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Comparison of biparametric and multiparametric magnetic resonance imaging in the detection of clinically significant prostate cancer – a prospective study with prostate-specific antigen density analysis

Компарација бипараметарске и мултипараметарске магнетне резонанце у откривању клинички значајног карцинома простате – проспективна студија са анализом густине простата-специфичног антигена

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Comparison of biparametric and multiparametric magnetic resonance imaging in the detection of clinically significant prostate cancer – a prospective study with prostate-specific antigen density analysis

Компарација бипараметарске и мултипараметарске магнетне резонанце у откривању клинички значајног карцинома простате – проспективна студија са анализом густине простата-специфичног антигена

SUMMARY

Introduction/Objective Multiparametric MRI (mpMRI) is the standard imaging method for detection of clinically significant prostate cancer (csPCa). Biparametric MRI (bpMRI), which omits dynamic contrast-enhanced imaging (DCE), may provide a faster and more accessible alternative. The aim of this study was to compare bpMRI and mpMRI in detection of csPCa and evaluate the role of PSA density (PSAD).

Methods This prospective study included 170 men with suspected prostate cancer. All patients underwent 3-T prostate MRI before biopsy. MRI findings were interpreted according to PI-RADS v2.1, and histopathology served as the reference standard. Diagnostic performance was assessed for PI-RADS ≥ 4 and ≥ 3 thresholds. ROC analysis and logistic regression were used to evaluate PSAD.

Results Agreement between bpMRI and mpMRI was 98.2%. At the PI-RADS ≥ 4 threshold, bpMRI showed sensitivity of 97.0%, specificity of 77.9%, and accuracy of 85.3%, comparable to mpMRI (97%, 76.9%, and 84.7%). PSAD showed good diagnostic performance (AUC 0.872, 95% CI, 0.813–0.931, p < 0.001). The optimal cutoff selected by the Youden index was 0.205 ng/mL/cm³. Non-inferiority analysis confirmed non-inferiority of bpMRI compared with mpMRI for overall diagnostic accuracy.

Conclusion Biparametric MRI demonstrated diagnostic performance comparable and non-inferior to mpMRI for detection of csPCa. PI-RADS ≥ 4 was the optimal diagnostic threshold, while PSAD improved risk stratification.

Keywords: prostate cancer; biparametric MRI; multiparametric MRI; PSA density; PI-RADS

САЖЕТАК

Увод/Циљ Мултипараметарска магнетна резонанца (*mpMRI*) представља стандард у дијагностици клинички значајног карцинома простате (*csPCa*). Бипараметарска *MR* (*bpMRI*), без динамичког постконтрастног снимања (*DCE*), може бити бржа и доступнија алтернатива. Циљ рада био је поређење дијагностичких перформанси *bpMRI* и *mpMRI*, као и процена улоге густине *PSA* (*PSAD*).

Методе У проспективну студију укључено је 170 мушкараца са сумњом на карцином простате. Сви су подвргнути 3Т *MR* пре биопсије. Налази су анализирани према *PI-RADS v2.1*, а хистопатологија је коришћена као референтни стандард. Процена је извршена за прагове *PI-RADS* ≥ 4 и ≥ 3, уз *ROC* анализу и логистичку регресију за *PSAD*.

Резултати Сагласност између *bpMRI* и *mpMRI* износила је 98,2%. За праг *PI-RADS* ≥ 4, *bpMRI* је показао сензитивност 97,0%, специфичност 77,9% и тачност 85,3%, готово идентично *mpMRI* (97%, 76,9% и84,7%). *ROC* анализа *PSAD* показала је *AUC* 0,872 (95% *CI* 0,813–0,931, $p < 0,001$). Оптимална гранична вредност, одабрана Јауденовим индексом, износила је 0,205 $ng/mL/cm^3$. Анализа неинфериорности потврдила је неинфериорност *bpMRI* у односу на *mpMRI*.

Закључак Бипараметарска *MR* показује дијагностичке перформансе упоредиве са *mpMRI* у откривању *csPCa*. Праг *PI-RADS* ≥ 4 представља оптимални дијагностички критеријум, док *PSAD* унапређује стратификацију ризика.

Кључне речи: карцином простате; бипараметарска *MRI*; мултипараметарска *MRI*; густина *PSA*; *PI-RADS*

INTRODUCTION

Prostate cancer is one of the most frequently diagnosed malignancies in men worldwide and remains a major public health issue [1, 2]. PSA testing has improved early detection, but its limited specificity may lead to unnecessary biopsies and overdiagnosis of clinically insignificant tumors. Current diagnostic pathways therefore aim to improve detection of clinically significant prostate cancer (csPCa) while reducing unnecessary invasive procedures [3].

PSA density (PSAD), calculated as serum PSA divided by prostate volume, has become an important adjunctive parameter in patients with suspected prostate cancer. It improves specificity compared with PSA alone and is particularly useful in men with equivocal MRI findings, especially PI-RADS 3 lesions. Although 0.15 ng/mL/cm³ is commonly used in clinical practice, recent studies suggest that optimal thresholds may vary according to clinical context and MRI category [4, 5, 6].

Multiparametric MRI (mpMRI) has become central to the diagnostic pathway of suspected prostate cancer. It improves detection of csPCa, enables lesion localization, facilitates targeted biopsy, and reduces unnecessary systematic biopsies [6–11]. The importance of MRI in prostate cancer diagnosis and staging has also been highlighted in regional clinical literature [12, 13]. PI-RADS v2.1 standardized MRI acquisition and interpretation, with the standard mpMRI protocol including T2-weighted imaging, diffusion-weighted imaging (DWI) with ADC mapping, and dynamic contrast-enhanced imaging (DCE) [14, 15].

DCE can be useful in selected cases, particularly for upgrading some PI-RADS 3 peripheral-zone lesions, but it prolongs examination time, increases costs, and requires gadolinium administration [14, 15]. Biparametric MRI (bpMRI), which omits DCE and relies on T2W and DWI, has therefore been proposed as a shorter protocol. Previous systematic reviews and recent prospective studies have reported comparable diagnostic performance of bpMRI and mpMRI for csPCa detection [16–24].

The aim of this study was to compare bpMRI and mpMRI in detection of csPCa, defined as Gleason score ≥ 3+4 / ISUP grade group ≥ 2. We evaluated diagnostic performance, the impact of omitting DCE on PI-RADS categorization, and the additional predictive value of PSAD.

METHODS

Study design and study population

This prospective study included patients with suspected prostate cancer based on PSA > 4 ng/mL and/or abnormal digital rectal examination. The study was conducted at the University Clinical Center Niš from January 1, 2021, to December 31, 2025. The protocol was approved by the institutional ethics committee, and written informed consent was obtained from all participants.

Of200 initially evaluated subjects, 170 men met the inclusion criteria and had complete clinical, imaging, and histopathological data. Inclusion criteria were clinical suspicion of prostate cancer, no previous prostate biopsy, and no prior therapy for prostate disease. Exclusion criteria were contraindications to MRI, contraindications to gadolinium administration, insufficient MRI quality, or absence of histopathological verification.

MRI protocol

All examinations were performed before biopsy using a 3.0 Tesla scanner (SIGNA Pioneer, GE Healthcare, Chicago, IL, USA) with a pelvic phased-array surface coil. Two protocols were evaluated: bpMRI (PI-RADS SHORT), consisting of T2W and DWI with ADC maps, and mpMRI (PI-RADS FULL), consisting of T2W, DWI with ADC maps, and DCE.

MRI interpretation

All MRI examinations were interpreted independently by two radiologists (AT and DS) with at least two years of experience in uroradiology. One radiologist interpreted only the bpMRI protocol and was blinded to the DCE sequence, mpMRI assessment, and report of the second reader. The second radiologist interpreted the complete mpMRI protocol and was blinded to the bpMRI report and assessment of the first reader. Since each protocol was evaluated by a different reader, interobserver agreement was not analyzed, the comparison focused on protocol-level diagnostic performance. Lesions were classified according to PI-RADS v2.1. Positive MRI was defined using two thresholds: PI-RADS ≥ 4 and PI-RADS ≥ 3.

Prostate biopsy and reference standard

Biopsy was performed 1–7 days after MRI. All patients underwent systematic 12-core biopsy, with three additional targeted cores obtained from the MRI-defined suspicious region using cognitive fusion with MR images. Histopathology was classified as malignant (csPCa, Gleason score ≥ 7 / ISUP grade group ≥ 2) or benign/clinically insignificant disease and served as the reference standard.

PSA density assessment

Prostate volume was calculated from MRI measurements using the ellipsoid formula: volume = length × width × height × 0.52. PSAD was calculated as PSA/prostate volume and analyzed as a continuous variable and using thresholds of 0.15 and 0.2 ng/mL/cm³. ROC analysis was used to determine the optimal cutoff, selected by the Youden index. AUC values were reported with 95% confidence intervals (CI) and p-values. A subgroup analysis was performed in patients with PI-RADS 3 lesions.

Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics for Windows, version 29 (IBM Corp., Armonk, NY, USA), with additional calculation of confidence intervals for paired diagnostic differences using standard formulas for paired proportions. Agreement between PI-RADS SHORT and PI-RADS FULL was assessed using cross-tabulation and Pearson's χ^2 test. Diagnostic performance was evaluated by sensitivity, specificity, and accuracy. The 95% CI for AUC values was calculated using the nonparametric DeLong method. Logistic regression was used to identify independent predictors of

malignancy, with PSAD scaled per 0.1 ng/mL/cm³ increase. Non-inferiority of bpMRI compared with mpMRI was assessed for overall diagnostic accuracy, with sensitivity and specificity as supportive endpoints. The prespecified non-inferiority margin was −5 percentage points for the paired difference between bpMRI and mpMRI. Confidence intervals for paired differences were calculated using the Wald method based on discordant pairs. Statistical significance was defined as $p < 0.05$.

Ethics: The study was conducted in accordance with the Declaration of Helsinki. The study protocol was approved by the Ethics Committee of the University Clinical Center Niš, Serbia, Decision no. 43428/5, from 3.12.2019. Written informed consent was obtained from all participants.

RESULTS

Study population

A total of 170 patients were included. Histopathology showed benign or clinically insignificant findings in 104 patients and csPCa in 66 patients (Table 1).

Agreement between PI-RADS SHORT and PI-RADS FULL

Agreement between bpMRI and mpMRI was almost perfect. Identical PI-RADS categories were observed in 167 of 170 patients (98.2%). Three discrepancies were found: two lesions classified as PI-RADS 4 on bpMRI were upgraded to PI-RADS 5 on mpMRI, and one lesion classified as PI-RADS 3 on bpMRI was categorized as PI-RADS 4 on mpMRI (Table 2). The latter case had a benign or clinically insignificant histopathological finding.

Diagnostic performance of MRI protocols

Diagnostic performance is summarized in Table 3. At the PI-RADS ≥ 4 threshold, bpMRI showed sensitivity of 97%, specificity of 77.9%, and accuracy of 85.3%, while mpMRI showed sensitivity of 97%, specificity of 76.9%, and accuracy of 84.7%. Lowering the threshold to PI-RADS ≥ 3 increased sensitivity to 98.5% but reduced specificity to 47.1%.

Non-inferiority analysis confirmed that bpMRI was non-inferior to mpMRI for overall diagnostic accuracy at the prespecified 5-percentage-point margin (Table 4). The paired accuracy difference was 0.6 percentage points (95% CI, −0.6 to 1.7), and the lower CI bound was above the non-inferiority margin.

PSA alone showed lower diagnostic performance than MRI-based parameters. The relationship between bpMRI findings and histopathology is presented in Table 5.

Using PI-RADS ≥ 4, csPCa was detected in 64 of 87 patients (73.6%) with positive bpMRI findings, compared with 2 of 83 patients (2.4%) with negative bpMRI findings.

Multivariate logistic regression analysis

Both PSAD and PI-RADS SHORT score were independent predictors of csPCa (Table 6). PSAD was significant when scaled per 0.1 ng/mL/cm³ increase, and each increase in PI-RADS category was associated with higher malignancy risk.

The unscaled PSAD model produced a very large odds ratio with a wide confidence interval; therefore, the scaled estimate was used and should be interpreted as evidence of association rather than a precise effect-size estimate.

ROC analysis of PSA density

PSAD showed good discriminative ability for csPCa, with AUC 0.872 (95% CI, 0.813–0.931, $p < 0.001$). The optimal cutoff selected by the Youden index was 0.205 ng/mL/cm³, with sensitivity of 75% and specificity of 92.7% (Table 7).

The commonly used threshold of 0.15 ng/mL/cm³ had higher sensitivity but lower specificity. A slightly higher threshold may therefore improve specificity and reduce unnecessary biopsies in selected patients.

Subgroup analysis of PI-RADS 3 lesions

The PI-RADS 3 subgroup included 34 patients, of whom 2 had csPCa and 32 had benign or clinically insignificant findings. In this subgroup, PSAD showed AUC 0.969 (95% CI, 0.798–1.000, $p < 0.001$); Figure 1. The optimal cutoff selected by the Youden index was again 0.205 ng/mL/cm^3, achieving 100% sensitivity and 93.8% specificity. Because only two malignant cases were present, these findings should be considered exploratory.

DISCUSSION

This prospective study showed that bpMRI was non-inferior to mpMRI for detection of csPCa. Agreement between protocols was 98.2%, with only three discordant cases. Two discrepancies did not affect binary categorization at the PI-RADS ≥ 4 threshold, while one PI-RADS SHORT 3 lesion was upgraded to PI-RADS FULL 4 after DCE but proved benign or clinically insignificant. This suggests that omitting DCE had minimal clinical impact in this cohort.

These findings are consistent with previous studies and meta-analyses reporting comparable diagnostic performance of bpMRI and mpMRI when DWI quality is adequate [16–19]. The prospective PRIME trial also confirmed non-inferiority of bpMRI compared with mpMRI in biopsy-naïve men [20, 21]. Together with PROMIS, PRECISION, STHLM3-MRI, and GÖTEBORG-2, and studies on MRI targeted biopsies, these data support MRI-first diagnostic pathways that improve csPCa detection while reducing unnecessary biopsies [7, 8, 10, 11, 25–27].

In our cohort, PI-RADS ≥ 4 provided the best balance between sensitivity and specificity. Lowering the threshold to PI-RADS ≥ 3 slightly increased sensitivity but markedly reduced specificity, reflecting the heterogeneous nature of PI-RADS 3 lesions [5, 28, 29]. The formal non-inferiority analysis supported

this interpretation: the 95% CI for the accuracy difference remained above the −5 percentage-point margin, with no reduction in sensitivity and a small numerical specificity advantage for bpMRI.

PSAD was an important adjunctive parameter. Although PSA alone performed worse than MRI-based assessment, PSAD showed good discrimination, with AUC 0.872 and an optimal cutoff of 0.205 ng/mL/cm³. This threshold was more specific than the commonly used 0.15 ng/mL/cm³ cutoff and may be useful when the clinical aim is to reduce unnecessary biopsies. Contemporary work from the EAU-YAU collaboration supports our results, emphasizing that biomarker-based, personalized diagnostic strategies- including PSA density-can safely reduce the number of unnecessary MRI examinations and prostate biopsies [30]. Therefore, PSAD thresholds should be interpreted in relation to MRI category and clinical context [4, 29, 31–36].

The PI-RADS 3 subgroup findings are clinically relevant but exploratory. Only two malignant cases were present, so the high AUC and excellent sensitivity at PSAD 0.205 ng/mL/cm³ require validation in larger cohorts. The logistic regression analysis also supports the independent value of PSAD, but the unscaled model produced an unstable estimate, therefore, PSAD was presented per 0.1 ng/mL/cm³ increase for clearer clinical interpretation.

This study has several limitations. It was single-center, with a moderate sample size and few discordant cases. In addition, bpMRI and mpMRI were interpreted by different independent readers, although blinded to each other's reports, this design does not permit assessment of interobserver agreement and cannot completely separate protocol effects from reader effects. Finally, PSAD thresholds, especially in PI-RADS 3 lesions, require external validation.

Overall, bpMRI appears to be a reliable and efficient alternative to mpMRI for csPCa detection. It reduces examination time, avoids contrast administration, and may improve accessibility of prostate MRI, while PSAD adds clinically useful risk stratification.

CONCLUSION

Biparametric prostate MRI demonstrated diagnostic performance comparable and non-inferior to mpMRI for detection of clinically significant prostate cancer. PI-RADS ≥ 4 provided the best balance between sensitivity and specificity, while PSAD was an independent predictor of malignancy and improved risk stratification. These findings support further evaluation of bpMRI and PSAD-based decision-making in larger multicenter cohorts.

AUTHOR CONTRIBUTIONS

Aleksandar Tasić: study conception and design, data collection, MRI interpretation, analysis and interpretation of results, manuscript drafting.

Dragan Stojanov: study supervision, interpretation of imaging findings, critical revision of the manuscript.

Aleksandra Aracki-Trenkić: MRI analysis, methodology development, data interpretation.

Dunja Radovanović: statistical analysis, interpretation of statistical results.

Dragoslav Bašić: urological evaluation, prostate biopsy procedures, clinical interpretation of findings, final revision of the manuscript being prepared for publication.

All authors have read and approved the final version of the manuscript.

DATA AVAILABILITY STATEMENT

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

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Conflict of interest: None declared.

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Table 1. Patient characteristics and histopathological findings

Variable	Value
Number of patients	170
Patients with complete data	170
Benign findings (B)	104
Malignant findings (M) (csPCa, Gleason ≥ 3+4)	66

Table 2. Agreement between PI-RADS SHORT (bpMRI) and PI-RADS FULL (mpMRI) classifications

PI-RADS FULL	PI-RADS SHORT 2	PI-RADS SHORT 3	PI-RADS SHORT 4	PI-RADS SHORT 5	Total
2	50	0	0	0	50
3	0	33	0	0	33
4	0	1	38	0	39
5	0	0	2	46	48
Total	50	34	40	46	170

PI-RADS FULL – mpMRI-based PI-RADS score; PI-RADS SHORT – bpMRI-based PI-RADS score:

Pearson $\chi^2 = 485.76$;

$p < 0.001$

Table 3. Diagnostic performance of bpMRI, mpMRI, and PSA using different diagnostic thresholds

Diagnostic parameter	Sensitivity (%)	Specificity (%)	Diagnostic accuracy (%)
PI-RADS SHORT ≥ 4	97	77.9	85.3
PI-RADS SHORT ≥ 3	98.5	47.1	67.1
PI-RADS FULL ≥ 4	97	76.9	84.7
PI-RADS FULL ≥ 3	98.5	47.1	67.1
PSA ≥ 4 ng/mL	73.5	72.7	73

PI-RADS SHORT – bpMRI-based PI-RADS score threshold for expected malignancy; PI-RADS FULL – mpMRI-based PI-RADS score threshold for expected malignancy; PSA – prostate-specific antigen threshold for expected malignancy

Table 4. Non-inferiority analysis of bpMRI compared with mpMRI at the PI-RADS ≥ 4 threshold

Endpoint	Difference (bpMRI – mpMRI) percentage points	95% CI (percentage points)	Conclusion
Sensitivity	0	No discordant malignant cases	Non-inferior
Specificity	1	-0.9–2.8	Non-inferior
Diagnostic accuracy	0.6	-0.6–1.7	Non-inferior

The prespecified non-inferiority margin was -5 percentage points

Table 5. Association between PI-RADS SHORT (bpMRI) classification (threshold ≥ 4) and histopathological findings

PI-RADS SHORT classification	Benign	Malignant	Total
Negative MRI (PI-RADS ≤ 3)	81	2	83
Positive MRI (PI-RADS ≥ 4)	23	64	87
Total	104	66	170

PI-RADS SHORT – bpMRI-based PI-RADS score; Negative MRI – expected benign; Positive MRI – expected malignancy;

Pearson $\chi^2 = 90.545$;

$p < 0.001$

Table 6. Multivariate logistic regression analysis for prediction of malignancy

Variable	Odds ratio	95% CI	p-value
PSA density (PSAD) per 0.1 ng/mL/cm^3 increase	1.56	1.1–2.21	0.012
PI-RADS SHORT	4.73	2.58–8.65	< 0.001

PSAD – prostate-specific antigen density; PI-RADS SHORT – bpMRI-based PI-RADS score

Table 7. ROC analysis of PSA density (PSAD) for detection of clinically significant prostate cancer

PSAD cutoff	Sensitivity (%)	Specificity (%)
0.1	95.6	52.3
0.15	83.8	75.2
0.2	75	92.7
0.25	58.8	95.4

AUC = 0.872; 95% CI, 0.813–0.931; $p < 0.001$;

Optimal cutoff value: PSAD = 0.205 ng/mL/cm^3 (Youden index)

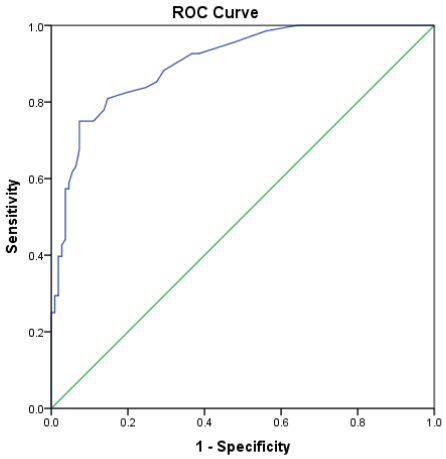

Figure 1. Receiver operating characteristic (ROC) curve of PSA density for detection of clinically significant prostate cancer