

Laparoscopic Regional Radical Hysterectomy Showed Promising Clinical Outcomes in Early-stage Cervical Cancer

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Abstract

Objectives: To evaluate the clinical outcomes of standardized and region-specific excision in laparoscopic radical hysterectomy (LRH) for early-stage cervical cancer (ECC).

Materials and Methods: This is a retrospective case–controlled study from 2011 to December 2016. A total of 328 women with ECC (IA1, IA2, IB1, or IIA1) underwent primary surgery by laparoscopy or laparotomy in our institute. Women diagnosed as stage IB1 or IIA1 were treated with radical hysterectomy (RH) by open or laparoscopic route. The total parametrium excision in the process of RH was measured and highlighted in the study.

Results: A total of 186 patients underwent open surgery and 142 ones were treated with laparoscopic surgery. Laparoscopic surgery was associated with less blood loss (194.43 ± 84.40 ml vs. 362.68 ± 253.36 ml, $P < 0.01$), shorter hospital stay (11 vs. 14 days, $P < 0.01$), and lower risk of blood transfusion (2.8% vs. 18.8%, $P < 0.01$). There was no significant difference in the postoperative complications between two groups (18/142, 12.7% vs. 21/186, 11.3%; $P > 0.05$). The rate of 5-year overall survival (OS) was 92.8% in laparoscopy group, similar to that of 94.4% in the open group ($P = 0.762$). Disease-free survival (DFS) rate at 3 years in laparoscopy group was decreased when compared to open group (91.8% vs. 95.0%, $P = 0.030$), but there was no significant difference in 3-year DFS among the women with tumor size < 2 cm (100% vs. 97.0%, $P = 0.818$).

Conclusion: Laparoscopic surgery was associated with better surgical outcomes compared to open surgery in ECC. 5-Year OS was comparable between the groups and cases with tumor size < 2 cm showed no difference in 3-year DFS. LRH may be a better fit for women with tumor size < 2 cm. Standardized region-specific RH helps to optimize the clinical outcomes of LRH in ECC.

Keywords: Disease-free survival, early-stage cervical cancer, laparoscopic radical hysterectomy, overall survival

INTRODUCTION

The recent study and publication of Laparoscopic Approach to Cervical Cancer Trial (LACC) questioned the survival outcomes of minimally invasive surgery (MIS) for early-stage cervical cancer (ECC).^[1,2] It concluded that minimally invasive radical hysterectomy (RH) was associated with lower rates of disease-free survival (DFS) and overall survival (OS) in ECC. The related reasons affecting the outcomes of MIS were thought to be CO₂ pneumoperitoneum, uterine manipulator,

unenclosed colpotomy, as well as the surgeon's skills and learning curve. As the results differ from the previous conventional viewpoints, it triggered the discussion of whether laparoscopic radical hysterectomy (LRH) is suitable for the treatment of ECC.^[3,4]

Following the Piver Classification in the 1970s and QM Classification in 2008,^[5,6] RH for cervical cancer has been

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progressively standardized. Some clinical studies showed similar therapeutic outcomes between LRH and abdominal radical hysterectomy (ARH). Moreover, LRH presented advantages in the form of reduced morbidity and improved postoperative quality of life.^[7-11] Laparoscopic surgery had been seen as the popular surgical approach for the treatment of ECC at one time.

It is very important to perform standardized RH for ensuring good surgical outcome. We proposed the concept of radical regional excision of the parametrium based on the precise anatomy in parametrial ligament, pararectal, and paravesical spaces. In this article, we retrospectively analyzed the clinical data of patients with IA1, IA2, IB1, and IIA1 staging cervical cancer (Federation of Gynecology and Obstetrics [FIGO] 2009), who underwent LRH or ARH in Tenth People's Hospital from 2011 to 2016. The purpose of this article is to compare the survival outcomes between laparoscopic and open surgery and thus evaluate the value of standardized RH focusing on regional excision of the parametrium in ECC.

METHODS

Patients

This investigation was designed as a retrospective case-control study. The patients undergoing surgical therapy by laparotomy or laparoscopy from 2011 to 2016 for primary early cervical cancer (FIGO Stage of IA1, IA2, IB1, and IIA1) were enrolled. They were from Tenth People's Hospital affiliated to Tongji University Medical School. The diagnosis of cervical cancer was confirmed by pathological examination before surgery. The tumor size was measured depending on the reports from magnetic resonance imaging (MRI) or transvaginal sonography. Exclusion criteria included the treatments of only radiotherapy or chemo-radiotherapy, loop electrosurgical excision, and fertility-sparing surgery. The recruited patients were divided into two groups, laparoscopic surgery group and open surgery group. Demographics such as age, body mass index, and education background were collected and compared between two groups.

The study was approved by the Ethical Committee of Tenth People's Hospital affiliated to Tongji University School of Medicine (Approval number: SHSY-IEC-4.1/19-177/01). Informed consent was obtained from all participants included in the study.

Standardized radical hysterectomy

All surgeries were carried out after the patients were under general anesthesia. The specialist gynecologic oncologists who are proficient in both laparoscopy and laparotomy performed the surgery. The patients diagnosed as Stage IA1 with no lymphovascular space invasion (LVSI) underwent extrafascial hysterectomy (Piver Type I or Q-M Type A), Stage

IA2 received modified RH (Piver Type II or Q-M Type B), and Stage IB1 and IIA1 underwent RH (Piver Type III or Q-M Type C). Surgical technique followed the principles of Piver–Rutledge classification with Querleu–Morrow classification of RH.^[5,6,12]

In the study, laparoscopic standardized RH (Type C) focusing on total parametrium excision was emphasized, the key steps of which were described as follows: (1) We opened the lateral peritoneum of pelvic wall in Cheng's triangle area and made the iliac vessels and ureter visible.^[13] The pararectal space and paravesical space were separated by removing the covering fascia and fatty tissue until the muscle or fascia tissue of pelvic floor was exposed [Figure 1a]. (2) The transection of cardinal ligament was done to laterally extend the pelvic wall and vertically touched the pelvic floor's fascia [Figure 1b]. The total paracervical excision contains the removal of both the vascular part and caudal neural part of cardinal ligament, except in the case of Type C1 RH. We named the complete removal of the cardinal ligament as "regional excision" [Figure 1b]. (3) We dissected the vesicocervical space and exposed the course of ureter into the bladder trigone [Figure 1c]. Then, the anterior, posterior, and lateral components of vesicouterine ligament were transected at the bladder to mobilize the ureter completely [Figure 1d]. (4) The uterosacral ligament was cutoff near the rectum. When considering the automatic nerve preservation in Type C1 RH, the uterosacral ligament was transected after the hypogastric nerve was mobilized prior [Figure 1c]. The cervical branches and bladder branches of the pelvic plexus were

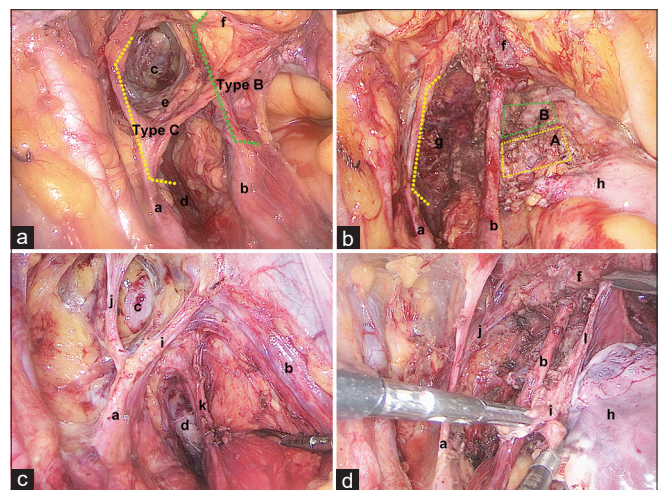


Figure 1: Before (a) and after (b) the cardinal ligament resection; before (c) and after (d) the vesical-cervical ligament transection: a internal iliac artery, b ureter, c lateral vesical space, d lateral rectal space, e cardinal ligament, f bladder, g the muscle and fascia tissue of pelvic floor, h uterus, i uterine artery, j superior vesical artery, k pelvic nerve plexus, l anterior vesical-cervical ligament after transection. Region A the complete removal of cardinal ligament; Region B the complete removal of paravaginal tissue, Type B/C extent of Type B/C radical hysterectomy

also identified.^[14] The bladder nerves should be preserved carefully in the lateral and posterior ligaments of the bladder. At last, the uterus was removed consistent with RH techniques along with routine pelvic lymphadenectomy. In the course of surgery, the uterine manipulator was used and the vaginal was opened laparoscopically.

The operative parameters containing operative time, intraoperative blood loss, postoperative length of hospital stay were recorded, as well as the perioperative complications were reported. In addition, data of postoperative adjuvant therapy were collected.

Follow-up

The patients were instructed to follow up at an interval of 3 months in the first 2 years after surgery and 6-monthly follow-up for the subsequent 3 years and yearly follow-up thereafter. The median follow-up time was calculated. As a routine, patients underwent laboratory testing and computed tomography/MRI examinations on each follow-up visit. Recurrent disease, if reported, included the locoregional recurrence and distant metastasis. The cases of death owing to cervical cancer were notified. Disease-free survival (DFS) was defined as the time from primary surgery to recurrence or death from cervical cancer. The rate of DFS at 3 years and overall survival (OS) at 5 years were evaluated as the primary oncologic outcomes.

Statistics

The Statistical Package for the Social Sciences Version 19.0 (IBM Corp., Armonk, NY, USA) was used for statistical analysis. Data were presented as mean \pm standard deviation or percentages. Continuous variables were compared using independent sample *t*-test (between two groups), while categorical variables were compared using χ^2 test or Fisher's exact test, as appropriate. A $P < 0.05$ was considered statistically significant. Kaplan–Meier survival curve was utilized to compare the differences of DFS rate at 3 years and OS rate at 5 years between the two groups. Log-rank *P* value was assessed and recorded, as well as 95% confidence interval.

RESULTS

A total of 479 patients with cervical cancer were treated in Tenth People's Hospital, Tongji University Medical School, from November 2011 to December 2016. A total of 328 patients received treatment in the form of primary surgery were enrolled. The mean age of the patients was 49 years. Of these patients, 56 was diagnosed with stage IA1 no LVSI, 67 with stage IA2, 138 with IB1, and 67 with IIA1. One hundred and eighty-six patients underwent open surgery and 142 were treated with laparoscopic surgery. There were no reported cases of conversion from laparoscopy to laparotomy.

The comparisons of demographic data between laparoscopy group and laparotomy group are listed in Table 1. The baseline characteristics including histologic subtype, tumor size, and positive lymph node were similar in two groups [Table 1].

As showed in Table 2, laparoscopic surgery was associated with less blood loss (194.43 ± 84.40 ml vs. 362.68 ± 253.36 ml, $P < 0.01$), shorter hospital stay (11 vs. 14 days, $P < 0.01$), and fewer risk of blood transfusion (2.8% vs. 18.8%, $P < 0.01$) when compared with open surgery. Twenty-one patients in the open group encountered postoperative complications and 18 patients in the laparoscopic group (11.3% vs. 12.7% $P > 0.05$). The main complications included infection (22 patients), dysuria/urinary retention (11 patients), deep vein thrombosis (4 patients), intestinal obstruction (1 patient), and postoperative blood loss (1 patient). Adjuvant treatment were carried out for patients who had pathologic risk factors (large primary tumors, deep stromal invasion, and/or LVSI).^[15,16] Postoperative radio-chemotherapy was indicated in 32 patients of laparoscopic group (32/142, 22.5%) and 55 patients of open group (55/186, 29.6%). There was no significant difference in the need for postoperative adjuvant treatments between two groups ($P > 0.05$).

In the present trial, the median follow-up time was 41 months (range, 20–84) in laparoscopic group and 49 months (range, 22–89) in open group. Thirteen (6.99%) recurrent cases in the open group were observed. Among them, 12 patients had locoregional recurrences and 1 patient was diagnosed with a new primary breast cancer after the follow-up of 59 months. Eighteen patients (12.68%) in the laparoscopic group had locoregional recurrences. A total of 15 deaths were noted, 9 in the open surgery group and 6 in the laparoscopic surgery group. All of the recurrences or deaths occurred in the patients with Stage IA2, IB1, and IIA1 who underwent modified RH or RH. The rate of 5-year OS in the laparoscopic surgery group was 92.8%, similar to that of 94.4% in the open group ($P = 0.763$) [Figure 2a]. The DFS at 3 years in the laparoscopy group was significantly decreased when compared to open group (91.8% vs. 95.0%, $P = 0.030$) [Figure 2b]. However, there was no difference in 3-year DFS rate between two groups with Stage IA1–IA2 cervical cancer (100% vs. 98.2%, $P = 0.472$) [Figure 3a]. Likewise, the rate of DFS at 3 years was not significantly different among two groups with Stage IB1–IIA1 accompanying tumor < 2 cm (100% vs. 97.0%, $P = 0.818$) [Figure 3b]. However, the 3-year DFS rate in the laparoscopic surgery group was remarkably lower than in the open surgery group among the women with Stage IB1–IIA1 associated with tumor size of ≥ 2 cm (75% vs. 92.4%, $P < 0.001$) [Figure 3c].

Table 1: Baseline characteristics

Characteristic	Open surgery (n=186)	Laparoscopic surgery (n=142)	P/ χ^2 (t)
Age	49.45±8.78	49.20±8.85	0.824 (0.222)
Body mass index	23.46±4.20	23.74±2.68	0.110 (1.604)
Education (%)			
University or above	18 (9.7)	13 (9.2)	0.873
High school	168 (90.3)	129 (90.8)	
Stage of disease (%)			
IA1	26 (14.0)	30 (21.1)	0.796
IA2	31 (16.7)	36 (25.4)	
IB1	86 (46.2)	52 (36.6)	
IIA1	43 (23.1)	24 (16.9)	
Histologic subtype (%)			
Squamous cell carcinoma	161 (86.6)	114 (80.3)	0.132
Adenocarcinoma	20 (10.8)	16 (11.3)	
Adenosquamous	2 (1.1)	4 (2.8)	
Others	3 (1.6)	8 (5.6)	
Positive lymph node (%)	2 (1.1)	3 (2.1)	0.447
Tumor size (cm)* (%)			
<2	34 (26.4)	28 (36.8)	0.114
≥2	95 (73.6)	48 (63.2)	

*Only the women with the Federation of Gynecology and Obstetrics staging of IB1 or IIA1 were compared. Among of them, 129 patients performed open surgery, the others of 76 patients underwent laparoscopic surgery

Table 2: Operative parameters and adjuvant therapy

	Open surgery (n=186)	Laparoscopic surgery (n=142)	P/ χ^2 (t)
Operative parameters			
Operation time (min)	199.72±62.35	215.15±53.71	0.039 (-2.074)
Blood loss (ml)	362.68±253.36	194.43±84.40	<0.001 (6.962)
Intraoperative transfusion (%)	35 (18.8)	4 (2.8)	<0.001
Postoperative length of hospital stays (day)	14.53±7.55	11.21±3.94	<0.001 (4.768)
30-day postoperative complications (%)	21 (11.3)	18 (12.7)	0.701
Adjuvant therapy			
Postoperative radiochemotherapy (%)	55 (29.6)	32 (22.5)	0.153

DISCUSSION

Surgical treatment has been the preferred modality for the treatment of ECC. However, the recent publication of LACC trial stated that conventional open surgery appeared to be the preferable approach for better survival outcomes compared with MIS.^[1,2] In this study, we retrospectively compared the perioperative parameters and the results of follow-up after LRH or open RH for ECC. Our data showed that LRH was superior to ARH in blood loss, the length of hospital stay, and the risk of blood transfusion [Table 2]. The results are consistent with the published researches by other authors.^[8-11,17] Kim *et al.* showed that LRH was associated with fewer intraoperative complications (9.9% vs. 12.0%, $P < 0.001$) and shorter median length of stay ($P < 0.001$), compared with ARH.^[11] Lee *et al.* indicated that the mean estimated blood loss and length of hospital stay in the LRH group were significantly less than those in the radical abdominal hysterectomy group (414.3 ml and 836.0 ml, respectively;

$P < 0.001$; 10.7 days and 18.8 days, respectively; $P < 0.01$).^[7] The study from Bogani *et al.* stated that patients undergoing LRH experienced less blood loss (200 vs. 500 mL; $P < 0.001$) and shorter length of hospital stay (4 vs. 8 days; $P < 0.001$), compared with the radical abdominal hysterectomy group. No intergroup differences in intraoperative complications were recorded ($P = 1.0$).^[18] It is seemingly suggested that LRH is safe and feasible in the management of ECC.

Over the median follow-up of 41 months in the laparoscopic group and 49 months in the abdominal surgery group, our data found that there were no differences in 5-year OS rate between two groups [92.8% vs. 94.4%, long-rank $P = 0.763$, Figure 2A]. Although the rate of DFS at 3 years in laparoscopic surgery group was significantly lower than in laparotomic groups [91.8% vs. 95.0 log-rank $P = 0.030$, Figure 2B], the difference of DFS was attributed to the existence of subgroup with IB1–IIA1 staging cervical cancer combined with tumor ≥ 2 cm [Figure 3C]. For the patients with the diagnosis of IA1–IA2

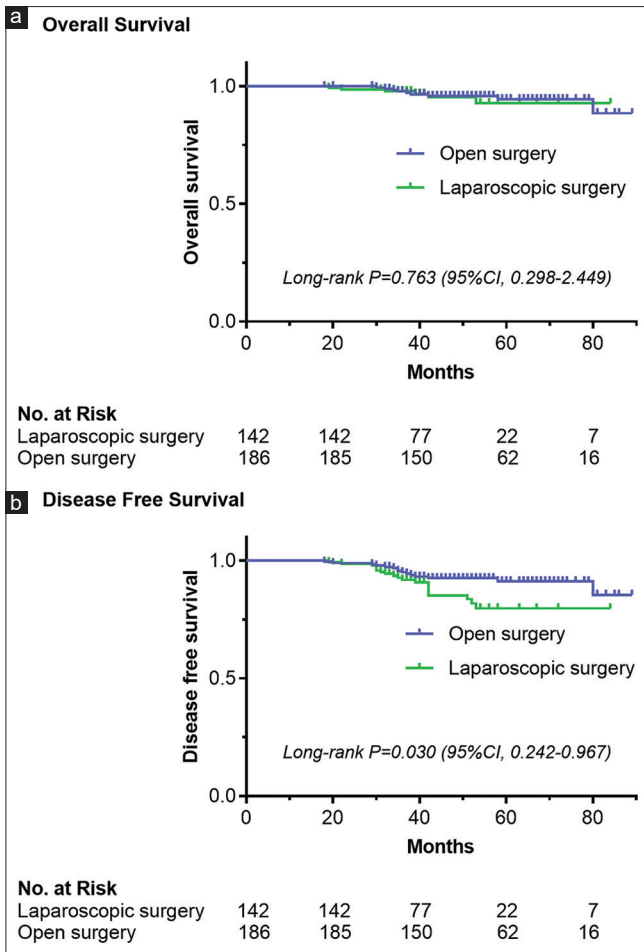


Figure 2: The rate of 5-year overall survival and 3-year disease-free survival were compared between laparoscopic group and open group by Kaplan–Meier survival curve method. (a) At 5 years after surgery, 14 patients had died, 6 in laparoscopic group and 8 in open group, accounting for an overall survival rate of 92.8% in the laparoscopic group and 94.4% in the open group ($P = 0.763$). (b) At 3 years, a total of 33 recurrences or deaths were noted, 19 in laparoscopic group and 14 in open group. The rate of 3-year disease-free survival was 91.8% in the laparoscopic group and 94.4% in the open group ($P = 0.030$)

or IB1–IIA1 with accompanying tumor of <2 cm, the rate of DFS was not significantly different between laparoscopic route and open approach [Figure 3a and b]. We believed that standardized RH was an important factor associated with the surgical and oncological outcomes. In the present study, we had an insight regarding the importance to delineate precise anatomy of paracervical structure focusing on the dissection of cardinal ligament, uterosacral ligament, and vesicocervical ligament. The regional excision of parametrium was proposed by us to perform a standardized RH [Figure 4]. According to the criterion of Type III or Type C RH, the proposed cardinal ligament transection followed the principles of boundary near the pelvic floor vertically and at the pelvic side wall laterally [Figure 1a and b] The anterior, lateral, and posterior parts of vesicocervical ligament were transected near the

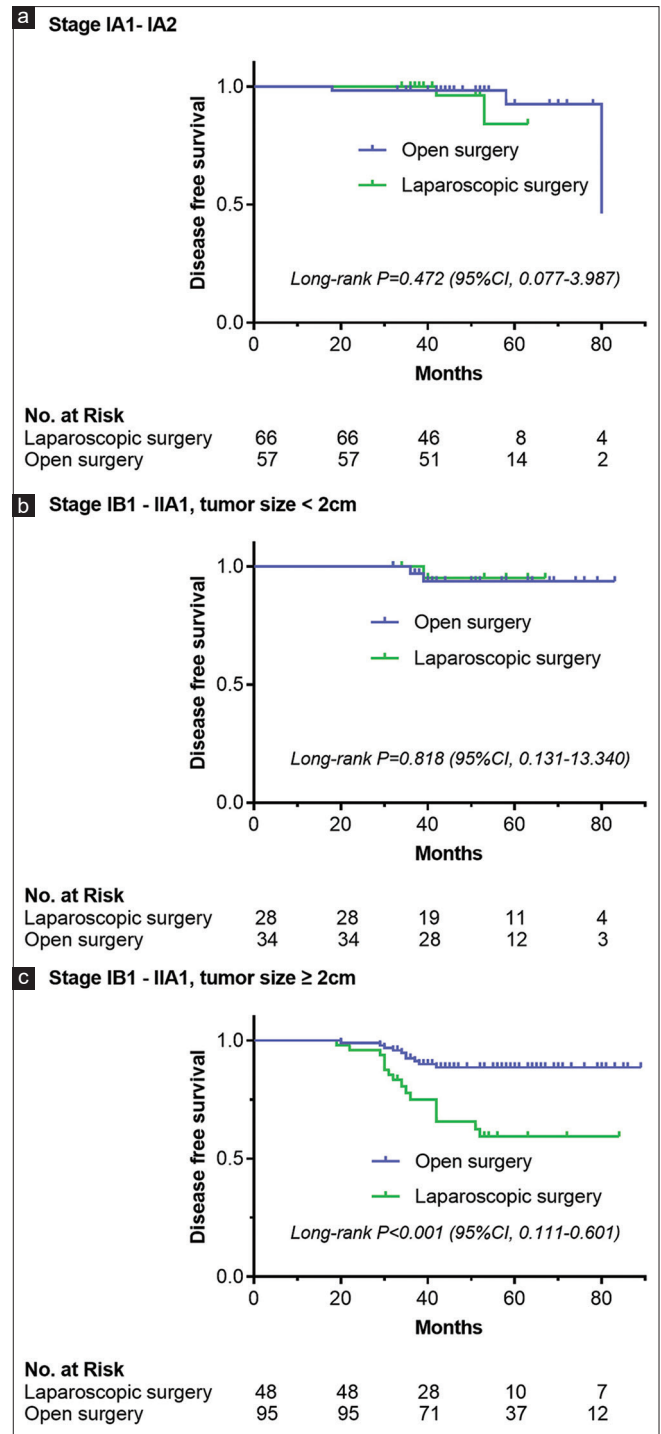


Figure 3: Three-year disease-free survival based on disease stage and tumor size. (a) Among the women with IA1–IA2, 3-year disease-free survival was 100% in laparoscopic group and 98.2% in open group ($P = 0.472$). (b) In the women with IB1–IIA1 accompanying tumor <2 cm, 3-year disease-free survival was 100% in laparoscopic group and 97.0% in open group ($P = 0.818$). (c) In the women with IB1–IIA1 accompanying tumor ≥ 2 cm, 18 patients had a recurrence, 11 in laparoscopic group and 7 in open group. The rate of 3-year disease-free survival was 75% in the laparoscopic group and 92.4% in the open group ($P < 0.001$).

bladder [Figure 1d]. Based on the elaborate anatomy of cardinal ligament and uterosacral ligament, hypogastric nerves as well

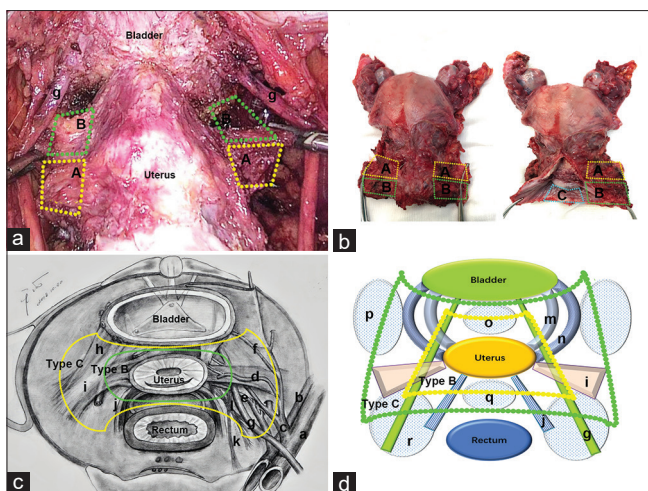


Figure 4: a external iliac artery, b external iliac vein, c internal iliac artery, d uterine artery, e uterine deep vein, f superior vesical artery, g ureter, h vesical-cervical ligament, i uterosacral ligament, j uterosacral ligament, k hypogastric nerve, l inferior hypogastric plexus (IHP), m ventral leaf of vesical-cervical ligament, n dorsal leaf of vesico-cervical ligament, o vesico-cervical space, p lateral vesical space, q uterine rectal space, r lateral rectal space, Region A/B same as Figure 1; Region C the enough length of vaginal resection (>1.5-2.0cm away from tumor), Type B/C same as Figure 1.

as bladder and cervical branches of the pelvic plexus were dissected and separated in order from the ventral and caudal part of the paracervix,^[14] which facilitated the nerve-sparing Type C1 RH. It was concluded that standardized RH based on the regional excision of parametrium promises better surgical and oncologic outcomes.

Of course, the adoption of LRH for ECC remains debatable. The factors affecting therapeutic results were considered to be associated with the use of uterine manipulation, vaginal colpotomy, and the circulating CO₂. The tumor surface was exposed to circulating CO₂ when intracorporeal colpotomy was performed. This may lead to the increased risk of tumor spillage.^[19-22] Uterine manipulators that were frequently used for visualization and retraction during minimally invasive hysterectomy may also disseminate tumor cells. In our study, for the patients with Stage IB1–IIA1 combined with tumor ≥2 cm, the rate of 3-year DFS in LRH group was relatively lower than in ARH group (75.0% vs. 92.4%, $P < 0.001$). It was suggested that the lower survival outcomes of LRH were closely linked to the tumor size. Cervical tumor ≥2 cm may have an increased risk of cancer cells spillage if the uterine manipulation was used and the unenclosed colpotomy was carried out in LRH. Some researchers have tried to perform the enclosed colpotomy without the use of uterine manipulation to obtain a relatively tumor-free removal and improve the surgical outcome of LRH for ECC.^[23]

In addition, there were previous studies that suggested laparoscopic hysterectomy for women with ECC was not

associated with the inferior oncologic outcomes. In the clinical trial of NCT 00096408, the use of total abdominal hysterectomy compared with total laparoscopic hysterectomy resulted in the equivalent rate of DFS at 4.5 years (81.6% vs. 81.3%, $P < 0.01$) and OS (risk difference, $P = 0.76$).^[24] An update of a previous Cochrane Review published in 2012, Issue 9 concluded that laparoscopy for the management of early endometrial cancer was associated with similar rates of OS and DFS compared with laparotomy.^[25] The study from APAGE concluded that 100% 5-year survival rate in LRH for ECC is an achievable task.^[26] It is inadequate to pinpoint CO₂ pneumoperitoneum and/or uterine manipulation as the contributing factors in the differences seen for OS and DFS after laparoscopy or laparotomy. Currently, we are attempting to use Air-Seal pneumoperitoneum system to reduce the possible adverse effects of smoke and plume generated during the use of electrosurgical devices. Our trial was not designed to determine whether this new approach will be able to replace the conventional intracorporeal colpotomy. Further investigation is warranted for the evaluation of survival outcomes with MIS.

There are some concerns that should be recognized when interpreting the results of this study. First, LRH and ARH were performed by senior gynecologic oncologists who are both skillful at laparotomic and laparoscopic surgeries. This evaded the shortcomings of lack of experience and techniques influencing the surgical outcome of standardized RH. Second, the effects of regional excision of the parametrium on the postoperative urinary function, defecation, and the risk of perioperative infection and bleeding need to be further investigated in subsequent trials. At last, the cohort study was designed as a retrospective study with a small sample size. In the future, multicenter prospective randomized study, especially taking into account methods for enclosed colpotomy not using a manipulator, is necessary for the evaluation of the value and feasibility of LRH for ECC.

CONCLUSION

Laparoscopic surgery was associated with less blood loss, shorter hospital stay, and lower risk of blood transfusion, when compared to open surgery for the treatment of ECC. Standardized RH based on total regional parametrium excision played an important role on optimizing the surgical and oncological outcomes in ECC. For patients with IB1–IIA1 stage cervical cancer with accompanying tumor size <2 cm, the rate of 3-year DFS after LRH was similar to that of ARH. Larger tumor (2–4 cm) treated by laparoscopic surgery may pose a higher risk of poor outcome.

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Conflicts of interest

There are no conflicts of interest.

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