EVALUATION OF ENHANCED RECOVERY AFTER COLORECTAL SURGERY

OUTCOMES IN ADULT ONCOLOGY PATIENTS: A RETROSPECTIVE CHART REVIEW

By
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Abstract

Cancers of the colon and rectum are amongst the most common worldwide and are often treated with surgical resection. Surgery for colorectal cancer is associated increased mortality and length of hospital stay. A local cancer center in Buffalo, NY utilizes Enhanced Recovery After Surgery (ERAS) for all their gastrointestinal patients and is seeking to evaluate its effectiveness in adult colorectal cancer patients. ERAS is a multimodal perioperative care pathway that seeks to reduce surgical stress, postoperative complications, and length of hospital stay. ERAS does this through the use of extensive preoperative education, minimally invasive techniques, and early postoperative nutrition and ambulation. Current literature indicates that ERAS appears to be safe and effective for use in colorectal cancer patients, but that there is a need for more current randomized controlled trials with larger sample sizes. A single-center retrospective chart review was done to determine if ERAS decreases length of hospital stay, 30-day readmissions, and postoperative complications in colorectal cancer patients compared to traditional perioperative care. Data analysis included chi-square analysis between ERAS and postoperative complications, and the Mann-Whitney test between ERAS and both length of hospital stay and 30-day readmissions. Correlations, chi-square analysis, and the Mann-Whitney test were performed between all three dependent variables and the covariates of age, surgical risk, and gender. ERAS was found to significantly decrease length of hospital stay without increasing the risk for 30-day readmissions or postoperative complications. Therefore, ERAS is safe and effective for use in this patient population. This study acts as a stepping-stone in supporting the implementation of ERAS in other oncologic fields in the U.S. population.

Keywords: Enhanced Recovery After Surgery, Fast-Track Surgery, colorectal, gastrointestinal, cancer, oncology
Surgery for gastrointestinal cancer is typically associated with extensive preoperative preparation, surgical stress, and prolonged recovery of gastrointestinal function (Mortensen et al., 2014). Patients who undergo these surgeries contend with long hospital stays, reduced mobility, increased system stress, and in some cases, increased morbidity and mortality (Li, Fang, Cai, Tang, & Wang, 2013). Due to these risks, it is imperative to determine the best methods that lead to a reduction in postoperative complications. One rehabilitation method is Enhanced Recovery After Surgery (ERAS) also known as fast-track surgery (FTS), which uses a variety of medical treatments to reduce postoperative stay, surgical stress, and morbidity associated with gastrointestinal surgeries, including those for colorectal cancer (Eriksgatan, 2016a).

**Background and Significance**

In 2012, there were an estimated 14.1 million cases of cancer worldwide (World Health Organization (WHO), 2018). In the United States (U.S.), an estimated 1,688,780 new cancer cases are expected to be diagnosed in 2017, and about 600,920 are expected to die from cancer (American Cancer Society, 2017). Among the new cases of cancer each year, gastrointestinal cancers are among the most prevalent, with colorectal cancer being the third most common cancer in the world (WHO, 2018). The majority of these gastrointestinal cancers are treated with surgical resection when the cancer has progressed into late stages. Unfortunately, surgical resection is associated with increased morbidity (Li et al., 2013). Elective colorectal resection is associated with morbidity between 20% and 30%, and an average length of postoperative hospital stay of 7-10 days (Li et al., 2013).

These negative outcomes led to a group of surgeons in the Netherlands in 2001, known as the Enhanced Recovery After Surgery (ERAS) Society, to collaborate to determine guidelines
for best evidence-based practice regarding perioperative surgical pathways to improve patient outcomes (Eriksgatan, 2016b). Enhanced Recovery After Surgery is a multimodal perioperative care pathway designed to achieve early recovery for patients undergoing major surgery (Eriksgatan, 2016b). The aims of ERAS are to improve surgical outcomes by reducing stress response postoperatively, to reduce length of hospital stay, and to reduce postoperative complications (Eriksgatan, 2016b). The major factors that prolong hospital stay postoperatively include the need for parenteral analgesia, intravenous fluids secondary to gut dysfunction, and bed rest due to lack of mobility (Eriksgatan, 2016a). This multidisciplinary approach aims to reduce those complications through extensive preoperative counseling, minimizing invasive techniques, maintaining normothermia, avoiding drains and nasogastric tubes, controlling pain, early initiation of oral feeding, and early mobilization. These interventions are meant to decrease time to first ambulation and feeding initiation to restore gastric motility postoperatively, and to decrease 30-day hospital readmission rates, morbidity rates, and cost (Eriksgatan, 2016a; Mortensen et al., 2014). The utilization of these interventions is what make ERAS differ from traditional perioperative care (Eriksgatan, 2016a; Mortensen et al., 2014).

ERAS is a potential solution for these negative statistics (Eriksgatan, 2016a). Oncology patients are a specialized group with different needs from the general hospitalized population. ERAS has developed protocols for oncologic surgical procedures, however there is a need to evaluate effectiveness of these protocols within the U.S. oncology population (Eriksgatan, 2016a; McCance & Huether, 2014). Currently, there are only two hospitals in the U.S. that are officially implementing ERAS via ERAS Society’s specific guidelines, the Mayo Clinic in Arizona, and the Carolinas Medical Center in North Carolina (Eriksgatan, 2016a). Additionally,
there are a limited number of current high quality studies focusing on ERAS/FTS in colorectal cancer patients, which can be seen below in the literature review section. Furthermore, none of the current high quality studies found occurred in the U.S., emphasizing the gap in knowledge and need for this study (Esteban, et al., 2013; Kennedy, et al., 2014; Lei, et al., 2015; Li, et al., 2013; Taupyk, Cao, Zhao, Wang, & Wang, 2015; Zhao, et al., 2014; Zhuang, Ye, Zhang, Chen, & Yu, 2013). In 2016, Roswell Park Comprehensive Cancer Center began to utilize ERAS in its colorectal patients, providing an opportunity to expand knowledge of how well ERAS works for the U.S. surgical oncology population, as they have yet to evaluate its effectiveness for this patient population.

**Purpose**

The purpose of this single-center retrospective chart review is to determine the effectiveness of ERAS compared to traditional perioperative care in reducing length of hospital stay, 30-day readmissions, and postoperative complications in adult oncology colorectal patients. Research into the effectiveness of ERAS for this population may lead to ERAS being utilized as the standard of care in U.S. (Eriksgatan, 2016b). This directly affects nurse practitioners as they play an integral role in the perioperative process, specifically in preoperative education and preparation and in postoperative recovery. The specific aim for this study is to examine if the ERAS pathway decreases length of hospital stay, 30-day readmissions, and postoperative complications when compared with traditional perioperative care in colorectal oncology patients at a single-center oncologic institute. The Capstone project question is as follows: In adult patients undergoing colorectal surgery for colon cancer, does Enhanced Recovery After Surgery lead to improved patient outcomes compared to traditional perioperative care?
Literature Review Search Strategy

The literature review was conducted systematically using Cumulative Index to Nursing and Allied Health Literature (CINAHL), Medline, Pubmed, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, and ClinicalKey to obtain the highest level and most current evidence available in regards to ERAS in colorectal oncology. Databases searched for this review were limited to scholarly peer reviewed publications published between 2013 and 2018. Other inclusion criteria for the literature search included: 1) a focus on the adult gastrointestinal oncology population undergoing colorectal surgery, and 2) studies which employed research methods such as randomized controlled trials (RCTs), systematic reviews, and meta-analyses. Studies that were not in English, focused on other patient populations, or used other methodology than the ones listed above were excluded from the initial review. Upon discovering that there were a limited amount of studies that met this criteria (four studies), three additional studies were included that met the criteria for publication date and utilization of ERAS/FTS for colorectal surgery. The following search terms were used in varying combinations to locate the evidence needed for this literature search: enhanced recovery after surgery, fast-track surgery, colorectal, cancer, oncology, and malignancy. A total of seven articles were included in this study. Table 1 provides details for all seven articles.

Summary of Evidence

A total of 33 RCTs, five Clinical Controlled Trials (CCTs), and one multicenter prospective study with a cumulative 5,371 patients were included in the seven studies found (Esteban, et al., 2013; Kennedy, et al., 2014; Lei, et al., 2015; Li, et al., 2013; Taupyk et al., 2015; Zhao, et al., 2014; Zhuang, Ye, Zhang, Chen, & Yu, 2013). The outcomes in each study varied with a main focus on length of postoperative hospital stay, morbidity rates, readmission
rates, postoperative complication rates, restoration of gastric motility, and stress indicators including C-reactive protein. One study was a prospective non-controlled trial, two of the studies were RCTs, and the remaining four studies were a systematic review and/or meta-analysis of RCTs. Five studies focused on the comparison of ERAS/FTS with traditional perioperative care (Esteban et al., Li et al., 2013; Taupyk et al., 2015; Zhuang et al., 2013; Zhao et al., 2014). The remaining two studies focused on open versus laparoscopic surgery in ERAS/FTS colorectal patients alone and did not compare to traditional perioperative care (Kennedy et al., 2014; Lei et al., 2015). Two meta-analyses included patients that underwent colorectal surgery for either benign or malignant disease, while the remaining studies focused on colorectal cancer patients alone (Lei et al., 2015; Zhuang et al., 2013). These studies were high in quality utilizing sound methodological technique and statistical analysis, and showed on average low to moderate levels of risk for bias. The RCTs utilized Analysis of Covariance (ANCOVA) with Breslow weight log-rank test, and independent t-test for their statistical analysis (Kennedy et al., 2014; Taupyk et al., 2015). The systematic reviews and meta-analyses used weighted mean difference (WMD) with 95% confidence interval (CI), standardized mean difference (SMD), odds ratio (OR), relative risk (RR), Chi-square analysis, and fixed or random effects models for their statistical analysis of the data (Lei, et al., 2015; Li, et al., 2013; Zhao, et al., 2014; Zhuang et al., 2013). The prospective study utilized Chi-square analysis, linear regression model, Analysis of Variance (ANOVA), and fisher’s exact test for data analysis (Esteban, et al., 2013).

Length of Hospital Stay

The results for length of hospital stay were the strongest outcome amongst the studies when compared to readmission rates and postoperative complication rates. The outcomes of the studies showed length of postoperative hospital stay was significantly decreased in all studies.
that included this as an outcome for ERAS/FTS colorectal surgical patients (Esteban, et al., 2013; Kennedy, et al., 2014; Lei, et al., 2015; Taupyk et al., 2015; Zhao, et al., 2014; Zhuang et al., 2013). Esteban et al. (2013) had a median length of hospital stay of 5 days for the laparoscopic FTS group and was statistically significant compared to open FTS and traditional perioperative care groups (p<0.001) (Esteban et al., 2013). Kennedy et al. (2014) found a significant decrease in hospital stay for the laparoscopic ERAS group compared to the open colectomy ERAS group (p=0.011) (Kennedy et al., 2014). Lei et al. (2015) had a significant decrease in hospital stay for the laparoscopic FTS group compared to open FTS (p=0.0009) in both patients with benign and malignant disease (Lei et al., 2015). Taupyk et al. (2015) had a significant decrease in length of hospital stay for the FTS group compared to traditional care (p<0.05) (Taupyk et al., 2015). Zhao et al. (2014) found a significant decrease in this outcome for laparoscopic FTS compared to traditional laparoscopic colectomy (p<0.001) (Zhao et al., 2014). Zhuang et al. (2013) had a significant decrease in primary hospital stay (p<0.00001) and total hospital stay (p=0.0003) in the ERAS group compared to traditional care in both patients with benign and malignant disease (Zhuang et al., 2013). Li et al. (2013) did not include length of hospital stay as an outcome (Li, et al., 2013).

**Readmission Rates**

The majority of the studies found no significant difference in readmissions amongst ERAS/FTS and comparison groups (Lei, et al., 2015; Li, et al., 2013; Zhao, et al., 2014; Zhuang et al., 2013). The total rate of readmission for all groups in Esteban et al. (2013) was 3.5%; however this was not compared to the conventional care group to determine significance (Esteban, et al., 2013). Kennedy et al. (2014) was the only study that had a significant decrease in 30-day readmission rates for patients who underwent ERAS laparoscopic colorectal resection.
compared to ERAS open resection (p=0.033) (Kennedy et al., 2014). There were no differences in rates of readmission between ERAS/FTS groups and conventional groups, as well as between patients who underwent FTS laparoscopic colectomy versus FTS open colectomy in Lei et al. (2015) (p=0.28), Li et al. (2013) (p>0.05), Zhao et al. (2014) (p=0.06), and Zhuang et al. (2013) (p=0.88) (Lei et al., 2015; Li et al., 2013; Zhao et al., 2014; Zhuang et al., 2013). Taupyk et al. (2015) did not include readmission rates as an outcome (Taupyk et al., 2015). None of the studies that included readmission as an outcome found an increase in readmission rates for ERAS/FTS (Esteban et al., 2013; Kennedy et al., 2014; Lei et al., 2015; Li et al., 2013; Zhao et al., 2014; Zhuang et al., 2013).

**Postoperative Complication Rates**

Postoperative complication rates varied amongst the studies. The majority found ERAS/FTS groups decreased postoperative complications, while no studies showed an increase in complications with ERAS/FTS (Esteban et al., 2013; Lei, et al., 2015; Li, et al., 2013; Zhao, et al., 2014; Zhuang et al., 2013). Esteban et al. (2013) found there were less postoperative complications with the laparoscopic FTS group compared to the rest of the groups (open FTS, open traditional, laparoscopic traditional) (p=0.005) (Esteban et al., 2013). Lei et al. (2015) found there was a significant decrease in overall complications for the laparoscopic FTS group compared to open FTS in patients with both benign and malignant disease (p=0.0007) (Lei et al., 2015). Li et al. (2013) had a significant decrease in postoperative complications for the laparoscopic FTS group compared to laparoscopic traditional group (p<0.05) (Li et al., 2013). Zhao et al. (2014) found there was a significant decrease in postoperative complications for laparoscopic FTS compared to laparoscopic traditional colectomy (p<0.001) (Zhao et al., 2014). Zhuang et al. (2013) had a significant decrease in both total complications (p=0.0006) and
general complications (p<0.0001) for ERAS compared to traditional care in patients with both benign and malignant disease (Zhuang et al., 2013). Kennedy et al. (2014) and Taupyk et al. (2015) did not find significant differences in ERAS/FTS groups with comparison groups (p=0.55 and p>0.05, respectively) (Kennedy et al., 2014; Taupyk et al., 2015).

Additional Outcomes

**Morbidity and Mortality.** Overall patient morbidity was 30.6% for Esteban et al. (2013); however there were no comparisons amongst groups to determine statistical significance. In addition, patient mortality was significantly higher in the traditional open colectomy group (p=0.001) compared to all other groups (FTS laparoscopic colectomy, FTS open colectomy, and traditional laparoscopic colectomy) (Esteban, 2013). There was no significant difference in mortality amongst FTS laparoscopic and FTS open colectomy in both patients with benign and malignant disease in Lei et al. (2015) (p=0.21), or in FTS colorectal surgery patients compared to traditional colorectal surgery for Zhao et al. (2014) and Zhuang et al. (2013) (p=0.51 and p=0.97, respectively) (Lei et al., 2015; Zhao et al., 2014; Zhuang et al., 2013). No studies that included this outcome showed an increase in morbidity or mortality for ERAS/FTS groups (Esteban et al., 2013; Lei et al., 2015; Zhao et al., 2014; Zhuang et al., 2013). The remaining studies did not measure morbidity or mortality as an outcome.

**Inflammatory markers and gastric motility.** Taupyk et al. (2015) was the only study that measured C-reactive protein levels as an outcome, and found it to be significantly lower for the laparoscopic FTS group compared to laparoscopic traditional group (p<0.05) (Taupyk et al., 2015). Likewise this study showed a significant decrease in time to first flatus (p<0.05) in FTS laparoscopic colectomy patients compared to traditional laparoscopic colectomy patients (Taupyk et al., 2015). Zhao et al. (2014) found time to first flatus (p=0.03) and time to first
bowel movement (p<0.001) were significantly decreased in FTS laparoscopic colorectal cancer surgery compared to traditional laparoscopy (Zhao et al., 2014). Zhuang et al. (2013) found time to first passage of flatus and stool was significantly decreased in ERAS (p<0.00001 for both outcomes) (Zhuang et al., 2013). The remaining studies did not measure these outcomes.

**Literature Review Discussion**

Based upon these outcomes, all studies concluded that ERAS/FTS pathways are safe to use in adult colorectal cancer patients undergoing colectomy because it reduces length of hospital stay without increasing risk for postoperative complications, readmission, or morbidity. While some studies did not find a significant difference in postoperative complications, readmission, or morbidity between ERAS/FTS and traditional care, none of the studies showed that ERAS/FTS increased risk for these outcomes, determining it be as safe as traditional care, and therefore a viable treatment pathway for colorectal cancer surgery. ERAS/FTS also showed decreased time to restoration of bowel function compared to traditional care for the studies that included this as an outcome, further supporting the use of ERAS in this patient population. The use of the ERAS pathway with laparoscopic colectomy appears to provide the largest benefit for reducing length of hospital stay, morbidity, mortality, and postoperative complications. The majority of the studies determined that further research was needed with increased sample sizes in the RCTs. The inclusion of studies that measured outcomes for both benign and malignant disease limits the conclusions of this review for colorectal cancer patients alone. Other limitations included studies being exclusive to one geographic location, single-center studies, significant heterogeneity in outcomes, moderate to high levels of bias for some RCTs, and the inclusion of a non-randomized prospective study.
This literature review indicates that ERAS has the potential to be the standard of care in perioperative practice in the future. This would mean changes would be implemented in nursing practice at the preoperative and postoperative phases, while changes in medicine would occur in the intraoperative phase. Preoperatively, new education would be provided to the patients that included the definition of ERAS, expectations for patients postoperatively, drinking juice preoperatively, and fasting for 4-6 hours prior to surgery. Intraoperatively, surgeons will attempt to use the least invasive techniques, maintain normothermia, decrease intraoperative fluids and blood loss, decrease the number of drains and tubes, and utilize multiple types of analgesia. Postoperatively, nurses will be expected to record time of first flatus, time of first bowel movement, when clear liquids are reintroduced into their diet, get patients out of bed 4-6 hours after surgery or first thing postoperative day 1, minimize use of intravenous narcotics, and encourage pulmonary toileting to decrease risk of pneumonia. The mindset in nursing and medicine will shift from treating issues as they occur to returning patients to their “norm” as soon as possible with a focus on preventative strategies for decreasing postoperative ileus, pneumonia, infection, and uncontrolled pain (Mortensen, et al., 2014).

The largest gap in nursing knowledge and science brought about by this review is determining why the rates of ERAS postoperative complications, readmission, and morbidity/mortality remain the same compared to traditional perioperative care pathways, instead of improving as expected for colorectal cancer patients for some studies. Some studies excluded patients with advanced cancer and high co-morbidities, while others did not, potentially affecting the results. Additional gaps identified include determining what role geographic location plays in ERAS outcomes, the cost-effectiveness of ERAS in this patient population, and whether patients are satisfied with ERAS. The majority of the studies identified took place in
Asia and Europe, while none of the studies were conducted in the U.S. Additionally, none of the studies evaluated patient satisfaction with ERAS. This literature review showed that there are a limited number of current studies within the last five years that focus on this topic, which indicate a need for new and updated research, specifically focusing on colorectal cancer patients alone.

**Theoretical Framework**

Rogers’ Theory of Adoption of Innovation is the theoretical framework chosen for supporting this capstone project and research question. Roger’s Theory of Innovation focuses on how the population adopts to change, such as a new idea or practice. Rogers states that an influential few who are open to the new practice are often responsible for initiating the process of adopting it for use within the facility (Rogers, 1983). Once the new practice is introduced, the population can be placed into one of five categories to explain how they respond to change, known as adopters. These five different types of adopters include innovators, early adopters, early majority, late majority, and laggards. Innovators are the individuals who bring new ideas to a facility, have a strong knowledge of the new idea, and are able to cope with the high degree of uncertainty associated with the new idea. Early adopters are more integrated into the social system than innovators, and have high opinion leadership which they use to influence others’ opinions on the new idea. Early majority adopters accept and use the new idea before the average members of the social system, and often deliberate for some time before adopting the new idea. Early majority adopters are the link for the interconnectedness in the system’s networks. Late majority adopters accept and use the new idea after the average members of the social system likely due to both an economic pressure and increasing network pressures. Late majority adopters are often skeptical and remain cautious, and are hesitant to adopt until the rest of the
group do. Laggards are the last in the social system to adopt the new idea, and tend to want to hold on to past practices. They typically adopt the new idea because they are forced to, and remain suspicious of new idea (Rogers, 1983).

The social network at Roswell is the multidisciplinary team of surgeons, anesthesiologists, nurses, physical therapists, occupational therapists, and more who administer various elements of ERAS to the patients. The GI surgical team is considered to be innovators because they introduced the new idea of ERAS to the facility. The innovators utilize early adopters who can strongly influence others with their opinions by providing them with data to support the use of ERAS (Rogers, 1983). Early adopters then bring the early majority adopters to support ERAS as they are highly involved in the social groups within the facility, and use their influence in these social groups to bring others onboard. Further data is given to the early adopters in order to eliminate any skepticism. The late adopters will see the changes in postoperative complications, length of hospital stay, and 30-day readmission rates, and possibly start supporting ERAS. The late adopters and laggards will utilize ERAS as the old traditional pathway will be phased out. The GI surgical team would take time to explain, educate, and show the data on the success/potential of ERAS to the late adopters and laggards to gain their support instead of forcing their hand (Rogers, 1983).

Roswell has already started utilizing ERAS and is in the process of adapting to this new pathway. They are currently trying to utilize early majority adopters to gain support of late adopters. This is because the facility is starting to determine the success of the program at Roswell for its patients, and will require statistical indicators about the program to further adapt to ERAS (Rogers, 1983). This study’s outcomes could be influential in helping late adopters decide if ERAS is worthy of adaptation. Once everyone in the multidisciplinary team has
adopted ERAS, it will benefit the patients in a substantial way as the team will be cohesive and fully collaborative towards reaching the goals and intended outcomes of ERAS (Rogers, 1983).

**Ethical Considerations**

Due to the nature of this study as a retrospective chart review, the protection of human subjects was maintained as follows: there was no physical interaction with the subjects and their medical records were accessed only. Approval for this capstone project was obtained from the Institutional Review Board (IRB) at University at Buffalo and Roswell Park prior to initiation of research. Data extracted from the medical records was deidentified to protect the privacy of the subjects. Protected health information such as medical record number, social security number, birthday, or name were not included in any data collection. Basic information such as age, gender, and health status were included in data extraction only. Additionally, all data was password protected and strict confidentiality was maintained between the Principal Investigator and the medical record data in accordance with the Health Insurance Portability and Accountability Act (HIPPA).

The capstone project was developed based upon gaps found in current literature and research needs that were discussed with the leading ERAS GI surgical oncologist at Roswell Park. The Principal Investigator does not own the rights to the studies selected in the literature review, and they are being utilized purely to support the need for this capstone project. There is no conflict of interest being presented with this capstone project because it is being completed as a curriculum requirement for the Doctorate of Nursing Practice at University at Buffalo, and has no financial gain implications. The capstone project outcomes were presented to University at Buffalo and Roswell Park, and all data extracted from the medical records remained the property of Roswell Park upon completion of this study.
Timeline

This retrospective chart review was completed as part of the requirements for the Doctorate of Nursing Practice (DNP) Capstone Project over the summer 2018 and fall 2018 semesters. The summer semester was dedicated to creating and proposing this project and obtaining IRB approval. The chart review, data analysis, and final submission of the results and conclusions of this study occurred in the fall 2018 semester. Editing of the project occurred through the entirety of the project timeline. Please see table 2 for more detail.

Design and Methods

To evaluate the effectiveness of ERAS on oncologic colorectal patients, a retrospective chart review with accompanying analysis was completed. The chart review took place at Roswell Park Comprehensive Cancer Center, a local oncology facility in Buffalo, New York. The population that was sampled included adults aged 18 to 99 years old who had undergone elective colorectal surgery (open, laparoscopic, partial, total, right, left, sigmoid, or rectal) for colorectal cancer. The use of the 16 CPT colectomy codes (44140, 44141, 44142, 44144, 44145, 44146, 44147, 44150, 44151, 44160, 44204, 44205, 44206, 44207, 44208, and 44210) were utilized to pull the charts that met the additional inclusion criteria. Exclusion criteria included patients under the age of 18, patients that had additional surgical procedures done during the same operating time, emergency surgery, and patients who underwent colorectal surgery without having colorectal cancer. Charts were reviewed from the last four years, the traditional perioperative care charts occurred from 04/01/2014-03/31/2016, and the ERAS charts occurred from 04/01/2016-05/31/2018 as this was when ERAS was formally initiated at Roswell. A total of 266 medical records were reviewed for this study, with 120 charts in the traditional perioperative care group and 146 charts in the ERAS group. Descriptive statistics were obtained
to evaluate demographic data including age, gender, and surgical risk. Inferential statistics using nonparametric tests were conducted to evaluate selected outcomes of this study. The independent variable for this study is ERAS. The dependent variables are the selected outcomes of 30-day readmissions, postoperative complications, and length of hospital stay. The covariates for this study are gender, age, and surgical risk.

Roswell Park utilizes the National Surgical Quality Improvement Program (NSQIP) for which data and outcomes are collected on surgical patients and compared to other facilities nationally to help prevent surgical complications. This data, which is collected and organized by the quality improvement team at Roswell, was utilized for this study. NSQIP collects demographic data and various surgical outcomes including postoperative complications, comorbidities, length of hospital stay, readmission rates, and more. Length of hospital stay is defined as the number of days a patient spends as an inpatient admission at Roswell for their colorectal surgery. Readmission is defined as a full admission as an inpatient as Roswell after being discharged for their colorectal surgery within 30 days. Postoperative complications as defined by NSQIP include surgical site infections (SSI), wound disruption, pneumonia, unplanned intubation, pulmonary embolism, ventilator dependent for >48 hours, progressive renal insufficiency, acute renal failure, urinary tract infection, stroke or cerebrovascular accident (CVA), cardiac arrest requiring cardiopulmonary resuscitation (CPR), myocardial infarction (MI), required blood transfusion, venous thrombosis requiring therapy, Clostridium difficile infection, sepsis, and septic shock (American College of Surgeons National Surgical Quality Improvement Project (ACS NSQIP), 2018a). Comorbidities and demographic data that are collected and used to determine level of preoperative risk for unfavorable postoperative outcomes by NSQIP include Body Mass Index (BMI), diabetes mellitus, current smoker,
dyspnea, functional health status, ventilator dependence, history of severe Chronic Obstructive Pulmonary Disease (COPD), ascites, Congestive Heart Failure (CHF), hypertension requiring medication, acute renal failure, currently on or requiring dialysis, disseminated cancer, presence of open wounds, on steroids or immunosuppressants for a chronic condition, greater than 10% loss of body weight, presence of bleeding disorder, received Red Blood Cell (RBC) transfusion, and presence of sepsis or septic shock. All of these factors are inputted in the NSQIP Surgical Risk Calculator by the anesthesia team prior to surgery to determine the level of risk for unfavorable outcomes (ACS NSQIP, 2018b). This same calculator was utilized to determine the surgical risk of all the patients that met the inclusion criteria for this study as a representation of their health status.

A total of 358 medical records were sent to the Principal Investigator’s secured Roswell email by the NSQIP team at Roswell. This team utilized the ERAS Colorectal Cancer Data Collection Tool as a guide for gathering the charts that met the inclusion criteria for this study (see Appendix A). This data was sent in an excel spreadsheet format and were reviewed by Roswell’s Institutional Review Board to ensure the data was completely deidentified prior to the initiation of organizing and coding of the data. Once the data was deemed to be completely deidentified and cleared for use off of Roswell campus, the Principal Investigator organized and coded the data using the ERAS Colorectal Cancer Data excel spreadsheet template. First, all 358 records were given an identification number (traditional data n=159, ERAS data n=199). Then any charts that had additional surgical procedures performed that were not colorectal in nature (i.e. didn’t utilize the 16 CPT colectomy codes mentioned above) were removed (traditional data n=146, ERAS data n=176). It was determined that procedures that included biopsies, ultrasounds, lysis of adhesions, and hernia repairs (which have different CPT codes) would be
included for this review, as they are common in most colorectal cancer surgeries and would have minimal impact on the outcome of the surgeries. Additional surgical procedures such as cystectomy, oophorectomy, abdominal wall resections, cholecystectomy, or hepatectomy were removed from the medical records to be included in the final analysis. Next, emergency surgery cases (traditional data \( n=142 \), ERAS data \( n=171 \)) and non-cancer patients (traditional \( n=120 \), ERAS \( n=147 \)) were removed. Then any records that were missing data were removed (traditional \( n=120 \), ERAS \( n=145 \)). Lastly, gender, postoperative complications, colectomy codes, and group (ERAS or traditional) were coded so that they could be utilized for analysis. This was done for both the traditional and ERAS data. All data was then rechecked to ensure no errors occurred, one record was added back into ERAS data, as it was incorrectly removed for including a hernia repair. The final number of records to be included in the analysis was 266, with 120 charts in the traditional perioperative care group and 146 charts in the ERAS group. Once the final number of medical records was determined for this study, surgical risk, an indicator of these patient’s health status, was calculated using the NSQIP Surgical Risk Calculator mentioned above. This risk level, deemed “any complication” in the calculator’s results, were coded as ratio data for analysis of the surgical risk covariant (see Appendix A for example).

Data Analysis

All data for the traditional group and ERAS group were combined and inputted into IBM SPSS version 24. Frequencies and statistics including mean, mode, standard deviation, skewness, and kurtosis were calculated first to better understand the data as a whole prior to initiating further analysis. To determine if the data was normally distributed, the Kolmogorov-Smirnov test was performed on the dependent variables. It was found to be significant (\( p=.000 \)), indicating that the data was not normally distributed and nonparametric tests would be utilized for the
remainder of the data analysis. Chi-square analysis was performed to determine if there was an association between ERAS and postoperative complications because this dependent variable was a nominal level of measurement. The Mann-Whitney U test was done to compare the differences in the ranked positions or distribution of scores between ERAS and both length of hospital stay and 30-day readmissions to determine whether an association exists because these dependent variables were ratio levels of measurement. The effect size was calculated for length of hospital stay and 30-day readmissions if the results of the Mann-Whitney U test was significant to determine how great the association among variables. Correlations were performed to evaluate if an association existed between all three dependent variables and the covariates of age and surgical risk because these covariates are ratio levels of data. Chi-square analysis was performed to determine if an association existed between gender and postoperative complications because these are both nominal levels of data. Next, the Kolmogorov-Smirnov test was performed with gender as the independent variable and length of hospital stay and 30-day readmissions as the dependent variables to determine if this data was normally distributed. It was found to be significant (p=.000), meaning that the data was not normally distributed. The Mann-Whitney U test was performed to compare the differences in the ranked positions or distribution of scores between gender and length of hospital stay and 30-day readmissions to determine whether an association exists because these dependent variables were ratio levels of measurement. Finally, the effect size was calculated for gender and both length of hospital stay and 30-day readmissions based upon the results of the Mann-Whitney U test for gender to determine how strong the association is if a significant result occurs. The p-value was set at 0.05 for statistical significance.
Results

Patient Characteristics

The average age for both the traditional perioperative care group and ERAS were both about 64 years old. Both groups were close to being evenly split for gender, however, the traditional group had slightly more women than men, and the ERAS group had slightly more men than women. The laparoscopic partial colectomy with removal of the terminal ileum with ileocolostomy procedure occurred most often for the traditional group, while the laparoscopic partial colectomy with anastomosis procedure occurred most often for the ERAS group. The average surgical risk for any complication occurring during the colectomy procedures, as calculated by the NSQIP Surgical Risk Calculator, was 13.6% for the traditional group and 14.5% for the ERAS group. To see details on patient demographics and surgical procedures see tables 3 and 4 respectively.

Length of Hospital Stay

The average length of hospital stay for the traditional group was 5.01 days and 5.16 days for the ERAS group. The Mann-Whitney test determined that there was a statistically significant difference in length of hospital stay for the ERAS group (mean rank=122.95, median=3 days) when compared to the mean rank for the traditional perioperative care group (mean rank=146.33, median= 4 days), $U=7220.0$, $z= -2.554$, $p=.011$, $r= -0.16$.

Readmissions

The average number of readmission occurrences within 30 days of discharge was 0.12 for the traditional group and 0.07 for the ERAS group. The Mann-Whitney test determined that there was not a statistically significant difference in the mean ranks of 30-day readmissions between
the traditional (mean rank=136.33) and ERAS (mean rank=131.18) groups, $U=8421.0$, $z=-1.162$, $p=.245$, $r=-0.07$.

**Postoperative Complications**

The percentage of postoperative complications that occurred within the traditional and ERAS groups was 16.7% and 19.2% respectively. Chi-square analysis determined that there was not a statistically significant association between postoperative complications and whether the patients were in the ERAS or traditional perioperative care group, $X^2=0.281$, $p=.596$. All individual postoperative complications measured by NSQIP occurred minimally for both groups. The following postoperative complications occurred in either one or both of the groups: superficial incisional surgical site infection (SSI), deep incisional SSI, organ/space SSI, wound disruption, pneumonia, unplanned intubation, pulmonary embolism, ventilator within 48 hours after surgery, progressive renal insufficiency, UTI, cardiac arrest, MI, transfusion within 72 hours of surgery start time, venous thrombosis requiring therapy, *clostridium difficile*, sepsis, septic shock, and other. To see the details of the specific postoperative complications that occurred and their frequencies, please see table 5.

**Covariates**

Correlations and Mann-Whitney tests were completed to determine how the covariates of age, gender, and surgical risk influence the outcomes for length of hospital stay, 30-day readmissions, and postoperative complications.
**Age.** Correlation for age and postoperative complications was not found to be statistically significant, $t=-.042$, $p=.402$. There was also not a statistically significant correlation for age and length of hospital stay, $r=.028$, $p=.645$. However, age and 30-day readmissions was found to have a statistically significant correlation, $r=-.164$, $p=.007$.

**Gender.** Chi-square analysis determined that there was not a statistically significant association between gender and postoperative complications, $X^2=.119$, $p=.730$. The Mann-Whitney test determined that there was not a statistically significant difference in the mean ranks of 30-day readmissions between males (mean rank=136.54) and females (mean rank=130.72) groups, $U=8440.0$, $z=-1.320$, $p=.187$, $r=-0.08$. The Mann-Whitney test determined that there was not a statistically significant difference in the mean ranks of length of hospital stay between males (mean rank=134.22) and females (mean rank=132.85) groups, $U=8735.5$, $z=-.150$, $p=.880$, $r=-0.01$.

**Surgical Risk.** Correlation for surgical risk and postoperative complications was found to be statistically significant, $t=-.150$, $p=.003$. There was also a statistically significant correlation between surgical risk and length of hospital stay, $r=.277$, $p=.000$. There was not a statistically significant relationship between surgical risk and 30-day readmissions, $r=.114$, $p=.064$.

**Discussion**

Colorectal cancer is not only the third most common cancer worldwide, it is also the third most common cancer diagnosed in the United States (American Cancer Society, 2017). Current literature on Enhanced Recovery After Surgery for colorectal cancer has indicated that it is a safe perioperative care pathway because it reduces length of hospital stay without increasing the risk for postoperative complications, readmissions, or morbidity. There is still the question of why ERAS does not reduce these outcomes as expected. However, most of this literature has occurred
in Europe and Asia, and was limited in the number of studies that focused on colorectal cancer alone, indicating the need for this study.

In this study, the patient population for both the traditional and ERAS groups were on average of senior age and had a low level of surgical risk based upon their age, weight, height, type of procedure, and comorbidities. While the data was not found to be normally distributed within the general population, this study’s patient demographics and balance between men and women is a good representation of the average colorectal cancer patient seeking surgical intervention. The median age of diagnosis in the U.S. for cancers of the colon and rectum in 2016-2017 was 68, and occurred in similar rates for both men and women (American Cancer Society, 2017). The average for both groups was 64 years old, and was well balanced between men and women in this study. Therefore, the sample utilized for this study is a good indicator for the generalizability of this study’s outcomes for colorectal cancer patients across the U.S.

Of the three measured outcomes, only length of hospital stay was found to be significantly decreased for ERAS when compared to the traditional perioperative care statistically. This indicates that length of hospital stay was significantly shorter for patients undergoing colorectal cancer surgery utilizing ERAS. There were less readmissions for the ERAS group compared to the traditional group, but it was not found to be significantly lower. Interestingly, the difference in postoperative complications between groups was not statistically significant, however ERAS had more postoperative complications occur than the traditional group. With the exception of more complications occurring in the ERAS group, these outcomes are concurrent with current literature.

A possible explanation as to why there were more postoperative complications for the ERAS group could have to do with the occurrences of different CPT colectomy codes between
The laparoscopic partial colectomy with anastomosis procedure occurred most often for the ERAS group while the partial laparoscopic surgical colectomy with removal of terminal ileum with ileocolostomy occurred most often for the traditional group. The variation in the types of colorectal cancer surgeries and number of subjects between the two groups likely influenced the outcomes of this study as they were not equal. Another possible explanation is that the ERAS population was at an increased risk for any postoperative complication compared to the traditional group with an average surgical risk of 14.5% for ERAS and 13.6% for the traditional group, therefore the ERAS group had on average a poorer health status than the traditional perioperative group. Interestingly, superficial incisional SSIs, organ/space SSIs, and transfusion with 72hr of surgery start time occurred most often for both groups and in similar frequencies, indicating that ERAS also did not improve or worsen these specific postoperative complications when compared to the traditional perioperative group.

The results regarding the influence of the covariables of age, gender, and surgical risk had over length of hospital stay, readmissions, and postoperative complications were mixed. Gender was found to have no significant impact on any of the dependent variables. Age did not have a significant impact on length of hospital stay or postoperative complications, however it was found to be significant for 30-day readmissions. The correlation between age and 30-day readmissions was found to be inversely significant. This indicates a weak correlation that as age increases, 30-day readmissions decreases, and vice versa. This result was odd and unexpected because typically as age increases, so does the likelihood of having a poorer health status, a slower recovery/healing time, and increased risk of postoperative complications, all of which would increase the chance of a readmission. A likely reason for this result is that the traditional group, which had more readmissions than the ERAS group, was also younger than the ERAS
group. The age that occurred most often (mode) for the traditional group was 26.5 years old, while the mode age for the ERAS group was 53.8 years old, thus showing a large difference in the variation of age between the two groups, and a possible explanation for this odd result.

Surgical risk was not found to have a significant impact on the outcomes for 30-day readmissions, but was significant for both length of hospital stay and postoperative complications. The relationship between surgical risk and postoperative complications was found to inversely significant. This relationship was weak and shows that as surgical risk decreases, postoperative complications increase. Again, this inverse relationship was unexpected. An expected pattern would be that as the risk for a postoperative complication increases, postoperative complications would also increase. This may also be explained by the large variation in mode age between the two groups as mentioned previously, as age is a factor utilized in the surgical risk calculator. The relationship between surgical risk and length of hospital stay was statistically significant. It was weakly positively correlated indicating that as surgical risk increases, length of hospital stay increases, and vice versa. This is an expected outcome because as your risk for a postoperative complication increases, so would the likelihood that the length of hospital stay would also increase. Overall, these results indicate that these covariables had minimal impact on the outcomes for this study, since a small number of statistically significant relationships were found and were weak.

It should be noted that although Roswell Park officially began their ERAS protocol in April 2016, the gastrointestinal surgeons have been improving their surgical practices using various elements of ERAS prior to this start date without labelling it as ERAS. This likely explains why there are minor differences in the two groups and why some outcomes were not as expected. For example, early ambulation and use of minimally invasive techniques have been
elements of the perioperative care plan for colorectal cancer patients long before the official implementation of ERAS. This can be seen in the use of laparoscopic procedures being utilized most of often for both groups. Some elements of ERAS that were added on once it was officially implemented and documented as such included the use of multimodal analgesia preoperatively, drinking apple juice preoperatively, and more extensive preoperative education of postoperative expectations. Therefore, it is difficult to truly separate ERAS from traditional care in the current study. This can potentially explain why the outcomes between the two groups were relatively the same, and in general did not result in significant outcomes. While it was thought that the ERAS pathway would lead to more favorable outcomes, it is a positive that this type of traditional surgical pathway that includes more minimally invasive techniques can result in good outcomes for the length of hospital stay, number of readmissions, and number of postoperative complications, indicating the effectiveness of both standard ERAS procedures and the refinements in traditional care in improving patient outcomes. This is an important implication as some medical centers may not be able to adopt a strict standard ERAS model, but may be able to consider using some of its principles which still could lead to an improved standard of care.

Based upon these results, it can be concluded that ERAS for colorectal cancer at Roswell Park is a safe and effective pathway. ERAS significantly decreased length of hospital stay without increasing risk for 30-day readmissions or postoperative complications. This is concurrent with current literature worldwide. While readmissions were not statistically significant, they were clinically significant because there were less 30-day readmissions for the ERAS group compared to the traditional group. This is meaningful to the patients and care providers at Roswell because it is a positive indication of improvement in care. Although postoperative complications occurred more in the ERAS group, it was not found to be
statistically significant and can be explained by the poorer health status (as measured by surgical risk percentage) in this group compared to the traditional group. This shows that even though the patient population is coming to Roswell in poorer health currently compared to four years ago, the use of ERAS is keeping postoperative complications statistically at the same rates over time, and not worsening as expected with poorer health status. There remains a need to determine how these postoperative complications can be decreased with improvements in perioperative care. While there was weak to no influence by the covariates on the outcomes, it is difficult to truly determine the accuracy of the relationships between the covariates and the outcomes at this time due to the variation between groups. These results indicate that further research is needed. The use of randomized controlled trials would be beneficial to truly evaluate these outcomes for this patient population. It would be useful to have the same number of patients, surgery performed, and surgeon for both groups to determine if significant differences exist between ERAS and traditional perioperative care for these outcomes. While there is a need for more U.S. randomized controlled trails, this study has aided in determining that ERAS is effective in Roswell’s colorectal cancer patients, and has the potential to be the standard of care.

This project’s results directly impact Roswell staff including surgeons, nurse practitioners, and nurses, and Roswell’s current practices in perioperative care because the gastrointestinal surgical team at Roswell can continue to utilize ERAS knowing that it is working as intended, especially in a sicker patient population. ERAS in this population did not significantly increase the risk for postoperative complications or readmissions, but remained the same between groups statistically. Clinically there was a decrease in readmissions for the ERAS group, further emphasizing its usefulness for this patient population. There is still a need for more research into why these outcomes occur and does not statistically decrease postoperative
complications or readmissions as expected. Roswell can use this study to continue current practice using ERAS in its colorectal cancer patients and make improvements over time as new research evidence is revealed. This study may be difficult to generalize to other populations on a large scale due to limitations set below, but can help to foster ERAS into other oncology perioperative populations within in Roswell. The next steps from this study include research into why the outcomes mentioned above did not occur as expected, and looking into how well ERAS works for other populations at Roswell including thoracic and gynecological cancer patients. Research into an explanation for the unexpected outcomes could be done through case studies on the specific patients that had postoperative complications and/or readmissions occur to determine what caused these adverse outcomes, and what interventions could be done to prevent those occurrences in the future. In addition to randomized controlled trials as mentioned previously, retrospective chart reviews could be done to evaluate ERAS effectiveness in the other oncologic patient populations mentioned above. Therefore, this study is a stepping stone for utilizing ERAS both on a local scale in WNY, but also within the U.S.

Strengths and Limitations

Strengths for this study include the large number of subjects obtained that increase likelihood of precision and power of the results of the study. Another strength for this study is that the sample is not standardized and therefore a more accurate representation of the naturally occurring population in society. This unselected data and study design may also be viewed as a limitation, as it not a randomized clinical trial where influencing external factors can be controlled for to strengthen the results of the study. In addition, this study is limited because the groups occurred at different time periods and had significant variation between groups such as different number of subjects and age. Other limitations for this study include the variation in
surgical practices amongst surgeons and the difficulty defining traditional perioperative care as it is constantly changing to improve surgical practices and can overlap with various elements of ERAS.
References


https://www.facs.org/quality-programs/acs-nsqip/participant-use


https://riskcalculator.facs.org/RiskCalculator/index.jsp


http://erassociety.org/patients/


http://erassociety.org/about/history/


doi:10.1097/DCR.0b013e3182812842
### Table 1

<table>
<thead>
<tr>
<th>Citation/ Database/ Study Number</th>
<th>Design/ Method /Sample</th>
<th>Purpose</th>
<th>Key Findings</th>
<th>Conclusions/ Limitations</th>
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<tr>
<td>Esteban et al., 2013 Pubmed</td>
<td>Multicenter prospective study controlled with a retrospective group, Chi-square analysis, Fisher’s exact test, linear and logistic models, ANOVA, 501 patients</td>
<td>To determine the influence of laparoscopic or open surgery on the postoperative recovery of colorectal cancer patients receiving traditional care or fast-track surgery protocol</td>
<td>Median for hospital stay was 7 days overall. Median length of hospital stay was 5 days for the laparoscopic fast-track group, and 6 days for the open fast-track group. The median hospital stay for the laparoscopic and traditional care was 9 days, and 10 days for open (p&lt;0.001). The greatest reduction in hospital stay was for the fast-track and laparoscopic group (p&lt;0.001). Overall patient morbidity was 30.6%. There were less postoperative complications associated with fast-track laparoscopic group (p=0.005), with no significant difference amongst the other groups. Patient mortality was significantly higher in the traditional care open group (p=0.001), with no significant differences amongst the other groups. There were no significant differences in re-intervention. Overall readmission was 3.5%.</td>
<td>Laparoscopic surgery in concurrence with fast-track protocol resulted in significantly faster recovery and a similar complication rate after colorectal surgery. The worst outcomes were for open traditional care group. The use of enhanced recovery or fast-track protocols significantly shortens length of hospital stay and reduces morbidity without increasing postoperative complications for cancer patients undergoing colectomy. Limitations include this being a prospective uncontrolled study with control group gathered retrospectively, and unequal sample size amongst groups.</td>
</tr>
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<td>Kennedy et al., 2014 Medline</td>
<td>RCT ANCOVA and repeated-measures ANCOVA, Mann-Whitney nonparametric test, Breslow weighted log-rank test 204 subjects</td>
<td>Evaluate the postoperative outcomes of laparoscopic vs open resection of colorectal cancer using an Enhanced Recovery Program</td>
<td>There was no significant difference for physical fatigue and postoperative complication rates between groups. There was a significant decrease in postoperative hospital stay (p=0.011), and 30-day readmission rates (p=0.033) in the enhanced recovery group.</td>
<td>There were no differences in physical fatigue, postoperative complication rates, and readmission rates between ERAS and traditional treatment. ERAS showed a significant decrease in length of hospital stay, and can be safely utilized in this population undergoing laparoscopy. Limitations include lack of power in the study due to small sample size. No other limitations were mentioned.</td>
</tr>
<tr>
<td>Lei et al., 2015 Medline</td>
<td>Meta-analysis WMD, 95% CI random effects model with chi-square analysis 7 RCTs, 714 patients</td>
<td>To assess the safety and efficacy of laparoscopic colorectal surgery by comparing with open operation within fast track surgery</td>
<td>There was no significant difference between groups with mortality or readmission rates. Decreased postoperative hospital stay (p=0.0009), and overall complications (p=0.0007) found in fast track group.</td>
<td>Laparoscopic surgery in fast-track programs can reduce the length of hospital stay and overall complications with compromising patient safety for patients undergoing colorectal surgery for benign or malignant implications. Limitations include moderate level of quality in methodology with bias for some studies included, potential publication bias, most sample sizes were small in the studies included.</td>
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<tr>
<td>Reference</td>
<td>Methodology</td>
<td>Study Design</td>
<td>Study Population</td>
<td>Findings</td>
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<tr>
<td>-----------------------------------------------</td>
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<tr>
<td>Li et al., 2013</td>
<td>Meta-analysis, pooled RR and SMD with 95% CI, chi-square analysis</td>
<td>6 RCTs, 655 patients</td>
<td>To evaluate the fast-track rehabilitation protocol with laparoscopic surgery versus conventional care with laparoscopic surgery for colorectal cancer</td>
<td>There was a significant decrease in postoperative complications for the fast-track laparoscopic group compared to laparoscopic conventional care (WMD=0.60, p&lt;0.05). There were similar rates of anastomotic leak, obstruction, readmission, and wound infection amongst the two groups.</td>
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<td>Taupyk, Cao, Zhao, Wang, &amp; Wang, 2015</td>
<td>RCT, mean and SD, independent t-test</td>
<td>70 patients</td>
<td>To compare the outcomes of fast-track laparoscopic surgery with conventional laparoscopic surgery for colorectal cancer patients</td>
<td>Length of hospital stay was lower for fast-track compared to control group (p&lt;0.05), time to first flatus was lower for fast-track (p&lt;0.05), no significant difference in postoperative analgesia, lower C-reactive protein levels for fast-track group (p&lt;0.05), and no significant difference in postoperative complications between the two groups.</td>
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<td>Zhao et al., 2014</td>
<td>Meta-analysis RR, WMD, 95% CI, Chi-square analysis, random effects model</td>
<td>10 studies analyzed (5 RCTs, 5 Clinical Controlled Trials), 1317 patients</td>
<td>To compare the effects of fast track surgery to traditional care in laparoscopic colorectal cancer surgery</td>
<td>Decreased postoperative hospital stay (p&lt;0.001), postoperative complications (p&lt;0.001), time to first flatus (p=0.03), and time to first bowel movement (p&lt;0.001) in fast track group. There was no significant difference in readmission rate or 30-day mortality rate.</td>
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<td>Zhuang, Ye, Zhang, Chen, &amp; Yu, 2013</td>
<td>Meta-analysis of ERAS</td>
<td>RCTs, RR, WMD, 95% CI, SD, Q test, I-squared index, random effects and fixed effects models</td>
<td>To assess the safety and efficacy of ERAS in colorectal surgery compared to traditional care</td>
<td>ERAS has significantly decreased length of primary hospital stay (p&lt;0.00001), total hospital stay (p=0.0003), total complications (p=0.0006), and general complications (p&lt;0.0001). There were no significant differences noted on readmission rates, surgical complications, and mortality compared to traditional care.</td>
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</table>

Note. SMD=Standard Mean Difference, OR=Odds Ratio, RCT=Randomized Controlled Trial, ERAS=Enhanced Recovery After Surgery, FTS=fast-track surgery, WMD= Weighted Mean Difference, CI= Confidence Interval, RR=Relative Risk. ANCOVA=Analysis of Covariance
Table 2

_Gantt Chart_

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Table 3

_Demographic Data_

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<th>Surgical Risk %</th>
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<td><strong>ERAS</strong> n=146</td>
<td>Mean</td>
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<td>Median</td>
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Table 4

*Surgical Procedures Frequencies*

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Note. 44140: colectomy; partial with anastomosis, 44141: colectomy; partial with skin level cecostomy or colostomy, 44143: colectomy; partial with end colostomy and closure of distal segment, 44144: colectomy; partial with resection with colostomy or ileostomy and creation of mucofistula, 44145: colectomy; partial with coloproctostomy (low pelvic anastomosis), 44146: colectomy; partial with coloproctostomy (low pelvic anastomosis) with colostomy, 44147: colectomy; partial with abdominal and transanal approach, 44150: colectomy; total abdominal without coloproctostomy with ileostomy or ileoproctostomy, 44151: colectomy; total abdominal without proctectomy with continent ileostomy, 44160: colectomy; partial with removal of terminal ileum with ileocolostomy, 44204: laparoscopy surgical colectomy; partial with anastomosis, 44205: laparoscopy surgical colectomy; partial with anastomosis with coloproctostomy, 44206: laparoscopy surgical colectomy; partial with anastomosis with coloproctostomy with colostomy, 44207: laparoscopy surgical colectomy; partial with anastomosis with coloproctostomy with ileostomy, 44208: laparoscopy colectomy; total abdominal without coloproctostomy with ileostomy or ileoproctostomy.
Table 5

Postoperative Complications Frequencies

<table>
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<tr>
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<th>Traditional n=120</th>
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<tr>
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<tr>
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<td>4.1</td>
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<td>0.7</td>
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<td>0.7</td>
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<tr>
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<tr>
<td>On ventilator and ggt. within 48hrs</td>
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<td>0.8</td>
<td>2</td>
<td>1.4</td>
</tr>
<tr>
<td>Progressive Renal Insufficiency</td>
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<td>1</td>
<td>0.7</td>
</tr>
<tr>
<td>Acute Renal Failure</td>
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<td>0</td>
<td>0.0</td>
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<tr>
<td>UTI</td>
<td>0</td>
<td>0.0</td>
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<td>0.7</td>
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<tr>
<td>CVA</td>
<td>0</td>
<td>0.0</td>
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<td>MI</td>
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<td>1</td>
<td>0.7</td>
</tr>
<tr>
<td>Transfusion within 72h of surgery start time</td>
<td>7</td>
<td>5.8</td>
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<td>5.5</td>
</tr>
<tr>
<td>Vein Thrombosis requiring therapy c.difficile</td>
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<td>0.0</td>
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<tr>
<td>Sepsis</td>
<td>0</td>
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<td>1.4</td>
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<td>Septic Shock</td>
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<td>Other</td>
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</table>

Note. SSI=Surgical Site Infection, PE=Pulmonary Embolism, ggt.=drip, UTI=Urinary Tract Infection, CVA=Cerebral Vascular Accident, CPR=Cardiopulmonary Resuscitation, MI=Myocardial Infarction.
Appendix A

ERAS Data Collection Tool

ID#: __________________________

Age: __________

Gender (circle one): Male or Female

Perioperative Care Pathway (circle one): Traditional Care or ERAS

Type of Surgery (CPT code): __________________________
(Options include: 44140, 44141, 44143, 44144, 44145, 44146, 44147, 44150, 44151, 44160, 44204, 44205, 44206, 44207, 44208, and 44210)

Describe the procedure: ____________________________________________

Surgical Risk (%): __________

Length of Hospital Stay (# of days): _______

30-Day readmission related to colorectal surgery (circle one): yes or no

Postoperative complication (circle one): yes or no

Check the postoperative complication(s) found:

- Surgical Site Infection: _____
- Wound disruption: _____
- Pneumonia: _____
- Unplanned intubation: _____
- Pulmonary Embolism: _____
- Ventilator dependent for >48hrs: _____
- Progressive renal insufficiency: _____
- Acute renal failure: _____
- Urinary tract infection: _____
- Cerebral vascular accident: _____
- Cardiopulmonary resuscitation: _____
- Myocardial Infarction: _____
- Required a blood transfusion: _____
- Venous thrombosis: _____
- c. difficile infection: _____
- Sepsis/Septic shock: _____

CPT Codes:

44140: colectomy; partial with anastomosis
44141: colectomy; partial with skin level cecostomy or colostomy
44143: colectomy; partial with end colostomy and closure of distal segment
44144: colectomy; partial with resection with colostomy or ileostomy and creation of mucofistula
44145: colectomy; partial with coloproctostomy (low pelvic anastomosis)
44146: colectomy; partial with coloproctostomy (low pelvic anastomosis) with colostomy
44147: colectomy; partial with abdominal and transanal approach
44150: colectomy; total abdominal without coloproctostomy with ileostomy or ileoproctostomy
44151: colectomy; total abdominal without proctectomy with continent ileostomy
44160: colectomy; partial with removal of terminal ileum with ileocolostomy
44204: laparoscopy surgical colectomy; partial with anastomosis
44205: laparoscopy surgical colectomy; partial with removal of terminal ileum with ileocolostomy
44206: laparoscopy surgical colectomy; partial with end colostomy and closure of distal segment
44207: laparoscopy surgical colectomy; partial with anastomosis with coloproctostomy
44208: laparoscopy surgical colectomy; partial with anastomosis with coloproctostomy with colostomy
44210: laparoscopy colectomy; total abdominal without coloproctostomy with ileostomy or ileoproctostomy

NSQIP Surgical Risk Calculator (example):
Access the calculator via this link: [http://riskcalculator.facs.org/RiskCalculator/index.jsp](http://riskcalculator.facs.org/RiskCalculator/index.jsp)
Fill in the sections according to the medical record
Generate PDF report on surgical risk
Number collected as surgical risk% for study
Appendix B

IRB Approval

University at Buffalo

August 16, 2018

Dear DESTINY RAFTER:

On 8/16/2018, the IRB reviewed the following submission:

Type of Review: Initial Study
Title of Study: Evaluation of Enhanced Recovery After Surgery in Colorectal Oncology: A Retrospective Chart Review
Investigator: DESTINY RAFTER

IRB ID: STUDY00002727

Documents Reviewed:
- Data Collection Tool v.2 ERAS Colorectal Cancer, Category: Other;
- NSQIP Surgical Risk Calculator Report Example v.1 ERAS Colorectal Cancer, Category: Other;
- HIPPA Waiver v.1 ERAS Colorectal Cancer, Category: Other;
- NSQIP Surgical Risk Calculator v.1 ERAS Colorectal Cancer, Category: Other;
- Data Collection Sheet v.1 ERAS Colorectal Cancer, Category: Other;
- Protocol HRP 503 v.3 ERAS Colorectal Cancer, Category: IRB Protocol;
- HIPPA De-Identification Form ERAS Colorectal Cancer, Category: Other

The IRB approved the study from 8/16/2018 to 8/15/2019 inclusive. The Initial study materials for the project referenced above were reviewed and approved by the SUNY University at Buffalo IRB (UBIRB) by Non-Committee Review. The IRB has determined that the study is no greater than minimal risk. Before 8/15/2019 or within 30 days of study closure, whichever is earlier, you are to submit a continuing review application with required explanations. In order to avoid a lapse in IRB approval, it is recommended that you submit your continuing review at least 30 days for an expedited study and at least 45-60 days for a full board study, prior to the approval end date of the study. You can submit a continuing review application by navigating to the active study in Click IRB and selecting 'Create Modification / CR'. Studies cannot be conducted beyond the expiration date without re-approval by the UBIRB.

In conducting this study, you are required to follow the requirements listed in the Investigator Manual (HRP-103), which can be found by navigating to the IRB Library within the IRB system.
Based on the information you have provided in the “University at Buffalo Human Research Protections Program Request for Full Waiver of Individual Authorization for Use of Individually Identifiable Health Information” form (waiver request), the UBIRB has determined a full waiver of the individual authorization required by 45 CFR §164.508 for use or disclosure of protected health information is warranted based on the following criteria as specified in 45 CFR 164.512(i) (2). Accordingly:

A) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

1) An adequate plan to protect the identifiers from improper use and disclosure;

2) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

3) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

B) The research could not practicably be conducted without the waiver or alteration; and

C) The research could not practicably be conducted without access to and use of the protected health information.

A brief description of the Protected Health Information for which this alteration or waiver has been granted is provided on the “Request for Waiver of the Authorization for Use of Individually Identifiable Health Information” or “Request for Limited Waiver of the Authorization for Use of Individually Identifiable Health Information for Study Recruitment” which is part of this approval. If HIV information is requested, this waiver is only valid for disclosures consistent with New York Code Public Health Article 27-F.

This full waiver has been reviewed and approved for the above referenced study by the UBIRB to permit you to receive personal health information as specified in section (1) of the waiver request.

UBIRB approval is given with the understanding that the most recently approved procedures will be followed and the most recently approved consent documents will be used. If modifications are needed, those changes may not be initiated until such modifications have been submitted to the UBIRB for review and have been granted approval.

As principal investigator for this study involving human participants, you have responsibilities to
the SUNY University at Buffalo IRB (UBIRB) as follows:

1. Ensuring that no subjects are enrolled prior to the IRB approval date.
2. Ensuring that the study is not conducted beyond the expiration date without re-approval by the UBIRB.
3. Ensuring that the UBIRB is notified of:
   • All reportable information in accordance with the New Information SOP (HRP-024).
   • Project closure/completion by submitting a Continuing Review/Modification submission.
4. Ensuring that the protocol is followed as approved by UBIRB unless a protocol amendment is prospectively approved.
5. Ensuring that changes in research procedures, recruitment or consent processes are not initiated without prior UBIRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.
6. Ensuring that the study is conducted in compliance with all UBIRB decisions, conditions, and requirements.
7. Bearing responsibility for all actions of the staff and sub-investigators with regard to the protocol.
8. Bearing responsibility for securing any other required approvals before research begins.

If you have any questions, please contact the UBIRB at 716-888-4888 or ub-irb@buffalo.edu. Please include the project title and number in all correspondence with the UBIRB.

---

**Roswell Park**

August 27, 2018
Destiny Ciemny

Elm & Carlton Streets Buffalo, New York 14263
Office of Research Subject Protection Acceptance Notice of External IRB Approval
This institution has an approved assurance of compliance on file with HHS which covers this activity FWA 00006731 Federal Wide Assurance identification number

Dear Destiny Ciemny:

On 8/27/2018, the IRB Office reviewed the following submission:

Type of Review: Initial Study
Title of Study: Evaluation of Enhanced Recovery After Surgery in Colorectal Oncology: A Retrospective Chart Review
Investigator: Destiny Ciemny

IRB ID: STUDY00000723 / IRB 072318
The external IRB’s approval for this study will expire on 8/15/2019.

Please be advised that only the Roswell Park stamped consent form can be used to enroll subjects.

As a reminder, this research project is subject to approval by the external IRB, but also requires acceptance by the Roswell Park IRB prior to initiation by the investigator. Please promptly notify the local IRB office upon:

1) Any new Unanticipated Problems or any other Reportable New Information
2) Any new or updated information regarding potential Conflict of Interests
3) Any changes in local study team members
4) Notification of renewal by the reviewing IRB. A progress report must be submitted to the ORSP at least ten days prior to the expiration date noted above for continuing review.
5) Any modifications/updates in the research project
6) Closure of the Study

The principal investigator is responsible for ensuring that the research complies with all applicable regulations. The Roswell Park IRB reserves the right to stop the research for violations of regulatory or IRB requirements.

In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103), including the reporting of Unanticipated Problems and any other Reportable New Information.

Sincerely,
Donald Handley MSc, MBA
Appendix C

EVALUATION OF ENHANCED RECOVERY AFTER COLORECTAL SURGERY OUTCOMES IN ADULT ONCOLOGY PATIENTS: A RETROSPECTIVE CHART REVIEW
By: Destiny Cienmy RN, BSN

A CAPSTONE PROJECT SUBMITTED TO THE SCHOOL OF NURSING
THE STATE UNIVERSITY OF NEW YORK
February 2018

Purpose
The purpose of this Capstone project was to determine the effectiveness of ERAS compared to traditional perioperative care for length of hospital stay, 30-day readmissions, and postoperative complications in adult oncology colorectal patients.

The specific aim was to examine if the ERAS pathway decreases length of hospital stay, 30-day readmissions, and postoperative complications when compared with traditional perioperative care in colorectal oncology patients at a single-center oncologic institute.

Study Question (PICO)
Population: Adult patients undergoing elective colorectal cancer surgery
Intervention: Enhanced Recovery After Surgery
Comparison: Traditional perioperative care
Outcomes: Improved patient outcomes including decreased length of hospital stay, 30-day readmissions, and postoperative complications
Background and Significance

- Cancers of the colon and rectum are amongst the most common worldwide and are often treated with surgical resection (WHO, 2018; Li et al., 2013)
- Surgery for colorectal cancer is associated with increased morbidity and length of hospital stay (Li et al., 2013)
- These negative outcomes led to the development of ERAS Society and the ERAS pathway (Eriksgatan, 2016b).

Background and Significance

- The aims of ERAS are to improve surgical outcomes (Eriksgatan, 2016b)
- The major factors that prolong hospital stay postoperatively (Eriksgatan, 2016a)
- How can ERAS reduce those major factors that prolong postoperative length of hospital stay? (Eriksgatan, 2016a, Mortensen et al., 2014)
- The differences in ERAS vs. traditional care (Eriksgatan, 2016a).

Background and Significance

- Oncology patients are a specialized group (McCance & Huether, 2014)
- ERAS has developed protocols for oncologic surgical procedures, however there is a need to evaluate effectiveness of these protocols within the U.S. oncology population (Eriksgatan, 2016a)
- There are a limited number of current high quality studies focusing on ERAS/FTS in colorectal cancer patients
- In 2016, Roswell Park Comprehensive Cancer Center (located in Buffalo, NY, U.S.A.)

Literature Review

- What does the current literature say about ERAS?
- A total of 33 RCTs, five Clinical Controlled Trials (CCTs), and one multicenter prospective study with a cumulative 5,371 patients were included in the seven studies found
- ERAS is safe and feasible in colorectal cancer patients
- Gap in knowledge identified (Esteban, et al., 2013; Kennedy, et al., 2014; Lei, et al., 2015; Li, et al., 2013; Tauppy et al., 2013; Zhao, et al., 2014; Zhuang, Ye, Zhang, Chen, et al., 2013)
Theoretical Framework: Rogers’ Theory of Adoption of Innovation

- Roger’s Theory of Innovation focuses on how a social network adopts to change, such as a new idea or practice (Rogers, 1983)
- An influential few create change (Rogers, 1983)
- Five categories used to explain how the population responds to change, known as adopters: innovators, early adopters, early majority, late majority, and laggards (Rogers, 1983)
- The social network at Roswell

Study Design and Setting

- Retrospective chart review
- Took place at Roswell Park Comprehensive Cancer Center
- Inclusion criteria: adults aged 18 to 99 years old who had undergone elective colorectal cancer surgery by using 16 CPT colectomy codes to pull the charts
- Exclusion criteria: patients under the age of 18, patients that had additional surgical procedures done during the same operating time, emergency surgery, and patients who underwent colorectal surgery

Study Methods

- Charts were reviewed from the last four years:
  - Traditional perioperative care charts occurred from 04/01/2014-03/31/2016
  - ERAS charts occurred from 04/01/2016-05/31/2018
- A total of 266 medical records were reviewed for this study:
  - 120 charts in the traditional perioperative care group
  - 146 charts in the ERAS group
- Independent variable: ERAS
- Dependent variables: 30-day readmissions, postoperative complications, and length of

Study Methods: NSQIP

- What is the National Surgical Quality Improvement Program (NSQIP)?
- This NSQIP data was utilized for this study
- NSQIP definition of outcomes:
  - Length of hospital stay
  - Readmissions
  - Postoperative complications
- NSQIP Surgical Risk Calculator:
  - This calculator was utilized to determine the surgical risk of all the patients as a representation of their health status.
Study Methods

- Total of 358 medical records were collected utilizing the EROG Colorectal Cancer Data Collection Tool by Roswell NRGI Team.
- Data was deidentified.

Data Analysis

- IBM SPSS version 24
- Frequencies and statistics including mean, mode, standard deviation, skewness, and kurtosis.
- Kolmogorov-Smirnov test: data was not normally distributed, so nonparametric tests were utilized for the remainder of the data analysis.
- Chi-square analysis between ERAS and postoperative complications.
- Mann-Whitney U test with effect size between ERAS and both length of hospital stay and readmissions.
- Correlations were performed between all three dependent variables and the covariates of age and surgical risk.
- Chi-square analysis between gender and postoperative complications.
- Mann-Whitney U test with effect size between gender and both length of hospital stay and readmissions.
- The p-value 0.05 for statistical significance.

Results

Patient Characteristics

- Average age for both groups was about 64 years old.
- Both groups close to evenly split for gender.
- Surgical procedures.
- Surgical Risk.

<table>
<thead>
<tr>
<th>Traditional</th>
<th>ERAS</th>
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<tbody>
<tr>
<td>Age at Time of Surgery</td>
<td>Surgical Risk %</td>
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<tr>
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<tr>
<td>Median</td>
<td>64.8</td>
</tr>
<tr>
<td>Mode</td>
<td>26.5</td>
</tr>
</tbody>
</table>
Results: Length of Hospital Stay

• The average length of hospital stay for the traditional group was 5.16 days and 5.01 days for the ERAS group.
• The Mann-Whitney U test determined that there was a statistically significant decrease in length of hospital stay for the ERAS group (mean rank=122.95, median=3 days) when compared to the mean rank for the traditional perioperative care group (mean rank=146.33, median=4 days).
  \[ U=7220.0, z=-2.554, p=.011, r=-0.16 \]

Results: 30-day Readmissions

• The average number of readmission occurrences within 30 days of discharge was 0.12 for the traditional group and 0.07 for the ERAS group.
• The Mann-Whitney U test determined that there was not a statistically significant difference in the mean ranks of 30-day readmissions between the traditional (mean rank=136.33) and ERAS (mean rank=131.18) groups.

Results: Postoperative Complications

• The percentage of postoperative complications that occurred within the traditional and ERAS groups was 16.7% and 19.2% respectively.
• Chi-square analysis was not a statistically significant association between postoperative complications and...

<table>
<thead>
<tr>
<th>Complication</th>
<th>Frequency</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
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<td>5.8</td>
</tr>
<tr>
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<td>1.4</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>0.7</td>
</tr>
</tbody>
</table>
Results: Covariates

Age:
- Correlation for age and postoperative complications was not statistically significant, \( r = .042, p = .402 \).
- Correlation for age and length of hospital stay was not significant, \( r = .028, p = .645 \).
- Age and 30-day readmissions was found to have a statistically significant correlation, \( r = .164 \).

Gender:
- Chi-square analysis for gender and postoperative complications was not significant, \( X^2 = 1.318, p = .733 \).
- The Mann-Whitney U test for gender and both readmissions and length of stay was not a statistically significant, \( U = 8735.5, z = -1.320, p = .187, r = -0.08 \), respectively.
- The Mann-Whitney U test for gender and both readmissions and length of stay was not a statistically significant, \( U = 8440.0, z = -1.320, p = .187, r = -0.08 \), respectively.

Surgical Risk:
- Correlation between surgical risk and postoperative complications was statistically significant, \( t = -1.318, p = .003 \).
- Correlation between surgical risk and length of hospital stay was statistically significant, \( r = .277, p = .000 \).

Discussion: Study Sample
- The data was not found to be normally distributed within the general population, but the study’s sample is a good representation of the average colorectal cancer patient seeking surgical intervention.
- The sample utilized for this study is a good indicator for the generalizability of this study’s outcomes for colorectal cancer.

Discussion: Outcomes
- Only length of hospital stay was found to be statistically significant, indicating that length of hospital stay was significantly shorter for patients undergoing colorectal cancer surgery utilizing ERAS.
- There were less readmissions for the ERAS group compared to the traditional group, but it was not found to be statistically significant.
- The difference in postoperative complications between groups was not statistically significant, however ERAS had more postoperative complications occur than the traditional group.
- With the exception of more complications occurring in the ERAS group, these...
Discussion: Postoperative Complications

- Why were there more postoperative complications for the ERAS group?
- Occurrences of different CPT colectomy codes between groups
- Number of subjects between groups
- The ERAS population was at an increased risk for any postoperative complication compared to the traditional group.
- Superficial incisional SSIs, organ/space SSIs, and transfusion with 72hr of surgery start time occurred most often for both groups and in similar frequencies, indicating that ERAS also did not improve or worsen these specific postoperative complications when compared to the traditional perioperative care.

Discussion: Covariables

- Correlation between age and 30-day readmissions was found to be inversely significant ($r = -0.164, p = 0.007$). This indicates a weak correlation that as age increases, 30-day readmissions decrease, and vice versa.
- The large difference in the variation of age between the two groups as a possible explanation for this odd result.

Discussion: Roswell Practices

- Although Roswell Park officially began their ERAS protocol in April 2016, the gastrointestinal surgeons have been improving their surgical practices using various elements of ERAS prior to this start date without labelling it as ERAS.
- This likely explains why there are minor differences in the two groups and why some outcomes were not as expected.
- Therefore, it is difficult to truly separate ERAS from traditional care for this type of study.
- This can be noted as a positive for the facility because in both groups the length of hospital stay, number of readmissions, and number of postoperative complications were low.
Conclusions

- ERAS for colorectal cancer at Roswell Park is a safe and effective pathway.
- ERAS significantly decreased length of hospital stay without increasing risk for 30-day readmissions or postoperative complications.
- This is concurrent with current literature worldwide.
- Readmissions were not statistically significant, but they were clinically significant because there were less 30-day readmissions for the ERAS group compared to the traditional.

Future Implications

- Roswell can use this study to continue current practice using ERAS in its colorectal cancer patients.
- This study may be difficult to generalize to other populations on a larger scale due to limitations, but can help to foster ERAS into other oncology perioperative populations within Roswell.
- The next steps from this study include research into unexpected outcomes, how well ERAS works for other populations at Roswell and use of randomized controlled trials with the same number of patients, surgery performed, and surgeon for both groups.
Strengths and Limitations

Strengths:
- Large number of subjects
- Sample is not standardized and therefore a more accurate representation of the naturally occurring population

Limitations:
- Not a randomized clinical trial
- The groups occurred at different time periods
- Significant variation between groups such as different number of subjects and demographics
- Variation in surgical practices amongst surgeons
- The difficulty defining traditional perioperative care

References


References

