3T multiparametric MRI's accuracy in detecting prostate cancer using Prostate Imaging Reporting and Data System (PIRADS) version 2.1 with prostate biopsy as a reference

Mohammad Abdullah Dhulaimi[1*] , Moroj Ahmad Aldarmasi[2], Areen Ghazi Almasri[3] and Syed Mohammad Mosharraf[4]

Abstract

Background Multiparametric magnetic resonance imaging (MRI) is valuable in detecting prostate cancer due to its high sensitivity to malignant lesions. It is commonly utilized to improve the identification of clinically significant cancers within the prostate. This study aimed to correlate the findings from 3T multiparametric MRI of the prostate using the updated Prostate Imaging Reporting and Data System version 2.1 (PIRADSv2.1) from 2019 with reference to prostate biopsy results. Additionally, PIRADSv2.1 was used to calculate the sensitivity, specificity, positive predictive value, and negative predictive value of the 3T multiparametric MRI of the prostate.

Methods and materials A retrospective study was conducted at a tertiary center, wherein we identified patients who underwent a prostate biopsy between June 2019 and June 2021 and had a corresponding MRI of the prostate performed at the same institution, evaluated with PIRADSv2.1 criteria.

Results A total of 50 patients were eligible for final analysis. The prevalence of prostate cancer was 69% (95% confidence interval (CI) 54–81%). Receiver operating characteristic (ROC) curves were generated for 3T multiparametric MRI of the prostate using PIRADSv2.1 to diagnose prostate cancer; the area under the ROC curve was 0.81 (95% CI 0.68–0.95, $p < 0.001$). The sensitivity, specificity, positive predictive value, and negative predictive value of the 3T multiparametric prostate MRI using PIRADSv2.1 were 74.0%, 87.0%, 92.9%, and 59.1%, respectively.

Conclusions PIRADSv2.1 exhibited good overall performance in the diagnosis of prostate cancer.

Keywords Prostate cancer, Multiparametric MRI, PIRADS, PIRADSv2.1, Prostate biopsy, MRI interpretation, Diagnostic accuracy, Prostate MRI guideline, Clinical significance

*Correspondence:
Mohammad Abdullah Dhulaimi
M_aldulaimi@hotmail.com
[1] King Abdulaziz Hospital, Ministry of Health -Jeddah, Jeddah, Saudi Arabia
[2] Faculty of Medicine, King Abdulaziz University, Jeddah, Saudi Arabia
[3] Prince Mohammed Bin Abdulaziz Hospital, Ministry of National Guard, Madinah, Saudi Arabia
[4] King Faisal Specialist Hospital and Research Centre, Riyadh, Saudi Arabia

Background

Prostate cancer, the most frequently diagnosed cancer in males, contributes to approximately 20% of cancer-related deaths. Among men, prostate cancer ranks as the second leading cause of death [1]. There is a lack of consensus regarding the definition of clinically significant prostate cancer [2]. However, it is commonly defined either histopathologically based on the criteria proposed by Wolters et al. [3] or radiologically [4].

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The Prostate Imaging Reporting and Data System (PIRADS) was introduced by the European Society of Urogenital Radiology in 2012 as a means to provide guidance and to standardize the acquisition, interpretation, and reporting of prostate magnetic resonance imaging (MRI) [5]. In March 2019, the guidelines were revised in PIRADS version 2.1 (PIRADSv2.1), incorporating changes to enhance interobserver agreement and simplify interpretation while maintaining the fundamental acquisition and scoring guidelines [6].

Multiparametric MRI is crucial in clinical practice and is valuable for detecting prostate cancer [7, 8]. It offers high sensitivity for identifying clinically significant tumors and has been employed to guide prostate biopsies [9]. By pinpointing the location of suspicious lesions, multiparametric MRI enables real-time co-registration with transrectal ultrasound (TRUS) images, facilitating targeted biopsy using MRI-TRUS fusion guidance. This technique allows for selecting lesions more likely to contain clinically significant cancers while reducing the detection of insignificant tumors [10].

Several guidelines highlight the significance of implementing quality assurance programs for MRI of the prostate, including comparing MRI findings with pathology results [7]. This study aimed to determine the prevalence of prostate cancer at a tertiary center and establish a correlation between the findings obtained from 3T multiparametric MRI of the prostate using PIRADSv2.1 and the subsequent results of the prostate biopsy, which served as the reference standard. Furthermore, sensitivity, specificity, positive predictive value, negative predictive value, and the receiver operating characteristic (ROC) curve were calculated for 3T multiparametric MRI of the prostate using PIRADSv2.1.

Methods
Study design
A retrospective study was conducted at King Faisal Specialist Hospital and Research Center (KFSHRC) in Jeddah, Saudi Arabia, a renowned tertiary and referral center for prostate cancer. The target population was identified through an electronic search of the prostate biopsy database, and data were collected from various sources, including the hospital database and the radiology system.

We included patients who underwent a prostate biopsy between June 2019 and June 2021 and had a prostate MRI conducted at the same hospital within a 6-month window before or after the biopsy. Patients with a history of recurrent prostate cancer and those with an MRI study performed on a 1.5T machine were excluded from the study (Table 1).

MRI interpretation
The interpretation of all prostate MRI studies was performed by abdominal imaging radiologists. The classification of prostate nodules and image interpretation was conducted using the PIRADSv2.1 criteria [11].

Prostate biopsy
The biopsy samples were examined by the pathologist at the same hospital using the Gleason classification system [12]. Histopathology results were categorized as positive if the Gleason classification system yielded a score of 7 or higher and negative if it was 6 or lower. The MRI findings were then compared and correlated with the pathology outcomes obtained from each site (Table 2).

### Correlation between prostate MRI and biopsy
Patient information such as age, prostate-specific antigen (PSA) level, prostate biopsy date, and the reason for the biopsy were collected. Furthermore, specific details from the prostate biopsy reports were gathered, including biopsy location, biopsy method, the number of cores obtained from each site, and the operator of the biopsy. The MRI lesion's zonal location was classified as peripheral zone, central gland, or a combination of both. Information such as the MRI procedure date, PIRADS scores with corresponding nodule sites, and the MRI reader was collected from the record of the MRI reports.

Ethical consideration
This study was conducted in accordance with the Helsinki Declaration, and approval to conduct the study was obtained from the Research Committee at

Table 1 PIRADSv2.1 criteria

PIRADS categories	Definition
PIRADS 1	Very low (clinically significant cancer is highly unlikely to be present)
PIRADS 2	Low (clinically significant cancer is unlikely to be present)
PIRADS 3	Intermediate (clinically significant cancer is equivocal)- Fig. 1
PIRADS 4	High (clinically significant cancer is likely to be present)- Fig. 2
PIRADS 5	Very high (clinically significant cancer is highly likely to be present)- Fig. 3

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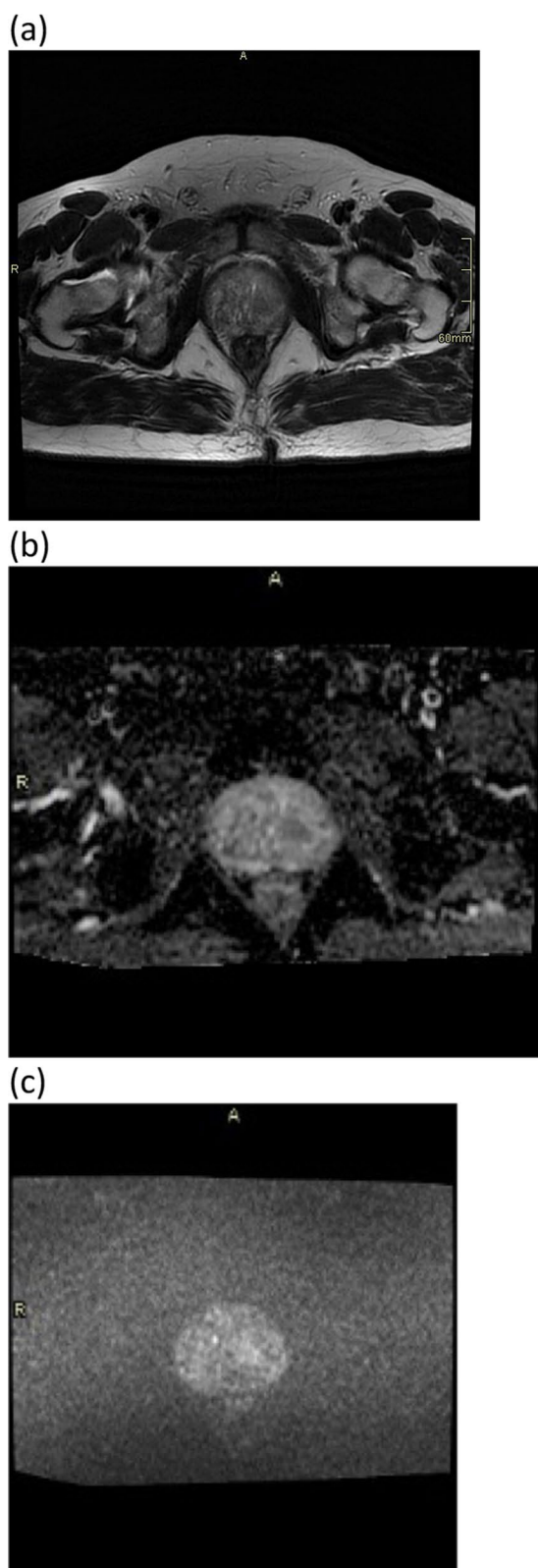
Fig. 1 These images represent PIRADS 3. T2 shows a left central zone heterogeneous lesion with an obscured margin (**a**). Diffusion-weighted images score less than or equal to 4 (**b** and **c**)
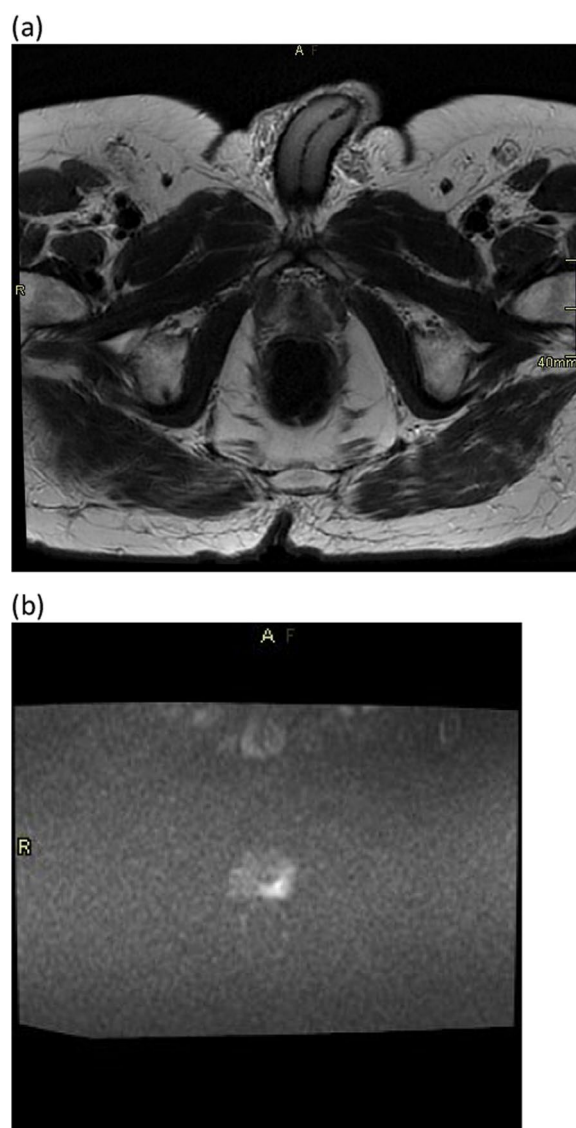
Fig. 2 These images represent PIRADS 4, as evidenced by 1.2 cm left peripheral zone lesion on T2 (**a**) with marked restricted diffusion (**b**)

KFSHRC—Jeddah. Informed consent was waived as the study involved a retrospective chart review. To ensure the confidentiality of the subjects, access to the completed forms and the database was limited to the research team. The data were securely stored in an office and were not shared with any unauthorized individuals.

Statistical analysis

The data were coded and entered into SPSS version 26 for analysis. Descriptive statistics were used to summarize the quantitative variables, presenting means and standard deviations, while qualitative variables were described using frequencies and percentages. Sensitivity, specificity,

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Fig. 3 These images represent PIRADS 5, as evidenced by marked restricted diffusion (**a** and **b**). Diffusion-weighted images show marked hyperintensity (**a**), while the Apparent Diffusion Coefficient (ADC) map displays marked hypointensity (**b**). T2 reveals a 3.6 cm mass involving the left peripheral zone with intermediate signal intensity (**c**)

positive predictive value, and negative predictive value were calculated. Cutoffs for the scoring systems were determined using the Youden index. The significance level was set at a *p* value of less than 0.05, with a 95% confidence interval (CI).

Results

We identified a total of 152 patients, out of which 63 had PIRADSv2.1 category 3 and above. However, 13 patients were excluded from the analysis as histopathology was not performed for them. As a result, only 50 patients met the criteria for inclusion in the final analysis. The prevalence of prostate cancer among the patients who underwent biopsy was determined to be 69% (95% CI 54–81%). The mean age (standard deviation [SD]) of the participants was 66.48 (7.5), and the mean PSA level (SD) was 44.5 (88.4). Further details on other variables can be found in Table 3.

Diagnostic accuracy of 3T multiparametric MRI

ROC curves were generated to evaluate the diagnostic performance of 3T multiparametric MRI of the prostate using PIRADSv2.1 for prostate cancer. The area under the ROC curves was calculated to be 0.81 (95% CI 0.68–0.95, $p < 0.001$, Fig. 4). The optimal cutoff value for diagnosis, determined by the Youden index, was found to be 5.

The sensitivity, specificity, positive predictive value, and negative predictive value of 3T multiparametric prostate MRI using PIRADSv2.1 were determined to be 74.0%, 87.0%, 92.9%, and 59.1%, respectively.

Discussion

Currently, the standard diagnostic approach for prostate cancer involves TRUS-guided systematic prostate biopsy [13]. While this method is generally considered safe, it is an invasive procedure with certain risks. These risks include rectal bleeding, vasovagal symptoms, genitourinary system infection, hematospermia, fever, dysuria, and macroscopic hematuria [13].

On the other hand, multiparametric prostate MRI offers a noninvasive approach to detect prostate cancer. In 2012, the European Society of Urogenital Radiology developed the first standardized guidelines for prostate MRI, aiming to enhance the accuracy of radiologic interpretations [4]. However, subsequent evaluations revealed practical limitations in this system, leading to the release

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Table 2 Gleason classification system

Risk group	Grade group	Gleason score
Low/very low	Grade group 1	Gleason score ≤ 6
Intermediate (favorable/unfavorable)	Grade group 2	Gleason score 7 (3 + 4)
	Grade group 3	Gleason score 7 (4 + 3)
High/very high	Grade group 4	Gleason score 8
	Grade group 5	Gleason score 9–10

Table 3 Characteristic features of participants

Variable	Item	Number (%)
Location of lesion	Peripheral zone	30 (60%)
	Central gland	8 (16%)
	Combined	12 (24%)
Histopathology result	Positive	35 (70%)
	Negative (benign prostatic disease)	15 (30%)
Biopsy method	TRUS	48 (96%)
	Surgery	2 (4%)
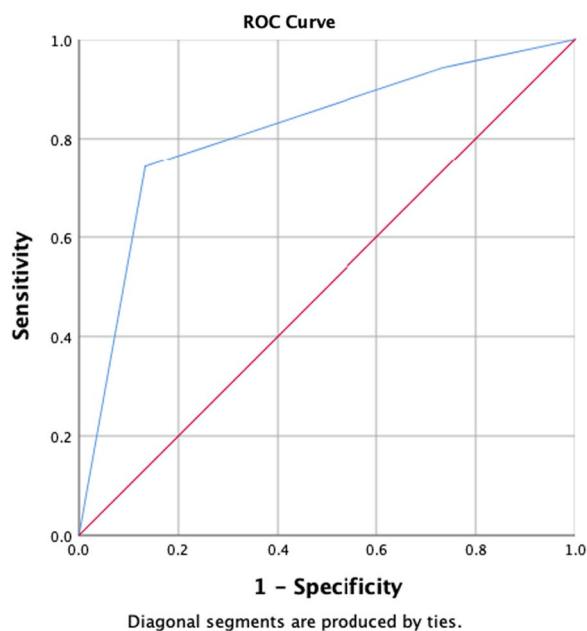
Fig. 4 Receiver operating characteristic curves for 3T multiparametric prostate MRI using PIRADSv2.1 to diagnose prostate cancer

of PIRADSv2.0 in 2015. Further refinements and assessments resulted in the latest version, PIRADSv2.1, which was introduced in 2019 [9].

This study evaluated the diagnostic accuracy of 3T multiparametric MRI using PIRADSv2.1 for detecting prostate cancer, with prostate biopsy as a reference.

Our findings indicated that at a cutoff point of a PIRADS score of 5, the overall accuracy of 3T multiparametric prostate MRI in diagnosing prostate cancer was 0.81. The corresponding sensitivity, specificity, positive predictive value, and negative predictive value were 74.0%, 87.0%, 92.9%, and 59.1%, respectively.

A previous validation study of PIRADSv2 reported an overall accuracy of 82.2%, sensitivity of 90.0%, specificity of 80.1%, positive predictive value of 83.3%, and negative predictive value of 81.8%. The study noted that the highest accuracy rate was observed for a PIRADS score of 5. [14]

In another study, the sensitivity, specificity, positive predictive value, and negative predictive value of PIRADSv2 were reported as 89.0%, 76.5%, 89.7%, 31.7%, and 98.4%, respectively [7]. When comparing our study to that previous one, we observed a similar overall accuracy, specificity, and positive predictive value. However, our study demonstrated lower sensitivity and negative predictive value.

This research has several limitations. First, it relied solely on the interpretation of a single radiologist, which may limit the generalizability of the findings. However, this approach does reflect routine practice. Second, setting a PIRADS score of 5 as the cutoff value may result in a higher incidence of clinically significant prostate cancer being missed. Third, the study focused on assessing specific zones of the gland rather than the entire prostate. Additionally, using biopsy specimens as the reference standard instead of radical prostatectomy specimens is another limitation. However, utilizing whole-mount prostate specimens for validation would have introduced a selection bias toward patients at higher risk, as only those who underwent prostatectomy would have been included. Lastly, because this study was retrospective, it cannot be ensured that the radiologists were blinded to the biopsy results.

Conclusions

PIRADSv2.1 exhibited favorable performance in diagnosing prostate cancer when compared to the gold standard of biopsy results. However, to confirm these findings, conducting larger-scale studies with a prospective design is advisable.

Abbreviations
PIRADS   Prostate Imaging Reporting and Data System
PIRADSv   Prostate Imaging Reporting and Data System version
MRI   Magnetic resonance imaging
TRUS   Transrectal ultrasound
KFSHRC   King Faisal Specialist Hospital and Research Center
PSA   Prostate-specific antigen
CI   Confidence interval
SD   Standard deviation
ROC   Receiver operating characteristic

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Availability of data and materials
The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
This study was conducted in accordance with the Helsinki Declaration, and approval to conduct the study was obtained from the Research Committee at KFSHRC—Jeddah. Informed consent was waived as the study involved a retrospective chart review. To ensure the confidentiality of the subjects, access to the completed forms and the database was limited to the research team. The data were securely stored in an office and were not shared with any unauthorized individuals.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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