Minimally invasive surgery for cervical cancer

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Abstract. The present study aimed to evaluate the oncologic outcomes of minimally invasive radical hysterectomy with no tumor exposure. Briefly, a multicenter, retrospective analysis was conducted between January 2017 and June 2020 involving 350 women with early-stage cervical cancer. Eligible patients were informed of the potential complications and benefits of abdominal radical hysterectomy and laparoscopic radical hysterectomy. During surgery, the use of a uterine manipulator was avoided. Myoma drill and uterine suture techniques were employed, accompanied by protective measures for vaginal closure of the colpotomy, such as clamps, vaginal cuffs or sutures. Specimens were placed in a collection bag, which was extracted through the vaginal route. Over a median follow-up period of 51 months (range, 30-72 months), five patients were lost to follow-up and three refused treatment following surgery; therefore, a total of 342 women with cervical cancer were followed up to the end of the study. The initial stage, according to the International Federation of Gynecology and Obstetrics 2018 classification system, was identified as IA1 with lymphovascular space invasion in 22 cases (6.29%), IA2 in 36 cases (10.29%), IB1 in 137 cases (39.14%), IB2 in 126 cases (36.00%), IIA1 in 14 cases (4.00%) and IIIC1P in 15 cases (4.29%). Histologically, squamous cell carcinoma was diagnosed in 269 patients (76.86%), adenocarcinoma in 75 patients (21.43%) and adenosquamous carcinoma in six patients (1.71%). Lymphovascular invasion was confirmed in 80 patients (22.86%). Lymph nodes were tumor-free in 335 patients (95.71%). After radical hysterectomy, 53 patients underwent brachytherapy and teletherapy, and 30 received chemotherapy alongside brachytherapy and teletherapy. After a median follow-up time of 51 months (range, 30-72 months), the disease-free and overall survival rates were recorded as 95.71% (335/350) and 98.86% (346/350) respectively. In conclusion, minimally invasive surgery using maneuvers to avoid peritoneal contamination yields good oncologic outcomes for patients with early-stage cervical cancer. The findings from the current retrospective analysis suggest that laparoscopic surgery could present a safe oncological option; however, further validation through randomized trials is essential.

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Introduction

Cervical cancer ranks among the leading causes of female cancer-associated mortality worldwide, especially in low-income countries and populations from socioeconomically disadvantaged areas, thereby posing a serious threat to women's health (1,2). Surgery via radical hysterectomy and systematic pelvic lymphadenectomy currently serves as the standard treatment for early-stage cervical cancer. In recent decades, minimally invasive approaches have become increasingly accepted and implemented in the global management of early-stage gynecologic cancer. Philp *et al* (3) previously compared the safety, morbidity and survival outcomes of abdominal radical hysterectomy (ARH) and laparoscopic radical hysterectomy (LRH), revealing lower short-term morbidity and similar survival outcomes in the LRH group compared with ARH (3). Jensen *et al* (4) revealed that the adoption of robotic minimally invasive surgery (MIS) for early-stage cervical cancer was not associated with increased risk of recurrence or a reduction in survival outcomes.

Prior to 2016, our gynecological departments (Department of Gynecology, Jinhua Maternity and Child Health Care Hospital, and Department of Gynecology, Jinhua Hospital of Zhejiang University; both Jinhua, China) used minimally invasive methods with a uterine manipulator to perform radical surgery for cervical cancer; however, since a number of cases of short-term central recurrence were subsequently observed, the surgical approach was revised. As of 2017, utilization of the uterine manipulator, myoma drill and vaginal cuff was discontinued. Following this modification, a notable decline in the incidence of central recurrence was detected among patients. Notably, the Laparoscopic Approach to Cervical Cancer (LACC) trial in 2018, which focused on the oncological safety of MIS for early-stage cervical cancer, indicated that the abdominal approach conferred a survival advantage over MIS (5). In light of these unexpected findings from the LACC trial, the majority of gynecologic oncology centers across Europe and the United States revised their clinical protocols regarding the management of women with early-stage cervical cancer, reversing from minimally invasive techniques to the

previously established abdominal surgical approach (6-8). In conventional MIS, the vagina is accessed laparoscopically above the manipulator, which can lead to exposure of the peritoneal cavity to tumor cells through insufflation of carbon dioxide. Potential tumor spillage into the peritoneal cavity may underlie the inferior outcomes of MIS. However, given the advantages of laparoscopic surgery, a significant number of patients select MIS as the preferred mode of surgical treatment. Combined with data from our analysis of patients with cervical cancer who underwent LRH showing a decreased rate of tumor recurrence (Hu *et al*, unpublished data), the current study provides a detailed evaluation of the oncologic outcomes of patients with early cervical cancer undergoing laparoscopic surgery incorporating protective methods to avoid tumor spread with a median follow-up time of 51 months (range, 30-72 months) after surgery.

Materials and methods

Patient selection. This multicenter (Department of Gynecology, Jinhua Maternity and Child Health Care Hospital, and Department of Gynecology, Jinhua Hospital of Zhejiang University) study involved a retrospective analysis of patients diagnosed with cervical cancer who received treatment at between January 2017 and June 2020.

Patients eligible for inclusion in the study were those diagnosed with IA1 lymphovascular space invasion [LVSI (+)] to IIA1 and IIIC1p cervical cancer [International Federation of Gynecology and Obstetrics (FIGO) 2018 (9)] who underwent LRH (type B-C). The exclusion criteria included cases with tumor sizes >4 cm, a past history of cervical colonization within 2 years, previous chemotherapy or radiation, and conversion from MIS to laparotomy. A total of 350 patients were identified who underwent LRH with complete pelvic lymphadenectomy. All eligible patients were informed of the potential complications, benefits and risks of both ARH and LRH procedures before enrollment. The operating time was recorded from the first skin incision to final closure. The tumor diameter was determined with the aid of pelvic MRI scans. Operative blood loss was estimated by collecting blood into suction bottles during the surgical procedure.

Surgical techniques. All surgical interventions were conducted by five proficient gynecologists. Patients were placed in the Trendelenburg position at an angle of 30˚. After general anesthesia, the vaginal cuff was created in the upper third of the vaginal region for patients with exophytic cervical cancer (tumor size >2 cm). Subsequently, the laparoscopic procedure was conducted using five trocars.

Initially, a myoma drill was applied (Fig. 1A) to grip the uterus for manipulation purposes; however, to prevent uterine tearing, and potential urologic and vascular complications associated with the use of a myoma drill, the approach was modified to incorporate thread fixation of the uterus (Fig. 1B), facilitating laparoscopic manipulation. During surgery, the use of a uterine manipulator was avoided, while using the remaining components of the MIS procedure. In addition, during the operation, excised specimens, such as lymph nodes, were placed in a specimen bag. In the final step before removal of the uterus, a special clamp was used to secure the vaginal tube in cases of endophytic type and ulcerative type cervical cancer (tumor size ≤2 cm; Fig. 1C-E). Cervical cancer classification was based on clinical observations with ulcerative type cervical cancer referring to cancerous tissue that developed ulcers. To ensure that the clamp remained in place during the surgery, both ends were fixed. During the later stages of the process, vaginal suturing was performed (Fig. 1F) prior to colpotomy in patients with smaller tumors (≤2 cm).

The steps incorporated (collection of excised specimens in a specimen bag, vaginal cuffing, vaginal suturing and clamping) were specifically designed to prevent tumor spillage during laparoscopic procedures. Following colpotomy, the vaginal cuff was secured above the special clamp, enabling the vaginal delivery of the specimen. The specimens included the uterus, fallopian tubes, a section of the vagina, parametrium and pelvic lymph nodes.

Statistical analysis. Statistical analyses were conducted using SPSS version 17.0 (SPSS, Inc.) Data were summarized using descriptive statistics. For time-to-event data, Kaplan-Meier estimates were provided. The estimates of hazard ratio (HR) and its 95% confidence interval (CI) were calculated using Cox proportional hazards model, and corresponding P-values were calculated using the log-rank test. $P<0.05$ was considered to indicate a statistically significant difference.

Results

Between January 2017 and June 2020, a total of 350 patients were recruited who were diagnosed with cervical cancer and underwent radical hysterectomy for stages IA1 LVSI (+) to IIA1. The baseline clinical characteristics of all patients are summarized in Table I. Overall, 83 patients (23.71%) were subjected to radiotherapy and/or adjuvant chemoradiation. After radical hysterectomy, 53 patients underwent brachytherapy and teletherapy, and 30 received chemotherapy alongside brachytherapy and teletherapy. Over a median follow-up period of 51 months (range, 30-72 months), five patients were lost to follow-up and three refused treatment following surgery (these patients were censored in the Kaplan-Meier analyses), the disease-free survival (DFS) and overall survival rates (OS) were 95.71% (335/350) and 98.86% (346/350), respectively. The peri-operative outcomes of the study population are summarized in Table II. Unadjusted Kaplan-Meier curves are illustrated in Fig. 2A and B. In the subgroup of 201 patients with tumor sizes ≤2 cm, three relapses (1.49%) and no deaths were recorded. Fig. 2A shows the DFS of patients with tumors sized ≤2 and >2 cm; the patients with tumor sizes ≤2 cm that underwent MIS had a reduced likelihood of relapse compared to those with tumors >2 cm in size (HR, 0.110; 95% CI, 0.025-0.488; P=0.0004). Fig. 2B shows the OS of patients with tumors sized ≤2 and >2 cm; there was no significant difference between the two groups (P=0.0176).

Discussion

Radical hysterectomy is the standard surgical mode of therapy for patients diagnosed with early-stage cervical cancer (10). Previous studies have suggested that LRH yields comparable

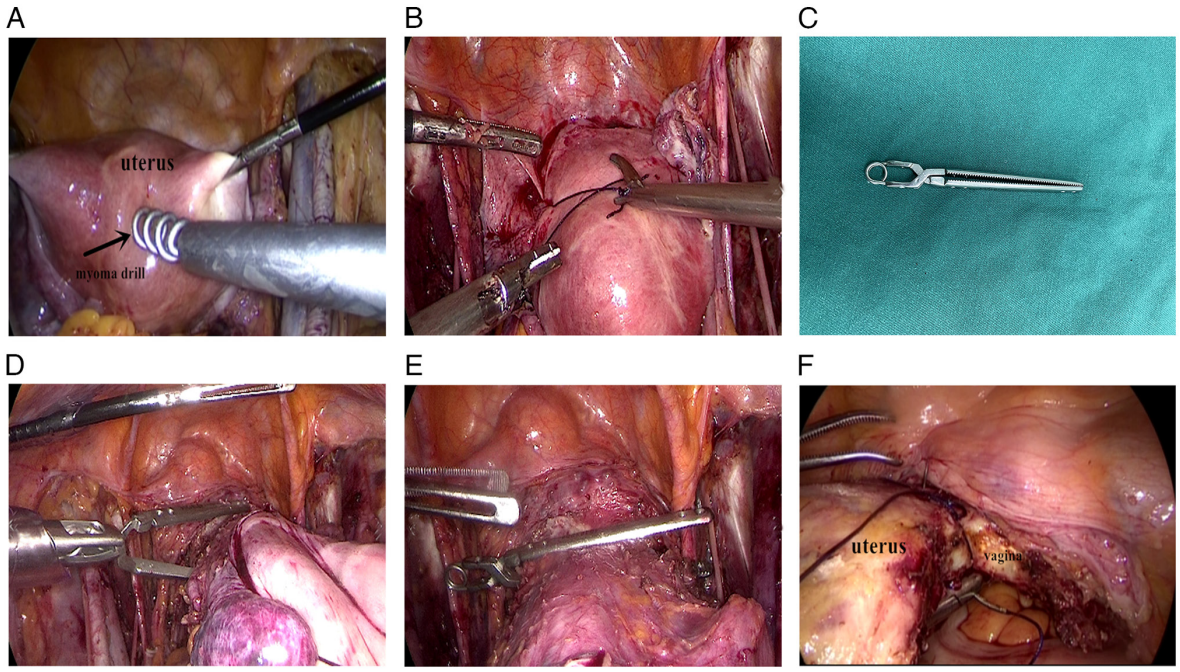

Figure 1. (A) Application of a myoma drill to grip the uterus for uterine manipulation. (B) Application of thread fixation of the uterus. (C) Clamp before surgery. (D and E) Utilization of the special clamp to secure the vaginal tube in endophytic type and ulcerative type, cervical cancer (tumor size, ≤2 cm). (F) Vaginal suturing prior to colpotomy in patients with smaller tumors (≤2 cm).

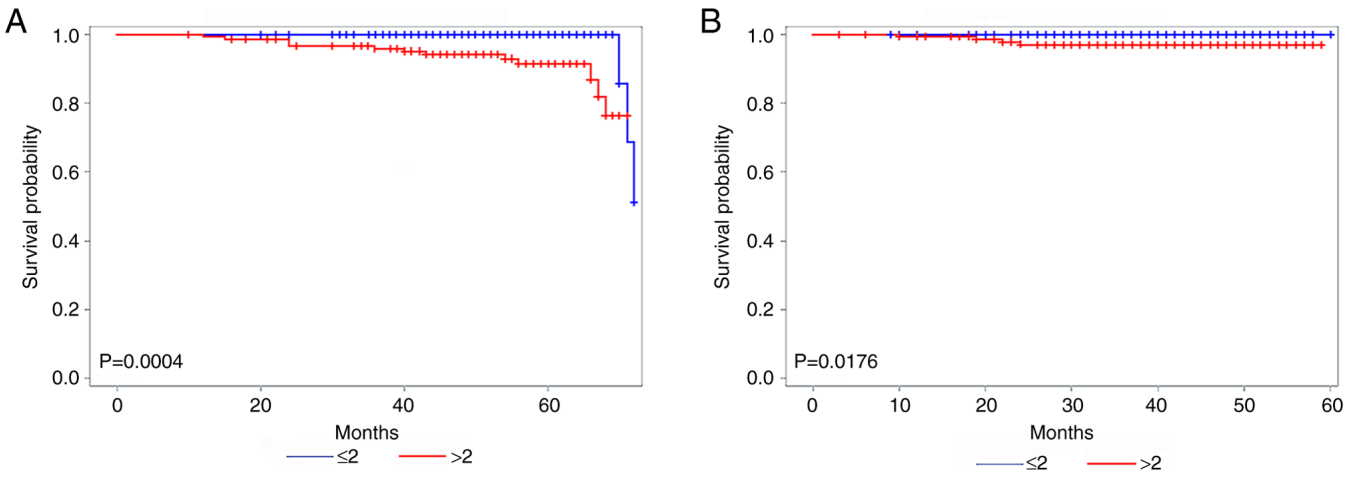

Figure 2. Unadjusted Kaplan-Meier survival curves of (A) disease-free survival and (B) overall survival of tumors sized ≤2 and >2 cm.

oncologic outcomes to those achieved with ARH (11-13). Similarly, Gallotta *et al* (14) demonstrated that LRH provides equivalent or superior intraoperative and short-term postoperative outcomes compared with ARH. However, Sert *et al* (15) and Kohler *et al* (16) showed no significant differences in the recurrence and survival rates between the two approaches. The benefits associated with MIS have led to an increasing preference for LRH in the management of cervical cancer. In a meta-analysis by Wang *et al* (11) on 12 studies comparing LRH with open radical hysterectomy (754 vs. 785 cases) for cervical cancer, no significant differences in the 5-year OS and DFS rates were observed between the two approaches. However, a phase III randomized clinical trial conducted in 2018 reported that minimally invasive radical hysterectomy was associated with lower rates of DFS (3-year rate, 91.2 vs. 97.1%) and OS (3-year rate, 93.8 vs. 99.0%) compared with ARH (17). In addition, several retrospective studies have demonstrated an association of minimally invasive radical hysterectomy with shorter survival compared with ARH (5,11,18); the observed shorter survival outcomes could be attributed to a number of factors, including a lower extent of resection, the level of surgeon's experience or the use of a uterine manipulator. Kim *et al* (19) observed no significant differences in the frequency of positive margins and, in most institutions, only individuals who had undergone several years of supervised training with a long learning curve were capable of effectively performing laparoscopic surgery. Therefore, the use of a uterine manipulator may be more significantly associated with decreased survival outcomes. Doo *et al* (20) reported no statistical difference in recurrence risk (P=0.22)

Table I. Patient characteristics.

Characteristic	Value
Median age, years (range)	43 (25-70)
Median BMI, kg/m^2 (range)	22.5 (19.2-25.3)
Histology, n (%)	
Squamous	269 (76.86%)
Adenocarcinoma	75 (21.43%)
Adenosquamous	6 (1.71%)
FIGO stage, n (%)	
IA1 LVSI (+)	22 (6.29%)
IA2	36 (10.29%)
IB1	137 (39.14%)
IB2	126 (36.00%)
IIA1	14 (4.00%)
IIIC1P	15 (4.29%)
Tumor size, n	
≤2 cm	201
2-4 cm	149
Conversion to laparotomy	0
Grading, n	
G1	101
G2	192
G3	57

LVSI, lymphovascular space invasion.

Table II. Peri-operative outcomes of the study population.

Characteristic	Value
Median surgical time, min (range)	221 (181-265)
Median estimated blood loss, ml (range)	145 (50-250)
LVSI, n	
Negative	270
Positive	80
Median number of lymph nodes (range)	25 (16-38)
Histology of lymph nodes, n	
Tumor free	335
Tumor involved	15
Post-operative complications, n	
Tumor tissue exposed to pelvic cavity after closure	0
Poor healing of vaginal stump	0
Lymphatic complications	0
Positive pathological examination of vaginal margin, n	0
Adjuvant therapy, n	
Radiotherapy and/or chemoradiotherapy	83/350
Median follow-up, months (range)	51 (30-72)
Recurrence, n	15/350
Death, n	4/350
Liver cancer	1/4
Cervical cancer	3/4

LVSI, lymphovascular space invasion.

and risk of death (P=0.18) between ARH and robotic radical hysterectomy groups. These conflicting data necessitate reconsideration of whether the decision to abandon MIS is in the best interest of patients.

Since 2013, the Department of Gynecology of Jinhua Maternity and Child Health Care Hospital, and Department of Gynecology, Jinhua Hospital of Zhejiang University has employed minimally invasive radical hysterectomy with a uterine manipulator as the preferred surgical procedure for early-stage cervical cancer, reflecting the global shift towards minimal invasive approaches worldwide. However, a number of cases involving tumors with larger diameters displayed recurrence only ~1 year after surgical treatment, regardless of subsequent radiotherapy and/or chemotherapy, and the majority of these individuals died as a result of central recurrence. Notably, one of the patients experiencing two episodes of central recurrence underwent laparoscopic surgery, and has survived for 11 years. Considering the short-term central recurrence and poor prognosis of larger tumors, it was considered that the issue of tumor exposure to the peritoneum was insufficiently addressed. As of 2017, the strategy for surgical treatment of early-stage cervical cancer was modified and a list of 'no-tumor' principles was designed, with the aim of improving patient survival while maintaining optimal quality of life. To facilitate further promotion of the surgical approach of abandoning the uterine manipulator in radical hysterectomy, a proposal for a new project within our hospital has been submitted.

Various strategies have been implemented to prevent contamination of the peritoneal cavity in the current study, such as application of a vaginal cuff prior to surgical intervention, as well as the use of a special vaginal clamp and vaginal suture before colpotomy, particularly in cases where the cervical tumor is encased within the vagina. However, the use of the clamp is solely restricted to endophytic type and ulcerative type cancer cases displaying smaller tumors (≤2 cm) without vaginal invasion. Notably, in accordance with the 'no-tumor' principle, the clamp needs to be repositioned from the vagina to cervix to close the vaginal canal. Failure to do so may mobilize tumor cells, potentially resulting in metastasis. Given the limitations of clamp usage, vaginal suture was performed prior to colpotomy in patients with smaller tumors (≤2 cm). The process of vaginal suturing is associated with an increased risk of mobilization of tumor cells; however, subsequent investigation revealed no instances of central recurrence in the present study. For tumors >2 cm, the vaginal cuff technique was primarily used, which is capable of effectively avoiding tumor spread; however, this procedure presents technical challenges, particularly in patients where cervix exposure is difficult, such as those who are obese or nulliparous (19). On the other hand, during the type C procedure, an incision was made into the deep uterine vein around the ureter and the vaginal wall was subsequently transected; however, the position of the vaginal incision

in laparoscopic surgery may not always be consistent with the level of the vaginal cuff, leading to positioning failure in colpotomy and challenges in proceeding with the operation. Additionally, the use of the myoma drill carries the risk of uterine perforation and subsequent damage to pelvic vessels or ureters. Considering the possible complications, the myoma drill approach was modified to a uterine suture approach at a later period of the study.

In the present study, myoma drill or uterine suture techniques were applied combined with protective vaginal closure techniques, such as clamping, vaginal cuffing or vaginal suturing, to avoid tumor spillage before colpotomy. In addition, the specimen was placed in a collection bag to prevent tumor spillage and its extraction was performed via the vaginal route. Based on the pathological results, 83 (23.71%) patients received radiotherapy and/or adjuvant chemoradiation. No central recurrences were observed after a median follow-up of 51 months (range, 30-72 months), with favorable DFS and OS outcomes of 95.71% (335/350) and 98.86% (346/350), respectively. The survival outcomes in all patients were comparable to the LACC trial laparotomy group (3-year DFS and OS rates of 97.1 and 99% respectively), which could be attributed to the techniques implemented for avoiding tumor spillage. and evolving treatment approaches for cervical cancer. Moreover, the subgroup of patients with tumors ≤2 cm that underwent MIS had a significantly lower likelihood of relapse compared to those with tumors >2 cm (P=0.0005). In contrast to the LACC trial, the current study did not reveal inferior outcomes associated with MIS. The strict principle of no contact with the tumor during excision may be a significant contributory factor. In addition, the lower percentage of lymph node positivity in all cases (4.29 vs. 12.4%) and relatively short follow-up compared with the LACC trial may have influenced the OS and DFS rates. Other studies (4,21) have similarly shown that MIS does not yield inferior oncological outcomes. For example, two cohort studies in Denmark and Sweden (4,22) demonstrated that a nationwide adoption of robot-assisted MIS for cervical cancer did not negatively impact oncologic outcomes, consistent with the current findings. While the follow-up duration in the present study was relatively short, it is important to highlight that at the time of analysis, 60.29% of cases (211/350) had successfully reached the 4-year time point. From the aforementioned results, it may be inferred that the laparotomy may not be the most appropriate method for treating early-stage cervical cancer and MIS approaches warrant further consideration.

The current study has a number of limitations that should be taken into consideration. The follow-up period was relatively brief, with a median of 51 months. Moreover, this investigation is an observational retrospective analysis and lacks a control group. The results highlight the need for further surveillance through new prospective randomized trials comparing LRH free from manipulators with ARH, with the goal of achieving optimal DFS over longer follow-up durations.

In conclusion, the procedure performed in the present study avoided the use of a uterine manipulator and implemented protective vaginal closure over the entire tumor to minimize the risk of tumor spillage in MIS. The results indicated no inferior oncologic outcomes, particularly in the subgroup of patients with tumor sizes ≤2 cm.

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Availability of data and materials

The data generated in the present study may be requested from the corresponding author.

Authors' contributions

MH conceived and designed the study. LiJ, LaJ and MS acquired, analyzed and interpretated the data. LiJ and MH drafted the article and revised it critically for important intellectual content. LiJ and LaJ confirm the authenticity of all the raw data. All authors read and approved the final version of the manuscript.

Ethics approval and consent to participate

The study was approved by the Ethics Committee of Jinhua Hospital of Zhejiang University and Jinhua Maternity and Child Health Care Hospital (ethics approval no. 2020-268). All patients provided written informed consent before recruitment.

Patient consent for publication

All patients provided written informed consent for publication of the images and data presented.

Competing interests

The authors declare that they have no competing interests.

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