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Prostate International xxx (2018) 1–6

Contents lists available at ScienceDirect

Prostate International

journal homepage: https://www.journals.elsevier.com/prostate-international

Original Article

Distribution of Prostate Imaging Reporting and Data System score and diagnostic accuracy of magnetic resonance imaging–targeted biopsy: comparison of an Asian and European cohort

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ARTICLE INFO

Article history:
Received 5 May 2018
Received in revised form
11 October 2018
Accepted 15 October 2018
Available online xxx

Keywords:
Asian
Magnetic resonance imaging
Prostate biopsy
Prostate cancer
Prostate Imaging Reporting and Data System

ABSTRACT

Background: This study aimed to compare the distribution of Prostate Imaging Reporting and Data System (PI-RADS) score and the diagnostic accuracy of magnetic resonance imaging (MRI)–targeted biopsy and systematic biopsy between a Chinese and a Dutch cohort.

Materials and methods: Our study includes 316 men from Shanghai Changhai Hospital, China, and 266 men from the Erasmus University Medical Center, Rotterdam, the Netherlands. All men had a suspicion for prostate cancer (PCa) and were offered an multiparametric MRI (mpMRI) scan.

Results: The distribution of the PI-RADS score was different between the two cohorts ($P = 0.008$). In the Chinese cohort of PI-RADS $\geq$3, the detection rate for high-grade PCa (Gleason $\geq$7) was 37.3% by systematic biopsy and 35.5% by MRI-targeted biopsy. The sensitivity of systematic biopsy was 0.80 for PCa and 0.75 for high-grade PCa. MRI-targeted biopsy achieved slightly higher sensitivity for PCa (0.82) and high-grade PCa (0.76). In the Dutch cohort of PI-RADS $\geq$3, the high-grade PCa detection rate was 44.4% and 54.5% for systematic biopsy and MRI-targeted biopsy. The sensitivity of systematic biopsy was 0.93 for PCa and 0.81 for high-grade PCa. By MRI-targeted biopsy, the sensitivity was 0.85 for PCa and 0.97 for high-grade PCa.

Conclusions: The distribution of the PI-RADS score was different with more PI-RADS 4/5 in the Chinese cohort. Applying a PI-RADS $\geq$3 cutoff resulted in a favorable overall sensitivity. MRI-targeted biopsy showed a higher sensitivity in the detection of high-grade PCa than systematic biopsy. The sensitivity of MRI-targeted biopsy and systematic biopsy for both PCa and high-grade PCa in the Dutch cohort was superior to those in the Chinese cohort.

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1. Introduction

Asia is known as one of the regions with the lowest prostate cancer (PCa) incidence and mortality worldwide.[1] However, the incidence has increased rapidly in the past two decades mainly because of the introduction of prostate-specific antigen (PSA) testing and subsequent prostate random biopsy.[2] Currently in Asian countries, especially in those developing regions, the proportion of advanced PCa at diagnosis (>20%) is still much higher than that in Europe.[3,4] Although the level of overdiagnosis appears to be lower, appropriate diagnostic methods are also essential in this rapidly changing setting. Magnetic resonance imaging (MRI)–targeted biopsy, applying visual estimation (cognitive fusion) system, MRI–ultrasound (MRI-US) fusion system, or MRI in-bore-guided system, achieves higher detection rate for clinically significant PCa using fewer cores than conventional transrectal ultrasound (TRUS)–guided biopsy.[5–8] Prostate Imaging Reporting and Data

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https://doi.org/10.1016/j.prnil.2018.10.001
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Please cite this article in press as: Zhang K, et al., Distribution of Prostate Imaging Reporting and Data System score and diagnostic accuracy of magnetic resonance imaging–targeted biopsy: comparison of an Asian and European cohort, Prostate International (2018), https://doi.org/10.1016/j.prnil.2018.10.001

System (PI-RADS) is a scoring system for multiparametric MRI (mpMRI) and can provide localization, characterization, and risk stratification for suspicious PCa lesions.[9] However, these new techniques are only available in very few Asian centers. Currently available data on, e.g., predictive value of the PI-RADS score and recommendations on how to use those in clinical practice are thus mainly based on European data and might not be applicable to the Asian setting.

In this study, we present data of mpMRI and biopsy outcome from one Chinese and one Dutch center, comparing the distribution of PI-RADS score and the diagnostic accuracy of MRI-targeted biopsy, with the aim to assess potential differences in the positive predictive value (PPV) of the PI-RADS score and the performance characteristics of the MRI-targeted biopsy.

2. Materials and methods

2.1. Study population and mpMRI protocol

From September 2013 until December 2015, a total of 316 men in Shanghai Changhai Hospital, Second Military Medical University and 266 men in Erasmus University Medical Center, Rotterdam, underwent an mpMRI scan because of a clinical suspicion of PCa (no prior PCa diagnosis) based on an elevated PSA and/or abnormal digital rectal examination (DRE).

In the Chinese cohort, MRIs were performed on a 3.0T system (Magnetom Skyra; Siemens Medical Solutions, Erlangen, Germany). The prostate MRI protocols included T1WI, triplanar (axial, sagittal, and coronal) T2WI, diffusion-weighted imaging, and dynamic contrast-enhanced imaging by using an 18-channel phased-array coil. A single radiologist (Qingsong Yang) with 10 years of experience in prostate MRI analyzed the images and marked all the lesions according to the PI-RADS, version 1.0.

In the Dutch cohort, a 3.0T MR system (Discovery MR750; General Electric Healthcare, Chicago, United States) with 32-channel pelvic phased-array coil was used, and the prostate MRI protocols also included T1WI, T2WI, diffusion-weighted imaging, and dynamic contrast-enhanced imaging. All the MRIs were reported by a single radiologist (Ivo G Schoots) with more than 4 years of experience in prostate mpMRI based on PI-RADS, version 1.0.

2.2. Systematic biopsy and MRI-targeted biopsy

In the Chinese cohort, the systematic biopsy was performed with a TRUS-guided approach (end-firing ultrasound probe) using a median number of 12 cores [interquartile range (IQR), 12–12) because of elevated PSA (≥4ng/ml) and/or abnormal DRE. MRI-targeted biopsy was implemented using cognitive fusion system, in which the biopsy operator used TRUS imaging to aim the suspicious lesions identified at MRI. The median number of MRI-targeted biopsy core was 3 (IQR, 2–4). In the Dutch cohort, a TRUS-guided systematic biopsy was performed with a median number of 12 cores (IQR, 10–12) using end-firing ultrasound probe because of elevated PSA (≥3ng/ml) and/or abnormal DRE. MRI-US fusion system (UroStation; Koelis, Meylan, France) was applied for MRI-targeted biopsy with a median number of 4 cores (IQR, 3–5) for PI-RADS ≥3 lesions. This system fuses the MRI and real-time TRUS images based on software and allows guiding biopsy on the TRUS images.[8]

2.3. Statistical analysis

Statistical analyses were performed by using SPSS for Windows (Version 21.0; IBM Corp Armonk, NY, USA). The Mann–Whitney U test and the Chi-square test for trend were used to determine differences between variables.

3. Results

3.1. Patient characteristics

The characteristics of the study population are shown in Table 1. In the Chinese cohort of 316 men with a median age of 66.0 years (IQR, 60.0–72.0), the median PSA value was 9.7 ng/ml (IQR, 6.7–15.7). Only 57 (18.0%) men had previous negative TRUS-guided biopsies, and 58 (18.4%) men had a suspicious DRE. All the men received an mpMRI scan, of whom 315 (99.7%) men underwent systematic biopsy. Cognitive MRI-targeted biopsy was performed in a total of 110 out of 186 (59%) men with an overall PI-RADS score ≥3 and additionally in 4 men with PI-RADS 2.

In the Dutch cohort of 266 men, the median age was 66.6 years (IQR, 61.1–70.0), and the median PSA value was 11.1ng/ml (IQR, 8.4–17.6). Unlike the Chinese cohort, a total of 256 (96.2%) men had a previous negative biopsy. Comparable to the Chinese cohort, a total of 56 (21.1%) men had a positive DRE result. A total of 115 (43.2%) men underwent systematic biopsy. MRI-US fusion biopsy was performed in all the men (N = 123) with an overall PI-RADS score ≥3.

3.2. Distribution of PI-RADS score

In the Chinese cohort, the PI-RADS score of the dominant lesion was 2 in 130 (41.1%), 3 in 47 (14.9%), 4 in 69 (21.8%), and 5 in 70 (22.2%) men. In the Dutch cohort, these numbers were 2 in 143 (53.8%), 3 in 28 (10.5%), 4 in 51 (19.2%), and 5 in 44 (16.5%) men (Table 2). The distribution of PI-RADS score varied between the two cohorts ($P = 0.008$). In the Chinese cohort, the distribution was also different between the group of men with initial biopsy and previous negative biopsy ($P = 0.03$) (Table 3).

3.3. Positive predictive value of the PI-RADS for PCa and high-grade PCa in MRI-targeted biopsy

In the Chinese cohort of 114 men with MRI-targeted biopsy, 66 men (57.9%) were diagnosed with PCa by MRI-targeted biopsy, of

Table 1
Patient characteristics.

Characteristic	Chinese cohort (n = 316)		Dutch cohort (n = 266)		*P*
	Median	IQR	Median	IQR	
Age (year)	66.0	60.0–72.0	66.6	61.1–70.0	0.50
PSA (ng/mL)	9.7	6.7–15.7	11.1	8.4–17.7	0.001
Prostate volume (mL)	41.5	27.2–61.8	46.0	34.0–65.0	0.01
	Number	%	Number	%	*P*
Positive DRE	58	18.4	56	21.1	0.41
Previous negative biopsy	57	18.0	256	96.2	<0.001

DRE, digital rectal examination; IQR, interquartile range; PSA, prostate-specific antigen.

Table 2
The distribution of PI-RADS score in the two cohorts.

PI-RADS score	Chinese cohort		Dutch cohort	
	Number	%	Number	%
Total number of men	316	100	266	100
PI-RADS 2	130	41.1	143	53.8
PI-RADS 3	47	14.9	28	10.5
PI-RADS 4	69	21.8	51	19.2
PI-RADS 5	70	22.2	44	16.5

PI-RADS, Prostate Imaging Reporting and Data System.

Please cite this article in press as: Zhang K, et al., Distribution of Prostate Imaging Reporting and Data System score and diagnostic accuracy of magnetic resonance imaging–targeted biopsy: comparison of an Asian and European cohort, Prostate International (2018), https://doi.org/10.1016/j.prnil.2018.10.001

Table 3
The distribution of PI-RADS score between initial and previously negative biopsy in the Chinese cohort.

Chinese cohort	Initial biopsy		Previous negative biopsy	
	Number	%	Number	%
Total number of men	259	100	57	100
PI-RADS 2	116	44.8	14	24.6
PI-RADS 3	34	13.1	13	22.8
PI-RADS 4	55	21.2	14	24.6
PI-RADS 5	54	20.8	16	28.1

PI-RADS, Prostate Imaging Reporting and Data System.

whom 39 (34.2%) men had high-grade PCa (Gleason score $\geq$ 7). The PPV of PI-RADS $\geq$3 was 60.0% for PCa (Table 4) and 35.5% for high-grade PCa (Table 5).

In the Dutch cohort of 123 men with MRI-targeted biopsy, 89 (72.4%) cases of PCa and 67 (54.5%) cases of high-grade PCa were detected. The PPV of PI-RADS $\geq$3 was 72.4% and 54.5% for PCa and high-grade PCa, respectively (Tables 4 and 5).

3.4. Comparison of outcomes between systematic biopsy and MRI-targeted biopsy

In the Chinese cohort, 130 men with negative MRI results (PI-RADS 1–2) underwent systematic biopsy; 12 (9.2%) cases of PCa and 6 (4.6%) cases of high-grade PCa were detected. Among 186 men with PI-RADS $\geq$3, 185 men underwent systematic biopsy, and 69 (37.3%) cases of high-grade PCa were detected; 110 men received MRI-targeted biopsy, 39 of 110 were high-grade PCa (35.5%) (Table 6).

In the Dutch cohort, 1 (1.9%) case of high-grade PCa was found in men with negative MRI results and systematic biopsy (N = 52). The positive rate for high-grade PCa among men with PI-RADS $\geq$3 was 44.4% (28/63) for systematic biopsy and 54.5% for MRI-targeted biopsy (67/123) (Table 7).

For PI-RADS 1–2 lesions, there was no significant difference in the PCa detection by systematic biopsy between the Chinese and Dutch cohorts. For PI-RADS $\geq$3 lesions, there was no significant difference in the high-grade PCa detection by systematic biopsy between the two cohorts. In all the other subgroups, cancer

Table 4
The PPV of PI-RADS classification for PCa in the two cohorts with MRI-targeted biopsy.

Chinese cohort (n = 114)			Dutch cohort (n = 123)		
PI-RADS score (number)	PCa	PPV	PI-RADS score (number)	PCa	PPV
PI-RADS 2 (4)	0	0	PI-RADS 2 (0)	0	0
PI-RADS 3 (34)	13	38.2%	PI-RADS 3 (28)	10	35.7%
PI-RADS 4 (39)	26	66.7%	PI-RADS 4 (51)	36	70.6%
PI-RADS 5 (37)	27	73.0%	PI-RADS 5 (44)	43	97.7%
PI-RADS $\geq$3 (110)	66	60.0%	PI-RADS $\geq$3 (123)	89	72.4%

MRI, magnetic resonance imaging; PCa, prostate cancer; PI-RADS, Prostate Imaging Reporting and Data System; PPV, positive predictive value.

Table 5
The PPV of PI-RADS classification for high-grade PCa in the two cohorts with MRI-targeted biopsy.

Chinese cohort (n = 114)			Dutch Cohort (n = 123)		
PI-RADS score (number)	High-grade PCa	PPV	PI-RADS score (number)	High-grade PCa	PPV
PI-RADS 2 (4)	0	0	PI-RADS 2 (0)	0	0
PI-RADS 3 (34)	9	35.3%	PI-RADS 3 (28)	7	25%
PI-RADS 4 (39)	15	61.5%	PI-RADS 4 (51)	24	47.1%
PI-RADS 5 (37)	15	78.4%	PI-RADS 5 (44)	36	81.8%
PI-RADS $\geq$3 (110)	39	35.5%	PI-RADS $\geq$3 (123)	67	54.5%

MRI, magnetic resonance imaging; PCa, prostate cancer; PI-RADS, Prostate Imaging Reporting and Data System; PPV, positive predictive value.

Table 6
Comparison of outcomes between systematic biopsy and MRI-targeted biopsy in the Chinese cohort.

Chinese cohort	PI-RADS 1–2 (130)		Chinese cohort	PI-RADS $\geq$3 (186)	
	PCa	High-grade PCa		PCa	High-grade PCa
Systematic biopsy (130)	12	6	Systematic biopsy (185)	104	69
MRI-targeted biopsy (4)	0	0	MRI-targeted biopsy (110)	66	39

MRI, magnetic resonance imaging; PCa, prostate cancer; PI-RADS, Prostate Imaging Reporting and Data System.

Table 7
Comparison of outcomes between systematic biopsy and MRI-targeted biopsy in the Dutch cohort.

Dutch cohort	PI-RADS 1–2 (143)		Dutch cohort	PI-RADS $\geq$3 (123)	
	PCa	High-grade PCa		PCa	High-grade PCa
Systematic biopsy (52)	14	1	Systematic biopsy (63)	50	28
MRI-targeted biopsy (0)	0	0	MRI-targeted biopsy (123)	89	67

MRI, magnetic resonance imaging; PCa, prostate cancer; PI-RADS, Prostate Imaging Reporting and Data System.

Please cite this article in press as: Zhang K, et al., Distribution of Prostate Imaging Reporting and Data System score and diagnostic accuracy of magnetic resonance imaging–targeted biopsy: comparison of an Asian and European cohort, Prostate International (2018), https://doi.org/10.1016/j.prnil.2018.10.001

detection rate in the Dutch cohort was significantly higher than in the Chinese cohort (Table 8).

3.5. Sensitivity of Systematic biopsy and MRI-targeted biopsy

In the Chinese cohort, 109 men with PI-RADS ≥3 underwent systematic plus MRI-targeted biopsy (combined biopsy), in which systematic biopsy detected 63 PCa and 38 high-grade PCa and MRI-targeted biopsy detected 65 PCa and 39 high-grade PCa. In the group of men with PI-RADS ≥3, the sensitivity of systematic biopsy was 0.80 for PCa and 0.75 for high-grade PCa. By contrast, MRI-targeted biopsy achieved slightly higher sensitivity for PCa (0.82) and high-grade PCa (0.76) (Table 9).

In the Dutch cohort of 63 men with PI-RADS ≥3 who received combined biopsy, the sensitivity of systematic biopsy was 0.93 for PCa and 0.81 for high-grade PCa. By MRI-targeted biopsy, the sensitivity was 0.85 for PCa and 0.97 for high-grade PCa (Table 10).

Table 9
Sensitivity of systematic biopsy and MRI-targeted biopsy in the Chinese cohort.

Chinese cohort (239)		Systematic biopsy	
	PCa/High-grade Pca	Positive	Negative
PI-RADS 1–2 (n = 130)	No biopsy (accept for 4 men)	12/6	118/124
PI-RADS ≥3 (n = 109):	Positive	49/26	16/13
(MRI-targeted biopsy)	Negative	14/12	30/58

MRI, magnetic resonance imaging; PCa, prostate cancer; PI-RADS, Prostate Imaging Reporting and Data System.

Table 10
Sensitivity of systematic biopsy and MRI-targeted biopsy in the Dutch cohort.

Dutch cohort (115)		Systematic biopsy	
	PCa/High-grade PCa	Positive	Negative
PI-RADS 1–2 (n = 52)	No biopsy	14/1	38/51
PI-RADS ≥3 (n = 63):	Positive	42/28	4/7
(MRI-targeted biopsy)	Negative	8/1	9/27

MRI, magnetic resonance imaging; PCa, prostate cancer; PI-RADS, Prostate Imaging Reporting and Data System.

4. Discussion

Multiparametric MRI with PI-RADS grading and MRI-targeted biopsy have shown great potential to improve diagnostic accuracy of clinically significant PCa in multiple European and North American studies.[5,10–16] PCa incidence and mortality differ greatly between European and Asian countries,[17] suggesting that tumor characteristics might vary among races and regions. In both cohorts of this study, PI-RADS showed favorable predictive value for PCa and high-grade PCa although the distribution of PI-RADS was different between the two cohorts. In both cohorts, MRI-targeted biopsy showed high sensitivity for high-grade PCa in men with PI-RADS ≥3.

To our knowledge, this study is the first to analyze the distribution of PI-RADS score between European and Asian populations. PI-RADS was developed by experts from the European Society of Urogenital Radiology in 2012, with the aim to build up clinical guidelines and standards for mpMRI.[18] Nowadays, it has been widely used in prostate MRI diagnosis worldwide. In our study, based on 582 men with a suspicion of PCa and who underwent mpMRI scans, the distribution of PI-RADS varied between the two cohorts, with more PI-RADS 3/4/5 in the Chinese cohort. However, this variation could at least in part be explained by the difference in biopsy history. Most Dutch men had a previous negative biopsy, whereas only 18% of Chinese men had a previous negative biopsy. This effect of biopsy history is confirmed in the Chinese data where there was a difference in PI-RADS distribution between the first and repeat biopsy. This might be a reflection of the practice in European countries. High proportion of men with a suspicion of PCa and previous negative biopsy underwent mpMRI and subsequent MRI-targeted biopsy following the European Association of Urology guidelines. In these guidelines, MRI-targeted biopsy is not recommended for initial biopsy. Conversely, there is no guideline regarding the MRI-targeted biopsy in China and most Asian countries. Decision-making is usually based on patients' will and the access of MRI.

Our study results indicated that PI-RADS ≥3 could be used as a cutoff for MRI-targeted biopsy in a Chinese population. Currently, also in Europe, there is no specific PI-RADS score cutoff recommended for biopsy as other factors such as laboratory findings, clinical history, and local preferences should also be considered in decision-making.[18,19] In the Chinese cohort of our study, the PPV of PI-RADS ≥3 for PCa was 60.0% for PCa and 35.5% for high-grade PCa, and if it was set as the cutoff for biopsy, no case of PCa would be missed. As comparison, in an Irish study, 81 prostatic areas underwent MRI-targeted biopsy in 52 patients. The PPV of overall PI-RADS scores of 3, 4, and 5 was 10.6%, 44%, and 100%, respectively. PI-RADS ≥3 showed a PPV of 30.9% for PCa.[12] A Japanese study of 288 men also indicated that the PPV of PI-RADS ≥3 was 41.7% and 37.5% for PCa and high-grade PCa, respectively.[20] Our study findings compare favorably with previous series, evaluating the performance of MRI-targeted biopsy in men with mixed indications for biopsy, but are comparable between our Chinese and Dutch cohorts. Our results demonstrate the potential of PI-RADS in selecting men who would most benefit from MRI-targeted biopsy and in avoiding unnecessary biopsies.

A topic of debate is the necessity of performing systematic biopsy in men with a negative MRI. In our study, 95.4% of biopsies could be saved in men with PI-RADS 1–2 in the Chinese cohort, and only 6 cases of high-grade PCa (4.6%) would be missed. In the Dutch cohort, only 1 case of high-grade PCa would be missed, and 98.1% of systematic biopsies could have been avoided in men with negative MRI. Comparable data from an Austrian study with 73 men showed that the PI-RADS score was correlated with PCa incidence and aggressiveness. A proportion of 31% of men with

Table 8
Comparison of outcomes between systematic biopsy and MRI-targeted biopsy in the Chinese cohort and the Dutch cohort.

Prostate biopsy	Detection rate in the Chinese cohort	Detection rate in the Dutch cohort	*P*
Systematic biopsy for PCa in PI-RADS 1–2 lesions	9.2%	26.9%	0.002
Systematic biopsy for high-grade PCa in PI-RADS 1–2 lesions	4.6%	1.9%	0.394
Systematic biopsy for PCa in PI-RADS ≥3 lesions	56.2%	79.4%	0.001
Systematic biopsy for high-grade PCa in PI-RADS ≥3 lesions	37.3%	44.4%	0.315
MRI-targeted biopsy for PCa in PI-RADS ≥3 lesions	60%	72.4%	0.046
MRI-targeted biopsy for high-grade PCa in PI-RADS ≥3 lesions	35.5%	54.5%	0.004

MRI, magnetic resonance imaging; PCa, prostate cancer; PI-RADS, Prostate Imaging Reporting and Data System.

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PI-RADS 1–2 had no PCa detected.[21] An American study also showed that men with negative lesion on MRI only had a risk of 2% for high-grade PCa.[22] However, an American study reviewed 84 men without suspicious regions on MRI or only with PI-RADS 1–2 lesions who underwent systematic biopsy. Overall, 22 (26.2%) cases of PCa were detected, including 11 (13.1%) high-grade PCa.[23] Although further evaluation is needed, based on our study, including 185 men with negative MRI who underwent systematic biopsy, it could be concluded that further risk stratification, especially considering retesting intervals in this group, is warranted.

In the Chinese cohort of 186 men with PI-RADS ≥3, systematic biopsy detected 104 PCa (56.2%) including 69 high-grade PCa (37.3%). Also in this subgroup, 109 men underwent systematic biopsy plus MRI-targeted biopsy, and 79 PCa (72.5%) including 51 high-grade PCa (46.8%) were detected. In a French study of 555 men undergoing 10–12 cores systematic biopsy plus targeted biopsy, 252 (71.8%) PCa were detected among 351 men with positive MRI, and systematic biopsy alone could detect 236 (67.2%) PCa.[24] In a Korean prospective study, the outcomes of 44 men with systematic biopsy plus MRI-targeted biopsy and 41 men with systematic biopsy were compared.[25] It showed that combined biopsy group had a significantly higher PCa detection rate and positive core rate than systematic biopsy group.[25] Based on our study and other available data, combined biopsy seems to achieve optimal PCa and high-grade PCa detection rate among men with PI-RADS ≥3.

In this study, MRI-targeted biopsy showed high sensitivity for PCa and high-grade PCa. In a European systematic review, 1,926 men with a positive MRI from 16 studies were included with the aim to compare MRI-targeted biopsy with systematic biopsy. MRI-targeted biopsy showed higher sensitivity in overall PCa detection (85% vs. 81%) and significant PCa detection (91% vs. 76%).[11] In the Chinese cohort of our study, MRI-targeted biopsy achieved higher sensitivity in the detection of PCa (82% vs. 80%) and high-grade PCa (76% vs. 75%) compared with systematic biopsy. In the Dutch cohort, the sensitivity comparison was 85% versus 93% for PCa and 97% versus 81% for high-grade PCa. It is noteworthy that MRI-targeted biopsy was comparable with systematic biopsy in overall PCa detection; however, in high-grade PCa detection, MRI-targeted biopsy had the distinct superiority, which was consistent with the conclusions of the European study.[11]

The strength of this study lies in the fact that it includes two cohorts from different area (continents) and both represent a true clinical situation.

Our study is limited by its retrospective nature. Most men in the Dutch cohort have previously negative biopsies, but in the Chinese cohort, 82% of men have no history of biopsy. It reflected the real practice in European countries because MRI-targeted biopsy is only recommended for repeat biopsy according to the European Association of Urology guidelines. In addition, the MRI-targeted biopsy procedures of the two cohorts are different. However, a recently published study showed that there was no significant difference in the performance of MRI-US fusion biopsy compared with cognitive fusion biopsy in the detection rate of overall PCa and clinically significant PCa.[26]

In conclusion, the distribution of the PI-RADS score was different, largely reflecting daily clinical practice. In both cohorts, PI-RADS ≥3 achieves favorable PPV for detecting PCa and high-grade PCa, and there was very small benefit when performing systematic biopsy in men with PI-RADS 1–2. MRI-targeted biopsy plus systematic biopsy however achieved the optimal PCa and high-grade PCa detection rate among men with PI-RADS ≥3. MRI-targeted biopsy showed higher sensitivity in the detection of high-grade PCa than systematic biopsy in both cohorts. The PI-RADS system seems to be applicable in an Asian setting.

Conflicts of interest

The authors have no conflicts of interest or financial disclosures to declare.

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