Diagnostic Performance of PI-RADS v2.1 for Clinically Significant Prostate Cancer in Indonesian Patients Undergoing MRI Fusion Prostate Biopsy

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Abstract

Background:
Prostate cancer is the second most common malignancy among men and one of the leading causes of cancer-related death. MRI evaluation using prostate imaging and data system (PI-RADS) v2.1 is widely applied to detect clinically significant prostate cancer (csPCa). However, data on its diagnostic performance in Indonesian population remain limited.

Methods:
An analytical observational study with retrospective cross-sectional design was conducted on patients with PI-RADS category 3-5 who underwent MRI fusion prostate biopsy at Siloam Hospitals Kebon Jeruk between 2021 and 2025. Sensitivity, specificity, predictive values, and accuracy of PI-RADS v2.1 were evaluated against histopathological findings. Statistical analyses include Chi-Square and Mann-Whitney U test.

Result:
A total of 75 patients were included, with a median age of 71 years (range: 49-84). The csPCa detection rates for each PI-RADS category were 14.29% for PI-RADS 3, 48.28% for PI-RADS 4 and 89.74% for PI-RADS 5. Histopathology confirmed csPCa in 50 patients (66.67%) and non-csPCa or benign lesions in 25 patients. The sensitivity of PI-RADS v2.1 at a cutoff ≥4 was 98% (95% CI 89.35–99.95), specificity 24% (95% CI 9.36–45.13), positive predictive value (PPV) 72.06%, negative predictive value (NPV) 85.71%, and overall accuracy 73.33% (95% CI 61.86–82.89). Bivariate analysis showed that older age, higher PSA, larger lesion size, PSA density ≥0.15 ng/ml2, and PIRADS 4/5 category were significantly associated with csPCa.

Conclusions:
PI-RADS v2.1 demonstrates very high sensitivity and good NPV for excluding csPCa but has low specificity, resulting in moderate overall accuracy (73.33%).

Introduction

Prostate cancer is one of the most prevalent malignancies affecting men worldwide and remains a major contributor to cancer-related morbidity and mortality. According to Global Cancer Observatory (GLOBOCAN) 2022, prostate cancer accounts for an estimated 1,467,854 new cases globally (7.3% of all cancers), ranking fourth overall and second among men, with 397,430 deaths (4.1%) placing it eighth among leading causes of cancer mortality.[1] In Indonesia, the burden of prostate cancer continues to increase, with an incidence of 13,130 new cases (7% of all male cancer cases) among 140.5 million men.[2] This makes prostate cancer the fifth most common malignancy in the country after lung, colorectal, liver, and nasopharyngeal cancers.[2] Mortality remains substantial, reaching 4,860 deaths (2% of total cancer deaths).[2] These data underscore the importance of early detection and accurate diagnosis for improving prognosis and guiding optimal management strategies.

Screening for prostate cancer typically involves digital rectal examination (DRE) and measurement of serum prostate-specific antigen (PSA).[3] While PSA testing demonstrates high sensitivity (93%), its specificity is relatively low (20%), often leading to false-positive results and unnecessary biopsies.[4] Elevated PSA levels usually prompt saturation biopsy; however, conventional systematic biopsy techniques frequently miss clinically significant prostate cancer (csPCa) and may over-detect indolent disease. These limitations highlight the need for more precise diagnostic tools that can differentiate clinically significant from insignificant disease, thereby minimizing unnecessary interventions and overtreatment.

Advances in magnetic resonance imaging (MRI) have revolutionized prostate cancer detection by providing superior visualization of prostate anatomy and lesion characteristics. The Prostate Imaging Reporting and Data System (PI-RADS) was developed to standardize MRI interpretation and improve diagnostic consistency. PI-RADS v2.1 stratifies lesions from categories 1 to 5 according to the likelihood of csPCa, with higher categories correlating with greater malignancy potential. Integration of MRI with targeted biopsy, particularly MRI fusion biopsy, has been shown to improve diagnostic yield and accuracy, especially for lesions not easily accessible by standard transrectal biopsy.[5–8] Moreover, MRI-fusion biopsy reduces infectious complications compared to conventional approaches.[9] Despite its clinical potential, data on the diagnostic performance of PI-RADS v2.1 remain limited in Indonesia. Therefore, this study aims to evaluate its diagnostic performance in predicting csPCa using MRI-fusion biopsy at Siloam Hospitals Kebon Jeruk, Indonesia.

Material And Methods

This study employed a retrospective cross-sectional design. Data were collected from patients who underwent prostate MRI and MRI fusion biopsy at Siloam Hospitals Kebon Jeruk, Indonesia, between September 2021 and April 2025. Eligible participants were men with PI-RADS categories 3–5 on MRI who proceeded to biopsy within three months of imaging. Patients with a history of prior prostate surgery, prostate cancer treatment, or incomplete imaging or histopathology records were excluded. This study received approval from the Ethics Committee of the Faculty of Medicine, Universitas Pelita Harapan, Indonesia (Approval number: 251/K-LKJ/ETIK/VIII/2025) and Hospital Director of Siloam Hospitals Kebon Jeruk (Approval number: 805/SHKJ-DIR/VIII/2025).

All MRI examinations were performed using a 1.5-Tesla MRI scanner (MAGNETOM Avanto Fit 1.5T, Siemens Healthineers, Erlangen, Germany), following the PI-RADS v2.1 protocol. The sequences included T2-weighted imaging (T2WI), diffusion-weighed imaging (DWI) with apparent diffusion coefficient (ADC) maps, and dynamic contrast-enhanced (DCE) imaging.[10,11] Each study was independently reviewed by two radiologists with at least five years of experience in prostate MRI interpretation, who were blinded to clinical and histopathological results. Discrepancies were resolved by consensus. Lesions were categorized according to PI-RADS v2.1 then divided into two categories, PI-RADS 3 and 4/5 category. Lesion size was measured as the largest diameter on MRI.[10,11] Lesion location was defined based on prostate sector map as recommended by PI-RADS and European Society of Urogenital Radiology (ESUR)[10,12], then categorized into peripheral zone (PZ), transitional zone (TZ), both PZ and TZ, and other (including central zone (CZ) and anterior fibromuscular stroma (AFS)). Prostate was measured in length, width, and height, then multiplied by 0.52 to obtain prostate volume based on PI-RADS v2.1 recommendation.[10] Patients' age and PSA were collected from medical records. PSA density was obtained from dividing PSA by prostate volume[10], then categorized into <0.15 ng/ml^2 and ≥0.15 ng/ml^2.[13–15]

All histopathological specimens were obtained from MRI-fusion biopsy using transperineal approach under local anesthesia. Fusion targeting was achieved through integration of MRI lesion maps with real-time transrectal ultrasound (TRUS) images using an MRI-fusion biopsy system. A minimum of two targeted cores were obtained from each lesion identified on MRI. Histopathological findings were divided into two groups based on Gleason score (GS), csPCa group and non-csPCa group (including non-csPCa and benign lesions). Clinically significant prostate cancer was defined as GS ≥ 7, while non-csPCa was defined as GS 6.[5–7,16,17]

Statistical analyses were performed using IBM SPSS Statistics version 23.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were used to summarize patient characteristics. Continuous variables were expressed as median (interquartile range) or mean ± standard deviation, depending on data distribution. Categorical variables were presented as frequencies and percentages. Normality testing was performed using Kolmogorov-Smirnov test. Diagnostic performance of PI-RADS v2.1 was evaluated using sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy, with histopathology as the gold standard. The receiver operating characteristic (ROC) curve and area under the curver (AUV) were used to assess discriminative performance. Chi-square test was used to assess associations between categorical variables. Mann-Whitney U test was applied for comparisons between continuous (nonparametric) and categorical variables. P-values < 0.05 were considered statistically significant.

Result

Out of 758 patients who underwent prostate MRI at Siloam Hospitals Kebon Jeruk between September 2021 and April 2025, 683 were excluded due to PI-RADS 1 or 2 category, did not undergo MRI-fusion prostate biopsy, or has incomplete histopathology. A total of 75 patients who met the inclusion criteria were analyzed. Patient characteristics are presented in Table 1. Normality testing using Kolmogorov-Smirnov test for continuous variables (age, prostate volume, PSA, and lesion size) showed that the data were not

normally distributed. The median age was 71 years (IQR: 61-75). Median serum PSA level was elevated across the patients. Based on histopathological examination, 50 men (66.67%) were diagnosed with csPCa and 25 patients (33.33%) had non-csPCa or benign findings. In bivariate analysis, older age, higher PSA level, larger lesion size, PSA density ≥0.15 ng/ml2, and PI-RADS 4/5 category were significantly associated with the presence of csPCa ($p < 0.05$). Although not statistically significant ($p > 0.05$), csPCa group has smaller prostate volume and lesion found dominantly in PZ.

Table 1. Characteristics of Patients Undergoing MRI-Fusion Prostate Biopsy at Siloam Hospitals Kebon Jeruk between September 2021 and April 2025 (n = 75).

Variable	All patients (n = 75)	csPCa (n = 50)	Non-csPCa (n = 25)	P value#
Age (year), median (IQR)	71 (61-75)	72.5 (53-84)	65 (49-78)	<0.001*
Prostate volume (ml), median (IQR)	38 (27-63)	34.45 (15-201)	45 (23-169)	0.089
PSA (ng/ml), median (IQR)	14.25 (8.38-32)	17.94 (3.88-490)	9.2 (6-50)	0.011*
Lesion size (mm), median (IQR)	18 (13-27)	21.5 (5-82)	13 (4-29)	<0.001*
PSA density (ng/ml^2), n (%)				
○ ≥0.15	71 (94,7)	50 (100)	21 (84)	0.010*
○ <0.15	4 (5.3)	0 (0)	4 (16)	
PI-RADS category, n (%)				
○ PIRADS 4/5	68 (90.7)	49 (98)	19 (76)	0.005*
○ PIRADS 3	7 (9.3)	1 (2)	6 (24)	
Lesion location, n (%)				
○ PZ	43 (57.3)	29 (58)	14 (56)	0.253
○ TZ	23 (30.7)	13 (26)	10 (40)	
○ PZ and TZ	6 (8)	6 (12)	0 (0)	
○ Other	3 (4)	2 (4)	1 (4)	

Note: clinically significant prostate cancer (csPCa), interquartile range (IQR), prostate-specific antigen (PSA), prostate imaging reporting and data system (PI-RADS), peripheral zone (PZ), transitional zone (TZ), other (central zone, anterior fibromuscular stroma)
P values were calculated using Chi square test for categorical variables and Mann-Whitney U test for continuous nonparametric data
* P value < 0.05 was considered statistically significant

Most of the patients presented with PI-RADS 5 (n = 39, 52%) followed by PI-RADS 4 (n = 29, 38.67%) and PI-RADS 3 (n = 7, 9.33%). The detection rate of csPCa increased proportionally with higher PI-RADS category. The csPCa detection rates which were 14.29% (n = 1) for PI-RADS 3, 48.28% (n = 14) for PI-RADS 4, and 89.74% (n = 35) for PI-RADS 5. Using a diagnostic threshold of PI-RADS ≥4, PI-RADS v2.1 achieved a sensitivity of 98% (95% CI: 89.35-99.95) and a specificity of 24% (95% CI: 9.36-45.13). The PPV was 72.06% (95% CI: 67.34-76.34), the NPV was 85.71% (95% CI: 43.29-98.72), and the overall diagnostic accuracy was 73.33% (95% CI: 61.86-82.89). The ROC analysis of PI-RADS v2.1 (Figure 1) yielded an AUC of 0.610 (95% CI: 0.466-0.754) indicating low discriminative ability for detecting csPCa. These findings suggest that while PI-RADS v2.1 demonstrates excellent sensitivity and NPV for ruling out csPCa, its low specificity results in a moderate overall accuracy.

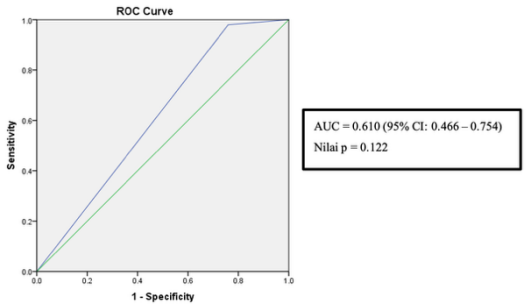

Figure 1. ROC curve of PI-RADS v2.1.

Discussion

This study evaluated the diagnostic performance of PI-RADS v2.1 in detecting csPCa using MRI-fusion prostate biopsy as the reference standard at Siloam Hospitals Kebon Jeruk, Indonesia. The findings demonstrate the PI-RADS v2.1 achieves high sensitivity (98%) and good NPV (85.7%), confirming its reliability in excluding csPCa. However, its relatively low specificity (24%) resulting in moderate overall diagnostic accuracy of 73.33%. These results are mostly consistent with previous studies that have reported excellent sensitivity but variable specificity of PI-RADS in detecting csPCa.18,19 AUC value of 0.610 in this study was lower than several studies reporting high AUC (0.825 - 0.897). 4,36,37 These findings may be due to the study conducted in higher-risk populations.

Table 1. PI-RADS v2.1 Diagnostic Performance in Comparison to Other Studies.

Reference	Sensitivity	Specificity	PPV	NPV
This study	98% (89,4-99,9)	24% (9,4-45,1)	72,06% (67,3-76,3)	85,71% (43,3-97,90)
Oerther et al[18]	86% (82-89)	66% (58-74)	-	-
Wen et al[19]	86,2% (77,4-91,9)	84,7% (79,6-88,8)	67,6% (58,0-76,1)	94,3% (90,3-97,0)

% (95% CI), positive predictive value (PPV), negative predictive value (NPV)

The progressive increase in csPCa detection with higher PI-RADS categories observed in this study–14.29% for PI-RADS 3, 48.28% for PI-RADS 4, and 89.74% for PI-RADS 5–was consistent with other studies which was summarized in Table 3. 5–7,18,19 This finding supports the validity of PI-RADS v2.1 as a reliable imaging-based risk stratification system and emphasizing that PI-RADS 4 and 5 lesions are strongly associated with csPCa confirmed by targeted biopsy. The high sensitivity in our study suggests that PI-RADS v2.1 effectively identifies patients at risk for significant malignancy, although its lower specificity indicates a tendency to overestimate cancer probablity, particularly among PI-RADS 3 lesions.

Table 3. Detection Rates of csPCa for Each PI-RADS Category in Comparison to Other Studies

Reference	Detection Rates of csPCa		
	PI-RADS 3	PI-RADS 4	PI-RADS 5
This study	14.29% (1/7)	48.28% (14/29)	89.74% (35/39)
Hakozaki et al[6]	1.0% (1/98)	35,1% (47/134)	73,1% (57/78)
John et al[5]	11,1% (3/27)	42,9% (24/56)	35,6% (21/59)
Osses et al[7]	10,34% (3/29)	77,38% (65/84)	88,89% (32/36)
Oerther et al[18]	19%	54%	84%
Wen et al[19]	10,52% (8/76)	67,12% (49/73)	68,42% (26/38)

% (csPCa / total per PI-RADS category)

The results emphasize the clinical value of PI-RADS v2.1 and MRI-fusion biopsy as an integrated diagnostic pathway for prostate cancer detection. PI-RADS v2.1 provides a reliable non-invasive method for risk stratification before biopsy, allowing clinicians to identify patietns most likely to harbor csPCa. The high sensitivity and NPV value indicate that a low PI-RADS score (≤3) can help safely defer unnecessary biopsy, while higher categories (≥4) warant targeted sampling. Incorporating several factors such as age, lesion size, serum PSA, and PSA density combined with clinical judgement further refine decision-making, reducing patient morbidity and healthcare costs associated with unnecessary procedures.

This study has several limitations. It was a retrospective single-center study, which mayh limit the generalizability of findings. The inclusion of only patients who underwent MRI-fusion prostate biopsy may introduce selection bias, as this group likely represented a high-risk population with higher pretest probability of cancer. Future research should employ prospective multicenter design with larger populations to validate the diagnostic performance of PI-RADS v2.1 and to assess inter-reader agreement.

Conclusion

In conclusion, PI-RADS v2.1 demonstrated very high sensitivity and good NPV for detecting csPCa using MRI-fusion biopsy, though its specificity remained low, yielding moderate overall accuracy. The results support the role of PI-RADS v2.1 as a sensitive imaging tool for csPCa detection and its integration into prostate cancer diagnostic workflows. This study contributes important regional data to the growing evidence base supporting MRI-guided diagnostic strategies in prostate cancer evaluation, particularly within Indonesian clinical context.

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References

1. Ferlay J, Ervik M, Lam F, Laversanne M, Colombet M, Mery L, et al. Global Cancer Observatory: Cancer Today. Cancer site ranking: Prostate [Internet]. Lyon, France; 2024 [cited 2025 Jun 11]. Available from: https://gco.iarc.who.int/today

2. Ferlay J, Ervik M, Lam F, Laversanne M, Colombet M, Mery L, et al. Global Cancer Observatory: Cancer Today. Country: Indonesia [Internet]. Lyon, France; 2024 [cited 2025 Jun 11]. Available from: https://gco.iarc.who.int/today

3. Bratt O, Auvinen A, Arnsrud Godtman R, Hellström M, Hugosson J, Lilja H, et al. Screening for prostate cancer: evidence, ongoing trials, policies and knowledge gaps. Vol. 2, BMJ Oncology. BMJ Publishing Group; 2023.

4. Merriel SWD, Pocock L, Gilbert E, Creavin S, Walter FM, Spencer A, et al. Systematic review and meta-analysis of the diagnostic accuracy of prostate-specific antigen (PSA) for the detection of prostate cancer in symptomatic patients. BMC Med. 2022 Dec 1;20(1).

5. John S, Cooper S, Breau RH, Flood TA, Cagiannos I, Lavallée LT, et al. Multiparametric magnetic resonance imaging-transrectal ultrasound-guided cognitive fusion biopsy of the prostate: Clinically significant cancer detection rates stratified by the Prostate Imaging and Data Reporting System version 2 assessment categories. Canadian Urological Association Journal. 2018 Dec 1;12(12):401–6.

6. Hakozaki Y, Matsushima H, Murata T, Masuda T, Hirai Y, Oda M, et al. Detection rate of clinically significant prostate cancer in magnetic resonance imaging and ultrasonography-fusion transperineal targeted biopsy for lesions with a prostate imaging reporting and data system version 2 score of 3–5. International Journal of Urology. 2019 Feb 1;26(2):217–22.

7. Osses DF, van Asten JJ, Kieft GJ, Tijsterman JD. Prostate cancer detection rates of magnetic resonance imaging-guided prostate biopsy related to Prostate Imaging Reporting and Data System score. World J Urol. 2017 Feb 1;35(2):207–12.

8. Choomark S, Aussavavirojekul P, Woranisarakul V, Srinualnad S. Cancer Detection Rate of MRI Ultrasound Fusion Prostate Biopsy in 1,039 Patients and Number Needed to Biopsy in Targeted Lesion. Siriraj Med J. 2023;75(11):770–7.

9. Zhu K, Qin Z, Xue J, Miao C, Tian Y, Liu S, et al. Comparison of prostate cancer detection rates between magnetic resonance imaging-targeted biopsy and transrectal ultrasound-guided biopsy according to Prostate Imaging Reporting and Data System in patients with PSA ≥4 ng/mL: A systematic review and meta-analysis. Transl Androl Urol. 2019;8(6):741–53.

10. Turkbey B, Rosenkrantz AB, Haider MA, Padhani AR, Villeirs G, Macura KJ, et al. Prostate Imaging Reporting and Data System Version 2.1: 2019 Update of Prostate Imaging

Reporting and Data System Version 2. Vol. 76, European Urology. Elsevier B.V.; 2019. p. 340–51.

11. Weinreb JC, Barentsz JO, Choyke PL, Cornud F, Haider MA, Macura KJ, et al. PI-RADS Prostate Imaging - Reporting and Data System: 2015, Version 2. Eur Urol. 2016 Jan 1;69(1):16–40.

12. Barentsz JO, Richenberg J, Clements R, Choyke P, Verma S, Villeirs G, et al. ESUR prostate MR guidelines 2012. Eur Radiol. 2012 Apr 10;22(4):746–57.

13. Ullrich T, Schimmöller L. Perspective: a critical assessment of PI-RADS 2.1. Abdominal Radiology. 2020 Dec 1;45(12):3961–8.

14. Beyer T, Schlemmer HP, Weber MA, Thierfelder KM. PI-RADS 2.1 - Image Interpretation: The Most Important Updates and Their Clinical Implications. Fortschr Röntgenstr. 2021 Jul 1;193(7):787–95.

15. Sundaram AD. PI-RADS 2.1: A Practical Overview. Journal of Gastrointestinal and Abdominal Radiology. 2024 Sep;07(03):169–82.

16. Ahdoot M, Wilbur AR, Reese SE, Lebastchi AH, Mehralivand S, Gomella PT, et al. MRI-Targeted, Systematic, and Combined Biopsy for Prostate Cancer Diagnosis. New England Journal of Medicine. 2020 Mar 5;382(10):917–28.

17. Noureldin ME, Connor MJ, Boxall N, Miah S, Shah T, Walz J. Current techniques of prostate biopsy: An update from past to present. Vol. 9, Translational Andrology and Urology. AME Publishing Company; 2020. p. 1510–7.

18. Oerther B, Nedelcu A, Engel H, Schmucker C, Schwarzer G, Brugger T, et al. Update on PI-RADS Version 2.1 Diagnostic Performance Benchmarks for Prostate MRI: Systematic Review and Meta-Analysis. 2024 Aug 13;312(2).

19. Wen J, Liu W, Shen X, Hu W. PI-RADS v2.1 and PSAD for the prediction of clinically significant prostate cancer among patients with PSA levels of 4–10 ng/ml. Sci Rep. 2024 Dec 1;14(1).

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