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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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 System

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 a 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 ≥3, the detection rate for high-grade PCa (Gleason ≥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 ≥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 ≥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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System (PI-RADS) is a scoring system for multiparametric MRI (mpMRI) and can provide localization, characterization, and risk stratification for suspicious PCa lesions. 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.

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 whom 34 (51.5%) were diagnosed with high-grade PCa.

Table 1

| 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          | 46.9 34.0–65.0         | 0.01  |

Table 2

| PI-RADS score | Chinese cohort | Dutch cohort | P       |
|---------------|---------------|--------------|---------|
|               | 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.

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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.

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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 whom 34 (51.5%) were diagnosed with high-grade PCa.
whom 39 (34.2%) men had high-grade PCa (Gleason score ≥7). The PPV of PI-RADS 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 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 ≥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 ≥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 ≥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

| 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 ≥3 (110)       | 66 | 60.0% | PI-RADS ≥3 (123)       | 89 | 72.4% |

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

| 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 ≥3 (110)       | 39 | 73.5% | PI-RADS ≥3 (123)       | 67 | 54.5% |

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

| Chinese cohort | PI-RADS 1–2 (130) | Chinese cohort | PI-RADS ≥3 (186) |
|----------------|-------------------|----------------|------------------|
| Systematic biopsy (130) | 12 | 6 | Systematic biopsy (185) | 104 | 69 |
| MRI-targeted biopsy (4) | 0 | 0 | MRI-targeted biopsy (110) | 66 | 39 |

| Dutch cohort | PI-RADS 1–2 (143) | Dutch cohort | PI-RADS ≥3 (123) |
|--------------|------------------|--------------|------------------|
| 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.
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).

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.3,6–10 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 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](attachment:image.jpg)

**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.
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, 25 (85% vs. 81%) and significantly higher 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.

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 optimalPPV 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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