Original Article

# Total Laparoscopic Hysterectomy with Laparoscopic Lymphadenectomy versus Conventional Abdominal Hysterectomy with Lymphadenectomy for Early-Stage Endometrial Cancer: A Prospective Randomized Study

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## Abstract:

**Background:** Endometrial cancer is the commonest gynecological neoplasm in developed nations. The current study aimed at comparing, in a series of females the usefulness, security as well as morbidity of total Laparoscopic and Laparoscopic for early-stage EC.

**Methods:** This prospective randomized study of 50 females with clinical stage I endometrial carcinoma. cases were classified into 2 equal groups: group 1 was managed by total LPS, and group 2 were treated with Laparoscopic. At admission, each woman was subjected to a gynecological and rectal examination, US and hysteroscopic evaluation. biopsies from the endometrium, chest X-ray, and MRI and/ or CT scan. LN dissection was done in selected patients in both groups.

**Results:** Characteristics of the studied groups (Hb decline, blood loss and time of postoperative ileus) revealed significant reduction in the Laparoscopic group in comparison with Laparoscopic group. The incidence of fever revealed a significant decrease in Laparoscopic group compared to Laparoscopic group as well. Hospital stay and operative time were insignificantly different between the studied groups. The incidence of fever was significantly lower in Laparoscopic group compared to Laparoscopic group. Complications including (bladder and ureteric injuries, conversion to laparotomy, missed intestinal injury, postoperative hematoma, and wound infection) were insignificantly different between the studied groups.

**Conclusions:** Laparoscopy is an appropriate method in treating early endometrial carcinoma .

**Keywords:** Laparoscopic Hysterectomy, Laparoscopic Lymphadenectomy, Conventional Abdominal Hysterectomy, Endometrial Cancer

## Introduction:

Endometrial cancer (EC) is the commonest gynecological tumor in developed nations. The standard method for staging and treating EC is abdominal hysterectomy (TAH) with bilateral salpingo-oophorectomy, washing of the peritoneum, removal of the pelvic & para-aortic LN through an open surgery. [1] Nevertheless, the laparoscopic procedure has been utilized in females suffering EC with better outcomes and the vast majority of investigators have revealed that total or trans vaginal laparoscopic hysterectomy (LPS), accompanied by laparoscopic removal of the LN through

the pelvis, can be considered an acceptable altern-ate to open approach. [2]

Obese females are most probably to get benefits from laparoscopic approach since this operation is accompanied by less pain postoperatively, early ambulation, short hospital staying duration and less complications of the wounds and less inci-dence of pelvic abscesses. [3] During the last few years, improvement achieved in the laparoscopic approaches was evident, thus; it becomes broadly accepted for gynecological

surgeries due to several benefits including absence of scar, few blood loss and less pain following surgery. [4] Currently, this approach reported in lit-erature has enabled to perform laparoscopic sta-ging and 2$^{nd}$ look in addition to radical hyster-ectomy with pelvic lymphadenectomy in gynec-ologic malignancy.The current study aimed at comparing, in a series of females the usefulness, security as well as morbidity of total LPS and LPT for early-stage EC. [2]

**Patients and Methods:**
This prospective randomized study was conducted on 50 women, with clinically staged as EC stageI aiming at performing a total LPS with selective pelvic LN dissection or LPT with selective pelvic LN dissection. All cases agreed to utilize their data prospectively. The study was done from January 2018 to November 2020 following appro-val from the Ethical Committee Faculty of Medi-cine, Sohag University. An informed written cons-ent was obtained from the patient.

Exclusion criteria include the presence of ovarian tumors, proved metastasis outside the uterus, the presence of any contraindication for GA, altered papanicolau smear, cases with evidenced advan-ced stage of the neoplasm clinically according to the routine pre-operative investigations, cases ma-naged previously by pelvic RT and/or CT. cases without available follow-up data, bulky uterus sized greater than twelve weeks or in cases in which removal of the uterus through the vagina might necessitate morcellation, confirmed marked cardiopulmonary problem detected by the a histo-ry of HF, MI, unstable angina, or COPD, poorly controlled or contraindication of trendelenburg position for long duration; marked hip disease preventing the usage of the dorso lithotomy posit-ion; insufficient bone marrow, kidney, and liver functions; BMI $\geq$ 40 kg/m2 or and age $\geq$ 80 y .

All cases that were subjected to LPS were acquainted that LPT might be done if LPS method faced any difficulty, and all females agreed and wrote a consent. At entry, every case were subje-cted to gynecological & rectal assessment, US and hysteroscopic evaluation. biopsies from the endo-metrium, chest X-ray, and MRI and/ or CT scan to rule out the possibility of metastasis from other tumors. Lymph node dissection was done in sele-cted cases in both groups according to the histo-pathology of endometrial biopsy and MRI study.

The females were classified into 2 equal groups: group 1 was managed using total LPS while group 2 were treated with LPT. Out of which, twelve cases in LPS group and eleven cases in LPT group were candidates for lymphadenectomy.

Previous operation in the abdomen wasn't considered a contraindication for laparoscopy.

All procedures were carried out under GA. cleaning of the vagina was done using povidone-iodine solution and placing of a Foley's catheter in the urinary bladder was carried out. Additi-onally, we used lower extremity elastic compre-ssion equipment to protect against venous throm-bosis intraoperatively. After induction of GA in laparoscopic cases, insertion of an oro-gastric tube was done by the anesthesiologist aiming at decompressing the stomach then removal of this tube was done on finishing the surgery. The cases were often placed in the dorso lithotomy position.

Preoperative ureteric stents were inserted through cystoscopy in four patients of the LPS group. The patient's characteristics documented were age, BW, BMI, stage, histologic type, operation time, amount of blood lost, peri-operative blood transf-usion, duration of hospitalization and intraopera-tive & postoperative complications (during hosp-ital stay). Estimation of the blood loss was calculated according to the ordinary rules as follows: The amount of blood in the suction equipment in addition to Gauze and dressing pads that were soaked with blood. Post-operative fever denotes that the body temperature was $\geq$ 38 °C in 2 subsequent measurements $\geq$ 6 hours apart. The data concerning the patients were obtained from the hospital record, physician, in addition to direct reports from the patient. Cases of the two groups were subjected to surgical staging that consists of intraperitoneal cavity inspection, peritoneal wash, total hysterectomy, sapling-oophorectomy
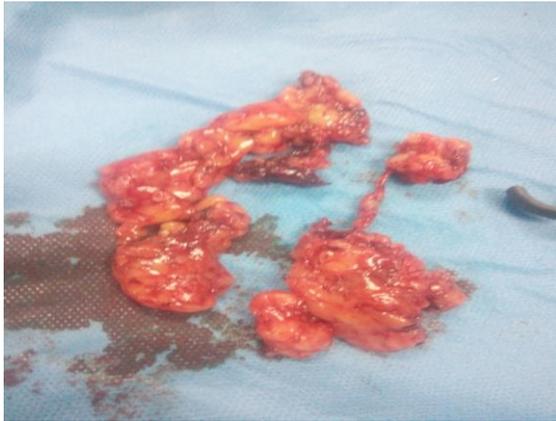
bilaterally, and in selected patients we carried out systematic pelvic lymphadenectomy bilaterally.
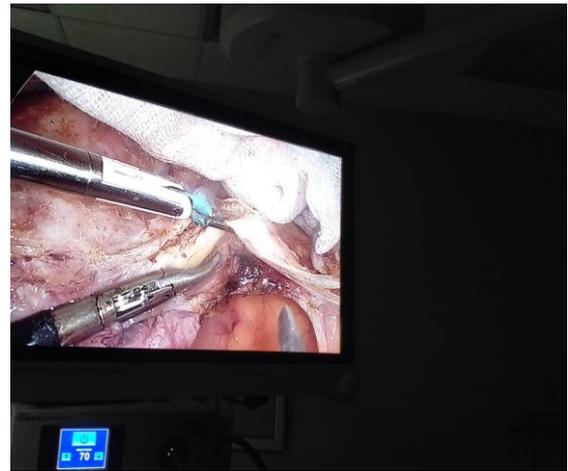
## Surgical technique

1. The approach used for the LPT in this study relied on routine; obtaining the abdominal access through a midline skin incision vertically and the hysterectomy composed of an extra fascial TH. For the laparoscopic surgery: insertion of a uterine manipulator was performed with insertion of A 10-mm trocar incorporating the 30 ° laparoscope across a supra umbilical vertical incision, following pneumoperitoneum by inducing Veress needle at the umbilicus. We utilized 3 suprapubic trocars ; a trocar in each iliac fossa (5 mm ) lateral to inferior epigastric vasculature on both sides, respectively. The third one was inserted by about one hand breadth above the left trochar

2. Before the operation, inspection of all the components of the pelvis was performed and exploration of the abdomen via laparoscopy was done as well . Routine peritoneal (50 ml) washing was performed for cytological examination. Uterine manipulator was used to enable moving the uterus during laparoscopic surgery. We carried out an "en-bloc" trans-peritoneal pelvic lymphadenectomy bilaterally with the female about a 30-degree Trendelenburg position. (Figure 1 A)

3. The pelvic lymphadenectomy begins to develop in para-vescical space. Coagulation of the round ligament close to the wall of the pelvis and transected with. The anterior & posterior layers of the peritoneum. opening of the broad ligament was done to and identify the ureter. Dissection of the para-vescical space and the bipolar forceps (at first at the areola lateral to the obliterated umbilical artery, (Figure 1 B) the obturator nerve was determined. Removal of the External and common iliac LN was done from vessel surfaces via blunt or sharp dissection. Determination of the ureter at the pelvic brim

was done, tracing into the pelvis and separated from the hind leaf of the broad ligament

4. entery to the obturator fossae from the lateral aspect was done, and the obturator nerve & vessels were skeletonized, prior to the removal of the superficial & deep obturator LNs (Figure 1 C)

5. Dissection of the Interiliac LNs that are medially and caudally related to the external iliac blood vessels was done on both sides. Opening of the retroperitoneum to remove the nodal tissue was carried out the site of common iliac vessels. detection of the uterine vessels to help better skeletonization of the obliterated artery through preparation of the anterior & posterior web was done. Coagulation and transaction of the uterine artery was done . coagulation of the infundibu-lopelvic ligament was performed using bipolar forceps and transaction was done using scissors. (Figure 1 D). Grasping and incision of the vescico-uterine fold with isolation of the bladder was done following vescico-uterine fold division, the suction-irrigator probe pushed the bladder entirely through the upper part of the vagina .

6. The upper vaginal 3rd was visualized and transection of 1cm edge of vaginal cuff surrounding the cervix was done using monopolar, incision of the vagina circumferentially using the porcelain-valve of the uterine manipulator as a guide. Removal of the uterus, adnexial and the upper vaginal 3rd was done through the vagina. (Figure 1 E)

7. Closure of the vault of the vagina was carried out using continuous 0- viral suturing by laparoscopy and pneumoperitoneal re-establishing was done using CO2. Laparoscopic controlling of bleeding was done. Closure was done by 5 & 10 mm incisions using mattress suture of 2-0 vicryl. Intraperitoneal drain was left. (Figure 1 F)
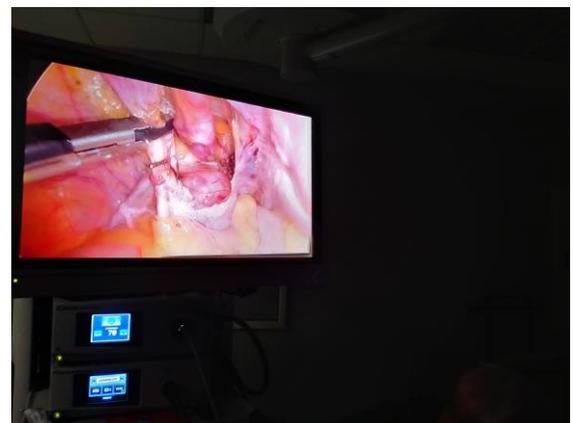
**Figure 1: Surgical approach of laparoscopic hysterectomy with lymphadectomy**

**Statistical analysis**

It was done using SPSS v26 (IBM Inc., Chicago, IL, USA). Quantitative variables were presented in the form of mean and SD and comparing the 2 groups was done using unpaired Student's t- test. Qualitative variables were presented in the form of frequency and % and were analyzed by the Chi-square test or Fisher's exact test. A 2 tailed P value of less 0.05 was referred as statistically signify-cant.

## Results:

In this study, 84 females were evaluated for competence, 21 cases of them didn't meet the criteria and 13 cases didn't agree to share in our study. The remaining 50 cases were divided into 2 groups in a random manner. 25 cases were managed using total LPS and 25 were managed using LPT. Out of which, 12 cases in LPS group and 11 patients in LPT group were candidates for lymphadenectomy. follow-up of All patients (50) was done followed by statistical analysis of data. (Figure 1)
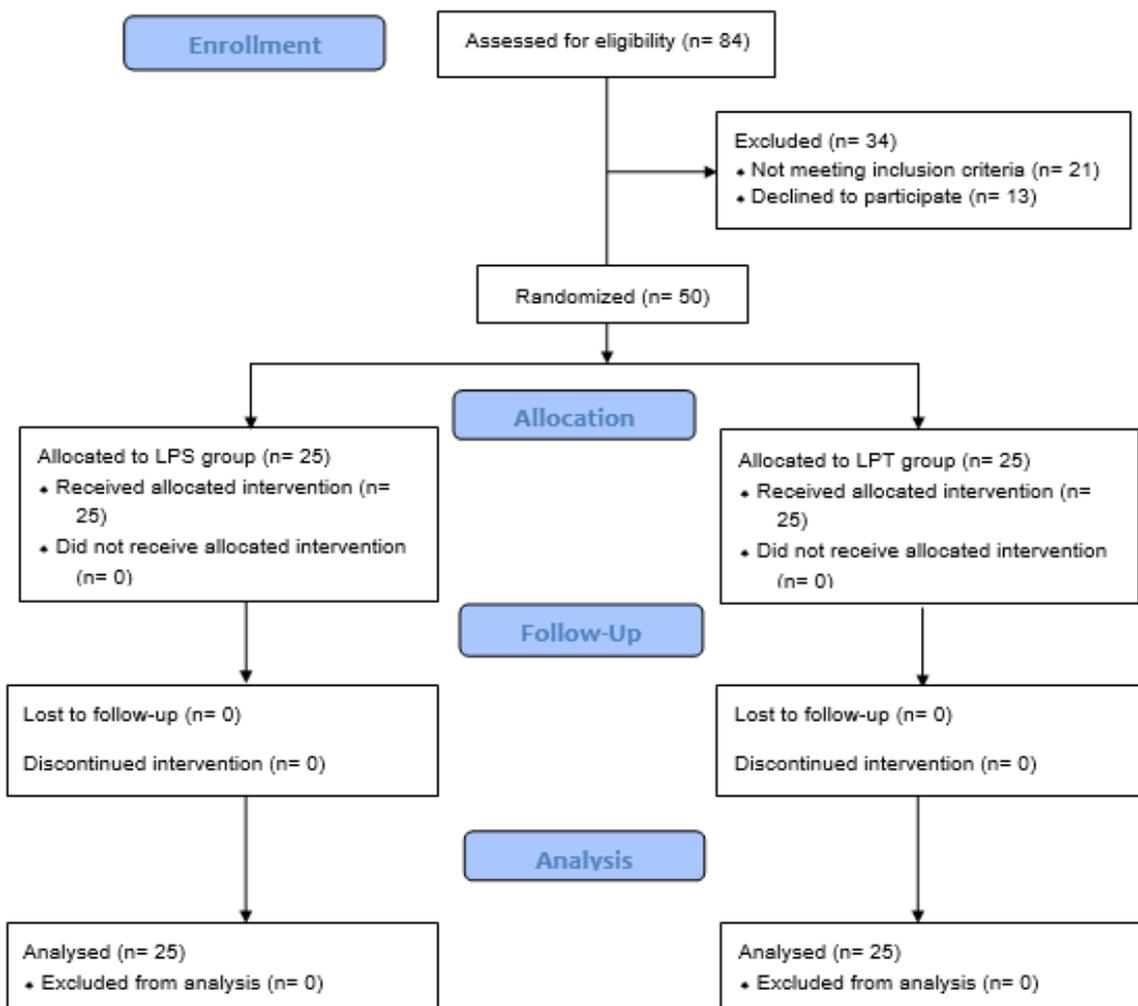


**Figure 2:** CONSORT flowchart of the enrolled patients

Age and BMI showed an insignificant difference between the two groups. (Table 1)

**Table 1: Age and BMI of the studied groups**

|  |  | LPS (n=25) | LPT (n=25) | P value |
|---|---|---|---|---|
| **Age (years)** | **Mean ± SD** | 52.68 ± 7.23 | 54.72 ± 6.27 | 0.292 |
|  | **Range** | 41 - 64 | 45 – 65 |  |
| **BMI (kg/m²)** | **Mean ± SD** | 22.12 ± 3.38 | 21.36 ± 2.74 | 0.387 |
|  | **Range** | 18 - 30 | 17 – 25 |  |

Data are presented as Mean ± SD, BMI: Body mass index, LPS: Laparoscopic hysterectomy, LPT: Abdominal hysterectomy.

Characteristics of the studied groups (Hb decline, blood loss and time of postoperative ileus) showed significant decrease in the LPS group compared to LPT group. Hospital stay and operative time revealed insignificant differences between the studied groups. (Table 2)

**Table 2:** Characteristics of the studied groups

|  |  | LPS (n=25) | LPT (n=25) | P value |
|---|---|---|---|---|
| **Hb decline (g/dL)** | **Mean ± SD** | 0.32 ± 0.15 | 1.09 ± 0.54 | **< 0.001\*** |
|  | **Range** | 0.1 - 0.6 | 0.6 - 2 | |
| **Blood loss (ml)** | **Mean ± SD** | 253.20 ±121.89 | 968.80 ± 344.36 | **< 0.001\*** |
|  | **Range** | 100 -500 | 500 -1500 | |
| **Hospital stays (days)** | **Mean ± SD** | 4.04 ± 2.07 | 5.20 ± 2.52 | 0.081 |
|  | **Range** | 2 – 10 | 3 - 10 | |
| **Time of postoperative ileus (h)** | **Mean ± SD** | 21.08 ± 7.68 | 28.76 ± 9.02 | **0.002\*** |
|  | **Range** | 11 – 35 | 10 - 45 | |
| **Operative time (min)** | **Mean ± SD** | 115.20 ± 22.38 | 122 ± 22.78 | 0.265 |
|  | **Range** | 90 -150 | 90 - 150 | |

Data are presented as Mean ± SD, LPS: Laparoscopic hysterectomy, LPT: Abdominal hysterectomy.
*: significant P value < 0.05

The incidence of fever exhibited a significant decrease in LPS group in comparison with LPT group. Complications including (bladder injury, ureter injury, conversion to laparotomy, missed intestinal injury, postoperative haematoma, and wound infection) were insignificantly different between the studied groups. (P value = 0.05). (Table 3)

**Table 3:** Complications of the studied groups

|  | LPS group (n=25) | LPT group (n=25) | P value |
|---|---|---|---|
| **Fever** | 3 (12%) | 10 (40%) | **0.05\*** |
| **Bladder injury** | 1 (4%) | 2 (8%) | 1 |
| **Ureteric injury** | 2 (8%) | 0 (0%) | 0.49 |
| **Missed intestinal injury** | 1 (4%) | 0 (0%) | 1 |
| **Post-operative haematoma** | 0 (0%) | 2 (8%) | 0.49 |
| **Wound infection** | 0 (0%) | 2 (8%) | 0.49 |

Data are presented as number of (%), LPS: Laparoscopic hysterectomy, LPT:
Abdominal hysterectomy. *: significant P value < 0.05

## Discussion:

The surgical treatment for early-stage EC shows wide variability and is currently subjected to lots of investigation. [5, 6]

Laparoscopic role in managing gynecological tumors draws great attention that resulted in reasonable conflict during the last years.[7]

Currently , surgeons have started to carry out hysterectomy in addition to salpingo-oophorectomy bilaterally with pelvic and/or aortic LN dissection via a total laparoscopic procedure and documented, as other studies , that this approach provides various benefits in comparison with the open method [8] essentially considering the reduction of the hospital charges and short hospital staying as the principal advantage,[9] post-operative draw-backs following laparoscopic management are decreased or the same,[10] probably depending on the laparoscopic experience of the operating physician as well as the presence of comorbidities. Nevertheless, long-term risk of recurrence and survival following laparoscopy for EC aren't efficiently studied ; yet, this approach doesn't seem to affect the incidence of recurrence or the overall survival. [11]

This approach shows some benefits over the laparoscopic- assisted approach; it prevents the time loss important for shifting from the laparoscopy to the transvaginal procedure and it allows to easily remove the uterus along with the

adnexa, even in the presence of a fixed uterus and with narrowed vagina. [12]

Three trials have similar results to our study as regards the patients and severity of the disease, [6, 13, 14] in such studies pelvic and-aortic LN removal was carried out and the survival outcome of the cases with FIGO stage I showed great similarity . Currently, Manolitsas et al.[15] assumed that the total LPS in addition to surgical staging as a good method and documented, that this approach has several benefits in comparison with the open method mainly as regard the reduced hospital charge and short duration of hospitalization as the principal advantages.

Recently, single study revealed significantly reduced rates of intra-operative complications, decreased blood loss, decreased transfusion rate and Hb reduction , along with a rapid return of git activity in the LPS group. The approach was converted to LPT because of complication development in 1.4 percent. No significant differences concerning duration of the operation

with sixty percent of cases undergoing pelvic lymphadenectomy in the two groups. Long-term complications that occurred postoperatively showed significant reduction in the LPS group [13] of the surgical data of our series revealed that the mean operative time of 136 minutes for the LPS group was the same as that documented by other studies that carried out pelvic lymphadenectomy in a greater percentage of cases [11, 16, 17],Despite the time for surgical staging in the LPS group showed significant elevation in comparison with in the LPT group. In the current study, the mean intraoperative blood losses, the differences of serum hemoglobin levels and hematocrit values prior to and following operation showed significant reduction in the LPS group; in conjunction with rapid return of gut activity in such group.

None of the patients needed intraoperative blood transfusion. Also, no difference regarding the number of eradicated LNs was detected. No significant differences between intraoperative & postoperative complications in either method were proved.

In fact, laparoscopy aided by magnification of small vessels provided by the recently designed optical systems decreases intraoperative blood loss. [5, 11]

Obermair et al.[18]documented significant decrease numbers of LNs on using the laparoscopic

method yet, in our work, a larger count of LNs were involved in cases of the LPS group and might be explained by more ability to expose the operative field in addition to the advance achieved in the laparoscopic methods helping good dissection of the pelvic spaces as well as the fact that laparoscopy was often carried out by the same surgical group.

The mean number of LNs restore in the pelvis was the same as data documented in other research [9, 11, 13, 19] where lymphadenectomy was carried out completely via laparoscopy. Besides, the removal of pelvic as well as aortic LN didn't cause an adverse effect on the surgical morbidity of early EC staging. [20]

Only one case needed to convert the procedure to laparotomy that compares favorably with percentage from 4.4 - 22.4 percent documented in other studies in particular because of vascular complications, excessive adhesion, and obesity.

Only few studies have concluded the survival of females having EC following LPS procedure compared with LPT. [6, 9, 11, 13, 16, 18, 19] The vast majority of these studies were retrospectively done except for 2 prospective randomized ones. [6, 21] Obermair et al., [18] revealed in the results of a retrospective review on five hundred ten cases subjected to total LPS operation or LPT operation, that at 29-month follow-up the same pattern of recurrence and the same overall survival in the 2 groups. In a randomized study that compared the laparoscopic-vaginal techniques versus the traditional transabdominal technique, Malur et al. [13] emphasized these results, yet on small numbers of cases.

Recently a study of one hundred thirteen cases with prolonged follow-up (forty-five months) evaluated the type of recurrence and survival following total LPS approach or LPT approach for early EC; only one cases had a pelvic recurrence in the LPS group (5.3 percent), and seven cases had isolated pelvic recurrence in the LPT group (7.4 percent). Both approaches had the same disease-free survival along with overall survival. [11]

One of the limitations of our study is that it was deficient in follow up of overall survival or disease-free survival based on surgical management procedure. Nevertheless, in the current study depending on the cases with clinical stage I EC in the 2 studied groups have the same surgical

staging, grade and postoperative management; our finding confirmed the findings of previous series, denoting that the impact of the surgical technique on regional relapse is improbable. Also, limitations of the present study lie in the existence of several institutional series and the procedures were done by different surgeons.

## Conclusions:

Laparoscopy is an efficient approach in treating cases suffering e EC and might provide the essential benefits of reduced discomfort with reduced recovery period time, yet it should be restricted for expertise surgeons of oncology  who did training in extensive laparoscopic approaches . Multicenter RCT along with long-term follow-up are crucial to assess the entire oncology outcomes of this approach, the recurrence rates, disease-free survival and the overall survival as well .

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