Original Article

Creating a novel multiparametric magnetic resonance imaging-based biopsy strategy for reducing unnecessary prostate biopsies: a retrospective cohort study

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Background: The overdiagnosis of prostate cancer (PCa) caused by unnecessary prostate biopsy has become a worldwide problem that urgently requires a solution. We aimed to reduce the unnecessary prostate biopsies and increase the detection rate of clinically significant PCa (csPCa) by creating a novel multiparametric magnetic resonance imaging (mpMRI)-based strategy.

Methods: A total of 1,194 eligible patients who underwent transperineal prostate biopsies from January 2018 to December 2022 were included in this retrospective study. Of these patients, 1,080 who received prostate biopsies from January 2018 to July 2022 were regarded as cohort 1 for primary analysis, and 114 patients who received prostate biopsies from August 2022 to December 2022 were collected in cohort 2 for validation. All the mpMRI images were quantitatively evaluated by the Prostate Imaging Reporting and Data System version 2.1 (PI-RADS v. 2.1). The diagnostic performances were assessed through the receiver operating characteristic (ROC) curve and area under the curve (AUC) and were compared with the DeLong test. Cancer diagnosis–free survival analysis was performed using the Kaplan-Meier method and log-rank test. The primary endpoint of this study was clinically significant PCa with an International Society of Urological Pathology (ISUP) grade ≥2.

Results: In cohort 1, the results of ROC curves demonstrated that the PI-RADS score had a higher diagnostic accuracy (AUC =0.898 for any-grade PCa; AUC =0.917 for csPCa) than did the other clinical variables (P<0.001). Under the novel mpMRI-based biopsy strategy, all patients with PI-RADS 1 can safely avoid prostate biopsy. For patients with PI-RADS 2, prostate biopsy should be considered for patients with prostate-specific antigen density (PSAD) ≥0.3 ng/mL^2 and prostate volume <65 mL. As for patients with PI-RADS 3, structured surveillance programs can be a viable option if PSAD <0.3 ng/mL^2 and prostate volume ≥65 mL. Finally, patients with a PI-RADS score of 4 and 5 should undergo prostate biopsy due to the high probability of clinically significant PCa. In the validation analysis of cohort 2, 48 patients were placed into a biopsy-spared group with no csPCa cases, while 66 patients were placed in a biopsy-needed group,

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with an csPCa detection rate of 50.0%. Overall, the novel strategy demonstrated a sensitivity, specificity, positive predictive value, and negative predictive value of 98.9%, 57.5%, 50.5%, and 99.2%, respectively, for diagnosing csPCa.

Conclusions: An mpMRI-based biopsy strategy can effectively avoid about 40% of prostate biopsies and maintain a high detection rate for clinically significant PCa. It can further provide valuable guidance for patients and physicians in considering the necessity of prostate biopsy.

Keywords: Prostate cancer (PCa); prostate biopsy; multiparametric magnetic resonance imaging (mpMRI); Prostate Imaging Reporting and Data System (PI-RADS)

Submitted Jun 15, 2023. Accepted for publication Jan 05, 2024. Published online Jan 22, 2024.
doi: 10.21037/qims-23-875
View this article at: https://dx.doi.org/10.21037/qims-23-875

Introduction

Prostate cancer (PCa) is the second most common malignant tumor in men (1). Early detection and timely treatment of patients with clinically significant PCa (csPCa) can markedly benefit survival (2). Currently, transrectal ultrasound-guided prostate biopsy is still the most widely used approach for the diagnosis of PCa, but it has some drawbacks, such as perioperative complications, increased psychological and an economic burden to patients, and false-negative results (3). Moreover, the cancer detection rate of prostate biopsy is unsatisfactory, and more than half of men who are biopsied will have benign diseases or indolent PCa leading to unnecessary biopsies and severe overdiagnosis (4,5). Two recent papers by Gulati (6) and Arnold and Webster (7) suggest that the overdiagnosis of PCa by unnecessary prostate biopsies has already become a global problem requiring an immediate resolution (6,7).

At present, the nonspecific elevation of serum prostate-specific antigen (PSA) and abnormal digital rectal examinations are the cornerstone indications for prostate biopsy. However, both lack sufficient sensitivity and specificity, as the serum PSA level can be influenced by many factors other than PCa, and the digital rectal examination only has very low efficacy for the early diagnosis of PCa (8). With the recommendation of authoritative guidelines, multiparametric magnetic resonance imaging (mpMRI) has become a routine examination for biopsy-naive patients (9). Prostate mpMRI images can be interpreted with the Prostate Imaging Reporting and Data System (PI-RADS) on a 5-point Likert scale (10). Several studies have confirmed that the diagnostic accuracy of using PI-RADS outperforms the traditional serum PSA test or digital rectal examination. Although using mpMRI imaging can mitigate the overdiagnosis of PCa, false-positive and false-negative results are often encountered in clinical practice (11-13). The use of mpMRI as a triage test prior to prostate biopsy remains controversial. In addition, one study also indicated that MRI-guided and transrectal ultrasound fusion transperineal biopsy achieves better detection for csPCa and anterior lesions as compared to transrectal biopsy, while being associated with a lower risk of rectal bleeding and infective complications (14).

In this study, we used the results of prostate MRIs and transperineal prostate biopsy results over a 5-year period to develop biopsy strategies for each PIRADS score to optimize detection of clinically significant PCa. These measures were adopted in conjunction with PSA density (PSAD) and prostate volume to reduce the false-negatives in PIRADS 1–2 lesions and the false-positives in PIRADS 3–5 lesions. We aimed to provide a novel strategy for considering indications for prostate biopsy that can significantly avoid unnecessary biopsies and maintain a high detection rate of csPCa. We present this article in accordance with the STARD reporting checklist (15) (available at https://qims.amegroups.com/article/view/10.21037/qims-23-875/rc).

Methods

Study design and patients

A total of 1,757 patients who underwent transperineal prostate biopsies in The First Affiliated Hospital of USTC were screened, and 1,194 eligible patients were ultimately included in this retrospective study. Of these patients, 1,080 eligible patients who received prostate biopsies from January 2018 to July 2022 were placed into cohort 1 (primary analysis cohort), while 114 patients who received prostate

biopsies from August 2022 to December 2022 were placed in cohort 2, as a validation cohort. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013) and was reviewed and approved by the Ethics Committee of The First Affiliated Hospital of USTC (No. 2023-RE-008). All patients signed an informed consent form before the prostate biopsy. The exclusion criteria were as follows: (I) patients with an incomplete clinical record, (II) repeated prostate biopsy, (III) no mpMRI before biopsy, (IV) serum total PSA (tPSA) <4 or ≥100 ng/mL, and (V) no clear Gleason score in the pathological report. Clinical information including age, serum tPSA, prostate volume, and PSAD (the ratio of tPSA to prostate volume) were recorded. Prostate volume was calculated as follows: maximum anteroposterior diameter (cm) × maximum transverse diameter (cm) × maximum longitudinal diameter (cm) ×0.52 (16).

mpMRI acquisition and interpretation of PI-RADS score

All mpMRI examinations in this study were performed in our center. Two types of 3.0T scanners (Trio Tim and Vida, Siemens Healthineers, Erlangen, Germany) with an external 6-channel body array coil and no endorectal coils were used. The imaging sequences consisted of T1-weighted imaging (T1WI); transverse, sagittal, and coronal T2-weighted imaging (T2WI) without fat suppression; transverse diffusion-weighted imaging (DWI) with apparent diffusion coefficient (ADC) map (Trio Tim scanner b values: 50, 800, and 1,400 s/mm^2; Vida scanner b values: 50, 800, 1,500 s/mm^2); and dynamic contrast-enhanced T1WI. The images were interpreted by two experienced radiologists who were blinded to the pathological results. They first read the images alone, and discrepancy were processed via multidisciplinary discussion. For the final score, the criteria of PI-RADS v. 2.1 were applied (17). Each suspicious lesion was given a definite score from 1 to 5. If patients had multiple lesions, the lesion with highest score was used.

Prostate biopsy and pathological diagnosis

The prostate biopsy in our hospital was performed by two professional physicians via the transperineal route. Each patient received standard 12-core systematic biopsy. For patients with abnormal MRI lesions (PI-RADS score ≥3), additional targeted cores were conducted with the cognitive fusion method. After pathological evaluation, all cancer samples received a report in accordance with the 2014 International Society of Urological Pathology (ISUP) classification system (18). In the data analysis, high-grade PCa with ISUP grade ≥2 was considered to be csPCa, while low-grade PCa with ISUP grade 1 was considered to be clinically insignificant PCa (cisPCa).

Statistical analysis

Normality tests were first carried out for all continuous variables. Skewed variables are presented as the median and interquartile range (IQR) and were compared using the Mann-Whitney test or the Kruskal-Wallis test. Categorical variables are presented as frequencies and percentages and were compared with the chi-squared test. The diagnostic performances of different clinical variables were evaluated using the receiver operating characteristic (ROC) curves and area under the curve (AUC). Sensitivity, specificity, positive predictive value, and negative predictive values were also calculated. The comparisons of different ROC curves were performed via the DeLong test (19). For follow-up results, Kaplan-Meier curves and the log-rank test were used for cancer diagnosis-free survival analysis. The cancer diagnosis-free survival time was considered to be from the time of initial negative prostate biopsy to the diagnosis of any-grade PCa or censoring at follow-up. Statistical analyses were completed with SPSS 25.0 (IBM Corp., Armonk, NY, USA), GraphPad Prism 7.0 (GraphPad Software, San Diego, CA, USA), and MedCalc 18.9.1 (MedCalc Software Ltd., Ostend, Belgium) software. All tests were two-sided, and a P value <0.05 was considered statistically significant.

Results

Clinicopathological characteristics of the patients

After careful screening, a total of 1,080 patients were included in cohort 1 and 114 patients were included in cohort 2. *Figure 1* displays the study flowchart and patient selection criteria. The clinical information of all the eligible patients is summarized in *Table 1*. In cohort 1, the median age, tPSA, prostate volume, and PSAD were 69 (IQR, 63–75 years), 13.44 (IQR, 9.12–21.56 ng/mL), 47.07 (IQR, 31.56–67.98 mL), and 0.29 (IQR, 0.16–0.53 ng/mL^2), respectively. Negative mpMRI results (PI-RADS 1–2) were found in 518 (48.0%) patients, while positive mpMRI results (PI-RADS 3–5) were found in 562 (52.0%) patients. csPCa was detected in 331 (30.6%) patients, cisPCa was detected in 104 (9.6%) patients, and another 645 (59.7%)

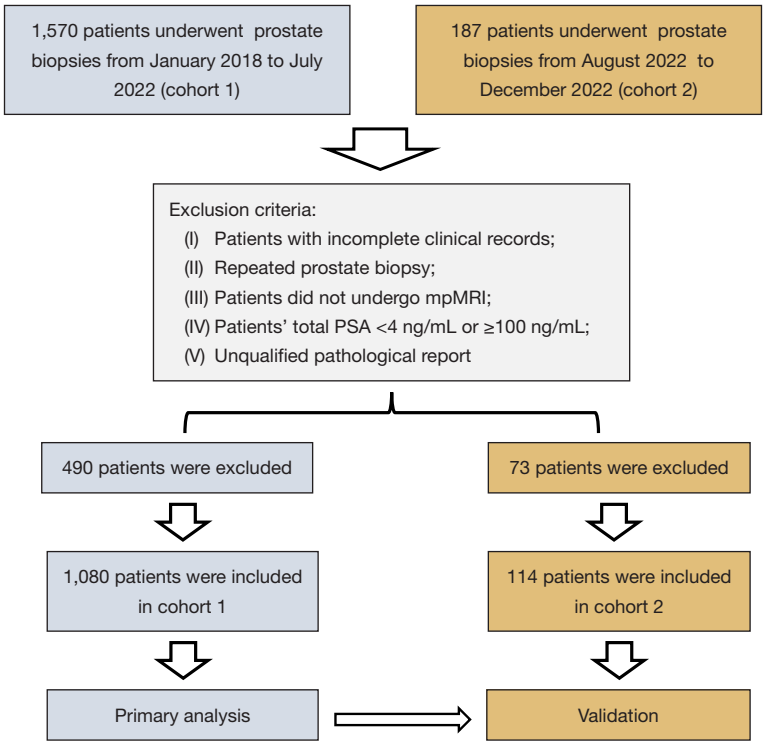

Figure 1 Study flowchart. mpMRI, multiparametric magnetic resonance imaging; PSA, prostate-specific antigen.

Table 1 Demographic characteristics of the eligible patients

Clinical variables	Cohort 1 (N=1,080)	Cohort 2 (N=114)	P value
Age (years), median (IQR)	69.00 (63.00–75.00)	68.00 (61.50–74.00)	0.553
tPSA (ng/mL), median (IQR)	13.44 (9.12–21.56)	11.68 (8.35–20.52)	0.193
PV (mL), median (IQR)	47.07 (31.56–67.98)	49.61 (36.58–76.35)	0.096
PSAD (ng/mL^2), median (IQR)	0.29 (0.16–0.53)	0.26 (0.14–0.53)	0.241
PI-RADS v. 2.1, case (%)			0.727
1	56 (5.2)	5 (4.4)	
2	462 (42.8)	48 (42.1)	
3	192 (17.8)	23 (20.2)	
4	166 (15.4)	13 (11.4)	
5	204 (18.9)	25 (21.9)	
ISUP grade, case (%)			0.558
0, no cancer	645 (59.7)	73 (64.0)	
1	104 (9.6)	8 (7.0)	
≥2	331 (30.6)	33 (28.9)	

IQR, interquartile range; tPSA, total prostate-specific antigen; PV, prostate volume; PSAD, prostate-specific antigen density; PI-RADS v. 2.1, Prostate Imaging Reporting and Data System version 2.1; ISUP, International Society of Urological Pathology.

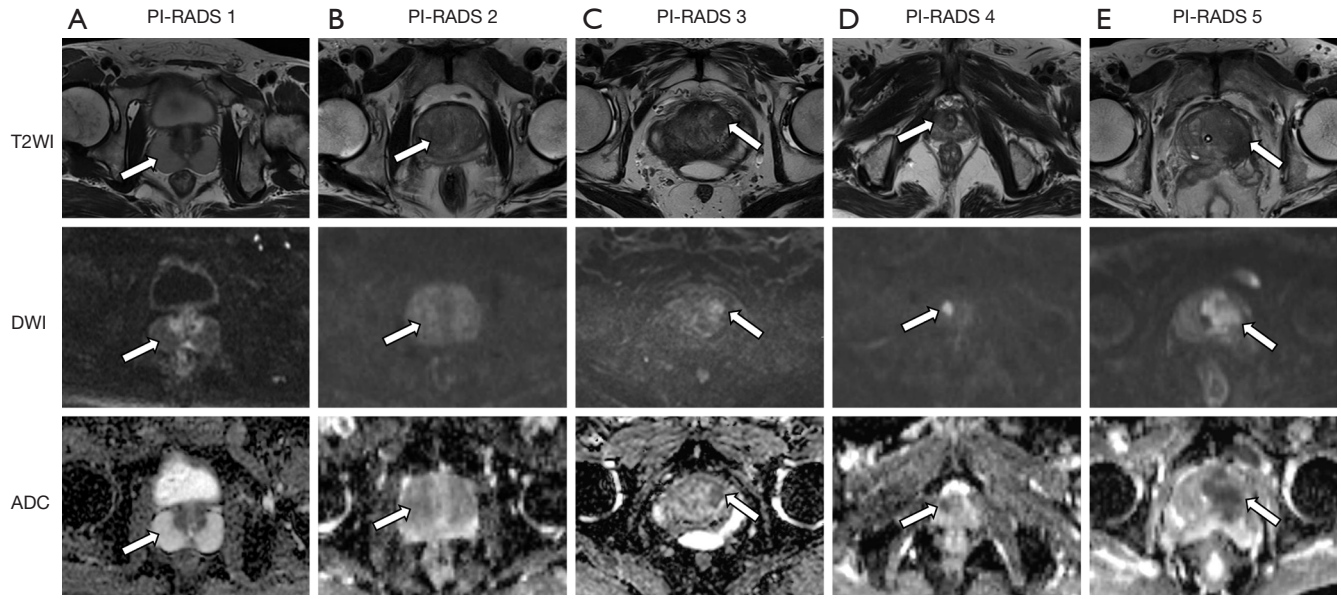

Figure 2 The representative mpMRI images of five patients with different PI-RADS scores. (A) PI-RADS score 1: normal peripheral zone showing a uniform hyperintensive signal on T2WI, with DWI and ADC showing no abnormality. (B) PI-RADS score 2: T2WI showing diffuse hypointensity with an indistinct margin on the right lobe, with DWI displaying slight hyperintensity and ambiguous hypointensity on ADC. (C) PI-RADS score 3: T2WI showing irregular moderate hypointensity in the left peripheral zone, with DWI showing mild hyperintensity and ADC showing mild hypointensity. (D) PI-RADS score 4: T2WI showing circumscribed moderate hypointensity confined in the right peripheral zone, with obvious focal hyperintensity apparent on DWI and corresponding hypointensity on ADC. (E) PI-RADS score 5: T2WI showing non-circumscribed, homogenous hypointensity in the left transition zone and peripheral zone, with DWI showing conspicuous hyperintensity and apparent hypointensity on ADC. White arrows indicate the suspicious lesions. PI-RADS, Prostate Imaging Reporting and Data System; T2WI, T2-weighted imaging; DWI, diffusion-weighted imaging; ADC, apparent diffusion coefficient; mpMRI, multiparametric magnetic resonance imaging.

patients were diagnosed with noncancer diseases. There were no significant differences in the clinical data between cohort 1 and cohort 2 (P>0.05).

The diagnostic performance of the PI-RADS score was superior to that of tPSA and other clinical variables

In this study, PI-RADS score was mainly assessed via T2WI, DWI, and ADC maps obtained from two 3.0T scanners; *Figure 2* shows the representative pictures of lesions with different scores. After patients were divided into different subgroups via PI-RADS score or tPSA intervals, the detection rate of csPCa was significantly increased with the increase of PI-RADS score and tPSA level (*Figure 3A,3B*). The results of ROC curve analysis demonstrated that the PI-RADS score had a higher diagnostic accuracy compared with tPSA both for any-grade PCa (agPCa) (PI-RADS: AUC =0.898; tPSA: AUC =0.666; P<0.001) and csPCa (PI-RADS: AUC =0.917; tPSA: AUC =0.726; P<0.001) (*Figure 3C-3E*). We also compared the diagnostic performance of the PI-RADS score with age, prostate volume, and PSAD. DeLong tests revealed that the PI-RADS score has the best diagnostic value (P<0.001) (*Table 2*). These findings support mpMRI as being a more reliable triage test compared to other traditional methods.

Prostate biopsy for patients with negative mpMRI results

In cohort 1, 56 patients had PI-RADS 1, no patients were diagnosed with csPCa, and only 2 patients had cisPCa on biopsy. This suggests that prostate biopsy is unnecessary in patients with PI-RADS 1. For the 462 patients with PI-RADS 2, only 13 patients and 27 patients were diagnosed with csPCa and cisPCa, respectively. Patients with csPCa had higher levels of PSAD but a smaller prostate volume compared to non-PCa patients (Figure S1A-S1D). ROC curves also indicated the better diagnostic performance of PSAD and prostate volume compared to age and total PSA

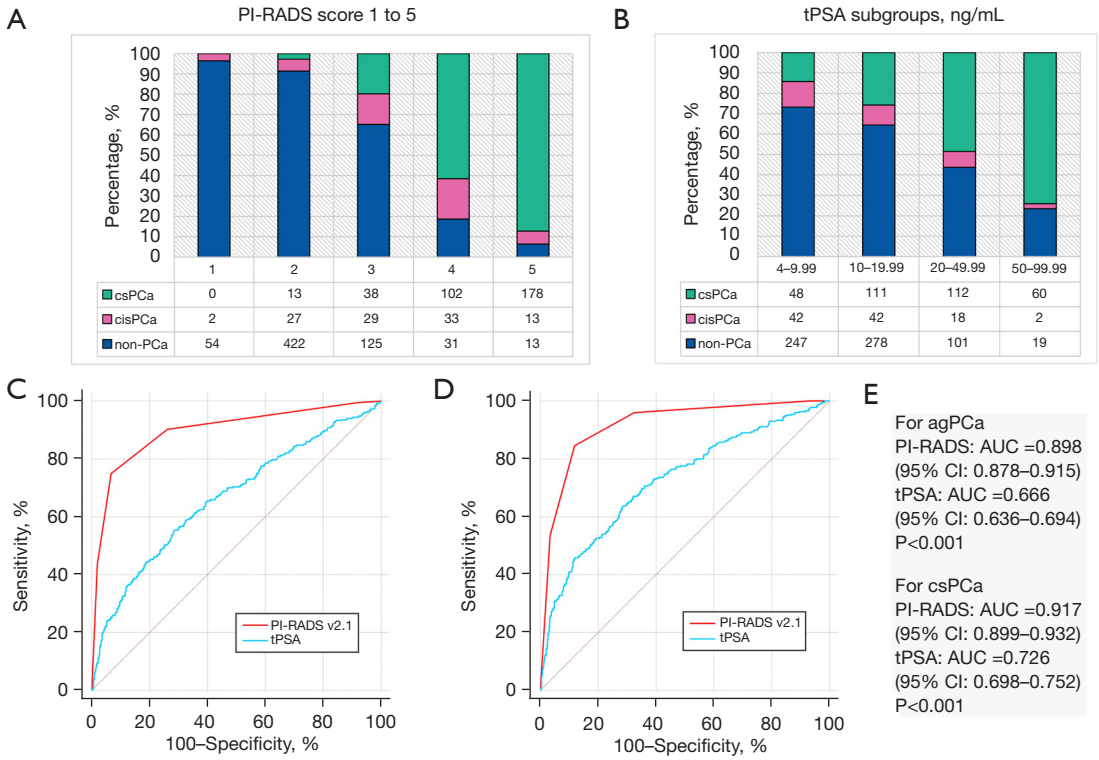

Figure 3 Biopsy results in the different subgroups of PI-RADS score and tPSA intervals and the diagnostic performance of PI-RADS score and tPSA. The frequency distributions show that the detection rate of csPCa was significantly increased with the increase of (A) PI-RADS score and (B) tPSA level (ng/mL). ROC curves of PI-RADS score and tPSA for the diagnosis of agPCa (C), csPCa (D), and the comparison results (E). PI-RADS, Prostate Imaging Reporting and Data System; tPSA, total prostate-specific antigen; csPCa, clinically significant prostate cancer; cisPCa, clinically insignificant prostate cancer; agPCa, any-grade prostate cancer; ROC, receiver operating characteristic; AUC, area under curve; CI, confidence interval.

(Figure S1E). Among the 13 patients with csPCa, 11 had PSAD ≥0.3 ng/mL^2 while 11 had a prostate volume <65 mL (*Figure 4A*,*4B*). If prostate biopsy were only performed for patients with PSAD ≥0.3 ng/mL^2 and a prostate volume <65 mL, 342 patients could be exempted from biopsy operations, 3 csPCa would be missed, and cisPCa would not be detected in 21 patients. Biopsy would still need to be performed in 120 patients, and among these patients, csPCa would be detected in 10 (*Table 3*).

Refusal of prostate biopsy for patients with positive mpMRI results

For 192 patients with PI-RADS 3 in cohort 1, 38 patients were diagnosed with csPCa and 29 with cisPCa. Compared to patients with csPCa, non-PCa patients had lower PSAD but a larger prostate volume (Figure S2A-S2D). PSAD and prostate volume outperformed age and tPSA in the diagnosis of csPCa (Figure S2E). Of the 38 patients with csPCa, 17 patients had PSAD <0.3 ng/mL^2 and 1 patient had a prostate volume ≥65 mL (*Figure 4C*,*4D*). If prostate biopsy were not performed in patients with PSAD <0.3 ng/mL^2 and prostate volume ≥65 mL, 45 patients could avoid biopsy, with only 1 case of csPCa being missed and 5 cases of cisPCa being missed. Biopsy would still be required in 147 patients, and 37 cases of csPCa would be detected (*Table 3*).

Of the 166 patients with PI-RADS 4, 102 patients were diagnosed with csPCa and 33 patients with cisPCa. The results and diagnostic performance of PSAD and prostate volume were similar (Figure S3). Although the detection rate of csPCa was lower for patients with PSAD <0.3 ng/mL^2 and a prostate volume ≥65 mL (*Figure 4E*,*4F*), more than 30% of patients were finally diagnosed with csPCa in these subgroups. Among 204 patients with PI-RADS 5, only 13 had noncancer diseases on biopsy. This

Table 2 Diagnostic performance of the clinical variables for agPCa and csPCa

Clinical variables	AUC	SE	95% CI	Sensitivity, %	Specificity, %	P value
For agPCa						
Age (years)	0.628	0.017	0.598–0.657	51.03	68.53	<0.001
tPSA (ng/mL)	0.666	0.017	0.636–0.694	55.40	71.47	<0.001
PV (mL)	0.718	0.016	0.691–0.745	60.92	72.56	<0.001
PSAD (ng/mL^2)	0.772	0.015	0.746–0.797	64.37	78.76	<0.001
PI-RADS v. 2.1	0.898	0.010	0.878–0.915	74.94	93.18	Reference
For csPCa						
Age (years)	0.636	0.018	0.606–0.664	50.15	71.30	<0.001
tPSA (ng/mL)	0.726	0.017	0.698–0.752	63.75	71.43	<0.001
PV (mL)	0.730	0.016	0.702–0.756	77.64	58.74	<0.001
PSAD (ng/mL^2)	0.829	0.013	0.805–0.851	75.23	77.57	<0.001
PI-RADS v. 2.1	0.917	0.009	0.899–0.932	84.59	87.98	Reference

agPCa, any-grade prostate cancer; csPCa, clinically significant prostate cancer; AUC, area under the curve; SE, standard error; CI, confidence interval; tPSA, total prostate-specific antigen; PV, prostate volume; PSAD, prostate-specific antigen density; PI-RADS v. 2.1, Prostate Imaging Reporting and Data System version 2.1.

definitively demonstrates that patients with a PI-RADS score of 4 and 5 still require prostate biopsy due to the high probability of csPCa.

A novel biopsy strategy and temporal validation

We here propose a novel clinical biopsy strategy based on mpMRI (*Figure 5A*). Patients with PI-RADS 1 can safely avoid prostate biopsy. For patients with PI-RADS 2, prostate biopsy could be considered for patients with PSAD ≥0.3 ng/mL^2 and a prostate volume <65 mL. As for patients with PI-RADS 3, structured surveillance programs can be a viable option if PSAD <0.3 ng/mL^2 and the prostate volume ≥65 mL. Finally, patients with a PI-RADS score of 4 and 5 should definitely undergo prostate biopsy. According to the proposed scheme, the patients could be stratified into a biopsy-spared group and a biopsy-needed group (*Figure 5A*). In cohort 1, there were 433 (40.1%) patients in the biopsy-spared group, among whom just 4 (0.4%) had csPCa. The detection rate of csPCa in the biopsy-needed group was 50.5% (*Figure 5B*). We then performed temporal validation in cohort 2, and 48 (42.1%) patients were placed into the biopsy-spared group with no csPCa cases. The biopsy-needed group had 66 (57.9%) patients, and the csPCa detection rate was 50.0% (*Figure 5C*). Overall, the proposed strategy demonstrated a sensitivity, specificity, positive predictive value, and negative predictive value of 98.9%, 57.5%, 50.5%, and 99.2%, respectively, for diagnosing csPCa.

Follow-up results

We also conducted a systematic follow-up of patients with negative prostate biopsy in cohort 1. A total of 507 patients were followed up, and the median follow-up time was 24 months (IQR, 14–44 months). Of the 324 patients in the biopsy-spared group, 3 (0.9%) were diagnosed with csPCa by repeated prostate biopsy or other prostate operations. Of the 183 patients in the biopsy-needed group, 10 (5.5%) were diagnosed with agPCa and 8 (4.4%) with csPCa. The csPCa diagnosis-free survival was significantly different between the biopsy-spared group and the biopsy-needed group (P=0.011) (*Figure 6*).

Discussion

In this study, the PI-RADS score outperformed tPSA and other clinical variables in the diagnosis of csPCa. For patients with negative mpMRI results (PI-RADS score 1–2), prostate biopsy can be considered for patients with PI-RADS 2 if their PSAD ≥0.3 ng/mL^2 and their prostate volume <65 mL; moreover, for patients with

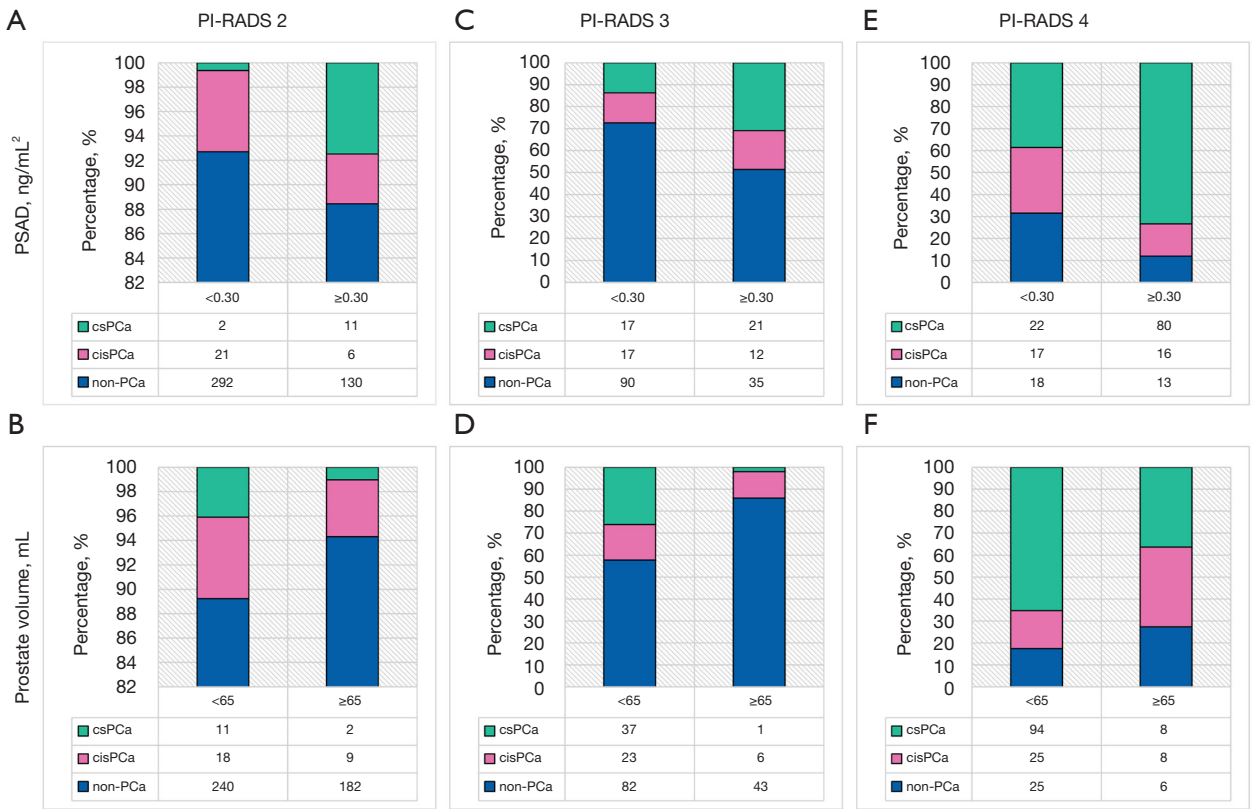

Figure 4 Frequency distributions of biopsy results in the different subgroups of PSAD and prostate volume. Frequency distributions of biopsy results for patients with PSAD <0.3 ng/mL^2 and PSAD ≥0.3 ng/mL^2. (A) Patients with PI-RADS 2, (C) patients with PI-RADS 3, and (E) patients with PI-RADS 4. Frequency distributions of biopsy results for patients with prostate volume <65 mL and prostate volume ≥65 mL. (B) Patients with PI-RADS 2, (D) patients with PI-RADS 3, and (F) patients with PI-RADS 4. PI-RADS, Prostate Imaging Reporting and Data System; PSAD, prostate-specific antigen density; csPCa, clinically significant prostate cancer; cisPCa, clinically insignificant prostate cancer.

Table 3 The summary of the mpMRI-based biopsy strategy

PI-RADS v. 2.1	Screening criteria	Non-PCa, n (%)	cisPCa, n (%)	csPCa, n (%)	Biopsy strategy
1	None	54 (5.0)	2 (0.2)	0 (0.0)	Biopsy-spared[†]
2	PSAD <0.3 ng/mL^2 or PV ≥65 mL	318 (29.4)	21 (1.9)	3 (0.3)	Biopsy-spared
	PSAD ≥0.3 ng/mL^2 and PV <65 mL	104 (9.6)	6 (0.6)	10 (0.9)	Biopsy-needed[‡]
3	PSAD <0.3 ng/mL^2 and PV ≥65 mL	39 (3.6)	5 (0.5)	1 (0.1)	Biopsy-spared
	PSAD ≥0.3 ng/mL^2 or PV <65 mL	86 (8.0)	24 (2.2)	37 (3.4)	Biopsy-needed
4	None	31 (2.9)	33 (3.1)	102 (9.4)	Biopsy-needed
5	None	13 (1.2)	13 (1.2)	178 (16.5)	Biopsy-needed

[†], prostate biopsy can be avoided; [‡], prostate biopsy should be performed. mpMRI, multiparametric magnetic resonance imaging; PI-RADS v. 2.1, Prostate Imaging Reporting and Data System version 2.1; PCa, prostate cancer; cisPCa, clinically insignificant prostate cancer; csPCa, clinically significant prostate cancer; PSAD, prostate-specific antigen density; PV, prostate volume.

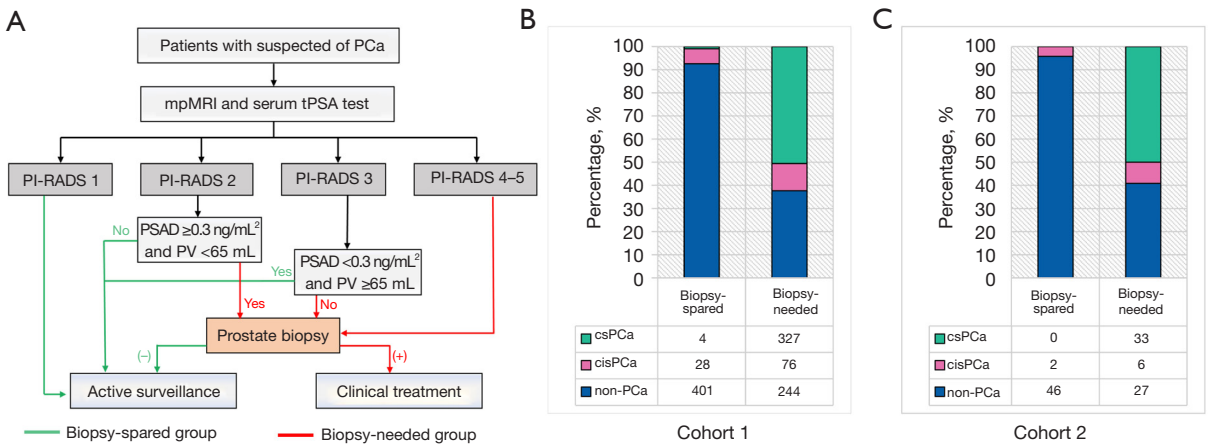

Figure 5 Proposed prostate biopsy strategy and biopsy results based on this strategy. (A) Scheme of the proposed prostate biopsy strategy. The biopsy results of cohort 1 (B) and cohort 2 (C) if the new scheme were adopted. PCa, prostate cancer; mpMRI, multiparametric magnetic resonance imaging; tPSA, total prostate-specific antigen; PI-RADS, Prostate Imaging Reporting and Data System; PSAD, prostate-specific antigen density; PV, prostate volume; csPCa, clinically significant prostate cancer; cisPCa, clinically insignificant prostate cancer.

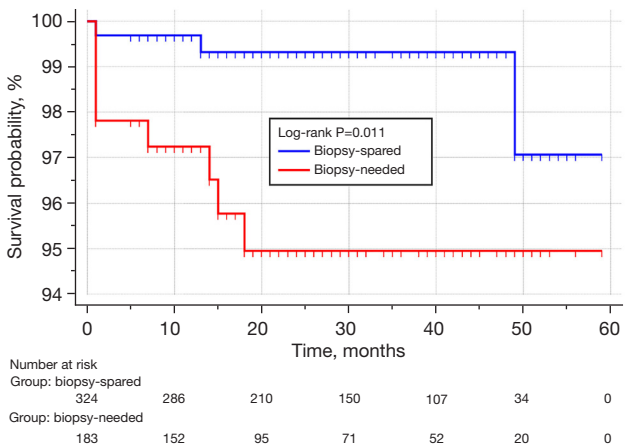

Figure 6 Kaplan-Meier curves for the comparison of csPCa diagnosis-free survival between the biopsy-spared group and the biopsy-needed group. csPCa, clinically significant prostate cancer.

positive mpMRI results (PI-RADS score 3–5), structured surveillance programs can be a viable option for patients with PI-RADS 3 if their PSAD <0.3 ng/mL^2 and their prostate volume ≥65 mL. Finally, the Kaplan-Meier curves showed a longer csPCa diagnosis-free survival time of patients in the biopsy-spared group than in the biopsy-needed group.

In clinical practice, abnormal serum tPSA level and digital rectal examination followed by standard 10 to 12-core prostate biopsy is the classical diagnostic approach for PCa. Newer techniques such as index lesion overlapping cores and saturated biopsy have also been applied (20). However, these diagnostic methods are invasive and can cause perioperative complications or false-negative results (21). mpMRI is an improvement for the diagnosis of PCa and mainly includes four sequences: T1WI, T2WI, DWI, and dynamic contrast-enhanced imaging. T2WI is the most important sequence of mpMRI, as PCa tissues will appear hypointense for high cell density and low water content. DWI sequences reflect the capability of random movement of water molecules, with a bright-signal area at high b values contrasting with surrounding tissue being suggestive of PCa, On the contrary, PCa lesion appears as a low-signal area on the ADC map. T1WI alone can be used to assess the regional lymph nodes and bone structures but is also capable of evaluating cancer angiogenesis after intravenous injection of contrast agent (10,12). PI-RADS is a joint framework and has standardized the acquisition and interpretation of mpMRI. The negative predictive value of mpMRI (PI-RADS 1–2) was evaluated in a meta-analysis that included 42 studies comprising 7,321 patients. The pooled negative predictive value was 90.8% for biopsy-naive patients and 92.7% for those with a previous prostate biopsy negative for csPCa. Negative mpMRI results can provide important information for patients who want to temporarily delay prostate biopsy (22). Another study also analyzed the positive predictive value of csPCa in mpMRI (PI-RADS

3–5) and included 56 studies. The positive predictive values were 13%, 40%, and 69% for patients with PI-RADS 3, 4, and 5, respectively, and the pooled positive predictive value was only 40% (23). It should be noted that many patients may obtain false-positive results from mpMRI. To further differentiate these suspected lesions, new biomarkers, technologies, or nomograms can be used in combination with mpMRI.

PSAD is the most widely studied biomarker for improving the diagnostic accuracy of mpMRI. Studies have reported that the detection rate of csPCa is very low in patients with PI-RADS ≤3 and PSAD ≤0.15 ng/mL^2, but the addition of PSAD to mpMRI can significantly increase the AUC value (16,24). However, only a few studies have examined the diagnostic value of prostate volume and PSAD within the context of different PI-RADS scores. Using the PI-RADS score, clinical information, and serum biomarkers to construct clinical predictive nomograms can also improve the diagnostic performance of mpMRI. These models provide efficient tools for the individual risk calculation of PCa but still need more regional validations before they can be more extensively adopted (25-27). Additionally, some innovative MRI methods have also been developed for the detection of PCa; these include MR spectroscopy; vascular, extracellular, and restricted diffusion for cytometry in tumor (VERDICT); MRI; hybrid multidimensional MRI; and luminal water imaging. The accuracy and cost-effectiveness of these novel approaches also require further validation in high-quality research (28,29).

In addition to serving as a triage test prior to biopsy, mpMRI can also provide important information for targeted biopsy. In recent years, several studies have compared the diagnostic value of MRI-targeted biopsies and systematic biopsies. The findings consistently indicate the following: MRI-targeted biopsy is noninferior to standard biopsy and MRI-targeted biopsy can detect more clinically significant cancers and fewer clinically insignificant cancers compared to systematic biopsy (30-33). However, some high-grade tumors might be missed by targeted biopsy alone, and systematic biopsy cannot be completely replaced by MRI-targeted biopsy currently (34,35). Of note, there are at least three techniques that can be used for MRI-targeted biopsy, including visual registration (also known as cognitive fusion), software registration, and in-bore biopsy (36). There remains controversy regarding which method is best for characterizing PCa (37). The visual registration method is easiest to implement because it does not require additional equipment; however, the learning curve effect significantly influences the precision of targeted biopsy (38,39).

There are several limitations to this study. First, in the interpretation the MR sequences, dynamic contrast-enhanced T1WI was only performed in a small fraction of patients. This might have affected the final PI-RADS score, especially the lesions located in the transitional zone (40). Second, for all patients with PI-RADS ≥3, MRI-targeted biopsy was performed using the visual registration method, and the accuracy could have been affected by the learning curve effect. Third, we employed a single-center design in a tertiary and class A hospital, which might have influenced the diagnostic performance, and validation in external cohorts is necessary (41). Finally, a retrospective study inevitably involves selective bias, and future studies with prospective designs are required to confirm our conclusions.

Conclusions

We proposed a novel mpMRI-based biopsy strategy, which can effectively reduce about 40% of prostate biopsies and maintain a high detection rate of csPCa. It can provide valuable guidance for patients and physicians in considering the necessity of prostate biopsy. Our findings warrant further confirmation in subsequent prospectively designed studies.

Acknowledgments

The authors would like to deeply thank all investigators for their contributions to this study and all patients who participated in this study.

Funding: This study was partly supported by the National Natural Science Foundation of China (No. 82072807) and the University Scientific Research Program of the Education Department of Anhui Province (No. 2022AH040182).

Footnote

Reporting Checklist: The authors have completed the STARD reporting checklist. Available at https://qims.amegroups.com/article/view/10.21037/qims-23-875/rc

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://qims.amegroups.com/article/view/10.21037/qims-23-875/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013) and was approved by the Ethics Committee of the First Affiliated Hospital of USTC (No. 2023-RE-008). All patients signed an informed consent form before the prostate biopsy.

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Cite this article as: Wang C, Shen D, Yuan L, Dong Q, Xu S, Liu Y, Xiao J. Creating a novel multiparametric magnetic resonance imaging-based biopsy strategy for reducing unnecessary prostate biopsies: a retrospective cohort study. Quant Imaging Med Surg 2024;14(2):2021-2033. doi: 10.21037/qims-23-875

