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# A Critical Analysis of the Magnetic Resonance Imaging Lesion Diameter Threshold for Adverse Pathology Features

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**Abstract:** To investigate the relationship between lesion size determined using multiparametric magnetic resonance imaging (mpMRI) and histopathological findings of specimens obtained after mpMRI fusion biopsy and radical prostatectomy (RP). We retrospectively analysed 290 patients with PCa who underwent an MRI fusion biopsy. We measured the diameter of suspicious tumour lesions on diffusion-weighted mpMRI and stratified the cohort into two groups. Group A included patients with a suspicious tumour lesion 10 mm and Group B included those with a suspicious tumour lesion > 10 mm. In Group B, the PI-RADS score determined in mpMRI was higher than Group A, and there was a statistically significant difference between the two groups in terms of clinical T-stage. The PCa detection rate and the number of positive cores were statistically significantly higher in Group B than in Group A. In addition, there was a statistically significant difference between the two

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groups in relation to the biopsy, the International Society of Urological Pathology (ISUP) grade values, and the presence of clinically significant PCa. In Group B, pathological T-stage and extraprostatic extension (EPE) and surgical margin (SM) positivity were found to be higher among the patients who underwent RP. In the multivariate analysis, the mpMRI lesion size being > 10 mm was found to be an independent predictive factor for SM and EPE positivity. The clinical results of this study support the modification of the lesion size threshold as 10 mm for use in the differentiation of PI-RADS scores 4 and 5.

## Introduction

Prostate cancer (PCa) is the most common cancer among males and the second most common cancer worldwide. PCa is divided into clinically significant (csPCa) and clinically insignificant tumours (cisPCa), and this differentiation is directly related to the survival of the patient (Epstein et al., 2016). Although the widespread use of serum prostate specific antigen (PSA) screening has led to a decrease in cancer-related deaths, it also results in a greater rate of cisPCa diagnosis and treatment (Schröder et al., 2014). The priority in the management of patients diagnosed with PCa is to accurately evaluate the presence of csPCa, effectively demonstrate the extent of the disease at the time of diagnosis, and predict the risk of progression (Schröder et al., 2014). For this purpose, multiparametric magnetic resonance imaging (mpMRI) has been increasingly used in recent years, extending the area of use of targeted biopsies and increasing accuracy rates in the differentiation of csPCa and staging (Turkbey et al., 2011). The Prostate Imaging Reporting and Data System (PI-RADS) scoring, which is used to classify and standardize findings defined in the prostate, facilitates the clinical use of mpMRI (Weinreb et al., 2016). Since the PI-RADS scoring used during the evaluation of mpMRI includes some subjective criteria, the sensitivity of the examination varies depending on the experience of the evaluating physician (Weinreb et al., 2016). This increases the importance of using parameters that can be standardized, such as prostate lesion size in order to increase the capacity of mpMRI in determining morphological and functional results, and the lesion size is considered to be correlated with clinical parameters (Lee et al., 2013).

In this study, we aimed to investigate the relationship between lesion size determined using mpMRI and histopathological findings of specimens obtained after mpMRI/transrectal ultrasound (TRUS) fusion biopsy and radical prostatectomy (RP).

## Material and Methods

*Patient selection and data collection*

After obtaining institutional review board approval (2021-258), we retrospectively reviewed the medical records of the patients who were admitted to the urology clinic of our hospital with the suspicion of PCa from January 2017 to June 2019. Inclusion criteria were (i) patients who underwent 3-T mpMRI, (ii) patients who had Prostate Reporting Imaging and Data System v2 (PI-RADS v2) ≥ 3 peripheral zone

lesion with PSA value > 4 ng/ml (iii) patients who had a PI-RADS 2 peripheral zone lesion with PSA value > 10 ng/ml and/or digital rectal examination (DRE) positivity. The exclusion criteria were absence of a 3-T mpMRI examination or the available mpMRI examination having non-diagnostic image quality, having any contraindication to MRI, and absence of fusion biopsy results. The patients included in the study and considered to be eligible for RP underwent robot-assisted laparoscopic RP (RALP) performed by two expert surgeons (S.Ş., A.İ.T.) using DaVinci Xi Surgical System® (Intuitive Surgical, USA). The clinical features of the patients, including age, PSA levels, PSA density (PSAD), prostate volume (PV), number of positive biopsy cores, the largest diameter of suspicious tumour lesions on diffusion-weighted MRI (DW-MRI), postoperative Gleason score, pathological stage, extraprostatic extension (EPE), surgical margin (SM) positivity, seminal vesicle invasion (SVI), and tumour volume were recorded. csPCa was defined according to the Epstein criteria (Epstein et al., 2016).

*Multiparametric MRI examination and image analysis*

mpMRI was performed using a 3.0-T MR unit (Verio; Siemens Medical Solutions, Germany) with a 16-channel pelvic phased array coil. Imaging sequences comprised thin-section turbo spin echo T2-weighted images (number of slices, 20; slice thickness, 3 mm with no intersection gap; TR/TE, 5800/100 ms; number of signals acquired, 2; and resolution, 0.8×0.8 mm) in the transverse, sagittal and coronal planes. DW images were obtained using multiple b-values (b-factor, 50/500/1000/1500 s/mm$^2$; number of slices, 20; slice thickness, 3 mm; TR/TE, 3900/75; and resolution, 1.4 mm × 1.4 mm) in the transverse plane and apparent diffusion coefficient maps were constructed from the b50, b100, b1000 and b1500 images by utilizing SyngoVia WorkStation software. Dynamic contrast-enhanced (DCE)-MRI sequences (T1 high-resolution isotropic volume with fat suppression) obtained after the administration of a gadolinium injection (slice thickness, 3 mm; intersection gap, none; TR/TE, 5.08/1.77; resolution, 1.4 mm × 1.4 mm, contrast agent injection started 24 seconds after first acquisition; temporal resolution, 8 seconds; total DCE time, 200 seconds; and number of dynamic time points). The categories determined according to the probability of the csPCa is existed. PI-RADS 2 score is defined as a csPCa unlikely to be present, PI-RADS 3 is equivocal and PI-RADS 4, 5 results were considered as a malignancy is likely to be present. We stratified the study cohort into two groups using a tumour diameter of 1 cm. Group A consisted of patients with normal MRI findings or a suspicious tumour lesion of 1 cm (Figure 1).

*Biopsy protocol*

Biopsies were performed with the Toshiba (Japan) Aplio-500 Platinum image fusion system. Regions suspicious for malignancy on mpMRI (targeted lesions) were sampled with two cores. This was followed by standard 10-core systemic biopsy. Each biopsy was performed by the same experienced radiologist (R.T.).

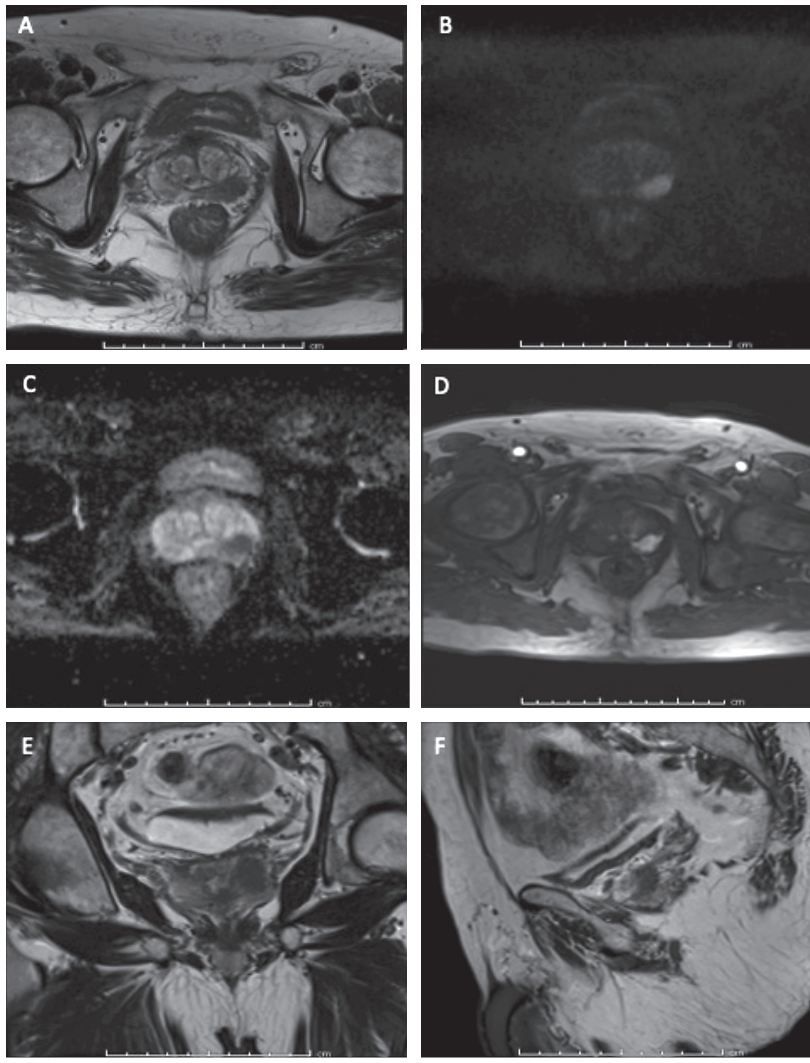


*Figure 1 – T2 weighted images of a patient with history of high PSA (prostate specific antigen) values (4.8 ng/ml). There is a lesion on left peripheral zone which is hypointense on axial T2 weighted image (A) and showing diffusion restriction (B and C) and early arterial enhancement (D). The lesion was reported as PI-RADS 5 and largest dimension of lesion was delineated and measured better on coronal T2 sequence (E) than sagittal (F) and axial (A) T2 weighted images. After biopsy, the histopathological result was Gleason 4 + 5.*

*Histopathological analysis*

The histopathological analysis of the biopsy materials was performed by an experienced uropathologist (F.T.). The reports were structured in accordance with the 2016 the International Society of Urological Pathology (ISUP) Gleason grading system (Epstein et al., 2016). The pathological long-axis diameter of the lesion on

the specimens and the biopsy core numbers for the pathologic lesions were also recorded.

The RP specimen's features were recorded. After separating the seminal vesicles from the specimen, 2 mm-thick slices were taken from the apex and bladder neck for the SMs of the apex and bladder neck. The remaining prostate tissue was sliced at 4–5 mm thickness, starting from the apex. All the slices were mapped as right, left, anterior and posterior, and each quadrant was processed with a separate block. Then, all the seminal vesicles separated into right and left were processed with cross-sections. Routine hematoxylin-eosin stained sections with a thickness of 4 micrometers were examined under a microscope after 12 hours of routine tissue processing.

In addition to the SMs of the apex and bladder neck, the anterior, anterolateral, posterior and posterolateral SMs were evaluated, and the tumour quadrants were marked and mapped. All the tumour-containing blocks were examined and graded according to the 2016 ISUP consensus (Schröder et al., 2014). The prognostic parameters of tumours included in RP reports were as follows: perineural invasion, lymphovascular invasion, SVI, EPE, tertiary pattern if present, ratio of secondary pattern to tumour, diameters of predominant tumours, ratio of tumour tissue to the whole prostate, presence/absence of prostate incision, presence/absence of prostate incision, and involvement of lymph nodes, if any. In addition, the presence of intraductal involvement in tumours was investigated and reported. Mostly, the diagnosis of acinar type adenocarcinoma and the presence and rate of ductal differentiation were also noted.

*Statistical analysis*

Statistical analysis was performed using SPSS v. 15.0 for Windows. Categorical variables were given as numbers and percentages. The conformance of continuous data to a normal distribution was evaluated using the Shapiro-Wilk test. The independent *t*-test was used for the comparison of groups with a normal distribution, and the Mann-Whitney U test was used for the comparison of groups that did not comply with a normal distribution. In the comparison of categorical variables, the Pearson chi-square and exact tests were used as appropriate. Parameters with a possible predictive value associated with EPE and positive SM were evaluated using univariate and multivariate logistic regression analyses. A p-value of $< 0.05$ was considered statistically significant.

## Results

A total of 290 patients were stratified into Group A (n=144) and Group B (n=146). The mean age of the patients was 63.9 ± 7.9 years, and the median PSA value was 6.49 ng/dl (range: 4.7–9.5 ng/dl). According to the mpMRI examination, 17 (5.9%) cases were evaluated as PI-RADS 2, 77 (26.6%) as PI-RADS 3, 165 (56.9%) as PI-RADS 4, and 31 (10.7%) as PI-RADS 5. The fusion biopsy results revealed

the detection rates of ISUP Grade 1, 2, 3, 4 and 5 to be 65 (22.4%), 51 (17.6%), 34 (11.7%), 13 (4.5%), and 6 (2.1%), respectively. RALP was performed in 53 (18.3%) of the patients included in the study, who underwent a fusion biopsy. The histopathological analysis of these cases after RALP showed that 22 (41.5%) patients had EPE, 16 (30.1%) had SM positivity and four (7.5%) had SVI positivity.

**Table 1 – Clinical characteristic of the study groups according to the multiparametric magnetic resonance imaging lesion size**

| Variables | mpMRI lesion size | | p-value |
|---|---|---|---|
| | <10 mm (n=144) | ≥10 mm (n=146) | |
| Age, years | 63.3 ± 7.7 | 64.7 ± 8.1 | 0.137 |
| PSA, ng/dl | 6.0 (4.6–9.2) | 6.9 (4.8–9.8) | 0.078 |
| PSAD, ng/dl/ml | 0.13 (0.00–0.21) | 0.16 (0.11–0.28) | **0.012** |
| Prostate volume, ml | 48 (35–63) | 45 (30–61.25) | 0.195 |
| MRI lesion size, mm | 7 (6–8) | 13 (11–16.25) | **<0.001** |
| Number of positive cores | 2 (1–5) | 4 (1–7) | **0.007** |
| Biopsy results | | | |
| Benign | 74 (51.4)[a] | 47 (32.2)[b] | **0.001#** |
| PCa | 70 (48.6)[a] | 99 (67.8)[b] | |
| PI-RADS score, n (%) | | | |
| II | 8 (5.6)[a] | 9 (6.2)[a] | |
| III | 50 (34.7)[a] | 27 (18.5)[b] | **<0.001#** |
| IV | 85 (59.0)[a] | 80 (54.8)[a] | |
| V | 1 (0.7)[a] | 30 (20.5)[b] | |
| Clinical T-stage | | | |
| T1c | 132 (91.7)[a] | 108 (74.0)[b] | **<0.001#** |
| T2 | 10 (6.9)[a] | 30 (20.5)[b] | |
| T3 | 2 (1.4)[a] | 8 (5.5)[a] | |
| Biopsy-ISUP grade, n (%) | | | |
| Benign | 74 (51.4)[a] | 47 (32.2)[b] | |
| I | 38 (26.4)[a] | 27 (18.5)[a] | |
| II | 21 (14.6)[a] | 30 (20.5)[a] | **<0.001#** |
| III | 8 (5.6)[a] | 26 (17.8)[b] | |
| IV | 3 (2.1)[a] | 10 (6.8)[b] | |
| V | 0[a] | 6 (4.1)[b] | |
| Disease significance, n (%) | | | |
| No PCa | 74 (51.4)[a] | 47 (32.2)[b] | **<0.001#** |
| Clinically insignificant | 14 (9.7)[a] | 8 (5.5)[a] | |
| Clinically significant | 56 (38.9)[a] | 91 (62.3)[b] | |

#Pearson's chi-square test; PSA – prostate specific antigen; PSAD – prostate specific antigen density; MRI – magnetic resonance imaging; PI-RADS – Prostate Imaging Reporting and Data System; ISUP – International Society of Urological Pathology; same superscripts show no statistically significant difference between variables

When the patients were evaluated according to the mpMRI lesion size, it was observed that the PSAD value was statistically significantly higher in Group B than in Group A (p=0.012). The PI-RADS score was also higher in Group B compared to Group A, and the two groups statistically significantly differed in terms of clinical T-stage (p<0.001 and p<0.001, respectively). According to the fusion biopsy results, the rate of PCa detection and the number of positive cores were statistically significantly higher in Group B than in group A (p=0.001 and p=0.007, respectively). In addition, there was a statistically significant difference between the biopsy-ISUP grade values of the two groups (p<0.001). Another significant difference was detected in relation to the presence of clinically significant PCa (p<0.001). While the rate of csPCa detection among all biopsies was 62.3% in Group B, it was determined

**Table 2 – Clinical data and pathological results of patients that underwent radical prostatectomy**

| Variables | MRI lesion size | | p-value |
|---|---|---|---|
| | <10 mm (n=26) | ≥10 mm (n=27) | |
| Preoperative clinical T-stage, n (%) | | | |
| T1c | 21 (80.8) | 21 (77.8) | 0.728^ |
| T2 | 4 (15.4) | 6 (22.2) | |
| T3 | 1 (3.8) | 0 | |
| Pathological T-stage, n (%) | | | |
| T2 | 21 (80.8)[a] | 11 (40.7)[b] | **0.003#** |
| T3 | 5 (19.2)[a] | 16 (59.3)[b] | |
| Biopsy-ISUP grade, n (%) | | | |
| I | 10 (38.5) | 9 (33.3) | |
| II | 11 (42.3) | 12 (48.1) | 0.919^ |
| III | 4 (15.4) | 4 (11.1) | |
| IV | 1 (3.8) | 2 (7.4) | |
| RP-ISUP grade, n (%) | | | |
| I | 3 (11.5) | 5 (18.5) | |
| II | 15 (57.7) | 10 (37.0) | 0.313^ |
| III | 8 (30.8) | 10 (37.0) | |
| IV | 0 | 2 (7.4) | |
| Gleason upgrade, n (%) | 10 (38.5) | 10 (37.0) | 0.915# |
| csPCa | | | |
| EPE, n (%) | 5 (19.2) | 17 (63.0) | **0.001#** |
| SM, n (%) | 3 (11.5) | 13 (48.1) | **0.004#** |
| SVI, n (%) | 1 (3.8) | 3 (11.1) | 0.610^ |
| Lymph node metastases, n (%) | 0 | 1 (3.7) | 1.000^ |

#Pearson's chi-square test; ^Fisher's exact test; MRI – magnetic resonance imaging; ISUP – International Society of Urological Pathology; csPCa – clinically significant prostate cancer; EPE – extraprostatic extension; SM – surgical margin; SVI – seminal vesicle invasion; same superscripts show no statistically significant difference between variables

to be 38.9% in Group A. The rate of cisPCa detection was statistically similar in the two groups (Table 1).

It was observed that the pathological T-stage in the patients who underwent RALP was more advanced in Group B (p=0.003). In addition, the EPE and SM positivity rates were higher in Group B compared to Group A (p=0.001 and p=0.004, respectively). The two groups were statistically similar in terms of preoperative clinical stage, ISUP grade of specimen pathology, Gleason upgrade rate, and SVI and lymph node metastasis (LNM) detection rates among the patients who underwent RALP (Table 2).

Possible variables associated with EPE positivity after RALP (age, PSA, PSAD, biopsy-ISUP grade, number of positive cores, clinical T-stage, and mpMRI lesion size) were evaluated using the univariate analysis, and the mpMRI lesion size being > 10 mm was determined to be significant in predicting EPE positivity. The multivariate analysis revealed only the mpMRI lesion size being > 10 mm as an independent predictor of EPE positivity. According to the univariate analysis of the possible variables associated with SM positivity (age, PSA, PSAD, PI-RADS, biopsy-ISUP grade, number of positive cores, clinical T-stage, D'Amigo risk group, and mpMRI lesion size), the mpMRI lesion size being > 10 mm and the presence of biopsy-ISUP grade 2 significantly predicted SM positivity. In the multivariate analysis, the mpMRI lesion size being > 10 mm was found to be an independent predictive factor for SM positivity (Table 3).

## Discussion

The result of the analyses undertaken in our study showed that PCa aggressiveness increased clinically and histopathologically in the patients with an index lesion size over 10 mm and the increase in lesion size was able to predict the aggressiveness

**Table 3 – Results of the logistic regression analysis of parameters associated with EPE and SM positivity in patients that underwent radical prostatectomy**

| | | Multivariate | | |
|---|---|---|---|---|
| | | **OR** | **95% CI** | **p-value** |
| *EPE** | | | | |
| MRI lesion size (cat.) | <10 mm | ref | | |
| | ≥10 mm | 10.023 | 2.008–50.036 | **0.005** |
| *SM** | | | | |
| MRI lesion size (cat.) | <10 mm | ref | | |
| | ≥10 mm | 15.303 | 1.390–168.466 | **0.026** |

*age, PSA, PSAD, biopsy-ISUP grade, number of positive cores, and clinical T-stage; EPE – extraprostatic extension; cat. – categorical; SM – surgical margin; ISUP – International Society of Urological Pathology; OR – odds ratio; CI – confidence interval; ref – reference variable

of the disease. We took 10 mm as the threshold lesion size since a sphere of 0.5 cc corresponds to 1 cm, which is the standard limit for cisPCa according to the Epstein criteria (Epstein et al., 2016). Lee et al. (2013) determined that lesion size detected in mpMRI was an independent predictive factor for the presence of cisPCa.

The role of mpMRI in PCa management has been continuously increasing over the last decade. The guidelines recommend the use of mpMRI in various indications in patients who have not yet been diagnosed with PCa or before treatment in those who have been diagnosed with this cancer (Mottet et al., 2019). In addition, the use of mpMRI has become more popular in the last decade to increase the detection of csPCa and reduce the number of complications associated with biopsy procedures (Godtman et al., 2015; Caverly et al., 2016). PI-RADS scoring system, 15 mm lesion size was determined as the cut-off value in T2-weighted and DW imaging in distinguishing between category 4 and 5 lesions (Weinreb et al., 2016). Rosenkrantz et al. (2017) reported that when they reduced the 15 mm size criterion to 10 mm, resulting in increasing PI-RADS score 4 to 5, they detected PCa in 33 (79%) of 42 cases and csPCa in 26 (62%) and suggested that the size limit in score 5 should be reduced to 10 mm for PI-RADS versions. In a study by Lee et al. (2013) including 188 patients, when the index lesion size cut-off value was taken as 10 mm, no difference was found between the groups in terms of the number of positive biopsy cores and clinical T-stage. However, in our study with a higher number of patients, we determined that the rate of positive cores, clinical T-stage, biopsy-ISUP grade, and PI-RADS scores were higher among the patients in Group B. An mpMRI-targeted fusion biopsy is known to have a higher rate of detecting csPCa compared to the standard systematic TRUS biopsy, and the former also has higher upgrade rates in the Gleason score obtained from RP (Steinberg et al., 1997; Freedland et al., 2007). In our study, an mpMRI fusion biopsy was performed in all patients, and it was observed that the patients in both groups had similar rates (38.5% vs. 37%) in terms of Gleason upgrade, and these rates were consistent with the literature (Arsov et al., 2015).

According to the PCa risk classification models, the pathological stage in the RP specimen can be predicted by examining tumour size, localization and extension in mpMRI images. Studies on this subject have revealed that mpMRI not only provides anatomical tumour localization but also predicts pathological stage in the RP specimen (Lebacle et al., 2017; Morlacco et al., 2017). In our study, when we took the lesion size cut-off value as 10 mm in the patients who underwent RALP, there was no difference in the clinical T-stage of the patients, but we observed higher pathological T-stage in Group B. In contrast, Lee et al. (2013) determined no difference in pathological T-stage between the patients with a lesion size of less than or more than 10 mm.

In studies investigating the relationship between the PI-RADS index lesion size determined in mpMRI and the ISUP-Gleason grade, it has been reported that the ISUP grade was more advanced and the tumour progressed more aggressively in

larger lesions. It has also been shown that increased lesion size and other factors had prognostic value for the course of the disease (Kattan et al., 1997; Toledano and Obuchowski, 2016; Nassiri et al., 2018). Considering these factors, it has been suggested that mpMRI has a potential role in risk classification before definitive treatment in patients with PCa (Felker et al., 2016). EPE, SVI, LNM, and SM are important oncological prognostic markers in histopathological evaluation after RP (Sanda et al., 2008; Ho et al., 2016). Dvorak et al. (2005) showed that when the maximal tumour lesion size was 13 mm and above, the positivity of SM was significantly higher. Tonttila et al. (2018) investigating the relationship between lesion size in mpMRI and the pathology of the RP specimen, found higher EPE, SVI and LNM rates and higher ISUP grades in patients with lesions larger than 15 mm. In our study, we observed that the index lesion size being > 10 mm was an independent predictive factor for EPE and SM positivity.

In the PAIREDCAP study, the PCa detection rates based on PI-RADS scores determined according to the index lesion size were evaluated and the effect of lesion size on PCa detection was emphasized. That study provided guidance in determining the treatment protocol according to lesion size (Elkhoury et al., 2019). Related to this, Lee et al. (2013) stated that if the lesion size measured in mpMRI was over 10 mm, there was a much higher possibility of csPCa, and these patients were not suitable for active surveillance (AS). They found that among the patients with PCa who were suitable for AS, there was a significant rate of Gleason upgrade according to the prostatectomy pathology those with a DW-MRI lesion diameter of > 10 mm. Thus, the authors suggested that patients with a lesion larger than 10 mm were not suitable for AS (Lee et al., 2013). Similarly, in our study, we found an increased probability of having csPCa among the patients with a lesion size of over 10 mm. Özden et al. (2021) reported that the rate of csPCa detection increased in patients with an mpMRI lesion size of > 10 mm among those who underwent a cognitive-targeted biopsy. Considering these findings, our study supports the literature and can shed light on future studies to revise the 15 mm criterion used for the differentiation of PI-RADS 4 and 5 categories.

This study has several strengths, including all biopsies being in the form of fusion biopsies performed by a single experienced radiologist, RALP being performed by two specialist urologists, and histopathological evaluation being undertaken by a single uropathologist. The use of fusion biopsy combined with systematic biopsy in all patients reduced the possibility of overlooking csPCa in patients with large prostate volumes. Since the number of cisPCa was low in our study, the difference between the two groups may not have been statistically significant. The limitations of the study include the retrospective design and the low rate of RALP in our cohort.

## Conclusion

The radiologists and clinicians should be aware of the possibility of presence of features that may affect local staging, such as EPE positivity, in the presence of

lesions larger than 10 mm in which prostate cancer is detected. For index lesion size, 10 mm was determined as a cut-off value for the prediction of the positivity of SM and EPE, which are prognostic factors affecting survival after RP. However, the results obtained from our study need to be supported by prospective studies with a higher number of patients.

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