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Does Experience Affect the Cancer Detection Rate in Cognitive Fusion Prostate Biopsy? A Comparison of the First and Last 60 Cases

Kognitif Füzyon Prostat Biyopsisinde Deneyim Kanser Tespit Oranını Etkiliyor Mu? İlk ve Son 60 Vakanın Karşılaştırılması

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Abstract

Objective: We aimed to determine the contribution of the clinical experience gained in cognitive fusion prostate biopsy with the increase in the number of cases to the cancer detection rate.

Materials and Methods: The records of 120 patients who underwent cognitive fusion biopsy were retrospectively analyzed. All patients underwent 3-T multiparametric magnetic resonance imaging (Mp-MRI) and they were evaluated with Prostate Imaging Reporting and Data System (PIRADS). The initial 60 cases were included in group 1, and the later subsequent 60 cases performed by the same surgeon were included in group 2. Any cancer and clinically significant prostate cancer (CSPrCa) detection rates in groups 1 and 2 were compared.

Results: The mean ages of the patients for group 1 and group 2 were determined as 64.08 ± 8.15 and 65.15 ± 6.93 years, respectively. Age, prostate specific antigen (PSA), prostate volumes and the number of suspicious lesions of the groups were similar. Any cancer positivity rate was 33.3% for group 1, and 40% for group 2, without any significant intergroup difference (p=0.494). CSPrCa positivity was 40% and 70.83% for groups 1 and 2, respectively, and there was a significant improvement in CSPrCa detection in favor of group 2 (p=0.027).

Conclusion: Regarding the cognitive fusion biopsies, a learning curve is required. It was concluded that the rate of detecting clinically significant prostate cancer was almost doubled with the increased experience in fusion biopsy.

Keywords: Biopsy, Cognitive Fusion, Learning Curve, Magnetic Resonance İmaging, Prostate Cancer

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Öz

Amaç: Bilişsel füzyon prostat biyopsisinde elde edilen klinik deneyimin vaka sayısındaki artışla birlikte kanser tespit oranına katkısını belirlemeyi amaçladık.

Gereç ve Yöntemler: Kognitif füzyon biyopsisi yapılan 120 hastanın kayıtları geriye dönük olarak incelendi. Tüm hastalara 3-T multiparametrik manyetik rezonans görüntüleme (Mp-MRG) yapıldı ve Prostat Görüntüleme Raporlama ve Veri Sistemi (PIRADS) ile değerlendirildi. İlk 60 vaka grup 1'e dahil edildi ve daha sonra aynı cerrah tarafından gerçekleştirilen sonraki 60 vaka grup 2'ye dahil edildi. Herhangi bir kanser ve klinik olarak anlamlı prostat kanseri (CSPrCa) tespit oranları grup 1 ve 2'de karşılaştırıldı.

Bulgular: Grup 1 ve grup 2 hastaların yaş ortalamaları sırasıyla 64.08 ± 8.15 ve 65.15 ± 6.93 yıl olarak belirlendi. Grupların yaş, prostat spesifik antijen (PSA), prostat hacimleri ve şüpheli lezyon sayıları benzerdi. Herhangi bir kanser pozitifliği oranı grup 1 için %33.3 ve grup 2 için %40 idi ve gruplar arası anlamlı bir fark yoktu (p=0.494). Grup 1 ve 2 için CSPrCa pozitifliği sırasıyla %40 ve %70.83 idi ve CSPrCa tespitinde grup 2 lehine anlamlı bir gelişme vardı (p=0.027).

Sonuç: Bilişsel füzyon biyopsileri ile ilgili olarak bir öğrenme eğrisi gereklidir. Füzyon biyopsisinde artan deneyim ile klinik olarak anlamlı prostat kanseri tespit oranının neredeyse iki katına çıktığı sonucuna varıldı.

Anahtar Kelimeler: Biyopsi, Kognitif Füzyon, Öğrenme Eğrisi, Manyetik Rezonans Görüntüleme, Prostat Kanseri

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Introduction

Prostate cancer was reported to be the second most common cancer in men and ranked fifth among the causes of cancer related deaths all over the world (1). Increased prostate specific antigen (PSA) levels or detection of induration in digital rectal examination (DRE) cause suspicion of prostate cancer. Transrectal ultrasonography (TR/US) guided systematic prostate biopsies are cornerstone for the histological diagnosis of prostate cancer. First in 1989, random TR/US-guided systematic six-core (sextant biopsy) prostate biopsy was described. Up to know, saturation biopsies with 20 cores have been started to be performed (2). Contemporarily, standard TR/US guided prostate biopsies usually includes 12 cores.

TR/US-guided 12 core systematic prostate biopsies have the advantage of lower cost and faster implementation. However, there are serious limitations such as detection of excessive and clinically insignificant prostate cancer (CISPrCa), unnecessary overtreatment, lower detection rates of clinically significant prostate cancers (CSPrCa), and false negativity (3). In order to avoid these limitations, with developments in magnetic resonance imaging (MRI) recently, multiparametric prostate MRI (Mp-MRI) targeted biopsies have been started to be performed. The latest European Urology guidelines strongly suggest MRI even for biopsy naive patients and a combined targeted and systematic biopsy is recommended when there is a suspicious lesion on MRI (4).

Cognitive targeted biopsy (COG-TB) where biopsies are obtained from suspicious lesions which are determined priorly by Mp-MRI (5). Therefore, in COG-TB technique the surgeon should interpret MRI and can locate the suspicious areas pre-described on MRI during TR/US imaging. Consequently, of the surgeon performing the biopsy plays an important role in the success of cognitive biopsy. As with all new surgical techniques, there must be a learning curve for cognitive biopsy which is an operator dependent approach. This learning curve includes identifying lesions in TR/US, determining the lesions or region of the lesions detected in MRI, and taking samples from appropriate areas during biopsy. As the experience of the surgeon increases, the chance of proper sampling may increase even more. There is a study in the literature on the learning curve for prostate biopsy under the guidance of Magnetic Resonance Imaging / Ultrasound Fusion (6). However, there is no data showing to what extent the learning curve is necessary for cognitive targeted biopsy (COG-TB).

In this study, the first and the last 60 cases of COG-TB performed by the same surgeon experienced in standard TR/US guided biopsies were evaluated in two groups. The aim of this study was to determine the effect of increasing clinical experience with the increase in the number of cases on the detection rate of any prostate cancer and CSPrCa. In addition, it was aimed to determine the relationship between Prostate Imaging Reporting and Data System version 2 (PIRADS v2) score and lesion size detected in Mp-MRI and cancer rates determined in both groups.

Materials and Methods

The records of 144 patients who underwent COG-TB between July 2018 and February 2021 were analyzed retrospectively. Patients with high PSA or suspicious for prostate cancer in DRE were included in the study. Patients with suspected lesions in Mp-MRI taken before biopsy were included in the study. Patients for whom MRI was contraindicated (n=6), patients with extensive hard nodules in their prostate (n=7), and patients with a previous history of negative biopsy (n=11) were excluded from the study. This study was conducted in accordance with the Helsinki Declaration, and approval was obtained from the ethics committee of our institution (Biruni univesity Register No: 2018 /15–13). Written consent was obtained from the participants.

Mp-MRI was performed on all patients before the biopsy procedure (GEHealthcare 3T MRI units; PioneerSigna MLG, Japan). MRI images were examined by highly an experienced genitourinary radiologist (16 years of experience), and suspicious lesions were identified and PIRADS v2 scoring was performed (7). After the surgeon performing the prostate biopsy was informed by the radiologist, the biopsy procedure

was realized. All Mp-MRIs were evaluated by the same radiologist and all COG-TBs were performed by the same urologist. The urologist renewed the Mp-MRI scans immediately prior to the biopsy. According to the order of biopsies performed, the first 60 patients were included in the group 1 and the last 60 patients in the group 2.

TR/US probe (4-9 MHz endorectal probe, Toshiba, Japan) was inserted rectally to determine the lesions described in Mp-MRI. After two core biopsies per lesion in regions containing suspicious lesions in Mp-MRI were obtained, 12-core systematic TR/US biopsies were performed. Biopsy results in both groups were compared in terms of detecting any cancer and whether the cancer detected was CSPrCa. The cores taken with COG-TB were also examined and the detection rates of CSPrCa were compared between the groups. Again, according to the PIRADS v2 scoring system and the size of the lesion in the MRI taken before biopsy, any rates of cancer and CSPrCa detected were compared between the groups. Since there is no consensus on the definition of CSPrCa, we chose one of the frequently used definitions and determined our CSPrCa rates. Those with a Gleason score (GS) of ≥7 or GS 6 with a tumor length of more than 5 mm in any of the cores were considered as CSPrCa (8).

SPSS program was used for statistical evaluation. Descriptive statistical methods, as well as chi-square tests and Mann–Whitney U-test were used to evaluate the data. P <0.05 was considered statistically significant. This study was conducted in accordance with the Helsinki Declaration, and approval was obtained from the ethics committee of our institution (Register No: 2018 /15–13).

Results

Hundred and twenty patients out of a total of 144 cases (Group 1 n=60, Group 2 n=60) who were screened during the study were included in the study. The mean ages of the patients for Group 1 and Group 2 were determined as 64.08±8.15 and 65.15±6.93 years, respectively. Mean serum PSA values were 7.49±2.99 ng/mL in Group 1, and 7.61±3.07 ng/mL in Group 2. Mean prostate volumes were found as 68.48±28.4 and 67.54±38.3 g in Groups 1 and 2, respectively. Age, PSA and prostate volumes of the groups were similar.

Similarly, the suspicious lesion rate (PIRADS>3) was similar in both groups based on Mp-MRI examination (p=0.317). The mean PIRADS v2 scores in Mp-MRI for Groups 1 and 2 were 3.2±0.7 and 3.15±0.5, respectively. Again, the average maximum length of positive MRI lesions in Groups 1, and 2 were 14.97±3.2 mm and 13.27±2.1 mm, respectively (Table 1). The mean number of cores taken per patient were determined as 3.63±0.7 and 3.68±0.5 in Groups 1 and 2, respectively, without any difference between the groups (p = 0.811).

Any prostate cancer was detected in 20 patients (33.3%) in Group 1 and 24 patients (40%) in Group 2, without any statistically significant difference between the groups (p=0.444). Detection rates of CSPrCa were 40% (8/20 patients) and 70.83% (17/24 patients) in Groups 1 and 2, respectively, and there was a significant difference in favor of Group 2 (p = 0.027). The mean positive cancer core length was 4.37±0.2 mm in Group 1 and 6.25±0.9 mm in Group 2 (p = 0.452) (Table 2). The median Gleason scores were determined as 6.35 and 6.29 for Groups 1 and 2, respectively.

In Group 1, 2 of 8 patients diagnosed with CSPrCa had cancer in the cores taken only with COG-TB. In 4 cases, cancer was detected only in the cores taken with 12-core systematic TR/US biopsies. In the remaining 2 cases, CSPrCa was detected in the cores in both COG-TB and 12-core systematic TR/US biopsies. In Group 2, 6 of 17 patients diagnosed with CSPrCA had cancer in the cores taken only with COG-TB. In 5 cases, cancer was detected only in the cores taken with 12-core systematic TR/US biopsies. In the remaining 6 cases, cancer was detected in the cores in both COG-TB and 12-core systematic TR/US biopsies (Table 3). Cancer was detected with COG-TB in 4 (50%) patients in Group 1 and 12 (70.5%) patients in Group 2. This situation was found statistically significant for group 2 (p<0.001).

Radical prostatectomy was performed in 3 of 8 patients with CSPrCa in Group 1 in our institution. Tumor focus was found to be compatible with MRI and biopsy in one of 3 patients. While the other 2 patients had lesion/cancer in a single lob according to the both in MRI and biopsy results, histolological evaluation of radical prostatectomy specimens revealed tumor in both lobes. Similarly, 8 of 17 patients with CSPC in Group 2 underwent radical prostatectomy. Tumor focus was found to be compatible with COG-TB (positive MRI lesions and biopsy) and prostatectomy specimens of 4 patients. On the other hand, while MRI lesion and COG-TB result suggested single lob tumor; radical prostatectomy revealed bilateral cancer in other cases.

Table 1
Comparison of patient characteristics in Group 1 and Group 2

	Group 1 (n=60)	**Group 2 (n=60)**
Patient age (years)	64.08 ± 8.15	65.15 ± 6.93
	(Min 49 – Max:77)	(Min 51 – Max:79)
Serum PSA value (ng/mL)	7.49 ± 2.99	7.61 ± 3.07
	(Min 3.2 – Max:14)	(Min 3.5 –Max:16.8)
Prostate volume (gram)	68.48 ± 28.4	67.54 ± 38.3
	(Min 20 – Max:166)	(Min 16 – Max:210)
Mean PIRADS v2	3.2± 0.7	3.15± 0.5
PIRADS 2 (n)	16	19
PIRADS 3 (n)	20	17
PIRADS 4 (n)	22	18
PIRADS 5 (n)	2	6
Median Gleason score	6.35 ± 1.1	6.29± 0.9
Mean length of the lesion in the MRI (mm)	14.97 ± 3.2	13.27 ± 2.1

Data are presented as mean±standard deviation **Min**:Minimum **Max**:Maximum **n**: number of patients
MRI: Magnetic resonance imaging **PSA**: Prostate specific antigen **PIRADS**: Prostate Imaging Reporting and Data System

Table 2
Comparison of Biopsy Results and Complications Between Group 1 and Group 2

	Group 1 (n=60)	**Group 2 (n=60)**	**P Value**
Median number of cores taken per patient	3.63 ± 0.7	3.68± 0.5	0.811
Positive for any cancer (n)	20 (33.3%)	24 (40%)	0.449
Positive for clinically significant cancer (n)	8 (40%)	17 (70.83%)	0.027*
Mean positive cancer core length (mm)	4.37 ± 0.2	6.25 ± 0.9	0.452
Mean operation time (minutes)	11.1 ± 3.2	12.2 ± 4.1	0.147
Complications (n)	12 (20%)	9 (15%)	0.852
Hematospermia	4 (6.66%)	3 (5%)	
Infection	2 (3.33%)	2 (3.33%)	
Significant hematuria	2 (3.33%)	1 (1.66%)	
Urinary retention	2 (3.33%)	2 (3.33%)	
Sepsis	1 (1.66%)	1 (1.66%)	
Significant rectal bleeding	1 (1.66%)	-	

Data in parentheses represent percentages **n**: number of patients **mm**:milimetre *statistically significant

Table 3

Cancer detection method according to PIRADS scores in patients diagnosed with CSPrCa in Group 1 and 2

	PIRADS 3 (n)	PIRADS 4 (n)	PIRADS 5 (n)
Grup 1 (n=8)			
COG-TB*	1 (12.5%)	1 (12.5%)	-
TR/US-biopsy *	-	4 (50%)	-
Both COG-TB and TR/US-biopsy*	-	-	2 (25%)
Grup 2 (n=17)			
COG-TB*	1 (5.8%)	4 (23.5%)	1 (5.8%)
TR/US-biopsy *	-	5 (29.4%)	-
Both COG-TB and TR/US- biopsy *	1 (5.8%)	2 (11,7%)	3 (7.6%)

*Detection method n: number of patients Data in parentheses represent percentages
CSPrCa: Clinically significant prostate cancers PIRADS: Prostate Imaging Reporting and Data System
COG-TB: Cognitive targeted biopsy TR/US: Transrectal ultrasonography

Table 4

The Detection Rates of Any Cancer and CSPrCa Between Groups According to PIRADS Scores and Lesion Sizes Determined in MRI

	Grup 1	Grup 2	P value
Positive for any cancer	**n=20**	**n=24**	
According to PIRADS score			
PIRADS 2	1/20 (5%)	2/24 (8,33%)	0,091
PIRADS 3	9/20 (45%)	3/24 (12,5%)	0,013*
PIRADS 4	8/20 (40%)	15/24 (62,5%)	0,009*
PIRADS 5	2 /20 (10%)	4/24 (16,67%)	0,865
According to the size of the MRI lesion			
≤5	1/20 (5%)	3/24 (12,50%)	0,35
6-15mm	12/20 (60%)	14/24 (58,33%)	0,671
>15 mm	7/20 (35%)	7/24 (29,17%)	0,087
Positive for CSPrCa*	**n=8**	**n=17**	
According to PIRADS score			
PIRADS 2	-	-	
PIRADS 3	1/8 (12,5%)	2/17 (11,76%)	0,994
PIRADS 4	5/8 (62,5%)	11/17 (64,71%)	0,654
PIRADS 5	2/8 (25%)	4/17 (23,53%)	0,347
According to the size of the MRI lesion			
≤5	-	-	
6-15mm	4/8 (50%)	10/17 (58,82%)	0,121
>15 mm	4/8 (50%)	7/17 (41,18%)	0,098

Data in parentheses represent percentages n: number of patients *statistically significant
CSPrCa: Clinically significant prostate cancers
COG-TB: Cognitive targeted biopsy
MRI: Magnetic resonance imaging
PIRADS: Prostate Imaging Reporting and Data System
TR/US: Transrectal ultrasonography

When patients were categorized according to PIRADS v2 scores, in terms of any prostate cancer detection rates, a statistically significant difference was found in favor of Group 1 in patients with PIRADS 3 scores and in favor of Group 2 for patients with PIRADS 4 scores (p = 0.013). There was no significant difference between the groups in terms of detecting any cancer in patients with PIRADS 2 and PIRADS 5 scores. Again, PIRADS scores did not show a statistically significant difference between the groups in terms of detecting CSPrCa between patients with PIRADS 2-3-4 and 5 scores (p=0.994), (Table 4). When patients with established prostate cancer were categorized according to the lesion diameter detected in MRI there was no significant difference between the groups in terms of any cancer and CSPrCa detection rates (p = 0.671) (Table 4). The complication rate was 20% in group 1 and 15% in group 2. The complications and their rates are summarized in table 2. There was no significant difference between the groups in terms of complications (p = 0.852).

Discussion

In the presence of suspected prostate cancer, mostly a standard prostate biopsy from 10 to 14 cores performed under TR/US guidance (9). However, in systematic TR/US-guided prostate biopsies cancer detection rates have been reported to range between 27% and 44% (10). In order to detect prostate cancer that cannot be sampled especially with standard biopsy techniques, parallel to the developments in MRI, prostatic Mp-MRI has been started to be performed. Then, MRI targeted prostate biopsies were started to be realized and added to the standard systematic TR/US random biopsies.

Although it is reported that in prostate fusion biopsies fewer cores are sampled than standard TR/US biopsies and detection rate of clinically significant cancers is increased by 30% these methods are both costly and time consuming (11). COG-TB has a lower cost and applied faster which is the most important advantage of cognitive biopsy. However, the success rate should depend on the experience of the operator. Especially small and isoechoic lesions detected in Mp-MRI are often overlooked in TR/US. Therefore, multiple core biopsies are taken from the area where suspicious lesions are detected in MRI, and a cognitive fusion biopsy is performed (12). Venderik et al. have reported that anatomical landmarks as cysts, calcifications, gland contours could be used as internal reference points to target the lesion during biopsy. In the same study, the authors stated that large lesions in the peripheral region of the prostate that appear as hyperintense lesions in the MP-MRI T2-weighted imaging can be easily identified in the ultrasound images. In such cases, they reported that it is unnecessary to target such lesions with MRI in-bore targeted biopsies or MRI-ultrasonography fusion targeted biopsies, which is relatively more costly and COG-TB would be sufficient in such cases (13).

Although biopsies performed using MRI in-bore and MRI-ultrasonography fusion have been reported to be more advantageous than cognitive fusion, there was no statistically significant difference in detection rates of any prostate cancer or CSPrCa between the three techniques (14). In their study Wysock et al., reported that there was no significant difference in cancer detection rates among patients whom they applied MRI-ultrasonography fusion and COG-TB, but cancer detection rate was higher in MRI-ultrasonography fusion when small lesions were targeted (15). In the PRECISION study, it was reported that fusion biopsies performed in biopsy-naive patients had a higher rate of clinically significant cancer detection rate compared to standard biopsy (16). Also in the recent PROMIS study, Ahmet et al. reported that Mp-MRI, which was used as a triage test before biopsy in biopsy-naive patients, can reduce unnecessary biopsies by a quarter, as well as reduce the overdiagnosis of CISPrCa and increase the detection rate of CSPrCa (17). At another study, Acar et al. reported cancer detection rate of 55.1% using COG-TB and 70.3% of these cases were CSPrCa (18). In conclusion, all of studies postulated that MRI targeted biopsies have a better success particularly for CSPrCa. However, the type of MRI targeting does not significantly differ regarding CSPrCa rates. Therefore, COG-TB is currently a reasonable cost-effective technique in tissue sampling for prostate cancer.

The major drawback of COG-TB is that this modality is operator dependent. There is no strict standards and no accurate biopsy and target location documentation. Therefore there should be a learning curve as in all invasive procedures. The only study on the learning curve in the literature has been reported for Magnetic Resonance Imaging / Ultrasound Fusion guided prostate biopsy (6). In this study, it was emphasized that greater experience is required for a better sampling. However, there is no data showing to what extent the learning curve is necessary for cognitive targeted biopsy (COG-TB). In our study, the cancer detection rate was 33.3% in the first 60 cases, while it was 40% in the last 60 cases. No statistically significant difference was observed in any cancer detection rate between the groups. However, CSPrCa detection rate rate was found to be statistically significantly higher in Group 2. The change of detecting CSPrCa was increased from 40% to 71% in the second group after 60 cases. Similarly, although the number of patients who underwent radical prostatectomy after biopsy was low, biopsy results in Group 2 were found to be more compatible with radical prostatectomy results. With the increase of the number of COG-TB performed by the surgeon, it was seen that the rate of detecting CSPrCa increased. Our results suggest that a learning curve is essential get a better CSPrCa detection rate.

Regarding the size of the MRI lesion, Yamada et al. did not find a significant difference between MRI-ultrasonography fusion and COG-TB in terms of detection rates of any cancer and CSPrCa based on their classification of the size of the suspicious lesions identified in MRI (5). In our study, although greater number of cancerous lesions were detected in Group 2 when the lesion length was ≤5 mm in the MRI taken before biopsy, this was not statistically significant. In cases where the lesion was> 5 mm, there was no difference between the groups in terms of any cancer detection rate. Also, we could not detect CSPrCa in cases with ≤5 mm lesions. Again consistent with previous studies, our CSPrCa detection rates increased in patients with higher PIRADS scores (18).

Some limitations of our study should also be considered. Among these limitations are the retrospective nature of the study and the small number of patients. In addition, the fact that radical prostatectomy could not be performed on all eligible patients and therefore pathological examination of the prostate specimen was not performed, is another limitation of our study.

Conclusion

In cognitive fusion biopsies, one of the most important factors for the location of the lesion on ultrasound and sampling from the appropriate area is the surgeon's experience; since this is a subjective operator dependent modality. The present study has indicated for the first time that the detection rate of clinically significant cancers increased in line with accumulated experience in cognitive fusion biopsy technique. We observed almost doubled ratio of significant prostate cancer after a learning curve of about 50 cases.

Ethics Committee Approval: This study was conducted in accordance with the Helsinki Declaration, and approval was obtained from the ethics committee of our institution (Biruni univesity Register No: 2018 /15–13).

Informed Consent: Written consent was obtained from the participants.

Conflict of Interest: Authors declared no conflict of interest.

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