Original Article

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Comparison of Systematic, Targeted and Combined Prostate Biopsy: Our Clinical Outcomes

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Abstract

Objective: Our aim was to compare the diagnostic efficacy of the standard systematic, targeted and combined prostate biopsy methods in prostate cancer.
Materials and Methods: Total of 161 patients who underwent prostate biopsy combined with magnetic resonance imaging-ultrasonography fusion method between August 2018 and March 2021 was evaluated retrospectively. Clinically important and insignificant cancer detection rates of biopsy results between standard, targeted and combined biopsy (CB) methods were compared. Changes in the results were also evaluated in terms of Prostate Imaging-Reporting and Data System (PIRADS) scores.
Results: Prostate cancer was diagnosed in 46 (28.6%) patients by CB. Fourteen (8.7%) patients were interpreted as a clinically insignificant disease. Prostate cancer and clinically significant disease detection rates were statistically significant in favor of CB compared to targeted biopsy (TB). There was no statistically significant difference between systematic biopsy and TB results. Additionally, it was observed that cancer detection rates were higher in PIRADS ≥4 lesions compared to PIRADS 3 lesions in all biopsy methods.
Conclusions: Our results have shown that combined prostate biopsy led to higher detection of prostate cancer and provides increased detection of clinically significant disease. High rates of clinically significant cancer, especially in patients with PIRADS ≥4 lesions, suggest that the PIRADS scoring is a high-level guide in detecting malignancy.
Keywords: Prostate cancer, clinical significance, targeted biopsy, MRI US fusion, combined biopsy

Introduction

Prostate cancer is the first among the most commonly diagnosed cancers in men in the world (1). It also ranks second in cancer-related deaths (2). The diagnosis is based on transrectal ultrasonography (TRUS)-guided biopsy and histopathological examination of biopsy materials is considered the gold standard in diagnosis (3). The TRUS-guided 12-core systematic biopsy is used as the standard method for detecting prostate cancer (4). However, in studies comparative with the autopsy series, prostate biopsy sensitivity was found to be 53% (5).

About a third of cases undergo repeat-biopsy within five years and malignancy is detected in 13-41% of them due to these uncertainties. While the malignancy detection rate is 27-40% with the standard method, 20-25% of clinically significant cancers cannot be detected (6). Saturation biopsy that is recommended to solve these problems, increases the rate of clinically insignificant malignancy detection and therefore may cause overdiagnosis and overtreatment (7). Also, it has also been shown to increase intervention-related morbidity compared with other biopsy methods. It has been stated that the increase in complications is a limiting factor for this method (8).

Suspicious lesions in the prostate gland are more frequently detected with advances in magnetic resonance imaging (MRI) hardware and software and with the widespread use of multiparametric prostate magnetic resonance imaging (mpMRI). With the detection of suspicious malignant lesions with MRI, the targeted prostate biopsies have begun to be performed for these lesions. MpMRI has high sensitivity in detecting clinically significant prostate cancer (9). MRI fusion with ultrasonography (US), a advance in the technology era, enables the imaging of the lesions in the prostate and reduces unnecessary intervention by enhancing to take the biopsy from the right localization (10,11,12).

Fusion imaging provides a safer method for diagnosis by providing a clear correlation between different modalities to show the same anatomy from the same angles. The MRI-US fusion imaging technique by combining the advantages of accurate lesion detection of MRI and real-time imaging of

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the US, has been developed rapidly recently and has been frequently used as an important guiding method in prostate biopsies. The detection of cancer and clinically significant cancer are higher in patients by the use of mpMRI and MRI-US targeted biopsies (13).

Current guidelines recommend a combined biopsy (CB) technique based on the addition of targeted biopsy (TB) to systematic biopsy (SB) (14).

In this retrospective study, patients who underwent MRI-US fusion combined prostate biopsy because of high PSA or abnormal rectal examination findings were evaluated. Standard systematic and targeted prostate biopsies were performed on the patients in the same session. We studied the diagnostic efficacy of the SB, TB, and CB methods.

Materials and Methods

Ethical approval was granted by the local ethics committee of clinical research of Duzce University Ethics Committee (2021/50) on 1 March 2021. Patients who underwent prostate biopsy combined with MRI-US Fusion prostate biopsy were accepted for a retrospective study at the Urology Department of Düzce University Faculty of Medicine Hospital in August 2018 and March 2021. MpMRI was performed in all patients and all lesions were evaluated by radiology Prostate Imaging-Reporting and Data System (PIRADS) version 2 before the biopsy. Suspicious lesions with a PIRADS score of 3 or above were marked and targeted with MRI-US fusion prostate biopsy transrectally.

Siemens AG MagnetomR Skyra (Munich, Germany) 3 Tesla magnet MRI device was used for mpMRI. Based on the mpMRI protocol, T2-weighted imaging was performed in the axial, coronal and sagittal planes with a slice thickness of 3.5 mm. In addition to T1-weighted axial images, diffusion-weighted imaging and dynamic contrast-MRI sequences were used for functional examination. The suspicious lesions were evaluated according to the recommendations in PIRADS version 2.

All biopsies were performed under local anesthesia with appropriate antibiotic prophylaxis by three clinicians in the urology department. All imaging-guided biopsy procedures were performed using an US device (Logiq S8; GE Healthcare, USA) and an 8-10 Mhz endorectal convex probe. Simultaneously, fusion imaging procedures were performed using an US device and an integrated volume navigation system (V Nav; GE Healthcare). The fixed (rigid) method was used as the correlation algorithm of the images.

For volume navigation, an electromagnetic transmitter was placed next to the patient table and electromagnetic sensors were attached to the probe. The transmitter system and sensors were connected to the position sensing unit of the US device (Ascension Technology Corporation, Burlington, USA). The previously obtained MRI images were uploaded to the device. The screen was frozen by selecting one of the transverse MRI images on the right side of the monitor, and the real-time US section passing through this section was determined on the other side of the screen. Plan matching was made to these sections as the first step of matching. As the second step, the patient-specific cyst, calcification, nodule, or other distinctive anatomical points were determined as the reference point. These reference points determined on the real-time US image were matched with the MRI sections on the screen.

After positional matching, MRI images with multiplanar reconstruction, were viewed side-by-side on the screen in synchronization with real-time US images. At least 2 TB cores were obtained from each lesion detected on MRI. After the TB procedure was completed, standard SB of 12 cores of the prostate was performed under the guidance of US only, regardless of the MRI images. The patients whose CB was completed were kept under observation in the daily room for an average of 2 h in terms of pain and spontaneous micturition.

Statistical Analysis

Statistical analysis was performed using SPSS v.21 (IBM Analytics) program. Descriptive statistics were performed to summarize the demographics of the patients. The comparison of qualitative data between dependent groups was performed using the Mc Nemar test, and that of dependent groups was made using Fischer's Exact tests. The odds ratio was calculated for relative risk ratios. Differences were considered statistically significant at $p \leq 0.05$.

Results

In the study, 80 of 161 patients underwent a first biopsy and 81 patients had previous negative biopsy. Because of mpMRI and radiological evaluation of patients, one lesion was detected in 129 (80.1%) of 161 patients and two lesions in 32 (19.8%). Total of 193 lesions, 138 (71.5%) were reported as PIRADS 3 score, 47 (24.3%) as PIRADS 4 and 8 (4.1%) lesions were reported as PIRADS 5 score. The demographic characteristics of the patients are shown in Table 1.

Prostate adenocarcinoma was found in 46 (28.6%) of the patients who underwent prostate biopsy. The histopathological and clinical characteristics of 14 (8.7%) patients were interpreted as clinically insignificant disease according to Epstein's criteria (clinical stage T1c, PSA density <0.15 ng/mL/cc, lack of Gleason 4 or 5, <50% cancer per Cor) (15).

Clinically significant cancer was detected in 26 (16.1%) of 34 (21.1%) patients diagnosed with prostate cancer when using the TB method only, whereas a clinically significant cancer was detected in 28 (17.4%) of 41 (25.5%) patients diagnosed with prostate cancer with SB alone. There was no statistically

Table 1. Demographic characteristics of the patients included in the study

Age	64.19±6.43
PSA (ng/mL)	7.38±5.11
fPSA (ng/mL)	1.47±1.11
Prostate volume (cc)	66.73±39.13
PSA density (ng/mL/cc)	0.13±0.11
Number of biopsy cores	15 (14-20)
Number of cores taken from target lesions per patient	3 (2-8)

PSA: Prostate spesific antigene, fPSA: Free prostate spesific antigene, Data are presented as mean ± SD or mean ± range

significant difference in cancer detection rates between the two methods. (p=0.143, p=0.754)

When the CB results were examined, 32 (19.9%) of 46 (28.6%) patients diagnosed with prostate cancer were found to have clinically significant cancer. Although the rates of diagnosing cancer and clinically-significant cancer in CB method are higher, compared with SB; this difference was not statistically significant (p=0.063, p=0.125). However, prostate cancer and clinically significant cancer detection rates were statistically significant in favor of CB compared with TB (p=0.0001, p=0.031) (Table 2).

There is no significant difference between SB and CB methods applied to patients with only PIRADS 3 lesions in terms of detection of prostate cancer. Both methods were found to be statistically superior to TB in terms of diagnosis of prostate cancer ($p<0.05$). However, no significant difference was found in terms of clinically significant cancer between the 3 groups in patients with PIRADS 3 lesions ($p>0.05$).

There is no significant difference between biopsy methods performed on patients with PIRADS score of ≥4 reported in mpMRI in terms of cancer detection and clinically-important cancer diagnosis ($p>0.05$).

Of the patients with PIRADS ≥4 scored lesions, 55.6% were diagnosed with prostate cancer, and the rate of clinically significant cancer detection in these patients was 48.1%. We observed that the rates of cancer and clinically significant cancer were significantly higher in the PIRADS ≥4 group compared to patients with only PIRADS 3 lesions (p=0.0001) (Table 3).

The odds of diagnosis of prostate cancer [odds ratio (OR): 7.1 95% confidence interval (CI): 3.341-15.130] and clinically significant prostate cancer (OR: 15.6 95% CI: 5.858-41.708) were increased with PIRADS ≥4 lesions compared to PIRADS 3 lesions.

Table 2. Pathology results of SB, TB, CB

	SB[1] n (%)	TB[2] n (%)	CB[3] n (%)
PCa (-)[a]	120 (74.5%)	127 (78.9%)	115 (71.4%)
PCa (+)[a]	41 (25.5%)	34 (21.1%)	46 (28.6%)
Clinically-insignificant PCa[b]	13 (8.1%)	8 (4.9%)	14 (8.7%)
Clinically-significant PCa[b]	28 (17.4%)	26 (16.2%)	32 (19.9%)
Total	161 (100%)	161 (100%)	161 (100%)

SB: Standart biopsy, TB: Targeted biopsy, CB: Combined biopsy, PCa: Prostate cancer, $p_{1a\text{-}2a}$=0.143, $p_{1b\text{-}2b}$=0.754, **$p_{2a\text{-}3a}$=0.0001**, **$p_{2b\text{-}3b}$=0.031**, $p_{1a\text{-}3a}$=0.063, $p_{1b\text{-}3b}$=0.125

Table 3. Combined biopsy; pathology results of patients with only PIRADS 3 and PIRADS ≥4 scored lesions

	PIRADS score	
	3 n (%)[a]	**4 or 5 n (%)[b]**
PCa (-)[1]	91 (85%)	24 (44.4%)
PCa (+)[1]	16 (15%)	30 (55.6%)
Clinically-insignificant PCa[2]	10 (9.3%)	4 (7.4%)
Clinically-significant PCa[2]	6 (5.6%)	26 (48.1%)
Total	107 (100%)	54 (100%)

PIRADS: Prostate imaging-reporting and data system, PCa: Prostate cancer, **$p_{a1\text{-}b1}$= 0.0001, $p_{a2\text{-}b2}$= 0.0001**

The TB is examined based on cores, average number of TB cores taken from lesions per patient was 3 (2,3,4,5,6,7,8). When the pathology results of 138 lesions scored as PIRADS 3 in mpMRI were examined, 8 (5.7%) had cancer and only 2 (1.4%) were compatible with clinically significant prostate cancer. Cancer was detected in 22 (46.8%) of 47 lesions evaluated as PIRADS 4. Eleven (23.4%) of these lesions were clinically-significant. Clinically-significant cancer was detected in all 8 (100%) patients with PIRADS 5. A statistically significant difference was found in cancer detection rates between lesion groups (p=0.0001). It was observed that as the PIRADS score of the lesion increased, the rates of cancer and clinically significant cancer detection increased (Table 4).

Discussion

At present, overdiagnosis and overtreatment of prostate cancer is still discussed and the most effective method for prostate cancer diagnosis remains unclear. It is thought that these uncertainties can be elucidated by the success of MRI in imaging of suspicious lesions, suggesting a clinically significant prostate cancer and the effectiveness of MRI-US fusion-guided biopsy for these lesions (16,17).

In this study, although there was no statistically significant difference in cancer and clinically-significant cancer diagnosis rates of CB and SB, CB had the highest cancer detection rate. We have seen that this success of CB is compatible with the literature (18,19).

Fourcade et al. (20) reported that the prostate cancer detection rate was 55.5% and the clinically significant cancer detection rate was 45%. CB was reported to have the highest rates and no statistically significant difference was found between the results of the TB and SB methods and as in our study. In the same research, patients with a serum PSA value >4 ng/mL were included and the mean serum PSA value was 9 ng/mL. More than half of the patients had PIRADS 5 lesions on the mpMRI. These may have caused the cancer and clinically significant cancer rates to be higher compared to our study. Additionally, unlike the rigid MRI-US fusion biopsy method in our study, performing biopsy with the elastic mpMRI/3D TRUS image fusion method, which was reported by a single experienced radiologist, may have provided more accurate targeting to the lesions (20).

In the literature, studies have reported that the CB and SB methods have statistically similar results as in our study (21). The lack of statistical difference in the results of these two methods can be attributed to the fact that statistical methods are very sensitive to the sample size. Results can be expected to be more meaningful in studies with more patients. Additionally, depending on the fact that biopsy methods are performed by the same physician consecutively, knowing which area is suspicious during standard biopsy may have caused it to be taken like a kind of cognitive biopsy. This may cause the BP and SB results to be similar.

Alternatively, it was observed that there was no statistically significant difference in both cancer detection and clinically-significant cancer diagnosis between TB for which less than 12 cores were taken and the SB methods. This leads to the idea of fewer complications with fewer cores and the same results.

Table 4. Pathology results of cores taken by targeted biopsy from PIRADS 3, 4 and 5 lesions				
PIRADS score	**3 n (%)**	**4 n (%)**	**5 n (%)**	**Total n (%)**
Number of cores	138 (100%)	47 (100%)	8 (100%)	193 (100%)
PCa (-)	130 (94.3%)	25 (53.2%)	0 (0)	155 (80.3%)
PCa (+)	8 (5.7%)	22 (46.8%)	8 (100%)	38 (19.7)
Clinically-significant PCa	2 (1.4%)	11 (23.4%)	8 (100%)	21 (10.8%)
Clinically-insignificant PCa	6 (4.3%)	11 (23.4%)	0 (0)	17 (8.8%)
PIRADS: Prostate imaging-reporting and data system, PCa: Prostate cancer, p=0.0001				

It is thought that the use of MRI-US fusion- TB alone can be discussed.

In a study involving 382 patients, a 15% increase was observed in the diagnosis of clinically-important cancer with the addition of TB, while 62% of tumors missed using this method were found to have clinical-insignificant cancer criteria (22). In our study, TB contributed to a standard method at similar rates in detecting clinically-important cancer. In patients in whom TB could not detect cancer, clinically-insignificant cancer was detected with SB at a similar rate. Additionally, in our study, it was observed that not performing SB would cause cancer to not be detected in 12 (7.4%) patients and clinically significant cancer to be missed in 6 (14.8%) patients.

There are studies reported that TB is superior to SB in the diagnosis of clinically important cancer (23,24,25). Rouvière et al. (26) evaluated CB as a potential improvement in diagnostic methods. Future studies with large numbers of subjects may suggest that only MRI-targeted biopsies may be performed in selected patients.

To determine the treatment options by the actual diagnosis, the true Gleason score, and therefore the actual risk classes; it may be possible by performing a biopsy from the correct lesion. In prostate cancer imaging and the biopsy, the main purpose is to detect clinically-important diseases (27,28).

In the meta-analysis conducted by Gayet et al. (29), considering the studies in which sub-analyzes were performed on the basis of lesions, lesions were grouped as low risk and medium-high risk; PIRADS 3 lesions were considered low risk, and PIRADS 4-5 lesions were considered medium-high risk. Because of this grouping, it was seen that the highest clinically-significant cancer rates were in the medium-high risk group.

Similar to the literature, when we retrospectively examined our biopsy results, cancer and clinically significant cancer levels were significantly increased in patients with a PIRADS ≥4 scored lesion; however, in our study, no difference was found between the biopsy methods applied to patients in this group (20).

However, statistical differences between the methods were found only in patients with PIRADS 3 lesions. In 10 (9.3%) patients, it was observed that CB provided additional benefit in diagnosis compared with the use of SB or TB alone. This statistical superiority makes us think of the CB method as the preferred method, especially for PIRADS 3 lesions.

High rates of cancer and clinically-significant cancer, especially in patients with PIRADS ≥4 lesions, suggest that the PIRADS scoring is a high-level guide in detecting malignancy. In the PROMIS study, it was shown that prostate biopsies can be safely avoided in a quarter of men when mpMRI is used as a triage test. It has also been reported that it gives confidence in the unnecessary diagnosis of clinically-insignificant cancers and the diagnosis rates of clinically-important cancers (23). MpMRI can assist in pre-biopsy risk classification and provide guidance in the decision of biopsy and method selection for detecting high-risk disease considering these findings.

Study Limitation

MRI-US fusion biopsy method, which is a new technology still under development, requires a certain time of learning and experience for optimum results. The limited sample size of the patients in our study, including our first experiences, may have caused the results to be affected by the learning curve process. These two reasons were the limitations of our study.

Conclusions

Among men undergoing biopsy for suspected prostate cancer, combined prostate biopsy, compared with other biopsy methods, was associated with a higher incidence detection of prostate cancer and increased detection of clinically significant disease. High rates of clinically significant cancer, especially in patients with PIRADS ≥4 lesions, suggest that the PIRADS scoring is a high level guide in detecting malignancy. Future studies will be needed to assess the ultimate clinical implications of TB.

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Ethics

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Authorship Contributions

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