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An enhanced recovery program in colorectal surgery is associated with decreased organ level rates of complications: a difference-in-differences analysis

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Abstract

Background Perioperative care has lacked coordination and standardization. Enhanced recovery programs (ERPs) have been shown to decrease aggregate complications across surgical specialties. We hypothesize that the sustained implementation of an ERP will be associated with a decrease in a broad range of complications at the organ system level.

Study design Adult patients undergoing elective colorectal procedures between 1/2011 and 10/2016 were included. Patients were stratified based on exposure to a sustained ERP (7/2014–10/2016) after an 18-month wash-in period in a pre-post analysis. The primary outcome was 30-day complication rate by organ category as collected by National Surgical Quality Improvement Program (NSQIP) abstractors. Demographic and other patient level data were collected. Complication rates were compared using multivariable regression employing a differences-in-differences (DiD) approach using the national NSQIP PUF file to account for secular trends.

Results A total of 1182 patients were included in this study, with 47% treated in an ERP. The two groups were similar in age, gender, race, BMI, comorbidity index, and procedure type. In a multivariable DiD analysis, significant reductions were seen in surgical site infection (OR 0.30; 95% CI 0.20–0.43), postoperative pulmonary complications (OR 0.46; 95% CI 0.24–0.90), transfusion (OR 0.27; 95% CI 0.15–0.51), urinary tract infections (OR 0.34; 95% CI 0.18–0.66), sepsis (OR 0.35; 95% CI 0.20–0.61), and cardiac complications (OR 0.10; 95% CI 0.01–0.84). A reduction in return to the operating room and 30-day readmission was also observed. Median length of stay (LOS) decreased from 5.2 to 3.5 days ($p < 0.001$). No significant changes occurred for acute kidney injury and hematologic complications.

Conclusion An ERP was associated with reduced complication rates across a wide range of organ categories and > 1.5-day reduction in LOS in a colorectal surgery population.

Keywords Colorectal surgery · Outcomes · Enhanced recovery after surgery · Enhanced recovery program · Surgical site infection · Perioperative care

Successful surgical outcomes depend on far more than actions taken between skin incision and closure. Historically, perioperative care in the USA has been fragmented

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and costly. Enhanced recovery programs (ERPs) address this issue with the goals of attenuating the surgical stress response, reducing complications, and shortening hospital stays [1]. ERP care pathways have been employed for several decades in Europe and have recently gained popularity in North America [2–9]. A series of studies conducted over two decades have demonstrated that ERPs substantially reduce hospital length of stay (LOS) and decrease healthcare costs [10–13]. However, the bulk of studies have dealt with postoperative complications in one of two ways. They have either addressed specific complications, such as urinary tract infection [5, 14], or they have analyzed complications in a composite or pooled manner [15–18].

Beginning in 2012, our group observed that our surgical site infection rates were beyond a standard deviation higher than the national average. In order to achieve outcomes associated with ERAS, we had previously implemented and have sustained a highly coordinated care program for colorectal surgical (CRS) patients from the time a decision was made to operate through the entire perioperative period [19]. Our ERP focused on infection risk reduction, non-opioid multimodal pain therapy (preoperative to post-discharge), early ambulation, enteral nutrition, and euvolemia. While these elements are similar to previous reports of ERPs, we believe that one of the unique strengths of our ERP is the level of coordination between our anesthesiologist and our surgeons. We have previously shown that initial implementation was associated with reduced LOS, but the question of sustained effect over time remained as did any effect on perioperative morbidity. The aim of this study was to compare a wide range of postoperative outcomes before and after implementation of a sustained ERP. Accordingly, we hypothesized that this ERP will be associated with a reduction in a broad range of postoperative outcomes as well as a reduction in LOS over the study period.

Methods

Study design

We performed a retrospective, observational cohort case control study. This study was reviewed and deemed exempt by the Vanderbilt University Institutional review board (Protocol 170096). Our cohort included all patients undergoing elective colorectal procedures between 1/2011 and 10/2016. Exclusion criteria included emergency cases and colorectal resections performed outside of the colorectal service. Patients were stratified based on exposure to an enhanced recovery protocol (7/2014–10/2016). The details of the protocol have been previously reported and are summarized in Fig. 1 [19]. Perioperative management of patients in the pre-ERP group (1/2011–12/2012) was not standardized in

respect of perioperative pain management, surgical management, postoperative nausea and vomiting prophylaxis, intraoperative fluid management, early ambulation, or early oral intake. Patients undergoing surgery for the 18 months prior to 7/2014 were excluded as several components of the ERP were instituted in a stepwise manner during this time period (e.g., goal-directed fluid management, non-opioid multimodal pain management, early ambulation, intraoperative SSI bundle). We obtained data from our electronic medical records and from our institution's National Surgical Quality Improvement Project (NSQIP) entries based upon manual chart reviews. There was a high degree of fidelity in the abstraction which resulted in no missing data. To adjust for comorbidities, we calculated a Charlson Comorbidity score on all patients [20]. To ensure that results were due to the ERP and not merely an observational or Hawthorne effect [21], an internal audit was conducted on a section of the cohort to assess compliance rates of several components of the pathway over time. This audit was conducted over the calendar year 2015 by independent data analysts under the direction of the perioperative ERP leadership.

Outcomes

The primary outcomes were adjusted rates of organ-specific complications (Table 1). Organ-based categories were selected to describe outcomes as they were most closely aligned with significant clinical categories. In addition to initial improvements in patient outcomes, one of the goals of the ERP evaluation was to identify areas for future quality improvement projects. Perioperative data were linked with our institutional NSQIP entries, which captures data for all CRS patients, rather than for a sample as is commonly done for NSQIP cohorts. As a participant of NSQIP, data were abstracted for all of the procedures included in the colectomy and proctectomy modules in the targeted procedure program. Published NSQIP definitions for all of the demographic and outcome data were strictly followed [22]. Organ-specific complications were grouped according to NSQIP definitions [23]. (Table 1) Secondary outcomes included LOS, readmission, return to the emergency department (ED), and cost. Due to a software conversion in our cost accounting system over the study period, we were unable to directly compare the pre-ERP costs with the ERP costs. We instead used the median of the variable costs in the ERP phase and divided by LOS in the ERP phase to estimate cost/day and then multiplied this by the decrease in LOS between pre-ERP and ERP phases to estimate a median variable cost savings per patient.

Statistical analysis

Continuous and categorical variables are expressed as mean with standard deviation and proportions throughout
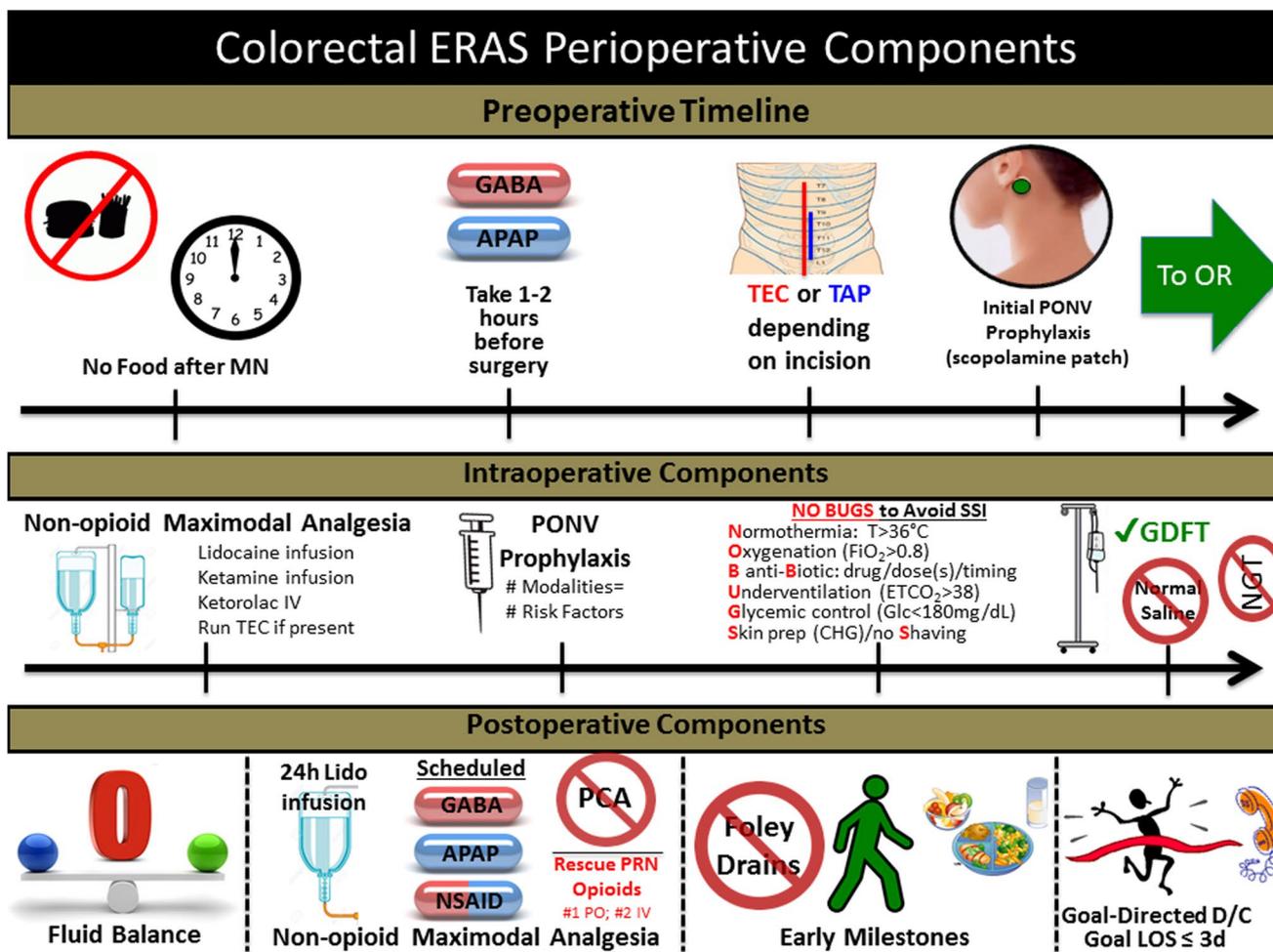
Fig. 1 Overview of Vanderbilt University Medical Center Enhanced Recovery Protocol

Table 1 NSQIP complications by category

SSI	Respiratory	Transfusion	Renal/AKI	UTI	Sepsis	Cardiac	Heme
Organ/space SSI	On ventilator > 48 h	Transfusion intraop/post-op (72 h of surgery start time)	Progressive renal insufficiency	Urinary tract infection	Septic shock	Myocardial infarction	Vein thrombosis requiring therapy
Superficial incisional SSI	Unplanned intubation		Acute renal failure		Sepsis	Cardiac arrest requiring CPR	Pulmonary embolism
Deep incisional SSI	Pneumonia						

the study, with the exception of continuous variables with non-normal distributions that are reported as the median with the interquartile range. Bivariate analysis of continuous and categorical variables was performed with either the Student's t test or the Wilcoxon rank-sum test, depending on distribution, and Fishers exact test, respectively. To determine risk adjusted odd ratios for each postoperative complications while taking into account national secular trends, a difference-in-difference (DiD) approach was used. DiD is an econometric method for evaluating changes occurring after the implementation of a policy [24–26]. This approach isolates the improvement in outcomes related to an intervention that exceeds changes over the same time period that was not exposed to the intervention. For our control group, we used the national PUF of the ACS NSQIP database. Because the NSQIP PUF may

not be representative of our group, two separate strategies were employed to adjust for potential differences. First, we used the same exclusion criteria for our study as used when developing the national PUF cohort. Second, we performed a 1:1 propensity score matching based on age, gender, race, procedure, ASA, wound class, history of smoking, steroid use, history of weight loss, history of diabetes, history of disseminated cancer, and history of hypertension. The C-statistic for the propensity score model was 0.76, indicating good discrimination. Using a caliper width of 0.1, the propensity score yielded a

100% match. The matching ensured risk adjustment for all outcomes.

To perform the DiD analysis, regression models were used to evaluate the relationship between each dependent outcome (Fig. 2) and use of the ERP. For the dichotomous outcome variables, logistic regression was used. For the continuous LOS variable, generalized linear models with a log link were used. A dummy variable was included, indicating whether the patient had surgery before or after ERP. Finally, the interaction terms of the institutional cohort (vs. national NSQIP PUF [control]) variable and the before ERP or after

Fig. 2 **A** Pre- and post-ERP surgical site infection rates by cohort. **B** Pre- and post-ERP outcomes
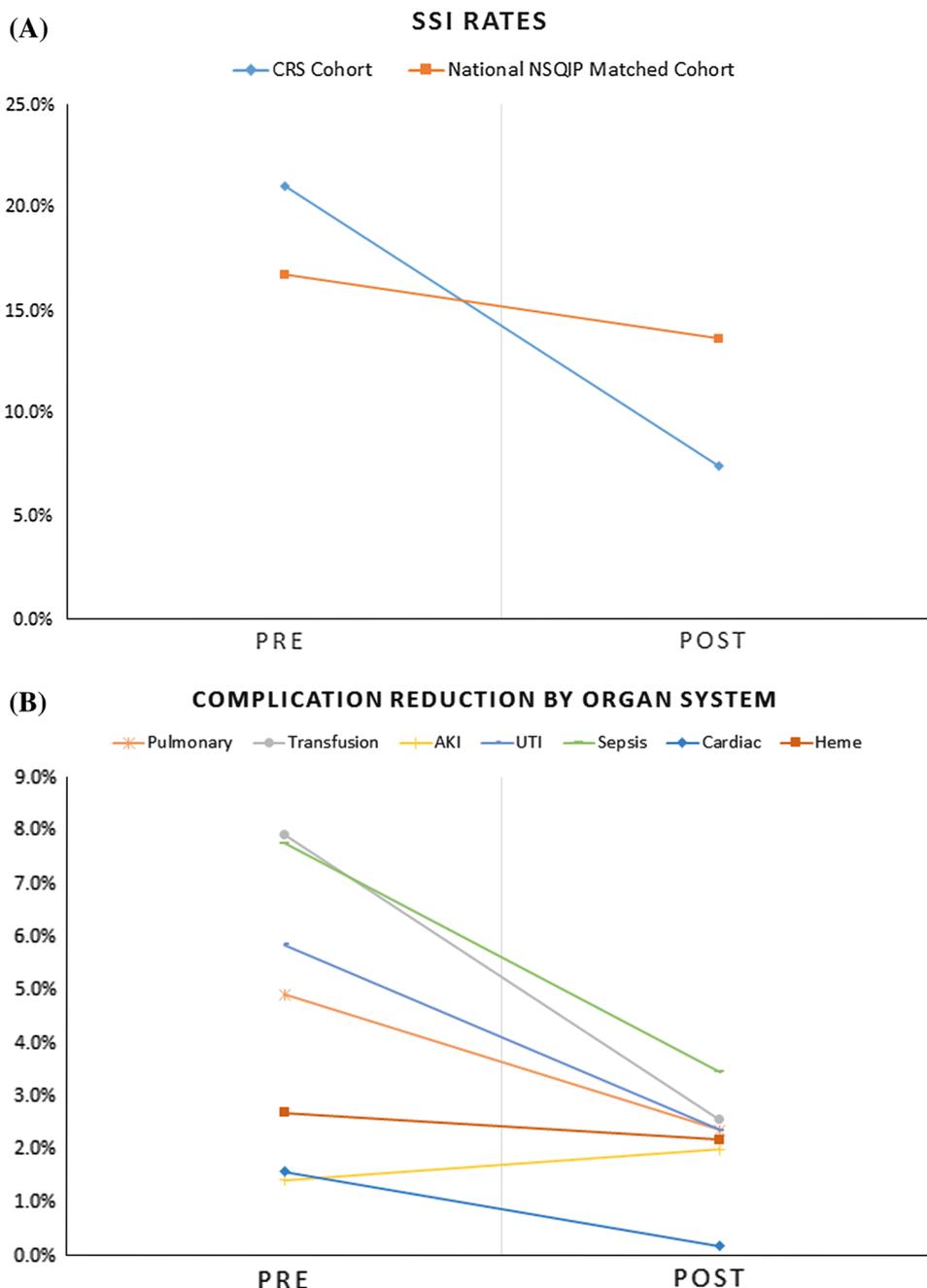
ERP variable were added. The coefficient from these inter-action terms (i.e., the DiD estimators) can be interpreted as the independent relationship of ERP and postoperative outcomes [26–28]. In all models evaluating outcomes and ERP, we adjusted for patient characteristics by using a stepwise procedure (backwards Wald) with a p value of 0.20 to enter and 0.05 to eliminate variables. For secondary outcomes, including LOS, return to ED, readmission, and charges, a similar analysis was performed but without the DiD variables. SAS statistical software (version 9.3; SAS Institutes Inc., Cary NC, USA) was used for all analyses. All tests were two sided with an alpha level of 0.05.

Results

Between January 1, 2011 and October 31, 2016, a total of 1625 patients underwent elective colorectal surgery by the colorectal service. Four hundred and thirty-nine were excluded during the wash out period for a total cohort of 1182. Of these, 632 (53%) were in the pre-ERP group and 550 (47%) were in the group after full ERP implementation. An audit of compliance in 265 patients revealed > 89% compliance in a number of key protocol components (Table 2). Demographic and operative variables comparing these two groups are demonstrated in Table 3. There were no differences in age, gender, race, BMI, comorbidity ASA, surgical procedure, etiology, or estimated blood loss. In the ERP group, there was a decreased rate of laparoscopic procedures compared to pre-ERP (56% vs. 65%; $p = 0.001$) reduced median duration of surgery (178 vs. 195 min; $p = 0.003$) and reduced median intraoperative fluid administration (1700 vs. 2400 cc; $p < 0.001$).

Unadjusted outcomes are shown in Table 4. A significant decrease was seen in SSI (Fig. 2A), pulmonary complications, transfusion, UTI, sepsis, and cardiac complications (Fig. 2B). No difference was seen in the rate of acute kidney

injury (AKI) or hematologic complications. The ERP cohort was associated with a decrease in unplanned return to the OR (3% vs. 6%; $p = 0.009$) and a decrease in readmission rate (11% vs. 16%; $p = 0.01$) (Table 5). Median length of stay was decreased in the ERP group (3.5 vs. 5.2 days; $p < 0.001$).

These findings persisted in the DiD analyses. Unadjusted rates for the propensity matched national cohort are given in Table 4. Even when adjusting for secular trends and preoperative variables, an ERP was associated with improvements in SSI (OR 0.30; 95% CI 0.20–0.43; $p < 0.001$), pulmonary complications (OR 0.46; 95% CI 0.24–0.90; $p = 0.03$), transfusion (OR 0.27; 95% CI 0.15–0.51; $p < 0.001$), UTI (OR 0.34; 95% CI 0.18–0.66; $p = 0.006$), sepsis (OR 0.35; 95% CI 0.20–0.61; $p = 0.002$), and cardiac complications (OR 0.10; 95% CI 0.01–0.84; $p = 0.02$). There was no difference observed in odds of AKI (OR 1.46; 95% CI 0.60–3.56; $p = 0.28$) or hematologic complications (OR 0.71; 95% CI 0.33–1.51; $p = 0.44$).

The reduction of LOS found in the univariate analysis persisted in the multivariate analysis (β: − 1.51; Std error: 0.29; p value < 0.001). The odds of return to the OR (OR 0.45; 95% CI 0.25–0.81; $p = 0.008$) and readmission (OR 0.66; 95% CI 0.47–0.94; $p = 0.02$) decreased in the ERP period. There was no significant change in 30-day emergency room utilization. In an analysis of cost, we calculated the median of the variable costs in the ERP phase and divided by 3.5-day LOS in the ERP phase to get cost/day and then multiplied this by 1.7 days (which is the decrease in LOS between pre-ERP and ERP phases) to get a reduction in median variable costs in the ERP phase over the pre-ERP phase of 32.7%.

Discussion

Perioperative care in the USA often remains fragmented and costly in many hospitals [12, 29]. ERPs aim to address this issue, but the effect of ERPs on surgical complications remains unknown, especially when considering individual outcomes rather than composite. In 2014, we designed an ERP based on best practices using input from surgeons, anesthesiologists, nurses, and pharmacists with the stated purpose of implementing and sustaining highly coordinated and standardized care for CRS patients from the time a decision was made to operate through post-discharge follow-up. In this prospective, observational (before and after) study of our health-care redesign project, we examined the impact of an ERP for colorectal surgery on 30-day postoperative outcomes. We found that a major restructuring of perioperative care delivery resulted in a sustained reduction not only in LOS and aggregate complications but also organ-specific complications, return to OR and readmission. These

Table 2 Compliance audit of key ERP components ($n = 265$)

ERP component	Compliance rate (%)
Bowel prep	91
Oral antibiotics	91
Chlorhexidine gluconate wipes	95
Glucose	93
Preoperative warming	94
Towels	90
Gown & gloves changed after anastomosis	89
Segregation of dirty instruments	90

ERP enhanced recovery protocol

Table 3 Demographic data

Variable	All (n=1182)	Pre-ERP (n=632)	ERP (n=550)	p value
Age [year, median (IQR)]	55 (40–66)	54 (41–65)	55 (40–67)	0.55
Female gender	592 (50.1%)	310 (49.1%)	282 (51.3%)	0.44
Race				
Caucasian	1084 (91.7%)	577 (91.3%)	507 (92.2%)	0.85
African American	78 (6.6%)	44 (6.9%)	34 (6.2%)	
Other	20 (1.7%)	11 (1.7%)	9 (1.6%)	
BMI [median (IQR)]	26.8 (23.2–31.1)	27.0 (23.3–31.2)	26.4 (23.1–30.9)	0.27
ASA				
1 and 2	512 (43.3%)	284 (44.9%)	228 (41.4%)	0.23
3 and 4	670 (56.7%)	348 (55.1%)	322 (58.5%)	
Comorbidity index [median (IQR)]	1 (0–2)	1 (0–2)	1 (0–2)	0.26
Type of surgery				
Colectomy	767 (64.9%)	403 (63.7%)	364 (66.2%)	0.12
Proctectomy	293 (24.8%)	153 (24.2%)	140 (25.4%)	
Ostomy	102 (8.6%)	61 (9.7%)	41 (7.4%)	
Other	20 (1.7%)	15 (2.4%)	5 (0.9%)	
Etiology				
Benign	174 (14.7%)	82 (12.9%)	92 (16.7%)	0.09
Neoplasia	502 (42.4%)	271 (42.8%)	231 (41.9%)	
IBD	353 (29.8%)	185 (29.3%)	168 (30.5%)	
Ostomy	154 (13.0%)	94 (14.8%)	60 (10.9%)	
Laparoscopic approach	720 (60.9%)	412 (65.2%)	308 (56.0%)	0.001
Duration of surgery [min, median (IQR)]	188 (134–252)	195 (142–263)	178 (128–241)	0.003
Duration of anesthesia [min, median (IQR)]	235 (180–300)	236 (183–309)	233 (176–293)	0.13
EBL [cc, median (IQR)]	75 (25–175)	100 (0–200)	50 (25–150)	0.31
Intraoperative fluid [cc, median (IQR)]	2000 (1500–2700)	2400 (1750–3000)	1700 (1200–2200)	<0.001

ERP enhanced recovery protocol, *IQR* interquartile range, *BMI* body mass index, *ASA* American society of anesthesiologist

Table 4 Unadjusted and Difference-in-Difference adjusted outcomes

Outcome	CRS cohort incidence		Unadjusted model for ERP		Propensity matched national cohort incidence			D-in-D adjusted model for ERP	
	Pre (%)	ERP (%)	OR (95% CI)	Wald p value	Pre (%)	ERP (%)	p value	OR (95% CI)	Wald p value
SSI	21.0	7.4	0.30 (0.21–0.44)	<0.001	16.1	11.8	0.03	0.30 (0.20–0.43)	<0.001
Pulmonary	4.9	2.4	0.47 (0.24–0.91)	0.02	4.1	2.9	0.31	0.46 (0.24–0.90)	0.03
Transfusion	7.9	2.5	0.30 (0.16–0.56)	0.0001	15.9	11.1	0.02	0.27 (0.15–0.51)	<0.001
AKI	1.4	2.0	1.41 (0.58–3.43)	0.44	0.7	1.2	0.43	1.46 (0.60–3.56)	0.28
UTI	5.8	2.4	0.39 (0.20–0.74)	0.004	5.4	3.6	0.17	0.34 (0.18–0.66)	0.006
Sepsis	7.7	3.4	0.42 (0.25–0.73)	0.002	7.9	6.1	0.24	0.35 (0.20–0.61)	0.002
Cardiac	1.5	0.2	0.11 (0.01–0.88)	0.03	0.5	1.1	0.30	0.10 (0.01–0.84)	0.02
Heme	2.7	2.2	0.80 (0.38–1.70)	0.57	1.0	2.3	0.16	0.71 (0.33–1.51)	0.44

CRS colorectal surgery, *ERP* enhanced recovery protocol, *SSI* surgical site infection, *AKI* acute kidney injury, *UTI* urinary tract infection

improvements persist even when accounting for national decreases.

The literature is replete with success stories of ERP. The majority of reports describe a significant decrease in LOS while maintaining or reducing readmission rates [30–35]. Geltzeiler et al. also reported a reduction in narcotic use and cost in a community setting [36]. Stowers et al. found implementation of ERPs to be cost-effective [37]. But data describing reduction in specific surgical complications are scarce. Miller et al. reported a decrease

Table 5 Secondary outcomes

Outcome	Incidence		Unadjusted model for post		Adjusted model for post	
	Pre (%)	Post (%)	OR (95% CI)	Wald p value	OR (95% CI)	Wald p value
Return to OR	6.2	2.9	0.45 (0.25–0.82)	0.009	0.45 (0.25–0.81)	0.008
Readmission	16.1	11.3	0.66 (0.47–0.92)	0.01	0.67 (0.47–0.94)	0.02
Return to ED	4.7	4.4	0.92 (0.53–1.59)	0.75	0.95 (0.55–1.64)	0.84
	Median		β (SE)	p value	β (SE)	p value
LOS, d	5.2	3.5	− 1.45 (0.28)	< 0.001	− 1.51 (0.29)	< 0.001

ERP enhanced recovery protocol, *ED* emergency department

in incidence of urinary tract infection [5]. A large, multicenter European group described a decrease in aggregate complications [11]. However, our study is the first to demonstrate the power to decease a broad range of postoperative complications for individual organ systems. In addition, we observed a reduction in both return to the operating room and a decrease in readmission rate. These findings highlight the power that a successfully implemented ERP can have for our patients.

Important in this analysis is the adjustment for national, secular trends in organ-specific complication rates. In our propensity matched national NSQIP PUF cohort, there were a number of significant and nonsignificant decreases in complication rates. Our adjustment for these decreases allows us to isolate the improvement in outcomes related to the ERP that exceeds changes at the national level over the same time period. Also, by conducting an internal audit into compliance, we are confident that the changes observed are due to the ERP and not merely a Hawthorne effect. In fact, our institutional rates of organ-specific complications for CRS patients are now below national norms in all areas, which was not the case when this project was started.

So how does an ERP designed initially to reduce LOS result in the reduction in a broad range of organ level complications? While difficult to determine from the data at hand, there are two distinct possibilities. First, certain components were designed to address certain organ-specific complications. The "NO-BUGS" bundle of normothermia, oxygenation, antibiotics, underventiliation, glucose control, and Skin Prep was designed to address surgical site infection. Similarly, the focus on early Foley catheter removal has been shown to reduce urinary tract infections. The second theory is that the act of streamlining our perioperative care to a standardized "best practice" type model had positive downstream consequences. ERPs are an example of healthcare redesign that shifts the current culture to focus on patient and disease centered standardization of care. This type of "best practice" model can improve the quality of care and consistency in treatment [38]. By focusing efforts in this direction, teams have increased communication, efficiency,

and a decrease in non-value added activities. This shift in focus helps to improve the global outcomes after surgery.

While most of our complication rates dropped, rates of AKI and hematologic complications did not. A focus of our ERP was to restrict fluid administration in keeping with data that high fluid utilization is associated with increased presence of postoperative ileus for both rectal and colon surgery patients [39]. In fact, a restrictive fluid practice could conceivably increase rates of AKI. The fact that we did not see a significant increase in AKI, along with the decrease in other complications, should be viewed as a positive finding and offer support for restrictive fluid practices. As for the lack of reduction of hematologic complications (DVT and PE) there were no systems changes that targeted DVT and PE reduction, such as extended chemoprophylaxis. We had already stressed daily walking as part of the normal post-op routine for patients since at least 2010. A focus on hematologic complications will be part of the second iteration of our ERP.

The finding of a reduction in the use of laparoscopic surgery in our ERP was counterintuitive, especially as one of the tenets of our ERP was to use a laparoscopic approach whenever possible. Possible reasons for this could be an increase in reoperative surgery or an increase in operative complexity in the post-ERP group. Regardless, we would expect the decrease in laparoscopic to bias the results toward worse postoperative outcomes rather than better, especially for surgical site infections [40]. We instead found a sustained reduction not only in LOS and aggregate complications but also organ-specific complications.

This study must be viewed in the context of its limitations. In the data abstraction process, errors in coding are always possible. However, by using a prospectively collected data warehouse and trained NSQIP abstractors, we sought to minimize this. There is the issue of generalizability. It was conducted within a CRS unit in a tertiary care center with an entire perioperative service dedicated to its implementation. Other centers may not be able to engage the resources to fully implement such a broad reaching program. Second, as with all ERPs, the multimodal nature of the intervention makes it difficult to parse out the essential measures of

the ERP. We had an extended 18-month wash-in period that excluded 439 patients. This was necessary as multiple facets of the ERP were instituted in a stepwise fashion. Rather than compare a population that only underwent partial exposure to our ERP, we chose to exclude these patients and only compare two populations that either had no exposure or full exposure to the protocol. Pre-post studies do not have control over other elements that are also changing at the same time as the intervention is implemented. We were able to adjust for a number of factors that could bias our data—secular trends in complication rates, age, comorbidity, BMI, case mix, ASA classification. There were some elements which we were unable to match to relevant items in the PUF. Certain factors, such as bowel preparation, postoperative hyperglycemia, surgeon experience, and other institutional trends, were unable to be captured but are unlikely to explain the large effect size we observed. We also did not include patient diagnosis as a factor in the propensity score matching. Thus, our conclusions depend on the assumption that our practice diagnosis pattern is similar to that of the PUF. We believe this is reasonable given the fact that we are a large, general colorectal practice. While we were able to assess compliance to the ERP protocol in a selection of our ERP cohort, this mainly centered on the SSI prevention measures. We were unable to accurately assess compliance to other measures such as education, pre-op analgesia, and PONV prevention.

It is well established that an ERP will decrease LOS, but with our data we are able to demonstrate that nearly every category of complication was significantly reduced by standardizing the way we approached patient care. It is hard to find one component of the ERP that can account for this, and some of the components we used in the study period have variable results when looked at individually at other institutions. What we do see is that by standardizing our approach to perioperative care and increasing our collaboration between the surgical and anesthesia teams, we created and maintained a positive effect on our patient outcomes at a level not previously reported.

Conclusion

In a colorectal surgery population, a comprehensive, multispecialty ERP has the power to decrease not only LOS but also a broad range of surgical complications at the organ level, as well as rates of return to the operating room and readmission.

Compliance with ethical standards

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