Original Article

Overall detection rate of prostate cancer using MRI/US fusion-guided prostate biopsy in Rajavithi Hospital

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Abstract

Objective: To study the detection rate of prostate cancer by using targeted MRI/US guided prostate biopsy in Rajavithi Hospital.

Materials and Methods: Patients with elevated PSA levels or abnormal digital rectal examinations who underwent prostate MRI with abnormal lesions (PIRADS ≥ 3) from January 2021 to October 2023 were enrolled onto the study. Patients underwent targeted MRI/US-guided biopsy, followed by a 12-core systematic transrectal ultrasound (TRUS) biopsy. The primary outcome was the overall detection rate of prostate cancer using MRI/US fusion-guided prostate biopsy. Secondary outcomes were the detection rate of prostate cancer in each PIRADS, detection of clinically significant prostate cancer in MRI/US-guided biopsy and complications.

Results: Patients 203 fulfilled the entry criteria and underwent both targeted MRI/US-guided biopsy and TRUS biopsy. The overall detection rate of prostate cancer from targeted MRI/US-guided biopsy was 32.50% which was significantly higher than detection by TRUS biopsy (25.60%, $p < 0.05$). In a subgroup analysis of each of PIRADS 3, 4 and 5, the detection rate was 8.8%, 40.50%, and 50.50%, respectively. MRI/US guided biopsy can more accurately detect clinically significant prostate cancer than TRUS biopsy (75.80% and 69.20%, respectively, OR1.39.95%CI 0.62-3.14, $p = 0.54$) with lower rates of insignificant prostate cancer (24.20% and 30.80%). However, the results did not reach statistical significance. The detection rate of prostate cancer when combining MRI/US fusion guided and TRUS biopsy was more successful than TRUS biopsy alone (38.90% vs. 25.60%, $p < 0.05$) or targeted MRI/US guide biopsy alone (38.90% vs. 32.50% $p < 0.05$). Complications included gross hematuria, fever, urinary retention and hematoma.

Conclusion: Targeted MRI/US-guided biopsy resulted in a higher detection rate of prostate cancer than systematic TRUS biopsy.

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Introduction

Cancer is the leading cause of death globally, and prostate cancer ranks as the second most common type of cancer in men. The mortality rate of prostate cancer can be significantly reduced by screening programs and early detection. The screening program[1] includes the use of prostate-specific antigen (PSA) tests and digital rectal examinations (DRE). While the current gold standard diagnostic procedure for patients suspected of prostate cancer is transrectal ultrasound (TRUS)-guided biopsy, which involves randomly sampling tissue from the entire prostate gland, multiparametric magnetic resonance imaging (mpMRI) of the prostate is now strongly recommended, if available, to improve the screening protocol and potentially reduce the number of men requiring prostate biopsies. Furthermore, in diagnosing prostate cancer, several studies advocate that multiparametric MRI-targeted biopsy can enhance the detection rate of clinically significant cancers and reduce the diagnosis of clinically insignificant prostate cancer. The aim of this study was to evaluate the detection rate of prostate cancer using targeted MRI/US-guided biopsy at Rajavithi Hospital.

Materials and Methods

Study design

This study is a retrospective observational study and was approved by the Ethics Committee of Rajavithi Hospital. Data were collected from the medical records of patients who met the inclusion criteria at Rajavithi Hospital between January 2021 and October 2023.

Adult men with elevated PSA levels or abnormal DRE who underwent prostate MRI and had abnormal lesions identified in the MRI prostate, and who consented to undergo a prostate biopsy, were eligible for enrollment onto the study. Exclusion criteria included the abnormal lesion with a PIRADS score of 2 or less and incomplete medical records.

Data collection included patient demographics, preoperative PSA levels, MRI findings, indications for biopsy, pathological reports, length of stay, and postoperative complications during admission.

Imaging

All patients underwent MRI of the prostate with T2-weighted, contrast-enhanced, and diffusion-weighted series, which were reviewed and targeted for lesions by one of two radiologists. MRI lesions were reported using the Prostate Imaging Reporting and Data System (PIRADS) score version 2.1[2] and were contoured using Symphony Dx-Lite software. Patients with a PI-RADS score of 3 or higher were scheduled for a prostate biopsy.

Prostate biopsy protocol

All patients due for pre-operative protocol were admitted to hospital 24 hours before surgery and received prophylactic antibiotics 30 minutes before surgery. Prostate MRI imaging with lesion contouring was integrated into the ultrasound (BK5000, BK medical).

During the biopsy procedure, either a urologist or a urology resident performed the procedure under general anesthesia. The prostate gland was identified using an ultrasound probe, employing a biplane transducer for transperineal biopsy and a triplane transducer for transrectal biopsy, guided by software provided by BK fusion. Biopsies were conducted using an 18-gauge biopsy gun. All patients underwent 12-core systematic TRUS biopsy followed by targeted MRI/US-guided biopsy.

For the postoperative protocol, all patients remained admitted to hospital for at least 24 hours for observation of any postoperative complications and were prescribed oral antibiotics for five days. Biopsy pathological results were reported by a pathologist.

Outcome

The primary outcome was the overall detection rate of prostate cancer using targeted MRI/US-guided biopsy. The secondary outcomes included the detection of prostate cancer in each PIRADS category, the detection of clinically significant prostate cancer in MRI/US-guided biopsy compared to TRUS-guided biopsy of the prostate, and complications.

Insignificant or very low-risk prostate cancer was as defined by Epstein and colleagues[3-5] as clinical stage T1c, biopsy Grade Group 1, the presence of disease in fewer than 3 biopsy cores, ≤ 50% prostate cancer involvement in any core, and PSA density.

Statistical analysis

The data in this study were analyzed using IBM SPSS software. A p-value of ≤ 0.05 was considered significant. Qualitative data are reported as percentages and numbers, while quantitative data are reported as mean, median, minimum-maximum range, and standard deviation (SD).

Comparisons of data between groups were made using Pearson Chi-square, Continuity correction, Likelihood ratio, Fisher's exact test, and Linear-by-linear association analyses.[6]

Results

A total of 208 men were enrolled in the study. After excluding patients who did not fulfil the criteria, 203 men were included. The mean age was 69.77 years, and the mean pre-operative PSA level was 14.07 ng/ml.

The majority (90.65%) of men in this study underwent targeted MRI/US-guided biopsy using a transperineal approach, while the remaining 9.35% underwent the procedure via a transrectal approach.

The mean length of stay was 3 days, with a minimum of 3 days and a maximum of 6 days, as depicted in Table 1.

The targeted MRI/US fusion-guided biopsy resulted in a cancer detection rate of 32.50% with a significantly higher detection rate than the systematic TRUS biopsy, with rates of 32.50% and 25.60%, respectively ($p < 0.05$), as indicated in Table 2. The sensitivity and specificity of the MRI/US fusion biopsy were found to be 75.00% and 82.00%, respectively.

Table 1. Patient characteristics

	Sample size (n=203)
Age, mean (SD), y	69.77 (7.078)
Pre-operative PSA, mean, ng/ml	14.05 (14.13)
Abnormal DRE, n (%)	37 (18.22)
Score on PIRADS, n (%)	
3	68 (33.50)
4	79 (38.90)
5	56 (27.60)
Approach	
Transperineal, n (%)	184 (90.65)
Transrectal, n (%)	19 (9.35)
Length of stay, mean (SD), day	3 (0.502)

SD = standard deviation, PSA = prostate specific antigen, DRE = digital rectal examination

Patients were categorized based on abnormal lesions in prostate MRI as PIRADS 3, 4, and 5, constituting 33.49%, 36.94%, and 27.60%, respectively. Subgroup analysis for PIRAD3, 4, and 5 revealed cancer detection rates of 8.80%, 40.50%, and 50.50%, respectively, demonstrating a trend of higher PIRADS scores correlating with higher detection rates, as illustrated in Table 3.

When combining MRI/US fusion-guided biopsy with systematic TRUS biopsy, the detection rate of cancer surpasses that of systematic TRUS biopsy alone (38.90% vs. 25.60%, $p < 0.05$) and MRI/US fusion-guided biopsy alone (38.90% vs. 32.50%, $p < 0.05$).

There were no patients with positive findings in either TRUS or MRI alone but negative findings when combined.

Table 2. Cancer detection rates

	Benign n (%)	Cancer n (%)	P-value
Systematic TRUS biopsy	151 (74.40)	52 (25.60)	< 0.05
Targeted MRI/US guided biopsy	137 (67.50)	66 (32.50)	

TRUS = transrectal ultrasound, MRI/US = magnetic resonance imaging/ultrasound

Table 3. Patient categorized base on PIRADS

		PIRADS n (%)			Total
		PIRADS3	PIRADS4	PIRADS5	
Count		68 (33.49)	79 (38.94)	56 (27.60)	203 (100.00)
Targeted MRI/US guided biopsy	Benign	62 (91.20)	47 (59.50)	28 (49.50)	137 (67.50)
	Prostate cancer	6 (8.80)	32 (40.50)	28 (50.50)	66 (32.50)

MRI/US = magnetic resonance imaging/ultrasound

Table 4. The detection of significant prostate cancer

Group	Targeted MRI/US guided biopsy positive (n) %	Systematic TRUS positive (n) %	P-value
Significant prostate cancer	50 (75.80)	36 (69.20)	0.54
Insignificant prostate cancer	16 (24.20)	16 (30.80)	

Group	Combined positive (n)	Systematic TRUS positive (n)	P-value
Significant prostate cancer	58 (73.40)	36 (69.20)	0.69
Insignificant prostate cancer	21 (26.60)	16 (30.80)	

TRUS = transrectal ultrasound, MRI/US = magnetic resonance imaging/ultrasound

Twenty-seven (13.30%) patients had positive findings on targeted MRI/US fusion-guided biopsy but negative findings on systematic TRUS biopsy. Conversely, thirteen (6.40%) patients had negative findings on targeted MRI/US fusion-guided biopsy but positive findings on systematic TRUS biopsy.

Table 4 shows that for the detection of significant prostate cancer, the targeted MRI/US-guided biopsy method identified more cases in comparison to systematic TRUS biopsy (75.80% vs. 69.20%, OR 1.399, 95%CI 0.62-3.14, p = 0.54), albeit with a lower detection rate of insignificant prostate cancer. Similarly, when comparing the combined technique with systematic TRUS biopsy alone, the results were not statistically significant (73.40% vs. 69.20%, OR 1.22, 95%CI 0.57-2.66, p = 0.69). With regard to insignificant prostate cancer, the detection rate using the combined technique was higher than that of systemic TRUS biopsy, although this difference was not statistically significant (26.60% vs. 30.80%).

The most common complication observed was gross hematuria, affecting 9.30% of patients, all patients showing spontaneous improvement before discharge from the hospital. Other complications were relatively insignificant and included fever (1.47%), urinary retention (0.98%), perineal hematoma (0.49%), and scrotal hematoma (0.49%). Notably, no cases of sepsis, severe infection, or complications related to general anesthesia were detected in this study, as outlined in Table 5.

Table 5. Complications from TRUS and MRI/US guided prostate biopsy

Complication	n (%)
Gross hematuria	19 (9.30)
Fever	3 (1.47)
Urinary retention	2 (0.98)
Perineal hematoma	1 (0.49)
Scrotal hematoma	1 (0.49)

Discussion

Systematic TRUS biopsy has traditionally been considered the gold standard for a diagnosis of prostate cancer, with a positive biopsy rate of approximately 60%. However, with the emergence of mpMRI of the prostate, which provides both anatomical and functional information, there has been a growing recognition of its utility in diagnosis.

In this study the overall detection rate of prostate cancer by targeted MRI/US fusion-guided higher than the systematic TRUS biopsy has been identified, moreover, results from the multicenter randomized noninferior trial, PRECISION[7,8], have shown that targeted MRI/US-guided biopsy detects more clinically significant cancer than systematic TRUS biopsy (38% vs. 26%, respectively). Our study yielded similar results, with detection rates of 75.80% and 69.20% for targeted MRI/US-guided biopsy and systematic TRUS biopsy, respectively, although the results were not statistically significant (p = 0.532). Additionally, the incidence of insignificant prostate cancer was lower in targeted MRI/US-guided biopsy compared to systematic TRUS

biopsy (24.20% vs. 30.90%, respectively). Our findings suggest that targeted MRI/US-guided biopsy is effective in the detection of prostate cancer and reduces the diagnosis of insignificant cancer.[9] Furthermore, when combining both techniques, there was a higher detection rate of prostate cancer compared to targeted MRI/US-guided biopsy or TRUS alone.[10-12] In the subgroup analysis of this study, we observed that higher PI-RADS scores were associated with higher detection rates, results consistent with findings from a prospective validation study by Hofbauer et al. in 2018.

From a systematic review of complications associated with prostate biopsy, it is evident that common complications[13] include bleeding (hematuria, hematospermia, rectal bleeding), fever, and urinary retention. Gross hematuria, as observed in our study, has been identified as the most common complication in several studies. All patients in our study underwent both targeted MRI/US-guided biopsy and systematic TRUS biopsy, leading to an increased number of biopsy cores and potentially, consequentially, more bleeding. All of the patients with hematoma were identified and were under observeationin the hospital; fifteen patients showed spontaneous improvement, while four patients were treated with continuous bladder irrigation without the need for surgical intervention. Postoperative fever was observed in three patients, all of whom were given antibiotics. No pathological organisms were isolated from urine cultures or blood cultures, despite compelling evidence of urinary tract infection. It is also noteworthy that no serious complications such as sepsis or readmission were observed.

Despite the valuable insights gained from our study, several limitations need be acknowledged. Firstly, the analysis was retrospective, which may introduce patient bias. Secondly, we included mpMRI of the prostate from external sources, utilizing both 1.5-Tesla and 3.0-Tesla mpMRI machines. However, all suspected lesions were reviewed by only two radiologists who were experts in prostate MRI before scheduling the biopsy. Thirdly, there is potential bias in the biopsy procedures as they were performed by different urologists which could impact the biopsy result. Lastly, while the data were corrected for complications during the hospital stay, there was no further follow-up conducted beyond this period. These limitations underscore the need for cautious interpretation of our findings and highlight areas for future research.

Conclusion

In men with suspected prostate cancer detected via mpMRI and undergoing biopsy, targeted MRI/US-guided biopsy yielded a higher detection rate of prostate cancer in compareison to systematic TRUS biopsy alone. Additionally, acombination of the techniques of targeted MRI/US-guided biopsy and systematic TRUS biopsy demonstrated an improved detection rate over TRUS biopsy and mpMRI alone. These findings suggest that the combined approach enhances the accuracy of the detection of prostate cancer, highlighting the complementary nature of these diagnostic methods in clinical practice.

Conflict of Interest

The authors wish to affirm that there are no conflicts of interest associated with this study with regard to academic or funding sources

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