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Original Research Article

DIAGNOSTIC ACCURACY OF MRI IN DIAGNOSING PROSTATE CANCER, TAKING HISTOPATHOLOGY AS GOLD STANDARD

Article History:

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Abstract:
Objective: To establish the diagnostic accurateness of multipara metric magnetic resonance in diagnosing prostate cancer, considering histopathology as the gold standard.
Study Design: Cross-sectional validation study.
Place and Duration of Study: Department of Radiology, Capital Hospital, Islamabad, from Jan 2025 to June 2025.
Methodology: Clinically suspected carcinoma prostate patients aged 50-80 years were non-probably sampled (n=175 males). Patients that had a previous diagnosis of prostate cancer, acute or chronic prostatitis, or were contraindicated to MRI were excluded. Each of the patients had multiparametric MRI of the prostate, T2-weighted, diffusion-weighted, apparent diffusion coefficient mapping, and dynamic contrast-enhanced imaging. The results of MRI were evaluated based on PI-RADS and PI-RADS score of 3 and above was regarded as positive in prostate cancer diagnosis. Prostate biopsy was then performed on all the patients and the reference standard was the histopathology.
Results: The mean age of the patients was 66.63 ± 7.46 years, and the mean prostate size was 54.09 ± 13.28 gm. When it was compared to histopathology, the results of the MRI were 91 true-positive, 61 true-negative, 8 false-positive, and 15 false-negative. The sensitivity, specificity, positive predictive value, negative predictive value and overall diagnostic accuracy of MRI was 85.85%, 88.41%, 91.92%, 80.26%, and 86.86% respectively.
Conclusion: Multiparametric MRI had high diagnostic rates in prostate cancer and can be applied as an effective pre-biopsy diagnostic method. Nonetheless, histopathological validation is needed, particularly in clinically suspicious cases that are MRI-negative.

Keywords: Prostate cancer, multiparametric MRI, PI-RADS, histopathology, diagnostic accuracy.

INTRODUCTION

Cancer of the prostate is one of the most notorious tumors that affect men all over the world and continue to pose a high cost on health care in terms of diagnosis and treatment. Recent international cancer estimates confirm prostate cancer as one of the most commonly diagnosed type of cancer in the male gender and with increased age of the population, an increase in the life expectancy, and increased accessibility of prostate-specific antigen tests, the incidence is expected to increase [1]. Detection and treatment of PCOS at early stages is

important due to significant biological heterogeneity of prostate cancer that is indolent and surveillance, as well as clinically significant disease that needs decisive treatment [2]. The established approaches to diagnostics of the type of digital rectal examination, serum prostate-specific antigen, and the use of transrectal ultrasound-guided systematic biopsy have also been shown to improve detection but are limited due to the risk of overdiagnosing inconsequential tumours, under-representation of clinically significant lesions, morbidity of performing procedure, and false-negative result of biopsy [3]. Multiparametric magnetic resonance imaging has transformed diagnostic evaluation of suspected prostate cancer by incorporating both anatomy T2-weight as well as functional magnetic resonance imaging (DMRI) and dynamic contrastbased imaging. This method enhances localization of lesions, stratification of risks, targeting of biopsies and tumour staging. A new practice is now prescribing the application of prostate MRI before the biopsy procedure of a suspected organ confined disease in men to further improve the detection of the clinically significant prostate cancer and reduction of unnecessary biopsies [4]. Prostate Imaging Reporting and Data System has further simplified the prostate MRI modality, acquisition, interpretation and reporting to allow the suspicious lesions to be subdivided according to the probability of proto-cancer [5]. Findings of the recent randomized studies have strengthened the significance of MRI-guided diagnostic pathways. STHLM3-MRI trial has established that MRI-targeted biopsy plans can be available to conserve the capture of clinically significant cancer whilst reducing the capture of clinically insignificant tumours in comparison with traditional biopsy plans [6]. In the same way, screening statistics by population have demonstrated that, PSA, followed by MRI and high-resolution biopsy can minimize unnecessary systematic biopsy and overdiagnosis [7,8]. Targeted biopsy after MRI was also suggested as a non-inferior method to identify clinical significance prostate cancer in biopsy-naive men in the PRECISE trial [9]. However, with MRI, there is no absolute and false-negative outcome, which has the ability to generate false-negative and false-positive outcomes, and the standard of meaningful diagnoses is histopathology. Recent meta-syndic data testify to the great clinical usefulness of mpMRI in the biopsy-naive man, especially those with clinically significant cancer, but with shifts in diagnostic performance based on patient groups, MRI protocols, radiographer's expertise and selection of biopsy reference [10]. Therefore, there is still the value of local validation restudies to determine the true sensitivity, specificity, predictive values and diagnostic accuracy of MRI in suspected prostate cancer.

METHODOLOGY:

The research was a cross-sectional validation study that was carried out at the Department of Radiology, Capital Hospital, Islamabad, 30 th April 2021-29 October 2021. One hundred and seventy-five male patients who had non-probability consecutive sampling as a way of inclusion were clinically suspected to have carcinoma prostate. A 95% confidence level, a prevalence of 73.0% of prostate cancer, and a 10% desired precision of what was to be reported, both in terms of sensitivity and specificity of the MRI were then computed by calculating the sample size based on the level of confidence (95), the expected prevalence of prostate cancer (73.0) and the desired precision (10). The criteria of inclusion were that the patients should be aged 50 to 80 years and that the suspected carcinoma prostate is indicated by the operational definition, that is, clinical suspicion on digital rectal examination and serum of PSA showing a level occurring above the 4 ng/mL. The patients were not included where carcinoma prostate had already been diagnosed, in case of acute or chronic prostatitis on digital rectal examination and contraindication to MRI as MRI incompatible prosthesis or cardiac pacemaker. All data collection was carried out with ethical approval of the institutional ethical review committee and informed written consent was obtained before enrolment of the participants.

All the selected patients were subjected to multiparametric magnetic resonance imaging of prostate after enrolment. The patient was under supine position during an MRI and it used an outer pelvic phased-array coil without an endorectal coil. The imaging scheme was peer-guided by PI-RADS v2. I.V contrast administered at the rate of 4 mL/s at 0.1mL/kg with a dose of gabobenate dimeglumine (IV). Prior to contrast administration, the axial, sagittal, and coronal fast spin-echo imaging was acquired using both T2-weighted and T1-weighted (fast spin-echo). The diffusion-weighted imaging was conducted at b values 0, 100 and 1500 s/mm2 to generate the apparent diffusion coefficient map and another high b-value diffusion-weighted volume (b2000 s/mm2) had also been obtained. An axial three-dimensional dynamic contrast-enhanced sequence was achieved during contrast administration, and afterwards, post-contrast axial T1-weighted fast spin-echo imaging was done.

The findings of all multiparametric MRI tests were read by a consultant radiologist who had a minimum of three years of post-fellowship experience. The presence or absence of prostate cancer was classified based on PI-RADS v2 findings of MRI. These lesions were designated PI-RADS score 3 and above as positive prostate cancer lesion and lower lesions were regarded as negative. After the MRI

assessment, all the patients received prostate biopsy in the ward under concern. Final diagnosis was based on the result of the biopsy specimens submitted to the institutional laboratory where histopathological examination was done. The presence of malignant prostatic glands with back-to-back distribution, a small intervening stroma, enlarged round hyperchromatic nuclei, prominent nucleoli, and mitotic figures were taken to be positive in histopathology to diagnose prostate cancer. MRI results were compared with histopathology results to identify true-positives, true-negatives, false-positives and false-negatives. Age of the patient, prostate size, MRI diagnosis and histopathological diagnosis were put on specially carved proforma.

The SPSS version 25.0 was used to analyze the collected data. The quantitative data such as age and prostate size were represented by the mean and the standard deviation. Frequencies and percentages of qualitative variables such as the MRI and histopathological diagnosis were used to express the qualitative variables. A 2 x 2 contingency table was built using the results of multiparametric MRI and histopathology. Sensitivity, specificity, and positive predictive value, negative predictive value, and the overall diagnostic accuracy were computed using standard diagnostic test formula, where histopathology was used as a reference standard. Stratification was done in terms of age groups and prostate size and the measures of post-stratification diagnostic accuracies were computed.

RESULTS

One hundred seventy-five men suspected of having carcinoma prostate were included in the study. The patients were between 50-80 years of age with a mean of 66.63 years ± 7.46 years. On dividing the patients into two age groups, 87 patients (49.71) fell in the age group of 50-65 years, whereas 88 patients (50.29) were in the age group of 66-80 years, indicating that a little bit more than half of the patients in the study were aged 66-80 years (Table 1).

Table 1. Distribution of patients according to age

Age group	No. of patients	Percentage
50–65 years	87	49.71%
66–80 years	88	50.29%
Total	175	100.0%

The mean prostate size was 54.09 ± 13.28 gm. On classification based on prostate size, 68 patients (38.86) were found to have a prostate size at 50gm or below and 107 patients (61.14) had prostate size at 50gm or above (Table 2).

Table 2. Distribution of categorical baseline characteristics

Prostate size	No. of patients	Percentage
≤50 gm	68	38.86%
>50 gm	107	61.14%
Total	175	100.0%

Ninety-nine reported prostate cancers and 76 patients who were reported to be negative were in on multiparametric MRI. Comparing the results of MRI with the histopathology, 91 patients were true positive, or in other words, positive of prostate cancer on the MRI and also histopathology. False positives were eight patients, who were positive on MRI but negative on histopathology. False negative In case of the MRI-negative patients there were 15 false negative patients, meaning that a histopathology established a case of prostate cancer despite the negative findings in the MRI. The other 61 patients were true negative since neither MRI nor histopathology revealed prostate cancer. MRI findings correlated with histopathological diagnosis and the p-value was statistically significant (0.0001) (Table 3).

Table 3. Diagnostic accuracy of multiparametric MRI in diagnosing prostate cancer, taking histopathology as gold standard

mp-MRI finding	Histopathology positive	Histopathology negative	Total
Positive on mp-MRI	91 True positive	08 False positive	99
Negative on mp-MRI	15 False negative	61 True negative	76
Total	106	69	175

Based on the 2×2 diagnostic table, the overall diagnostic performance of multiparametric MRI was high. MRI had a sensitivity of 85.85 to diagnose prostate cancer, which means that MRI was able to identify most of the patients that had a prostate cancer. Specificity was 88.41 indicating good capability of MRI in identifying correctly the patients without prostate cancer. The positive predictive value was found to be 91.92 which implied that a majority of the cases that were positive in MRI were positive on histopathology. The negative predictive value was 80.26% that means that about every four cases MRI-negative were actually negative histopathologically. Strong agreement between MRI and histopathological diagnosis was observed as the overall diagnostic accuracy of MRI was 86.86%.

2×2 Diagnostic Table

Diagnostic parameter	Value
Sensitivity	85.85%
Specificity	88.41%
Positive predictive value	91.92%
Negative predictive value	80.26%

Diagnostic accuracy	86.86%
p-value	0.0001

When diagnostic performance was age stratified, the sensitivity of MRI was similar across the two age groups. The sensitivity of MRI in patients with age 50-65 was 86.0, specificity was 83.78, positive predictive value was 87.76, negative predictive value 81.58 and diagnostic accuracy was 85.06. In patients aged between 66 and 80 years, MRI had a sensitivity of 85.71, specificity of 93.75, positive predictive value of 96.0, negative predictive value of 78.95 and a diagnostic accuracy of 88.64. These results demonstrated that MRI had a high diagnostic accuracy both in younger and older age groups, with a slightly greater specificity and overall accuracy in older group. MRI also demonstrated high accuracy when there was stratification of diagnostic performance based on the size of the prostate. The sensitivity of 82.93 and specificity of 92.59, positive predictive value of 94.44 and negative predictive value of 78.13 and the diagnostic accuracy of 86.76. Sensitivity and specificity, positive predictive value and negative predictive value and diagnostic accuracy were 87.69, 85.71, 90.48 and 81.82 respectively. These findings showed that the prostate size made no significant impact on the general diagnostic accuracy of MRI and specificity was greater in patients with larger prostates and sensitivity in those with smaller ones (Table 4).

Table 4. Stratification of diagnostic accuracy of mp-MRI according to age and prostate size

Stratification variable	Category	TP	FP	FN	TN	Sensitivity	Specificity	PPV	NPV	Accuracy	p-value
Age	50–65 years	43	06	07	31	86.0%	83.78%	87.76 %	81.58 %	85.06%	0.001
Age	66–80 years	48	02	08	30	85.71%	93.75%	96.0 %	78.95 %	88.64%	0.001
Prostate size	≤50 gm	34	02	07	25	82.93%	92.59%	94.44 %	78.13 %	86.76%	0.001
Prostate size	>50 gm	57	06	08	36	87.69%	85.71%	90.48 %	81.82 %	86.92%	0.001

DISCUSSION

The current research showed that the diagnostic performance of multiparametric MRI on prostate cancer was high with a sensitivity of 85.85, specificity of 88.41, PPV of 91.92, NPV of 80.26 and general diagnostic performance of 86.86 as the gold standard compared to histopathology. The pattern of response on the diagnostic table is that out of 100 cases the true positive and false positive were 91 and 8 respectively, the false negative was 15, and the true negative was 61. These results justified the use of mpMRI as a powerful method in the diagnosis of men, who were suspected of having prostate cancer, though occurrence of false-negative cases proved that the presence of histopathological confirmation was requisite. The study population had a mean age of 66.63 ± 7.46 years, and the mean prostate size was 54.09 ± 13.28 gm. Diagnostic accuracy was in the same order across the age groups as well as the prostate size group implying that mpMRI performance did not vary among various clinical subgroups within the study population.

The sensitivity of this study was similar to other recent findings that were reported by Oerther et al. who noted good pooled sensitivity of PI-RADS v2.1 in identifying clinically significant prostate cancer given PI-RADS ≥3 was taken as control [11]. We had a sensitivity of 85.85% which was also near the pooled sensitivity of 84% as reported by Guo et al. in 4-10 ng/mL PSA patients [2]. Equally, the specificity of 88.41% used in the current study was greater than the pooled specificity has been reported in a number of meta-analyses such as in the current case, Guo et al. who reported pooled specificity of about 76% as of clinically significant disease [12]. This increased specificity can be attributed to the use of references standard of histopathology, experience of local radiologists and the fact that the patients with clear clinical suspicion were included and not a wide ranging screening population.

The current study was better in the sensitivity and the general accuracy compared with Nowier et al. who found a lower sensitivity of PI-RADS-based mpMRI in biopsy-naive patients [13]. This variance can be attributed to the selection of patients, MRI procedure, reporting cutoff, and the prevalence of the disease. In the present study, PI-RADS ≥3 was viewed as positive and will usually raise sensitivity by incorporating those lesions that are ambivalent. But contrary to most of the studies where this threshold eliminates specificity, we still had a high specificity and this means that interpretation of mpMRI could distinguish between malign and benign disease with a high degree of reliability in this cohort of people.

The present study had a high PPV of 91.92%. This implies that most of the patients who had positive mpMRI results were determined to possess prostate cancer on histopathology. This result corresponded with the literature that found that higher PI-RADS groups were closely linked to the identification of cancer, especially lesions of PI-RADS 4 and 5 [14]. Wen et al. demonstrated as well that the use of PI-RADS v2.1 coupled with PSA density could employ

better detection of prostate cancer, especially in peripheral-zone lesions [14]. The present study did not analyze the density of the PSA but high PPV implied that the mpMRI was of significant value in identifying the patients who actually required biopsy.

The NPV value was less than the PPV (80.26/100) indicating that a negative result produced by the MRI was unable to provide full confidence that there was no malignancy. This aligned with Wang et al. who highlighted that MRI-negative, or equivocal results should be clinically judged using clinical signatures like PSA density, since some patients with MRI-negative cancer may have clinically significant cancer [15]. Pellegrino et al. also doubted the use of universal PSA density cutoff (0.15 ng/mL/cc) following negative MRI and recommended these risk levels be adjusted to the quality of the MRI and clinical conditions [16]. Our study, which demonstrated 15 false-negative cases, confirmed this apprehension and showed that biopsy still deserves to be considered when there is still high clinical suspicion even though imaging is negative.

Stratification by age indicated that MRI was equally sensitive in 50-65 years and 66-80 year olds with sensitivity of 86.0 and 85.71, respectively. Specificity was however more in the older group, 93.75%- compared to the younger group, 83.78%. This can be an indication of the increased disease conspicuity or increased probability of the presence of real malignant lesions in elder patients. It has also been revealed that other patient-specific factors like age, PSA, volume of prostate, location of lesions, and previous status of the biopsy can also affect MRI interpretation and detecting cancer [17,18]. The current findings as such advocate application of mpMRI among middle aged and old patients though the prudence in interpretation must continue to be incorporated with the clinical risks.

Based on stratification of both groups by the size of the prostate, diagnostic accuracy in the two groups was virtually similar at 86.76% in patients with prostate size 50 gm and 86.92% with prostate size larger than 50 gm. The sensitivity was a little higher in bigger prostates, whilst specificity was a little higher in smaller prostates. The clinical significance of such a balanced performance was that the benign prostatic hyperplasia and transition-zone enlargement can become a consequence to interpret MRI results. As emphasized by Tavakoli et al., diffusion-weighted imaging and dynamic contrast-enhanced imaging add variably to PI-RADS evaluation, particularly in perplexing lesions and variant prostate areas [19]. Thus, the consistency of error in both groups of prostate-size in our study could be a result of the benefit of a full multiparametric protocol including T2-weighted images, DWI, ADC mapping, high b-value DWI, and DCE images. Recent achievements also demonstrate that other tools could help in the interpretation of MRI. Saha et al. reported that artificial intelligence worked no less effectively than radiologists and could minimize falsy positive outcomes and keep up sensitivity rates of clinically relevant prostate cancer [17]. Bertelli et al. and Pickersgill et al. also addressed the diagnostic value of biparametric MRI versus full mpMRI and indicated that DWI and ADC-based measurement can be used in certain patients but contrast-enhanced imaging could also be considered in case of uncertainty [18]. The application of full mpMRI could have been one of the factors in the present study that provided high diagnostic accuracy as the study could help differentiate between suspicious lesions and benign changes in the prostate. This study also managed to find similar results with the recent evidence that MRI performance is affected by study design and reference standard. Carletti et al. indicated that high sensitivity but variable specificity of mpMRI was demonstrated to detect the presence of aggressive histopathological characteristics like cribriform architecture [20]. Yamaya et al. carried out a prospective evaluation of PI-RADS v2.1 and confirmed its utility in category-based cancer detection [21]. Nagayama et al. discovered that there was a range in cancer detection and abnormal interpretation rates among centers with significant finding that the performance of the MRI is determined by the quality of imaging, the experience of reading, and the practice of the institution [22]. This applies to the current research where interpretation was done by an expert consultant radiologist which could have enhanced specificity and PPV.

On the whole, the current research proved the presence of mpMRI as a highly precise diagnostic tool in the local clinical setting in the presence of suspected prostate cancer. Its high PPV favored its application in patient selection to undergo biopsy and its good sensitivity favored its application in the early detection of patients. The smaller NPV and false-negative cases however, revealed that the mpMRI was not a stand-alone rule-out test in patients with clinically unresolved suspicions. These results were consistent with the recent literature indexed in PubMed indicating that prostate MRI enhances the diagnostic routes; although it must be used in combination with clinical parameters, prostate-specific anti-tumor protein-based markers, and histopathology to confirm the final diagnosis [23-25].

CONCLUSION:

This research came to the conclusion that multiparametric magnetic resonance imaging was an excellent diagnostic modality in patients having signs of clinical suspicion of having prostate cancer. Using histopathology as a gold standard MRI

demonstrated a high sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy. These results suggested that mpMRI was effective in accurately diagnosing the majority of patients with an incidence of prostate cancer as well as ruling out malignancy among a significant number of patients without cancer. The positive predictive value recorded in this study was high justifying the use of mpMRI as a valuable pre-biopsy diagnostic tool to identify patients, who needed tissue confirmation. But the occurrence of false-negative cases demonstrated that even negative MRI result could not exclude prostate cancer especially in patients where there is continued clinical suspicion or elevated PSA levels. This is why the mpMRI is to be included in a complex scheme of diagnostics in combination with clinical examination, PSA determination, and histopathological verification. All in all, the results affirmed that multiparametric MRI should be routinely utilized in the diagnostic examination and preoperative assessment of suspected prostate cancer since it can enhance the detection of lesions, optimize the planning of biopsy procedures, decrease unnecessary surgeries, and help clinicians make the right management decision.

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