

# Primerjava onkološkega izhoda kirurškega zdravljenja zgodnjega stadija raka endometrija glede na vrsto kirurškega pristopa (laparoskopski, laparotomijski)

## Laparoscopy versus laparotomy for the management of early-stage endometrial cancer: Effect on oncological outcomes

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### Izvleček

**Izhodišče:** Rak endometrija je najpogostejši ginekološki rak v razvitem svetu. V 80 % ga odkrijemo v zgodnjem stadiju. V tem primeru poteka zdravljenje najprej kirurško, z odstranitvijo maternice, adneksov in oceno retroperitonealnih bezgavk. Z razvojem laparoskopije se je minimalno invazivni pristop prenesel tudi v kirurgijo malignih bolezni. Vsak novi pristop v zdravljenju malignih bolezni mora biti ovrednoten v smislu vpliva na onkološki izhod. V prispevku prikažemo onkološki izhod svojih bolnic z zgodnjim stadijem raka endometrija, zdravljenih kirurško, glede na pristop (laparotomija, laparoskopija).

**Metodologija:** Opravili smo retrospektivno analizo bolnic z zgodnjim stadi-

### Abstract

**Background and aim:** Endometrial cancer is the most common gynecologic malignancy diagnosed in an early stage in 80% of patients. The standard treatment for this includes hysterectomy, bilateral salpingo-oophorectomy, and pelvic lymph node dissection. The advancement of laparoscopy has facilitated the use of minimally invasive techniques also in the field of oncologic surgery. Every new approach should be evaluated in terms of oncological outcomes. This study aimed to compare the oncological outcomes among women with early-stage endometrial cancer treated using laparotomy and a laparoscopic approach.

**Methods:** We conducted a retrospecti-

jem raka endometrija, zdravljenih na Oddelku za ginekološko onkologijo in onkologijo dojk, UKC Maribor. V raziskavo smo vključili zaporedne bolnice z zgodnjim stadijem raka endometrija, ki so se zdravile kirurško, v dveh časovnih obdobjih, ko smo pristopali z laparotomijo (od leta 2001 do 2006) ali laparoskopsko (od leta 2008 do 2016). Vključili smo bolnice, ki so imele klasičen operativni poseg za zdravljenje raka endometrija, in sicer histerektomijo, adnektomijo in pelvično limfadenektomijo. Naredili smo analizo prognostičnih dejavnikov v posamezni skupini, ki bi lahko vplivali na primarni in sekundarni cilj. Primarni cilj raziskave je bil določiti stopnjo ponovitev bolezni v obdobju sledenja vsaj 5 let po zdravljenju, sekundarni cilj pa določiti preživetje do ponovitve bolezni v obdobju sledenja vsaj 5 let po zdravljenju.

**Rezultati:** V raziskavo smo vključili 73 zaporednih bolnic, zdravljenih z laparotomijo, in sicer od leta 2001 do 2006 in 60 zaporednih bolnic, zdravljenih z laparoskopijo, od leta 2008 do 2016. Bolnice obeh skupin se niso razlikovale v prognostičnih dejavnikih, le več bolnic je imelo pooperativno obsevanje v laparotomijski skupini (sprememba indikacije). Stopnja ponovitev v laparotomijski skupini je znašala 6/73 (8,2 %), v laparoskopski skupini pa 2/60 (3,3 %). Razlika ni bila statistično značilna ( $p = 0,238$ ). Prav tako ni bilo statistično značilne razlike v preživetju do ponovitve bolezni ( $p = 0,180$ ).

**Zaključek:** Z raziskavo nismo ugotovili pomembnih razlik v onkološkem izhodu v obdobju sledenja vsaj 5 let po kirurškem zdravljenju zgodnjega stadija raka endometrija glede na kirurški pristop (laparotomija, laparoskopija). Raziskava je pomemben retrospektivni pregled, največjo moč pa bodo imele prospektivne randomizirane raziskave.

ve analysis of patients with early-stage endometrial cancer treated in the Department of Gynecologic Oncology and Breast Oncology, University Medical Center Maribor. All consecutive patients who underwent laparotomy (from 2001 to 2006) or laparoscopy (from 2008 to 2016) were included. All patients had a standard surgical treatment: hysterectomy, bilateral salpingo-oophorectomy, and pelvic lymph node dissection. We analyzed the prognostic factors in each group of patients, which could affect our primary and secondary goals. The primary goal (the recurrence rate) and secondary goal (the disease-free survival) were determined during a follow-up of at least 5 years.

**Results:** A total of 73 consecutive patients who underwent laparotomy from 2001 to 2006 and 60 consecutive patients who underwent laparoscopy from 2008 to 2016 were included in the analysis. No statistically significant between-group difference was found in the prognostic factors, except the adjuvant radiotherapy being more frequent in the laparotomy group (change in clinical practice). No statistically significant between-group difference was found in the disease recurrence rate [6/73 (8.2%) laparotomy group vs. 2/60 (3.3%) laparoscopy group ( $P = 0.238$ )] or in the disease-free survival during at least 5-year follow-up ( $P = 0.180$ ).

**Conclusion:** No statistically significant difference was found in oncological outcomes during a 5-year follow-up of women with early-stage endometrial cancer treated using laparotomy or laparoscopy. This finding was an important retrospective overview, but future prospective randomized trials should validate this.

## INTRODUCTION

Endometrial cancer is the most common cancer of the gynecological tract in women in developed countries. During 2009–2013, an average of 313 women per year developed cancer of the corpus uteri (30.2/100,000), while 49 died (4.7/100,000) (1). In almost 80% of cases, cancer presents itself in an early stage (The International Federation of Gynecology and Obstetrics (FIGO) stage I), with the expected 5-year survival of such patients being no less than 95% (2).

In approximately 80% of cases, the histological image showed endometrial adenocarcinoma. In up to 20% of cases, however, rarer forms develop: papillary, serous, clear cell, mucinous, carcinosarcoma, or mixed carcinoma. These had a poorer prognosis and a greater probability of distant metastases.

The treatment of FIGO stage I endometrial cancer is primarily surgical and includes total hysterectomy with bilateral adnexectomy. In the past, the surgical

treatment also included lymphadenectomy, which was abandoned after 2015 in accordance with the European Society for Medical Oncology, European Society for Radiotherapy & Oncology and European Society of Gynaecological Oncology (ESGO-ESTRO-ESMO) guidelines for patients with low or medium risk endometrial cancer, while the sentinel node biopsy was introduced for assessing the status of retroperitoneal lymph nodes (2).

Traditionally, the surgical procedure was carried out through laparotomy. Laparoscopic surgery is a more modern approach, while robotic surgery has also become increasingly common. Compared with laparotomy, the laparoscopic approach is safer, mainly in overweight women, as it has a lower risk of postoperative wound infection, less blood loss, and less bowel obstruction (ileus) (3). In the case of laparoscopy, the duration of hospitalization is shorter, recovery is faster, and treatment is cheaper (4). Studies indicate that laparoscopy and laparotomy are comparable in terms of long-term disease management (5,6). However, when laparoscopy was introduced for the treatment of endometrial cancer, the main concern was that metastatic tumors or lymph nodes that were difficult to reach, which could otherwise be sensed by touch in laparotomy, would be overlooked due to the loss of tactile sensitivity. Moreover, the potential change in the pattern of recurrence due to the high intra-abdominal pressure caused by CO<sub>2</sub> or a potential tumor spillage due to the use of an intrauterine manipulator was also a cause of concern. The world of scientific research was shocked in 2018 with the results of the LACC (Laparoscopic Approach to Cervical Cancer) prospective randomized study comparing the oncological outcome of patients with operable early-stage cervical cancer who were treated laparoscopically/robotically or with laparotomy (7). For safety reasons, this study ended early, and it clearly showed a significantly poorer oncological outcome for patients treated laparoscopically/robotically. This was not, however, expected considering the data from retrospective analyses. No explanation could clarify the mechanism behind the higher recurrence rate when using laparoscopy, but the laparoscopic/robotic treatment of cervical cancer was abandoned nonetheless. The results of this study led to questions

concerning the safety of the laparoscopic approach when treating endometrial cancer.

As of 2008, mainly laparoscopic surgical treatment of FIGO stage I endometrial cancer has been gradually performed at the Department of Gynecologic and Breast Oncology at the University Medical Center Maribor. We wanted to know whether the recurrence rate and disease-free survival in patients who received laparoscopic treatment or laparotomy were comparable. Therefore, we carried out a retrospective analysis of patients suffering from FIGO stage I endometrial cancer treated from 2001 to 2006 using the laparotomy approach, and from 2008 to 2016 using the laparoscopic approach.

## METHODS

A retrospective analysis of patients with early-stage endometrial cancer was carried out at the Department of Gynecologic and Breast Oncology at the University Medical Center Maribor. The treatment of these patients at the department was carried out exclusively using laparotomy until 2008, while the laparoscopic approach was gradually introduced. The analysis included all consecutive patients with FIGO stage I endometrial cancer who received surgical treatment from 2001 to

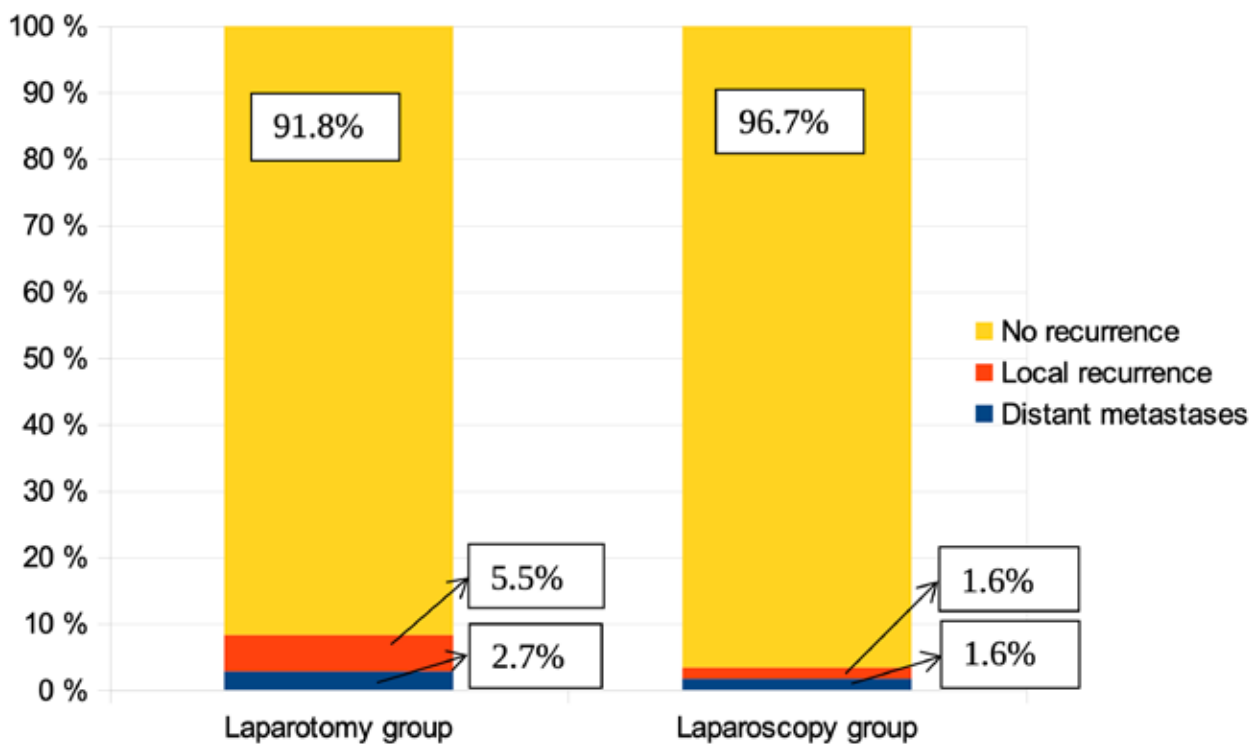
**Table 1.** Prognostic risk groups, according to Concin (8)

Low risk	FIGO stage IA, endometrioid, well differentiated (G1 and G2), and LVI negative or focal
Medium risk	FIGO stage IA, endometrioid, poorly differentiated (G3), and LVI negative or focal FIGO stage IB, endometrioid, well differentiated (G1 and G2), and LVI negative or focal FIGO stage IA, nonendometrioid, and without myometrial invasion
High-medium risk	FIGO stage I, endometrioid, and LVI present FIGO stage IB, endometrioid, and poorly differentiated (G3), regardless of the presence of LVI FIGO stage II
High risk	FIGO stage I-IVA, nonendometrioid, with myometrial invasion, and without residual disease FIGO stage III-IVA and without residual disease
Advanced disease	FIGO stage III-IVA and with residual disease FIGO stage IVB

2006 using laparotomy and all consecutive patients treated from 2008 to 2016 using laparoscopy. Therefore, the inclusion criteria were as follows: surgical FIGO stage I, standard surgical treatment using hysterectomy, adnexectomy, and pelvic lymphadenectomy, and standard postoperative treatment. The analysis did not include those patients for whom lymphadenectomy had not been performed, who wished to retain their reproductive capability, or who had been subjected to nonstandard treatment and did not participate in postoperative follow-up in a period of at least 5 years. The prognostic factors (the age of the patient, histological type, depth of myometrial invasion, and positive peritoneal washing cytology), presence of other comorbidities (arterial hypertension, diabetes, and others), duration of the procedure, and postoperative radiation treatment were compared between the groups. Four risk levels for the recurrence of the disease were determined in accordance with the ESGO-ESTRO-ESP (European Society of

Pathology) recommendations for treating patients with endometrial cancer (8). The definition of the groups is shown in Table 1.

We were interested in the recurrence rate and disease-free survival in both groups at least 5 years after the treatment. The disease-free survival was defined as the time from surgery until the first occurrence of clinical, laboratory, or imaging signs of recurrence, either local or with distant metastases. The statistical analysis was performed using the software International Business Machines Corporation (IBM) Statistical Package for the Social Sciences Statistics 25.0 (NY, USA). All parameters were evaluated using the Student's t-test for continuous variables and the chi-square test and Mann-Whitney test for attributes. The survival analysis was performed by the Kaplan-Meier method and the log-rank test. A P value <0.05 indicated a statistically significant difference. The study was approved by the Medical Ethics Committee at the University Medical Center Maribor.



**Figure 1.** Comparison of the recurrence rate between the groups: 6/73 (8.2%) in the laparotomy group compared with 2/60 (3.3%) in the laparoscopy group. Two (2.7%) patients in the laparotomy group had distant metastases, while four (5.5%) had local recurrence. One (1.6%) patient in the laparoscopy group had distant metastases, and one (1.6%) had a local recurrence. Patients in both groups were followed up for at least 5 years.

**Table 2.** Features of the patients in the laparotomy and laparoscopy groups

	Laparotomy group (n = 73)	Laparoscopy group (n = 60)	P value
Age, mean value	62.8 ± 9.4	63.4 ± 11.1	0.751 <sup>a</sup>
Histological type			
Endometrioid carcinoma	70/73 (95.9%)	60/60 (100%)	
Serous carcinoma	1/73 (1.4%)	0%	
Carcinosarcoma	1/73 (1.4%)	0%	
Mixed-cell carcinoma	1/73 (1.4%)	0%	
Tumor grade			<0.001 <sup>b</sup>
G1	22/71 (31%)	42/60 (70%)	
G2	43/71 (60.6%)	14/60 (23.3%)	
G3	6/71 (8.4%)	4/60 (6.7%)	
FIGO 2009 stage			0.523 <sup>b</sup>
Ia	37/66 (56.1%)	37/60 (61.7%)	
Ib	29/66 (43.9)	23/60 (38.3%)	
Positive peritoneal washing cytology	0/7 (0%)	3/48 (6.3%)	* c
Group according to recurrence risk			0.101 <sup>b</sup>
Low risk	32/64 (50%)	33/60 (55%)	
Medium risk	25/64 (39.1%)	19/60 (31.7%)	
High-medium risk	4/64 (6.2%)	8/60 (13.3%)	
High risk	3/64 (4.7%)	0%	
Number of removed lymph nodes	23.6 [3–46]	26.2 [3–59]	0.184 <sup>a</sup>
Surgery duration in minutes, mean value	97.4 ± 59.2	186.2 ± 44.3	<0.001 <sup>a</sup>

<sup>a</sup>t-test.

<sup>b</sup>chi-squared test.

<sup>c</sup>Due to an insufficiently large sample (value zero), the chi-squared test could not be performed.

## RESULTS

In accordance with the inclusion criteria, the study included 133 patients with FIGO stage I endometrial cancer. Among these, 73 (54.9%) underwent laparotomy from 2001 to 2006 and 60 (45.1%) underwent laparoscopy from 2008 to 2016.

The information about the age, histological subtype, tumor grade, FIGO stage, cytological analysis of the washing, risk level for the recurrence of the disease, number of removed lymph nodes, and duration of the surgical procedure between the groups are shown in Table 2. We were able to obtain the data regarding lymphovascular invasion (LVI) for most of the laparoscopy groups, where LVI was present in 8/57 cases (14%), while no data were obtained for the majority (90.4%) of the laparotomy group (it was only present in three cases).

The groups of patients did not differ based on the presence of comorbidities: 45/73 (61.6%) in the laparotomy group compared with 44/60 (73.3%) in the laparoscopy group (P = 0.593).

Significantly more patients underwent postoperative radiation: 34/72 (47.2%) in the laparotomy group compared with 13/60 (21.7%) in the laparoscopy group (P = 0.02).

Figure 1 shows the comparison of the recurrence rate between the groups [6/73 (8.2%) in the laparotomy group compared with 2/60 (3.3%) in the laparoscopy group, P = 0.238], also separately for local recurrence and distant metastases. Patients in both groups were followed up for at least 5 years postoperatively. The groups of patients did not differ in terms of disease-free survival: 69.7 months (11–130) in the laparotomy group compared with 57 months (42–72) in the laparoscopy group (P = 0.180).

Table 3. Features of patients with recurrence

	Laparotomy group (n = 6)	Laparoscopy group (n = 2)
Age, mean value	63.1 (54–78)	72 (60–84)
Comorbidities	6/6 (100%)	2/2 (100%)
Histological type		
Endometrioid carcinoma	5/6 (83.3%)	2/2 (100%)
Carcinosarcoma	1/6 (16.7%)	0%
Tumor grade		
G1	4/6 (66.7%)	1/2 (50%)
G2	1/6 (16.7%)	1/2 (50%)
G3	1/6 (16.7%)	0%
FIGO 2009 stage		
Ia	1/6 (16.7%)	0%
Ib	5/6 (83.3%)	2/2 (100%)
Positive peritoneal washing cytology	0/1 (0%)	0/2 (0%)
Group according to recurrence risk		
Low risk	1/6 (16.7%)	0%
Medium risk	4/6 (66.7%)	1/2 (50%)
High–medium risk	0%	1/2 (50%)
High risk	1/6 (16.7%)	0%
Number of removed lymph nodes	15 (7–20)	15.5 (5–26)
Surgery duration in minutes, mean value	113.3 (60–145)	172.5 (150–195)
Postoperative radiation	2/6 (33.3%)	0/2 (0%)
Time to recurrence (months), mean value (range)	69.7 (11–130)	57 (42–72)

Table 3 shows the features of the patients in both groups with disease recurrence. In the laparotomy group, six patients developed recurrence, of which two had metastases in distant organs (one of them underwent postoperative radiation) and four had local recurrence (one of them underwent postoperative radiation). Four of the six patients had the endometrioid subtype of endometrial carcinoma, G1/G2; the basic condition of one patient was endometrioid subtype, poorly differentiated (G3); and one had carcinosarcoma. In the laparoscopy group, two patients had recurrence, one with local recurrence and one with distant metastases; neither of them underwent adjuvant radiotherapy. Both had the endometrioid subtype of endometrial carcinoma, G1/G2.

## DISCUSSION

This study confirmed that the recurrence rate and disease-free survival of FIGO stage I endometrial cancer did not significantly differ between patients who underwent surgical treatment using laparotomy and those who underwent the laparoscopic procedure.

The recurrence rate of endometrial cancer is generally about 13% and only up to 3% in patients with low risk disease (9). Recurrence in terms of anatomical location is evenly distributed between local recurrence and distant metastases. Most frequently, the disease recurs in the vaginal vault, the lesser pelvis, abdominal cavity, or in the lungs. The prognostic factors affecting the recurrence rate are histological type, tumor grade, depth of myometrial invasion, LVI, tumor size, growth into the bottom segment of the uterus, positive peritoneal cytology, presence of metastases in the lymph nodes,

age of the patient, and specific molecular markers (1, 8, 10). Survival is also affected by comorbidities, American Society of Anesthesiologists score, and postoperative complications within 30 days following surgical treatment (9). The disease-free 5-year survival for patients without metastases in the lymph nodes is estimated to be 90%. Therefore, we found that the recurrence percentage at our center was comparable with the published data as expected, for both the laparoscopy and laparotomy groups (11).

The laparoscopic approach has numerous advantages, including a lower risk of serious postoperative complications, such as infection and the dehiscence of the postoperative wound, major blood loss, and bowel obstruction (ileus). Also, the postoperative recovery is significantly faster, the duration of hospitalization is shorter; the reported quality of life is significantly higher up to 6 months after the procedure, and, finally, the treatment cost is lower. Both approaches are comparable in terms of the frequency of major intraoperative complications. For this reason, it was a logical step in the past to ensure that the laparoscopic approach also spread to oncological surgery, especially in the event of localized diseases. Therefore, the introduction of the laparoscopic approach to treating endometrial cancer also began at the Department of Gynecologic and Breast Oncology, University Medical Center Maribor in 2008. Whenever a new approach becomes available in oncological surgery, it must be evaluated in terms of safety and its impact on the oncological outcome. For this reason, we performed the first clinical study in our center to find the impact of the new approach on the oncological outcome after 5 years of primary treatment. As expected, this study confirmed that the laparoscopic approach had a longer duration of surgery, which was consistent with the findings of previous studies; however, in clinical terms it outweighed the benefits of laparoscopy (5, 12). We also confirmed that one of the quality indicators for the oncological surgery of endometrial cancer, that is, the number of removed pelvic lymph nodes, did not differ depending on the approach. As already stated, we also could not confirm any differences in the recurrence rate and disease-free survival.

A meta-analysis of randomized studies looking into the advantages of laparoscopic treatment of early-

stage (specifically FIGO stage I to IIA) endometrial cancer was recently conducted (in 2018). The meta-analysis data proved the safety of laparoscopy in long-term disease management, as the recurrence rate in patients who were monitored for an average of 38–59 months after laparoscopic treatment was 7.9%–12.6%, while the recurrence rate in patients after treatment with laparotomy was 8.1%–11.5% (3). The pattern of recurrence in terms of local or distant recurrence was, just like in this study, evenly divided between the laparoscopy group and the laparotomy group (3). The largest randomized study called LAP2, which included 2616 patients with FIGO stage I–IIA endometrial cancer, showed that the cumulative recurrence rate 3 years after the procedure was 11.4% in the laparoscopy group and 10.2% in the laparotomy group (1.14% difference) (13). However, the study did not meet the specific criteria for assessing the noninferiority of the laparoscopic method, perhaps mainly due to the expected low recurrence rate. The overall survival compared between the groups was practically identical (89.8%). The study also included patients with a nonendometrioid tumor. Although the authors highlighted that the power of the study was not sufficient to assess whether the surgical method was suitable for these patients, they also did not note any differences in the recurrence rate between the laparoscopy and laparotomy groups. The recurrence rate at the site of the trocar after laparoscopic surgery was extremely low (0.24%). The study also emphasized the better reported quality of life of patients after laparoscopic surgery (13). Then, another larger retrospective study analyzed patients who received surgical treatment for FIGO stage II endometrial cancer, where the tumor had spread to the cervix. The study included 2175 patients and confirmed the best short-term perioperative outcome for patients and even an improved 3-year overall survival of patients after a minimally invasive surgical procedure (14).

This study had multiple shortcomings. First, the retrospective approach of the study made the gravity of the results lesser. However, we still found that this constituted a significant data overview, as the active monitoring and publishing of oncological outcomes is the most important quality indicator of every oncological center. The groups were also poorly comparable due to this retrospective approach and the selection. We wished to counteract this as much as possible by including all

consecutive patients as well as patients for whom the standard procedure had been fully carried out (total hysterectomy, adnexectomy, and lymphadenectomy). The groups of patients did not differ depending on the recurrence risk, which was the most important fact that could be related to survival differences. However, the groups did differ in the percentage of patients who received postoperative radiation. This could be related to the impact on recurrence. However, we must be aware that the indications for postoperative radiation have changed over the years, mainly toward radiation being performed less frequently than in the past. The reason for the decrease in indications for radiation was that no evidence showed the relation of radiation to any benefits for the oncological outcome. This was also confirmed by our results, as the group with a lower level of postoperative radiation did not have more recurrences. The groups also differed in the percentage of patients with positive peritoneal washing cytology, but mostly because we failed to obtain test results for the majority (90.4%) of the laparotomy group, while the higher percentage in the laparoscopy group was the result of more frequently performed hysteroscopy prior to surgical treatment (15). In theory, the laparoscopic approach (with the use of an intrauterine manipulator) could be correlated with an increased frequency of LVI and a higher recurrence rate; however, studies have not shown this to be the case (16, 17). We wished to verify this in our study, but we could not reach any conclusions because of the lack of relevant data. The data concerning LVI only became significant and required histological parameters for early endometrial cancer with the latest guidelines for treating endometrial cancer published in

2020 (8); previously, it had not been routinely prescribed in regular clinical practice.

The biggest statistical problem, not just of our analysis but also of other studies, when studying the oncological outcomes of patients with FIGO stage I endometrial cancer, is the excellent prognosis and long-term survival, which means that a very high number of participating patients and a very long period of observation are necessary for the statistical and clinical values of the analysis. For endometrial cancer, this should optimally be at least 10 years.

## **CONCLUSIONS**

This study and the studies published thus far have indicated a comparable oncological outcome of the surgical treatment of early-stage endometrial cancer in addition to all the advantages of the laparoscopic approach compared with laparotomy. Therefore, the laparoscopic approach has been classified in the latest ESGO guidelines as a recommended approach for all patients with early-stage endometrial cancer. Furthermore, constant monitoring and research are recommended, as the low frequency of recurrence and long disease-free survival make it more difficult to determine the effects on the oncological outcomes.

## **DISCLOSURE**

The authors declare no conflicts of interest.



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