



OPEN Correlation of clinically significant prostate cancer sites across multiparametric MRI, prostate biopsy, and whole-mount pathology for optimal prostate biopsy strategy

Matteo Pacini^{1,7}, Alessandro Zucchi¹, Riccardo Morganti², Filippo Dazzi¹, Antonio Luigi Pastore³✉, Fabio Maria Valenzi³, Andrea Fuschi³, Yazan al Salhi³, Gianluca Giannarini⁴, Vincenzo Ficarra⁵, Alchiede Simonato⁶, Petar Antonov⁷, Pinuccia Faviana⁸ & Riccardo Bartoletti¹

Data from patients with suspicious lesions on multiparametric magnetic resonance (mpMRI) and a diagnosis of clinically significant prostate cancer (csPCa) who underwent radical prostatectomy (RP) were collected. The aim was to compare csPCa sites identified through whole-mount pathological analysis (WMA) after RP with PI-RADS ≥ 3 lesions identified on mpMRI, and with csPCa foci detected through targeted-biopsy (TB) or combined targeted + systematic biopsy (TSB). A paired Student's t-test and Pearson correlation analysis were performed to evaluate the agreement between these diagnostic methods. A total of 106 patients were included in the TSB group and 95 in the TB group. The correlation between mpMRI, PB, and WMA was moderate and comparable in both groups. No correlation between PB and WMA was found in the TB group for PI-RADS3 lesions, while a moderate-strong correlation was observed when comparing mpMRI, PB, and WMA for PI-RADS > 3 lesions. About 50% of csPCa sites remained undetected by mpMRI. TSB was able to identify 16.5% more csPCa sites than TB. mpMRI is an accurate method in the diagnosis of PCa, especially for PI-RADS > 3 lesions, although some csPCa sites remained undetected. The use of TSB improved the location agreement between PB and WMA, increasing detection rates up to 79%.

Keywords Prostate cancer diagnosis, Multiparametric magnetic resonance, Targeted fusion prostate biopsy, Systematic prostate biopsy, Whole mount pathological analysis

Diagnostic tools for prostate cancer (PCa) include total Prostate Specific Antigen serum level (tPSA), Digital-Rectal Examination (DRE), multiparametric Magnetic Resonance imaging (mpMRI) and Prostate Biopsy (PB)¹.

Early detection of PCa may be promoted by elevated total PSA (tPSA) levels, particularly when coupled with an unfavorable free-to-total PSA ratio. However, this approach carries the risk of overdiagnosing non-clinically significant PCa (nsPCa) or missing clinically significant PCa (csPCa). These risks could result in overtreatment or necessitate repeated assessments under active surveillance protocols, thereby increasing the overall burden of care²⁻⁴. The definition of csPCa includes the pathological evidence of intermediate/high risk PCa (International

¹Department of Translational Research and New Technologies in Medicine and Surgery, University of Pisa, Pisa, Italy. ²Azienda Ospedaliero Universitaria Pisana, UO statistica, Pisa, Italy. ³Department of Medical and Surgical Science and Biotechnology, La Sapienza University, Rome, Italy. ⁴Urology Unit, Santa Maria della Misericordia University Hospital, Udine, Italy. ⁵Department of Clinical and Experimental Medicine, University of Messina, Messina, Italy. ⁶Department of Precision Medicine in Medical, Surgical and Critical Area, University of Palermo, Palermo, Italy. ⁷Department of Urology and General Medicine, Medical University of Plovdiv, Plovdiv, Bulgaria. ⁸Department of Department of Surgery, Medical, Molecular, and Critical Area, University of Pisa, Pisa, Italy. ✉email: antonioluigi.pastore@uniroma1.it

Society of Urological Pathology [ISUP] score ≥ 2)^{1,5}. Multiparametric magnetic resonance of the prostate has improved the diagnostic accuracy for PCa detection thanks to diffusion-weighted and dynamic contrast-enhanced imaging sequences⁶. Previous studies already investigated on the presence of csPCa by the correlation between mpMRI lesions and radical prostatectomy specimens^{7–10}. mpMRI diagnostic accuracy for the diagnosis of PCa was found as variable from 50 to 89% according to several clinical series of patients^{10–12}. In particular, mpMRI showed conflicting results for patients with Prostate Imaging and Reporting Data System (PI-RADS) 3 classification. Current literature shows that PI-RADS 3 lesions are confirmed as cancers in 14,8% to about 30% of cases (the detection of csPCa may be lower) and that the interpretation of those lesions may vary depending on the referring radiologist skill and experience on the topic^{13–15}. In addition, tumor sites not recognized and reported by mpMRI may be often easily identified by systematic samples and related to the number of cores performed on the same patient^{1,16}. The 2023 guidelines from the European Association of Urology (EAU) recommend performing both targeted and systematic biopsies in biopsy-naïve patients when mpMRI results are positive¹. Few existing studies regarding the correlation between tumor site and tumor burden in clinically localized PCa also showed conflicting results^{17,18}.

The aim of this study was to describe the location and characteristics of clinically significant prostate cancer sites as described in whole mount pathological analysis (WMA) after radical prostatectomy and to compare the obtained results with PI-RADS v2.1 ≥ 3 lesions found at preoperative mpMRI and at fusion (TB) or fusion plus additional systematic prostate biopsy (TSB).

Materials and methods

Participants. Clinical and pathologic data were retrospectively collected from patients who underwent radical prostatectomy for clinically significant Prostate Cancer (csPCa). Eligibility for the study was restricted to patients with suspicious mpMRI findings (at least one PI-RADS ≥ 3 lesion) and subsequent confirmation of csPCa via targeted or targeted plus systematic biopsy.

Inclusion criteria

- Preoperative PSA serum level between 4 and 20 ng/ml and/or suspicion of PCa at DRE and/or familiarity for PCa.
- Preoperative mpMRI with at least one PI-RADS ≥ 3 lesion.
- No previous prostate biopsy.
- Biopsy matching of ISUP ≥ 2 PCa (defined as csPCa).
- Patients who had undergone radical surgical treatment for localized csPCa.

Exclusion criteria

- Patients with preoperative PSA serum levels > 20 ng/ml.
- Patients without suspicion of PCa at mpMRI.
- Patients with extra-prostatic disease at pre-operative staging procedures.
- Contraindications to mpMRI, prostate biopsy or radical surgery.

Compliance with ethical standards This multicenter retrospective analytical cohort study was approved on 12.12.2022 by the Institutional Review Board and Ethics Committee of the Department of Medical and Surgical sciences and Biotechnologies of Sapienza University in Rome (UROLT_DEC22/7834). The principles of the Declaration of Helsinki were followed and written informed consent was obtained from all participants.

mpMRI and biopsy Patients underwent a 3.0 Tesla multiparametric magnetic resonance imaging before PB. All mpMRIs were revised from two intra/extra observer expert radiologists for the study review although the first report was used by urologists as a guide for targeted prostate biopsy. According to consensus guidelines T2 weighted, diffusion weighted, and dynamic contrast-enhanced sequences were acquired. Positive areas at mpMRI were stratified by expert urogenital radiologists according to PI-RADS v2 or 2.1 classification (v2 were applied for mpMRI performed before v2.1 publication). All patients who had undergone to mpMRI with subsequent reporting of at least one PI-RADS ≥ 3 lesion were thus submitted to prostate biopsy. Expert urologists performed prostate biopsies. The systematic sampling was performed according to the following template with a total of 16 cores acquired: right/left base, parasagittal right/left, lateral right/left and right/left apex. Both trans perineal and trans rectal approaches were used. For trans perineal biopsies no antibiotic prophylaxis was administered. In contrast, for transrectal biopsies, antibiotic prophylaxis with Fosfomycin 3 g plus Ceftriaxone 1 g and a rectal cleansing with povidone-iodine were administered.

UroFusion and bkFusion software were used to run targeted samples.

Staging Evaluations According to EAU latest guidelines, patients with intermediate and high-risk cancers underwent contrast-enhanced abdominopelvic CT scan and whole-body bone scan. Whole body Prostate Specific Membrane Antigen (PSMA) PET/CT was also performed in high-risk to minimize the risk of metastatic disease.

Radical Prostatectomy Once the histological diagnosis of csPCa was acquired, all patients underwent robot-assisted radical prostatectomy (RARP) with Montsouris approach. All surgical procedures were performed by expert surgeons with da Vinci Xi surgical system (Intuitive Surgical, Sunnyvale, CATM). All WMA pathologic reports included intra-prostatic disease locations to allow the comparison with mpMRI and PB.

Outcomes Assuming that mpMRI enhances the diagnostic pathway for PCa and helps avoid unnecessary biopsies, the primary outcome was to evaluate the accuracy of mpMRI in detecting all prostatic disease foci compared to prostate biopsy and WMA.

Secondary outcomes of the study included estimating the added value of systematic samplings during prostate biopsy in terms of csPCa foci detection rate. Additionally, the study aimed to assess the correlation between multiparametric MRI (mpMRI), prostate biopsy (PB), and whole-mount analysis (WMA) concerning PI-RADS scores and Gleason Scores observed during PB and WMA.

Statistical analysis and study drafting

Our manuscript was drafted according to STROBE Statement items for cohort studies.

Categorical data were described with absolute and relative (%) frequency, continuous data were summarized with mean and standard deviation (sd).

To compare groups (TB, TBS) with continuous and categorical population characteristics, t-test for independent sample and chi square test was applied, respectively.

To assess the agreement between methods (mpMRI ROIs, biopsy positive areas, WMA), t-test for paired data and Pearson's correlation analysis were performed.

Significance was set at 5% and all analyses were carried out by SPSS v.29 technology.

Results

Population

A total of 201 biopsy-naïve patients were found to be eligible for the study, with 95 (47.26%) undergoing TB and 106 (52.74%) undergoing TSB. No significant differences were observed between the two groups in terms of age at the time of surgery, Body Mass Index (BMI), pre-surgery tPSA levels, age-adjusted Charlson Comorbidity Index (aaCCI), DRE findings, and smoking habits (Table 1: Pre-Surgery Demographic and Clinical Characteristics of the Patients).

Spatial correlation with whole-mount analysis of mpMRI and prostate biopsy

As expected, the best location agreement was found between mpMRI lesions and TB, with a Pearson's correlation coefficient (R) of 0.778 ($p < 0.001$). In contrast, a moderate correlation was observed when comparing TB with WMA and mpMRI with WMA in the same group, with Pearson's correlation coefficients of 0.515 ($p = 0.01$) and 0.446 ($p = 0.01$), respectively.

In the TSB group, a lower correlation was found when comparing mpMRI suspicious lesions and TSB positive cores ($R = 0.425$, $p = 0.01$), suggesting that this biopsy approach may detect some disease foci that remain undetected by mpMRI. A moderate correlation ($R = 0.401$, $p = 0.02$) was observed between mpMRI and WMA, while a fairly strong correlation was found between TSB and WMA, with an R of 0.704 ($p < 0.001$).

Notably, in 9 (8.5%) patients within the TSB group, the systematic biopsy was essential for diagnosing csPCA, as TB had not detected the presence of the disease.

Similar results were observed when stratifying by PI-RADS score, particularly for PI-RADS scores of 4 and 5. The TB showed the strongest correlation with mpMRI for PI-RADS 5 lesions ($R = 0.815$, $p < 0.001$). However, for PI-RADS 3 ROIs, TB did not achieve a statistically significant correlation with WMA ($R = 0.267$, $p = 0.218$). Results are summarized in Table 2.

A moderate correlation was found between the mpMRI report, PB, and WMA analysis, with TB showing a stronger correlation with mpMRI than TSB. Conversely, TSB performed better when compared to WMA. This can be explained by the fact that systematic samples may detect some prostate cancer foci that are not identified by mpMRI.

When stratified by PI-RADS score, the results remained consistent, except for the comparison between TB and WMA for PI-RADS 3 lesions, where no statistically significant correlation was observed.

Characteristic	TSB group	TB group	<i>p</i> -value
Age (yrs)	70 (6.5)	69 (6.6)	0.197
BMI (kg/m ²)	26.3 (3.1)	25.7 (3.7)	0.408
tPSA (ng/ml)	11.1 (8.6)	11.8 (7.9)	0.635
aaCCI	5.2 (1.1)	5.3 (1.3)	0.532
DRE			0.505
Neg.	65 (61.3)	53 (55.8)	
Pos.	41 (38.7)	42 (44.2)	
Smoking Habit			0.519
No	90 (84.9)	77 (81.1)	
Yes	16 (15.1)	18 (18.9)	

Table 1. Pre-surgery demographic and clinical characteristics of the patients. Statistics: mean (sd) or frequency (%). Abbreviations: Targeted and Systematic Biopsy (TSB), Targeted Biopsy (TB), Body Mass Index (BMI), total Prostate Specific Antigen (tPSA), age adjusted Charlson Comorbidity Index (aaCCI), Digital Rectal Examination (DRE). We found no significant differences in baseline characteristics.

		mpMRI ROIs	Biopsy positive areas	WMA
TB group				
mpMRI ROIs	Pearson's r	1	0.778	0.446
	p-value		<0.001	0.01
Biopsy positive areas	Pearson's r	0.718	1	0.515
	p-value	<0.001		0.01
WMA	Pearson's r	0.446	0.515	1
	p-value	0.01	0.01	
TSB group				
mpMRI ROIs	Pearson's r	1	0.425	0.401
	p-value		0.01	0.02
Biopsy positive sectors	Pearson's r	0.425	1	0.704
	p-value	0.01		<0.001
WMA	Pearson's r	0.401	0.704	1
	p-value	0.02	<0.001	
			Biopsy positive areas	WMA
PI-RADS 5				
TB group				
mpMRI ROIs	Pearson's r		0.815	0.460
	p-value		<0.001	0.01
TSB group				
mpMRI ROIs	Pearson's r		0.560	0.533
	p-value		0.002	0.005
PI-RADS 4				
TB group				
mpMRI ROIs	Pearson's r		0.601	0.433
	p-value		<0.001	0.01
TSB group				
mpMRI ROIs	Pearson's r		0.529	0.465
	p-value		0.002	0.01
PI-RADS 3				
TB group				
mpMRI ROIs	Pearson's r		0.691	0.267
	p-value		0.002	0.218
TSB group				
mpMRI ROIs	Pearson's r		0.702	0.519
	p-value		0.002	0.03

Table 2. Correlation analysis between mpMRI, PB and WMA stratified by group and by group and PI-RADS score. Abbreviations: Multiparametric Magnetic Resonance (mpMRI), Region of Interest (ROI), Whole Mount Analysis (WMA), Targeted and Systematic Biopsy (TSB), Targeted Biopsy (TB). Spatial correlation between mpMRI ROIs, PB positive areas and whole-mount analysis was found as good. Pearson's correlation was good also stratifying different PI-RADS categories in both groups. The best correlation was found for PI-RADS 5 lesions in TB group. TSB has the best performance in PI-RADS 3 ROIs. Concerning PI-RADS 3 lesions, mpMRI does not correlate with WMA in TB group.

Comparison between mpMRI, PB and WMA concerning csPCa areas

A paired data Student's t-test was performed to compare the average number of positive areas detected by mpMRI, PB, and WMA in both groups. As shown in Table 3, mpMRI detected fewer lesions than those later identified by PB and WMA. This was consistent for both TB and TSB groups.

In the TB group, mpMRI detected an average of 2.03 ± 1.22 lesions, PB detected 2.50 ± 1.34 positive areas, and WMA identified 4.00 ± 1.53 positive areas ($p < 0.001$ for all comparisons). Similarly, in the TSB group, mpMRI detected 1.90 ± 1.29 lesions, PB identified 3.35 ± 1.60 positive areas, and WMA detected 4.27 ± 1.62 positive areas ($p < 0.001$ for all comparisons). These findings remained significant even when stratified by PI-RADS score (Table 3).

The average percentage of mpMRI-detected lesions compared to WMA was similar between the two groups: mpMRI identified 50.8% of the lesions later confirmed by WMA in the TB group and 44.8% in the TSB group ($p = 0.139$). A significant difference was found when comparing the two biopsy approaches: TB identified 62.5% of the csPCa lesions, while TSB identified 79% of the lesions ($p < 0.001$).

Our results suggest that mpMRI can identify less than 50% of csPCa lesions, consistent across both groups. However, there is a significant difference between the two biopsy techniques when compared to WMA. This implies that the addition of systematic sampling may lead to better local staging and spatial assessment of the disease.

Correlation between PCa Gleason score and mpMRI PI-RADS score

Among patients who underwent TB, a weak but significant correlation was found between mpMRI lesion PI-RADS scores and Gleason scores from both PB and WMA ($R = 0.341$, $p = 0.01$ and $R = 0.323$, $p = 0.01$, respectively). In contrast, a moderate correlation was observed between PB and WMA GS within the same group, with a Pearson's correlation coefficient of 0.511 ($p < 0.001$).

Similar outcomes were observed in the TSB group. There was a weak correlation between mpMRI PI-RADS scores and WMA GS ($R = 0.233$, $p = 0.025$), and a moderate correlation between PB and WMA GS ($R = 0.526$, $p < 0.001$). However, in the TSB group, the correlation between mpMRI PI-RADS scores and PB GS did not reach statistical significance ($R = 0.125$, $p = 0.235$) (Table 4).

Similar rates of upgrading and downgrading were found ($p = 0.78$ and $p = 0.43$, respectively). In particular, in TB group 20 (21.1%) patients had a GS upgrade at WMA. Similarly, in TSB group 24 (22.6%) patients had a higher reported GS at WMA than at PB. Downgrading was less frequent, occurring in 13.6% of patients in the TB group and 14.3% of patients in the TSB group.

Our results suggest that while mpMRI can provide some indication of tumor aggressiveness, the correlation between PI-RADS scores and Gleason Scores (GS) from both PB and WMA was found to be weak.

Discussion

The accuracy of mpMRI and MRI-targeted biopsy in detecting and localizing clinically significant prostate cancer (csPCa) may be influenced by several factors. The European Society of Urogenital Radiology and the European Association of Urology section of Urologic Imaging recently participated in a Delphi consensus process regarding the role of mpMRI in PCa detection. This consensus highlighted mpMRI's well-established role in the updated EAU guidelines and the American Urological Association recommendations. It also emphasized the need for established quality criteria for image acquisition and reporting^{1,19}.

Many of these quality criteria are often not adhered to, resulting in conflicting findings from different authors regarding the characterization of csPCa sites by mpMRI.

Radtke et al. and Baco et al., in two retrospective analyses conducted on patients who underwent radical prostatectomy for prostate cancer, found a significant correlation between the tumor sites identified by mpMRI and whole-mount specimens in 92% and 95% of cases, respectively^{17,20}.

In contrast, in similar studies, Tan et al. and Lourenco et al. reported a 46.7% and 33.3% correlation between mpMRI findings and whole-mount analysis (WMA), respectively^{18,21}.

However, the ability of mpMRI to detect csPCa sites likely depends not only on the experience of individual radiologists but also on other factors such as tumor multifocality, tumor volume, and pathological characteristics. Steenbergen and Di Campli demonstrated that interobserver variability may not significantly impact prostate cancer diagnosis. However, Riney reported conflicting results, suggesting that interobserver evaluation plays a significant role in selecting the PIRADS classification²²⁻²⁴.

Based on our experience, we have found that mpMRI and prostate biopsy yield fairly strong results in terms of correlation for characterizing clinically significant prostate cancer in cases with previously diagnosed PIRADS 4 and 5 lesions. However, they appear to be less accurate in defining PIRADS 3 lesions. Additionally, regardless of the agreement between tumor sites defined by mpMRI and whole-mount analysis after radical prostatectomy, approximately 50% of csPCa tumor sites were undetected by mpMRI.

Specifically, the interpretation of tumor sites, even those indicative of csPCa, may be missed by mpMRI. These findings are consistent with those reported by Lee in a retrospective study involving patients with prostate cancer who underwent radical prostatectomy following mpMRI²⁵. In their study, Lee et al. identified 237 tumor sites on whole-mount analysis among 107 patients. They reported a sensitivity of 46% for detecting all tumors sites using mpMRI, but a higher sensitivity (75.5%) and specificity (77%) specifically for csPCa.

Likewise, Ahdoot et al. highlighted the impact of a cross-sectional study comparing systematic biopsy to mpMRI-TB in a cohort of 2103 patients with clinical suspicion of prostate cancer. They found that mpMRI-TB alone, without systematic biopsy, would have resulted in the non-detection of ISUP ≥ 2 cancers in 164 (7.8%) patients¹⁶.

	Mean	Sd	p-value
TB group			
mpMRI ROIs (n°)	2.03	1.22	<0.001
WMA positive areas (n°)	4.00	1.53	
Biopsy positive areas (n°)	2.50	1.34	<0.001
WMA positive areas (n°)	4.00	1.53	
mpMRI ROIs (n°)	2.03	1.22	<0.001
Biopsy positive areas (n°)	2.50	1.34	
TSB group			
mpMRI ROIs (n°)	1.90	1.29	<0.001
WMA positive areas (n°)	4.27	1.62	
Biopsy positive areas (n°)	3.35	1.60	<0.001
WMA positive areas (n°)	4.24	1.63	
mpMRI ROIs (n°)	1.90	1.29	<0.001
Biopsy positive areas (n°)	3.36	1.60	
PI-RADS 5			
	Mean	Sd	p-value
TB group			
mpMRI ROIs (n°)	2.46	1.56	<0.001
WMA positive areas (n°)	4.83	1.81	
mpMRI ROIs (n°)	2.46	1.56	0.005
Biopsy positive areas (n°)	3.04	1.49	
TSB group			
mpMRI ROIs (n°)	2.89	1.52	<0.001
WMA positive areas (n°)	5.07	1.56	
mpMRI ROIs (n°)	2.89	1.52	0.003
Biopsy positive areas (n°)	3.89	1.85	
PI-RADS 4			
	Mean	Sd	p-value
TB group			
mpMRI ROIs (n°)	1.95	1.11	<0.001
WMA positive areas (n°)	3.68	1.28	
mpMRI ROIs (n°)	1.95	1.11	0.031
Biopsy positive areas (n°)	2.37	1.40	
TSB group			
mpMRI ROIs (n°)	1.61	0.78	<0.001
WMA positive areas (n°)	3.91	1.46	
mpMRI ROIs (n°)	1.61	0.78	<0.001
Biopsy positive areas (n°)	3.02	1.34	
PI-RADS 3			
	Mean	Sd	p-value
TB group			
mpMRI ROIs (n°)	1.78	0.90	<0.001
WMA positive areas (n°)	3.65	1.37	
mpMRI ROIs (n°)	1.78	0.90	0.008
Biopsy positive areas (n°)	2.13	0.87	
Continued			

PI-RADS 3	Mean	Sd	p-value
TB group			
TSB group			
mpMRI ROIs (n°)	1.58	0.90	<0.001
WMA positive areas (n°)	3.33	1.50	
mpMRI ROIs (n°)	1.58	0.90	<0.001
Biopsy positive areas (n°)	2.58	1.00	

Table 3. Paired data student t test results stratified by prostate biopsy group and PI-RADS score. Abbreviations: Multiparametric Magnetic Resonance (mpMRI), Region of Interest (ROI), Whole Mount Analysis (WMA), Targeted and Systematic Biopsy (TSB), Targeted Biopsy (TB). mpMRI detects fewer lesions than those later detected at PB and at WMA in both groups. TB was able to point out about 64% of PCa lesions, whereas TSB 80% ($p < 0.001$). That finding is significant also stratifying by PI-RADS score.

		PI-RADS	GS PB	GS WMA
TB group				
PI-RADS	Pearson's r	1	0.341	0.323
	p-value		0.01	0.01
GS PB	Pearson's r	0.271	1	0.511
	p-value	0.012		<0.001
GS WMA	Pearson's r	0.353	0.511	1
	p-value	0.001	<0.001	
TSB group				
PI-RADS	Pearson's r	1	0.125	0.233
	p-value		0.235	0.025
GS PB	Pearson's r	0.125	1	0.526
	p-value	0.235		<0.001
GS WMA	Pearson's r	0.233	0.526	1
	p-value	0.025	<0.001	

Table 4. Correlation between PI-RADS score and GS. Abbreviations: Gleason Score (GS), Prostate Biopsy (PB), Targeted and Systematic Biopsy (TSB), Targeted Biopsy (TB), Whole Mount Analysis (WMA). In TB group we found a significant correlation between PI-RADS score and GS at PB and WMA. Similar outcomes were found in TSB group, but in this group correlation doesn't reach the statistical significance comparing PI-RADS score and PB GS.

Drost et al., in a recent Cochrane meta-analysis, reported that systematic biopsy detected 4.3% of ISUP ≥ 2 and 2.8% of ISUP ≥ 3 prostate cancer cases missed by the targeted approach in biopsy-naïve patients. However, it appeared to be less accurate in patients who underwent re-biopsy¹⁰.

Comparably, two prospective trials involving 1003 and 1042 patients, respectively, led by Siddiqui et al. and by Filson et al., concluded that relying solely on a targeted biopsy approach would result in missing 10–26% of PCa diagnoses^{26,27}.

A recent prospective study indicated that adding systematic cores to TB would have resulted in a non-significant improvement in the rate of tumor diagnoses (7.3%, $p = 0.12$). Additionally, they found that including systematic samplings homolaterally to the mpMRI index lesion would have only detected 3% more prostate cancer foci compared to using targeted biopsy alone²⁸.

Our findings indicate that TSB correlates more closely with WMA in fully defining csPca sites compared to mpMRI or targeted biopsy alone. This suggests that adding systematic sampling to targeted biopsy could improve the accuracy of local staging for the disease. However, further investigation is needed to assess the implications of these results on surgical planning.

Similarly, we observed a weak but significant correlation between mpMRI PIRADS scores and Gleason score at targeted biopsy, whereas the comparison with TSB did not yield significant results. In contrast, a moderate correlation was found when comparing PB and WMA Gleason scores in both groups.

Ahdoot et al. reported comparable results in terms of diagnostic accuracy, but mpMRI-TB showed more significant results in characterizing Gleason scores, although they were responsible for upgrading events in 458 cases (21.8%) when combined with systematic biopsy. The differences in rates of upgrading between systematic and targeted biopsy were statistically significant¹⁶. Conversely, similar to what was observed in Porpiglia et al.'s prospective study, our experience revealed comparable rates of tumor Gleason Score upgrading or downgrading²⁸.

In conclusion, a meta-analysis assessing the efficacy of targeted + systematic biopsy concluded that systematic cores remain necessary in addition to targeted biopsy. A targeted approach alone would result in a missed diagnosis of 5–15% of clinically significant prostate cancer cases⁴⁹.

Limitations of the study

The use of different systems for targeted biopsies represents a significant factor, as well as the variability introduced by having several radiologists perform mpMRI. However, to ensure consistency, all mpMRIs were reviewed by both intra- and inter-observer radiologists during the study follow-up.

Systematic biopsy cores were consistently taken according to a bi-planar evaluation, while both mpMRI and whole-mount analysis (WMA) utilized a tri-planar evaluation. To achieve more homogeneous results, a precise template for systematic biopsy cores was adopted.

Another limitation of the study is its retrospective design.

Conclusions

The results confirmed a fairly strong/moderate correlation between PIRADS 4 and 5 ROIs, prostate biopsy (TB and TSB), and whole-mount histological analysis, although about 50% of clinically significant prostate cancer (csPCa) sites were undetected mpMRI. The addition of systematic biopsy increased the likelihood of detecting all csPCa sites to 79%, a significant improvement over targeted biopsy alone. In fact, accurately defining tumor sites within the prostate gland, as revealed by WMA, remains crucial for local staging of PCa. Consistent with current literature, our study supports the recommendation that systematic mapping of the prostate should always be included alongside targeted cores in biopsy-naïve patients when csPCa is suspected.

Data availability

The datasets generated and/or analyzed during the current study are not publicly available due to national privacy law, but they are available from the corresponding author on reasonable request.

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Author contributions

M.P., R.B., A.Z. and A.L.P. designed the study and wrote the main manuscript text and tables R.M. performed statistical analysis A.S., V.F., P.F., G.G., A.F. supervised the study F.M.V, Y.S., F.D. contributed at final manuscript revision P.A played a key role in the revision process, specifically addressing post-reviewer comments.

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Declarations

Competing interests

The authors declare no competing interests.

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Correspondence and requests for materials should be addressed to A.L.P.

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