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The role of shear wave elastography in predicting endometrial cancer in patients presenting with abnormal uterine bleeding

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Abstract. – OBJECTIVE: Shear Wave Elastography (SWE) is an objective quantitative ultrasound elastography technique that can demonstrate the stiffness of anatomical structures to aid in their detection and characterization. We aimed to evaluate the role of shear wave elastography in differentiating endometrial carcinoma from benign uterine pathologies in women with abnormal uterine bleeding.

PATIENTS AND METHODS: This prospective study was conducted at our institution from January 2020 to April 2020. A hundred patients with endometrial sampling planned and SWE due to abnormal uterine bleeding were included in the study. According to the histopathological results of the patients, those with normal and atrophic endometrium results were defined as group I (control group), those with benign results such as polyps and endometrial hyperplasia were defined as group II, and those with endometrial cancers were defined as group III.

RESULTS: After adjustment for age, a statistically significant difference was found in Emean (mean and adjusted mean) value between the study groups ($F_{2,96}$=86.37, p<.001, η^2=0.64). The post-hoc analysis was performed with a Bonferroni adjustment. The mean Emean value was found to be statistically significantly higher in group III (17.14±0.40) compared to group I (10.39±0.26) and group II (11.49±0.32) (p<0.001). In addition, a statistically significant difference was found between the benign and normal groups.

CONCLUSIONS: As a new diagnostic technique in gynecology, elastography appears to be a valuable tool in differentiating malign endometrial pathologies from normal or benign endometrial pathologies in females with abnormal uterine bleeding.

Key Words:
Abnormal uterine bleeding, Elasticity, Endometrial cancer, Shear wave elastography, Ultrasonography.

Introduction

Abnormal uterine bleeding (AUB) is a common gynecological complaint accounting for one-third of outpatient visits to the gynecologist and accounting for more than 70% of all gynecological consultations in the perimenopausal and postmenopausal years[1]. The International Federation of Gynecology and Obstetrics (FIGO) System systematically defines the most common etiologies for AUB with structural (PALM) and nonstructural (COEIN) causes of AUB[2] [acronym PALM-COEIN (polyps, adenomyosis, leiomyoma, malignancy, coagulopathy, ovulatory dysfunction, endometrial disorders, iatrogenic, and not yet classified)]. In a gynecological environment, the first step is usually to determine structural abnormalities (PALM causes). Common diagnostic options for defining PALM options include ultrasonography, endometrial sampling, and hysteroscopy. These options, alone or in combination, are adequate to diagnose most females with abnormal bleeding. Contrast sonography with saline or gel infusion, 3D- ultrasonography, and Magnetic resonance imaging may be added[2].

Endometrial biopsy is the standard for early detection of endometrial cancer and promises better treatment outcomes. However, the endometrial biopsy procedure is not without complications. Endometrial biopsy occurs in females with risk factors for endometrial neoplasia. Age is a risk factor in itself, but there is no consensus on the age limit for recommending a biopsy. The National Institute for Health and Care Excellence (NICE) recommendations recommend a biopsy over 45 years, but this threshold has been lowered to 40 years in the recommendations of the Royal College of Obstetricians and Gynecolo-

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gists (RCOG). Canadian recommendations suggest "considering" a biopsy in females who are aged 40 and older, while the American College of Obstetricians and Gynecologists (ACOG) recommends they be over 45 years old[3].

Sonographic elastography is a technique based conceptually on tissue elasticity. Sonographic elastography is used for tissue characterization through the application of compressions due to their degree of elasticity, for the quantitative measurement of elasticity and stiffness of compressible tissues in different areas. There are different types of elastography, including strain elastography, shear-wave elastography (SWE), acoustic radiation force impulse elastography (ARFI), and transient elastography (TE)[4].

Shear wave elastography is an objective quantitative ultrasound elastography technique, which can depict the stiffness of anatomic structures to aid in their detection and characterization. SWE uses a push pulse, often referred to as acoustic radiation force, from the imaging transducer to generate shear waves in soft tissues. Shear waves propagate perpendicular to the direction of the push pulse, and their velocity can be tracked by sonography, directly assessing tissue stiffness[5]. SWE has been extensively studied[6-9] in liver fibrosis, thyroid, breast neoplasms, and sciatic nerve in the past decade. In all instances, the pathologic condition tends to be firmer than normal visceral parenchyma. In contrast, obstetric and gynecologic implementations are underexplored, and strain elastography was used in most of these studies.

In this study, we aimed to assess the role of shear wave elastography in differentiating endometrial carcinoma from benign uterine pathologies in women with abnormal uterine bleeding.

Patients and Methods

This study was conducted prospectively at our institution from January 2020 to April 2020 after the approval of the local research Ethics Committee (Selcuk University, Faculty of Medicine, with decision numbered 2020/301). A total of 104 females who were scheduled for endometrial sampling due to abnormal uterine bleeding were included in the study. Four females were excluded due to insufficient pathology results. All patients were referred to the imaging department for pelvic ultrasonographic examination. During the ultrasonographic examination, the endometrium was evaluated with SWE. Written informed consent was obtained from all participants before the procedure.

According to the histopathological results of the patients, those with normal and atrophic endometrium results were defined as group I (control group), those with benign results such as polyps and endometrial hyperplasia were defined as group II, and those with endometrial cancers were defined as group III.

Inclusion criteria: females with perimenopausal or postmenopausal hemorrhage with an endometrial thickness ≥5 mm.

Exclusion criteria: patients who had undergone endometrial sampling before SWE examination, patients diagnosed with metastatic uterine disease, and patients receiving estrogen therapy. Demographic data (age, gravida, parity, menopausal status) of the patients were recorded. All grayscale US and SWE examinations of the endometrium were performed by an experienced radiologist using a 3.5 MHz convex abdominal probe (PVT-375BT probe, Toshiba Aplio 500, Toshiba Medical Systems, Tokyo, Japan). Since the use of transvaginal probes compatible with SWE is not yet common in gynecology, the more easily accessible abdominal probe was preferred. Elastography examinations were performed by lightly touching the probe skin. In order to achieve higher image quality in SWE reviews, we chose a five-second single-shot scan. Tissue elasticity measurements were made using a map with a color range from dark blue to red (soft to hard) (Figures 1 and 2). Elastography values were measured in propagation mode with three 5-mm diameter regions of interest (ROIs). We calculated the obtained SWE values as the mean in kPa and then the average of the values of the three ROIs.

Statistical Analysis

All statistical analyses were performed using R 3.6.0 (The R Foundation for Statistical Computing, Vienna, Austria).

Shapiro-Wilk normality test, Q-Q plot, and Levene's test were used to control the normality of the data and the homogeneity of the variances, respectively. Numerical data were expressed as mean ± standard deviation and corrected mean (estimated marginal means) with a 95% confidence interval. Categorical data were defined as numbers (n) and percentages (%). One-way ANOVA (analysis of variance) was used to compare

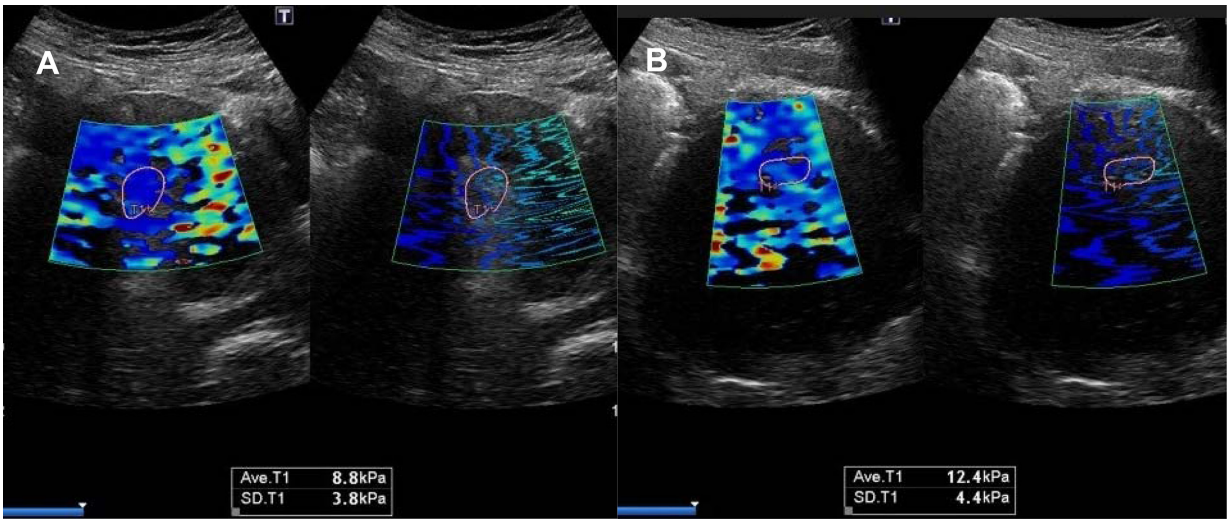

Figure 1. **A**, Normal endometrium SWE image (E_{mean} was 8.80 kPa). **B**, Endometrial polyp SWE image (E_{mean} was 12.40 kPa).

study groups in terms of age, gravida, and parity. Then, the Tukey HSD test was used for multiple comparisons of parameters found crucial after One-way ANOVA. A Yates continuum correction Chi-square test was performed on patients and study groups to examine the relationship between menopauses. After the Chi-square test, the Bonferroni-corrected two-ratio Z test was used for multiple comparisons. In addition, both Welch's F test, followed by Games-Howell and One-Way ANCOVA tests, followed by Bonferroni multiple test correction, were performed to determine

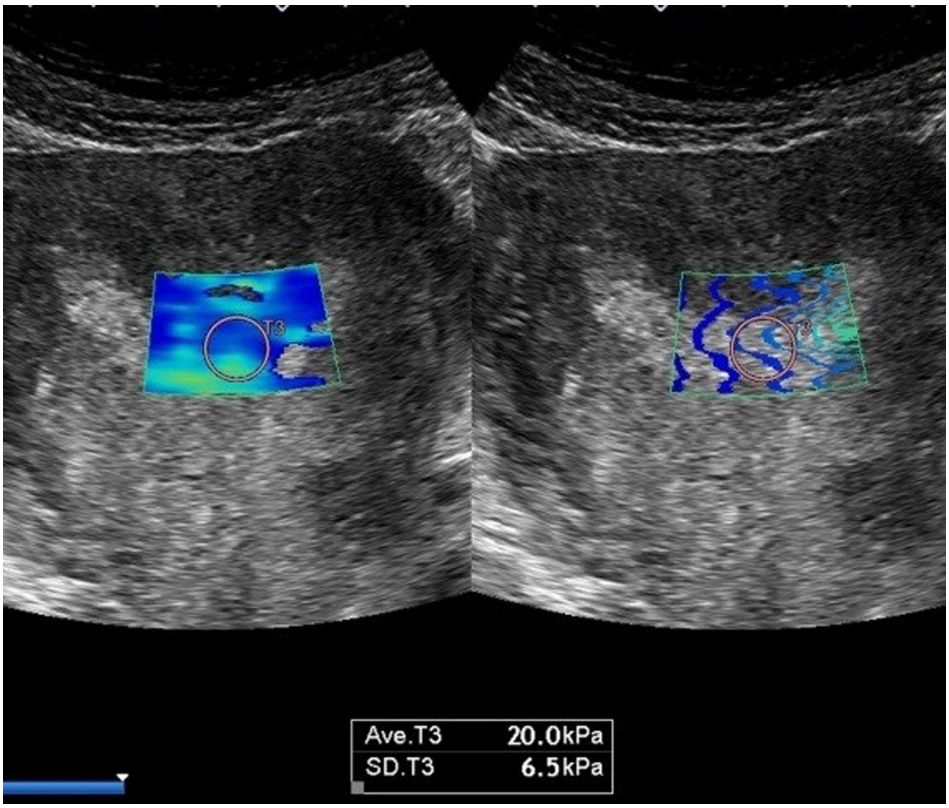

Figure 2. Endometrial adenocarcinoma SWE image (E_{mean} was 20.0 kPa).

whether there was a significant difference in E_{mean} values among study groups. Since there was a difference between the ages of the groups, after controlling the age of the participants, a one-way ANCOVA was conducted to determine the effect of the study groups on the E_{mean} value. Receiver operating characteristic (ROC) curve analysis is performed to test the diagnostic performance of E_{mean} in differentiating malign and benign lesions. Cut-off values were determined according to the Youden index criteria. Sensitivity, specificity, negative predictive value (NPV), and positive predictive value (PPV) were calculated with a 95% confidence interval for the statistical diagnostic performance of the determined cut-off values. A *p*-value lower than 0.05 was considered statistically significant.

Results

A total of 100 patients were included in the study. No significant pathology was detected in 48 (48%) patients. Endometrial polyps were diagnosed in 20 (20%) cases, endometrial hyperplasia in 6 (6%) cases, and endometrial cancer in 26 (26%) cases. The mean age of the patients was 52.60 ± 9.83 (range: 30-81), the mean gravida was 3.36 ± 1.41 (range: 0-7), and the mean parity was 3.14 ± 1.41 (range: 0-7).

The demographical characteristics and clinical findings of the groups are given in Table I. The mean age of the patients in group III was 63.08 ± 8.38, which was statistically significantly higher than the mean age of the patients in group 1 (47.81 ± 7.18) and group II (50.96 ± 7.37). However, the mean age of the patients in group 1 and group 2 was similar. There was no statistically significant difference between the groups in terms of gravida and parity (p=.948 and p=.878, respectively). There was a statistically significant relationship between the study groups in terms of menopause (p<.001). Menopause rate was higher in group III (n=23, 88.5%) when compared to group I (n=14, 29.2%) and group II (n=12, 46.2%). Menopause rates of the patients in group I and group II were similar.

The mean and adjusted mean of the E_{mean} according to study groups are given in Table II. After adjusting for age, a statistically significant difference in E_{mean} value between the study groups ($F_{2,96}$=86.37, p<.001, η^2=0.64) was found. The post hoc analysis was performed with a Bonferroni adjustment. The mean E_{mean} value was found to be statistically significantly higher in group III (17.14 ± 0.40) when compared to group I (10.39 ± 0.26) and group II (11.49 ± 0.32). Moreover, a statistically significant difference was detected between group I and group II (Table II).

ROC curve analysis to establish the cut-off point to differentiate between group III and group I results showed that the cut-off value for E_{mean} of 13 kPa had a sensitivity of 96.15% (80.4-99.9%), a specificity of 100% (92.6-100%), a PPV of 100% (100-100%) and a NPV of 98% (87.5-99.7%). The area under the ROC curve (AUC) was 0.996 (0.943-1.000) for the level of 13 (Figure 3). In addition, ROC curve analysis to establish the cut-off point to differentiate between group III and group II showed that the cut-off value for E_{mean} of 13 kPA had a sensitivity of 96.15% (80.4-99.9%), a specificity of 100% (86.8-100%), a PPV of 100% (100-100%) and an NPV of 96.3% (79.2-99.4%). The area under the ROC curve (AUC) was 0.986 (0.906-1.000) for the level of 13 (Figure 3).

Table I. The demographical characteristics and clinical findings of the groups.

Variables	Study groups			p
	Control group (Group 1) (n = 48)	Benign group (Group 2) (n = 26)	Malign group (Group 3) (n = 26)	
Age (years)	47.81 ± 7.18[a]	50.96 ± 7.37[a]	63.08 ± 8.38[b]	< 0.001[1]
Gravida	3.31 ± 1.27	3.38 ± 1.50	3.42 ± 1.60	0.948[1]
Parity	3.08 ± 1.30	3.12 ± 3.27	3.27 ± 1.59	0.878[1]
Menopause	14 (29.2)[a]	12 (46.2)[a]	23 (88.5)[b]	< 0.001[2]

Data were presented as mean ± standard deviation or count (n) and percentage (%). [1]One-way ANOVA was followed by Tukey HSD post-hoc test. [2]Yates continuity correction Chi-square test followed by Two proportion Z-test with Bonferroni correction. p<0.05 was considered statistically significant. Different small superscripts ([a,b]) in each column indicate a statistically significant difference.

Table II. The E_{mean} values of the study groups.

E_{mean} (kPa)		
Study groups	**Mean ± SD**	**Adjusted mean (95% CI)**
Group 1 (n = 48)	10.33 ± 1.34[a]	10.39 (9.88-10.91)[a]
Group 2 (n = 26)	11.47 ± 1.11[b]	11.49 (10.85-12.13)[b]
Group 3 (n = 26)	17.27 ± 2.39[c]	17.14 (16.35-17.92)[c]
p	< 0.001[1]	< 0.001[2]

Data were presented as mean ± standard deviation and estimated marginal mean (95% confidence intervals). [1]Welch's F test followed by Games-Howell post-hoc test. [2]One-Way ANCOVA followed by Bonferroni multiple testing corrections. $p < .05$ was considered statistically significant. Different small superscripts ([a,b,c]) in each row indicate a statistically significant difference.

Discussion

Abnormal uterine bleeding is a common symptom in females. When endometrial lesions are suspected, endometrial biopsy and pathological examinations are usually performed by clinicians to provide a definitive diagnosis. Although endometrial biopsy results are the universal gold standard for definitive diagnosis, these procedures are invasive and sometimes cause serious complications in patients with vaginal or cervical stenosis[10,11]. Non-invasive methods have been used in the literature to differentiate endometrial pathologies from endometrial cancer. From these studies, Benati et al[12] reported that cell-free DNA relative telomere length analysis could be a diagnostic tool for the detection of endometrial cancer from its early stages. Its sensitivity and specificity were reported to be 80.5% and 80.5%, respectively. However, this happens because the shortening of telomere length is not specific to endometrial cancer but is also affected by other oncologic and non-oncologic diseases, and its association with preinvasive conditions of the endometrium has not been investigated. Besides, Casarin et al[13] reported that the presence of glandular cells in preoperative cervical smear might predict local recurrence of endometrial cancer. Recurrence of endometrial cancer is more important for research than the diagnosis of endometrial cancer. However, this study is different from this study because it consists of only patients diagnosed with endometrial cancer. Scioscia et al[14] reported that vascular ultrasound can improve the detection rate of endometrial cancer in perimenopausal and postmenopausal women. Vascular ultrasound is also easy to perform and interpret. However, they reported that the assessment of sub-endometrial vascularity by vascular ultrasound is not sufficient for the diagnostic accuracy of endometrial cancer in women with abnormal uterine bleeding, and further studies are needed to clarify the relationship between adenomyosis and endometrial cancer[14]. Previous studies differ from this study since it compared adenomyosis with endometrial cancer.

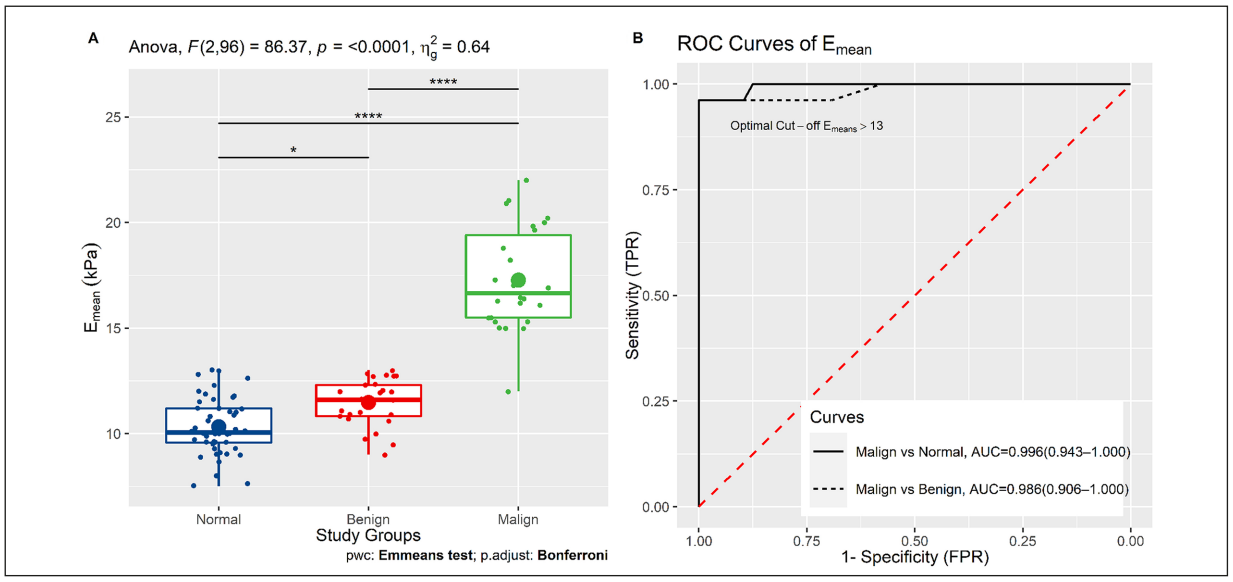

Figure 3. A, Boxplot showing the value of E_{mean} (kPa) levels between the study groups. Data are presented as median with interquartile range. **B**, Receiver operating characteristic curve of E_{mean} (kPa) levels for diagnosis of malign patients against normal and benign patients. AUC values were 0.996 (0.943-1.000) and 0.986 (0.906-1.000), respectively.

Elastography-based imaging techniques have received important caution in recent years for the non-invasive evaluation of tissue mechanical properties[15]. These techniques provide qualitative and quantitative information that can be used for diagnostic purposes by taking advantage of the changing soft tissue elasticity in various pathologies[15]. Two-dimensional SWE is widely used to measure the stiffness of tissues, especially for superficial organs such as the breast, thyroid, testis, tendons, and lymph nodes. Additionally, SWE can be used for intraabdominal and intrathoracic organs like the thymus, liver, spleen, kidney, and pancreas[16-20]. Studies in literature have shown that the stiffness of endometrial lesions is closely related to their biological characteristics, and this shows us that elastography may be an option in the differential diagnosis of endometrial pathologies. This idea formed the cornerstone of our study.

In this study, we aimed to evaluate the role of shear wave elastography in differentiating endometrial carcinoma from benign uterine pathologies in females with abnormal uterine bleeding. We evaluated the flexibility characteristics of different endometrial pathologies, such as normal endometrium, benign pathologies, and endometrial carcinoma in females presenting with abnormal uterine bleeding. The mean E_{mean} value was statistically significantly higher in group III when compared to group I and group II. In addition, there was a statistically significant difference between group I and group II.

Domidova et al[21] reported that 46 healthy females evaluated the elasticity properties of the normal endometrium and an average of 16.5 ± 1.0 kPa of elasticity for the endometrium as assessed by the SWE.

The stiffness of endometrial lesions is closely related to their biological characteristics. Preis et al[22] reported that normal and atrophic endometria seem softer on elastography than in endometrial polyps, hypertrophy, and cancer in perimenopausal females with an endometrial thickness greater than 5 mm. Vora et al[23] studied 73 endometrial lesions. E_{mean} for the endometrial polyps was 12.25 ± 6.13 kPa, while the E_{mean} value for the malign groups was 26.60 ± 7.27 kPa.

In a recent study, Ma et al[24] studied 122 endometrial lesions. E_{mean} for the benign group was 17.96 ± 8.05 kPa, while E_{mean} values for the EC and AEH groups were 38.46 ± 17.10 kPa. E_{mean} for both groups was found to be statistically significant with $p<.001$. This difference between the benign and malignant groups was additionally consistent with the findings in our study.

Che et al[25] found that using elastography's cut-off value of 3.02 strain rate (SR) value, it achieved 81.7% and 85% sensitivity and specificity in differentiating between endometrial carcinoma and the benign endometrial mass group, respectively. In our study, analysis of the ROC curve according to shear wave ratio to differentiate between malign lesions and normal results showed that the cut-off value for E_{mean} was 13 kPa, had a sensitivity of 96.15%, a specificity of 100%, a PPV of 100%, and an NPV of 98%. In addition, ROC curve analysis to define cut-off to differentiate between malign lesions and benign lesions showed that the cut-off value for E_{mean} of 13 kPA had a sensitivity of 96.15%, a specificity of 100%, a PPV of 100%, and an NPV of 96.3%.

Limitations

The main limitations of our study are the number of study groups and its inability to assess interobserver and intraobserver variability, which could cause statistical bias.

Conclusions

An optimal protocol with standard technical specifications for the use of SWE in the uterus has not been defined so far, which may cause inconsistency in results across different studies. As a new diagnostic technique in gynecology, elastography appears to be a valuable tool in differentiating malign endometrial pathologies from normal or benign endometrial pathologies in females with abnormal uterine bleeding.

Conflict of Interest

The authors declare that they have no conflict of interests.

Funding

None.

Data Availability

The datasets generated during and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Authors' Contribution

Abdul Hamid Guler, Mete Can Ates, and Fazıl Avcı contributed to the conception and design of the study, acquisition of data, analysis, and interpretation of data, drafting of the

article, validation, and final approval of the version of the article to be published. Nusret Seher, Muslu Kazım, Korez, and Mustafa Koplay contributed to the design of the study, analysis, and interpretation of data, supervision, and final approval of the version of the article to be published. Ersin Cintesun, Ahmet Bilgi, and Cetin Celik contributed to the conception and design of the study, reviewing and editing the article, supervision, validation, and final approval of the version of the article to be published.

Ethics Approval

The ethical approval of this study was approved by the Ethics Committee of the Faculty of Medicine of Selçuk University, with the decision number 2020/301.

Informed Consent

Written informed consent was obtained from all participants before the procedure.

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