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# A prospective diagnostic accuracy study of Prostate Imaging Reporting and Data System version 2 on 3 Tesla multiparametric multiparametric magnetic resonance imaging in detecting prostate cancer with whole-mount pathology

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## INTRODUCTION & OBJECTIVES

- Little data is available on the performance of the Prostate Imaging Reporting and Data System version 2 (PI-RADS v2) on 3.0 Tesla multiparametric magnetic resonance imaging (mpMRI) in detecting prostate cancer (PCa) on definitive pathology after radical prostatectomy (RP).
- In this prospective study, we assessed the diagnostic accuracy of PI-RADS v2 in detecting any PCa and clinically significant PCa on 3.0 Tesla mpMRI using whole-mount histology after RP as the standard of reference.

## PATIENTS & METHODS

- Between May 2016 and February 2017 we prospectively enrolled patients with biopsy-proven PCa who underwent 3.0 Tesla mpMRI without endorectal coil before open RP.
- Two radiologists with 8- and 6-year experience in mpMRI reading, and blinded to all clinical data as well as final histology, independently analyzed mpMRI images, recorded and scored all findings in accordance with PI-RADS v2 (Figure 1). All lesions identified by the readers were mapped on the 36-sector scheme.

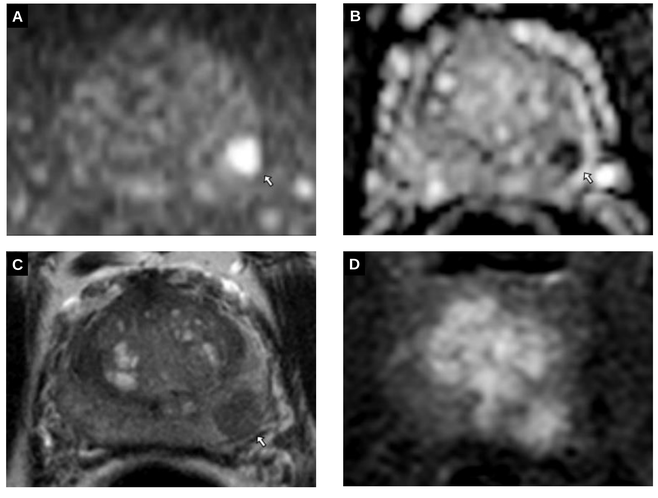


Figure 1. Multiparametric MRI of a 61-year-old man with serum PSA of 6.3 ng/mL and ISUP 1 prostate cancer on biopsy. A 10-mm focal lesion was identified in the left midgland peripheral zone: A) markedly restricted diffusion at high b-value; B) hypointensity on ADC map; C) hypointensity on T2-weighted imaging (D) post-contrast enhancement. Both readers assigned a PI-RADS v2 score 4 to this finding. Final pathology revealed a ISUP 2 prostate cancer.

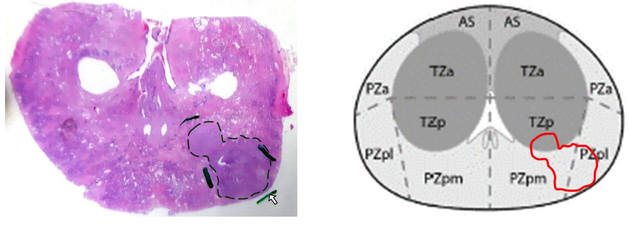


Figure 2. Pathology analysis. Cancer foci in the whole-mount slides (white arrow) were mapped in a bidimensional illustration of the corresponding prostate sections (red line) with the purpose to create a reliable three-dimensional model of the identified tumours. The same sector division as in the 36-sector PI-RADS v2 scheme was adopted.

- A single uropathologist with 10-year experience processed all RP specimens. Whole-mount sections were analyzed (Figure 2). Clinically significant PCa was defined as any tumour with diameter ≥1 cm (as surrogate for volume ≥0.5 cc) or International Society of Urological Pathology grade ≥2 or extraprostatic extension/seminal vesicle invasion. An independent radiologist together with the uropathologist analyzed the two maps per patient to match each lesion identified on mpMRI to the corresponding findings on definitive histology.
- Sensitivity and specificity of PI-RADS v2 in detecting any PCa and clinically significant PCa according to the threshold score of ≥3 and ≥4, were calculated on a per-lesion and per-patient basis. Inter-reader agreement was also assessed using Cohen's kappa statistic.

## RESULTS

- Of 53 enrolled patients, five with MRI examinations of suboptimal quality due to severe artefacts were excluded. The final study population comprised 48 patients. Mean (SD) age was 65.8 (6.5) years. Median (IQR) preoperative PSA level was 7.2 (5.2-10) ng/ml. Median (IQR) time from mpMRI to RP was 3.4 (2.1-4.6) weeks.
- Of the 48 patients, 41 (85%) had a clinically significant PCa. A total of 71 cancer foci were detected on final histology. One focus was detected in 25 (52%) patients, and two foci were detected in 23 (48%) patients. Of all 71 foci, 51 (71.8%) were clinically significant PCa.
- On a per-lesion basis, sensitivity was slightly higher with PI-RADS ≥3 vs. ≥4 threshold (range 0.55-0.62 vs. 0.48-0.60 for any PCa, and 0.67-0.74 vs. 0.61-0.72 for clinically significant PCa, respectively) at the expense of lower specificity (range 0.11-0.30 vs. 0.56-0.71 for any PCa, and 0.28-0.30 vs. 0.55-0.71 for clinically significant PCa, respectively). Accuracy improved on a per-patient basis, with 0.64-0.77 sensitivity and 0.73-0.83 specificity for clinically significant PCa with a PI-RADS ≥4 threshold.
- Inter-reader agreement was moderate to substantial. k values for the two readers were 0.47 and 0.72 for PI-RADS v2 threshold score ≥3, and 0.51 and 0.71 for PI-RADS v2 threshold score ≥4.

## CONCLUSIONS

**PI-RADS v2 showed good diagnostic performance in detecting clinically significant PCa, with acceptable inter-reader agreement. PI-RADS ≥4 threshold offered a better trade-off between sensitivity and specificity.**