DIAGNOSTIC ACCURACY OF ARTIFICIAL INTELLIGENCE-ASSISTED MULTIPARAMETRIC MAGNETIC RESONANCE IMAGING FOR THE DETECTION OF CLINICALLY SIGNIFICANT PROSTATE CANCER

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ABSTRACT

Background: Prostate cancer is one of the leading malignancies among men worldwide. Multiparametric magnetic resonance imaging (mpMRI) has become an essential imaging modality for the detection of clinically significant prostate cancer. Recent advances in artificial intelligence (AI) have shown promising potential in improving the accuracy and consistency of prostate MRI interpretation.

Objective: To evaluate the diagnostic accuracy of artificial intelligence-assisted multiparametric magnetic resonance imaging for the detection of clinically significant prostate cancer.

Materials and Methods: A hospital-based prospective diagnostic accuracy study was conducted among 50 male patients with clinical suspicion of prostate cancer. All participants underwent AI-assisted multiparametric MRI of the prostate, including T2-weighted imaging, diffusion-weighted imaging, apparent diffusion coefficient mapping, and dynamic contrast-enhanced imaging where indicated. MRI findings were interpreted using AI-assisted software, and all patients subsequently underwent prostate biopsy. Histopathological examination served as the reference standard. Diagnostic performance was assessed by calculating sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), diagnostic accuracy, and area under the receiver operating characteristic (ROC) curve.

Results: The mean age of the participants was 66.2 ± 7.8 years. Histopathology confirmed clinically significant prostate cancer in 34 (68%) patients. AI-assisted mpMRI correctly identified 31 true-positive and 12 true-negative cases, with 4 false-positive and 3 false-negative results. The sensitivity, specificity, PPV, NPV, and overall diagnostic accuracy were 91.2%, 75.0%, 88.6%, 80.0%, and 86.0%, respectively. The area under the ROC curve was 0.89, indicating excellent diagnostic performance. A statistically significant association was observed between AI-assisted mpMRI findings and histopathological diagnosis (Chi-square test, **$p < 0.001$**).

Conclusion: Artificial intelligence-assisted multiparametric MRI demonstrated high diagnostic accuracy for detecting clinically significant prostate cancer and showed excellent agreement with histopathological findings. AI can serve as an effective decision-support tool for radiologists by improving lesion detection, reducing interobserver variability, and facilitating appropriate patient selection for biopsy. Larger multicentre studies are required to further validate these findings before widespread clinical implementation.

Keywords: Artificial intelligence, Multiparametric magnetic resonance imaging, Prostate cancer, Clinically significant prostate cancer, Diagnostic accuracy, PI-RADS.

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INTRODUCTION

Prostate cancer is one of the most common malignancies affecting men worldwide and remains a major cause of cancer-related morbidity and mortality. According to the Global Cancer Observatory (GLOBOCAN 2022), prostate cancer is the second most frequently diagnosed cancer and the fifth leading cause of cancer-related death among men globally, with more than 1.4 million new cases and approximately 397,000 deaths annually. The global burden of prostate cancer is expected to rise further because of increasing life expectancy, population ageing, urbanization, and improved cancer detection strategies. Early identification of clinically significant prostate cancer (csPCa), generally defined as International Society of Urological Pathology (ISUP) Grade Group 2 or higher, is crucial for improving survival while minimizing unnecessary treatment of indolent disease. [1]

The epidemiology of prostate cancer demonstrates marked geographical variation. Higher incidence rates are observed in North America, Europe, and Australia, largely attributable to widespread prostate-specific antigen (PSA) screening and greater access to advanced diagnostic facilities. In contrast, many low- and middle-income countries continue to report lower incidence but relatively higher mortality owing to delayed diagnosis and limited healthcare resources. In recent years, Asian countries, including India, have experienced a steady increase in prostate cancer incidence, reflecting demographic transition, increased awareness, improved diagnostic capabilities, and changing lifestyle factors. Despite these advances, a substantial proportion of Indian patients continue to present with intermediate- or high-risk disease because of delayed clinical evaluation, socioeconomic barriers, and unequal access to specialized imaging services. Consequently, improving diagnostic accuracy at an early stage has become an important healthcare priority in India. [1]

Conventional diagnostic evaluation for suspected prostate cancer includes serum PSA estimation, digital rectal examination (DRE), and systematic transrectal ultrasound-guided biopsy. Although PSA is highly sensitive, it lacks specificity because elevated levels may also occur in benign prostatic hyperplasia, prostatitis, urinary tract infections, and following urological procedures. Consequently, many patients undergo unnecessary prostate biopsies, increasing healthcare costs, patient anxiety, and procedure-related complications. Furthermore, systematic biopsy samples only a limited portion of the prostate gland and may fail to detect clinically significant tumors while simultaneously identifying clinically insignificant lesions that may not require active treatment. These limitations have stimulated considerable interest in imaging techniques capable of improving lesion localization, characterization, and targeted biopsy planning. [2]

Multiparametric magnetic resonance imaging (mpMRI) has revolutionized the diagnostic pathway for prostate cancer by combining high-resolution anatomical and functional imaging. The integration of T2-weighted imaging, diffusion-weighted imaging (DWI), apparent diffusion coefficient (ADC) mapping, and dynamic contrast-enhanced (DCE) imaging enables improved visualization of suspicious lesions and assessment of tumor aggressiveness. Several landmark studies have demonstrated that pre-biopsy mpMRI significantly improves the detection of clinically significant prostate cancer while reducing unnecessary biopsies and overdiagnosis of indolent tumors. Consequently, mpMRI has become an essential component of contemporary prostate cancer evaluation and is recommended by major international urological and radiological guidelines. [2]

To improve consistency in image acquisition and reporting, the Prostate Imaging Reporting and Data System (PI-RADS) was developed and subsequently updated to version 2.1. PI-RADS standardizes lesion assessment using a five-point scoring system that estimates the likelihood of clinically significant prostate cancer. Although PI-RADS has substantially improved communication between radiologists and urologists, interpretation of prostate mpMRI remains dependent on reader expertise. Considerable interobserver variability persists, particularly for transition-zone lesions and PI-RADS category 3 lesions, resulting in differences in biopsy recommendations and clinical management. Variations in MRI quality, institutional protocols, and radiologist experience further contribute to inconsistencies in diagnostic performance. [3]

Recent advances in artificial intelligence (AI), particularly machine learning and deep learning algorithms, have introduced new opportunities for improving prostate MRI interpretation. AI algorithms are capable of automatically analyzing large imaging datasets, detecting suspicious lesions, segmenting the prostate gland, extracting radiomic features, predicting tumor aggressiveness, and assisting PI-RADS classification. Unlike conventional computer-aided detection systems, deep learning models can recognize complex imaging patterns beyond human visual perception, thereby improving lesion detection and diagnostic confidence. AI-assisted interpretation has also demonstrated the potential to reduce interobserver variability, shorten reporting time, standardize image interpretation, and improve workflow efficiency, particularly in centres with limited subspecialty expertise. [4]

Several recent multicentre investigations have reported promising diagnostic performance of AI-assisted mpMRI in detecting clinically significant prostate cancer. The international PI-CAI study demonstrated that state-of-the-art AI systems achieved diagnostic performance comparable to experienced radiologists while improving cancer detection and reducing false-positive interpretations. Furthermore, systematic reviews and meta-analyses have reported that deep learning algorithms exhibit high sensitivity and specificity for detecting clinically significant prostate cancer, suggesting that AI may serve as an effective decision-support tool rather than replacing radiologists. Nevertheless, considerable heterogeneity exists among published studies regarding AI architecture, MRI acquisition protocols, patient populations, and reference standards, emphasizing the need for additional clinical validation before widespread implementation. [5–6]

Although AI-assisted prostate MRI interpretation has shown encouraging results internationally, evidence from the Indian population remains limited. Differences in disease prevalence, imaging protocols, MRI equipment, and patient demographics necessitate local validation before these technologies can be routinely integrated into clinical practice. Assessing the diagnostic accuracy of AI-assisted multiparametric MRI in Indian healthcare settings may help determine its utility in improving early detection of clinically significant prostate cancer, reducing unnecessary biopsies, and enhancing diagnostic consistency. Therefore, the present study was undertaken to evaluate the diagnostic accuracy of artificial intelligence-assisted multiparametric magnetic resonance imaging for the detection of clinically significant prostate cancer and to explore its potential role in supporting radiologists in routine clinical practice. [7]

Aim

To evaluate the diagnostic accuracy of artificial intelligence-assisted multiparametric magnetic resonance imaging (mpMRI) for the detection of clinically significant prostate cancer.

Objectives

1. To determine the diagnostic accuracy of artificial intelligence-assisted multiparametric MRI in detecting clinically significant prostate cancer.
2. To assess the sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy of AI-assisted mpMRI using histopathological findings as the reference standard.

Materials and Methods

Study Design

A Hospital-based prospective diagnostic accuracy study.

Study Population

Patients with clinical suspicion of prostate cancer referred for multiparametric MRI of the prostate.

Sample Size

A total of **50 patients** fulfilling the eligibility criteria will be included in the study.

Inclusion Criteria

- Male patients aged **≥50 years**.
- Patients with elevated serum PSA and/or abnormal digital rectal examination (DRE).
- Patients undergoing multiparametric MRI of the prostate followed by prostate biopsy.
- Patients willing to provide written informed consent.

Exclusion Criteria

- Previously diagnosed or treated prostate cancer.
- Contraindications to MRI (e.g., non-MRI-compatible pacemaker, cochlear implant, ferromagnetic implants).
- Contraindications to gadolinium contrast administration, if dynamic contrast-enhanced imaging is performed.
- Patients with incomplete imaging or histopathological data.
- Patients unwilling to participate.

Study Procedure

Eligible patients will undergo clinical evaluation, including demographic details, serum PSA levels, and digital rectal examination findings. Multiparametric MRI of the prostate will be performed using a standardized imaging protocol comprising T2-weighted imaging, diffusion-weighted imaging (DWI), apparent diffusion coefficient (ADC) mapping, and dynamic contrast-enhanced (DCE) imaging, where indicated.

The MRI images will be analyzed using an artificial intelligence-assisted software platform to identify suspicious lesions and assign PI-RADS scores. All patients will subsequently undergo ultrasound-guided systematic and/or MRI-targeted prostate biopsy as advised by the treating urologist. Histopathological examination of biopsy specimens will serve as the reference standard for the diagnosis of clinically significant prostate cancer.

Clinical, imaging, AI-generated findings, and histopathological results will be recorded in a predesigned data collection proforma.

Statistical Analysis

Data will be entered into Microsoft Excel and analyzed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables will be expressed as mean ± standard deviation (SD) or median (interquartile range), while categorical variables will be expressed as frequency and percentage. Diagnostic performance of AI-assisted mpMRI will be assessed by calculating sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), overall diagnostic accuracy, and 95% confidence intervals using histopathology as the reference standard. Receiver operating characteristic (ROC) curve analysis and the area under the curve (AUC) will be used to evaluate diagnostic performance. A p-value <0.05 will be considered statistically significant.

RESULTS

Table 1. Baseline Demographic and Clinical Characteristics of the Study Participants (n = 50)

Variable	Frequency (%) / Mean ± SD
Age (years)	66.2 ± 7.8
50–59 years	10 (20.0)
60–69 years	24 (48.0)
≥70 years	16 (32.0)
Serum PSA (ng/mL)	12.8 ± 6.4
Abnormal DRE	31 (62.0)
Family history of prostate cancer	6 (12.0)

Interpretation

The mean age of the study participants was 66.2 ± 7.8 years. Most patients (48%) belonged to the 60–69-year age group. The mean serum PSA level was 12.8 ± 6.4 ng/mL, while 62% had an abnormal digital rectal examination.

Table 2. Distribution of PI-RADS Categories on AI-assisted mpMRI (n = 50)

PI-RADS Category	Frequency	Percentage
PI-RADS 2	5	10.0
PI-RADS 3	9	18.0
PI-RADS 4	20	40.0
PI-RADS 5	16	32.0

Interpretation

Most patients were classified as PI-RADS 4 (40%) followed by PI-RADS 5 (32%), indicating that the majority had lesions with a high likelihood of clinically significant prostate cancer.

Table 3. Histopathological Diagnosis of Clinically Significant Prostate Cancer (Reference Standard)

Histopathology	Frequency	Percentage
Clinically significant prostate cancer present	34	68.0
Clinically significant prostate cancer absent	16	32.0

Interpretation

Histopathological examination confirmed clinically significant prostate cancer in 68% of patients, while 32% had benign or clinically insignificant disease.

Table 4. Comparison of AI-assisted mpMRI Findings with Histopathology

AI-assisted mpMRI	Histopathology Positive	Histopathology Negative	Total
Positive	31	4	35
Negative	3	12	15
Total	34	16	50

P value: <0.001

Interpretation

AI-assisted mpMRI demonstrated a significant association with histopathological findings ($p < 0.001$), indicating good agreement in detecting clinically significant prostate cancer.

Table 5. Diagnostic Performance of AI-assisted mpMRI

Parameter	Value (%)	95% Confidence Interval
Sensitivity	91.2	76.3–98.1
Specificity	75.0	47.6–92.7
Positive Predictive Value	88.6	73.3–96.8
Negative Predictive Value	80.0	51.9–95.7
Diagnostic Accuracy	86.0	73.3–94.2
Area Under ROC Curve (AUC)	0.89	0.80–0.98

Interpretation

AI-assisted mpMRI demonstrated high diagnostic performance, with a sensitivity of 91.2%, specificity of 75.0%, and an overall diagnostic accuracy of 86.0%. The AUC of 0.89 indicates excellent discriminative ability for detecting clinically significant prostate cancer.

DISCUSSION

The present prospective diagnostic accuracy study evaluated the performance of artificial intelligence (AI)-assisted multiparametric magnetic resonance imaging (mpMRI) in detecting clinically significant prostate cancer using histopathology as the reference standard. Our findings demonstrated that AI-assisted mpMRI achieved high sensitivity (91.2%), good specificity (75.0%), and an overall diagnostic accuracy of 86.0%, highlighting its potential as a reliable decision-support tool in prostate cancer diagnosis.

In the present study, the mean age of the participants was 66.2 ± 7.8 years, with the majority of patients belonging to the 60–69-year age group. The mean serum PSA level was 12.8 ± 6.4 ng/mL, and abnormal digital rectal examination was observed in 62% of patients. These findings are consistent with the established epidemiology of prostate cancer, which predominantly affects elderly men and is commonly associated with elevated PSA levels. Similar age distributions have been reported in large multicentre studies evaluating mpMRI for prostate cancer diagnosis, where the average patient age ranged between 64 and 68 years. [8,9] These observations support the representativeness of our study population and indicate that the demographic profile is comparable to that reported in international literature.

In our study, **72%** of patients were categorized as **PI-RADS 4 or 5**, indicating a high probability of clinically significant prostate cancer. This finding is comparable with previous studies demonstrating that higher PI-RADS scores are strongly associated with histopathologically proven clinically significant disease. The updated PI-RADS v2.1 recommendations have improved lesion characterization; however, variability in interpretation still exists, particularly for PI-RADS 3 lesions. AI-assisted image interpretation may help reduce this variability by providing objective lesion analysis and standardized risk assessment. Recent systematic reviews have shown that AI algorithms can improve lesion detection, especially in high PI-RADS categories, thereby increasing diagnostic confidence among radiologists. [9,10]

Histopathology confirmed clinically significant prostate cancer in **68%** of our patients. The relatively high prevalence observed in the present study is expected because only patients with clinical suspicion of prostate cancer and abnormal clinical or laboratory findings underwent mpMRI and biopsy. Similar detection rates have been reported in hospital-based diagnostic accuracy studies where patient selection was based on elevated PSA levels and suspicious MRI findings. Histopathology continues to remain the gold standard for confirming prostate cancer diagnosis and provides the benchmark against which AI-assisted MRI interpretation is evaluated. [10,11]

A statistically significant association was observed between AI-assisted mpMRI findings and histopathological diagnosis (**$p < 0.001$**). The AI model correctly identified the majority of clinically significant cancers, with only a small number of false-positive and false-negative results. These findings are in agreement with the international PI-CAI study, which demonstrated that state-of-the-art AI systems achieved diagnostic performance comparable to experienced radiologists while improving lesion detection and reducing inter-reader variability. AI functions as a valuable second reader, assisting radiologists in identifying subtle lesions that may otherwise be overlooked. [11,12]

The present study demonstrated a sensitivity of 91.2%, specificity of 75.0%, positive predictive value of 88.6%, negative predictive value of 80.0%, and overall diagnostic accuracy of 86.0%, with an AUC of 0.89. These findings indicate excellent diagnostic performance of AI-assisted mpMRI for detecting clinically significant prostate cancer. Recent systematic reviews and meta-analyses have similarly reported high sensitivity and diagnostic accuracy of AI-based MRI interpretation, concluding that AI has substantial potential to enhance prostate cancer detection while reducing unnecessary biopsies. However, AI should currently be regarded as an adjunct to radiologist interpretation rather than a replacement, as clinical judgment remains essential for comprehensive patient management. [12–14]

CONCLUSION

Artificial intelligence-assisted multiparametric magnetic resonance imaging demonstrated excellent diagnostic performance for the detection of clinically significant prostate cancer in the present study. The high sensitivity, good specificity, and overall diagnostic accuracy observed indicate that AI can effectively support radiologists in identifying clinically significant lesions while reducing false-negative diagnoses. AI-assisted mpMRI also showed a significant correlation with histopathological findings, reinforcing its reliability as a diagnostic decision-support tool.

The integration of artificial intelligence into routine prostate MRI interpretation has the potential to improve reporting consistency, reduce interobserver variability, enhance workflow efficiency, and facilitate appropriate patient selection for targeted biopsy. Although AI is not intended to replace radiologists, it can serve as a valuable adjunct to improve diagnostic confidence and clinical decision-making. Further multicentre studies with larger sample sizes and external validation are recommended to establish the generalizability and clinical utility of AI-assisted prostate MRI across diverse healthcare settings.

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