Comparison of cervical cancer outcomes following open and laparoscopic surgery performed by experienced surgeons: a retrospective study

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Running title: Cervical cancer outcomes post-surgery

Abstract

Objective: Compare the outcomes associated with laparoscopic radical hysterectomy (LRH) and abdominal radical hysterectomy (ARH) for cervical cancer.

Design: Retrospective, multicenter observational analysis

Setting: Select patients of LRH and ARH from cervical cancer database and compare their outcomes.

Population: Patients with stage IA1 (Lymphovascular space invasion [LVSI]-positive) and stage IIA2 cervical cancer (N=6804) were enrolled, of whom 3003 underwent laparoscopy (LRH group), and 3801 underwent laparotomy (ARH group).

Methods: Kaplan-Meier survival analysis,propensity score matching (PSM) and Cox regression.

Main Outcome Measures: Five-year overall survival (OS) and 5-year disease-free survival (DFS)

Results: Before PSM, there was no difference in outcomes between the groups (5-year OS: LRH 89.2% vs. ARH 90.6%, *P*=0.903.; 5-year DFS: LRH 84.5% vs. ARH 87.1%, *P*=0.155). Surgical approach did not affect 5-year OS; however, it did affect 5-year DFS (hazard ratio [HR]=0.827, 95% confidence interval [CI]: 0.711-0.962, *P*=0.014). After PSM, there was no difference in 5-year OS between the LRH (*N*=1828) and ARH (*N*=1828) groups (91.0% vs. 93.1%, *P*=0.220); but there was a significant difference in 5-year DFS between the LRG and ARH groups (86.2% vs. 90.6%, *P*=0.002). Cox regression revealed that the surgical approach did not affect 5-year OS; however, it did affect 5-year DFS (HR=0.701, 95% CI: 0.563-0.874, *P*=0.002).

Conclusions: For IA1 (LVSI-positive) and IIA1 cervical cancers, the recurrence rate following laparoscopic surgery was higher than that following open surgery, regardless of the surgeon's experience.

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Key words: cervical cancer, open surgery, laparoscopy, oncology outcomes, high-volume surgeon, propensity score matching

Tweetable Abstract:

We use Kaplan-Meier survival analysis, PSM and Cox regression to compare outcomes associated with LRH and ARH for cervical cancer. For IA1 and IIA1 cervical cancers, the recurrence rate following laparoscopic surgery was higher than following open surgery, regardless of the surgeon's experience.

Introduction

In 1992, Nezhat reported laparoscopic pelvic lymphadenectomy, while Dargent reported laparoscopic-assisted radical vaginal hysterectomy and laparoscopic radical hysterectomy (LRH) separately.[1] Thereafter, laparoscopic surgery has been widely used for cervical cancer. Moreover, it has become popular due to characteristics such as further reduced invasiveness and bleeding, and shorter recovery time than open surgery. Before 2018, many international guidelines,[2-5] including those by the United States National Comprehensive Cancer Network, recommended laparoscopic surgery for stage IIIA1-IIA2 cervical cancer. However, recent studies,[6-9] have shown that minimally invasive surgery for cervical cancer is associated with higher recurrence and mortality rates than open surgery. Several factors have been proposed to account for these findings, including the use of carbon dioxide for pneumoperitoneum,[10] a lack of tumor,[11] and complications resulting from use of a uterine manipulator.[12-14] In addition, lack of surgical experience might have contributed to poor outcomes associated with laparoscopic surgery for cervical cancer. For example, Yang et al.[15] suggested that these poor outcomes might not have resulted from the laparoscopic approach itself and that the surgical team and the equipment used could affect outcomes. Many recent studies have compared the outcomes of cervical cancer surgery using laparotomy and laparoscopic surgery; however, the experience of the surgeons was not included in these studies. Indeed, in some studies, the surgeons were only required to complete a minimum of ten surgeries; thus, these surgeons were still in their learning phase.[16] As a result, the impact of a surgeon's experience on surgical outcomes remains unclear.

Our research team used a cervical cancer clinical diagnosis and treatment database to

select experienced doctors in advanced medical centers who have performed LRH and abdominal radical hysterectomy (ARH) in more than 50 cases. We aimed to retrospectively analyze their patients and compare the outcomes associated with LRH and ARH for cervical cancer.

Methods

Data source

This study was a multicenter, retrospective, observational study, using data extracted from the Four C database, which is dedicated to cervical cancer (N = 49,187) and includes patients treated at 40 hospitals in mainland China between January 2004 and December 2016.[17,18] The establishment of the cervical cancer database was reviewed by the Ethics Committee of Nanfang Hospital, Southern Medical University (NFEC-2017-135). The identifier of the clinical trial is CHiCTR180017778 (International Clinical Trials Registry Platform Search Port, http://apps.who.int/trialsearch/).

Participant selection

Patients were eligible for this study if they met the following criteria:

1) Selection of physicians: Surgeons who had performed LRH and ARH in more than 50 cases were selected.

2) Selection of cases: age ≥18 years; confirmed squamous cell carcinoma, adenocarcinoma, or adenosquamous carcinoma; confirmed 2009 International Federation of Gynecology and Obstetrics stage IA1-IIA2 (Lymphovascular space invasion [LVSI]-positive); underwent laparoscopic or open surgery between January 2009 and December 2016; no adjuvant

125 treatment before surgery; operation type either QM type B or type C radical hysterectomy
126 with pelvic lymph node resection with or without para-aortic lymph node resection; survival
127 outcomes available.

128 Patients signed the consent, and were excluded from this study if they met any of the
129 following criteria: pregnancy, accidental cervical cancer, residual cancer, and presence of
130 other sites of the primary tumor.

131 *Observation index*

132 Five-year overall survival (OS) and five-year disease-free survival (DFS) rates were the
133 outcomes of interest. OS was defined as the time from the operation until death from any
134 cause. DFS was defined as the time from the operation until disease recurrence.

135 *Statistical analysis*

136 Statistical Product and Service Solutions (SPSS 23.0, Inc., Chicago, IL, USA) was used
137 for data analysis. *P*-values < 0.05 were considered statistically significant. Continuous
138 variables were expressed as mean ± standard deviation (x±s); categorical variables were
139 expressed as count and percentage (%). The t-test was used to compare the average values.

140 Propensity score matching (PSM) was performed based on patient age, stage,
141 histological type, lymph node metastasis, para-uterine infiltration, vaginal incision margin,
142 cervical infiltration depth, LVSI, tumor diameter, and postoperative adjuvant treatment. The
143 matching tolerance parameter was set at 0.001. Finally, the balance between the two groups
144 was tested with the $\chi 2$ test.

145 The Kaplan-Meier method and Cox regression analysis were used. Variables included in
146 Cox regression were patient age, stage, histological type, lymph node metastasis, para-uterine

infiltration, vaginal incision margin, cervical infiltration depth, LVSI, tumor diameter, and surgical approach. All statistical methods and procedures performed in this study were reviewed by statistical experts.

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Results

Participants' baseline characteristics

A total of 6804 patients were included in this study (Figure 1). The patients were aged from 19 to 86 years (48.38±9.51), with a median age of 48 years. There were 3003 cases of laparoscopy and 3801 cases of laparotomy. Histological types included squamous cell carcinoma (*N*=5977), adenocarcinoma (*N*=680), and adenosquamous carcinoma (*N*=147). The median follow-up time was 39 months, including 30 months for the LRH groups and 48 months for the open surgery (ARH) group. Patients undergoing laparotomy were slightly older than those undergoing laparoscopic surgery, and the proportion of cases of squamous cell carcinoma was greater in the laparoscopic group than in the laparotomy group. The proportion of cases with stage IB1, IB2, IIA1, and IIA2 in the LRH group was higher than that in the ARH group. The incidence of LSVI was higher in the LRH group than in the ARH

group The rate of positive surgical margins in the ARH group was higher than that in the LRH group, and the rate of pelvic lymph node metastasis in the ARH group was higher than that in the LRH group (all $P < 0.05$). There were no differences between the groups in other baseline characteristics.

Survival analysis for laparoscopy and laparotomy before propensity score matching

Before PSM, there was no significant difference in the 5-year OS or 5-year DFS between the LRH and ARH groups treated by experienced surgeons (5-year OS: 89.2% vs. 90.6%, P=0.903; 5-year DFS: 84.5% vs. 87.1%, P=0.155) (Figure 2). Multivariate Cox analysis revealed that for experienced surgeons, the type of surgery performed did not affect 5-year OS; however, it did affect 5-year DFS (hazard ratio [HR]=0.827, 95% confidence interval [CI]: 0.711-0.962, P=0.014). In addition, the depth of cervical infiltration, LVSI, parastatal metastasis, tumor diameter, pelvic lymph node metastasis, and histological type independently affected 5-year OS and DFS (Table 1).

Multivariate survival analysis after matching

After 1:1 PSM (LRH, N=1828; ARH, N=1828), there was no significant difference in 5-year OS between the groups (91.0% vs. 93.1%, P = 0.220).However, laparotomy was associated with a relatively poorer 5-year DFS (86.2% vs. 90.6%, P = 0.002) (Figure 3). Cox regression revealed the surgical approach of an experienced surgeon independently affected 5-year DFS among patients with cervical cancer (HR=0.701, 95% CI: 0.563-0.874, P=0.002); however, it did not affect 5-year OS. In addition, the depth of cervical infiltration, LVSI, the

positive margin of vaginal resection, pelvic lymph node metastasis, and histological type were independently associated with 5-year OS. Finally, tumor stage, cervical infiltration depth, LVSI, positive margin of vaginal resection, and pelvic lymph node metastasis independently affected 5-year DFS.

There was no significant difference in the 5-year OS between the groups (91.0% vs. 93.1%, $P = 0.220$). However, laparotomy was associated with a relatively poorer 5-year DFS (86.2% vs. 90.6%, $P = 0.002$). Cox regression analysis revealed that the surgical approach of an experienced surgeon independently affected the 5-year DFS of patients with cervical cancer (HR=0.701, 95% CI: 0.563-0.874, P=0.002); however, it did not affect the 5-year OS.

Discussion

This large, multicenter, retrospective study has shown that laparoscopic surgery for cervical cancer is associated with a higher recurrence rate than open surgery even when performed by highly experienced surgeons. This finding suggests that the surgeon's experience does not account for the poorer outcomes of LRH.

Evidence regarding the impact of surgeon's experience on outcomes following an operation for cervical cancer is limited; in fact, previous studies involved surgeons with modest experience (23-50 cases) and reported on outcomes of few cases (45-271).[19-21] Experts differ in the number of cases required to achieve proficiency; for example, Reade et al.[20] suggested that the number of cases should exceed 23; nevertheless, studies by as Chong et al.,[19] Hwang et al.,[21] and Liu et al.[22] suggested that this number should be at least 50. This study included patients who underwent surgeries performed by physicians who have

completed at least 50 laparoscopic or open extensive hysterectomies for cervical cancer, which was considered a criterion for skill maturity.

Following this standard, we included 3003 and 3801 cases in the LRH and ARH group, respectively, extracted from a large clinical database. Patient outcomes were compared depending on the type of surgery received.

In this study, before and after PSM, there was no between-group difference in 5-year OS. This finding is consistent with some previous studies,[17] but slightly inconsistent with others.[3,4] This discrepancy can be accounted for by the sample composition; the previous studies included only early-stage (I A1 [LVSI-positive] ~ I B1) patients, while our study included patients at several stages, such as IA1 (LVSI positive) to IIA2. Moreover, these cases used adjuvant therapy after the operation. In this study, before matching, the percentage of adjuvant radiation and chemotherapy after the operation was 55.9% (30.3% vs. 25.6%: laparoscopic vs. laparotomy). Meanwhile, after matching, the percentage was 59.2% (29.6% vs. 29.6%: laparoscopic vs. laparotomy). This finding suggests that postoperative adjuvant radiation and chemotherapy might, improve outcomes associated with laparoscopic surgery to a certain extent.

Before PSM, there was no significant difference between the LRH and ARH groups in 5-year DFS (84.5% vs. 87.1%, P=0.155); however, after PSM, 5-year DFS was worse for the LRH than for the ARH group, even when the operation was performed by a highly experienced surgeon (86.2% vs. 90.6%, P= 0.002). This finding indicates that laparoscopic surgery is associated with a higher mortality and recurrence rate than open surgery, which is consistent with previous studies.[7-9]

The Cox regression analysis revealed that the surgical approach of experienced surgeons affected the 5-year DFS of cervical cancer patients; however, it did not affect 5-year OS. This indicates that, for highly skilled surgeons, the surgical approach may still play a significant role in the surgery outcome. This result was confirmed using PSM as well as Cox regression analysis. The surgeon's experience cannot compensate for the limitations of laparoscopic surgery. In this study, skilled doctors used a uterine manipulator in 95% of cases; this technique is associated with a risk of displacing cancer cells into the micro and lymphatic vessels, increasing the risk of metastasis.[18] In contrast, during open surgery, the vagina is cut and partially sealed with gauze to protect the incision, reducing the risk of local shedding of tumor cells and planting.[23] Moreover, quite a few skilled doctors are accustomed to using an ultrasonic knife, resulting in atomized particles floating in the abdomen and accelerating the spread of the tumor. Finally, skilled doctors tend to put the pelvic lymph node in the iliac fossa until the end of the operation when it is removed; these lymph nodes are immersed in carbon dioxide for an extended period, increasing the risk of tumor metastasis.[24] These factors might account for poorer outcomes associated with laparoscopic surgery, compared to open surgery for cervical cancer.

This study has some limitations. First, this study included patients with stage IB2 and IIA2 disease who underwent an extensive hysterectomy. In other countries, these patients would receive chemoradiotherapy instead of surgery. Second, this was a retrospective study. Although multivariate analysis and PSM can reduce the impact of confounders, they cannot eliminate it.

The third edition of the National Comprehensive Cancer Network guidelines on cervical

cancer published in 2019 does not recommend laparoscopic surgery. Our findings suggest that even when performed by skilled surgeons, laparoscopic surgery has a higher mortality and recurrence rate than open surgery. Surgery type might affect outcomes, and recommendations on laparoscopy should be made with caution.

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Disclosure of Interest

The authors declare no conflict of interest

Authors' Contribution

C.C. and P.L. conceived and planned the study; J.Lan wrote the article; C.C. and P. Li provided scientific revisions to the drafted paper; and J.G. X.B., J.Lang, W.W, A.L., M.H., W. L., H.D.[1],

from different hospitals provided the data.

Details of Ethics Approval

The establishment of the cervical cancer database was reviewed by the Ethics Committee of Nanfang Hospital, Southern Medical University (Ethics number NFEC-2017-135). The identifier of the clinical trial is CHiCTR180017778 (International Clinical Trials Registry Platform Search Port, http://apps.who.int/trialsearch/).

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382 **Figure Captions**

383 **Figure 1**. Patient selection process

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385 **Figure 2**. Kaplan-Meier survival analysis before matching for LRH and ARH groups. LRH,

386 laparoscopic radical hysterectomy; ARH, abdominal radical hysterectomy

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388 **Figure 3**. Kaplan-Meier survival analysis of LRH and ARH for high-volume operational.

389 LRH; laparoscopic radical hysterectomy, ARH; abdominal radical hysterectomy

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