Original Article

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The Additive Value of MRI Targeted Biopsy on Prostate Cancer Detection in Patients with Serum Prostate-specific Antigen 20-100 ng/mL and Normal Digital Rectal Examination

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Abstract

Objectives: The study investigates whether multiparametric magnetic resonance imaging (mpMRI) targeted biopsy (MRI-TB) is necessary in the setting of prostate-specific antigen (PSA) 20-100 ng/mL and normal digital rectal examination (DRE).
Materials and Methods: Patients undergoing MRI-TB and concomitant systematic biopsies (SB) with a PSA 20-100 ng/mL and normal DRE were retrospectively reviewed in Prostate Cancer Database of Turkish Urooncology Association. Pathological data of MRI-TB was compared to the SB data. All patients underwent mpMRI followed by transrectal/transperineal MRI-TB of any Prostate Imaging Reporting and Data System lesion and 12-core SB. The prostate cancer (PCa) and clinically significant PCa (csPCa) (grade group ≥2) detection on MRI-TB, SB and MRI-TB+SB were determined for all patients. A subgroup analysis of combined (MRI-TB+SB) group was also performed to identify performances of MRI-TB alone, SB alone and combination of MRI-TB+SB for the prediction of final pathology at radical prostatectomy (RP). Statistical significance was set at $p<0.05$.
Results: In the study 65 patients were evaluated. Among them, 35 have PCa and 32 of them were csPCa. The detection rate of PCa for MRI-TB+SB, MRI-TB and SB were 53%, 46% and 36%, respectively, and csPCa detection rates were 49%, 41% and 33%, respectively. TB added 31.4% of any grade PCa and 31.25% csPCa detection over SB. csPCa detection rate improved with increased PSA density for TB. Among 15 patients who underwent RP, 6 patients were found to have csPCa on final pathology which went undetected or undergraded with SB biopsy initially.
Conclusion: MRI-TB based on mpMRI presents a valuable addition to SB in patients with PSA 20-100 ng/mL and normal DRE.
Keywords: Prostate cancer, targeted biopsy, MRI/US fusion, prostate biopsy, concordance

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Introduction

Prostate cancer (PCa) is the second most common malignancy among men worldwide (1). Previous researches have shown that multiparametric magnetic resonance imaging (mpMRI) targeted biopsy (MRI-TB) identifies clinically significant PCa (csPCa) more accurately than conventional systematic biopsy (SB) in men with PCa (2-5). MRI-TB has resulted in greater detection of csPCa with less detection of clinically insignificant PCa than SB alone (6,7). Nevertheless, 12-core SB is often performed in addition to MRI-TB in a combination schema is increased detection of csPCa (3,8). Additionally, such a practice allows for the non-lesional sampling beyond suspicious lesions, as 10-24% of csPCa are not visualized on mpMRI (9).

Patients with prostate specific antigen (PSA) >20 represent csPCa (≥ Gleason grade group 2) between 72-90% of all cases (10-14). Given the high prevalence of such csPCa in these patient population, the utility of MRI-TB is uncertain. Few studies suggested omitting mpMRI and MRI-TB in patients with PSA >10 ng/mL and abnormal digital rectal examination (DRE) (14). Low evidence suggests that patients with PSA >10 and an abnormal DRE do not benefit from pre-biopsy mpMRI and MRI-TB (14). On the contrary, in the analyzing of 91 patients, it was shown that a significantly higher detection rate of csPCa with MRI-TB compared with SB in patients with both normal and abnormal DRE (15). The authors stated that the contribution of mpMRI and MRI-TB was more pronounced in patients with normal DRE compared with those with abnormal DRE.

Little or no data exist in the current literature about the value added from performing MRI-TB in patients with PSA 20-100 ng/mL with normal DRE. In this context, we aimed to investigate the utility of MRI-TB in addition to SB in patients with PSA 20-100 ng/mL to determine whether some patients can be spared from additional or unnecessary mpMRI and MRI-TB.

Materials and Methods

We retrospectively reviewed data from completely anonymized patients enrolled by nation-wide tertiary centers in Prostate Cancer Database of Turkish Urooncology Association. MRI-TB in conjunction with 12-core SB for PSA 20-100 ng/mL and normal DRE at our database were included in the study. All patients gave consent for the study.

All mpMRI for TB were reviewed by specified institutional radiologists. In patients with a Prostate Imaging Reporting and Data System (PI-RADS)-lesion 1-5 (according to PI-RADS-v2 classification) (10), MRI targeted ultrasound fusion biopsy using different software-based platforms according to participant center's property [MIMS Symphony Dx® (MIM Software), bk3000® (BKMedical), UroNav® (Invivo Corp, Philips)] were conducted. MRI image fusion biopsies (MRI-TB) were taken, obtaining ≥3-core samples, from each lesion. In addition to MRI-TB, SB were also performed using a 12-core biopsy schema.

All patients underwent both MRI-TB and SB. PCa detection rate was obtained from combination of both methods and then from each method separately. MRI-TB cancer detection determined when only target lesions yielded as cancer, and SB cancer detection rate was determined when target lesions were negative but SB were positive for cancer. A missed cancer rate is determined by subtracting individual performance of each biopsy methods from combined method cancer ratio.

Prostate biopsies were performed by transrectal or transperineal route in 55 and 10 patients, respectively. Sedation anesthesia was administered during the biopsy procedures. An indwelling foley urethral catheter was used to visualize the urethra on ultrasound images. A transrectal ultrasound (TRUS) probe was used for needle placement and guidance. MRI-TB cores are taken via the appropriate grid holes to ensure sampling of the designated area. If patients had more than one PI-RADS lesion, lesions were analyzed together (such that per patient rather than per lesion). Analysis was performed by reporting percentages of PCa and csPCa for MRI-TB, SB and MRI-TB+SB.

Statistical Analysis

Study data were collected and managed using Research Electronic Data Capture (REDCap) electronic data capture tools hosted at Turkish Urooncology Association (16,17). REDCap is a secure and web-based software platform designed to support data capture for research studies, providing an intuitive interface for validated data capture, automated export procedures for seamless data downloads to common statistical packages, audit trails for tracking data manipulation and export procedures and procedures for data integration and interoperability with external sources (16,17).

In the statistical analysis, Statistical Package for the Social Sciences (SPSS) version 22.0 was used. The Mann-Whitney U test, t-test and chi-square test were used to analyze the relationship of categorical and continuous variables between two biopsy methods and three biopsy schemes of combined biopsy method. In the multivariate analysis, regression model was used to identify independent risk factors for csPCa detection. P-values less than 0.05 were considered statistically significant.

Results

Data from 65 patients who underwent MRI-TB+SB, with PSA levels of 20-100 ng/mL and normal DRE were evaluated. Demographic data of the study cohort stratiŞed by biopsy approach are given in Table 1. Median number of MRI-TB cores sampled per region of interest was 5.8. Mean age and PSA were 65.3 years, 33.2 ng/mL respectively.

PI-RADS 5 lesions were detected in 44% of the patients. PCa was detected in 35 patients with combined MRI-TB+SB (53.8%) patients. PCa detected in 30 and 24 patients by targeted and systematic only biopsy, respectively. SB alone missed 11 patients and MRI-TB missed only 5 patients of any grade cancer. There was significant difference in missed PCa ratio between MRI-TB and SB (14.2% vs 31.4%) of any grade PCa, but csPCa detection by SB alone was significantly lower than MRI-TB alone. Most of the patients with cancer identified as csPCa (91.4%). SB alone missed 10 patients and MRI-TB missed only 5 patients with csPCa. TB added 10/32 (31.25%) of csPCa detection.

We analyzed that clinical factors impact csPCa detection risk by MRI-TB-SB. In the multivariate analysis, the regression model proved that the following clinical parameters were significantly

increasing the probability of PCa detection: prostate volume, PSA density (PSAD) >0.75 ng/mL^2 and higher PI-RADS scores (Table 2).

Fifteen patients who underwent radical prostatectomy (RP) were evaluated for concordance analysis. MRI-TB showed significantly higher concordance over SB at RP (Table 3). Six patients were found to have significant PCa on RP whom went undetected or undergraded with SB biopsy. Gleason score downgrading at final pathology was lowest in both methods.

Table 1. Descriptive characteristics and pathologic results of patients

		PSA 20-100 DRE normal (n=65)
Age		65.3±8
BMI		27±6.7
PSA		33.2±16.4 (20-100)
PV		82.3±57.7
PSAD		0.50±0.51
mpMR-PI-RADS	PI-RADS <3	1 (1.5%)
	PI-RADS 3	12 (18.5%)
	PI-RADS 4	23 (35.4%)
	PI-RADS 5	29 (44.6%)
PCa • MRI-TB+SB • MR-TB • SB		 35 (53.8%) 30 (46.2%) 24 (36.9%)
csPCa • MRI-TB+SB • MR-TB • SB		 32 (49.2%) 27 (41.5%) 22 (33.8%)
RP (n=57) • Upgrade • Concordance • Downgrade		(n=15) 4 (26.7%) 9 (60%) 2 (13.3%)

BMI: Body mass index, PSA: Prostate specific antigen, PSAD: PSA density, PV: Prostate volume, DRE: Digital rectal examination, RP: Radical prostatectomy, SB: Systematic biopsies, PI-RADS: Prostate Imaging Reporting and Data System, MRI: Magnetic resonance imaging, TB: Targeted biopsy

Table 2. Multivariable logistic regression analyses predicting factors effecting biopsy results

		PSA 20-100 ng/mL MRI-TB		
		Benign (n=35)	PCa (n=30)	p-value
Age		63.2±6.2	67.8±9.1	0.068
PV		111.1±58	47.3±33.3	<0.001
PSAD		0.28±0.23	0.75±0.63	0.002
mpMRI-PI-RADS	PI-RADS <3	1 (2.9%)	0 (0%)	<0.001
	PI-RADS 3	9 (25.7%)	3 (10%)	
	PI-RADS 4	19 (54.3%)	4 (13.3%)	
	PI-RADS 5	6 (17.1%)	23 (76.7%)	
Number of cores per lesion		7.2±4.4	5.8±4.4	0.146

PSAD: Prostate specific antigen density, PV: Prostate volume, PI-RADS: Prostate Imaging Reporting and Data System, MRI: Magnetic resonance imaging, PCa: Prostate cancer, TB: Targeted biopsy

Table 3. Concordance at radical prostatectomy

		RP insPCa (n=2)	RP csPCa (n=13)
PSA		24.6±5:2	29±10
mpMRI-PI-RADS	PI-RADS <3	0 (0%)	0 (0%)
	PI-RADS 3	0 (0%)	3 (23.1%)
	PI-RADS 4	0 (0%)	4 (30.8%)
	PI-RADS 5	2 (100%)	6 (46.2%)
MRI-TB+SB • insPCa • csPCa		 2 (100%) 0 (0%)	 1 (7.7%) 12 (92.3%)
MRI-TB • benign • insPCa • csPCa		 1 (50%) 1 (50%) 0 (0%)	 2 (15.4%) 2 (15.4%) 9 (69.2%)
SB • benign • insPCa • csPCa		 0 (0%) 2 (100%) 0 (0%)	 6 (46.2%) 0 (0%) 7 (53.8%)

insPCA: Insignificant prostate cancer, RP: Radical prostatectomy, SB: Systematic biopsies, PI-RADS: Prostate imaging-reporting and data system, MRI: Magnetic resonance imaging, TB: Targeted biopsy, PCa: Prostate cancer

Discussion

The main goal of our study was to investigate whether omitting MRI-TB in PSA 20-100 ng/mL and normal DRE could impact the csPCa detection rate. Our results confirmed that in these patients MRI-TB has a significantly higher csPCa detection rate compared to SB, 41% vs 33%, respectively. We also confirmed that omitting MRI-TB may contribute to a significant reduction in the csPCa detection rate by 31.25%.

In the literature, studies regarding PSA thresholds and the biopsy technique were mainly focused on the patient groups who had PSA levels less than 20 ng/mL (10,14). Most of the clinicians and patients' perception is that once they had a PSA level of >20 ng/mL, there would be a high probability of having PCa. In the literature and guidelines however, there is a paucity of data for the exact cancer detection rates which would help significantly in counseling those patient groups.

In our study most patients had PI-RADS 5 lesions. A low csPCa detection rate in patients with PI-RADS 3 and 4 but high in those with PI-RADS 5 lesions was consistent with the findings of others indicating that mpMRI is beneficial to men with PSA 20-100 ng/mL and normal DRE. Overall, these results emphasize the advantages of the proposed combined strategy. Therefore, allocating time and resources for pre-interventional mpMRI is warranted in most patients with suspected PCa, since inaccurate initial risk stratification could lead to avoidable morbidities that significantly exceed the expenses of establishing a precise diagnosis.

There are several arguments that advise MRI-TB omission mostly in patients with PSA>20 and normal DRE.

For patients presenting with PSA levels >20 ng/mL and abnormal DRE, some reports suggest that performing only SB may be a reasonable option, as it reduces the need for cost-effective diagnostic procedures prior to prostate biopsy (18). In line

with this, skipping pre-interventional mpMRI to avoid delays in diagnosis and the associated psychological burden could be considered, particularly in settings with limited resources and inadequate infrastructure (18). Nevertheless, such an approach should be carefully weighed against available facilities and potential limitations. On the other hand, in an analysis of 91 patients, demonstrated a significantly higher detection rate of csPCa with MRI-TB compared to SB, both in cases with normal and suspicious DRE findings (15). In that study, Omri et al. (15) emphasized that the added value of mpMRI and TB was more evident in patients with a negative DRE, although they still recommended the combined use of TBx and SBx for those with suspicious DRE. Similarly, Morote et al. (13) assessed the impact of mpMRI and MRI-TB in 34 men with PSA >20 ng/mL and normal DRE, showing that MRI-TB could enhance SB in identifying the highest proportion of csPCa in this context. In the subgroup analysis of patients with PSA >20 ng/mL revealed a mean PSA of 58 ng/mL, with levels reaching up to 912 ng/mL, indicating a heightened likelihood of csPCa presence, including metastatic disease. Importantly, 95% of these patients were diagnosed with csPCa, and SB alone yielded accurate diagnoses in 87% of cases (13). Still, even in this subset, the combination of biopsy methods of MRI-TB+SB provided superior diagnostic performance. Overall, evidence suggests that mpMRI offers greater benefit in patients with a normal DRE; however, both MRI-TB and SB remain advisable regardless of DRE status (13,15,18,19).

Beyond PSA levels, several additional factors are being investigated as potential predictors of csPCa detection through MRI-TB, including PSAD, DRE findings, lesion location, prostate volume and biopsy procedure. To date, however, no clear risk-adapted model or nomogram has been proposed to omit TB. In our analysis, a PSAD threshold of 0.75 ng/mL^2 emerged as an important data for identifying csPCa. These findings align with existing literature, which consistently highlights PSAD and PI-RADS score as strong predictors of csPCa detection. Abnormal DRE remains one of the classic indications for biopsy and also provides clinical insight into disease extent. Yang et al. (12) reported PCa detection rates of 66.3% in patients with PSA 20-100 ng/mL and positive DRE, compared with 64.9% in those with negative DRE. In our cohort, overall PCa detection was 53.8%. Higher PSA values were shown to correlate with abnormal DRE findings, and among patients with PSA levels between 20-99.99 ng/mL, positive DRE findings were significantly linked with PCa diagnosis (10,12). Interestingly, while PSA level did not correlate with PCa in men presenting with palpable nodules on DRE, a higher PSA was associated with PCa diagnosis in patients without nodules on DRE (10,12).

In our cohort, 15 patients who underwent RP were evaluated for concordance. MRI-TB was superior in prediction of the final histopathological results than SB. MRI-TB showed significantly higher concordance over SB at RP. Six patients were found to have csPCa on RP whom went undetected or undergraded with SB only. If MRI-TB omitted, our results showed that 6 patients (40%) with csPCa at RP would be missed initially. This supports previous researches that has highlighted the superior concordance of combined biopsy of MRI-TB+SB with final pathological tumor grading, emphasizing the signifcance of performing both SB and MRI-TB to reduce the risk of misdiagnosis (15,19).

Study Limitations

The major limitations of our study are its retrospective nature and analysis. Our study is multi-centric and retrospective. Given the specific patient population definition as normal DRE with PSA 20-100 ng/mL, our study sample size is not low and provides important insights for clinical practice. The study population was heterogeneous, as it included both transperineal and transrectal biopsies. The analysis did not include epidemiological factors such as body mass index or comorbidities. Part of the mpMRI images were obtained from external radiological centers, and they were read by radiologists with different experiences; therefore, wider inter-observer variability is certainly possible in the assessment of the PI-RADS scores. Another limitation is that MRI-TB data was obtained from 5 different centers performed by 7 different urologists using different MRI and MRI-US fusion devices. Failure of mpMRI fusion biopsy due to incorrect mpMRI image registration or mismatch of image planes, inaccurate sampling and intralesion Gleason score heterogeneity may have impacted our results. Another important limitation is that there was no centralized pathological examination, multicentric pathological examinations by uropathologists at respective centers. The comparisons of biopsy methods were performed per patient rather than per lesion. Nevertheless, our data reflect the real-life nationwide picture and therefore important.

Conclusion

The results of our study indicate that in patients with normal DRE and PSA 20-100 ng/mL, the probability of detecting csPCa in SB is significantly lower than in MRI-TB. Omitting MRI-TB is associated with the risk of missing csPCa in one-third of cases. In patients with PSA 20-100 ng/mL and normal DRE, MRI-TB adds non-negligible clinical value. Therefore, sparing these patients from MRI-TB should not be considered to reduce patient morbidity and cost in order to avoid reduced cancer detection, local staging error and misleading therapeutic decisions.

Ethics

Ethics Committee Approval: Ethics committee approval is not required.

Informed Consent: All patients gave consent for the data collection.

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Footnotes

Authorship Contributions

Surgical and Medical Practices: G.A., S.S., L.T., S.Y., C.Y.B., İ.A., E.S., Concept: G.A., S.Ç., Design: G.A., S.Ç., Data Collection or Processing: S.Çet., S.S., S.Y., İ.A., S.E., B.Ş., C.Y.B., Analysis or Interpretation: B.Ş., S.Ç., G.A., Literature Search: S.Çet., B.Ş., Writing: G.A.

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