Study Protocol and Statistical Analysis Plan:

Our study was designed as prospective cohort study. 65 women between the ages of 18-52 who applied to the Istanbul Medical Faculty Gynecology and Infertility departments due pelvic pain, infertility or abnormal bleeding between October 2018-October 2021 were included in the study. As a result of their gynecological examination and transvaginal ultrasonography results, these women were divided into adenomyosis (n=34) and fibroids (n=31) groups. Women with a history of malignancy, oral contraceptive use, hormonal intrauterine device users or women using gonadotropin-releasing hormone agonists were not included in the study. Ethical committee approval was given and informed consents were obtained from the patients before the examination.

The definitive diagnosis of patients with suspected adenomyosis and fibroids according to transvaginal ultrasound examination was confirmed by intravenous contrast-enhanced pelvic MRI. Thus the reference method used for confirmation was MRI. Magnetic resonance imaging was evaluated by a separate radiology specialist with 17 years of experience in pelvic MRI. If the junctional zone was observed to be thicker than 1.2 cm in magnetic resonance imaging, or the difference between the maximum and minimum measurement values taken from the junctional zone was more than 0.5 cm, adenomyosis diagnosis was established. Focal lesions with clear borders in the uterus were interpreted in favor of myoma uteri. (1)

In the study group, detailed anamnesis was taken from the patients, their menstrual cycles, body mass indexes, current drug use, family history, and smoking habit were questioned. The patients included in the study (adenomyosis group) and control group (fibroid group) were examined with both transvaginal ultrasound and transvaginal elastography devices.

Siemens Acuson X600 EV9F10 endovaginal ultrasound with 3-9 MHz frequency and 180 degree viewing angle probe was preferred for transvaginal ultrasound examination. Canon Applio İ800 11C3 endovaginal ultrasound with 3-11 MHz frequency and 180 degree viewing angle probe was used for elastography examination.

Elastography data of the study and control groups were compared. Shear wave elastography was used with a transvaginal transducer providing a clear image up to 3 cm depth. No additional pressure or compression was applied to the transvaginal probe during the procedure. Minimum pressure was applied to the cervix for imaging and the probe was held still for approximately 2-5 seconds to obtain a fixed, stabile image of the imaging field which contains the pathological lesion. The technique implemented in our study was adopted from the literature published by Mitkov et al. (2)(3)

Transvaginal gray scale ultrasound was performed in B-Mode by a gynecologist with at least 10 years of gynecological ultrasonography experience. In the study group, the presence/absence of hypoechoic areas, anechoic pools, asymmetric uterine growth, global uterine enlargement, deletion of the endo-myometrial zone, subendometrial thickening, global uterine growth, and linear shadows extending in the form of fans in the myometrium were recorded. Then, patients listed in study group were evaluated with elastography, and the hardness of the existing lesions was expressed in Young's modulus and recorded as elastographic data. Sonoelastography imaging was performed by an expert radiologist with 20 years of transabdominal/ transvaginal ultrasonography and 7 years of sonoelastography experience.

To measure tissue stiffness in shear-wave elastography, Young's modulus, whose unit is kilopascal (kPa), was used in gynecological mode, with an upper limit of 180 kPa. Numerical values of Young's modulus were measured in areas with maximum myometrial stiffness for the respective pathologies. (Adenomyosis/ Fibroid) Measurements were recorded on images in which the color window containing the lesion was completely stained and shear waves were completely set with equal distances over the pathological lesion in shear wave elastography. Tissue stiffness of the examined area was visualized with a color map in real-time mode. Harder tissues with high kPA values are mapped in red, green and yellow colors, while relatively soft tissues with lower kPA values are indicated in blue-violet colors. Evaluation of tissue stiffness was made in selected regions of interest with round-shaped circles adjustable up to 10 mm in diameter. All images and data were saved in the memory of the ultrasound device for further evaluation and processing. The numerical values which represent the mean stiffness value of the region of interest; were set automatically in terms of kilopascal according to Young's Modulus by the device. These mean stiffness values were defined, and the minimum and maximum mean stiffness values were recorded for both study and control groups.

While evaluating the findings, IBM SPSS Statistics 22 program was used for statistical analysis. The conformity of the parameters to the normal distribution was evaluated with the Shapiro Wilks test. During the assessment of the study data, in addition to descriptive statistical methods (mean, standard deviation, minimum, maximum, median frequency), Student's t-test was used for comparisons between groups of normally distributed parameters and Mann Whitney U test was used for comparisons of non-normally distributed parameters between two groups. Fisher's Exact Chi-Square test, Fisher Freeman Halton Exact Chi-square test, Continuity (Yates) Correction and Mc Nemar test were used to compare qualitative data. Kappa coefficient of agreement was calculated for the level of agreement between MR diagnosis and transvaginal ultrasound. The most appropriate cut-off point was chosen based on the ROC curve analysis. Significance was evaluated at the $p<0.05$ level.

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