference between versions was, however, not statistically significant, P 0.32 chi-square test (Fig. 6d).

At 3.0T field strength PI-RADS v1 and -v2 performed similarly with AUC±SEM 0.69±0.03, P < 0.0001 for both versions. The sensitivity/specificity at the optimal Youden cut-off point of 4.5 were 68.07/69.57 and 47.06/83.33 for v1 and v2, respectively. No statistically significant difference was observed between versions, P 0.99 chi-square test (Fig. 6d).
**Fig. 3:** Figure 3. What’s new in PI-RADS v2. (i) The 15-20 point system is abandoned. PI-RADS v2 defines as dominant sequences the DWI for the peripheral zone and the T2w for the transitional zone. The dominant sequence determines almost exclusively the final PI-RADS score for it can be only minimally affected by other sequences. (ii) DCE in PI-RADS v2 is dichotomous. Its role has been drastically restricted only between PI-RADS 3 and 4 in the peripheral zone. (iii) MRS is no longer included in the scoring system. (iv) The graphical map has been adapted and improved.

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**Fig. 4:** Figure 4. Descriptive statistics of MR-guided biopsy series 4/2010-8/2016 from our hospital.

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**Fig. 5:** Figure 5. Histological identity of PI-RADS v1 and -v2 classified lesions scanned in 1.5T and 3.0T field strength. (a-d) Stacked bar plots with the histological identity of PI-RADS classified lesion as % percent for - v1, -v2, 1.5T and 3.0T field strengths. (e,f) Histological identity of PI-RADS classified lesions and positive predictive value (PPV) for each PI-RADS grade (2-5) -v1, -v2, 1.5T and 3.0T field strength.

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**Fig. 6:** Figure 6. (a,b) ROC analysis for PI-RADS v1 and v2 at 1.5T and 3.0T field strength. (c,f) Tabular ROC parameters. Although PI-RADS v2 performs optimally at 3.0T, the maximum AUC remains moderate (~0.70) and no statistical difference is shown between v1 and v2 in either field strength.

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Conclusion

The performance of PI-RADS, especially PI-RADS v2 is superior in 3.0T field strength. However, ROC analysis showed no statistical difference between PI-RADS versions for neither of the tested field strengths. Retrospective application of PI-RADS v2 in previously -v1 scored and histologically confirmed prostate lesions showed a PPV (1.5T/3.0T) of 55.32/53.60 in over- and undernaming.

Clinical significance

PI-RADS v2 introduces a simplified, more user-friendly classification of prostate lesions with equal or tendentially improved performance compared to the more complicated -v1. Importantly, PI-RADS v2 classification is largely independent from DCE MRI and can be reliably applied in patient groups with contraindications such as renal insufficiency or allergic reactions to contrast media.
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