





Outcomes of open radical hysterectomy following implementation of an enhanced recovery after surgery program

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HIGHLIGHTS

- Patients in the post-enhanced recovery after surgery (ERAS) group were discharged from hospital earlier compared with those in the pre-ERAS group (median 3 vs 4 days).
- The proportion of patients discharged within 48 hours was significantly higher in the post-ERAS group (47.3% vs 17.3%).
- There were no differences in reoperation and readmission rates comparing pre-ERAS with post-ERAS.

ABSTRACT

Objective Open surgery has become the standard approach for radical hysterectomy in early stage cervical cancer (International Federation of Gynecology and Obstetrics (FIGO) 2018 IA1 with lymphovascular space invasion-IIA1). Our primary objective was to compare the length of stay in patients undergoing open radical hysterectomy before and after implementation of an enhanced recovery after surgery (ERAS) program.

Methods This was a single center, retrospective, before-and-after intervention study including patients who underwent open radical hysterectomy for cervical cancer from January 2009 to December 2020. Two groups were identified based on the time of ERAS implementation: pre-ERAS group included patients who were operated on between January 2009 and October 2014; post-ERAS group included patients who underwent surgery between November 2014 and December 2020.

Results A total of 81 patients were included, of whom 29 patients were in the pre-ERAS group and 52 patients in the post-ERAS group. Both groups had similar clinical characteristics with no differences in terms of median age (42 years (interquartile range (IQR) 35–53) in pre-ERAS group vs 41 years (IQR 35–49) in post-ERAS group; $p=0.47$) and body mass index (26.1 kg/m^2 (IQR 24.6–29.7) in pre-ERAS group vs 27.1 kg/m^2 (IQR 23.5–33.5) in post-ERAS group; $p=0.44$). Patients in the post-ERAS group were discharged from the hospital earlier compared with those in the pre-ERAS group (median 3 days (IQR 2–3) vs 4 (IQR 3–4), $p<0.01$). The proportion of patients discharged within 48 hours was significantly higher in the post-ERAS group (47.3% vs 17.3%, $p=0.013$). There were no differences regarding either overall complications (44.8% pre-ERAS vs 38.5% post-ERAS; $p=0.57$) or readmission rates within 30 days (20.7% pre-ERAS group vs 17.3% ERAS group; $p=0.40$). Adherence to the ERAS pathway since its implementation in 2014 has remained stable with a median of 70% (IQR 65%–75%).

Conclusions Patients undergoing open radical hysterectomy on an ERAS pathway have a shorter length of hospital stay without increasing overall complications or readmissions rates.

INTRODUCTION

Cervical cancer is one of the most common gynecological cancers among women worldwide.¹ The standard recommendation for patients with early stage cervical cancer (International Federation of Gynecology and Obstetrics (FIGO) 2018 IA1 with lymphovascular space involvement-IIA1) remains radical hysterectomy in conjunction with lymph node assessment.² Until recently, either laparotomy or minimally invasive surgery was considered an acceptable approach to radical hysterectomy.³ However, the Laparoscopic Approach to Cervical Cancer (LACC) trial showed that minimally invasive surgery led to a lower disease free survival rate compared with open hysterectomy in patients with FIGO 2009 stage IA1 with lymphovascular space involvement-IB1 disease.⁴ As a result of this landmark trial and numerous other studies,^{5–9} recent clinical practice guidelines^{2 10–13} recommend open surgery as the standard approach when performing a radical hysterectomy.

Given the increasing change in practice to an open radical hysterectomy,¹⁴ some might argue that the open approach may delay recovery for patients undergoing this procedure. Enhanced recovery after surgery (ERAS) protocols¹⁵ are a multidisciplinary and multimodal approach to optimize perioperative care and facilitate a faster recovery from surgery.

In gynecologic oncology surgery, these protocols have been associated with reduced length of stay and improved patient reported outcomes.¹⁶ Given the paucity of data on recovery after open radical hysterectomy in the setting of an established ERAS program, we aimed to evaluate as our primary objective the length of stay after open radical hysterectomy for patients with early stage cervical cancer before and after the implementation of an ERAS program in a tertiary cancer center. We hypothesized that under current standards of well established ERAS protocols,



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recovery after an open radical hysterectomy is expedited, allowing for a faster return to full functional activity.

METHODS

We conducted a single center, retrospective, before-and-after intervention study of patients who underwent open radical hysterectomy for early stage cervical cancer (FIGO 2009 stage IA1 with lymphovascular space involvement-IIA1) from January 2009 to December 2020. Patients were stratified into two groups based on the time of surgery. The time distinction between the two cohorts was based on the time of implementation of the ERAS pathway in the Department of Gynecologic Oncology and Reproductive Medicine, MD Anderson Cancer Center (November 2014): the pre-ERAS group included patients who were operated on between January 2009 and October 2014 and the post-ERAS group included patients who underwent surgery between November 2014 and December 2020.

Inclusion criteria were (1) patients who underwent a type II or III open radical hysterectomy (Rutledge classification)¹⁷ for cervical cancer at MD Anderson Cancer Center, (2) patients with early stage cervical cancer (FIGO 2009 stage IA1 with lymphovascular space involvement-IIA1), and (3) patients with a follow-up of at least 60 days. We excluded patients who underwent a radical hysterectomy for a diagnosis other than cervical cancer and those who received neoadjuvant chemotherapy and/or previous radiation therapy. In addition, it should be noted that as a result of the LACC trial,⁴ gynecologic oncologists at MD Anderson Cancer Center no longer performed minimally invasive radical hysterectomies for early stage cervical cancer after November 2017.

Before ERAS initiation, perioperative care was at the discretion of healthcare providers. Once ERAS was established, a multidisciplinary team (surgeons, anesthesiologists, nurses, pharmacists, and nutritionists) was involved in the perioperative care of patients undergoing gynecological surgeries. All surgeries were performed by gynecologic oncologists who followed perioperative management recommendations, as proposed by the ERAS guidelines.¹⁵ Key aspects of this protocol included prevention of prolonged fasting allowing oral intake of clear fluids up to 2 hours before induction of anesthesia, carbohydrate loading, avoidance of mechanical bowel preparation, thromboprophylaxis, pre-, intra-, and postoperative euvoemia, maintenance of normothermia, intraoperative and postoperative opioid sparing multimodal analgesia, avoidance of surgical drains, early removal of the urinary catheter, and early ambulation and feeding. There were no additional postoperative interventions outside of the ERAS guidelines that were implemented that could have impacted the outcomes.

Variables Evaluated

Clinical and demographic data were collected from the electronic medical records. Comorbidities were assessed using the American Society of Anesthesiologists classification of physical status. Perioperative data were also collected, including hospital stay, blood loss, transfusion rates, and intraoperative complications (major blood vessel, urinary, nerve, or bowel injury).

We evaluated discharge rates within 48 hours of surgery. Prolonged length of stay was considered more than 3 days (median) given results from our previous publication on overall outcomes of implementation of our ERAS program which demonstrated that our

median length of stay for patients undergoing open gynecologic surgery was 3 days.¹⁶ Postoperative complications were divided into those that occurred within 30 days after surgery and those that occurred later (31–60 days), and were classified as gastrointestinal, cardiac, pulmonary, infectious, wound related complications, and genitourinary. The Clavien–Dindo grading system was used to characterize complications as mild (grades I–II) or severe (grades III–IV).¹⁸ For patients with multiple complications at the same time, postoperative complications were categorized according to their highest grade of complication.

Data Collection

Data were collected retrospectively and managed using a REDCap (Research Electronic Data Capture) database¹⁹ hosted at the University of Texas MD Anderson Cancer Center. The institutional review board at the University of Texas MD Anderson Cancer Center approved the protocol (2020–0461).

Outcomes

Our primary outcome was length of stay after open radical hysterectomy in patients with early stage cervical cancer before and after the implementation of an ERAS pathway. Secondary outcomes included the rate of overall complications, organ specific complications, and readmission rate up to 60 days after surgery. We also reported our overall compliance with the ERAS pathway components (only for patients who underwent surgery after November 2014).

Statistical Analysis

Quantitative and categorical variables were initially explored in univariate analysis before and after implementation of the ERAS protocol. Data were represented using basic descriptives, including means or medians for quantitative variables based on the distribution of the data which was tested using the Smirnov–Kolmogorov test. Categorical variables were represented using relative frequencies (percentages). Additionally, postoperative complications were evaluated in univariate analysis for the periods pre-ERAS and post-ERAS. P values were reported using the χ^2 or Fisher's exact test in categorical variables according to the sample size in each subgroup. The Wilcoxon Mann–Whitney U test was used for quantitative variables. All analyses were performed in Stata 14.0 (StataCorp, College Station, Texas, USA).

Results

A total of 81 patients underwent an open radical hysterectomy, of whom 29 patients were in the pre-ERAS group and 52 patients in the post-ERAS group. Both groups had a comparable distribution of cancer histology ($p=0.19$), and there were no differences in terms of age, body mass index, American Society of Anesthesiologists classification, and preoperative stage (Table 1). There was no difference in the rates of types of radical hysterectomy between the pre-ERAS and post-ERAS groups (type II hysterectomy: pre-ERAS ($n=3$, 10.3%) vs post-ERAS ($n=2$, 3.8%), $p=0.08$; and type III hysterectomy: pre-ERAS ($n=26$, 89.7%) vs post-ERAS ($n=50$, 96%), $p=0.08$). Patients operated on before ERAS implementation were more likely to have a prolonged hospital stay (>3 days) (82.8% vs 57.7%, $p<0.01$). Patients who underwent surgery after implementation of the ERAS program were discharged from hospital significantly earlier compared with their counterparts (3 days (IQR 2–3)

Table 1 Univariate analysis for baseline characteristics

	Pre-ERAS group (2009–14) (n=29)	Post-ERAS group (2015–20) (n=52)	P value
Age (years) (median (IQR))	42 (35–53)	41 (35–49)	0.47
Body mass index (kg/m ²) (median (IQR))	26.1 (24.6–29.7)	27.1 (23.5–33.5)	0.44
American Society of Anesthesiologists classification (n (%))			0.76
II	1 (3.4)	7 (13.5)	
III	9 (31.0)	45 (86.5)	
Missing	19 (65.5)	0 (0)	
Preoperative stage (n (%))			0.24
IA1	2 (6.9)	3 (5.8)	
IA2	3 (10.3)	10 (19.2)	
IB1	23 (79.3)	34 (65.4)	
IB2	0 (0.0)	4 (7.7)	
IIA1	1 (3.4)	0 (0)	
Missing	0 (0)	1 (1.9)	
Preoperative hemoglobin (g/dL) (median (IQR))	13.6 (11.5–14.5)	13.1 (12.1–13.8)	0.46
Duration of surgery (minutes) (median (IQR))	244 (195–302)	272 (243–306)	0.07
Blood loss (mL) (median (IQR))	300 (200–550)	325 (150–500)	0.84
Pathology grade (n (%))			0.15
I	2 (6.9)	2 (3.8)	
II	8 (27.6)	20 (38.5)	
III	8 (27.6)	22 (42.3)	
Unknown	11 (37.9)	8 (15.4)	
Histology (n (%))			0.19
Squamous	6 (20.7)	21 (40.4)	
Adenocarcinoma	9 (31.0)	11 (21.1)	
Adenosquamous	2 (6.9)	4 (7.7)	
Neuroendocrine	1 (3.5)	0 (0)	
Undifferentiated	1 (3.5)	0 (0)	
No residual tumor	8 (27.6)	9 (17.3)	
Mixed	0 (0)	2 (3.8)	
Other	2 (6.9)	5 (9.6)	

vs 4 days (IQR 3–4), $p < 0.01$). In addition, the proportion of patients who were discharged within 48 hours was significantly higher in the post-ERAS group (47.3% vs 17.3%, $p = 0.013$). There was no difference in the proportion of overall complications in the pre-ERAS group compared with the post-ERAS group (44.8% vs 38.5%, $p = 0.57$). There were also no significant differences in the severity of complications, as measured by categories of the Clavien–Dindo classification ($p > 0.05$). Although it did not reach significance, patients in the pre-ERAS group were more likely to be readmitted within 31–60 days compared with the post-ERAS group (10.3%, pre-ERAS group vs 1.9%, ERAS group; $p = 0.05$) but there was no difference in readmission rates within 30 days (20.7% pre-ERAS group vs 17.3% post-ERAS group; $p = 0.40$) (Table 2). Details on each specific complication are listed in Table 3.

Compliance rate with the ERAS protocol was depicted over time in relation to length of hospital stay, as shown in Figure 1. Adherence to ERAS interventions since its implementation in 2014 has

remained stable to date, with a median of 70% (IQR 65%–75%). Given that prior to 2017 (when the results of LACC trial were available to our institution) our department primarily performed radical hysterectomy through a minimally invasive approach, we evaluated the number of open cases performed prior to and after 2017. The number of open radical hysterectomies performed from 2009 to 2017 was 35 and from 2018 to 2020 was 46.

DISCUSSION

Summary of Main Results

Patients undergoing open radical hysterectomy for early stage cervical cancer in conjunction with an ERAS protocol had a shorter length of hospital stay compared with those not on an ERAS protocol. We did not find differences regarding postoperative complications, reoperations, or readmissions rates within 30 days between the two groups.

Table 2 Postoperative outcomes before and after the enhanced recovery after surgery program

Outcome	Pre-ERAS group (2009–14) (n=29)	Post-ERAS group (2015–20) (n=52)	P value
Hospital stay (days) (median (IQR))	4 (3–4)	3 (2–3)	<0.01
Hospital discharged within ≤48 hours (days) (n (%))	5 (17.3)	23 (47.3)	0.013
Prolonged hospital stay (n (%))	24 (82.8)	30 (57.7)	<0.01
Blood transfusion (inhospital) (n (%))	8 (27.6)	8 (15.4)	0.18
Overall complication (≤60 days) (n (%))	13 (44.8)	20 (38.5)	0.57
Clavien–Dindo* (n (%))			
None	16 (55.2)	32 (61.5)	0.56
I	6 (20.7)	9 (17.3)	0.71
II	6 (20.7)	13 (25.0)	0.66
III	1 (3.4)	3 (5.8)	0.64
IV	1 (3.4)	3 (5.8)	0.64
≤30 days (n (%))			
Readmission	6 (20.7)	9 (17.3)	0.40
>30 to ≤60 days (n (%))			
Readmission	3 (10.3)	1 (1.9)	0.05

*The figures in this category reflect the composite of all complications for all patients and thus values may not add up to the total number of patients.

Table 3 Postoperative outcomes before and after the enhanced recovery after surgery program

Outcome	Pre-ERAS (2009–14) (n=29)	Post-ERAS (2015–20) (n=51)	P value
Hospital stay (median (IQR))	4 (3–4)	3 (2–3)	<0.01
Blood transfusion (inhospital) (n (%))	8 (27.8)	8 (15.4)	0.18
Overall complication events (n (%))	13 (44.8)	20 (38.5)	0.57
Clavien–Dindo (n (%))			
I	6 (20.7)	9 (17.3)	0.71
II	6 (20.7)	13 (25.0)	0.66
III	1 (3.4)	3 (5.8)	0.64
IV	1 (3.4)	3 (5.8)	0.64
<30 days (n (%))			
Readmission	6 (20.7)	9 (17.3)	0.40
Gastrointestinal	6 (20.7)	3 (5.8)	0.06
Cardiac	0 (0)	0 (0)	N.A.
Pulmonary	0 (0)	0 (0)	N.A.
Wound related	3 (10.3)	4 (7.7)	0.69
Infectious	10 (34.5)	13 (25.0)	0.44
Genitourinary	0 (0)	4 (7.7)	0.29
>30 days (n (%))			
Readmission	3 (10.3)	1 (1.9)	0.05
Gastrointestinal	0 (0)	0 (0)	N.A.
Cardiac	0 (0)	0 (0)	N.A.
Pulmonary	0 (0)	0 (0)	N.A.
Genitourinary	2 (6.9)	5 (9.6)	1.00

Results in the Context of Published Literature

The publication of the LACC trial led to a change in the standard of care, and many institutions have reverted to open radical hysterectomy in the management of patients with early stage cervical cancer. With such change, some have raised concerns regarding a potential delay in recovery for patients undergoing open radical hysterectomy. To this end, it is important to explore options that might have a positive impact on patient recovery when the open surgical approach is predominantly used. The ERAS protocols include evidence based techniques to minimize surgical trauma and postoperative pain, reduce complications, improve postoperative outcomes, and decrease hospital length of stay and costs.^{15 20}

In this study, we found a reduction of 25% in hospital length of stay after implementation of an ERAS protocol. These findings are consistent with our previous data evaluating all patients

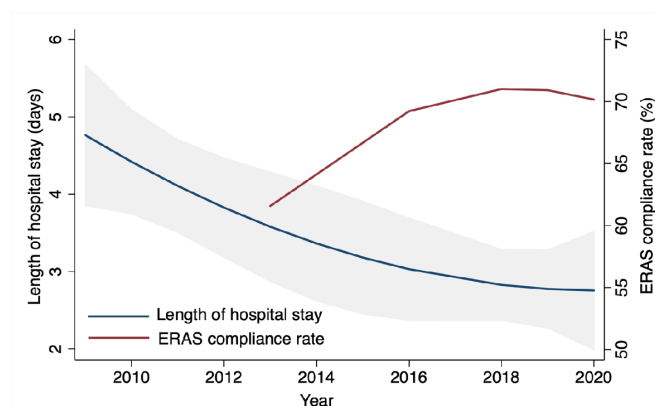


Figure 1 Compliance with enhanced recovery after surgery (ERAS) program and length of stay over the study period (2009–14). Implementation of the ERAS program (November 2014). Compliance rate with the ERAS protocol is depicted over time in relation to length of hospital stay.

Original research

undergoing laparotomy for gynecologic surgery in our institution.¹⁶ Therefore, these findings in the setting of radical hysterectomy are not unexpected but provide further evidence that by transitioning to the open approach for radical hysterectomy, patient outcomes and recovery are not compromised and that length of stay is, in fact, shorter than anticipated based on historical controls. Also, there was also no difference in complication rates, readmissions, or reoperations, further lending proof that a change in practice in conjunction with an ERAS program leads to overall shorter length of stay and equivalent perioperative outcomes. In a recent study by Matsuo et al,²¹ the authors noted that although the rate of minimally invasive radical hysterectomy has decreased since the publication of the LACC trial,⁴ there was an associated increase in the rate of complications with the change in practice to an open approach. However, the authors noted that a key limitation of the work was the fact that their study lacked information on the use of enhanced recovery after surgery.

Previous studies in the literature evaluating the impact of ERAS pathways have been characterized by heterogeneity of surgical interventions, ranging from simple hysterectomy to multivisceral resection in different tumor types.^{22–24} Our study specifically focused on outcomes of open radical hysterectomy in the setting of an ERAS pathway. Previously, Carter et al²⁵ performed a clinical audit of a fast track surgery program. Three hundred and eighty-nine patients underwent fast track surgical management after having a laparotomy for suspected or confirmed gynecological cancer. During the audit period, 21 patients had laparotomy for an invasive cervical cancer of whom 14 patients with stage I cervical cancer underwent either radical hysterectomy or radical trachelectomy. The median length of stay was 3 days (range 3–10). However, there was no comparison with control groups.

Prior retrospective data showed that minimally invasive radical hysterectomy was associated with lower postoperative complications compared with an open approach.^{26 27} By contrast, prospective data from the LACC trial²⁸ did not find differences in the overall incidence of postoperative adverse events when comparing the open approach with the minimally invasive approach. However, the use of ERAS protocols in such studies are not specified either in minimally invasive or open surgeries.

There are few data on the application of enhanced recovery pathways in relation to radical hysterectomy in early cervical cancer. Nevertheless, some studies evaluating the impact of ERAS measures in other gynecological tumors have also been published without showing differences in postoperative complications.^{23 29} Bisch et al³⁰ studied the impact of postoperative outcomes when applying ERAS protocols in debulking and staging gynecologic oncology surgeries and showed a significant reduction in complications prior to discharge from 53.3% to 36.2%. These differences might be explained by the heterogeneity in the type of surgeries, including benign and vaginal surgeries,^{29 31} and the different compliance rate reported for each ERAS element. Moreover, postoperative complications are usually secondary objectives of such studies, and thus the power of the sample size might limit the interpretation of the data.

Implementation of an ERAS program requires a multidisciplinary team with high compliance with individual ERAS protocol elements. Associations have been made which demonstrate improved patient outcomes with increased compliance that lead to reductions in

length of stay and postoperative complications.^{32 33} Carter et al²⁵ reported data from patients undergoing surgery for suspected gynecological cancer. The investigator found that further length of implementation of the ERAS program was associated with an increased percentage of patients discharged on day 2 from 10% in the first year to 39% in the fourth year.

Several studies have reported no difference in the readmission rate when applying ERAS programs.^{23 25 29 34} Consistent with the literature, in the current study the readmission rate after 30 days in post-ERAS group was lower (1.9%) than the pre-ERAS group (10.3%) but the difference was not statistically significant ($p=0.05$). However, we recognize that given the limited numbers of patients, our study did not have enough events that would allow detection of a difference if one actually existed.

Strengths and Weaknesses

Our study evaluated specifically the outcomes of patients undergoing open radical hysterectomy before and after implementation of an ERAS program. In addition, such programs have consistently maintained a compliance rate of more than 70% with all ERAS elements. We recognize a number of weaknesses in our study, such as its retrospective nature, the small sample size, and the fact that during the study period the majority of radical hysterectomies prior to 2017 were performed by a minimally invasive approach. We did not have documentation as to the indication for the selection of the open approach prior to 2017 and thus this could have been a patient population with unique criteria that led to the selection of such an approach. We also did not collect information for the purposes of this study on the rates of patients undergoing lymphadenectomy versus sentinel lymph node mapping, as we recognize these could have potentially impacted on length of hospitalization. Similarly, our study had a limited number of patients to detect small differences in complication and readmission rates. Lastly, our study did not collect data on a number of items that could have impacted the functional recovery of the patient, such as return of bowel function, postoperative pain requirements, time to first ambulation, or time to solid oral intake.

Implications for Practice and Further Research

Since the open surgical approach is considered the new standard of care in many institutions for patients with early stage cervical cancer, our study showed that under an ERAS protocol, one may strive towards shorter length of stay than previously documented in studies prior to integration of minimally invasive radical hysterectomy. This provides grounds for discussion during patient counseling when undergoing open radical hysterectomy.

CONCLUSION

This study showed that undergoing an open radical hysterectomy under an ERAS program was associated with a significantly decreased length of hospital stay without compromising postoperative complications, reoperations, or readmissions rates compared with those patients who did not undergo surgery under an ERAS pathway.

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