GYNECOLOGY

Robotic-assisted versus conventional laparoscopic surgery for endometrial cancer: long-term results of a randomized controlled trial

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BACKGROUND: Robotic-assisted laparoscopy has become a widely and increasingly used modality of minimally invasive surgery in the treatment of endometrial cancer. Due to its technical advantages, robotic-assisted laparoscopic surgery offers benefits, such as a lower rate of conversions compared to conventional laparoscopy. Yet, data on long-term oncological outcomes after robotic-assisted laparoscopy is scarce and based on retrospective cohort studies only.

OBJECTIVE: This study aimed to assess overall survival, progression-free survival, and long-term surgical complications in patients with endometrial cancer randomly assigned to robotic-assisted or conventional laparoscopy.

STUDY DESIGN: This randomized controlled trial was conducted at the Department of Gynecology and Obstetrics of Tampere University Hospital, Finland. Between 2010 and 2013, 101 patients with low-grade endometrial cancer scheduled for minimally invasive surgery were randomized preoperatively 1:1 either to robotic-assisted or conventional laparoscopy. All patients underwent laparoscopic hysterectomy, bilateral salpingo-oophorectomy, and pelvic lymphadenectomy. A total of 97 patients (49 in the robotic-assisted laparoscopy group and 48 in the conventional laparoscopy group) were followed up for a minimum of 10 years. Survival was analyzed using Kaplan-Meier curves, log-rank test, and Cox proportional hazard models. Binary logistic regression analysis was used to analyze risk factors for trocar site hernia.

RESULTS: In the multivariable regression analysis, overall survival was favorable in the robotic-assisted group (hazard ratio 0.39; 95% confidence interval [CI], 0.15—0.99, *P*=.047) compared to the conventional laparoscopy group. There was no difference in progression-free survival (log-rank test, *P*=.598). The 3-, 5-, and 10-year overall survival were 98.0% (95% CI, 94.0—100) vs 97.9% (93.8—100), 91.8% (84.2—99.4) vs 93.7% (86.8—100), and 75.5% (64.5—87.5) vs 85.4% (75.4—95.4) for the conventional laparoscopy and the robotic-assisted groups, respectively. Trocar site hernia developed more often for the robotic-assisted group compared to the conventional laparoscopy group 18.2% vs 4.1% (odds ratio 5.42, 95% CI, 1.11—26.59, *P*=.028). The incidence of lymphocele, lymphedema, or other long-term complications did not differ between the groups.

CONCLUSION: The results of this randomized controlled trial suggest a minor overall survival benefit in endometrial cancer after robotic-assisted laparoscopy compared to conventional laparoscopy. Hence, the use of robotic-assisted technique in the treatment of endometrial cancer seems safe, though larger randomized controlled trials are needed to confirm any potential survival benefit. No alarming safety signals were detected in the robotic-assisted group since the rate of long-term complications differed only in the incidence of trocar site hernia.

Key words: endometrial carcinoma, laparoscopy, lymphedema, lymphocele, oncological survival, port-site hernia, robotic, surgical outcome, trocar site hernia

Introduction

Endometrial cancer (EC) is the sixth most common cancer in women in developed countries with 417,000 new diagnoses made in 2020. The incidence is rising globally mostly due to the increasing prevalence of obesity and the aging of the population.[1,2] The mainstay of treatment is hysterectomy and bilateral salpingo-oophorectomy (BSO) by minimally invasive surgery (MIS), combined with evaluation of nodal status in most cases. Adjuvant therapy is given if high-risk features are encountered.[3]

Robotic-assisted laparoscopic surgery (RALS) is an extension of laparoscopic surgery used in gynecology since 2005. Due to the technical advantages of RALS, such as highly magnified 3D vision, precisely controlled movements of fatigue-resistant robotic arms with enhanced mobility, tremor infiltration, better ergonomics of the surgeon, and the relatively short learning curve, RALS has become a widely adopted and increasingly utilized method in many fields of thoracoabdominal surgery, including the treatment of EC.[4] In many centers, especially in the United States, RALS is by now the most common surgical approach in EC.[5—7]

In EC, RALS offers lower rates of conversions and enhanced recovery compared to conventional laparoscopic surgery (CLS). However, data on long-term survival after RALS are still scarce and based on retrospective cohort studies only. Most studies, but not all, indicate similar oncological long-term outcomes compared to CLS.[8] Given the rapid increase in the use of RALS in EC and the higher costs associated, there is an essential need to assess the oncological survival associated with RALS.

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AJOG at a Glance

Why was this study conducted?

This is the first randomized controlled trial comparing long-term oncological outcomes of endometrial cancer (EC) patients after robotic-assisted laparoscopy and conventional laparoscopic surgery (CLS).

Key findings

Overall survival (OS) was better in the robotic-assisted group compared to the CLS group in a 10-year follow-up.
There was no difference in progression-free survival.
Trocar site hernia was more common after robotic-assisted laparoscopy.

What does this add to what is known?

The results of this randomized trial suggest minor OS benefit in EC after robotic-assisted laparoscopy compared to CLS.
Using robotic-assisted technique in the treatment of EC seems safe.

To our knowledge, only 1 randomized controlled trial (RCT) has been conducted comparing RALS and CLS in EC. The primary analysis reporting shorter operating time in RALS was published in 2016.[9] The present study introduces the long-term results of this RCT after 10 years of follow-up.

Materials and methods

This RCT was conducted at the Department of Gynecology and Obstetrics of Tampere University Hospital, Tampere, Finland. Between December 2010 and October 2013, a total of 101 patients with low-grade EC scheduled for minimally invasive surgical staging operation were randomized preoperatively 1:1 either to RALS (da Vinci S Surgical System; Intuitive Surgical Inc, Sunnyvale, CA) or CLS. Exclusion criteria were a narrow vagina or uterus too large to remove via the vagina, contraindications for deep Trendelenburg position, and age under 30 or over 85 years. The groups were stratified for overweight (body mass index (BMI) <30 and ≥ 30 kg/m^2) and age (<65 and ≥ 65 years). The primary outcome of the trial was the overall operating time and the secondary outcome was short-term surgical complications. The power calculations were aimed to show a 25% difference in operative times. The primary results along with the detailed statistical design of the study were published in the American Journal of Obstetrics and Gynecology in 2016.[9] The study was approved by the Ethics Committee of Tampere University Hospital (identification number ETL R10081). The trial was registered at ClinicalTrials.gov, www.clinicaltrials.gov, NCT014 66777. Written informed consent was obtained from study participants.

All patients were scheduled for laparoscopic hysterectomy, BSO, and pelvic lymphadenectomy. The surgical techniques differed between the groups in terms of placement and size of trocars, entering the abdominal cavity, and closing the vagina. The open entry technique was used in the RALS group, and a 12-mm trocar was placed 10 cm above the umbilicus. In the CLS group, the entering was done in the umbilicus with a Verress needle, and the trocar used at the site was 10 mm wide. In both groups, the upper abdomen trocar site fascia was sutured in direct vision with a slowly absorbable suture. A more detailed description can be found in the previous article.[9]

Lymphadenectomy was omitted in 2 patients in both groups (a total of 4 patients) due to disseminated disease.[9] Two patients in the RALS group turned out to have extrauterine malignancy in the final histopathological analysis and were excluded from this analysis. Finally, a total of 97 patients were included in the 10-year follow-up analysis (Figure 1).

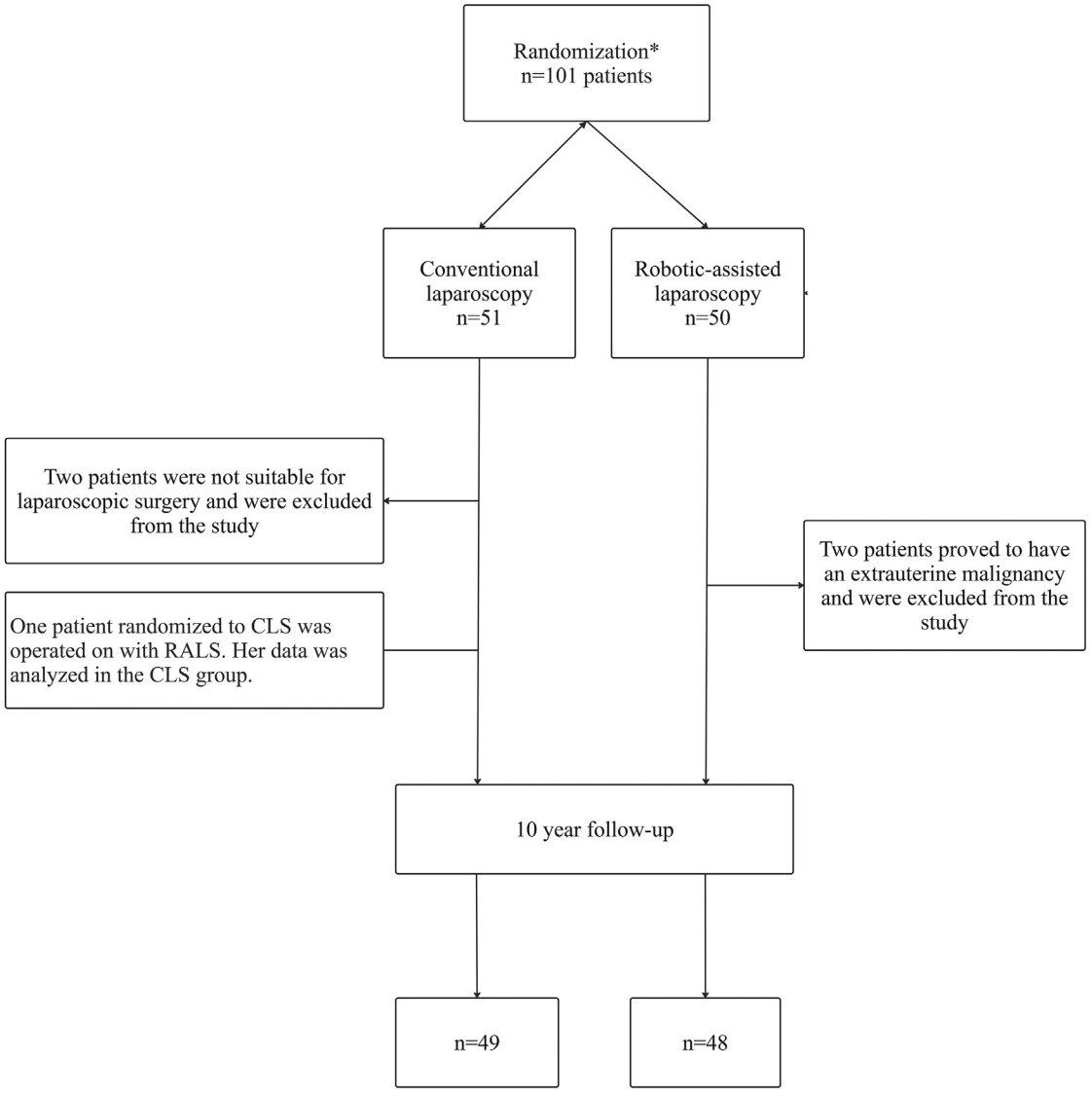
The secondary outcomes presented here were overall survival (OS), progression-free survival (PFS), and long-term surgical complications. OS was defined as the time from surgery to death or the end of follow-up whichever came first. PFS was defined as the time from surgery to the first EC recurrence or the end of follow-up. The long-term surgical complications of interest were defined as trocar site hernia, lymphocele, lymphedema of the lower extremity, and others. The parameters mentioned above were collected from the medical database, and the data were stored and analyzed in a secured platform provided by Tampere University Hospital.

Normally distributed variables were compared using an unpaired t test, while the Mann-Whitney U test was employed for variables not conforming to normal distribution. The chi-square test or Fisher's exact test was used for categorical variables. Kaplan-Meier curves with log-rank tests were used to evaluate differences in survival according to the surgical approach. The reported hazard ratios (HRs) for death are based on the Cox proportional hazard models. Binary logistic regression analysis was used to analyze risk factors for trocar site hernia. All tests were 2-sided, and a statistically significant difference was considered for $P<.05$. Statistical analysis was performed with SPSS software (version 29.0; IBM, Armonk, NY).

Results

Patients were followed up for at least 10 years. The mean follow-up time was 11.2 years (95% CI, 10.3−12.1) in the CLS and 11.9 (11.1−12.7) years in the RALS group. The CLS and the RALS groups were comparable in age, BMI, and medical history. Comorbidities were categorized using the original Charlson comorbidity index (CCI), which has proven to be a strong predictor of mortality among cancer patients.[10] The number of lymph nodes harvested, histopathological findings, or adjuvant therapy did not differ between the groups. The demographic and clinical characteristics of the patients are summarized in Table 1. There were 5 conversions to laparotomy in the CLS group and none in the RALS group.

FIGURE 1
The flow chart of the study



*Patients with low-grade endometrial carsinoma schedulded for operation

CLS, conventional laparoscopy; *RALS*, robotic-assisted laparoscopic surgery.

According to the Kaplan-Meier analysis, OS was better in the RALS group compared to the CLS group (log-rank test, P=.045; Figure 2). This difference persisted when only stage I and II patients were analyzed (log-rank test, P=.027), and remained significant even when nonendometrioid and high-grade endometrioid cancer patients were excluded (log-rank test, P=.046). During the follow-up period, 23 patients (23.7%) died altogether, 16 (32.7%) in the CLS group, and 7 (14.6%) in the RALS group. For those who died, the median time from surgery to death was 7.2 (range, 1.4−12.5) years in the CLS group and 6.2 (1.0−9.0) years in the RALS group (P=.175). Four deaths in both groups were confirmed as disease-related. For the majority of the other deceased, it cannot be stated with certainty whether the death was related to EC.

Three-year OS was 98.0% (95% CI, 94.0−100) in the CLS group vs 97.9% (93.8−100) in the RALS group, 5-year survival was 91.8% (84.2−99.4) vs 93.7% (86.8−100), and 10-year survival 75.5% (64.5−87.5) vs 85.4% (75.4−95.4), respectively. HR for death

TABLE 1
The demographic and clinical characteristics of the patients

Characteristics	Conventional laparoscopy n=49		Robotic-assisted laparoscopy n=48		*P* value
	n	%	n	%	
Age, y, mean (SD)	67.9 (8.3)		66.7 (8.9)		.511
BMI, kg/m^2, mean (SD)	29.7 (5.6)		29.5 (6.3)		.900
CCI					1.000
0	36	73.5	37	77.1	
1	9	18.4	8	16.7	
≥2	4	8.2	3	6.3	
Histology					.362
Endometrioid	45	91.8	47	97.9	
Nonendometrioid	4	8.2	1	2.1	
Stage					.325
IA	33	67.3	31	64.6	
IB	8	16.3	12	25.0	
II	3	6.1	0	0	
III–IV	5	10.1	5	10.5	
Grade					1.000
Low grade (gr I–II)	45	91.8	44	91.7	
High grade	4	8.2	4	8.3	
Lymph nodes harvested, mean (SD)	23 (9.8)		26 (8.9)		.168
LVSI +	10	20.4	7	14.6	.595
Adjuvant therapy					.537
None	30	61.2	28	58.3	
Pelvic radiation	6	12.2	3	6.3	
Brachytherapy	4	8.2	9	18.8	
Chemotherapy	3	6.1	2	4.2	
Chemotherapy and radiation	5	10.2	6	12.5	
Hormonal therapy only	1	2.0	0	0.0	

BMI, body mass index; *CCI*, Charlson comorbidity index; *LVSI*, lymphovascular space invasion; *SD*, standard deviation.

based on Cox proportional regression analysis seemed to be lower in the RALS group (HR 0.415; 95% CI, 0.171–1.010, *P*=.053) compared to the CLS group. In univariate analysis age, preexisting comorbidity (CCI≥1), and high-grade tumor were associated with worse OS. Still, in the multivariable regression analysis, only the mode of surgery (*P*=.047) and age (*P*=.008) remained statistically significant. This risk estimation analysis is shown in Table 2.

PFS was similar between the groups (Figure 3; log-rank test, *P*=.598). EC recurred in 8 patients (16.3%) in the CLS group and 6 (12.5%) in the RALS group. Of those who recurred, the median time from surgery to the first recurrence did not differ between the groups (24 months in the CLS group and 23 months in the RALS group, *P*=.852). Three-year PFS was 87.8% (95% CI, 78.6–97.0) in the CLS group vs 89.6% (81.0–98.2) in the RALS group, 5-year PFS was 85.7% (75.9–95.5) vs 87.5% (78.1–96.9), and 10-year PFS 83.6% (73.2–94.0) vs 87.5% (78.1–96.9), respectively.

The long-term complications in the RALS and the CLS groups are summarized in Table 3. Trocar site hernia developed significantly more often in patients in the RALS group than in the CLS group, 18.2% vs 4.1%, OR=5.42 (95% CI, 1.11–26.59), *P*=.037. All hernias occurred in the upper abdomen midline trocar site. All but 2 hernias in the RALS group were operated. The operations took place 7 to 35 months (median 16 months) after the primary operation. The nonoperated hernias were diagnosed during a routine gynecological follow-up visit. The patients experienced mild symptoms of a bulge, and the defect was palpable. Obesity was also noted as a risk factor for developing a trocar site hernia, OR=1.14 (1.02–1.28), *P*=.020, while wound infection was not, OR=2.96 (0.52–16.92), *P*=.222.

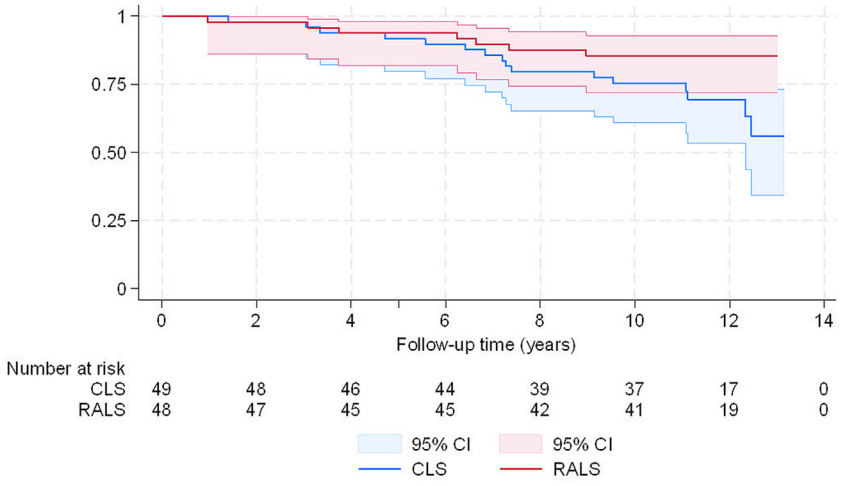
Lymphocele was detected in 4 patients (8.2%) in the CLS group and 9 patients (18.8%) in the RALS group (*P*=.169), of which 2 and 4, respectively, caused infection or pressure symptoms requiring antibiotics and/or radiological drainage (*P*=.436). The intervention occurred 1 to 22 months after the primary operation, and 3 out of 6 events occurred later than 6 months after surgery. Three of the symptomless lymphoceles in the RALS group disappeared spontaneously during follow-up. Two patients, 1 in each group, developed bothersome urgency urinary incontinence after surgery. In the CLS group, 1 patient suffered from vaginal vault prolapse after surgery and was treated conservatively with a pessary, and 1 patient began to experience occasional, but chronic pain in the left thigh a month after the operation.

Comment

Principal findings

In this RCT, the OS was better in the RALS group compared to the CLS group.

FIGURE 2
Overall survival of the patients by the mode of surgery



CLS, conventional laparoscopy; *RALS*, robotic-assisted laparoscopic surgery.

However, there was no difference in PFS. Trocar site hernia developed more often in the RALS group than in the CLS group. The incidence of lymphocele and lymphedema of lower extremities was similar between the groups.

Results in the context of what is known

MIS is the preferred approach in EC due to decreased perioperative morbidity, enhanced recovery, lower costs of care, and noninferior oncologic outcomes compared to open surgery.[3,11–13] There is also a convincing pool of evidence suggesting MIS does not compromise the oncological survival of the patients in EC. Two large randomized trials, the Gynecologic Oncology Group (LAP2) and the Laparoscopic Approach to Cancer of the Endometrium (LACE) trials, have shown equivalence in OS in stage I patients after laparotomy and CLS.[11,12]

Due to its advantages, RALS has become a progressively favored mode of MIS in EC. In a systematic review and meta-analysis of Ind et al,[14] RALS was shown to have fewer conversions, even shorter hospital stays, less blood loss, and fewer overall surgical complications than CLS. As a downside, the costs were higher, as noted also in a previously published cost analysis of this RCT cohort.[15] Although the costs associated with RALS are higher than those of CLS, RALS is a more cost-effective option than open surgery due to reduced overall surgical morbidity.[16]

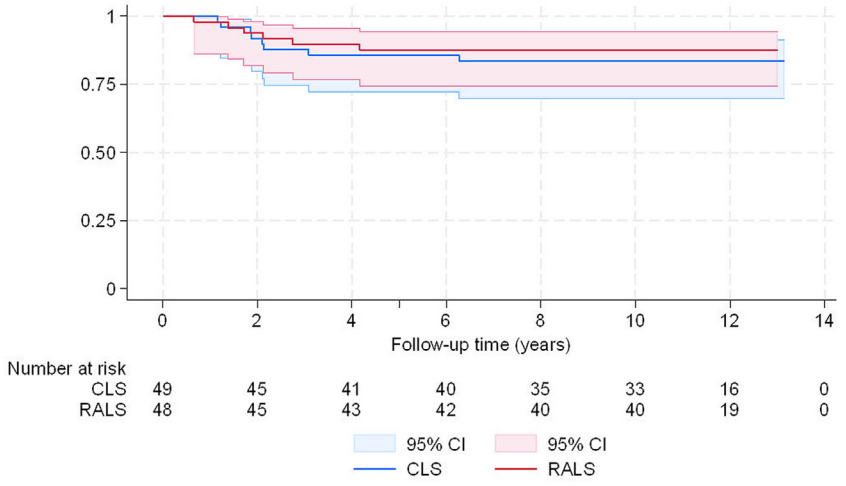
The previous data on long-term survival after RALS is based on retrospective studies only. In a recently published review and meta-analysis by Fu et al,[8] RALS was found to have superior oncological outcomes to laparotomy and comparable outcomes to CLS regarding OS and PFS. Many studies reported similar OS and PFS rates after RALS and CLS.[17–22] In 2 studies, better long-term outcomes were noted after the introduction of RALS in their institution.[5,7] Argenta et al,[6] on the other hand, reported poorer OS and PFS in stage I patients after RALS compared to CLS. The authors were unable to explain the results. For the retrospective nature of all the studies above, the possibility of selection and observation biases should be taken into account. In cervical cancer, 2 studies published in 2018 reported worse oncological survival after MIS compared to laparotomy in early-stage patients, which has raised concerns and enhanced academic interest regarding the influence of surgical approach on the

TABLE 2
Cox regression analysis for overall survival

	Univariate analysis			Multivariable analysis		
Covariate	HR	95% CI	*P* value	HR	95% CI	*P* value
RALS	0.42	0.17–1.01	.053	0.39	0.15–0.99	.047
Age, yr	1.10	1.04–1.18	.002	1.10	1.03–1.18	.008
BMI, kg/m^2	0.99	0.92–1.06	.670	Not entered		
CCI≥1	3.05	1.35–6.93	.008	2.09	0.84–5.20	.113
Stage>II	2.56	0.87–7.55	.088	2.30	0.60–8.83	.225
High grade	5.17	1.91–13.97	.001	3.11	0.94–10.30	.063
LVSI+	1.49	0.55–4.00	.434	Not entered		
Deep invasion>50%	2.23	0.98–5.05	.056	Not entered		

CCI, Charlson comorbidity index; *HR*, hazard ratio; *LVSI*, lymphovascular space invasion; *RALS*, robotic-assisted laparoscopic surgery.

FIGURE 3
Progression-free survival of the patients by the mode of surgery



CLS, conventional laparoscopy; *RALS*, robotic-assisted laparoscopic surgery.

oncological survival of patients also in EC.[23,24] Fortunately, apart from the study of Argenta et al, no alarming signals have been observed regarding MIS and RALS in EC.

Previous studies have reported 0.6% to 1.9% incidences of trocar site hernia after RALS for EC.[25,26] On the other hand, a systematic review by Bosanquet et al found the prevalence of trocar site hernia after midline incisions to be 12.8% (range: 0%–35.6%), thus it is likely that trocar site hernias are often underdiagnosed.[27] Trocar size is a known risk factor for trocar site hernia, and the entry technique may have an impact as well.[28] In our study, the technique of entering the abdominal cavity, and the size and placement of trocars varied between the groups, which may explain the differences in trocar site hernia development. With the newer robotics now used in our department, the entering is done directly with the trocar under laparoscopic visualization, and all trocars used are 8 mm wide. Hence, the incidence of trocar site hernias is likely to decline. Previous studies present quite similar rates of lymphocele and lymphedema after surgery with lymphadenectomy for EC.[29–31]

Clinical implications

In the light of this RCT, oncological long-term survival after RALS seems to be equal or even superior to CLS in EC. Hence, the increasing use of RALS in EC seems acceptable. The possibility of trocar site hernia should be kept in mind at follow-up visits of patients with EC after MIS and particularly RALS. The symptoms associated with the hernia can initially be mild, with noticeable discomfort emerging following the acute phase of cancer recovery.

Research implications

Larger RCTs would be needed to confirm the survival benefit observed in this RCT. The relatively high incidence of trocar site hernias detected in the RALS group warrants further studies including a comparison of patients operated with the old and the new robotic instruments to clarify the role of the entry technique and trocar size on hernia formation.

Strengths and limitations

Strengths of this study are the randomized setting of the trial and the long follow-up time. Our study is the first and so far the only randomized trial in this context. Additionally, no patients were lost from the follow-up. We were able to attain reliable information about the patients due to the structure of the Finnish healthcare organization, in which operative and oncological treatment is centralized in relatively few university and central hospitals.

TABLE 3
Long-term complications

	Conventional laparoscopy n=49		Robotic-assisted laparoscopy n=48		
Long-term complication	n	%	n	%	*P* value
Any complication	8	16.3	23	47.9	.001
Trocar site hernia	2	4.1	9	18.8	.028
Lymphocele	4	8.2	9	18.8	.147
Lymphocele requiring intervention	2	4.1	4	8.3	.436
Lymphedema	4	8.2	10	20.8	.090
Other	3	6.1	1	2.1	.617

Therefore, if a recurrence had been suspected or diagnosed, it would most likely be within our awareness. However, we are unable to demonstrate the disease-specific survival of the patients. The amount of deaths confirmed as disease-related was small and consistent across both groups. For the other deceased patients, the cause of death could only be classified as nondisease-related if they had been treated in a hospital for another condition leading to their death. Most of them did not have such records. Given their age and comorbidities, it is likely that the assumed and documented cause of death was unrelated to EC since, to our knowledge, recurrence had not been suspected or diagnosed before their deaths. However, some patients may have had undiagnosed disease recurrence contributing to their demise.

The main limitation is the relatively small sample size, which lacked sufficient power to show differences in survival outcomes. Nonetheless, we believe this randomized trial provides a valuable contribution to the existing retrospective data on the long-term safety of RALS in EC. The better OS observed after RALS strongly supports its noninferiority in the oncologic survival of patients with EC.

Another weakness is that the study was conducted before the implementation of routine preoperative multidisciplinary meetings in our unit therefore possibly affecting the rate of changes in the histopathological diagnosis. However, this did not impact the survival outcomes, since the OS curves remained consistent even when patients with high-grade histology were excluded from the analysis. It is of notice, that the difference in incidence of trocar site hernia is likely due to variation in insertion technique and trocar size, and not the MIS modality itself. Although this may not have current clinical relevance in the care of EC patients, as these factors have changed, it provides valuable insight for future studies on trocar site hernia formation. The surgical techniques employed were contemporary for the time, and both have evolved since then. However, the other long-term complications are comparable and were shown to be similar, further supporting the safety profile of RALS.

Conclusions

The results of this RCT suggest a small OS benefit in EC after RALS compared to CLS, albeit no difference was noted in PFS. Hence, it supports the findings of most of the previous retrospective studies demonstrating equivalent or superior oncological survival after RALS compared to CLS. The substantial increase in the use of RALS in EC, along with our observation of shorter operating times compared to CLS, refer to an excellent suitability of the technique in this domain. Adding the lower rates of conversions and enhanced recovery associated with RALS, the use of RALS in EC seems justifiable and safe but future studies are required to denote the possible survival benefits of RALS.

CRediT authorship contribution statement

Elina Kivekäs: Writing – original draft, Visualization, Validation, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Synnöve Staff:** Writing – review & editing, Validation, Supervision, Project administration, Methodology, Formal analysis, Conceptualization. **Heini S.A. Huhtala:** Writing – review & editing, Visualization, Validation, Methodology, Formal analysis. **Johanna U. Mäenpää:** Writing – review & editing, Validation, Resources, Project administration, Methodology, Conceptualization. **Kari Nieminen:** Writing – review & editing, Validation, Resources, Project administration, Methodology, Conceptualization. **Eija I. Tomás:** Writing – review & editing, Resources, Methodology, Conceptualization. **Minna M. Mäenpää:** Writing – review & editing, Visualization, Validation, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Conceptualization. ■

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Data availability: Data are available upon request from the corresponding author. To gain access, data requestors will need to sign a data access agreement. Data available: Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices), and study protocol. Investigators, who proposed the use of the data, have been approved by an independent review committee.

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