An enhanced recovery protocol decreases complication rates in high-risk gynecologic oncology patients undergoing non-emergent laparotomy

Teresa K.L. Boitano ¹, Haller J. Smith,¹ Alexander C. Cohen,² Allison Todd,² Charles A. Leath III,¹ J. Michael Straughn Jr.¹

¹Division of Gynecologic Oncology, Obstetrics and Gynecology, University of Alabama at Birmingham HCOP, Birmingham, Alabama, USA

²Obstetrics and Gynecology, University of Alabama at Birmingham, Birmingham, Alabama, USA

Correspondence to

Dr Teresa K.L. Boitano, Obstetrics and Gynecology, The University of Alabama at Birmingham, Birmingham, AL 35294-2172, USA; tiboitano@uabmc.edu

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HIGHLIGHTS

- Enhanced recovery protocols benefit obese and geriatric patient populations.
- No increase in the rate of acute kidney injuries was observed.
- Length-of-stay and complications rates were decreased without an increase in readmission rates.

ABSTRACT

Objective Enhanced recovery protocols are now established as the standard of care leading to improved perioperative outcomes and associated cost-benefits. The objective of this study was to evaluate the impact of an enhanced recovery program on complication rates in high-risk gynecologic oncology patients undergoing surgery.

Methods This retrospective cohort study included gynecologic oncology patients with pathology-proven malignancy undergoing non-emergent laparotomy from October 2016 to December 2018 managed on an enhanced recovery protocol, and a control group from October 2015 through September 2016 prior to enhanced recovery protocol implementation. The primary outcome was complication rates in a high-risk population pre- and post-enhanced recovery protocol. High-risk patients were defined as those with obesity (body mass index >30 kg/m²) and/or age ≥ 65 years. Analysis was performed using Statistical Package for Social Sciences (SPSS) v.24.

Results A total of 363 patients met the inclusion criteria: 104 in the control group and 259 in the enhanced recovery protocol group. Patient demographics, including age, body mass index, diagnosis, and performance status, were similar. Overall complication rates were less in the enhanced recovery protocol group (29% vs 53.8%; $p<0.0001$). The enhanced recovery protocol group had a shorter length-of-stay compared with control (3.3 vs 4.2 days; $p<0.0001$). The 30-day readmission rates were similar between the groups (9.6% vs 13.5%; $p=0.19$). In the enhanced recovery protocol group compared with control, complication rates were less in obese patients (29.4% vs 57.8%; $p<0.0001$), morbidly obese patients (20.9% vs 76.2%; $p<0.0001$), and age ≥ 65 (36.1% vs 57.1%; $p<0.0001$). The most common complications in the enhanced recovery protocol group were ileus (9.7%), pulmonary complications (2.7%), and blood transfusions (10.8%).

Conclusions Implementation of an enhanced recovery protocol decreases complication rates and length-of-stay in morbidly obese and geriatric patients with gynecologic malignancy without an increase in readmission rates.

INTRODUCTION

Enhanced recovery protocols have become widely accepted as the standard of care for surgical patients and have demonstrated significant improvement in both clinical outcomes and cost savings.^{1,2} The application of enhanced recovery protocols has demonstrated decreased length of hospital stay, costs, and surgical morbidity across a broad range of surgical fields.^{3–5} In gynecologic oncology patients specifically, enhanced recovery protocols have also been shown to decrease postoperative complications without increasing readmission rates.⁶ While enhanced recovery protocols have been studied in both benign and gynecologic oncology surgery,^{4,7} there are limited data on complication rates and outcomes in high-risk gynecologic oncology patients.

Forty percent of adults over the age of 20 in the USA are labeled as obese, which has led to an increase in associated disease burden and clinical consequences.^{8,9} In the field of gynecologic oncology, there has been a 1–2% increase in uterine cancer over the last 10 years which is largely associated with the increasing rates of obesity.¹⁰ In gynecologic surgery, obese patients have more intraoperative and postoperative complications which can be decreased if a minimally-invasive approach is possible.^{11,12} While many gynecologic oncology procedures can be performed using a minimally invasive approach, there are still a large number of cases where an open approach is indicated making it important to evaluate ways to decrease potential postoperative complications.

Uterine and ovarian cancer are the two most common gynecologic malignancies; with an average patient age of 60 and 63 years, respectively, at diagnosis. Geriatric patients are usually defined as anyone over the age of 64 years old and tend to have a higher rate of postoperative complications than the general

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population.¹³ This is largely due to functional, cognitive, and physiologic changes. Previous studies in colorectal surgery have shown that enhanced recovery protocols used in geriatric patients tend to have the same outcomes of decreased length-of-stay and time to resumption of normal activities as the younger population.¹⁴ However, there are very little data regarding the impact of enhanced recovery protocols on older gynecologic oncology patients.

Given the higher complication rates in the obese and geriatric patient populations, we sought to evaluate the effects of an enhanced recovery protocol on outcomes in these high-risk gynecologic oncology patients undergoing surgery.

METHODS

This is a retrospective cohort study that included gynecologic oncology patients with pathology-proven malignancy who underwent non-emergent laparotomy and were managed on an enhanced recovery protocol between October 2016 to December 2018. A historical control group was used for comparison and included all patients undergoing non-emergent laparotomy from October 2015 through September 2016 prior to enhanced recovery protocol implementation. Patients who underwent emergent surgery, had benign disease, did not have a laparotomy, or did not

receive preoperative enhanced recovery protocol counseling were excluded from the study. Our enhanced recovery protocol was based on the guidelines provided by Nelson et al,^{15–17} and components of the protocol are provided in Table 1. Patients were identified using an institutional database and were either established gynecologic oncology patients or had been referred due to concern for malignancy or surgical complexity. Institutional Review Board approval was obtained for this study.

Demographics, medical comorbidities quantified using the Charlson Comorbidity Index, postoperative complications, and 30-day hospital readmission rates were obtained from the electronic medical record. Surgical complexity was classified as low, moderate, or high according to the scoring system previously described by Aletti et al.¹⁸ Perioperative complications were categorized using the Clavien-Dindo classification system.¹⁹ The primary outcome was complication rates in the defined high-risk population, based on obesity (body mass index ≥ 30 kg/m²) and/or age ≥ 65 years, pre- and post-enhanced recovery protocol. Moreover, obesity was further defined as body mass index ≥ 30 kg/m² and morbid obesity as ≥ 40 kg/m². Relevant postoperative complications included postoperative pulmonary complications (pneumonia, reintubation, new and prolonged supplemental oxygen requirement), gastrointestinal complications (ileus or bowel obstruction), surgical

Table 1 Enhanced recovery after surgery protocol

Timing in relationship to surgery	Intervention
Preoperative assessment	Enhanced patient education and counseling Smoking cessation recommended 4 weeks prior to surgery Clear liquids up to 2 hours and solid food up to 6 hours prior to surgery. Carbohydrate loading with 400 mL of carbohydrate drink 2 hours prior to surgery
Preoperative (day of surgery)	Regional anesthesia: intrathecal morphine injection or TAP block Minimize opioid and benzodiazepine medications Give COX-2 selective NSAIDs, acetaminophen, and gabapentin preoperatively in absence of contraindications Prophylactic antibiotics administered within 60 min of skin incision with additional doses administered as needed for prolonged surgery and blood loss
Intraoperative	Avoidance of oral, nasogastric, or intra-abdominal drains Maintenance of normothermia via use of active warming devices Intraoperative lidocaine infusion Optimization of fluid balance by targeting cardiac output
Postoperative	Intravenous fluids limited to 40 mL/hour and discontinued within 24 hours or once patient is tolerating oral intake of fluids Clear diet allowed immediately postoperatively. Patient advanced to regular diet within 24 hours Patients encouraged to use chewing gum to stimulate gut motility. Early mobility. Patients required to be out of bed for 2 hours on day of surgery and at least 8 hours daily on subsequent days Scheduled NSAIDs and acetaminophen in absence of contraindications. Patients with breakthrough pain are given oral narcotics as needed Foley catheter removed within 24 hours of surgery Dual VTE prophylaxis with intermittent pneumatic compression and pharmacologic prophylaxis. Extending pharmacologic prophylaxis to 21 days should be utilized in patients undergoing a laparotomy for abdominal and/or pelvic malignancies

COX, cyclo-oxygenase; NSAIDs, non-steroidal anti-inflammatory drugs; TAP, transverse abdominis plane; VTE, venous thromboembolism.

site infection, unplanned transfer to an intensive care unit, acute kidney injury, perioperative blood transfusion (hemoglobin <7 g/dL), sepsis, cerebrovascular accident, myocardial infarction, and poorly-controlled hyperglycemia.

Patient demographics, clinical characteristics, and outcomes of interest were summarized using descriptive statistics. Characteristics among patients who were managed on the enhanced recovery protocol versus those pre-enhanced recovery protocol were compared using the independent t-test and χ^2 test. Odds ratios for individual risk factors were calculated using univariate logistic regression. Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) Statistics version 24 (International Business Machines Corporation (IBM), Armonk, NY). In accordance with the journal's guidelines, we will provide our data for the reproducibility of this study in other centers if such is requested.

RESULTS

A total of 363 patients met the inclusion criteria: 104 in the control group and 259 in the enhanced recovery protocol group. Patient demographics, including age, average body mass index, Charlson Comorbidity Index, and performance status, were similar (Table 2). Patients were evaluated by age groups of <65 years, ≥ 65 (including those ≥ 70), and ≥ 70 . Body mass index was divided into three groups of <30 kg/m², 30–39.9 kg/m² (obese), and ≥ 40 kg/m² (morbidly obese). While the average body mass index was not different between the groups (33.6 vs 31.8 kg/m²; $p=0.09$), there was a statistically significant higher number of patients with a body mass index ≥ 30 kg/m² in the control group (81.7% vs 67.6%); $p=0.01$). Types of gynecologic malignancy and surgical complexity scores were found to be similar between the two groups. Compliance with the enhanced recovery protocol ranged from 59.1% (early mobilization) to 94.2% (multi-modal pain analgesia) depending on the component of the protocol (a full list of tracked components is included in Table 3). If patients did not receive a preoperative block due to a contraindication (5.8% of patients), they were given a patient-controlled analgesia device.

The enhanced recovery protocol group had a shorter length-of-stay compared with the control group (3.3 vs 4.2 days; $p<0.0001$). The 30-day readmission rates were similar between the two groups (9.6% vs 13.5%; $p=0.19$). Overall complication rates were less in the enhanced recovery protocol group (29% vs 53.8%; $p<0.0001$). When evaluating patients with a body mass index ≥ 30 kg/m² in the enhanced recovery protocol group compared with the control group, complication rates were less in obese patients (29.4% vs 57.8%; $p<0.0001$) and morbidly obese patients (20.9% vs 76.2%; $p<0.0001$). Patients aged ≥ 65 were also found to have a significantly lower complication rate (36.1% vs 57.1%; $p<0.0001$); this was also seen in patients >70 with 26.2% decrease in complication rates ($p<0.0001$).

The most common complications in the enhanced recovery protocol group were blood transfusions (10.8%), hyperglycemia (10%), and ileus (9.7%) compared with ileus (20.2%), pulmonary complications (17.3%), surgical site infections (11.5%), and hyperglycemia (10.6%) in the control group. Significant decreases between the enhanced recovery protocol and the control group were seen in postoperative ileus rates (9.7% vs 20.2%; $p=0.007$),

Table 2 Patient demographics

	Control (n=104)	Enhanced recovery protocol (n=259)	P value
Average age (years) (mean $\pm$ SD)	61.0 $\pm$ 11.7	59.8 $\pm$ 13.5	0.4
Number of patients			
Age <65	62 (59.6%)	162 (62.5%)	0.87
Age $\geq 65^*$	42 (40.4%)	97 (37.5%)	
Age ≥ 70	28 (26.9%)	68 (26.3%)	
BMI (kg/m ²) (mean $\pm$ SD)	33.6 $\pm$ 9.9	31.8 $\pm$ 8.8	0.09
Number of patients			
BMI <30 kg/m ²	19 (18.3%)	90 (34.7%)	0.01
BMI 30–39.9 kg/m ²	64 (61.5%)	126 (48.7%)	
BMI >40 kg/m ²	21 (20.2%)	43 (16.6%)	
Charlson Comorbidity Index (median)	6.0	5.0	0.52
Performance status			
0	77 (74.0%)	176 (68.0%)	0.14
1	17 (16.3%)	50 (19.2%)	
2	6 (5.8%)	13 (5.0%)	
3	3 (2.9%)	3 (1.2%)	
Not reported	1 (1.0%)	17 (6.6%)	
Surgical complexity score			
Low	81 (77.9%)	208 (80.3%)	0.87
Moderate	22 (21.2%)	49 (18.9%)	
High	1 (0.9%)	2 (0.8%)	
Cancer diagnosis			
Ovarian cancer	58 (55.8%)	159 (61.4%)	0.71
Uterine cancer	39 (37.5%)	80 (30.8%)	
Cervical cancer	7 (6.7%)	17 (6.7%)	
Other cancer	0	3 (1.1%)	

*All patients over the age of 65.
BMI, body mass index.

pulmonary complications (2.7% vs 17.3%; $p=0.003$), sepsis (2.7% vs 7.7%; $p=0.03$), and surgical site infections (4.2% vs 11.5%; $p=0.01$). The percentage of grade I-II Clavien-Dindo complications in the enhanced recovery protocol group was significantly lower (50% vs 24.3%; $p<0.0001$), but grade III-IV complications were similar between groups. The specific postoperative complications experienced by both cohorts are summarized in Table 4.

DISCUSSION

Summary of Main Results

Enhanced recovery protocols streamline postoperative care in gynecologic oncology patients and decrease length-of-stay, costs, and complication rates.^{1,2} Enhanced recovery protocols

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Table 3 Enhanced recovery protocol compliance

Measured enhanced recovery protocol components	Control (n=104)	Enhanced recovery protocol (n=259)
Preoperative counseling		70.1%
No bowel preparation		93.4%
No routine nasogastric tube		94.4%
Preoperative block		94.2%
Normothermia maintenance		93.1%
Early mobilization	NA	59.1%
Early diet		94.1%
Early Foley catheter removal		81.5%
Multi-modal pain control		93.1%
Average compliance		85.9%

across several surgical specialties have effectively decreased costs by reducing length-of-stay and associated use of hospital resources.^{13–5} Previous studies have included benign gynecology patients in their results, but our current study was designed to focus solely on patients with gynecologic malignancy in order to evaluate outcomes in higher-risk gynecologic oncology patients. Our results regarding length-of-stay were similar to previous studies with a decrease of approximately 1 hour. This study also demonstrated no increase in 30-day readmissions in the enhanced recovery protocol group which is consistent with a previous study published by our group that included benign gynecology patients.²⁰

Results in the Context of Published Literature

Overall complication rates were decreased in the enhanced recovery protocol group by nearly 25%. The most significant changes occurred in the morbidly obese group with a decrease in postoperative complications by 55%. It is notable that some studies do not conclude obesity is a risk factor for perioperative complications,^{21 22} but these studies do not include laparotomies or abdominal procedures. A recent study in colorectal surgery patients did not demonstrate any difference in morbidity outcomes between non-obese and obese patients²³; however, it has been shown that obese gynecologic oncology patients tend to have more intraoperative and postoperative complications.¹¹ A recent study performed by Harrison et al described no difference in serious complication rates in obese patients compared with non-obese patients after the implementation of an enhanced recovery protocol in gynecologic oncology surgeries.²⁴ They also noted that obese patients were more likely to have grade 1–2 complications due to surgical site infections. Our study demonstrated a higher rate of postoperative complications in patients who were morbidly obese prior to the implementation of the enhanced recovery protocol. There was a significant decrease in grade I–II complication rates (ie, ileus rates, surgical site infections, sepsis, and pulmonary complications) in these patients as well. No significant changes were seen in grade III–IV complications. While the average body mass index was not different between groups, there was a statistically significant higher number of patients with a body mass index ≥ 30 kg/m² in the control group which could have an effect on the overall

Table 4 Patient outcomes

	Control (n=104)	Enhanced recovery protocol (n=259)	P value
Length of stay (days) (mean $\pm$ SD)	4.2 $\pm$ 1.6	3.3 $\pm$ 2.4	0.001
30-day readmission	14 (13.5%)	25 (9.6%)	0.2
Complication rates*			
Overall	56 (53.8%)	75 (29.0%)	<0.0001
BMI <30 kg/m ²	3 (15.8%)	29 (32.2%)	0.002
BMI 30–39.9 kg/m ²	37 (57.8%)	37 (29.4%)	<0.0001
BMI >40 kg/m ²	16 (76.2%)	9 (20.9%)	<0.0001
Age < 65	32 (51.6%)	40 (24.5%)	<0.0001
Age $\geq$ 65	24 (57.1%)	35 (36.1%)	<0.0001
Age $\geq$ 70	24 (57.1%)	21 (30.9%)	<0.0001
Complications			
Acute kidney injury	5 (4.8%)	17 (6.6%)	0.5
Blood transfusion	5 (4.8%)	28 (10.8%)	0.07
DVT/PE	2 (1.9%)	3 (1.2%)	0.6
Hyperglycemia	11 (10.6%)	26 (10.0%)	0.9
Ileus	21 (20.2%)	25 (9.7%)	0.007
Intensive care admission	1 (1.0%)	9 (3.5%)	0.19
Pulmonary	18 (17.3%)	7 (2.7%)	0.003
Sepsis	8 (7.7%)	7 (2.7%)	0.03
Surgical site infection	12 (11.5%)	11 (4.2%)	0.01
Unplanned reoperation	3 (2.9%)	3 (1.2%)	0.3
Percentage of grade of Clavien-Dindo complications*			
Grade I–II	52 (50.0%)	63 (24.3%)	<0.0001
Grade III–IV	4 (3.8%)	12 (4.7%)	0.4

*Number of patients with one or more complications.
DVT, deep vein thrombosis; PE, pulmonary embolism.

complication rate. Enhanced recovery protocols include components such as promoting euvoemia during surgery, multimodal pain control, and early ambulation after surgery which are several components that likely decrease complications in these gynecologic oncology patients.

Overall complications rates were also decreased in the geriatric population with the greatest difference seen in patients >70 years old. In acute care surgery, elderly patients managed on an enhanced recovery protocol had a lower rate of postoperative complications and reduced hospitalization time.²⁵ The geriatric patient population can be vulnerable given their generally decreased functional status, cognition, mobility, and changes in physiology.¹³ The American College of Surgeons created a geriatric surgery pilot program which found that risk factors such as cognition, decision-making, mobility, and function all play a role in outcomes.²⁶ Certain aspects of enhanced recovery protocols such as multimodal pain control which can decrease the amounts of sedating narcotics, encouraging

early ambulation and early feeding, likely all contribute to improved outcomes in older patients.

One of the goals of enhanced recovery protocols is to maintain a euvoletic state which is done through permissive oliguria (not extreme fluid restriction). There has been some concern in the colorectal field that enhanced recovery protocols lead to increased risk for acute kidney injury given the goal of minimizing perioperative fluid administration.^{27,28} However, the majority of these patients did have a return to their preoperative baseline creatinine prior to discharge.²⁹ Our study showed no increase in acute kidney injury diagnosis despite following the protocol for permissive oliguria.

Strengths and Weaknesses

The strength of this study is that it includes a sizeable number of patients from a tertiary care academic center with a large catchment area. This study has several limitations. As a retrospective cohort study, it is susceptible to several inherent biases that come with abstracting retrospective data. Given this study was performed at a large tertiary care center, readmission rates and complication rates may not be completely captured if a patient presents to an outside facility. However, the medical records were carefully reviewed for any communication notes that may indicate a patient was admitted at an outside facility. This was done to try and decrease this limitation associated with a retrospective study.

Implications for Practice and Future Research

Overall complication rates were decreased in all gynecologic oncology patients, but increased beneficial outcomes were seen in the morbidly obese group and geriatric patients >70 years old. This further encourages the use of enhanced recovery protocols in all non-emergent patient groups, even those that might be thought of as surgically vulnerable. Continued research looking at optimizing multimodal pain control and improving postoperative outcomes in these high-risk patient populations is needed.

CONCLUSIONS

This study demonstrated that enhanced recovery protocols positively affect the outcomes of gynecologic oncology patients, specifically in higher-risk groups including both obese and geriatric patients. Continuing to implement enhanced recovery protocols for all non-emergent cases will decrease length-of-stay and complication rates in patients with gynecologic malignancy without an increase in readmission rates.

Contributors TKB was involved with study design development, data collection, and statistical analysis. TKB wrote the manuscript. AC helped with data collection and reviewing the manuscript. AT, MSN, RN were part of the data collection set up, assisting with the study design, and reviewing the manuscript. HJS and CL were integral to the design and initiation of the ERP at UAB and also critically reviewed the paper. CL was supported in part by the UG1 CA23330 and P50 CA098252. JMS was involved in the initial study design development, supervised the project, and critically edited the manuscript.

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ORCID iD

Teresa K.L. Boitano <http://orcid.org/0000-0002-7786-4996>

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