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ORIGINAL ARTICLE

Diagnostic Accuracy of MRI in Patients with Elevated PSA Levels in Predicting Prostatic Carcinoma, Keeping Histopathology as Gold Standard

MUHAMMAD MOHSIN KAMAL SHAH[1], MUSHAIB MUHAMMAD KHAN[2], WARDA SATTAR[3], REETA RANI[4], FAREEHA SHAHID[5], ABURABEE AI[6]

[1]*Consultant Radiologist, THQ Kahuta, Rawalpindi*
[2]*Consultant Radiologist, Healthways Medical Diagnostic Centre, Rawalpindi*
[3]*Consultant Radiologist, Radiology Department Jinnah postgraduate Medical center Karachi*
[4] *Assistant Professor, Shaheed Mohtarma Benazir Bhutto Medical College Lyari, Karachi*
[5]*Assistant Professor Pathology, Akhtar Saeed Medical College Campus, Rawalpindi*
[6]*Centre of Medical Imaging, Faculty of Health Sciences, University Teknologi MARA Selangor, Malaysia*
Correspondence to: Aburabee AI, Email: abdalmalek199149@gmail.com

ABSTRACT

Background: Prostate cancer remains one of the most frequently diagnosed malignancies in men, where early detection plays a vital role in improving treatment outcomes. Elevated levels of prostate-specific antigen (PSA) often necessitate additional diagnostic assessments, with magnetic resonance imaging (MRI) emerging as a non-invasive and effective tool for evaluation.

Objective: This study aimed to assess the diagnostic accuracy of MRI in identifying prostate cancer among patients with elevated PSA levels, using histopathology as the gold standard.

Material and Methods: The study was conducted as cross-sectional validation study at the Shaheed Mohtarma Benazir Bhutto Medical College, Lyari, Karachi, during the six month period from January, 2022 to June, 2023. Two hundred and thirty of the patients with PSA levels at >4 ng/mL underwent prostate MRI, and if biopsy proved histopathologically positive, transrectal ultrasound guided biopsy was performed. Statistical analysis was performed in SPSS version 26.0 and key diagnostic measures, including sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were determined.

Results: MRI demonstrated a sensitivity of 92.3% and specificity of 54.1%**,** with a PPV of 80.9% and an NPV of 76.9%**.** The overall diagnostic accuracy was 79.6%**,** and the chi-square test ($p < 0.001$) indicated a significant association between MRI results and histopathology findings.

Conclusion: MRI exhibited high sensitivity and negative predictive value, supporting its utility as a screening tool for prostate cancer detection in patients with elevated PSA levels. However, its moderate specificity highlights the need for histopathological confirmation or the use of advanced imaging modalities to minimize false-positive results**.**

Keywords: Prostate cancer, MRI, PSA levels, Diagnostic accuracy, Histopathology, Sensitivity, Specificity.

INTRODUCTION

Prostatic carcinoma continues to be one of the most frequently encountered malignancies among men, and continues to represent a major health burden. Traditionally, detection and diagnosis of prostate cancer have been based on prostate specific antigen (PSA) testing, and digital rectal examination (DRE). Elevated PSA levels tend to require additional diagnostic work up including imaging and biopsy. Although PSA testing by itself has proven to be limited in specificity and leads to many unnecessary biopsies and potential overtreatment[1]. Therefore, advanced imaging modalities based especially on magnetic resonance imaging (MRI) have become particularly crucial to improve diagnostic accuracy.

Clinically significant prostate cancer detection using multiparametric MRI (mpMRI) has emerged as a powerful tool. This achieves integration of anatomic and functional imaging techniques, such as T2-weighted imaging (T2WI), diffusion-weighted imaging (DWI), and dynamic contrast enhanced (DCE) imaging, which together improve lesion characterization and localisation[2]. Several studies have shown that mpMRI improves cancer detection rates; it reduces the number of unnecessary biopsies; and aids in identifying malignant tumors at high grade[3]. Allam et al found that mpMRI reached a sensitivity of 91.7% and a specificity of 75%, which outperformed of histopathology making it a promising non invasive diagnostic method[4].

The standardized interpretation and reporting of mpMRI findings have been achieved by use of the Prostate Imaging Reporting and Data System (PI-RADS), which in turn has led to more uniform diagnosis. High diagnostic performance of PI-RADS version 2.0 was especially shown for distinguishing clinically significant prostate cancer from benign conditions[5]. More specifically, Gatsev et al. (2024) pointed out that MRI/ultrasound fusion guided biopsies, in combination with PI-RADS scoring, increase the targeting of lesions and the detection of high risk tumors[6].

Diagnostic accuracy of MRI has also been compared to other imaging modalities, including positron emission tomography/computed tomography (PET/CT). Soni et al. (2021) showed that mpMRI had both higher sensitivity (100%) than PET/CT (94.4%) at detecting prostate cancer in patients with PSA ranging from 4 to 20 ng/mL[7]. Ferraro et al. (2021) also showed PET/MRI had a high accuracy at 90% for detecting clinically significant prostate cancer with the added benefit of image fusion of these technologies[8].

With further advancement, prostate cancer diagnosis has been refined by advanced MRI techniques including diffusion weighted imaging (DWI) and magnetic resonance spectroscopy (MRS). Based on the results, Dwl achieved 87.5% accuracy in discriminating the prostate Carcinoma as a Non invasive and useful diagnostic tool[9] as reported by Siddiqui et al. (2021). Combining MRS with bi-parametric MRI, the diagnosis accuracy was improved to 96.8%, indicating that metabolic imaging may be integrated into clinical practice (Hasan et al., 2022)[10].

Although MRI has numerous benefits, there are issues of how to distinguish low and high grade tumors. According to Hoffmann et al (2017), a hybrid imaging method such as PSMA PET/MRI may be more sensitive and specific for detecting high grade lesions[11]. Similarly, Tosun and Uslu (2021) showed that combination of MRI with PSA density enhanced the diagnostic performance, particularly in patients with borderline PSA level[12].

Other studies add support to the role of MRI in prostate cancer detection, establishing it as an acceptable, likely superior alternative to transrectal ultrasound for its correlation with histopathological findings. Diffusion weighted imaging was found by Singla et al., (2023) to provide differentiation between benign and malignant lesions with 90.9% sensitivity and 80% specificity[13].

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These results confirm MRI as a reliable adjunct to more classic biopsy methods.

The diagnosis of prostate cancer has a great deal of morbidity and mortality for men worldwide, and early detection is key to early intervention and better outcomes. Suspicion of prostate cancer is typically triggered by elevated prostate specific antigen PSA, but PSA itself is not specific and leads to unnecessary biopsies and overdiagnosis of indolent cases. Magnetic resonance imaging (MRI) has shown promise as a noninvasive, highly sensitive imaging modality capable of assessing prostate abnormalities, improved lesion characterization, and targeted biopsy guidance. Growing use of MRI has occurred despite variations in its accuracy and the possibility of false positives warranting further validation in other clinical settings. The purpose of this study was to assess the diagnostic utility of MRI for prostate cancer diagnosis in patients with raised PSA using histopathology as the gold standard in order to determine the potential for MRI to enhance diagnostic algorithms and reduce inappropriate interventions.

MATERIAL AND METHODS

This cross-sectional validation study was conducted at the Shaheed Mohtarma Benazir Bhutto Medical College, Lyari, Karachi, during the six month period from January, 2022 to June, 2023. The study protocol was approved by the Institutional Ethical Review Committee, and written informed consent was obtained from all participants prior to enrollment, ensuring voluntary participation and confidentiality. The sample size was calculated using the sensitivity and specificity formula for diagnostic tests. Based on the study conducted by Din M et al., which reported a sensitivity of 92.3%, specificity of 82.7%, and disease prevalence of 76%, the following parameters were used: a 95% confidence level and 10% margin of error [14]. The final sample size required was 230 patients. Male patients aged 40–80 years with elevated PSA levels (>4 ng/mL) and referred for MRI and subsequent prostate biopsy were included. Patients with previously diagnosed prostate cancer, a history of prostate surgery or radiation therapy, contraindications to MRI (e.g., metal implants or pacemakers), or those who refused to give written informed consent were excluded. Patients fulfilling the inclusion criteria were recruited from outpatient clinics. MRI of the prostate was performed, and findings were evaluated using the Prostate Imaging Reporting and Data System (PI-RADS). Each patient subsequently underwent a transrectal ultrasound (TRUS)-guided biopsy. Histopathological analysis of biopsy samples served as the gold standard for comparison. MRI results were classified as positive or negative based on PI-RADS scoring, where scores ≥3 were considered positive. The histopathology results were used to confirm the presence or absence of prostate carcinoma.

The data were analyzed using SPSS version 26.0. Continuous variables, including age, PSA levels, and prostate volume, were expressed as means and standard deviations. Categorical variables, such as MRI results, histopathology findings, family history, and previous biopsy, were summarized as frequencies and percentages. The diagnostic performance of MRI in comparison to histopathology, considered the gold standard, was assessed by calculating sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy. Relationships between categorical variables were evaluated using the chi-square test, while Pearson correlation was applied to explore associations between continuous variables. A p-value of less than 0.05 was regarded as statistically significant.

RESULTS

A total of 230 patients were included in the study. The mean age of the participants was 59.68 ± 12.02 years. The mean PSA level was 12.04 ± 4.58 ng/mL, and the mean prostate volume was 50.23 ± 17.07 mL.

Table 1 presents the crosstabulation between MRI results and histopathology findings. Out of 230 cases, 144 patients were true positives, having both a positive MRI result and positive histopathology findings, while 40 patients were true negatives, with both tests showing negative results. However, 34 patients were false positives, showing positive MRI results but negative histopathology findings, and 12 patients were false negatives, where MRI failed to detect cancer confirmed by histopathology. This distribution highlights the ability of MRI to identify most cancer-positive cases but also indicates a proportion of false positives and false negatives.

Table 2 summarizes the diagnostic accuracy metrics of MRI. The test demonstrated high sensitivity (92.3%), indicating its effectiveness in detecting true positive cases. However, the specificity (54.1%) was moderate, suggesting a higher false positive rate. The positive predictive value (PPV) was 80.9%, meaning that 80.9% of patients with a positive MRI result truly had cancer. The negative predictive value (NPV) was 76.9%, indicating that 76.9% of patients with a negative MRI result were truly cancer-free. The overall diagnostic accuracy was calculated as 79.6%, reflecting the reliability of MRI as a diagnostic tool while emphasizing the need for confirmatory testing, especially in cases with positive MRI findings.

Table 3 reports the results of the chi-square test, showing a statistically significant association ($p < 0.001$) between MRI findings and histopathology results. This strong association supports the validity of MRI in detecting prostate cancer. The Pearson chi-square value (61.657), along with the continuity correction (59.036) and likelihood ratio (59.162), all confirm the statistical significance of this relationship. These findings suggest that MRI results are closely related to actual histopathology outcomes and are unlikely to be due to chance.

Table 4 presents the risk estimates. The odds ratio (14.118) indicates that patients with a positive MRI result are approximately 14 times more likely to have prostate cancer compared to those with a negative MRI result. For patients with positive histopathology findings, the relative risk was 3.506, suggesting a 3.5 times higher likelihood of being identified as positive by MRI. Conversely, for negative histopathology results, the relative risk (0.248) indicates a low likelihood of misclassification. The confidence intervals for these estimates do not cross 1, reflecting statistical precision and reinforcing the reliability of the findings.

In summary, the results demonstrate that MRI has excellent sensitivity and performs well as a screening tool for prostate cancer. However, its moderate specificity suggests a tendency for false positives, emphasizing the need for histopathological confirmation before proceeding with definitive management. The statistically significant association between MRI and histopathology results, along with risk estimates, highlights the clinical utility of MRI in diagnosing prostate cancer, particularly as an initial screening tool in patients with elevated PSA levels.

The correlation analysis assessed the relationships between PSA levels, prostate volume, and PI-RADS scores to evaluate their interdependence in predicting prostate cancer. The results revealed a weak positive correlation ($r = 0.085$, $p = 0.202$) between PSA levels and prostate volume, which was not statistically significant. This indicates that PSA levels do not necessarily increase with prostate size, suggesting that an elevated PSA may reflect pathological changes rather than just gland enlargement.

Similarly, the correlation between PSA levels and PI-RADS scores showed a weak negative relationship ($r = -0.095$, $p = 0.151$), which was also not statistically significant. This implies that higher PSA levels are not directly associated with higher PI-RADS scores on MRI. This finding reinforces the need for imaging techniques like MRI to complement PSA screening, as elevated PSA alone may not reliably predict cancer suspicion.

The relationship between prostate volume and PI-RADS scores demonstrated a very weak positive correlation ($r = 0.037$, $p = 0.574$), which was not significant. This suggests that prostate size has little influence on MRI findings, further highlighting the

ability of MRI to detect suspicious lesions independent of gland size.

Overall, these results emphasize the independent diagnostic value of MRI as a screening tool for prostate cancer, particularly in patients with elevated PSA levels or normal prostate volumes. The lack of significant correlations underscores the need for multimodal assessment, combining PSA testing, MRI evaluations, and histopathology, to improve diagnostic accuracy and reduce unnecessary biopsies. (Table 5)

Table 1: Crosstabulation of MRI Result vs. Histopathology Result

MRI Result	Histopathology Positive	Histopathology Negative	Total
Positive	144	34	178
Negative	12	40	52
Total	156	74	230

Table 2: Diagnostic Accuracy Metrics

Metric	Value (%)
Sensitivity	92.3
Specificity	54.1
Positive Predictive Value (PPV)	80.9
Negative Predictive Value (NPV)	76.9
Overall Accuracy	79.6

Table 3: Chi-Square Test Results

Test	Value	df	p-value
Pearson Chi-Square	61.657	1	0.000
Continuity Correction	59.036	1	0.000
Likelihood Ratio	59.162	1	0.000

Table 4: Risk Estimates

Risk Estimate	Value	95% Confidence Interval
Odds Ratio (Positive/Negative MRI Result)	14.118	6.699–29.754
For Histopathology Positive Cohort	3.506	2.123–5.788
For Histopathology Negative Cohort	0.248	0.177–0.348

Table 5: Correlation Analysis Between PSA Level, Prostate Volume, and PI-RADS Score

Variables	PSA Level (ng/mL)	Prostate Volume (mL)	PI-RADS Score
PSA Level (ng/mL)	1.00	0.085	-0.095
p-value (2-tailed)	-	0.202	0.151
Prostate Volume (mL)	0.085	1.00	0.037
p-value (2-tailed)	0.202	-	0.574
PI-RADS Score	-0.095	0.037	1.00
p-value (2-tailed)	0.151	0.574	-

DISCUSSION

Magnetic resonance imaging (MRI) has become an important means of differential diagnosis of prostate cancer in patients with an elevated prostate specific antigen (PSA). This study's results indicated that MRI is sensitive to prostate cancer (92.3%), but only moderately specific to prostate cancer (54.1%), and has a positive predictive value (PPV) of 80.9% and negative predictive value (NPV) of 76.9%. These results are consistent with published studies comparing MRI performance in the diagnosis of prostate cancer.

Din et al. [14] studied the diagnostic accuracy of MRI for raised PSA using histopathology gold standard. They found specificity of 82.7%, 92.3% sensitivity, and 90% diagnostic accuracy. In terms of sensitivity, our study correlates findings with these other studies, demonstrating the reliability of MRI as a sensitive tool for identifying prostate cancer. And our study also showed a lower specificity, that is, a greater number of false positives. This discrepancy may be difference in patient selection or imaging protocols.

The role of bi para metric MRI (bpMRI) in concordance with ultrasound guided biopsy technique to detect clinically significant prostate cancer (csPCA) was investigated by Noh et al. [15]. By showing that MRI was highly effective at detecting clinically relevant cancers but could reduce the number of unnecessary biopsies, they reported a sensitivity of 95.1% and an NPV of 89.6%. As such, our study also supports the high sensitivity and NPV of MRI, with its use in reducing unnecessary interventions.

As such, Cereser et al. [16] highlighted the usefulness of MRI in diagnosing, objectively and visually, clinically significant prostate cancer at the primary time (as opposed to the secondary time). They showed that MRI has a high sensitivity and NPV approximately 90% so no unnecessary biopsies in case of negative MRI. In our study, we demonstrated slightly lower NPV (76.9%) that may be due to difference in the imaging techniques, sample size or the demographics of the patients. Lastly, they discuss integrating Prostate-Specific Membrane Antigen (PSMA)-PET as a complementary test where its discussion of potential uses in indeterminate cases offers avenues to improve diagnostic accuracy.

A meta-analysis by Zhen et al. [17] supported the diagnostic value of multi-parametric MRI (mpMRI) in prostate cancer detection. Their pooled sensitivity and specificity were 87% and 68%, respectively, which align closely with the results of our study. The study emphasized the strength of mpMRI in identifying prostate cancer with higher sensitivity but acknowledged variability in specificity, reflecting similar challenges observed in our data.

Guo et al. [18] conducted a systematic review on MRI performance in patients with PSA levels between 4–10 ng/mL. They reported pooled sensitivity and specificity of 84% and 76%, respectively, for clinically significant prostate cancer. The excellent NPV (91%) supported the use of MRI as a triaging tool to guide biopsy decisions. Our findings similarly highlight MRI's potential as a reliable screening tool, particularly for patients in the PSA gray zone, despite differences in specificity values.

Merriel et al. [19] reviewed PSA's diagnostic accuracy and highlighted its high sensitivity (93%) but poor specificity (20%) for detecting prostate cancer in symptomatic patients. This aligns with our findings, as MRI demonstrated higher specificity compared to PSA, reinforcing its role as a complementary tool to PSA testing to reduce false positives and unnecessary biopsies.

Finally, Gul et al. [20] evaluated magnetic resonance spectroscopy (MRS) in prostate cancer detection. They reported sensitivity of 78.8%, specificity of 85.4%, and diagnostic accuracy of 81.2%. While MRS demonstrated good diagnostic performance, combining it with MRI was suggested to enhance cancer detection, especially in patients with equivocal findings. This supports the idea of integrating metabolic data with conventional imaging to refine diagnostic outcomes.

In summary, our findings reinforce the role of MRI as a highly sensitive diagnostic tool for prostate cancer, particularly in patients with elevated PSA levels. However, its moderate specificity necessitates careful interpretation to minimize false positives. Combining MRI with targeted biopsy techniques, newer modalities like PSMA-PET, or advanced spectroscopy approaches may further improve diagnostic performance and patient outcomes.

CONCLUSION

This study demonstrates that MRI is a highly sensitive diagnostic tool (92.3%) for detecting prostate cancer in patients with elevated PSA levels, although its moderate specificity (54.1%) highlights the potential for false positives. The findings align with previous studies, reinforcing MRI's role as a reliable screening method with a high negative predictive value (76.9%), effectively ruling out clinically significant cancer in most negative cases. However, the moderate specificity suggests that MRI should be complemented with targeted biopsy techniques or advanced imaging modalities such as PSMA-PET to improve diagnostic precision and reduce unnecessary interventions. Overall, MRI proves valuable as a non-invasive, accurate, and complementary tool to histopathology in

prostate cancer detection, supporting its integration into diagnostic workflows for patients with elevated PSA levels.

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