Gynecologic Oncology Reports 36 (2021) 100771

Contents lists available at ScienceDirect

Gynecologic Oncology Reports

journal homepage: www.elsevier.com/locate/gynor

Implementation of an enhanced recovery protocol in gynecologic oncology

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ARTICLE INFO

Keywords:
Enhanced Recovery
Perioperative outcomes
ERAS

ABSTRACT

Enhanced Recovery after Surgery (ERAS) is an evidence-based approach that aims to reduce narcotic use and maintain anabolic balance to enable full functional recovery. Our primary aim was to determine the effect of ERAS on narcotic usage among patients who underwent exploratory laparotomy by gynecologic oncologists. We characterized its effect on length of stay, intraoperative blood transfusions, bowel function, 30-day readmissions, and postoperative complications. A retrospective cohort study was performed at Abington Hospital-Jefferson Health in gynecologic oncology. Women who underwent an exploratory laparotomy from 2011 to 2016 for both benign and malignant etiologies were included before and after implementation of our ERAS protocol. Patients who underwent a bowel resection were excluded. A total of 724 patients were included: 360 in the non-ERAS and 364 in the ERAS cohort. An overall reduction in narcotic usage, measured as oral morphine milli-equivalents (MMEs) was observed in the ERAS relative to the non-ERAS group, during the entire hospital stay (MME 34 versus 68, $p < 0.001$ and within 72 h postoperatively (MME 34 versus 60, $p < 0.005$). A shorter length of stay and earlier return of bowel function were also observed in the ERAS group. No differences in 30-day readmissions ($p = 0.967$) or postoperative complications ($p = 0.328$) were observed. This study demonstrated the benefits of ERAS in Gynecologic Oncology. A significant reduction of postoperative narcotic use, earlier return of bowel function and a shorter postoperative hospital stay was seen in the ERAS compared to traditional perioperative care.

1. Introduction

Surgical stress induces a complex inflammatory response that can lead to significant morbidity for the patient (Kehlet, 1997; Kehlet and Wilmore, 2002). This response is marked by production of catabolic hormones and cytokines that results in increased tissue demand and organ dysfunction (Kehlet and Wilmore, 2002). Enhanced Recovery after Surgery (ERAS) is an evidence-based pathway that has replaced traditional perioperative care. Key tenets of this protocol aim to attenuate hypothermia, hypervolemia, starvation and immobilization that may further compound this response to surgical stress (Kehlet, 1997; Kehlet and Wilmore, 2002).

ERAS is a multimodal, multidisciplinary approach that has become standard of care at most surgical centers. This includes pre-, intra-, and post-operative tools used to hasten full functional recovery after surgery (Nelson et al., 2019). Benefits of ERAS have largely been studied in colorectal surgery (Lee et al., 2020; Varadhan et al., 2010; Lohsiriwat, 2019; Bagnall et al., 2014) and remain relatively undescribed in gynecologic oncology.

While the basic principles of ERAS involve early feeding, venous thromboembolism (VTE) prophylaxis, goal-directed fluid therapy and multimodal analgesia, specific protocols remain heterogeneous across institutions (Nelson et al., 2019; Helou et al., 2020). Variations of ERAS protocols in Gynecologic Oncology have included differences in VTE prophylaxis, local anesthesia with transversus abdominis plane blocks, local liposomal bupivacaine, subarachnoid blocks or thoracic epidural anesthesia and postoperative pain control regimens (Kalogera et al., 2013; Kalogera et al., 2016; Bergstorm et al., 2018).

The data surrounding implementation of ERAS protocols has suggested an overall reduction of narcotic usage (Kalogera et al., 2013;

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https://doi.org/10.1016/j.gore.2021.100771
Received 27 February 2021; Received in revised form 19 April 2021; Accepted 24 April 2021
Available online 30 April 2021

Kalogera et al., 2016; Barber and Van Le, 2015). However, due to a lack of consistent protocols, the true reduction of narcotic use among gynecologic oncology patients has yet to be described with ERAS at our institution. Further, less conclusive data is available for other perioperative outcomes in Gynecologic Oncology. Some studies demonstrate no decrease in overall length of hospitalization or postoperative complications (Bergstorm et al., 2018; Wijk et al., 2014). Others show that it can result in a shorter length of stay, reduction in postoperative complications, earlier return of bowel function and decrease in readmissions (Kalogera et al., 2013; Wijk et al., 2014; Boitano et al., 2018; Marx et al., 2006). This demonstrates the importance of studying institution-based ERAS protocols established in Gynecologic Oncology and subsequent effect on patient outcomes.

The aim of this study is to provide a detailed analysis of the effect of an implemented ERAS protocol established at our large, community-based hospital in Gynecologic Oncology and its effects on perioperative narcotic usage. We also characterize differences in length of hospital stay, return of bowel function, intraoperative use of blood transfusions, 30-day readmissions and postoperative complications.

2. Methods

A retrospective cohort study was performed at a single, high-volume community-based hospital. This study was approved via expedited review by the Institutional Review Board at Abington Hospital-Jefferson Health (study #19-057). Our ERAS protocol was established in 2014 by the division of Gynecologic Oncology along with operating room staff members, oncology nurses, and a group of anesthesiologists via a multidisciplinary conference. This protocol was developed with the use of evidence-based recommendations from the ERAS Society, but also accounted for issues that are unique to Gynecologic Oncology patients and hospital-specific capabilities (Table 1).

Women over age 18 undergoing exploratory laparotomy for all gynecologic indications through the Department of Gynecologic Oncology were included in this study. Patients both prior to ERAS implementation from 2011 to 2013 and after ERAS implementation from 2014 to 2016 at our institution were included in this study and compared as separate cohorts. All patients who underwent minimally invasive surgeries and those with non-gynecologic primary cancers were excluded. Patients who underwent any type of bowel resection did not receive the ERAS protocol and were thereby excluded from both cohorts. To limit selection bias and better standardize the patients studied, those who underwent bowel resections were excluded due to intraoperative involvement by other departments who did not adopt similar ERAS principles. In addition, a large portion of patients in this group were admitted to the intensive care unit and kept NPO in this group due to exceptional surgical complexity. Patients who received continuous epidurals were also excluded as this was not part of our final ERAS protocol.

Relevant data were abstracted from electronic medical records of all patients that met inclusion criteria. Complexity of procedure was determined internally and was stratified as low, moderate, or high which reflected the surgical procedure required. Low complexity cases consisted of any unilateral/bilateral salpingo-oophorectomy, total abdominal hysterectomy or lysis of adhesions. Any surgery that included an appendectomy or pelvic and/or paraaortic lymph node dissection was categorized as moderate. High complexity cases involved any upper abdominal surgery such as splenectomy, liver surgery, or diaphragm stripping.

Postoperative narcotic use was the primary outcome and defined as any opioid medication administered after surgical stop time and during length of hospitalization. Narcotic use was quantified for the entire duration of initial hospitalization and 72 h postoperatively using oral morphine milligram equivalents (MME) with standard conversion tables. Length of hospital stay was calculated as the number of postoperative days and included the day of primary surgery. Days of readmission to the hospital were not included in this measure. All readmissions within 30 days of initial surgery were calculated as a percentage of the total in each cohort group. Intraoperative characteristics including estimated blood loss and intravenous fluid resuscitation volume were documented in milliliters. Return of bowel function was defined as initial onset of flatus or bowel movement. Patients were generally discharged once all postoperative milestones were met, including sufficient pain control with oral medications, return of bowel function, ability to tolerate a diet and no immediate suspicion of complications.

Categorical variables were summarized using actual counts (percentages) and continuous variables using median due to the non-normal distribution of data presented. The Mann Whitney *U* test was used for all continuous variables. The chi-squared test was used to analyze all categorical data. A p-value <0.05 denotes statistical significance. IBM SPSS software was used for statistical analysis.

Table 1
ERAS protocol.

	Preoperative	Intraoperative	Postoperative
Education	- Verbal patient education on ERAS protocols		
Nutrition/fluid management	- List of high carbohydrate foods for preoperative carbohydrate intake - Encouraged to consume clear liquids 2 h prior to surgery	- Goal directed fluid administration with avoidance of over-resuscitation - avoidance of NG tube placement	Day 0: IVF at 40 mL/hr, clear liquid diet, Ensure as needed Day 1: Advance to transitional diet Day 2: Maintain regular diet
Antibiotic prophylaxis/ drains/ catheters	- Preoperative chlorhexidine wash usually performed day prior to surgery	- Cefazolin +/- metronidazole (Gentamycin, Clindamycin +/- metronidazole for PCN allergy) - Limit drains & nasogastric tubes - maintain normothermia with blanket warmer application	- Day 1: postoperative foley catheter removal
Medications/ pain regimen	Preoperative bundle: - celecoxib 200 mg PO - acetaminophen 1000 mg PO - Gabapentin 600 mg PO - Heparin 5000 units SQ	- preoperative IV steroids and 5-HT3 inhibitor - intravenous anesthesia at discretion of anesthesiologist - TAP block after surgery close	- avoidance of PCA - multimodal pain regimen: Ibuprofen 600 mg PO Q6H Acetaminophen 1000 mg PO Q6H Hydromorphone 2 mg PO Q4H PRN Hydromorphone 0.4 mg IV Q3H PRN - LMWH prophylaxis
Activity			- Day 0: Sit on edge of bed or chair - Day 1: Out of bed with early ambulation - Day 2 to discharge: Encourage labs around hallway

h, hour; mg, milligrams; IV, intravenous; PO, per os; SQ, subcutaneous; TAP, transversus abdominis plane; LMWH, low molecular weight heparin.

3. Results

A total of 724 women met inclusion criteria for this analysis; 360 patients in the traditional perioperative care cohort from 2011 to 2013 and 364 enhanced recovery cases from 2014 to 2016 were included (Fig. 1). Eight patients were excluded for non-gynecologic primaries, ten for incomplete data in the electronic system, one patient under age 18, and 117 patients with bowel resections, and 14 patients that received continuous epidurals were excluded. The average age was similar between the two cohorts. Overall, no differences in baseline characteristics between the ERAS and non-ERAS cohorts including BMI, race, diabetes, hypertension, major cardiovascular incident, smoking status, malignant versus benign disease, complexity of procedure, wound class and patient disposition were observed (Table 2).

Postoperative opioid use decreased by 50% in the ERAS population relative to the non-ERAS group for the entire duration of hospital stay (median, 34 MME versus 68 MME, $p < 0.001$) (Fig. 2), and decreased by 43% within the first 72 h (h) after surgery (ERAS, 34 MME and non-ERAS, 60 MME; $p < 0.000$).

Length of hospital stay differed by an average of 1 day (median of 4 days in non-ERAS versus 3 in ERAS, $p < 0.001$) (Table 3). More than 50% of patients were discharged between 0 and 3 days in the ERAS group relative to only 19% in non-ERAS ($p < 0.001$) (Table 3). Patients experienced a 1-day earlier return of bowel function ($p < 0.001$). The rate of 30-day readmissions ($p = 0.967$) and postoperative complications did not differ ($p = 0.328$). Intraoperative characteristics also differed substantially between the two groups (Table 3). Intraoperative fluid volume administered was significantly less, 2900 mL in ERAS and 3500 mL in non-ERAS cohort ($p < 0.001$). Estimated blood loss was 250 mL and 300 mL in ERAS and non-ERAS cohorts, respectively ($p = 0.015$). Consistent with this, intraoperative blood transfusions were used less frequently in the ERAS cohort (9.1% versus 15.6%, $p = 0.008$). Drain placement was also significantly less frequent in the ERAS cohort (2.5% versus 9.2%, $p = 0.008$).

Given that ERAS is a multidisciplinary protocol, a compliance analysis over the first 2 years of implementation (2014–2016) was retrospectively performed through data available via the electronic medical record (EMR) system (Table 4). Compliance with preoperative ERAS components such as administration of celecoxib, gabapentin and acetaminophen ranged from 65 to 70%; this was limited by patient specific contraindications to these medications. In the ERAS cohort, 69.8% of patients received a postoperative transversus abdominis plane (TAP) block performed by an anesthesiologist. The highest rate of compliance was with the postoperative components of the ERAS protocol including 96.4% for scheduled ibuprofen and 97.8% for oral or IV hydromorphone for breakthrough pain after primary surgery. Overall, the preoperative ERAS component had a much lower compliance rate with the exception of DVT prophylaxis. All patients received preoperative DVT prophylaxis in the form of heparin 5,000 units or low molecular weight heparin 40 mg administered subcutaneously. Patients who were on preoperative

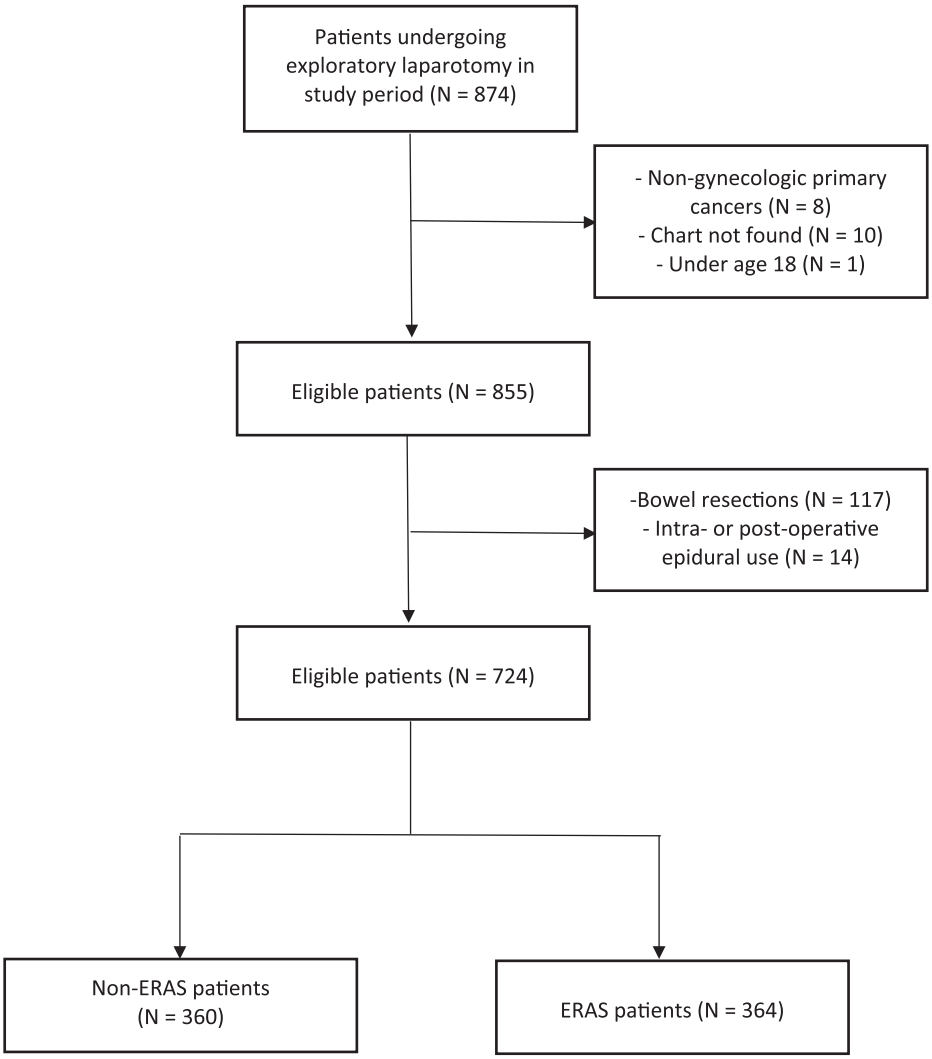

Fig. 1. Consort diagram of study population.

Table 2
Patient demographics.

	Non-ERAS N = 360	ERAS N = 364	*p*-value
Age, median	56	57	0.142
BMI, median	28.4	28.6	0.531
Race/ethnicity			0.093
White	284 (78.9)	301 (82.7)	
Black	56 (15.5)	36 (9.9)	
Asian	14 (3.8)	16 (4.4)	
Hispanic	6 (1.7)	11 (3.0)	
Diabetes	52 (14.4)	40 (11.0)	0.163
Hypertension	145 (40.3)	130 (35.7)	0.206
Major cardiovascular incident[1]	12 (3.3)	6 (1.7)	0.154
Smoker			0.150
Current	36 (10.0)	38 (10.4)	
Former	62 (17.2)	83 (22.8)	
Never	262 (72.8)	243 (66.8)	
Malignant disease	186 (51.7)	190 (52.2)	0.886
Complexity of procedure			0.145
Low[a]	186 (51.7)	178 (48.9)	
Moderate[b]	110 (30.6)	100 (27.5)	
High[c]	64 (17.8)	86 (23.6)	
Disposition			0.547
Home	307 (85.3)	314 (86.3)	
Skilled nursing facility	25 (6.9)	20 (5.5)	
Acute rehab[2]	28 (7.8)	30 (8.3)	
Wound class			0.483
I (clean)	54 (15.0)	48 (13.2)	
II (clean-contaminated)	306 (85.0)	316 (86.8)	

BMI, body mass index.
Data are n (%) shown above unless otherwise indicated.
[1] Includes heart failure, acute pulmonary embolism, stroke or acute myocardial infarction.
[a] Includes unilateral/bilateral salpingoophorectomy, total abdominal hysterectomy, lysis of adhesions.
[b] Includes appendectomy, pelvic and/or paraaortic lymph node dissection.
[c] Includes diaphragm stripping, liver surgery, and other upper abdominal surgery.
[2] Performed at a designated facility or via home care.

Table 3
Perioperative patient outcomes.

	Non-ERAS	ERAS	p-value
Length of hospital stay, median days (IQR)	4 (4 – 5)	3 (3 – 4)	<0.001*
Intraoperative measures, median			
Surgical time, min	171	169	0.989
Intraoperative fluid volume, mL	3500	2900	<0.001*
Estimated blood loss, mL	300	250	0.015*
Intraoperative blood Transfusion (%)	56 (15.6)	33 (9.1)	0.008
Postoperative complications N, (%)	17 (4.7)	12 (3.3)	0.328
Bladder injury	4 (1.1)	4 (1.1)	
Postoperative ileus	5 (1.3)	5 (1.4)	
Colonic injury	5 (1.3)	1 (0.3)	
Postoperative infection	–	1 (0.3)	
Incisional hematoma	–	1 (0.3)	
Wound dehiscence	1 (0.2)	–	
Return of flatus (median days) (IQR)	3 (3-4)	2 (2-3)	<0.001*
Drain placement (%)	33 (9.2)	9 (2.5)	0.001*
Optimal debulking (%)	171 (91)	166 (92.7)	0.534
Length of hospital stay, N (%)			0.001*
0 – 3 days	70 (19.4%)	185 (50.8%)	
4+ days	290 (80.6%)	179 (49.2%)	
Return of bowel function (flatus), N (%)			0.001*
0 – 3 days	300 (92.9%)	249 (75.9%)	
4+ days	23 (7.1%)	79 (24.0%)	

Perioperative patient outcomes between non-ERAS and ERAS cohorts reported as N (%) or median (IQR = interquartile range), as appropriate.
Return of bowel function was not recorded for several patient charts and therefore, these charts were excluded in this specific category.
mL, milliliters.
min, minutes.

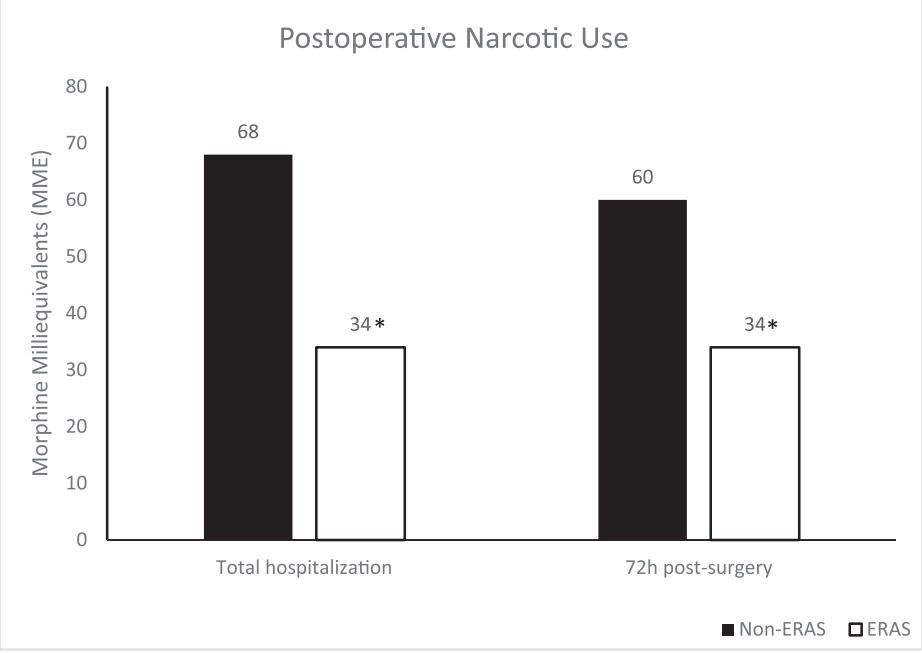

Fig. 2. Postoperative narcotic use. Differences are in median postoperative use before and after ERAS protocol implementation during patients' entire hospital stay after surgery (p-value < 0.001) and 72 h postoperatively (p-value < 0.001). *denotes significance. h, hours.

Table 4
Compliance analysis for ERAS components.

ERAS component	% compliance
Preoperative	
Celecoxib	65.1
Gabapentin	70.1
Acetaminophen	68.1
Heparin	95.8
Intraoperative	
Regional Block (TAP)	69.8
Postoperative	
Ibuprofen Q6H	96.4
Hydromorphone PO/IV PRN	97.8

TAP, transversus abdominis plane block.

therapeutic anticoagulation were counseled to discontinue this medication according to the current guidelines established by the American College of Surgeon's for perioperative management of antithrombotic medication (Hornor et al., 2018).

4. Discussion

Our study adds to the growing body of literature demonstrating effectiveness of ERAS protocol implementation on a Gynecologic Oncology service. Implementation of our ERAS protocol resulted in significant reduction of total postoperative narcotic usage during the entire hospitalization and 72 h after surgery in patients undergoing exploratory laparotomy. There was also a significant reduction in overall PCA use. This is consistent with most retrospective studies established in Gynecologic Oncology. (Kalogera et al., 2013; Kalogera et al., 2016; Wijk et al., 2014; Barber and Van Le, 2015; Boitano et al., 2018)

An overall 1-day reduction in LOS and 1-day earlier return of bowel function was also observed in our ERAS cohort. While most evidence in Gynecologic Oncology suggests reduction in overall length of stay, (Kalogera et al., 2016; Bergstorm et al., 2018; Wijk et al., 2014; Gerardi et al., 2008) some have shown no difference (Bergstorm et al., 2018). Furthermore, some studies show no difference in postoperative complications (Kalogera et al., 2016; Bergstorm et al., 2018; Wijk et al., 2014; Eberhart et al., 2008) and this is consistent with data presented here. However, Boitano et al. demonstrate a reduction in postoperative ileus(Boitano et al., 2018), while Marx et al. showed a decrease in other major surgical complications (Marx et al., 2006). While the tenets of early recovery remain similar, actual ERAS protocols vary across institutions in Gynecologic Oncology (Kalogera et al., 2016; Bergstorm et al., 2018; Wijk et al., 2014). A 2014 review of enhanced recovery in gynecologic oncology identified seven retrospective studies that utilized various perioperative ERAS components (Nelson et al., 2014). Due to differences noted in outcomes and protocols, it is essential to perform institution-based studies to analyze the effects of specific protocol implementation.

It is important to highlight specific aspects of our ERAS protocol that may differ from those protocols discussed in Gynecologic Oncology literature thus far. Specifically, while use of TAP blocks have shown a reduction in immediate intra- and post-operative opioid use in open abdominal surgeries (Bhattacharjee et al., 2014; McDonnell et al., 2007; Carney et al., 2010; Peltrini et al., 2020), administration of TAP blocks remains controversial in Gynecologic Oncology (Nelson et al., 2019; Bisch et al., 2019; Chang et al., 2018). To the best of our knowledge, most large retrospective studies of ERAS in Gynecologic Oncology have incorporated use of epidurals, incisional liposomal bupivacaine or sacral nerve blocks for multimodal pain control regimens (Nelson et al., 2019; Boitano et al., 2018; Kalogera et al., 2013; Kalogera et al., 2016; Bergstorm et al., 2018; Wijk et al., 2014; Modesitt et al., 2016; Wijk et al., 2019; Bisch et al., 2018). Though our study does not specifically address TAP block use as an independent variable, this does represent a significant difference in our protocol compared with the published literature.

Interestingly, our study also found a higher intraoperative EBL by an average of 50 mL in the non-ERAS cohort. It is unclear whether this is clinically significant. However, we also noted an increased use of intraoperative blood transfusions in the non-ERAS group. Of note, both our ERAS and non-ERAS cohorts received preoperative VTE prophylaxis at similar rates as our institution had adopted this measure before the complete ERAS protocol. While some studies have theorized an increase in surgical blood loss with preoperative NSAID use, a recent systematic review provides evidence that perioperative COX-2 inhibitor use did not increase intraoperative blood loss or rate of blood transfusions (Souter et al., 1994; Cawthorn et al., 2012; Teerawattananon et al., 2017; Ljungqvist et al., 2017). Our findings are also consistent with several other studies that demonstrate lower blood loss and transfusion rates in ERAS groups (Kalogera et al., 2013; Pang et al., 2018).

While this present study includes a transparent, critical analysis of ERAS protocol implementation over a large study period, there are important limitations to this study. The retrospective design limits analysis of subjective patient outcomes. Specifically, patient reports of adequate pain control, hunger, thirst and general satisfaction with immediate postoperative recovery could not be measured. Areas of improvement within our protocol implementation could further include standardization of preoperative carbohydrate loading and routine audits to ensure compliance given the multidisciplinary nature of ERAS (Bergstorm et al., 2018; Bisch et al., 2018). During a portion of the study period, specifically after 2014, our group conducted a randomized control trial that measured pain outcomes with use of liposomal bupivacaine versus bupivacaine for TAP blocks. Results from this study failed to reveal any significant differences in length of stay but did show some reduction in narcotic use. As we are unable to control for this during the current study, it represents a weakness for the current analysis.(Ching et al., March 2018) Lastly, patients who underwent a bowel resection were not included as noted above in this study. Further studies can include patients who underwent bowel resection as all departments have now adopted consistent ERAS principles at our institution.

Despite these limitations, we were able to show a significant reduction in overall postoperative narcotic use with the implementation of our ERAS protocol. Patients experienced an earlier return of bowel function, shorter duration of hospitalization, and decreased use of intraoperative blood transfusions. Further strengths of our analysis include the heterogeneity of our population and large sample size. We were also able to perform a compliance analysis, which showed a high rate of adherence to the ERAS protocol established at our institution. The preoperative components of our ERAS protocol had the lowest compliance rates; this may be due to patient specific allergies or intolerances to medications containing sulfa or acetaminophen, which limit utility of preoperative analgesics inherent to our protocol. Furthermore, preoperative components of ERAS at our institution are typically administered by preoperative nursing staff; it is certainly possible that medications may have simply not been give due to miscommunication or misplaced orders within the electronic medical system (EMR). Therefore, this identifies an area for quality improvement to increase compliance with the preoperative components of ERAS in our Gynecologic Oncology department.

In conclusion, our ERAS protocol for patients undergoing an exploratory laparotomy in Gynecologic Oncology reduced opioid consumption and produced favorable patient outcomes. This data provides additional support for adoption of ERAS in Gynecologic Oncology. Further studies are necessary to determine how this may affect long-term opioid use and the ability to initiate intended adjuvant cancer therapy such as chemotherapy or radiation.

5. Presentations

Oral presentation at the Mid-Atlantic Gynecologic Oncology meeting

in Charlotte, North Carolina (October 24–26, 2019).

Poster at the Society of Gynecologic Oncology meeting in Toronto, Ontario, Canada (March 28–31, 2020) Cancelled due to COVID-19

Author contributions

Tanvi Joshi, MD – corresponding author, chart review, data analysis, manuscript

Shaina Bruce, MD – chart review, manuscript editor

Rod Grim, Ph D – statistician

Drs. Tommy Buchanan, Sudeshna Chatterjee-Paer, Elizabeth Burton, Joel Sorosky, and Mark Shahin – manuscript editors

Mitchell Edelson, MD – principal investigator, manuscript editor

Informed consent

An informed consent from patients included was not required as all patient health information has been deidentified prior to analysis. A waiver of consent form is included in the IRB approval application and is available upon request if needed prior to publication.

Declaration of Competing Interest

Drs. Tanvi Joshi, Shaina Bruce, Rod Grim, Tommy Buchanan, Sudeshna Chatterjee-Paer and Joel Sorosky report no conflicts of interest.

Dr. Mark Shahin reports grants from GSK/Tesaro, Astra Zeneca, and Merck.

Dr. Mitchell Edelson reports spouse as employee of Merck.

Acknowledgements

None.

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