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Original Article

The efficiency of multiparametric magnetic resonance imaging (mpMRI) using PI-RADS Version 2 in the diagnosis of clinically significant prostate cancer

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ABSTRACT

Objectives: To investigate the efficiency of multiparametric MRI (mpMRI) based on Prostate Imaging Reporting and Data System (PI-RADS) Version 2 (v2) in detecting clinically significant prostate cancer (PCa) and to test the interobserver consistency.
Methods: Based on PI-RADS v2, two radiologists reviewed the images of 372 patients who underwent prostate biopsy and prebiopsy mpMRI.
Results: There's significant correlation between higher PI-RADS score and the presence of clinical significant PCa ($P<.001$). PI-RADS score 3 was the best cutoff point with sensitivity and specificity over 80%. The diagnostic concordance was moderate (kappa = 0.478).
Conclusions: PI-RADS v2 demonstrated good accuracy in detecting clinically significant PCa, however the interobserver consistency needs to be improved.

1. Introduction

There have been significant developments in the use of multiparametric magnetic resonance imaging (mpMRI) in detecting prostate cancer (PCa) before biopsy, staging of PCa after histological diagnosis, and selecting candidates for repeating biopsy or performing active surveillance [1–4]. Because of the inconsistence in the diagnostic procedures of PCa through MRI and the variety in medical conditions in different regions, the European Society of Urogenital Radiology (ESUR) has developed a standard protocol for mpMRI of prostate diseases for strengthening the communication with clinicians, early detection of lesions, and improving patients' outcome [5,6].

The Prostate Imaging and Reporting Archiving Data System (PI-RADS), published by ESUR in 2012, could help improve the diagnostic procedure of PCa and standardize the interpretation of mpMRI [7]. PI-RADS Version 2 (PI-RADS v2) published in December 2014 that modified and simplified the procedure and increased the efficiency of the schedule [8].

However, the diagnosis efficiency as well as the clinical utilization of PI-RADS v2 still needs to be verified by large clinical studies. Besides, there are few reports of the validation of PI-RADS v2 based on Chinese patients. The purpose of this study was to investigate the efficiency and accuracy of mpMRI based on PI-RADS v2 in the diagnosis of clinical significant PCa in this specific cohort of patients and to test the interobserver consistency.

2. Materials and methods

2.1. Subjects

Following the approval of the Institutional Review Board of Peking University First Hospital, we retrospectively evaluated 372 patients who underwent transrectal ultrasound (TRUS)-guided prostate biopsy and prebiopsy MRI examination due to increased serum prostate-specific antigen (PSA) level and/or suspicious digital rectal examination or TRUS between November 2010 and December 2013.

Exclusion criteria: (a) the interval between MRI and biopsy longer than 3 months; (b) previous history of transurethral resection of prostate (TURP); (c) MRI without enhancement phases; (d) MRI did not performed at 3.0 T.

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Table 1
MpMRI parameters

Parameter	T2WI	DWI	DCE
Repetition time (msec)	2900	4000	3.3
Echo time (msec)	90	70	1.6
Flip angle (degree)	90,180	90	15
Matrix	320×280	184×184	256×256
Field of view (mm^2)	260×260	260×260	260×260
No. of signal acquired	4	4	0.75
Section thickness (mm), no gap	4	4	2
b value	—	0, 800, 1000	—

2.2. Procedures and techniques

2.2.1. MRI

MRI studies were performed at 3.0 T. The body coils were applied. The mpMRI consisted of axial T2-weighted imaging (T2WI), diffusion-weighted imaging (DWI b = 0, b ≥ 800 s/mm^2) and corresponding apparent-diffusion coefficient (ADC) maps, and dynamic contrast enhanced (DCE). The mpMRI parameters are presented in Table 1.

2.2.2. Pathology

The TRUS-guided systematic plus targeted biopsies of 12–14 needle cores were performed within 3 months after MRI. The clinically significant cancer was defined as Gleason score ≥7 (including 3 + 4 with prominent but not predominant Gleason 4 component) according to the pathologic results.

2.3. Diagnostic evaluation

Two radiologists (A [CZ] and B [GG]) were experienced with PI-RADS v2, and then consistency was tested by 10 reference cases set for the system before the starting of evaluation. They reviewed all the images separately. Following the standards of diagnostic accuracy by using PI-RADS v2 (1, *highly unlikely to be present*; 2, *unlikely to be present*; 3, *intermediate*; 4, *likely to be present*; 5, *highly likely to be present*) (Supplementary Figs. 1–5 in the online version at http://dx.doi.org/10.1016/j.clinimag.2016.04.010.), based on T2WI, DWI, and DCE sequences (Supplementary Table 1 in the online version at http://dx.doi.org/10.1016/j.clinimag.2016.04.010.).

2.4. Statistical analysis

The statistical analyses were done with Statistical Product and Service Solutions (SPSS) 18.0 and MEDCALC 12.7.0. Data were presented by means ± standard deviation. Kappa test was used to evaluate the diagnostic concordance of the two radiologists (the agreement considered as kappa<0.4 was bad, kappa 0.4~0.75 was moderate, kappa≥0.75 was good). Receivers operating characteristic (ROC) curves were used to describe the diagnostic efficiency of two radiologists, and Wilcoxon rank sum test was used for evaluating the differences. Youden index was used to solve the best cutoff value. Area under curve (AUC), sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) with 95% confidence intervals (CIs) were calculated for diagnostic accuracy. $P<.05$ was considered statistically significant.

3. Results

3.1. Characteristics and biopsy outcomes

Among all the 372 patients included, the mean age was 68.5 ± 9.2 years, and the mean PSA was 15.0 ± 13.3 ng/ml. One hundred and eighty-five (49.7%) patients were diagnosed with PCa after TRUS-guided biopsy, and particularly clinical significant cancer was present in 155 (41.7%) patients.

3.2. Evaluation of MRI

Table 2 listed the results of the evaluation of all images by the two radiologists as well as the corresponding biopsy outcomes. There is significant correlation between higher score and the presence of PCa and clinically significant PCa (all $P<.001$). Although both radiologists could make satisfactory diagnosis based on the PI-RADS v2, the diagnostic concordance of the two radiologists was moderate (kappa = 0.478).

3.3. Best threshold for clinically significant cancer

After calculations of Youden index, PI-RADS v2 score 3 was selected as the best cutoff point at which Youden index was 0.649 (Radiologist A) and 0.727 (Radiologist B). The AUCs of the ROC curve at this cutoff point was 0.872 (Radiologist A) versus 0.911 (Radiologist B) (Fig. 1).

3.4. Diagnostic value

The diagnostic sensitivity, specificity, as well as PPV and NPV were shown in Table 3. It is obvious that when we set PI-RADS v2 score 3 as the cutoff value, the current diagnostic method could achieve high sensitivity and specificity in detecting the presence of clinically significant PCa.

Table 2
Performance of each of the readers scoring compared to the biopsy findings

PI-RADS Score					1	2	3	4	5	Total	*P* value
Radiologist A	Total				6	165	37	89	75	372	
		No PCa			6	141	19	16	5	187	
		PCa	Total		0	24	18	73	70	185	<.001*
			NCS	GS = 6	0	9	5	13	3	30	
			CS	GS = 7	0	11	9	36	25	81	<.001*
				GS = 8	0	4	3	16	17	40	
				GS = 9	0	0	1	8	21	30	
				GS = 10	0	0	0	0	4	4	
Radiologist B	Total				5	146	50	89	82	372	
		No PCa			5	135	30	13	4	187	
		PCa	Total		0	11	20	76	78	185	<.001*
			NCS	GS = 6	0	6	7	13	4	30	
			CS	GS = 7	0	2	10	43	26	81	<.001*
				GS = 8	0	3	3	12	22	40	
				GS = 9	0	0	0	8	22	30	
				GS = 10	0	0	0	0	4	4	

CS = clinically significant prostate cancer, GS = Gleason Score, NCS = no clinically significant prostate cancer.
There is significant correlation between higher PI-RADS score and the presence of PCa and CS PCa (all $P<.001$).
* Statistically significant.