Body Imaging

Can high b-value 3.0 T biparametric MRI with the Simplified Prostate Image Reporting and Data System (S-PI-RADS) be used in biopsy-naïve men?

Gang Wang a, Gang Yu a, Jing Chen b, Guang Yang b, Haixia Xu c, Zegu Chen b, Guoren Wang a, Zhiming Bai a, *

a Department of Urology, Central South University Xiangya School of Medicine Affiliated Haikou Hospital, No.43 Renmin Street, Meilan District, Haikou 570208, Hainan Province, China
b Department of Radiology, Central South University Xiangya School of Medicine Affiliated Haikou Hospital, No.43 Renmin Street, Meilan District, Haikou 570208, Hainan Province, China
c Department of Pathology, Central South University Xiangya School of Medicine Affiliated Haikou Hospital, No.43 Renmin Street, Meilan District, Haikou 570208, Hainan Province, China

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ABSTRACT

Objective: To analyze the clinical value of high b-value 3.0 T biparametric magnetic resonance with the Simplified Prostate Image Reporting and Data System (S-PI-RADS) in biopsy-naïve men.

Methods: A retrospective analysis of the data of 224 patients who underwent prostate biopsy (cognitive fusion targeted biopsy combined with systematic biopsy) after a high b-value 3.0 T magnetic resonance examination at Haikou Hospital from July 2018 to July 2020 was performed. Two radiologists performed multi-parameter magnetic resonance imaging (mp-MRI) with the prostate imaging report and data system version 2 (PI-RADS v2) and biparametric magnetic resonance imaging (bp-MRI) with the simplified prostate image reporting and data system (S-PI-RADS). The detection efficacy of the two regimens was evaluated by classifying prostate cancer (PCa) and clinically significant prostate cancer (csPCa) according to pathology, and the statistical significance of the differences between the two regimens was determined by Z-test.

Results: The area under the receiver operating curve (AUC) values of mp-MRI based on PI-RADS v2 and bp-MRI based on S-PI-RADS to detect PCa were 0.905 and 0.892, respectively, while the AUC values for the detection of csPCa were 0.919 and 0.906, respectively. There was no statistically significant difference between the two tests (Z values were 0.909 and 1.145, p > 0.05).

Conclusion: There was no significant difference in the detection efficacy of high b-value bp-MRI based on the S-PI-RADS score for prostate cancer and clinically significant prostate cancer compared with the standard PI-RADS v2 score with mp-MRI protocols, which can be applied clinically.

1. Introduction

Prostate cancer is one of the most common tumors in older men and has become the fifth leading cause of death among male cancer patients worldwide. Mp-MRI is the most comprehensive diagnostic imaging modality for prostate cancer. The content elaborated by mp-MRI is based on the prostate imaging reporting and data system (PI-RADS). The second version was released in 2014 (PI-RADS v2). Due to the drawbacks of dynamic contrast-enhanced imaging (DCE) and DCE has no significant added value for the diagnosis of csPCa, continuously weakening the role of DCE. Biparametric MRI, including T2WI and DWI sequences, is lower costs without using gadolinium, reducing the time to complete the study, and has similar results to mp-MRI for PCa detection and localization. However, PI-RADS v2 does not provide clinical management for each score, especially the score-3 lesion (equivocal for csPCa). Preferably, the criteria for PI-RADS category 3 should be redefined to reduce the number of csPCa in this category and the associated uncertainty in diagnostic examination and follow-up of csPCa. High b-value DWI provides better contrast, produces greater tissue diffusivity and less T2 shine-through effect, so high b-values are more

* Corresponding author.
E-mail addresses: wanggang_doctor@126.com (G. Wang), Zhiming_Bai@126.com (Z. Bai).

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suitable for 3.0 T MRI examination.\textsuperscript{11} Michele Scialpi et al.\textsuperscript{12} established a simplified prostate imaging reporting and data system (S-PI-RADS) based on bp-MRI to provide a rapid and straightforward clinical management option, especially for lesion scores of 3. The S-PI-RADS divides the lesions with PI-RADS v2 scores of 3 points into two subgroups, namely, 3a (<0.5 cm\textsuperscript{3}) and 3b (>0.5 cm\textsuperscript{3}), according to the volume of the lesion and considers scores of 4 and 5 points as one category. This study aimed to investigate whether there is a difference in S-PI-RADS detection efficacy based on bp-MRI and PI-RADS v2 based on mp-MRI in detecting PCa and csPCa furthermore to explore the clinical application of S-PI-RADS in biopsy-naïve men.

2. Materials and methods

Our institutional Research Ethics Committee approved this observational, retrospective study, and informed consent was waived. The clinical data of 224 patients who underwent initial prostate biopsy from July 2018 to July 2020 were included.

2.1. Inclusion and exclusion criteria

Inclusion criteria: (i) biopsy indication, including suspicious DRE and/or imaging and/or abnormal PSA value; (ii) Transrectal biopsy within one month after prostate mp-MRI examination with complete pathological findings; (iii) MRI sequences included T1WI, T2WI, axial DWI, and DCE, with three b-values of DWI, one of which was a high b-value (2000 s/mm\textsuperscript{2}); and (iv) complete clinical data. Exclusion criteria: (i) repeat prostate biopsy; (ii) image artifacts affecting image determination; (iii) transurethral surgery, rectal or anal surgery, hormonal therapy, chemotherapy, or radiotherapy before mp-MRI; or (iv) pathology is non-adenocarcinoma, such as uroepithelial carcinoma or sarcoma, or no Gleason score.

2.2. MRI protocol

The GE 3.0 T SIGNA HDX MRI scanner was used, with a composite 8-channel abdominal phased array coil, and no rectal coil was used. The scanning parameters are shown in Supplementary Table S1. As the signal intensity units have not been standardized across MRI scanners, nor are they similar to Hounsfield density units on CT. Therefore, there are no standardized “prostate windows” applicable to images obtained from all MRI scanners.\textsuperscript{13} The T2WI sequence was routinely scanned in the sagittal and coronal planes in addition to the axial plane to display more comprehensive three-dimensional spatial information of the lesion to improve the accuracy of the cognitive fusion target biopsy. After the High b-value DWI sequence (b = 50, 1000, 2000 s/mm\textsuperscript{2}) scan, the apparent diffusion coefficient (ADC) map was reconstructed; after the third phase of the dynamic enhancement, the elbow vein was injected with Gd-DTPA, the flow rate was 2.5 mL/s, the dose was 0.1 mmol/kg, and then 20 mL of saline was injected at the same flow rate to flush the tube. Before the examination, the patient emptied his bowel and, if necessary, used anticholinergic drugs such as scopolamine to reduce intestinal peristalsis.

2.3. MR image analysis

All MRI images were independently read by two radiologists with more than 8 years of experience each. A second more senior radiologist performed the final evaluation to reduce the interobserver discrepancy in case of disagreement. PI-RADS v2 and S-PI-RADS are different terms for the detection of suspicious lesions. Unlike PI-RADS v2, S-PI-RADS considers DWI as the dominant sequence in both transition zone and peripheral zone, and ADC maps are used to differentiate between category 3 and category 4 lesions, respectively moderately and markedly hypointense.\textsuperscript{13,14} The mp-MRI protocol was assessed by the PI-RADS v2. The bp-MRI protocol provided only T2 and DWI sequence images of the same patient, and the score 3 lesions were divided into two subgroups, 3a (<0.5 cm\textsuperscript{3}) (Fig. 1) and 3b (>0.5 cm\textsuperscript{3}) (Fig. 2), according to volume and assessed by the S-PI-RADS system\textsuperscript{11} (shown in Supplementary Table S2). The volume of score 3 lesions was calculated using the 3D reconstruction software Mimics (Mimics Innovation Suite, Materialise NV, Belgium) to outline the area of interest in the lesion (see Fig. 3). Besides, the volume can be calculated on DWI at high-b value using the ellipsoidal formula (width x height x length x 0.52).\textsuperscript{15} Before scoring, the patient’s clinical data were unknown to radiologists, and two protocols were performed more than one week apart to reduce bias. When multiple suspicious lesions were present, only the index lesion was scored and recorded. Index Lesion for PI-RADS\textsuperscript{13}: Lesion identified on MRI with the highest PI-RADS Assessment Category. If the highest PI-RADS\textsuperscript{15}: the index lesion to be not the one with a greater volume but the one with more marked hypointensity or restricted diffusion on ADC maps, which is correlated to a higher Gleason score. Due to the poor imaging quality of DWI, in S-PI-RADS that DWI at high b-value and corresponding ADC map help detect a suspicious PCa and that T2W is used to confirm and localize the lesion.\textsuperscript{13,14} As reported by Scialpi et al.,\textsuperscript{13} the step for reading the sequences by mp-MRI and bp-MRI: For mp-MRI, the first step is to observe T1W images to determine the presence of hemorrhage in the prostate and seminal vesicles and delineate the gland’s contours. Then, T2WI is observed to identify the prostate zonal anatomy, assess the abnormalities within the gland, and evaluate the seminal vesicle invasion and extraprostatic extension (EPE). Then the DWI (ADC) image is observed. Finally, the DCE image is observed. For bp-MRI, the reading starts with T1W images to rule out hemorrhage, and it continues to detect the lesions with the ADC map (focal moderate or marked hypointensity) and corresponding DWI with high b values/inverted/ADC, and finally to confirm and localize the lesions with the T2W images (focal hypointensity) according to sectors/regions prostate map. After that, the entire pelvic region should be analyzed for lymph node involvement, bone metastases, and other abnormalities.\textsuperscript{14}

2.4. Biopsy method and definition of csPCa

All patients underwent transrectal ultrasound-guided biopsy by a urologist, and the biopsy protocol was combined MRI-guided cognitive fusion targeted biopsy and systemic biopsy. The systemic biopsy was performed with 12 cores; the targeted biopsy was performed after MRI cognitive fusion, with 2–3 cores. The biopsy pathology results were used as diagnostic criteria. Due to the large number of definitions of csPCa and to avoid interobserver variation due to the complexity of the definitions, we selected the definition of csPCa for which the criteria are relatively simple and which is the one used to exclude the most active monitoring protocols in clinical practice: a Gleason score of $\geq 7$ a Gleason graded grouping of $\geq 2$ points.\textsuperscript{16}

2.5. Statistical analysis

Statistical analysis was performed using SPSS 23.0 and MedCalc Version 15.0 software. Quantitative data were tested for normality. Data conforming to a normal distribution are indicated, while non-normally distributed data are expressed as medians (first to third quartiles). The detection efficacy of PCa and csPCa was evaluated by the receiver operating characteristic (ROC) curve; the maximum Youden index was chosen as the critical value to calculate AUC and the sensitivity and specificity of detection. The Z-test was used to determine the difference in AUC between the 2 scenarios, and $p < 0.05$ was considered statistically significant.

3. Results

Among the 224 patients, 97 (43.3%) were positive, and 127 (56.7%)
were negative. Of all patients who underwent both biopsy methods, prostate cancer was detected in 81 patients (36.2%) by systemic biopsy alone and 80 patients (35.7%) by MRI-targeted biopsy alone. The addition of MRI-targeted biopsy to systematic biopsy increased 16 (7.1%) more prostate cancer diagnoses. Their ages were 71.97 ± 8.26 years and 65.93 ± 7.28 years, respectively, and their PSA scores were 37.24 (13.75, 104.26) ng/mL and 9.84 (6.40, 17.86) ng/mL, respectively. There were 79 (35.3%) cases of csPCa and 18 (8.0%) cases of ciPCa. The percentage of csPCa in systemic biopsy positive was 79.0% (64/81), and the percentage of csPCa in MRI-targeted biopsy positive was 87.5% (70/80). Lesions with scores of 3 with the S-PI-RADS totaled 97 cases, with a volume of 0.499 (0.245, 0.840) cm³. CsPCa and ciPCa accounted for the number and proportion of cases in each of the two scoring systems shown in Table 1.

3.1. Comparison of diagnostic accuracies

The AUC values were 0.905 and 0.892 for the mp-MRI and bp-MRI diagnosis of PCa, respectively, and 0.919 and 0.906 for the diagnosis of csPCa, respectively, with no statistically significant differences between them (Z-values of 0.909 and 1.145, respectively, and P-values of 0.364 and 0.252, respectively). The optimal threshold for diagnosing PCa was as follows: when the PI-RADS v2 score of the mp-MRI protocol was category 3, the Youden index was the largest (0.701), and when the S-PI-RADS score of the bp-MRI protocol was category 3b, the Youden index was the largest (0.707). Similarly, the optimal thresholds for diagnosing csPCa were as follows: when the PI-RADS v2 score of the mp-MRI scheme was 4, the Youden index was the largest (0.743), and when the S-PI-RADS score of the bp-MRI scheme was 3b, the Youden index was the largest (0.782), as detailed in Table 2 and Fig. 4.

3.2. mp-MRI versus bp-MRI for category 3

Our results for category 3 and score 3 lesions were based on a different definition with S-PI-RADS and PI-RADS v2, respectively. There were 86 lesions with a PI-RADS v2 score of 3 in the mp-MRI protocol, with 72 negative biopsies and 14 positive biopsies (csPCa 7 cases). Ninety-seven lesions had an S-PI-RADS score of 3 in the bp-MRI protocol, with 51 lesions in group 3a, 46 negative biopsies, and 5 positive biopsies (csPCa 2 cases), and 46 lesions in group 3b. There were 33 negative cases and 13 positive cases (csPCa 5 cases), as detailed in Table 1. The histopathology of bp-MRI score system category 3 lesions is shown in Table 3.

4. Discussion

In biopsy-naive men, it is minimizing overdiagnosis while better detecting csPCa should be a top priority. The PROMIS and PROTECT studies demonstrated the superiority of MRI over systemic biopsy in correctly diagnosing csPCa, reducing unnecessary biopsies, and decreasing ciPCa detection rates. However, in mp-MRI, the DCE sequence has many drawbacks. In contrast, the role of DWI in
assessing peripheral zone and T2WI features for the transitional zone has been increasing. The Omitted of DCE has three significant benefits: Risk related to gadolinium-based contrast agents, Scanning time, and Cost-effectiveness. Besides, radiomic and artificial intelligence analysis of prostate cancer MRI requires only T2 and DWI (and derived ADC) images without DCE sequences. In a meta-analysis of head-to-head comparisons, high b-value DWI showed significantly better sensitivity and specificity than standard b-value DWI for prostate cancer detection. Our literature reviews, the sensitivity of 3 T high b-value biparametric and multi-parametric MRI without endorectal coil in detecting any PCa are 85.3–87%, 86.7–91.1%, respectively. The sensitivity of bp-MRI for csPCa is 63–89.3%. These studies proved that biopsy-naïve men, the 3.0 T high b-value bp-MRI method, provided accurate prostate image fusion information for targeted biopsy and improved prostate cancer detection rate. A negative bp-MRI before biopsy had a high negative predictive value for ruling out clinically significant prostate cancer. It is why we used 3.0 T high b-value MRI to detect prostate cancer in biopsy-naive men.

In PI-RADS v2, score-3 lesions are equivocal, which has led some physicians to perform biopsies on all PI-RADS score 3 patients, leading to unnecessary biopsies, while others believe that the likelihood of csPCa in PI-RADS-score 3 patients is so low that biopsies should not be performed and that only regular monitoring is required. Do men with score 3 lesions need biopsy or monitoring? Many studies have demonstrated that lesion volume is a predictor of PCa aggressiveness and a good correlation between imaging and histological tumor volume. A minor proportion of csPCa is found in lesions <0.5 cm³ (~2%), whereas ciPCa is considered “indolent” due to slow progression and remains mostly stable after diagnosis. The S-PI-RADS scoring is based on the fact mentioned above that lesions with a PI-RADS v2 score of 3 are classified into 2 subgroups, namely, 3a (<0.5 cm³) and 3b (>0.5 cm³), based on their volumes, to reduce the uncertainty in the diagnosis and follow-up of the lesions in the score-3 category and to provide better clinical decision making. For S-PI-RADS, if a score-3 lesion reaches 0.5 cm³ or more during the follow-up period, it is changed from 3 to 4, and a targeted biopsy is recommended. S-PI-RADS has 4 categories that both consider the volume differences of score-3 lesions and include score-4 and -5 lesions in the same risk category (category 4) according to the clinical management strategy.

Because of the features and advantages of S-PI-RADS to conveniently guide clinical management, especially for score-3 lesions, we wanted to determine whether there was a difference in the diagnostic efficacy of S-PI-RADS versus PI-RADS v2 in biopsy-naive men who underwent 3.0 T MRI because of suspicion of prostate cancer. Our single-center results were as follows: mp-MRI and bp-MRI had AUC values of 0.905 and 0.892 for PCa, AUC values of 0.919 and 0.906 for csPCa, Z values of 0.909 and 1.145, and P values of 0.364 and 0.252, respectively, indicating that the differences in AUC values were not statistically significant (p > 0.05).

Fig. 2. A 76-year-old man with clinically significant PCa (Gleason score, 4 + 3), prostate-specific antigen level of 10.9 ng/mL, PSAD 0.22 ng/mL. The lesion is located in the right TZ of the middle part, and Biparametric prostate MRI shows S-PI-RADS category 3b lesion (lesion volume 0.68 cm³). PI-RADS v2 score 3 was assigned (T2WI 3; DWI/ADC 3; DCE –). (A) Axial T2WI: heterogeneous signal intensity with obscured medial margins, T2WI 3; (B) axial high-b value DWI; (C) ADC map: focal moderately hypo-intense on ADC and mildly hyperintense on DWI, DWI/ADC 3; (D) axial early DCE-MRI: no early focal enhancement in corresponding parts, DCE –. Where the arrow points to the lesion location. The red arrow indicates that there is cancer in the lesion. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)
That indicates no significant difference in the detection efficacy of bp-MRI based on the S-PI-RADS score for PCa and csPCa compared to mp-MRI based on the PI-RADS v2 score. The proportion of csPCa in MRI-targeted biopsies (87.5%) was higher than in whole-body biopsies (79.0%), and that combined biopsies resulted in an increased number of cancer diagnoses (7.1%), which is consistent with several studies.\textsuperscript{28,29} In our study, the detection rate of csPCa in the 3a category was only 3.9%, which was close to the results of a previous study,\textsuperscript{26} indicating that the odds of csPCa among score-3 lesions with a volume $<0.5 \text{ cm}^3$ were very low and that follow-up monitoring could be continued to avoid unnecessary biopsies. No urologist will perform a biopsy on a patient with less than a 5% risk of prostate cancer. The detection rate of csPCa in group 3b was 10.8%, accounting for 38.5% (5/13) of detected prostate cancers, and it could detect prostate cancers with higher grade pathology, proving the requirement for prostate biopsy in group 3b. According to Scialpi et al.,\textsuperscript{13} these results indicate that bpMRI avoids unnecessary biopsies. This study also found that an S-PI-RADS score $\geq 3b$ was the best diagnostic threshold for diagnosing PCa and csPCa by the Youden index, with positive predictive values of 87.50% and 80.70%, negative predictive values of 85.30% and 94.10%, respectively. The positive and negative predictive values of the 3b score were high, indicating that lesion volume $>0.5 \text{ cm}^3$ has perfect predictability. In particular, its negative predictive value for csPCa was 94.10%, indicating that biopsy-naive men with a score of 3b had a very low probability of suffering from csPCa, which could avoid unnecessary biopsies and complications. Additionally, the number of lesions with category 3 was not consistent between bp-MRI and mp-MRI because of

<table>
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<tr>
<th>Table 1</th>
<th>csPCa and ciPCa proportions of two scoring systems (%)</th>
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<tr>
<td>Category</td>
<td>Number</td>
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<tr>
<td>$3a$</td>
<td>51</td>
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<td>68</td>
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<th>Table 2</th>
<th>Detection efficacy of mp-MRI and bp-MRI for the diagnosis of PCa and csPCa</th>
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<td>Scoring system</td>
<td>AUC</td>
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<tr>
<td>Diagnosis of csPCa</td>
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</table>

CS: clinically significant; ciPCa: clinically insignificant; mp-MRI: multi-parametric magnetic resonance imaging; bp-MRI: biparametric magnetic resonance imaging; AUC: area under the curve; PPV: positive predictive value; NPV: negative predictive value.
the different criteria of two scorings. The bp-MRI group had 10 more lesions than the mp-MRI group. When a peripheral zone lesion was evaluated in 3 categories in the DWI sequence, it was not upgraded to 4 categories due to DCE positivity because bp-MRI did not contain the DCE sequence. The preceding also caused the number of S-PI-RADS category 4 lesions \((n = 88)\) does not correspond to PI-RADS v2 score 4 and 5 lesions (overall \(n = 98\)), in Table 1.

With the aging of the population, increased health awareness, changing dietary patterns, and the widespread PSA screening, the detection rate of PCa in China is increasing annually. The increasing incidence of PCa has led to a significant increase in prostate MRI examinations, thereby requiring an efficient and reliable protocol. Simultaneously, men who suspected PCa may forgo MRI as an outpatient procedure due to the high cost (basic medical insurance cannot reimburse costs), thus delaying the disease’s diagnosis and treatment. The examination time of prostate MRI is still a critical factor in determining patient examinations and an essential factor in reducing examination costs. Bp-MRI takes less time, has a significantly lower cost, and has essentially the same diagnostic performance. Meanwhile, the bp-MRI protocol has relatively few technical requirements for examination operators, which is more suitable for China’s current national conditions to benefit more patients.

4.1. Limitations

Our study had the following limitations: (i) biopsy pathology results may be inconsistent with the pathology results after radical surgery; (ii) the choice of Gleason score \(\geq 7\) defined as csPCa may lead to underestimation and misjudgment of some lesions; (iii) MRI-guided cognitive fusion targeted biopsy has individual bias and reproducibility limitations; and (iv) this study is a single-center retrospective study, which may be subject to selection bias.

5. Conclusions

Bp-MRI detects, localizes, and guides prostate biopsy in men with suspected prostate cancer and overcomes some of the limitations of mp-MRI. That is an excellent way to improve the efficiency of the examination and reduce the primary medical insurance burden. Using a rapid and straightforward bp-MRI method as a category seems to improve risk stratification and may be used to exclude aggressive disease and avoid unnecessary biopsies with its inherent risks. There is a need for prospective multicentre studies of bp-MRI in biopsy naïve men to enhance

Table 3

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<tr>
<td>3b</td>
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* The 2014 International Society of Urological Pathology Modified Gleason Grading System.

Table 4

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<th>First authors</th>
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<th>High b-value ((s/mm^2))</th>
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<th>bp-MRI sensitivity</th>
<th>bp-MRI NPV</th>
<th>mp-MRI accuracy</th>
<th>mp-MRI sensitivity</th>
<th>mp-MRI NPV</th>
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<td>87.5</td>
<td>94.6</td>
<td>97.7</td>
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<tr>
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<td>72.0</td>
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<tr>
<td>Jambor</td>
<td>2019</td>
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<td>cs</td>
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<td>98</td>
<td>97</td>
<td>-</td>
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<td>-</td>
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<tr>
<td>van der Leest</td>
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<td>&gt;1400</td>
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Any: any prostate cancer; cs: clinically significant prostate cancer; mp-MRI: multi-parametric magnetic resonance imaging; bp-MRI: biparametric magnetic resonance imaging; NPV: negative predictive value.
the reliability of the results and explore multi-omics and artificial intelligence methods for more accurate identification of csPCa.

Acknowledgements

Author contributions

Ensuring the integrity of the entire study: Gang Wang, Zhiming Bai. Concept and design: Gang Wang, Zhiming Bai. MRI image analysis: Jing Chen, Guang Yang, Zegu Chen. Pathology analysis: Haixia Xu.

Data analysis: all authors. Dissertation writing and revision: all authors. 3D reconstruction and volume calculation: Gang Wang, Gang Yu. Statistical analysis: Gang Wang, Gang Yu.

Ethical approval

All procedures involving human participants in this study followed the requirements of our ethics committee.

Informed consent

As this study was retrospective, informed consent from patients was not required.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.clinimag.2021.06.024.

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