### **ORIGINAL RESEARCH**

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### Comparison of intraoperative and early postoperative results of patients undergoing laparoscopic versus laparotomic staging surgery for ovarian cancer

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#### Abstract

Thus far, the traditional method of performing staging surgery in ovarian cancer has been laparotomy. Although randomized controlled trials are lacking, minimally invasive options are deemed safe and sufficient for staging and treatment of early-stage ovarian cancer. This study aims to compare the intraoperative and early postoperative outcomes of patients who underwent staging surgery via laparoscopy or laparotomy because of ovarian cancer. This retrospective study was conducted among 37 patients undergoing staging surgery done via laparoscopy (Group 1) or laparotomy (Group 2) between February 2018 and May 2022 at a single center. Intraoperative and early postoperative results were collected. Regarding postoperative complications between the two groups, the formation of lymphoceles and hernias in Group 2 was significantly higher compared to Group 1 (p = 0.019 and p = 0.050, respectively). When these groups were compared regarding Clavien-Dindo classification, Grade 1 complications were high among the laparoscopy group. In contrast, Grade 2, 3A and 3B complications were significantly higher in the laparotomy group (p = 0.002). Regarding hospital stay during the postoperative period, the patients in Group 2 stayed significantly longer compared to Group 1 (p = 0.001). As an alternative to open surgery for diagnosing and staging ovarian cancer, the laparoscopic approach is reliable and can be applied safely to patients. However, more prospective randomized studies are needed to support the obtained data.

### Keywords

Ovarian cancer; Staging surgery; Laparoscopy; Laparotomy; Complications

### **1. Introduction**

Being the seventh most common cancer as of 2018, ovarian cancer is fatal among gynecologic cancers, with 240,000 new cases each year around the world [1]. Despite much knowledge about it, disease-free and overall survival rates have not changed significantly because of the difficulty of establishing diagnosis due to asymptomatic progression. In the United States, only about 22,240 new cases of ovarian cancer are diagnosed, and 14,070 of such cases result in death related to the disease [2]. The prognosis of ovarian cancer is directly related to the stage of disease at the time of diagnosis. Although the 5-year survival rate of patients diagnosed at Stage I is around 90%, this is reduced to 25% in patients with metastatic disease [3].

When an adnexal mass is detected in the transabdominal/transvaginal ultrasonography performed in symptomatic (abdominal swelling, pain, abnormal uterine bleeding, compression symptoms) or asymptomatic (coming for routine control) patients, MRI (Magnetic Resonance Imaging)/CT (computed tomography)/PET (positron emission tomography) imaging together with tumor marker testing (CA (cancer antigen)-125, CA19-9, CA15-3, CEA (carcinoembryonic antigen), AFP (alpha fetoprotein)) are requested. Along with high tumor markers, the malignant character of the mass on MRI/CT, its atypical relationship with the surrounding tissues, an accompanying omental cake, peritoneal carcinomatosis, a bulky lymph node, and the presence of implants in the abdominal organs suggest ovarian cancer in patients [4]. However, since these findings can also be seen in benign diseases such as endometriosis, tuberculosis, actinomyces infection or metastasis of other intra-abdominal organs, tissue diagnosis is essential [5, 6].

Treatment of ovarian cancer includes adjuvant chemotherapy following surgery. Surgery mainly contributes to establishing diagnosis, staging and treatment. In patients with poor performance, who are not suitable for surgery due to comorbidities, and in whom optimal cytoreductive surgery cannot be achieved, surgery following neoadjuvant chemotherapy is preferred after tissue diagnosis (*via* acid cytology, tru-cut biopsy or LS/LT biopsy) [7]. In patients whose performance is appropriate, staging/cytoreductive surgery is performed, and frozen section results are reported to be malignant during laparoscopic or laparotomic surgery. The staging procedure includes extra fascial hysterectomy, bilateral salpingo-oophorectomy, radical omentectomy, appendectomy, pelvic and para-aortic lymphadenectomy, and peritoneal washing cytology. Treatment options vary considerably depending on tumor type, disease advancement and patient characteristics.

Thus far, the traditional method of performing staging surgery in ovarian cancer has been via laparotomy. In recent years, due the presence of imaging suggestive of early-stage disease in preoperative evaluation, laparoscopic staging surgery is primarily preferred [8]. Although randomized controlled trials are lacking, minimally invasive options are deemed safe and sufficient for staging and treatment of early-stage ovarian cancer, and their use in daily practice has gained widespread application [9]. Major concerns are related to minimizing intraoperative tumor rupture or tumor spread, intact removal of an adnexal mass, adequate retroperitoneal staging, and surgery that preserves fertility for young patients. The effectiveness of laparoscopy in patients with advanced stage disease is controversial. Adequate evaluation of areas such as the gastrosplenic ligament, lesser sac, mesenteric root, porta hepatis and retroperitoneum by laparoscopy and tumor resection are both difficult and risky in terms of complications [10]. In this context, the ISAAC (initial surgery in advanced asymptomatic colorectal) study contributed to the determination of the most appropriate strategy for the surgical approach to ovarian cancer with the effective use of preoperative imaging [11]. The main aim for patients with advanced-stage ovarian cancer involves establishing the best therapeutic strategy by assessing primary debulking surgery risks and benefits compared to interval debulking surgery after neoadjuvant chemotherapy. This study aims to compare the intraoperative and early postoperative outcomes of patients who underwent staging surgery via laparoscopy or laparotomy because of ovarian cancer.

### 2. Materials and methods

### 2.1 Study design

Performed retrospectively, this study was conducted among patients undergoing staging surgery done by laparoscopy or laparotomy, which was conducted by a single gynecologic oncologist between February 2018 and May 2022 at the Department of Obstetrics and Gynecology of the Faculty of Medicine of Bezmialem Vakif University. Data were collected by electronically assessing pathology and operation reports, including information on patients admitted to other departments during their hospital stay.

### 2.2 Participants

All women ages 17–80 who applied to outpatient clinics or were referred by other outpatient clinics with the preliminary diagnosis of ovarian cancer and who underwent surgery at our center and whose postoperative records were available were included in this study. These patients had an ECOG (eastern cooperative oncology group scale) performance score between 0 and 2; had not received neoadjuvant chemotherapy treatment; and had adequate hematology, cardiology, respiratory, liver and kidney function. The patients included in the study did not have endometriosis, pelvic tuberculosis or pelvic inflammatory disease (*e.g.*, actinomyces). Patients with pathology reports revealing non-ovarian malignancy or benign results; who we could not reach to give pathology results; who received NACT (neoadjuvant chemotherapy); and with poor ECOG performance status, renal failure, heart failure, a history of pulmonary embolism, deep vein thrombosis and/or sepsis were excluded from the series. Preliminary diagnosis of ovarian cancer was made by evaluating the patients' USG (ultrasound sonography test)/MRI and CT imaging and tumor markers.

### 2.3 Surgical techniques

In the laparoscopic approach, patients were prepared in the lithotomy position. In order to prevent possible intraabdominal adhesions and tumor rupture, the open technique (Hasson technique) was preferred in all patients during entry into the abdomen from the Lee-Huang point. After entering the abdomen, the operation was continued laparoscopically unless tumor formations that were difficult to visualize and resect were observed during intra-abdominal observation. An attempt was made to remove the adnexal mass outside the abdomen in the endobag without rupturing it. For the laparotomic approach, patients were prepared in the supine position. The abdomen was entered through a median incision below the umbilical cord. When tumor formations in widespread and difficult-to-resect areas were detected during the observation, above-umbilical median incision was also added to the surgery. Preoperative imaging determined the decision for laparoscopic or laparotomic approach in patients [11].

### 2.4 Research methods

Demographic characteristics of the included patients (age, body mass index, ECOG score, parity, menopausal status, desire for fertility, previous abdominal surgery and cancer history), primary of the peritoneal tumor, surgical stages, histopathological features and grade were included in the final pathology reports. Pelvic-paraaortic lymph node counts, lymphovascular stromal invasion, intraoperative tumor rupture, positive cytology, presence of fertility-sparing surgery and whether the patient was restaging or not. Operation-related variables (intraoperative and postoperative complications, blood transfusion, ICU (intensive care unit) need, hospitalization time, operation time, time to adjuvant chemotherapy, recurrence time and exitus) were examined in the hospital database, and statistical evaluations were made with these data. Two groups-the group in which laparoscopic surgery was performed and the group in which laparotomic surgery was performed-were compared in terms of the parameters mentioned above.

### 2.5 Statistical analysis

For the hospital stay, when the mean difference between the groups was taken, 4.7 (mean = 14.1, SD (standard deviation) =

4.2; mean = 9.4, SD = 4.0), the minimum sample size should be obtained as 14 for each group [9]. Descriptive statistics of qualitative variables in the study are given as numbers and percentages, while quantitative variables are given as means and standard deviations or medians, minimums and maximums. Pearson's chi-squared test and the Fisher-Freeman-Halton test were used to compare the groups regarding the incidence of related variables. The conformity of the quantitative variables to the normal distribution was examined using the Shapiro-Wilk test. For normally distributed variables, Student's ttest was used for the mean comparison of two independent groups. The Mann-Whitney U test was used for the mean comparison of non-normally distributed variables of the two independent groups. The statistical significance level was set at 0.05, and the SPSS (version 26; IBM Corp., Armonk, NY, USA) package program was used in the calculations.

### 3. Results

Thirty-seven patients who met the required inclusion criteria were included in the study. Group 1 comprised 18 patients operated on laparoscopically, and Group 2 comprised 19 patients operated *via* open surgery for ovarian cancer staging.

### 3.1 Characteristics of patients

The mean age for Group 1 was 44.9  $\pm$  10.1 years and for Group 2 was 47.3  $\pm$  9.9 years (p = 0.468). The average BMI (body mass index) value was 26.6  $\pm$  5.8 kg/m<sup>2</sup> for Group 1 and 26.6  $\pm$  4.8 kg/m<sup>2</sup> for Group 2. BMI values were comparable between the two groups (p = 0.991). No statistical significance was observed regarding ECOG scores (p = 0.335), parity (p = 0.284), menopausal status (p = 0.603), fertility desire (p = 0.405), previous abdominal surgery (p = 0.858), or history of cancer (p = 0.954). Demographic characteristics are shown in Table 1.

# 3.2 Tumor characteristics and surgical outcomes

It was revealed that the ovaries were the primary origin in all patients in Group 2 and all but one patient (whose tumor originated in the fallopian tube) in Group 1 (p = 0.486). Considering the histopathological types, endometrioid-type ovarian cancer was common in Group 1 (n = 5, 27.8%), while serous (n = 6, 31.6%) and clear cell (n = 6, 31.6%) carcinomas were more common in Group 2 (p = 0.198). No significant differences were found between the groups for tumor grade (p = 0.903), presence of LVSI (lymphovascular space invasion) (p = 0.582), positive peritoneal washing cytology (p = 0.331), or final FIGO (international federation of gynecology and obstetrics) grades (p = 0.448).

The median number of pelvic lymph nodes removed during surgery was 14 (range: 0–32) in Group 1 and 19 (range: 0–28) in Group 2 (p = 0.358). In addition, the median number of removed para-aortic lymph nodes was 16 (range: 12–55) in Group 1 and 14.5 (range: 4–33) in Group 2 (p = 0.188). Fertility-sparing surgery was performed for three patients in Group 1 (16.7%) and one patient in Group 2 (5.3%) (p = 0.340). One patient (5.6%) in Group 1 and three patients (15.8%) in Group 2 were selected for restaging after surgery (p = 0.604). Intraoperative tumor ruptures were seen in one patient (5.6%) in Group 1 and two patients (10.5%) in Group 2 (p = 1.000). Characteristics relating to surgery and tumors are presented in Table 2.

# 3.3 Intraoperative and postoperative details

Regarding postoperative complications between the two groups, the formation of a lymphocele or hernia was significantly higher in Group 2 compared to Group 1 (p = 0.019 and p = 0.050, respectively). When these groups were compared in terms of Clavien-indo classification, Grade 1

Variables	Group 1 Laparoscopy (n = 18)	Group 2 Laparotomy (n = 19)	<i>p</i> -value
Age (yr)	$44.9\pm10.1$	$47.3\pm9.9$	0.468
BMI (kg/m <sup>2</sup> )	$26.6\pm5.8$	$26.6\pm4.8$	0.991
ECOG score			
0	8 (44.4)	9 (47.4)	
1	9 (50.0)	6 (31.6)	0.335
2	1 (5.6)	4 (21.1)	
Parity	2 [0-3]	2 [0-7]	0.284
Menopause (yes)	7 (38.9)	9 (47.4)	0.603
Fertility desire (yes)	4 (22.2)	2 (10.5)	0.405
Previous abdominal surgery (yes)	8 (44.4)	9 (47.4)	0.858
History of cancer (yes)	2 (11.1)	2 (10.5)	0.954

#### TABLE 1. Patient characteristics.

Data are expressed as median [minimum–maximum], mean  $\pm$  standard deviation or number (%).

For comparison of groups,  $p \le 0.05$  was considered significant.

BMI: Body mass index, ECOG: Eastern Cooperative Oncology Group.

TABLE 2. Tumor characteristics and surgical outcomes.						
Variables	Group 1 Laparoscopy (n = 18)	Group 2 Laparotomy (n = 19)	<i>p</i> -value			
Primary site of disease	(11 10)	(11 17)				
Ovary	17 (94.4)	19 (100.0)	0.486			
Fallopian tube	1 (5.6)	-				
Histological type						
Serous	4 (22.2)	6 (31.6)				
Mucinous	1 (5.6)	1 (5.3)				
Endometrioid	5 (27.8)	3 (15.8)				
Clear cell	2 (11.1)	6 (31.6)				
Granulosa cell tm	4 (22.2)	-	0.198			
Steroid cell tumor	1 (5.6)	-				
Mucinous borderline ovarian tumor (containing focal intraepithelial carcinoma)	1 (5.6)	1 (5.3)				
Seromucinous	-	1 (5.3)				
Yolc sac tumor	_	1 (5.3)				
Histological grade						
1	11 (61.1)	10 (52.6)				
2	4 (22.2)	4 (21.1)	0.903			
3	3 (16.7)	5 (26.3)				
Pelvic lymph nodes	14 [0-32]	19 [0–28]	0.358			
Paraaortic lymph nodes	16 [12–55]	14 [4–33]	0.188			
LVSI						
Negative	12 (66.7)	11 (57.9)	0.582			
Positive	6 (33.3)	8 (42.1)				
Cytology						
Negative	14 (77.8)	12 (63.2)	0.001			
Positive	4 (22.2)	7 (36.8)	0.331			
Final FIGO stage						
1A	9 (50.0)	8 (42.1)				
2A	4 (22.2)	5 (26.3)				
1C	2 (11.1)	2 (10.5)	0.448			
2B	2 (11.1)	1 (5.3)				
3A	1 (5.6)	-				
3C	-	3 (15.8)				
Procedure						
Fertility sparing	3 (16.7)	1 (5.3)	0.240			
Radical	15 (83.3)	18 (94.7)	0.340			
Referred for restaging	1 (5.6)	3 (15.8)	0.604			
Intraoperative rupture of tumor	1 (5.6)	2 (10.5)	1.000			

Data are expressed as median [minimum-maximum] or number (%).

For comparison of groups,  $p \le 0.05$  was considered significant.

LVSI: Lymphovascular space invasion, FIGO: International Federation of Obstetrics and Gynecology.

complications were high among the laparoscopy group. In contrast, Grade 2, 3A and 3B complications were significantly higher in the open surgery group (p = 0.002).

Regarding hospital stay during the postoperative period, the patients in Group 2 stayed significantly longer compared to Group 1 (p = 0.001). No significant difference was observed regarding intraoperative complications, need for blood transfusion or ICU postoperatively, operation time, time to adjuvant chemotherapy, recurrence or death. Intra- and postoperative data are shown in Table 3.

Intraoperative blood transfusion was needed in one patient in the laparoscopic approach group due to right external iliac artery injury and in one patient in the other group due to vena cava injury. One patient in the laparotomy approach group required blood transfusion as a result of common iliac artery injury during lymph node resection. Regarding the procedures applied in addition to standard surgery, right inguinal lymphadenectomy was performed in one patient in the laparoscopic approach group, and rectosigmoid colon resection was performed in one patient in the laparotomic approach group.

### 4. Discussion

Despite its safe and routine use in endometrial cancer, laparotomy has been preferred over laparoscopy for the treatment of cervical cancer after receiving LACC (laparoscopic approach to carcinoma of the cervix) trial results [12]. While knowing these outcomes is critical, these data cannot offer reassurance that cancer outcomes are equivalent. In addition, laparoscopic staging procedures in early-stage ovarian cancer are still debatable. Because of different patterns of dissemination of ovarian cancer, some hypotheses suggest that laparoscopic surgery may contribute to and aggravate dissemination in various ways, including but not limited to transperitoneal dissemination, promoted tumor growth as a result of CO<sub>2</sub> (carbon dioxide)-induced hypercapnia, intraabdominal pressure (which makes the peritoneum more susceptible to tumor invasion), and diffuse mesothelial layer damage. Furthermore, according to some authors, a low level of local and systematic immunologic responses seen after laparoscopic surgery in comparison to laparotomy may encourage tumor cells to grow. The possibility of direct wound contamination and implantation by instruments and the chimney effect may favor the development of port-site metastasis [13].

The use of laparoscopy for ovarian cancer dates back to 1973, when Bagley et al. [14] described laparoscopic assessment before beginning a chemotherapy protocol. In 1994, Querleu and Leblanc [15] demonstrated that because of improvements in minimally invasive surgical technology, com-

	1		
	Group 1	Group 2	
Variables	Laparoscopy	Laparotomy	<i>p</i> -value
	(n = 18)	(n = 19)	
Intraoperative complications			
Vascular	3 (16.7)	7 (36.8)	0.167
Gastrointestinal	2 (11.1)	1 (5.3)	0.604
Intraoperative blood transfusion	2 (11.1)	1 (5.3)	0.604
Postoperative complications			
Fever	1 (5.6)	1 (5.3)	0.969
Bleeding	1 (5.6)	2 (10.5)	1.000
Abscess	1 (5.6)	2 (10.5)	1.000
Ileus	-	1 (5.3)	1.000
Lymphocele	1 (5.6)	8 (42.1)	0.019
Wound infection	1 (5.6)	5 (26.3)	0.180
Hernia	-	4 (21.1)	0.050
Need for ICU	3 (16.7)	3 (15.8)	0.942
Clavien-indo grade			
1	15 (83.3)	5 (26.3)	
2	2 (11.1)	8 (42.1)	
3A	1 (5.6)	2 (10.5)	
3B	-	4 (21.1)	0.002
Operating time	348 [179–626]	344 [150-415]	0.425
Postoperative hospital stay (day)	3 [1–11]	8 [3-36]	0.001
Time to adjuvant chemotherapy (day)	7 [0-44]	34 [0–153]	0.092
Recurrence time (mon)	0 [0–14]	0 [0-21]	0.799
Exitus	1 (5.6)	-	0.486
Data are expressed as median [minimum-r	maximum] or number (%	6).	

TABLE 3. Intraoperative and postoperative details.

For comparison of groups,  $p \le 0.05$  was considered significant.

ICU: intensive care unit.

plete laparoscopic surgical staging procedures for ovarian cancer were feasible. Since then, several published studies have supported the safety and feasibility of laparoscopic staging in early-stage ovarian cancer.

Staging surgery in ovarian cancer is a radical procedure. Serious lymphatic, nerve, vascular, intestinal and urinary complications may occur during the operation. In the postoperative period, wound infection, ileus, lymphocele, bleeding, abscess formation and hernia are among the common complications. We reviewed studies in the literature comparing intraoperative and postoperative complications in patients who underwent laparoscopic or laparotomic staging surgery. In the study conducted by Ghezzi et al. [16], it was found that the operation time was statistically significantly longer in the laparoscopy group, whereas the postoperative hospitalization time was statistically significantly longer in the laparotomy group. No intraoperative complications were observed in either group; postoperative complications were observed in 13.3% of the laparoscopy group and 42.1% of the laparotomy group. However, the details of the postoperative complications were not mentioned [16]. In the comparison made by Gallotta et al. [17], hospitalization time was significantly longer in the laparotomy group. In the study by Ran et al. [18], the laparoscopic approach was associated with shorter hospitalization time and shorter surgery time than the laparotomic approach. In our study, we found that the postoperative hospitalization time was longer in the laparotomy group, but there was no difference between the two groups in terms of operation time.

In addition to postoperative complications, lymphocele formation, which usually occurs in the first 8 weeks, was also investigated. Lymphocele refers to the accumulation of lymph fluid in the intraperitoneal space, which occurs due to damaged lymph channels during pelvic paraaortic lymph dissection. In our study, while there was no statistically significant difference in the number of pelvic paraaortic lymph nodes dissected between the two groups, when postoperative complications were considered, we saw that lymphocele formation was statistically significantly higher in the laparotomy group compared to the laparoscopy group. We believe that this difference is due to the higher number of postoperative adhesions in the laparotomic approach, thus deteriorating the absorption properties of the peritoneum [19, 20].

Vascular complications were any minor or major artery/vein injuries occurring during dissection. In our study, vascular complications were observed in three patients in the laparoscopy group and in seven patients in the laparotomy group. Similarly, in the German study by Trocchi et al. [21] based on a database spanning 10 years, the bleeding risk of the laparotomic approach in ovarian cancer was much higher than the laparoscopic approach. In our study, intraoperative blood transfusion was performed in two patients in the laparoscopy group and in one patient in the laparotomy group. We believe that this contradiction is due to the fact that the abdomens of patients in whom the laparotomy approach is preferred is more adherent. Vascular injuries are more common in areas where dissection is difficult, and bleeding control with suturation is easier for the surgeon, resulting in less bleeding and less need for transfusion.

One of the main concerns with laparoscopic staging surgery

is intraoperative capsule rupture. In a retrospective cohort study of more than 8000 ovarian cancer patients, Matsuo *et al.* [22] showed that the risk of capsular rupture was higher in the laparoscopic approach. However, in our study, intraoperative capsule rupture was observed in one patient in the laparoscopy group and two patients in the laparotomy group. There was no difference between the groups in this regard. This may be related to our small sample size. Alternatively, the relatively higher number of intra-abdominal adhesions in patients for whom the laparotomy approach was preferred may have caused rupture during dissection.

Compared our results with existing published data, our mean operation time and rate of intraoperative complications, such as vascular and gastrointestinal injuries, did not differ significantly. In our series, the laparoscopy group had fewer postoperative hospital days and a lower rate of postoperative complications, especially regarding lymphocele formation and hernia. One of the most important features observed in our study is the low Clavien-Dindo grade observed in the laparoscopy group. Although not statistically significant, average time to adjuvant chemotherapy was 7 days in the laparoscopy group compared to 34 days in the laparotomy group.

One limitation of our study is its retrospective design. Establishing diagnosis usually occurs at advanced stages of ovarian cancer, and thus, finding early-stage ovarian cancer is relatively rare. Therefore, the sample size to support our findings in the study was relatively small. In addition, sufficient followup time and data were not available in our study to analyze the hypothesis that laparoscopic ovarian cancer surgery, mentioned in the studies discussed above, causes procedural tumor invasion. Cancer and survival outcomes are also missing. Another limitation of our study is that not enough information can be provided regarding how the decision to use either the laparoscopic or laparotomic approach was made during the preoperative evaluation of the patients.

Because of the limited number of studies in the literature analyzing the effectiveness, advantages and disadvantages of these procedures in the surgical management of ovarian cancer, our study provides an important contribution to the literature. The adjustment for biases related to patient demographic information improved the value of our results. In addition, the fact that all operations included in the study were performed by the same experienced gynecologic oncologist at a single center increased the objectivity and minimized the complication rates of the study. Another strength of our study is the presentation of the Clavien-Dindo classification system results, which were not included in previous studies in the literature.

### 5. Conclusions

Being an alternative to open surgery for the diagnosis and staging of ovarian cancer, the laparoscopic approach is reliable and can be applied safely to patients. However, more prospective randomized studies are needed to support the obtained data.

#### **ABBREVIATIONS**

ECOG, eastern cooperative oncology group scale; ICU, intensive care unit; SPSS, statistical package for the social sciences; BMI, body mass index; LVSI, lymphovascular space invasion; FIGO, international federation of gynecology and obstetrics; LACC trial, laparoscopic approach to carcinoma of the cervix; MRI, magnetic resonance imaging; CT, computed tomography; PET, positron emission tomography; CA, cancer antigen; CEA, carcinoembryonic antigen; AFP, alpha fetoprotein; ISAAC, initial surgery in advanced asymptomatic colorectal; NACT, neoadjuvant chemotherapy; USG, ultrasound sonography test.

### AVAILABILITY OF DATA AND MATERIALS

The data presented in this study are available on reasonable request from the corresponding author.

### AUTHOR CONTRIBUTIONS

FBT and GK—designed the research study. GK—performed the research. CC—provided help and advice on methodology. OP—analyzed the data. FBT and SM—wrote the manuscript. All authors read and approved the final manuscript.

# ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study protocol was approved by the Non-Clinical Research Ethics Committee of Bezmialem University Hospital (reference number: E-54022451-050.05.04-89840) on 23 December 2022. All patients consented to use their information for the study.

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### **CONFLICT OF INTEREST**

The authors declare no conflict of interest.

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