

SUCCOR morbidity: complications in minimally invasive versus open radical hysterectomy in early cervical cancer

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ABSTRACT

Objective The aim of this study was to compare the incidence of intra-operative and post-operative complications in open and minimally invasive radical hysterectomy for patients with early-stage cervical cancer.

Methods Data were collected from the SUCCOR database of 1272 patients with stage IB1 cervical cancer (International Federation of Gynecology and Obstetrics (FIGO), 2009) who underwent radical hysterectomy in Europe between January 2013 and December 2014. We reviewed the duration of the surgeries, estimated blood loss, length of hospital stay, intra-operative and postoperative complications. The inclusion criteria were age ≥18 years and histologic type (squamous cell carcinoma, adenocarcinoma, or adenosquamous carcinoma). Pelvic MRI confirming a tumor diameter ≤4 cm with no parametrial invasion and a pre-operative CT scan, MRI, or positron emission tomography CT demonstrating no extracervical metastatic disease were mandatory. Outcomes of interest were any grade >3 adverse events, intra-operative adverse events, post-operative adverse events, length of hospital stay, length of operation, and blood loss.

Results The study included 1156 patients, 633 (54%) in the open surgery group and 523 (46%) in the minimally invasive surgery group. Median age was 46 years (range 18–82), median body mass index 25 kg/m² (range 15–68), and 1022 (88.3%) patients were considered to have an optimal performance status (ECOG Performance Status 0). The most common histologic tumor type was squamous carcinoma (n=794, 68.7%) and the most frequent FIGO staging was IB1 (n=510, 44.1%). In the minimally invasive surgery group the median duration of surgery was longer (240 vs 187 min, p<0.01), median estimated blood loss was lower (100 vs 300 mL, p<0.01), and median length of hospital stay was shorter (4 vs 7 days, p<0.01) compared with the abdominal surgery group. There was no difference in the overall incidence of intra-operative and post-operative complications between the two groups. Regarding grade I complications, the incidence of vaginal bleeding (2.9% vs 0.6%, p<0.01) and vaginal cuff dehiscence was higher in the minimally invasive surgery group than in the open group (3.3% vs 0.5%, p < 0.01). Regarding grade III post-operative complications, bladder dysfunction (1.3% vs 0.2%, p=0.046) and abdominal wall infection (1.1% vs 0%, p=0.018) were more common in the open surgery group than in the minimally invasive surgery group. Ureteral fistula was more frequent in the

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ In the Laparoscopic Approach to Cervical Cancer (LACC) trial, the use of minimally invasive surgery compared with open radical hysterectomy resulted in a similar overall incidence of intra-operative and post-operative adverse events.

WHAT THIS STUDY ADDS

⇒ There were no differences regarding overall intraoperative or post-operative complications in both groups but there were differences in certain postoperative complications. Performing an open approach resulted in shorter operating time, more intra-operative bleeding, and a longer length of stay. In the open surgery group, bladder dysfunction and abdominal wall infection were more frequent while the ureteral fistula rate was higher in the minimally invasive surgery group.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Performing a radical hysterectomy through an open approach does not increase the overall incidence of intra-operative or post-operative complications.

minimally invasive group than in the open surgery group (1.7% vs 0.5%, p=0.037).

Conclusion Our study showed that there was no significant difference in the overall incidence of intraoperative and post-operative complications between minimally invasive radical hysterectomy and the open approach.

INTRODUCTION

Radical hysterectomy and lymph node staging is the recommended procedure for patients with early-stage cervical cancer.^{1 2} Traditionally, this surgery has been performed either through an open approach or a vaginal approach,³ and more recently it has been performed through minimally invasive surgery (laparoscopic or robotic).⁴ Several retrospective and non-randomized studies concluded that minimally invasive radical hysterectomy was associated with better surgical outcomes, including fewer days of hospitalization, less post-operative pain, and faster

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recovery.^{5–8} The results of the Laparoscopic Approach to Cervical Cancer (LACC) trial showed that minimally invasive surgery is associated with a higher risk of relapse and death compared with the open approach.⁹ Additionally, the authors found that the overall incidence of intra-operative and post-operative adverse events did not differ between minimally invasive and open radical hysterectomy for early-stage cervical cancer.¹⁰ The SUCCOR study was a retrospective observational study conducted by our group which compared minimally invasive surgery versus open abdominal radical hysterectomy in European patients with stage IB1 cervical cancer.¹¹ The results of the SUCCOR study confirmed that minimally invasive surgery. The objective of the present study was to evaluate the rates of intra-operative and post-operative complications in the SUCCOR database.

METHODS

Accrual and Data Source

We collected data from the SUCCOR database. This database consisted of 1272 patients with stage IB1 cervical cancer (International Federation of Gynecology and Obstetrics (FIGO) 2009) who underwent a radical hysterectomy in Europe from January 2013 to December 2014. Researchers from 126 institutions in 29 European countries registered and contributed to the project.

Inclusion and Exclusion Criteria

As detailed in the study by Boria et al,¹² patients were eligible if they had undergone radical hysterectomy for stage IB1 cervical cancer (FIGO, 2009) in a European institution. A total of 1272 patients were evaluated; however, 116 patients did not meet the inclusion criteria of age \geq 18 years and histologic type (squamous cell carcinoma, adenocarcinoma, or adenosquamous carcinoma). Pelvic MRI confirming a tumor diameter ≤ 4 cm with no parametrial invasion and a pre-operative CT scan, MRI, or positron emission tomography (PET) CT demonstrating no extra-cervical metastatic disease were mandatory. The operative report had to describe type B-C radical hysterectomy with bilateral pelvic lymphadenectomy by either minimally invasive surgery (laparoscopic or robotic) or open surgery, including at least 10 pelvic nodes. Women who underwent only sentinel lymph node mapping were included in the study, but data regarding tumor size, margins, and nodal status were required. Exclusion criteria were as follows: (1) final tumor stage IA; (2) history of any invasive tumor other than cervical cancer; (3) previous chemotherapy or radiation; and (4) conversion from minimally invasive surgery to open laparotomy (as it was stated in the SUCCOR database).

Statistical Analysis

Baseline demographics were summarized in terms of frequency. Outcomes of interest were any grade >3 adverse events, intraoperative adverse events, post-operative adverse events, length of hospital stay, length of operation, and blood loss. An intra-operative adverse event was defined as any unfavorable medical complication that occurred during the surgery in an enrolled patient, irrespective of its causal relationship with the study treatment. A postoperative adverse event is a complication that occurs within 30 days after surgery. Intra-operative complications were classified according to the CLASSIC classification.¹³ Grade 1 is any deviation from the ideal intra-operative course without the need for any additional treatment or intervention. Grade 2 is any deviation from the ideal intra-operative course with the need for additional treatment or intervention, not life-threatening, and not leading to permanent disability. Grade 3 is any deviation from the ideal intra-operative course with the need for additional treatment or intervention, not life-threatening, and not leading to permanent disability. Grade 3 is any deviation from the ideal intra-operative course with the need for additional treatment or intervention, life-threatening, and/or leading to permanent disability. Grade 4 is any deviation from the ideal intra-operative course with death of the patient.

Post-operative complications were classified according to the Clavien–Dindo scale. Grade 1 is any deviation from the normal post-operative course without the need for pharmacological treatment other than the allowed therapeutic regimens or surgical, endoscopic, and radiological interventions. Grade 2 is requiring pharmacological treatment with drugs beyond those allowed for grade 1 complications, grade 3 is requiring surgical, endoscopic, or radiological intervention, grade 4 is life-threatening complication requiring critical care management, and grade 5 is death of the patient.

Continuous variables were summarized as mean (SD) and range and were compared between surgical techniques using a t-test. Categorical outcomes were summarized as frequency and were compared between surgical techniques using a χ^2 test. Adverse events were summarized in two ways: overall and by specific adverse events of interest. For all analyses, adverse events were not treated as mutually exclusive and patients were included in all appropriate summaries. In each case the numerator was the number of patients who had experienced the adverse event being described and the denominator was the total number of patients (per arm). P values <0.05 were considered statistically significant. The analyses were performed with SPSS v.26.0.

RESULTS

Baseline Characteristics

The final cohort was composed of 1156 patients. The mean (SD) age was 47.1 (10.8) years and the mean (SD) body mass index was 25.44 (4.9) kg/m². A total of 1022 (88.3%) patients were considered to have an optimal performance status (ECOG Performance Status 0). A total of 423 (36.6%) patients had undergone a cone biopsy before radical hysterectomy. The mean (SD) pre-operative maximum tumor diameter measured by MRI was 19.6 (12.6) mm. Table 1 shows the baseline characteristics of the patients according to the surgical approach.

Peri-operative Outcomes

The median duration of surgery was 210 min (range 80–720), and it was longer for the minimally invasive surgery group than for the open surgery group (240 vs 187 min, p<0.001). The median average length of stay in hospital was 6 days (range 1–42), and was lower in the minimally invasive group than in the open surgery group (4 vs 7 days, p<0.001). The median estimated blood loss was 100 mL (range 30–1700) for minimally invasive surgery and 300 mL (range 50–5000) for open surgery (p<0.001; Table 2).

Table 1 Baseline characteristics			
Baseline characteristics	Open surgery (n=633)	Minimally invasive surgery (n=523)	
Age, years, mean (SD)	48 (10.5)	46 (11)	
Body mass index, kg/m ² , mean (SD)	25.7 (4.6)	25.1 (5.3)	
Performance status ECOG, n (%)			
PS 0	558 (88.2%)	463 (88.5%)	
PS 1	51 (8.1%)	28 (5.4%)	
Not reported	24 (3.8%)	32 (6.1%)	
Tumor clinical size, mm, mean (SD)	21.2 (11.2)	17.6 (11.3)	
Histologic sub-type, n (%)			
Adenocarcinoma	155 (24.5%)	168 (32.1%)	
Adenosquamous	24 (3.8%)	15 (2.8%)	
Squamous	454 (71.7%)	340 (65%)	

Intra-operative and Post-operative Complications

A total of 108 (9.3%) patients experienced at least one intraoperative complication, 63 (58%) in the open group and 45 (42%) in the minimally invasive group (p=0.6). Intra-operative complications classified by surgery group are shown in Figure 1.

Globally, intra-operative bleeding (7.2%), bladder injury (4.1%), and vascular injury (3.0%) were the most common intra-operative complications.

A total of 21.5% of patients had at least one post-operative complication during the first month after surgery, 54% in the open surgery group and 45% in the minimally invasive surgery group (p=0.6). The most frequent post-operative complications were bladder dysfunction in 119 patients (10.3%), urinary infection in 70 (6.1%), and fever in 77 (6.7%).

Clavien–Dindo grade 3 or higher complications occurred in 56 (4.8%) patients. In the open surgery group, bladder dysfunction (1.3% vs 0.2%, p=0.046) and abdominal wall infection (1.1% vs 0%, p=0.018) were more frequent than in the minimally invasive group. On the other hand, the ureteral fistula rate was higher in the minimally invasive surgery group than in the open surgery group (1.7% vs 0.5%, p=0.037; Figure 2).

Regarding all grade post-operative specific complications, in the minimally invasive surgery group the incidence of vaginal bleeding (2.9% vs 0.6%, p<0.01) and the vaginal cuff dehiscence were higher than in the open surgery group (3.3% vs 0.5%, p<0.01).

DISCUSSION

Summary of Main Results

In the patients in the SUCCOR database we did not find any difference in the overall intra-operative and post-operative complications between minimally invasive surgery and open radical hysterectomy. When comparing the open approach to minimally invasive surgery, the duration of surgery was shorter with the open approach but there was a higher estimated blood loss and longer length of stay. However, when considering grade 3 complications, in the open surgery group there was a significantly higher incidence of wound complications and bladder dysfunction but a lower incidence of ureteral fistulas compared with the minimally invasive surgery group.

Results in the Context of Published Literature

Seven meta-analyses have been published comparing intraoperative and post-operative complications in radical hysterectomy, all prior to the release of the LACC trial results. These studies concluded that minimally invasive surgery results in lower estimated blood loss, shorter length of stay, and longer length of surgery than open surgery, a conclusion that is also supported by the LACC trial and the SUCCOR study.^{5 6 14–18}

Regarding intra-operative complications, all the meta-analyses found that the incidence of such complications was similar for minimally invasive surgery and open surgery. The LACC trial and SUCCOR study also came to the same conclusion. Four of the seven meta-analyses published before the LACC trial concluded that patients who underwent open surgery had more post-operative complications than those who underwent minimally invasive surgery.^{14–16} ¹⁸ The results of the study by Jin and colleagues showed that patients who underwent the robotic approach had fewer post-operative complications than those with the laparoscopic and open approach.¹⁶ In the SUCCOR study and the LACC trial, no differences were found in the overall incidence of intraoperative and post-operative complications when comparing minimally invasive radical hysterectomy to the open approach.

There are certain differences between these two studies. In the LACC trial the post-operative complications that had statistical significance were cardiac events and surgical wound complications, which were more frequent with the open approach. In the SUCCOR study, among the grade 3 post-operative complications patients in the open surgery group had a higher incidence of wound complications and bladder dysfunction but a lower incidence of ureteral fistulas compared with those in the minimally invasive surgery group.

Wang and colleagues had similar results to the SUCCOR study regarding a higher incidence of surgical wound infection with the open surgical approach (p=0.034).¹⁵ Regarding the incidence of

Table 2 Peri-operative outcomes by surgical technique			
Surgical outcome	Open surgery	Minimally invasive surgery	P value
Median (SD) length of surgery, min	187 (54.75)	240 (75)	<0.001
Median (SD) estimated blood loss, mL	300 (368.75)	100 (176.65)	<0.001
Median (SD) length of hospital stay, days	7 (4.1)	4 (3.41)	<0.001

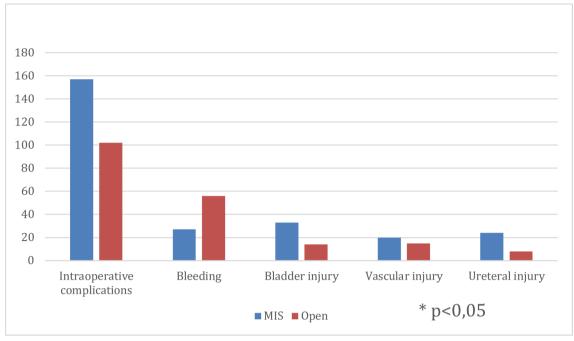


Figure 1 Intra-operative complications. MIS, minimally invasive surgery.

intra-operative complications, the previously mentioned metaanalyses report a rate of 5.1-7.1%. In the LACC trial the incidence was 11% and in the SUCCOR study it was 9.3%. In terms of post-operative complications, the meta-analyses report a rate of 10.1-25.4%. However, in the LACC trial the incidence was 42%and in the SUCCOR study it was 21.5%. We think this is probably because, given the prospective design of the LACC study, there is a more concrete assessment of variables of interest and therefore they have a higher incidence. Similarly, in retrospective studies the incidence may be lower because some data may not have been collected.

Strengths and Weaknesses

The strengths of this study include a collaborative effort of 126 European institutions from 29 countries where comprehensive data were collected on 1272 patients. Our study has several weaknesses due to the retrospective nature, including the fact that there was no formal auditing of the data. To account for these limitations, we provided the participating sites with a strict list of inclusion and exclusion criteria, and all investigators declared that the reported information adhered to the data in the reviewed charts. Moreover, patients converted from minimally invasive surgery to open surgery were excluded in the SUCCOR database (eight patients in total),

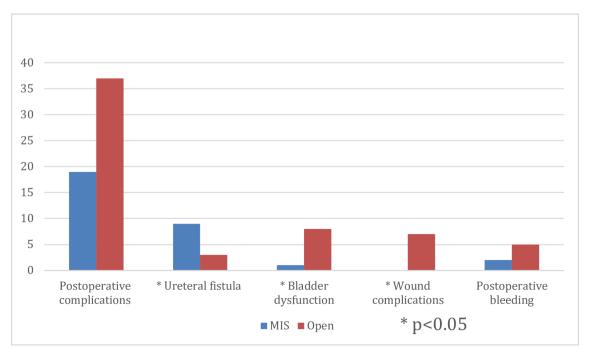


Figure 2 Post-operative complications grade 3. MIS, minimally invasive surgery.

which could have been a bias when evaluating intra-operative complications.

Implications for Practice and Future Research

Open radical hysterectomy did not have more complications in our cohort and is shown to have better oncologic outcomes in a prospective trial. Open radical hysterectomy should be the surgical goal in early-stage cervical cancer.

CONCLUSIONS

In the SUCCOR study there are no differences in intra-operative and post-operative complications between patients who underwent open surgery and those who had minimally invasive radical hysterectomy. Patients operated on by an open approach had a higher incidence of bladder dysfunction and wound complications but a lower incidence of ureteral fistula compared with those who underwent the minimally invasive surgery approach.

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Correction notice This article has been corrected since it was first published. The outcome values in the Results section of the Abstract were inaccurate and have now been updated.

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Data availability statement In accordance with the journal's guidelines, we will provide our data for independent analysis by a selected team by the Editorial Team for the purposes of additional data analysis or for the reproducibility of this study in other centers if such is requested.

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