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Narcotics reduction, quality and safety in gynecologic oncology surgery in the first year of enhanced recovery after surgery protocol implementation☆

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HIGHLIGHTS

- Enhanced recovery after surgery programs in open gynecologic surgery result in decreased inpatient narcotic utilization.
- Enhanced recovery after surgery programs in open gynecologic surgery result in fewer patient controlled analgesia devices.
- Auditing during the implementation of ERAS for compliance with protocol and core safety measures is imperative.

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ABSTRACT

Objectives. Enhanced Recovery After Surgery (ERAS) programs are mechanisms for achieving value-based improvements in surgery. This report provides a detailed analysis of the impact of an ERAS program on patient outcomes as well as quality and safety measures during implementation on a gynecologic oncology service at a major academic medical center.

Methods. A retrospective review of gynecologic oncology patients undergoing elective laparotomy during the implementation phase of an ERAS program (January 2016 through December 2016) was performed. Patient demographics, surgical variables, postoperative outcomes, and adherence to core safety measures, including antimicrobial and venous thromboembolism (VTE) prophylaxis, were compared to a historical patient cohort (January 2015 through December 2015). Statistical analyses were performed using *t*-tests, Wilcoxon rank sum tests, and Chi squared tests.

Results. The inaugural 109 ERAS program participants were compared to a historical patient cohort ($n = 158$). There was no difference in BMI, race, malignancy, or complexity of procedure between cohorts. ERAS patients required less narcotics (70.7 vs 127.4, $p = 0.007$, oral morphine equivalents) and PCA use (32.1% vs. 50.6%, $p = 0.002$). Despite this substantial reduction in narcotics, ERAS patients did not report more pain and in fact reported significantly less pain by postoperative day 3. There were no differences in length of stay (5 days), complication rates (13.8% vs. 20.3%, $p = 0.17$) or 30-day readmission rates (9.5 vs 11.9%, $p = 0.54$) between ERAS and historical patients, respectively. Compliance with antimicrobial prophylaxis was 97.2%. However, 33.9% of ERAS patients received substandard preoperative VTE prophylaxis.

Conclusions. ERAS program implementation resulted in reductions in narcotic requirements and PCA use without changes in length of stay or readmission rates. Compliance should be diligently audited during the implementation phase of ERAS programs, with special attention to adherence to pre-existing core safety measures.

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1. Introduction

Major abdomino-pelvic surgery induces a complex surgical stress response within the body [1]. This response is marked by hypermetabolism, variation in endocrine function and a profound cytokine-mediated inflammatory response. In turn, these acute pathophysiologic changes contribute to pain, metabolic catabolism, coagulopathy, pulmonary and cardiac compromise, and gastro-intestinal dysfunction [1–4]. In the perioperative setting, these sequelae are often further compounded by factors such as hypothermia, volume overload, hypoxemia, patient immobilization, and starvation and this may prolong postoperative recovery. Ritualistic, as opposed to evidence-based, utilization of many perioperative interventions such as nasogastric tubes, catheters, drains, and prolonged fasting is the major modifiable underlying cause [2,3].

Multimodal perioperative care protocols derived from scientific methodology, commonly referred to as Enhanced Recovery after Surgery (ERAS) programs, are designed to provide a standardized approach to reducing surgical stress and to improving the quality of perioperative care [5–7]. Over the past several years, ERAS programs have been developed and implemented by several surgical subspecialties. Colorectal, urologic, and gynecologic surgeons have been the most proactive [8–10]. Most protocols incorporate pre-, intra-, and postoperative bundled interventions to mitigate surgical stress. Outcomes research by colorectal, urologic, and gynecologic surgeons has shown that ERAS participation significantly decreases length of hospital stay, narcotic requirements and hospital costs [11–15]. While these programs have been successful, there is a lack of literature on the pitfalls of implementing broad changes in surgical care delivery such as ERAS.

This report provides a detailed analysis of the impact of ERAS program implementation on patient outcomes, specifically perioperative narcotics use, in addition to existing quality and safety measures during the inaugural year of patient participation on a gynecologic oncology service at a major academic medical center.

2. Methods

The ERAS program at Johns Hopkins was formally implemented by a multidisciplinary Comprehensive Unit Safety Program (CUSP) as a quality improvement project. CUSPs are interdisciplinary teams, including surgery, anesthesia, and nursing leaders who are designated to support the implementation of novel patient safety initiatives. The CUSP model was developed at our institution and has been utilized successfully to decrease surgical site infections in our colorectal and gynecologic oncology practice [16,17]. The current implemented ERAS program was a bundle of pre-, intra-, and postoperative interventions aimed to improve recovery among patients undergoing elective laparotomy by a gynecologic oncologist. (Table 1).

Institutional review board approval was obtained for this retrospective cohort study performed at Johns Hopkins Hospital, Baltimore, MD. The study population included all women undergoing elective laparotomy on the Kelly Gynecologic Oncology Service at Johns Hopkins Hospital, Baltimore, MD, during the inaugural 12 months of ERAS program implementation, January 1, 2016 through December 31, 2016. All women who underwent a laparotomy on the gynecologic oncology service the year prior to ERAS pathway implementation (January 1, 2015-December 31, 2015) were considered the historical cohort and used for comparison. Patients who underwent emergent laparotomy or unplanned conversion to laparotomy following laparoscopy were excluded.

The electronic medical record was reviewed for baseline data and included patient age at surgical intervention, race, body mass index, cancer type, and operation performed. Preoperative information, including administration of preoperative medications, thromboembolic prophylaxis, antibiotic prophylaxis, dietary status, carbohydrate loading, and epidural placement were recorded. Intraoperative data, including estimated blood loss, fluid resuscitation, and blood product administration were collected. Patient outcomes including opioid requirements (recorded in morphine equivalents), need for patient controlled analgesia (PCA), mean pain scores tabulated using a 0–10 Likert scale, length of stay (LOS), 30-day readmission rates, and index hospitalization major complication rates were examined according to ERAS program participation. Major complications were defined as deep incisional or organ space surgical site infection, facial dehiscence, unplanned intensive care unit (ICU) admission, venous thromboembolism, pneumonia, stroke, myocardial infarction, bowel obstruction or perforation, ileus lasting longer than 7 days, and bleeding requiring >4 units of packed red blood cell transfusion. Discharge eligible patients met the following criteria: (1) hemodynamically stable, (2) afebrile, (3) return of bowel function, (4) pain controlled with oral analgesics, (5) independent performance of activities of daily living, and (6) walking >250 ft plus climbing two flights of stairs. Return of bowel function was defined as tolerance of oral intake >24 h; patients status post bowel resection had to meet the additional metric of flatus.

Given that appropriate antibiotic and thromboembolic prophylaxis are the major measures distinguishing quality surgical care for gynecologic cancer patients in the U.S., compliance with perioperative antimicrobial and venous thromboembolism (VTE) prophylaxis was also monitored. Appropriate antimicrobial prophylaxis in our practice is defined as weight-based IV cefazolin for all laparotomies with the addition of IV metronidazole (500 mg) if bowel resection is indicated. Gentamicin and clindamycin are used for patients with a severe penicillin allergy, with the addition of metronidazole in the event of bowel resection [18]. Appropriate antimicrobial prophylaxis also includes adherence to recommendations from the American Society of Health-System Pharmacists (ASHP) Therapeutic Guidelines on Antimicrobial Prophylaxis in Surgery for optimal preoperative dosing 60 min prior to procedure and for weight-based dosing as well as intraoperative repeat dosing for prolonged procedures [19].

Appropriate preoperative VTE prophylaxis is considered to be 5000 units of subcutaneous heparin administered before or within 1 h of surgical incision. If a patient receives an epidural for pain control, administration of prophylactic dose heparin must be delayed 60 min, per recommendations from the American Society of Regional Anesthesia and Pain Medicine (ASRA) [20]. Therefore, inappropriate preoperative VTE prophylaxis was defined as either failure to administer or a > 60 min delay in administering prophylactic heparin.

Statistical analyses were performed using *t*-tests for continuous normally distributed variables, Wilcoxon rank sum tests for skewed continuous variables, and Chi squared tests for categorical variables. Statistical significance was defined at the $\alpha = 0.05$ level. All analyses were performed using Stata 14 statistical software.

3. Results

During the inaugural 12 months of ERAS pathway implementation, a total of 109 women were enrolled on the ERAS program for a planned laparotomy on the gynecologic oncology service at Johns Hopkins Hospital. These patients were compared to planned laparotomies performed by the gynecologic oncology service from January 1, 2015-December 31, 2015 ($n = 158$ cases). There was no significant difference between mean BMI, race, malignancy, or complexity of the case between the two cohorts. The mean age was older (55.2 vs. 51.7 years; $p = 0.04$) and the mean surgical time in minutes was longer in the ERAS cohort (285 vs. 238; $p < 0.01$). The total amount of intraoperative fluids, measured in mL, did not differ (3796 vs. 3822, $p = 0.95$) between ERAS and the historical cohorts, respectively, but the ratios of crystalloids (2984 vs. 3509, $p = 0.02$) to colloids (847 vs. 330, $p < 0.01$) did. (Table 2).

Compared to the historical cohort, the ERAS cohort required significantly less narcotics in the first 72 h postoperatively (127.4 vs. 70.7 measured in P.O. morphine equivalents, $p < 0.01$) and required a PCA

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