

Diagnostic Concordance of mpMRI and Ga68 PSMA PET/CT on Localization of Prostatic Lesions in Patients with Suspected Prostate Cancer and Negative TRUS-Guided Biopsy

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Abstract

Background and Objective:

Patients with persistently rising prostate-specific antigen (PSA) levels despite a negative transrectal ultrasound (TRUS)-guided biopsy present a significant diagnostic challenge. Multiparametric magnetic resonance imaging (mpMRI) and Gallium-68 prostate-specific membrane antigen positron emission tomography/computed tomography (Ga68 PSMA PET/CT) have emerged as promising imaging modalities for detection and localization of clinically significant prostate cancer (csPCa). This study evaluated the anatomical concordance of mpMRI and Ga68 PSMA PET/CT in patients with suspected prostate cancer and prior negative systematic biopsy.

Methods:

This observational study included 43 patients with persistently rising PSA levels despite a previous negative 12-core systematic TRUS-guided biopsy. All patients had a prior mpMRI demonstrating a PI-RADS ≥ 3 lesion and underwent repeat evaluation with mpMRI and Ga68 PSMA PET/CT within 6 months, followed by targeted biopsy. Lesion localization, SUVmax, Gleason score, ISUP grade, and histopathological findings were analyzed. Concordance between imaging modalities and histopathology was assessed.

Results:

Histopathology confirmed adenocarcinoma in 39/43 patients (90.7%), of whom 33 (84.6%) fulfilled criteria for clinically significant prostate cancer. mpMRI and Ga68 PSMA PET/CT demonstrated moderate-to-substantial agreement for lesion localization across multiple anatomical sites. The highest concordance was observed for seminal vesicle invasion ($\kappa=0.744$), left-lobe involvement ($\kappa=0.671$), and basal lesions ($\kappa=0.624$). Combined interpretation of mpMRI and Ga68 PSMA PET/CT demonstrated the highest concordance with histopathology (90.8%). A PSA density cutoff of 0.22 showed modest discriminatory ability for clinically significant disease.

Conclusion:

Ga68 PSMA PET/CT demonstrated high diagnostic yield and good concordance with mpMRI in patients with persistently rising PSA levels following a negative systematic TRUS-guided biopsy. Combined interpretation of both modalities may improve lesion localization and facilitate targeted detection of clinically significant prostate cancer.

Key Messages

- Patients with persistent suspicion of prostate cancer despite a negative TRUS-guided biopsy remain at significant risk of harboring clinically significant disease.
- Ga68 PSMA PET/CT demonstrated a high diagnostic yield, detecting adenocarcinoma in 90.7% of patients undergoing targeted biopsy.

- • mpMRI and Ga68 PSMA PET/CT showed good concordance for localization of prostatic lesions, particularly in clinically significant tumors.
- • Ga68 PSMA PET/CT was particularly useful for identifying anterior and apical lesions, common sites missed by conventional systematic TRUS-guided biopsy.
- • Combined interpretation of mpMRI and Ga68 PSMA PET/CT achieved the highest concordance with histopathology and may improve targeting of clinically significant prostate cancer.

Introduction

Prostate cancer is one of the most commonly diagnosed malignancies among men worldwide and remains a leading cause of cancer-related mortality [1]. Early and accurate localization of clinically significant prostate cancer (csPCa) is essential for appropriate risk stratification and treatment planning. Traditionally, transrectal ultrasound (TRUS)-guided systematic biopsy has been the standard diagnostic approach; however, false-negative biopsy results remain a major limitation, especially in patients with anterior, apical, or small-volume tumors [2].

Persistent clinical suspicion despite a negative TRUS-guided biopsy, characterized by elevated serum prostate-specific antigen (PSA), abnormal digital rectal examination, or rising PSA density, presents a difficult clinical scenario [3]. Repeated systematic biopsies increase patient morbidity while still carrying the risk of missed clinically significant lesions [4]. Consequently, advanced imaging modalities capable of accurate lesion localization have become increasingly important.

Multiparametric magnetic resonance imaging (mpMRI) has significantly transformed the diagnostic pathway for prostate cancer. mpMRI combines anatomical and functional imaging sequences including T2-weighted imaging, diffusion-weighted imaging (DWI), and dynamic contrast-enhanced imaging (DCE) to identify suspicious lesions [5]. The Prostate Imaging Reporting and Data System (PI-RADS) has standardized interpretation and improved reproducibility of mpMRI findings [6]. Several studies have demonstrated the utility of mpMRI in reducing unnecessary biopsies and improving detection of clinically significant disease [7]. Nevertheless, mpMRI has limitations, particularly in patients with prostatitis, post-biopsy hemorrhage, transition zone lesions, and equivocal PI-RADS 3 lesions [8].

Prostate-specific membrane antigen (PSMA) is a transmembrane glycoprotein highly overexpressed in prostate cancer cells. Ga68 PSMA PET/CT has emerged as a highly sensitive molecular imaging modality capable of detecting both primary and metastatic prostate cancer lesions [9]. Initially utilized in biochemical recurrence and staging, its role in primary diagnosis and lesion localization has expanded considerably in recent years [10]. Studies comparing Ga68 PSMA PET/CT with mpMRI have demonstrated promising diagnostic accuracy, especially in clinically significant and high-grade tumors [11].

Recent literature suggests that PSMA PET/CT may detect lesions missed by mpMRI and may improve localization accuracy when used in combination with MRI [12]. Gauthaman et al. reported higher lesion

detection rates with Ga68 PSMA PET/CT than mpMRI for primary prostate cancer evaluation. [13]. Similarly, Zhou et al. observed superior performance of PSMA PET/CT in high-risk prostate cancer, while mpMRI retained value in lower-risk disease [14].

Despite increasing evidence supporting the role of advanced imaging in prostate cancer diagnosis, data evaluating concordance between mpMRI and Ga68 PSMA PET/CT in patients with persistently rising PSA levels following a negative systematic biopsy remain limited.

The primary objective of this study was to evaluate the anatomical concordance between mpMRI and Ga68 PSMA PET/CT for localization of suspicious prostatic lesions in patients with persistent clinical suspicion of prostate cancer following a negative TRUS-guided biopsy. Secondary objectives included correlation with histopathological findings and assessment of clinically significant prostate cancer detection.

Methods

Study Design and Setting

This observational study was conducted at a tertiary care referral center between 2020 and 2021. Institutional ethical committee approval was obtained prior to commencement of the study, and informed written consent was obtained from all participants.

Study Population

A total of 43 consecutive patients with persistent clinical suspicion of prostate cancer despite a previous negative biopsy were included.

All patients had undergone pre-biopsy multiparametric MRI demonstrating a PI-RADS score ≥ 3 lesion followed by a standard 12-core systematic TRUS-guided biopsy that was negative for malignancy. Persistent clinical suspicion was defined as continuously rising serum PSA levels despite a negative biopsy result.

Following the negative biopsy, patients underwent repeat evaluation within 6 months using mpMRI and Ga68 PSMA PET/CT. Targeted biopsy was subsequently performed for suspicious lesions identified on imaging. Histopathological findings served as the reference standard for analysis.

Inclusion Criteria

- Age ≥ 18 years
- Persistently rising PSA levels following a negative 12-core systematic TRUS-guided biopsy
- Prior mpMRI demonstrating a PI-RADS ≥ 3 lesion

- Undergoing both mpMRI and Ga68 PSMA PET/CT before repeat biopsy
- Availability of complete histopathological data

Exclusion Criteria

- Previously treated prostate cancer
- Prior hormonal therapy, chemotherapy, or radiotherapy
- Contraindications to MRI
- Incomplete imaging or histopathological data

Imaging Protocol

mpMRI

All patients underwent multiparametric MRI using standardized prostate imaging protocols including T2-weighted imaging, diffusion-weighted imaging, apparent diffusion coefficient mapping, and dynamic contrast-enhanced sequences. Lesions were categorized according to PI-RADS version 2.

Ga68 PSMA PET/CT

Ga68 PSMA PET/CT imaging was performed following intravenous administration of Ga68-labelled PSMA tracer. Focal uptake exceeding background activity and corresponding to suspicious anatomical lesions was considered positive. SUVmax values were recorded for all lesions.

Combined imaging assessment was considered positive when a lesion was identified by either mpMRI or PSMA PET/CT and subsequently correlated with histopathology.

Histopathological Evaluation

Targeted biopsy was performed for suspicious lesions identified on imaging. Histopathological examination was reported according to the Gleason grading system and International Society of Urological Pathology (ISUP) classification.

Statistical Analysis

Data were analyzed using SPSS software. Continuous variables were expressed as mean $\pm$ standard deviation, while categorical variables were presented as frequencies and percentages. Diagnostic performance parameters including sensitivity, specificity, positive predictive value, negative predictive value, and accuracy were calculated. Concordance between mpMRI, PSMA PET/CT, and histopathology was assessed on a lesion-based basis using Cohen's kappa statistics. Combined imaging concordance

was defined as agreement between either imaging modality and the histopathological reference standard. Agreement was interpreted according to Landis and Koch criteria, with κ values of 0.41–0.60 indicating moderate agreement and 0.61–0.80 indicating substantial agreement.

Results

Baseline Characteristics

A total of 43 patients were included. Most patients were in the sixth and seventh decades of life. All patients had undergone a prior mpMRI demonstrating a PI-RADS ≥ 3 lesion followed by a negative 12-core systematic TRUS-guided biopsy. Persistent PSA elevation or progression prompted repeat evaluation within 6 months using mpMRI and Ga68 PSMA PET/CT before targeted biopsy.

Imaging Findings

mpMRI demonstrated suspicious lesions predominantly involving the peripheral zone and posterior aspect of the prostate. Seminal vesicle invasion and lymph node involvement were detected in selected patients.

On Ga68 PSMA PET/CT, lesions involving the anterior prostate were identified in 26 patients (60.5%), while apical involvement was noted in 21 patients (48.8%). These locations are known blind spots for conventional systematic TRUS-guided biopsy and may explain the initial false-negative biopsy results. The distribution of imaging findings on mpMRI and PSMA PET/CT is presented in (Table 1).

Table 1
Distribution of imaging findings on mpMRI and PSMA PET/CT.

Imaging Findings	mpMRI n (%)	Ga68 PSMA PET/CT n (%)
Left lobe involvement	27 (62.8%)	32 (74.4%)
Right lobe involvement	18 (41.9%)	15 (34.9%)
Anterior lesions	17 (39.5%)	26 (60.5%)
Posterior lesions	10 (23.3%)	17 (39.5%)
Peripheral zone lesions	16 (37.2%)	29 (67.4%)
Central zone lesions	4 (9.3%)	16 (37.2%)
Transitional zone lesions	3 (7.0%)	4 (9.3%)
Basal involvement	28 (65.1%)	34 (79.1%)
Apical involvement	19 (44.2%)	21 (48.8%)
Whole prostate involvement	2 (4.7%)	2 (4.7%)
Seminal vesicle invasion	6 (14.0%)	5 (11.6%)
Lymph node involvement	5 (11.6%)	8 (18.6%)

Peripheral zone lesions were the most common, accounting for 67.4% of all detected lesions. The mean SUVmax was higher in histopathologically confirmed adenocarcinoma compared to benign lesions, suggesting increased tracer uptake in clinically significant disease.

Ga68 PSMA PET/CT demonstrated increased tracer uptake corresponding to suspicious prostatic lesions and showed excellent lesion conspicuity in clinically significant disease (Fig. 1).

Histopathological Findings

Most patients demonstrated intermediate- to high-grade disease. Gleason score 3 + 4 and 4 + 3 lesions were among the most common pathological findings (Fig. 2). ISUP grade group 2 and 3 lesions predominated (Table 2).

Table 2
Histopathological characteristics including Gleason score and ISUP grading.

Histopathological Parameter	Number of Patients (%)
PSMA-Targeted Biopsy Findings	
Adenocarcinoma	39 (90.7%)
Benign pathology	3 (7.0%)
Acute prostatitis	1 (2.3%)
Gleason Score Distribution	
Gleason score 3 + 3	6 (15.0%)
Gleason score 3 + 4	9 (22.5%)
Gleason score 4 + 3	11 (27.5%)
Gleason score 4 + 4	8 (20.0%)
Gleason score ≥ 9	4 (10.0%)
ISUP Grade Groups	
ISUP Grade 1	7 (17.5%)
ISUP Grade 2	9 (22.5%)
ISUP Grade 3	11 (27.5%)
ISUP Grade 4	10 (25.6%)
ISUP Grade 5	2 (5.0%)
Clinically Significant Prostate Cancer (Epstein Criteria)	33 (84.6%)

Histopathological examination of targeted biopsy specimens demonstrated adenocarcinoma in 39 of 43 patients (90.7%).

Of 39 patients diagnosed with adenocarcinoma, 33 (84.6%) fulfilled Epstein criteria for clinically significant prostate cancer.

PSA Density and Diagnostic Performance

Receiver operating characteristic (ROC) analysis for PSA density demonstrated an area under the curve (AUC) of 0.564 (95% CI: 0.281–0.847), suggesting modest discriminatory ability (Fig. 3). The diagnostic performance parameters of PSA density are summarized in (Table 3).

Table 3
Diagnostic performance parameters of PSA density.

Parameter	Prostate Adenocarcinoma	Clinically Significant Prostate Cancer
PSA density cutoff	0.22	0.22
Area under ROC curve (AUC)	0.564	0.614
95% Confidence Interval	0.281–0.847	0.410–0.818
Sensitivity	61.54%	63.64%
Specificity	25.00%	50.00%
Positive Predictive Value (PPV)	88.89%	87.50%
Negative Predictive Value (NPV)	6.25%	20.00%
Positive Likelihood Ratio	0.82	1.27
Negative Likelihood Ratio	1.54	0.73
Disease Prevalence	90.70%	84.62%
Overall Diagnostic Accuracy	58.14%	61.54%
p-value (ROC analysis)	0.676	0.421

Using a PSA density cutoff of 0.22:

- Sensitivity for prostate adenocarcinoma detection was 61.54%
- Specificity was 25%
- Positive predictive value was 88.89%
- Overall diagnostic accuracy was 58.14%

For clinically significant prostate cancer:

- Sensitivity was 63.64%
- Specificity was 50%
- Positive predictive value was 87.5%

Concordance Between mpMRI and Ga68 PSMA PET/CT

Both imaging modalities demonstrated concordance in localization of suspicious prostatic lesions, particularly in clinically significant disease. Comparative lesion localization on mpMRI and Ga68 PSMA PET/CT is illustrated in (Fig. 4).

Ga68 PSMA PET/CT demonstrated excellent lesion visualization and showed high concordance with histopathological findings. Combined interpretation improved confidence in lesion localization and biopsy targeting (Fig. 5). The diagnostic concordance between mpMRI and Ga68 PSMA PET/CT is presented in (Table 4). The combination of mpMRI and Ga68 PSMA PET CT showed the highest concordance with histopathology (90.8%), compared to mpMRI alone (80%) and PSMA PET/CT alone (72.3%), with a p-value < 0.05 (Fig. 6). On Ga68 PSMA PET/CT, basal lesions were the most common (79.1%), followed by left-lobe involvement (74.4%), peripheral zone lesions (67.4%), and anterior lesions (60.5%). Apical involvement was observed in 48.8% of patients.

Table 4
Diagnostic concordance between mpMRI and Ga68 PSMA PET/CT.

Site of Lesion	Agreement (Kappa Value)	p-value	Interpretation
Anterior lesions	0.595	0.002	Moderate agreement
Posterior lesions	0.595	0.002	Moderate agreement
Central zone lesions	0.511	0.003	Moderate agreement
Peripheral zone lesions	0.409	0.021	Fair agreement
Basal lesions	0.624	0.001	Substantial agreement
Apical lesions	0.482	0.008	Moderate agreement
Left lobe involvement	0.671	< 0.001	Substantial agreement
Right lobe involvement	0.438	0.017	Moderate agreement
Seminal vesicle invasion	0.744	< 0.001	Substantial agreement
Lymph node involvement	0.392	0.041	Fair agreement

Discussion

The present study evaluated the anatomical concordance of mpMRI and Ga68 PSMA PET/CT in a clinically challenging cohort of patients with persistently rising PSA levels despite a previous negative 12-core systematic TRUS-guided biopsy. Our findings demonstrate high malignancy detection rates on repeat targeted biopsy and show that combined interpretation of mpMRI and Ga68 PSMA PET/CT achieved the highest concordance with histopathology.

Negative TRUS-guided biopsy despite persistent clinical suspicion remains a well-recognized challenge in urologic practice. Systematic biopsy may fail to detect anteriorly located, apical, or small-volume tumors [15]. Advanced imaging techniques therefore play a pivotal role in lesion localization and targeted biopsy.

mpMRI has become an established tool in the diagnostic pathway for prostate cancer because of its ability to identify suspicious lesions and reduce unnecessary biopsies [5, 6]. However, mpMRI interpretation may be limited by post-inflammatory changes, transition zone heterogeneity, and indeterminate PI-RADS 3 lesions [8]. In the present study, mpMRI successfully localized suspicious lesions in most patients, particularly within the peripheral zone.

Ga68 PSMA PET/CT demonstrated excellent lesion localization and high positivity rates in our cohort, with adenocarcinoma confirmed in 90.7% patients undergoing PSMA-targeted biopsy. These findings are concordant with previous studies demonstrating high sensitivity of PSMA PET/CT for clinically significant prostate cancer.

Gauthaman et al. reported a sensitivity of 99.08% for Ga68 PSMA PET/CT compared with 84.40% for mpMRI in detecting primary prostate lesions [13]. Similarly, Zhou et al. demonstrated superior diagnostic performance of PSMA PET/CT in high-risk prostate cancer cohorts [14]. Their study further suggested that mpMRI may retain greater utility in low- and intermediate-risk disease.

Several investigators have suggested that combined interpretation of mpMRI and PSMA PET/CT improves localization accuracy and biopsy guidance [16]. PSMA PET/CT may identify lesions occult on MRI, particularly in patients with equivocal or negative mpMRI findings. Furthermore, molecular imaging with PSMA allows assessment of biological tumor activity, which may correlate with tumor aggressiveness [17].

In our study, PSA density demonstrated modest diagnostic utility, with limited specificity at the evaluated cutoff. Although PSA density remains a useful adjunctive marker, imaging-based localization appears superior for identifying clinically significant lesions.

The major strength of this study lies in evaluation of a clinically important subgroup of patients with persistent suspicion of malignancy despite prior negative biopsy. Such patients often undergo repeated invasive procedures, resulting in increased morbidity and psychological distress.

This study has several limitations. First, the sample size was relatively small and derived from a single-center experience. Second, histopathological confirmation was based on targeted biopsy rather than whole-mount prostatectomy specimens. Third, the retrospective assessment of concordance was not supplemented by centralized blinded image review. Finally, the study cohort consisted exclusively of patients with prior PI-RADS ≥ 3 lesions and persistently rising PSA levels, which may limit generalizability to broader screening populations.

The high malignancy detection rate of 90.7% observed in our cohort underscores the limitations of conventional TRUS-guided systematic biopsy and highlights the value of advanced imaging-guided lesion targeting in patients with persistent clinical suspicion.

Future multicentric prospective studies with larger cohorts and standardized imaging protocols are required to establish the precise role of combined mpMRI and PSMA PET/CT in biopsy-naïve patients

and those with prior negative biopsy.

Conclusion

Ga68 PSMA PET/CT demonstrated high diagnostic yield and good concordance with mpMRI for localization of suspicious prostatic lesions in patients with persistently rising PSA levels following a negative systematic TRUS-guided biopsy. Combined interpretation of both imaging modalities achieved the highest concordance with histopathology and may improve targeting of clinically significant prostate cancer during repeat biopsy. Further prospective multicenter studies are required to define the optimal integration of PSMA PET/CT into contemporary diagnostic pathways.

Declarations

Ethics approval and consent to participate

The study protocol was approved by the Institutional Ethics Committee, (IEC Approval No. INT/IEC/2020/SPL-548).

Consent for publication

Written informed consent for publication of anonymized clinical and research data was obtained from all participants.

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Author Contribution

All authors contributed to the conception, data collection, manuscript drafting, critical revision, and approval of the final manuscript.

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Figures

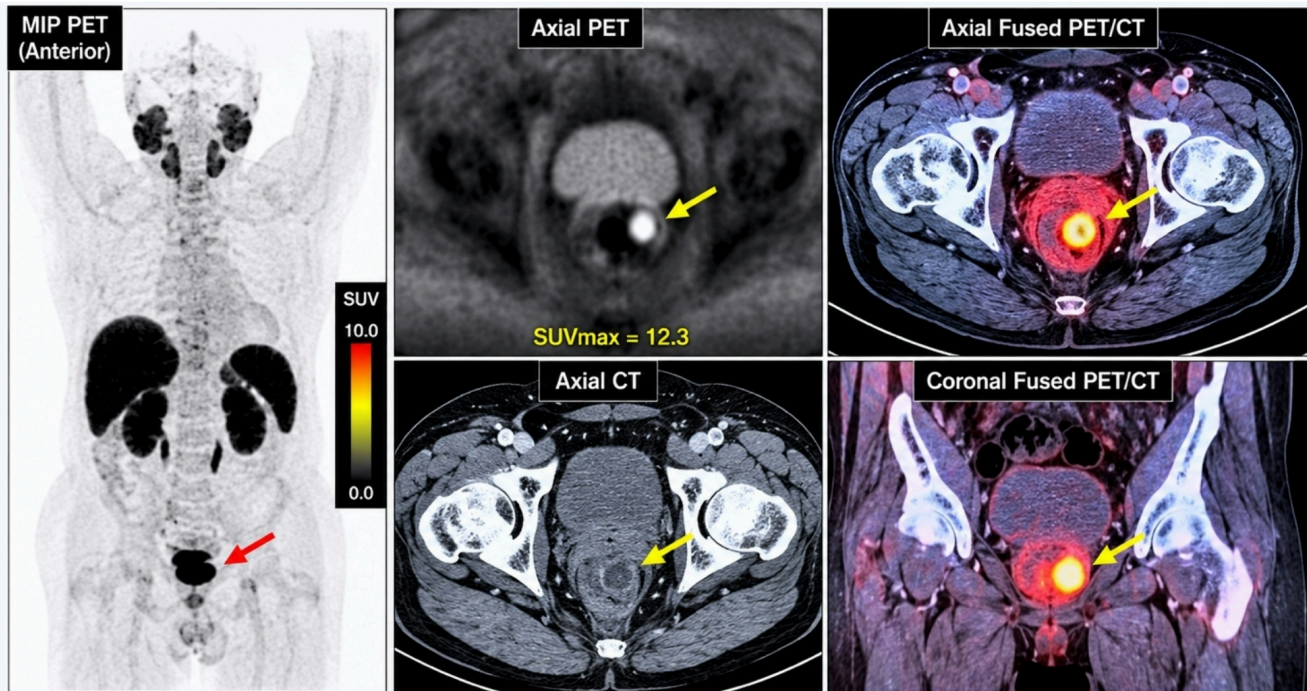


Figure 1

Ga68 PSMA PET/CT demonstrating focal increased tracer uptake in left posterolateral peripheral zone prostatic lesion.

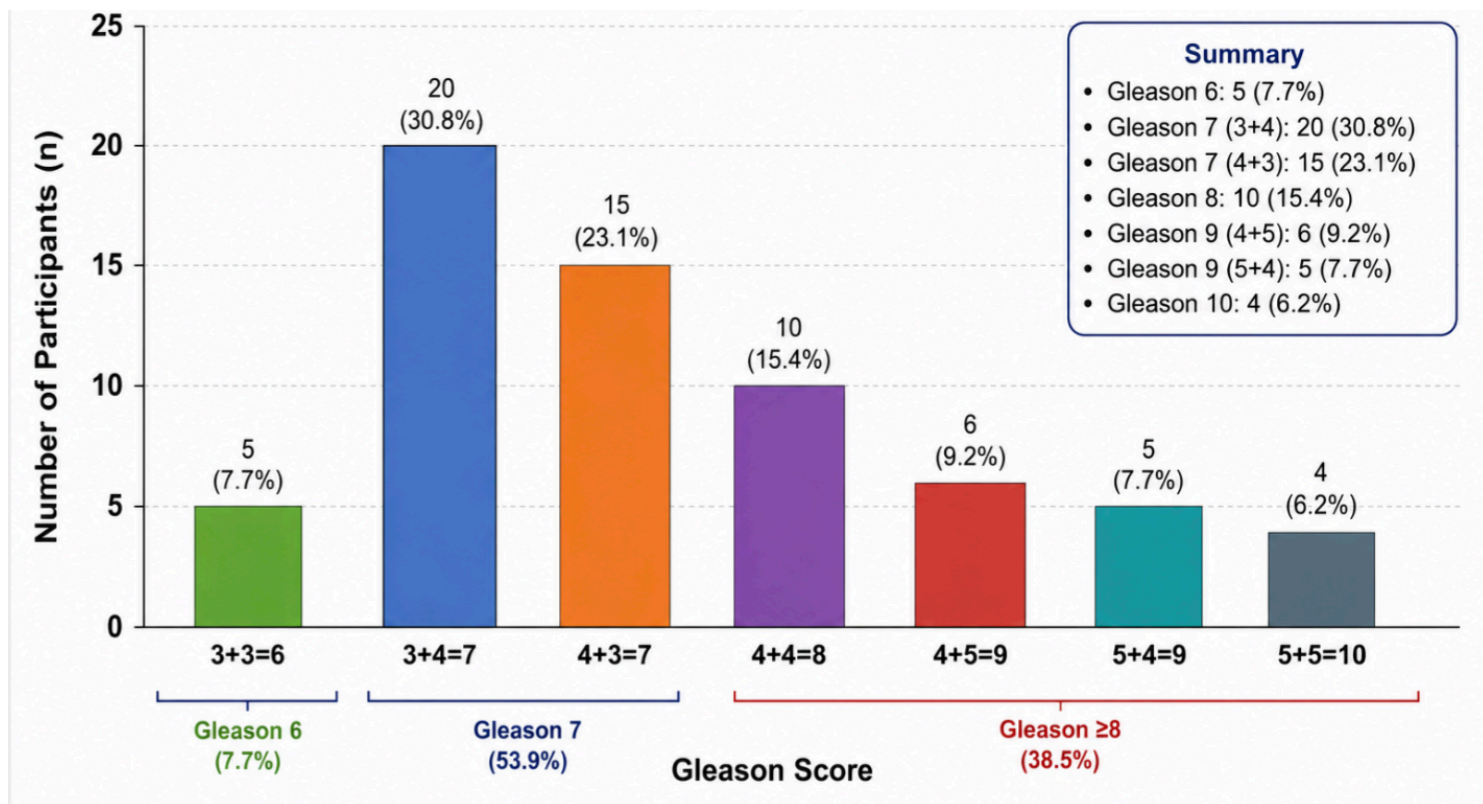


Figure 2

Distribution of Gleason scores among study participants, most common Gleason score 7 (3+4) 30.8%.

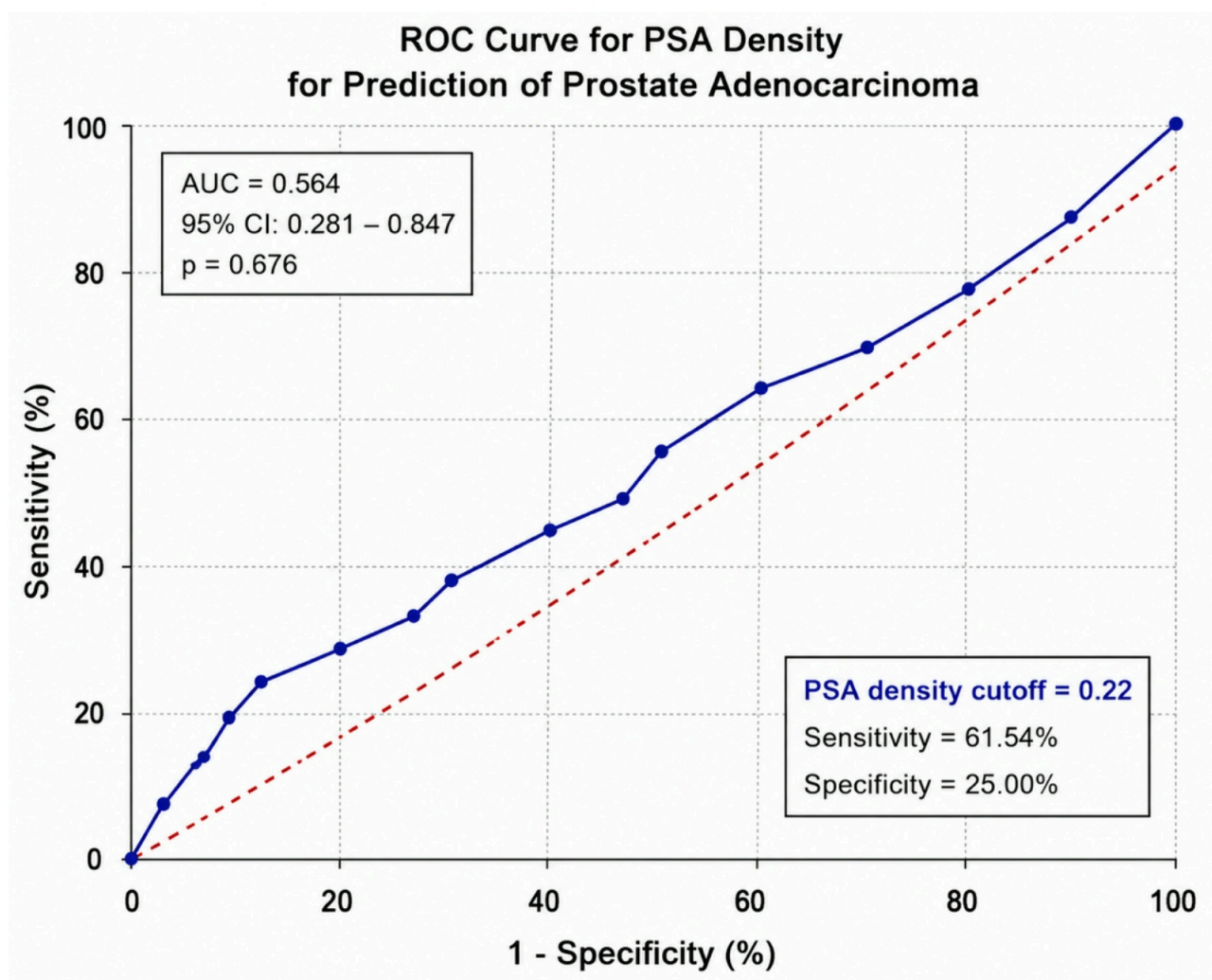


Figure 3

ROC curve demonstrating diagnostic performance of PSA density for prediction of prostate adenocarcinoma.

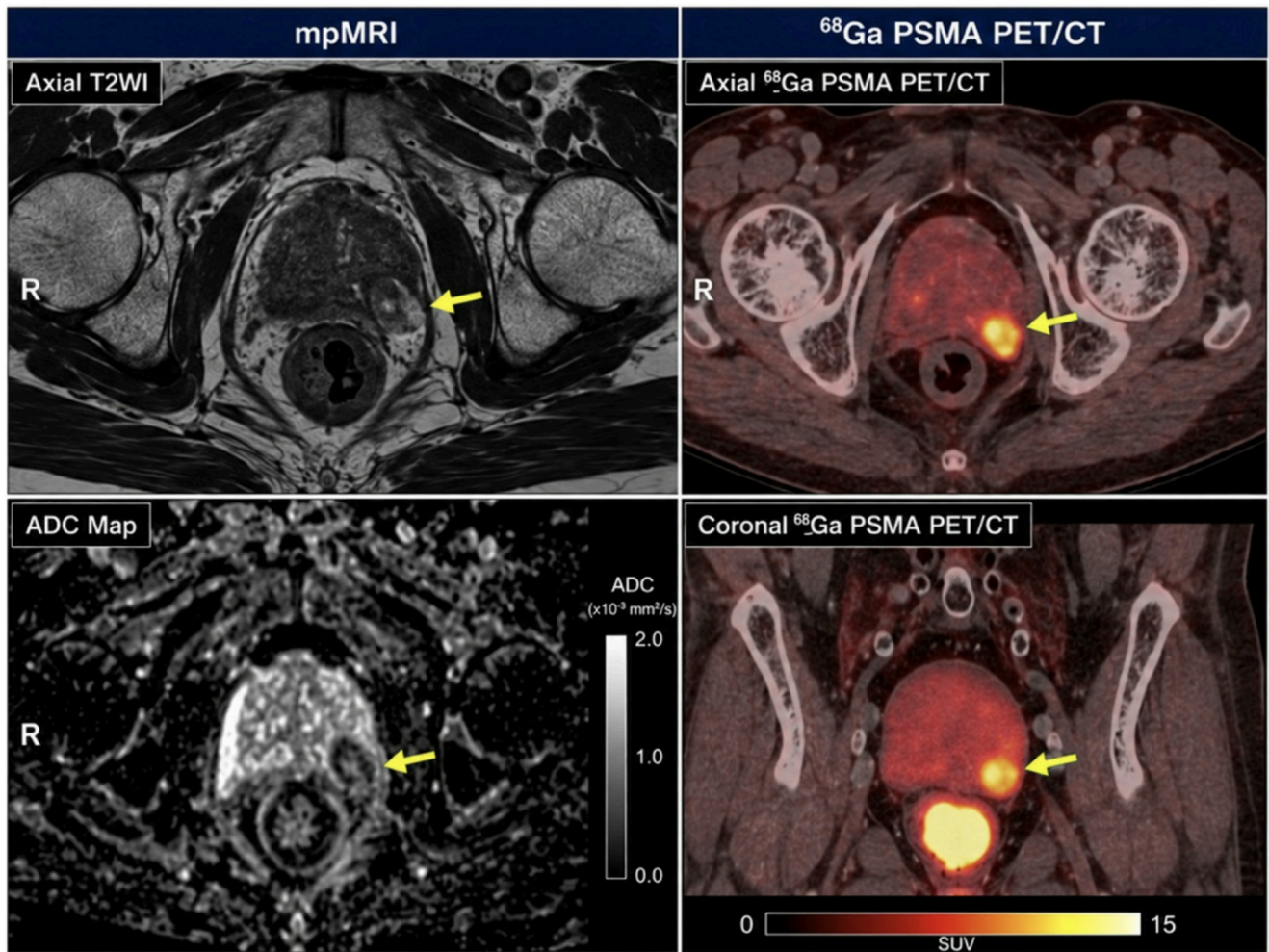


Figure 4

Comparative concordant left posterolateral peripheral zone lesion localization on mpMRI and PSMA PET/CT.

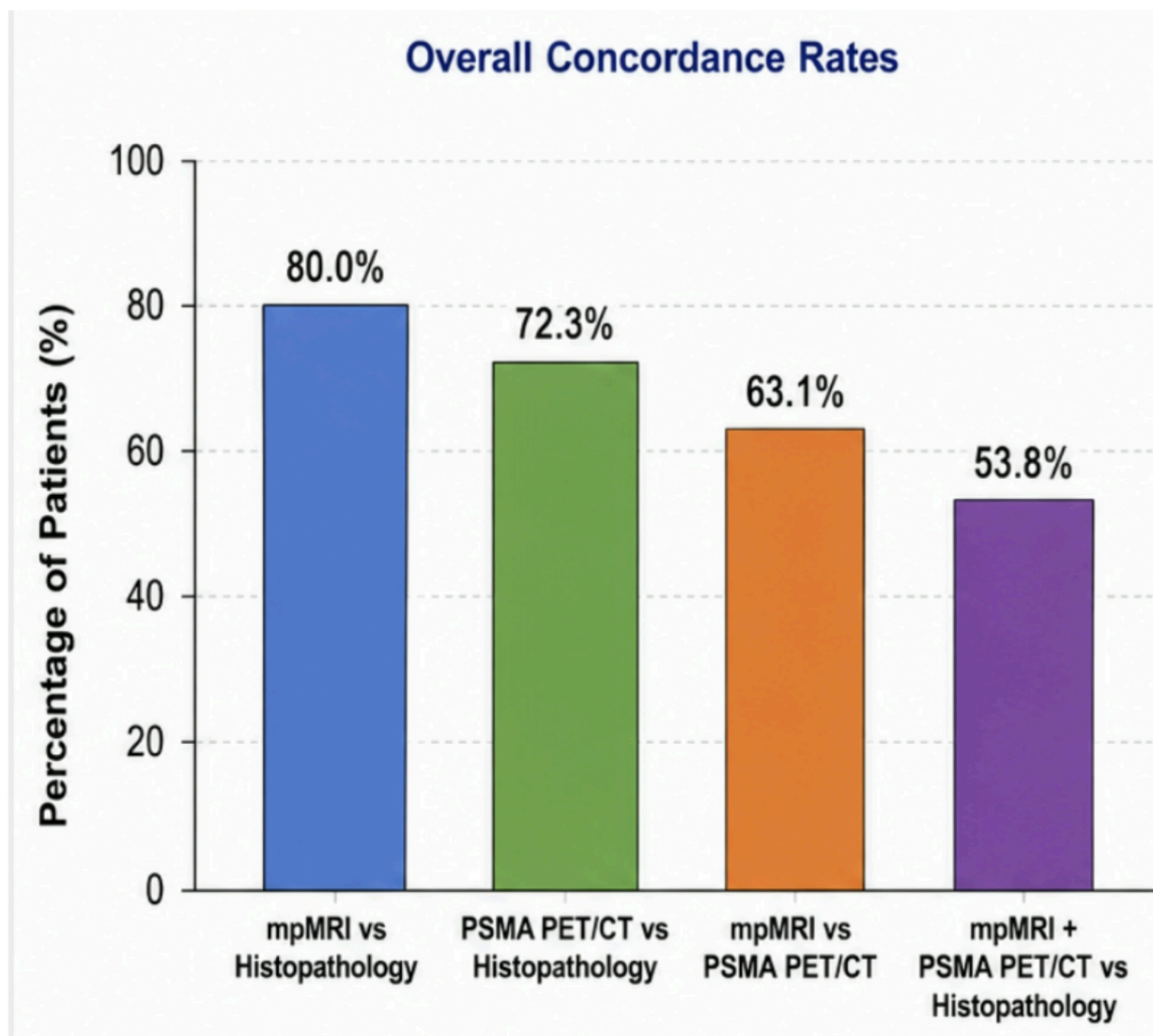


Figure 5

Concordance between mpMRI, PSMA PET/CT, and histopathology.

Lesion-Level Concordance (Patient-Based)

Concordance Category	mpMRI & PSMA PET/CT Concordant	mpMRI or PSMA PET/CT Discordant	Total (n)	Concordance (%)
Both Positive & Histopathology Positive	35 (53.8%)	2 (3.1%)	37	53.8%
Both Negative & Histopathology Negative	18 (27.7%)	4 (6.2%)	22	27.7%
One Positive, Other Negative & Histopathology Positive	6 (9.2%)	0 (0.0%)	6	9.2%
Both Negative & Histopathology Positive (False Negative)	0 (0.0%)	0 (0.0%)	0	0.0%
Total	59 (90.8%)	6 (9.2%)	65	90.8%

Figure 6

Lesion level concordance