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Does total biopsy core length in prostate fusion biopsy affect the diagnosis of clinically significant prostate cancer?

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Abstract

Aim: The aim of our study was to determine the optimal total core length for multiparametric magnetic resonance imaging (MpMRI)-guided prostate fusion biopsy (PFB) that would standardize clinical practice and maximize the detection rate of clinically significant prostate cancer (csPC) while reducing procedural complications, overdiagnosis, and cost.

Materials and Methods: A total of 212 patients with at least 1 lesion with Prostate Imaging Reporting and Data System score of ≥3 were evaluated retrospectively. Biopsy core lengths from the lesions were summed, and total core lengths (TCL) were calculated. Multiple logistic regression analyses were conducted for PIRADS 3, 4, and 5 lesions and the effects of TCL on the detection of csPC were analyzed separately.

Results: A total of 365 lesions were detected by MPMRI in 212 men included in the study. The mean TCL was 43.66 ± 12.91 mm in PIRADS 3 lesions, 47.71 ± 11.78 mm in PIRADS 4 lesions, and 60.36 ± 14.64 mm in PIRADS 5 lesions. As TCL increased, the probability of detecting both csPC (1.26-fold per unit increase in TCL) and clinically insignificant prostate cancer (cIPC)(1.25-fold per unit increase in TCL) increased for PI-RADS 3 lesions at a statistically significant level,while for PIRADS 4 lesions, only the probability of detecting csPC (1.13-fold for each unit increase in TCL) increased.

Conclusion: This study has shown that the frequency of PCa detection rises with increasing TCL. For PI-RADS 3, both csPC and cIPC rise with increasing TCL, whereas for PI-RADS 4 only the frequency of csPC rises.

Introduction

Multiparametric magnetic resonance imaging (MpMRI)-guided prostate fusion biopsy (PFB) has recently become the standard approach in patients with suspected prostate cancer. Compared with transrectal ultrasonography-guided systematic prostate biopsy (TRUS-Bx), PFB is more effective in detecting clinically significant prostate cancer (csPC) [1]. For this reason, MpMRI is recommended by the European Association of Urology (EAU) Guidelines for all patients with an indication for prostate biopsy [2]. Although there are recommended core numbers for biopsies to be taken from lesions detected on MpMRI, there is no standard TCL.

According to the American Urological Association (AUA) Guidelines, it is recommended to take more than 2 biopsies from lesions to diagnose prostate cancer (PCa) [3]. It has been shown in many studies that increasing core numbers help diagnose more Pca [4-6]. Additionally, it has been argued that it is unnecessary to take more than three biopsies of csPC lesions [7]. The effect of core lengths in prostate biopsy on the diagnosis of Pca is controversial. Some publications are suggesting that it does not affect the detection of PCa [8] as well as those claim that it increases the frequency of diagnosis [9-11]. The effect of the core lengths of the biopsies taken from the lesions during PFB for lesions detected on MpMRI on the diagnosis of csPC is not known.

A guideline called 'Prostate Imaging Reporting and Data System' (PI-RADS) was developed by the European Society of Urogenital Radiology (ESUR) in 2012 to standardize MpMRI evaluation and reporting and was updated in 2019 [12,13]. The risk of csPC was considered 'very low' for PI-RADS 1, 'low' for PI-RADS 2, 'high' for PI-RADS 4, and 'very high' for PI-RADS 5. For PI-RADS 3 lesions, it was stated that 'the presence of clinically significant prostate cancer is uncertain' [13]. In our study, we separately examined the effect of total core lengths of biopsies from PI-RADS 3, PI-RADS 4, and PI-RADS 5 lesions on the diagnosis of csPC. The study aimed to determine the

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optimal TCL for MpMRI-guided PFB that would standardize clinical practice and maximize the rate of csPC detection while reducing procedural complications, overdiagnosis, and cost.

Materials and Methods

Study design

This study was designed as a retrospective review of the data of 212 patients who underwent MpMRI-guided PFB in the Urology Clinic of Yuksek Ihtisas University Memorial Ankara Hospital between 2017 and 2020. The lengths of biopsy cores taken from PI-RADS 3, 4, and 5 lesions detected on MpMRI were collected separately for each lesion, and the effect of total core length on the diagnosis of csPC was analyzed. A power analysis was conducted for the minimum sample size and a total of 159 individuals were found to be adequate (power analysis conditions; effect size = .25, α = .05, 1-β = .80). This study was approved by the ethics committee of Omer Halisdemir University (Decision no: 2023/23).

Data selection

All patients who underwent biopsy for the first time and those who had previously undergone biopsy were included in the study. Clinically, age, total PSA, and prostate volume, radiologically, number of lesions, PI-RADS classification (Since the study included patients from 2017 to 2020, the lesions on mpMRI were evaluated according to both PI-RADS version 2 and version 2.1 [13,14]), and pathologically, the International Society of Urological Pathology [ISUP] grade group [GG] was used [15]. Clinically significant cancer was described as ISUP GG $\geq$ 2. Those with ISUP GG = 1 are defined as clinically insignificant prostate cancer (cIPC). Systematic biopsy data after PFB were excluded from the study. The inclusion criteria were as follows: (i) having undergone 3-T mpMRI, and (ii) having a lesion with a PI-RADS v2 score of 3. Exclusion criteria were (i) no 3-T mpMRI (ii) any contraindication for MRI, and (iii) no PFB results.

Multiparametric magnetic resonance imaging guided prostate fusion biopsy and pathology

Mp-MRI/TRUS fusion biopsy was performed by a single urologist under the guidance of an UroNAV device and General Electronic Ultrasonography (USG). Periprostatic nerve blockade was performed in all patients with a 22-gauge needle and 10 ml of lidocaine. For each lesion, we did 3-7 cores biopsy with an 18-gauge biopsy needle from the lesions drawn by synchronizing the MpMRI and USG images. Biopsy core lengths were collected separately for each lesion, and total core lengths were determined. 3.0T Discovery MR750 HDx was used for MpMRI. All MpMRI results were evaluated by a single radiologist with more than 10 years of experience in prostate MRI. All the pathology results were evaluated by a single pathologist with more than 10 years of experience in prostate cancer.

Statistical analysis

In the data analysis, firstly, descriptive statistical measures (frequencies and percentages) were shared. Binary and multinominal logistic regression analyses were conducted to determine the effect of TCL on csPC. In logistic regression analysis, the selection algorithm is taken as enter method. In addition, Kruskal Wallis-H test was conducted to compare the groups according to cancer diagnosis. Mann Whitney U test was used for significant differences. SPSS (version 25, SPSS Inc., Chicago, IL, USA), GPower (version 3.1.19) and Microsoft Office Excel software were used for data analysis. An alpha level of 0.05 was accepted for statistical significance.

Assumptions of logistic regression analysis;

1. Missing value and extreme value analysis: It was determined that there were no missing values during the data collection process, and the standardized values of the dependent variable were calculated and all values were within the range of ± 1.96.
2. Multicollinearity problem: It has been determined that there is no multicollinearity problem since there is a single independent variable within the scope of the research.
3. Model data fit: Chi square value was calculated for model data fit and it was determined that it was statistically significant, in other words the model was significant. After all assumptions were tested, data analysis was started.

Results

The baseline clinical, radiologic, and pathologic characteristics of the patients included in the study are presented in Table 1. For a total of 212 males, the mean age was 61.52 ± 7.83 years , PSA was 8.39 ± 6.61 ng/mL and prostate volume was 55.85 ± 26.11 mL. A total of 365 lesions, including 197 PI-RADS 3, 143 PI-RADS 4, and 25 PI-RADS 5, were detected by MPMRI in 212 males. The mean total biopsy core lengths were 43.66 ± 12.91 mm in PI-RADS 3 lesions, 47.71 ± 11.78 mm in PI-RADS 4 lesions, and 60.36 ± 14.64 mm in PI-RADS 5 lesions.

When Table 2 is examined, it is seen that PFB was performed for 212 patients. Pathology revealed 111 benign (52.4 %), 26 cIPC (12.3 %), and 75 csPC (35.4 %). PSA levels and the mean age of the patients diagnosed with csPC was found to be higher than the others ($p<0.001$). TCL was longer in csPC and CIPC patients ($p<0.001$).

After examining the socio-demographic variables of the participants, logistic regression analyses were conducted to investigate the effect of TCL on the diagnosis of csPC, which was the main objective of the study. Multinominal logistic regression analysis was used since the dependent variable had 3 categories in the logistic regression analysis.

PFB was performed for 197 PI-RADS 3 lesions. Pathology revealed 143 benign (72.6%), 43 cIPC (21.8%), and 11 csPC (5.6%). The effect of TCL on csPC in biopsies from PI-RADS 3 lesions was tested and the results are presented in Table 3. For PI-RADS 3, TCL appears to be effective on both csPC and cIPC compared to the referenced benign group ($p<0.001$). When Exp (B) values are analyzed, it is noticed that both values are very close to each other. Accordingly, for PI-RADS 3, if the TCL increases by one unit, the odds of finding a cIPC increase

Table 1. Values on socio-demographic characteristics of the patients.

Variables	Variable levels	f	%
Number of patients	One lesion	171	80.7
	Two lesions	36	17.0
	Three lesions	5	2.4
Total		212	100
Number of lesions	PIRADS 3	197	53.9
	PIRADS 4	143	39.2
	PIRADS 5	25	6.9
Total		365	100

Continuous Variables	N	min-max	Mean/Median	SD	Skew.	Kur.
Age (year)	212	44-87	61.52	7.83	.27	-0.02
PSA	212	1-57	6.50	6.61	3.74	19.52
PV	212	12-140	55.85	26.11	1.03	1.01
PIRADS 3 TCL (mm)	197	24-92	43.66	12.91	0.87	0.35
PIRADS 4 TCL (mm)	143	24-73	47.71	11.78	0.25	-0.70
PIRADS 5 TCL (mm)	25	33-93	60.36	14.64	-0.01	-0.10

Abbreviations: PI-RADS, Prostate Imaging Reporting and Data System; PSA, prostate specific antigen; PV, prostate volume; TCL, total core length.

Table 2. Comparison of the patients with all lesions according to their characteristics (N = 212).

Variable	Benign (1)	cIPC (2)	csPC (3)	p-value	Comparison (Bonferroni)
Number of patients	111 (52.4%)	26 (12.3%)	75 (35.4%)	–	
Age (year)	59.78±7.28	60.81±8.88	64.33±7.53	<0.001	3 > 1; 3 > 2
PSA	6.62±3.26	5.80±2.06	11.92±9.35	<0.001	3 > 1; 3 > 2
PV	57.82±27.34	48.08±23.48	55.63±24.87	<0.001	1 > 2
TCL (mm)	39.95±10.03	59.54±9.98	58.61±12.24	<0.001	2 > 1; 3 > 1

Note p = Anova Test. Abbreviations: PI-RADS, Prostate Imaging Reporting and Data System; PSA, prostate specific antigen; PV, prostate volume; TCL, total core length.

Table 3. Multivariable logistic regression analysis demonstrating the relationship between PIRADS 3 TCL and csPC .

Diagnosis (dependent variable)			B	Wald	p	Exp(B) (95% CI)
cIPC	Coefficient		-11.96	55.62	<0.001	1.25 (1.18-1.34)
	TCL		0.23	50.33	<0.001	
csPC	Coefficient		-13.76	36.64	<0.001	1.26 (1.17-1.37)
	TCL		0.23	31.79	<0.001	
Model fitness information		Cox& Snell R^2	Nagelkerke R^2	Model data fitness (Goodness-of-fit)		
Chi-square (fd)	136.01(2)	0.50	0.65	Chi-square (fd)		61.84 (88)
p	<0.001			p		0.985
Percentage of correct classification (%)						87.3

Reference group: Benign. Abbreviations: cIPC, clinically insignificant prostate cancer; csPC, clinically significant prostate cancer; PI-RADS, Prostate Imaging Reporting and Data System; TCL, total core length.

by 1.25 (95% CI: 1.18-1.34) times. Similarly, if TCL increases by one unit, the odds of finding a csPC increase by 1.26 (95% CI: 1.17-1.37) times. Accordingly, the higher the TCL for PI-RADS 3, the higher the odds of diagnosing both non-clinically significant and clinically significant prostate cancer. Furthermore, as a result of logistic regression, the probability of each value in the independent variable falling into the categories of the dependent variable was calculated and the cut-off value was found. This value was found to be 52.5. Accordingly, for PI-RADS 3, the odds of detection of csPC increase when TCL>52.5 mm.

PFB was performed for 143 PI-RADS 4 lesions. Pathology revealed 75 benign (52.4%), 8 cIPC (5.6%), and 60 csPC

Table 4. Multivariable logistic regression analysis demonstrating the relationship between PIRADS 4 TCL and csPC.

Diagnosis (dependent variable)			B	Wald	p	Exp(B) (95% CI)
cIPC	Coefficient		-2.77	2.62	0.106	1.01 (0.94-1.09)
	TCL		0.01	0.10	0.746	
csPC	Coefficient		-6.07	31.95	<0.001	1.13 (1.08-1.18)
	TCL		0.12	30.86	<0.001	
Model fitness information		Cox& Snell R^2	Nagelkerke R^2	Model data fitness (Goodness-of-fit)		
Chi-square (fd)	46.43(2)	0.28	0.34	Chi-square (fd)		70.19 (84)
p	<0.001			p		0.860
Percentage of correct classification (%)						69.9

Reference group: Benign. Abbreviations: cIPC, clinically insignificant prostate cancer; csPC, clinically significant prostate cancer; PI-RADS, Prostate Imaging Reporting and Data System; TCL, total core length.

(42%). TCL of biopsies obtained from PI-RADS 4 lesions was effective on csPC compared with the reference benign group ($p<0.001$), but not on cIPC ($p=0.746$) (Table 4). Accordingly, for PI-RADS 4, when the TCL increases by one unit, the odds of detecting a csPC increase by 1.13 (95% CI: 1.08-1.18) times. Hence, for PIRADS 4, as TCL increases the odds of diagnosing csPC will also increase. Furthermore, as a result of logistic regression, the probability of each value in the independent variable falling into the categories of the dependent variable was calculated and the cut-off value was found. This value was found to be 50.5. Accordingly, for PI-RADS 4, the odds of detecting csPC above 50.5 mm in TCL increase.

PFB was performed for 25 PI-RADS 5 lesions. Pathology revealed 1 benign (4%), 1 cIPC (4%), and 23 csPC (92%). It is noticed that the majority of patients with PI-RADS 5 lesions are diagnosed with csPC and very few are diagnosed as benign and with cIPC. It was found that the age, PSA, and prostate volume levels of the patients with the lesion type PI-RADS 5 were not statistically significant. When the difference according to the total biopsy core length was examined, it was found that it was not statistically significant.

Discussion

It is well-documented that MpMRI-guided targeted biopsy (PFB) is more effective than TRUS-Bx in the detection of csPC. The effect of total biopsy core length on the diagnosis of csPC, which is the aim of our study, has not been studied before. We found that increasing the total biopsy core length by taking more biopsies from the lesions increased the odds of detecting both csPC and cIPC in PI-RADS 3 lesions, whereas, in PI-RADS 4 lesions, it only increased the detection of csPC. Each unit increase in the total biopsy core length increased the frequency of detection of csPC 1.26-fold in PI-RADS 3 lesions and 1.13-fold in PI-RADS 4 lesions. This increase in frequency was evident for PI-RADS 3 lesions when the TCL $>$ 52.5 mm and for PI-RADS 4 lesions when TCL $>$ 50.5 mm. For PI-RADS 5 lesions, there was no significant correlation between TCL and csPC.

As the number of biopsies taken from the lesions increases, the total biopsy core length will naturally increase. Numerous studies report that more PCA can be detected with an increase in the number of cores [16-18]. Zhang et al. found in their study that the higher the number of cores, the more frequent csPC was detected [19]. Lu AJ. et al. reported in their study that taking 5 core biopsies from the lesion instead of 2 increased the detection rate of csPC [4]. Similarly, in our study, as the number of cores and total length of cores increased, csPC was found more frequently. Furthermore, for PI-RADS 3 lesions, the frequency of cIPC has increased as well. Some researchers disagree. Dimitroulis et al. reported that 89% Pca was detected in the first biopsy core taken from the lesion in PFB, and additional cores provided partial gain [20]. Moreover, Beetz et al. reported that taking 3 core biopsies from the lesion detected cancer in 97% of cases [21]. In the study by Çetin et al. taking 2 core biopsies from the lesion was found to be more effective in terms of detecting csPC than taking 1 core biopsy. However, taking 3 and 4 core biopsies did not contribute significantly [22]. Likewise, Leyh-Bannurah et al. found that taking 2 biopsies from the lesion was sufficient and only 8% of Pca was not detected [23]. In our study, we retrospectively analyzed the effect of the total lengths of the cores we obtained on the csPC. Since we did not put the cores in separate containers and did not evaluate them in order, we do not know the odds of detecting csPC in the first, second, or third core.

European Association of Urology guidelines and the European Randomized Prostate Cancer Screening Study pathology committee give the shortest acceptable core length at the time of biopsy as 10 mm [24]. In most studies for TRUS-Bx, an increase in core length increases the chance of Pca detection [9-11,25]. Dell-Atti et al. found the optimal core length to be 11.8 mm, Obek et al. 11.9 mm, and Fiset et al. 13 mm. There are also studies claiming that there is no relationship between core length and Pca [8,26,27]. On the other hand, total core lengths have not been studied in the literature. In our study, the increase in TCL significantly increased the frequency of detection of csPC. In our study, the odds of detecting a csPC were significant above 52.5 mm for PI-RADS 3 lesions and above 50.5 mm for PI-RADS 4 lesions. If we take the acceptable mean core length as 10 mm [24], we can say that the frequency of csPC increases significantly for 5 cores taken from the lesion and beyond.

Our study also has limitations. First, our study was ret-

rospective and nonrandomized. It includes data from a single institution. Patients who had undergone biopsy before and those who underwent biopsy for the first time were included in the study as a whole. Systematic biopsy data were excluded from the study. The sample size may not be relatively large enough. We did not evaluate the association between the number of biopsies, mean core length or the frequency of prostate cancer detection. TCL has not been studied before in the literature and there is a need for further studies with wider participation. Moreover, biopsy cores were not evaluated separately, but the core lengths were summed and the relationship between TCL and csPC was analyzed. For this reason, no information could be obtained about the relationship of each core with Pca. Nevertheless, our study, which is the first in the literature, has provided a high level of evidence for the optimal total length of biopsy cores to be taken from suspicious lesions detected by MpMRI.

Conclusion

Our study showed that as TCL increases, more csPC are detected. One unit rise in TCL increases the odds of detecting csPC 1.26 times in PI-RADS 3 lesions and 1.13 times in PI-RADS 4 lesions. Furthermore, this rise increases the odds of detecting csPC in PI-RADS 3 lesions by 1.25 times. This increase in the detection rate of csPC becomes evident when TCL $>$ 52.5mm for PI-RADS 3 lesions and PI-RADS 4 lesions when TCL $>$ 50.5mm.

Ethical approval

This study was approved by the ethics committee of Omer Halisdemir University (Decision no: 2023/23).

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