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ERAS protocol validation in a propensity-matched cohort of patients undergoing colorectal surgery

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Abstract

Purpose Enhanced recovery after surgery (ERAS) provides many benefits. However, important knowledge gaps with respect to specific components of enhanced recovery after surgery remain because of limited validation data. The aim of the study was to validate a mature ERAS protocol at a different hospital and in a similar population of patients.

Methods This is a retrospective analysis of patients undergoing elective colorectal surgery from 2009 through 2016. Patients enrolled in ERAS are compared with those undergoing the standard of care. Patient demographic characteristics, length of stay, pain scores, and perioperative morbidity are described.

Results Patients (1396) were propensity matched into two equal groups (ERAS vs non-ERAS). No significant difference was observed for age, Charlson Comorbidity Index, American Society of Anesthesiologists score, body mass index, sex, operative approach, and surgery duration. Median length of stay in ERAS and non-ERAS groups was 3 and 5 days (P < .001). Mean pain scores were lower in the ERAS group, measured at discharge from the postanesthesia unit (P < .001), on postoperative day 1 (P = .002) and postoperative day 2 (P = .02) but were identical on discharge.

Conclusions This ERAS protocol was validated in a similar patient population but at a different hospital. ERAS implementation was associated with an improved length of stay and pain scores similar to the original study. Different than most retrospective studies, propensity score matching ensured that groups were evenly matched. To our knowledge, this study is the only ERAS validation study in a propensity-matched cohort of patients undergoing elective colorectal surgery.

Keywords Colorectal surgery · Propensity score · Patient readmission · Pain management · Patient discharge

Introduction

The protocol of enhanced recovery after surgery (ERAS) has evolved since inception and has been more uniformly

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implemented by multiple surgical specialties [1-4]. It is now considered the standard of care for colorectal surgery [5]. The underlying principle of ERAS is to maintain normal physiologic function in the perioperative period through encouragement of early oral intake, ambulation, maintenance of euvolemia, and use of multimodal analgesia. Previously reported benefits include decreased length of stay (LOS), reduced postoperative morbidity, improved postoperative pain control, improved patient satisfaction, and decreased cost of care [6–9].

Although consensus exists regarding the concept of an ERAS bundle, implementation of its components continues to be variable [10]. These differences in implementation have proven problematic in the design and use of studies to evaluate the influence of ERAS [11–13]. Randomized prospective trials are generally small and single-institution assessments, whereas meta-analyses and systematic reviews attempt to merge heterogeneous data

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with the differing ERAS elements or with different patient populations [14–16]. As a result, no validation studies use the exact same protocol in a similar patient population. Herein, we assess the implementation (process and outcomes) at Mayo Clinic in Jacksonville, Florida (MCJ), of a previously described ERAS protocol in its entirety [8, 17]. The primary objective was to determine the effect of ERAS implementation on LOS and pain control. The secondary objective was to establish the effect of ERAS implementation on postoperative complications (i.e., re-admissions, surgical site infection (SSI), anastomotic leaks, and bleeding).

Methods

Patients

Inclusion criteria described adult (age > 18 years) patients who underwent an elective inpatient colorectal operation at MCJ from January 2009 through December 2016. The ERAS protocol was implemented at MCJ in September 2013. The exact pathway described and implemented at Mayo Clinic in Rochester, Minnesota (MCR), was used (Table 1) [8, 17]. Although MCJ and MCR are different sites, they are of the same institution; therefore, patient pathways, services, formulary medications, and staff follow the same guidelines. Patient demographic characteristics included age, sex, body mass index, Charlson Comorbidity Index, and American Society of Anesthesiologists (ASA) classification. Outcome variables included LOS, analog pain score, postoperative complications (e.g., bleeding, anastomotic leak, SSI), and readmissions were obtained from the electronic health record. Compliance with the ERAS protocol was measured reviewing medical records whether protocol requirements were implemented. Total (100%) compliance meant that all ERAS components were followed (Table 1).

To capture all possible SSIs, we used expanded SSI criteria, modified from the American College of Surgeons National Surgical Quality Improvement Program (NSQIP), the Centers for Disease Control and Prevention National Healthcare Safety Network (NHSN), and the Centers for Medicare and Medicaid Services Hospital–Acquired Condition (Box). Our definition of postoperative bleeding followed the description of Moriarty et al. [18]. Briefly, bleeding was classified as involving at least 2 of the following 4 criteria: hemoglobin decrease ≥ 3 g/dL, red blood cell transfusion, a bleeding diagnosis, or a return to the operating room for hemorrhage, or a combination. Postoperative pain was measured with the 10-point analog scale at discharge from the postanesthesia care unit and at 4

and 8 h postoperatively. Average pain scores were recorded on postoperative days 1 and 2 and at discharge.

Statistical analysis

Descriptive statistics for categorical variables are reported as frequency and percentage, continuous variables, as mean (SD) and median (range). Since some patients had multiple surgical procedures, preoperative and outcome variables were compared between ERAS group and non-ERAS group through generalized linear models with generalized estimating equations to account for within-patient correlation.

In addition, ERAS patients were matched with non-ERAS patients using propensity score matching. The calipers used were ± 0.15 (0.25*SD of logit propensity scores) for the probability of ERAS procedure. Control patients were selected randomly from the control group, defined with the calipers. The propensity of an ERAS protocol surgery was estimated through a logistic regression model. The response variable was ERAS procedure (yes or no). Independent variables were age at surgery, sex, body mass index (BMI), Charlson Comorbidity Index, ASA class, wound class, surgeon, extensiveness of the procedure, and surgery type. Standardized differences were calculated when the matched baseline variables were compared between the ERAS group and the non-ERAS group. Generalized linear models with the generalized estimating equations approach were used to assess differences in outcome variables between the two matched groups with the following distribution and link function: LOS (γ distribution and log-link function), pain scores (normal distribution and identity link function), and complication and readmission (binary distribution and logit link function).

All statistical tests were two-sided with the α level set at 0.05 for statistical significance. The analysis was performed with statistical software (SAS version 9.4; SAS Institute Inc). The Mayo Clinic Institutional Review Board approved this retrospective study. This study followed the reporting guide-lines of the Strengthening the Reporting of Observational Studies in Epidemiology.

Results

The population was 1556 patients undergoing 1915 operations (861 ERAS vs 1054 non-ERAS) during the study period. Baseline demographic characteristics were compared between the groups (Table 2). In the unmatched analysis, patients in the ERAS group were younger, had lower Charlson Comorbidity Index and ASA scores, and were more likely to undergo minimally invasive surgery. However, after propensity score matching, the resulting

ERAS Category	Component			
Preoperative analgesia	Celecoxib 400 mg			
	Gabapentin 600 mg			
	Acetaminophen 1000 mg			
Postoperative nausea prophylaxis	0-2 risk factors: dexamethasone 4-8 mg IV and 5HT-3 antagonist ^a			
	> 2 risk factors: add droperidol 0.625 mg			
Fluid balance	Intraoperatively: NS (maximum, 500 mL/h)			
	Postoperatively: NS 40 mL/h and saline lock at 0800 on POD 1			
Intraoperative analgesia	Intrathecal hydromorphone, 0.1 mcg at discretion of anesthesiologist			
	IV fentanyl as needed			
	IV ketorolac			
Postoperative analgesia	Oral oxycodone 5-10 mg as needed			
	Scheduled acetaminophen			
	Scheduled NSAIDs (ie, ketorolac, then ibuprofen)			
Diet	OGT removed at end of procedure			
	Goal of 80 mL oral intake within 4 h of PCU arrival			
	Soft diet started night of procedure			
Ambulation	Day of surgery (POD 0): 1 walk and > 2 h out of bed			
	POD 1 and forward: >4 walks and >8 h out of bed			

ERAS enhanced recovery after surgery, *5HT-3* 5-hydroxytryptamine type 3, *IV* intravenous, *NSAID* nonsteroidal anti-inflammatory drug, *NS* normal saline, *OGT* oral gastric tube, *PCU* postoperative care unit, *POD* postoperative day

^a Ondansetron or granisetron

groups showed no significant differences in regard to patient characteristics. Among operations, 698 pairs of procedures were propensity matched on the basis of baseline variables. Standardized differences before and after matching were plotted (Fig. 1). Median LOS was significantly shorter in the ERAS group than the non-ERAS group (3 vs 5 days, P < .001) (Table 3). During the study period, LOS showed a decreasing trend overall; however, a significant decrease was observed with subsequent stabilization after protocol implementation in 2013 (Fig. 2). Postoperative bleeding was less in the ERAS group than the non-ERAS group (3.9 vs 6.4%, P = .03). Postoperative pain scores in the ERAS group were significantly lower than in the non-ERAS group up to postoperative day 2 but were not statistically different at discharge (Fig. 3). Finally, 30-day readmission, reoperation, anastomotic leakage, and SSIs were statistically similar between the two groups. During 2013, compliance with the ERAS pathway was 80%; it subsequently increased to 92% in 2016.

Discussion

While ERAS has evolved since its early description, its adoption has increased largely because of improved patient outcomes compared with traditional care. Our study of the implementation of an ERAS pathway demonstrated three observations. First, the ERAS pathway implemented at another institution (MCR) was successfully validated at our institution (MCJ) with nearly identical results. Second, ERAS implementation was associated with shorter LOS and better pain control. Third, the implementation was not associated with higher rates of re-admissions or postoperative complications.

The findings of this ERAS study are largely congruent with other reported studies [8, 9, 15, 17, 19–22]. However, in a recent Cochrane review, Bond-Smith et al. [23] highlighted elevated risk of bias and unstandardized pathways across different sites in the studies included in the meta-analysis; thus, given the uncertainty of the validity of the results, a routine implementation of the ERAS protocol might be challenging. Other meta-analyses of ERAS protocol report favorable outcomes but are unable to show that these outcomes are generalizable because of the heterogeneity of the included studies [19, 20].

The present study is distinctive in that the ERAS protocol was first implemented at a different hospital (MCR) and was applied with a similar patient population, measuring the same primary outcome of LOS. In addition, the propensity score matching ensured that patients in each group shared preoperative characteristics and had similar lengths of surgery (a surrogate for procedural complexity) and modes of surgery (minimally invasive or open). Any unmeasurable differences between surgeons were minimized. This study found the same difference in LOS as

Characteristic	Unmatched ^a				Matched ^a			
	No ERAS (<i>n</i> = 1054)	ERAS (<i>n</i> = 861)	Total (<i>n</i> = 1915)	p value	No ERAS (<i>n</i> = 698)	ERAS (<i>n</i> = 698)	Total (<i>n</i> = 1396)	Standardized difference
Age, year				.001				- 0.02
Mean (SD)	56.7 (17.4)	57.1 (16.4)	56.9 (17.0)		56.5 (17.3)	56.0 (17.0)	56.3 (17.2)	
Median	59	60	59		58	60	59	
Sex				.72				-0.01
Female	557 (52.8)	438 (50.9)	995 (52.0)		366 (52.4)	374 (53.6)	740 (53.0)	
Male	497 (47.2)	423 (49.1)	920 (48.0)		332 (47.6)	324 (46.4)	656 (47.0)	
BMI				.90				0.02
Underweight	51 (4.8)	36 (4.2)	87 (4.5)		34 (4.9)	31 (4.4)	65 (4.7)	
Normal	443 (42.1)	367 (42.6)	810 (42.3)		301 (43.1)	306 (43.8)	607 (43.5)	
Overweight	339 (32.2)	298 (34.6)	637 (33.3)		225 (32.2)	223 (31.9)	448 (32.1)	
Obese	219 (20.8)	160 (18.6)	379 (19.8)		138 (19.8)	138 (19.8)	276 (19.8)	
Missing	2	0	2		150 (19.0)	150 (19.0)	270 (19.0)	
Charlson Comorbidity Inde	-	0	2	< .001				- 0.02
0	435 (41.3)	464 (53.9)	899 (46.9)	<i< td=""><td>332 (47.6)</td><td>338 (48.4)</td><td>670 (48.0)</td><td>0.02</td></i<>	332 (47.6)	338 (48.4)	670 (48.0)	0.02
1	283 (26.9)	204 (23.7)	487 (25.4)		179 (25.6)	190 (27.2)	369 (26.4)	
2	180 (17.1)	137 (15.9)	317 (16.6)		126 (18.1)	115 (16.5)	241 (17.3)	
≥ 3	156 (14.8)	56 (6.5)	212 (11.1)		61 (8.7)	55 (7.9)	116 (8.3)	
ASA class	150 (14.0)	50 (0.5)	212 (11.1)	.02	01 (0.7)	55 (1.5)	110 (0.5)	0.01
1/1E to 2/2E	386 (36.7)	354 (41.1)	740 (38.7)	.02	279 (40.0)	275 (39.4)	554 (39.7)	0.01
3/3E to 5/5E	667 (63.3)	507 (58.9)	1174 (61.3)		419 (60.0)	423 (60.6)	842 (60.3)	
Missing	1	0	0		FI (00.0)	425 (00.0)	00.5)	
surgery method	ĩ	v	U U	<.001				0.01
Laparoscopic	557 (53.9)	574 (67.8)	1131 (60.2)	<.001	428 (61.3)	437 (62.6)	865 (62.0)	0.01
Open	476 (46.1)	273 (32.2)	749 (39.8)		270 (38.7)	261 (37.4)	531 (38.0)	
Surgery duration, min	-70 (40.1)	213 (32.2)	(39.0)	.28	210 (30.1)	201 (37.4)	551 (50.0)	- 0.01
No. of patients	1053	861	1914	.20	698	698	1396	0.01
Mean (SD)	221.7 (117.4)	249.7	234.3		231.3 (120.4)	229.9	230.6	
medii (SD)	221.7 (117.4)	(144.5)	(131.0)		231.3 (120.4)	(136.6)	(128.7)	
Median	207	239	218		219	217	(128.7)	
wiculan	207	239	∠10		219	21/	∠10	

Table 2 Baseline characteristics of patients with and without eras protocol, matched and unmatched

ASA American Society of Anesthesiologists; BMI body mass index; ERAS enhanced recovery after surgery

^a Values are presented as number and percentage of patients unless specified otherwise

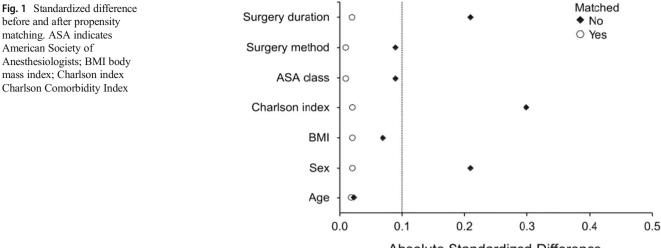
seen at MCR. Despite the difficulty in comparing these outcomes to previous studies, our results not only replicate but also further demonstrate the potential benefits of ERAS when previously defined protocol standards are implemented [4, 9, 15, 24].

As in the MCR study, the MCJ ERAS patients reported lower postoperative pain scores than those receiving usual care. In addition, they were discharged with the same pain score; they arrived at the "ideal" pain score faster and were not discharged with higher pain scores than the control group. Complications in the ERAS group were less overall, and the 30-day readmission was the same as in the control group. This outcome is especially important because a historical concern in the literature about the ERAS pathway is that although patients enrolled in ERAS return home sooner, they might be at risk for a higher readmission rate (i.e., they may be discharged prematurely) [25, 26]. In this MCJ study, we found that this was not the case, a finding similar to the MCR study.

We wanted to assess the true incidence of SSIs. As previously mentioned, NSQIP and NHSN infection rates are discordant with each other and with the individual hospital's internal data [27, 28]. When initially assessing the SSI rate for the present study, we found that the NSQIP and NHSN rates were indeed discordant to each other and were lower than the rates found with the criterion described in the Box. It is impossible to know how many infections the algorithm missed, but SSIs were not the main focus of this work. Nevertheless, all efforts were made to ensure completeness of the analyzed data. The SSI numbers between the two groups were similar and within the acceptable range of today's standards [27, 28].

Box surgical site infection criteria with presence of any 1 category, code, or treatment occurring within 30 days of discharge

Initial compliance with the ERAS protocol was 80%; a peak compliance of 92% was reached within 2 months. On the basis of this model, achievement of a LOS decrease may be possible within 4 months of complete ERAS implementation. This is an important consideration for any financial modeling, although the financial effect and effort necessary for implementation vary by institution. Most institutions have



Absolute Standardized Difference

realized a financial advantage with ERAS implementation [9, 14, 29, 30].

Limitations of this study include its retrospective design,

CCS diagnosis category
2, septicemia (except in labor)
3, bacterial infection, unspecified site
135, intestinal infection
148, peritonitis and intestinal abscess
197, skin and subcutaneous tissue infection
238, complication of surgical procedure or medical care
CCS procedure category
168, incision and drainage; skin subcutaneous tissue and fascia
ICD-9/ICD-10 specific codes
998.5
998.59
T81.4XXA
K68.11
CPT-4 code
49,021
49,061
Antibiotics administered in absence of UTI or pneumonia
Cefazolin
Cephalexin
Amoxicillin
Ciprofloxacin
Metronidazole

CCS clinical classifications software, CPT-4 Current Procedural Terminology, Fourth Edition, ICD-9 International Classification of Diseases, Ninth Revision, ICD-10 International Classification of Diseases, Tenth Revision, UTI, urinary tract infection

with the biases therein. The study period was 8 years long; therefore, there is risk for lead time bias; however, median LOS before ERAS implementation in non-ERAS group was 5.0 days each year from 2009 through 2012. A stable trend can also be seen in the ERAS group after the ERAS implementation, with a median LOS of 3.0 days each year from 2014 to 2016. Therefore, it is unlikely that time significantly influenced our results. Propensity matching was used, thereby balancing the treatment and control groups across the covariates identified as significant. A risk exists that other unidentified variables could also influence the outcomes. The use of propensity score matching led to an exclusion of 30 and 18% of the study population from the first and the second time periods respectively. While the exclusion of patients is often a limitation of this type of analysis, there is no difference between matched and unmatched records among the surgical procedures (p = 0.204). Furthermore, in the multivariable analysis adjusting for the same covariates in the original population, results are similar compared to the matched analysis. In addition, this was a single-institution experience, which may be not representative sample. Further validation from other institutions will be beneficial.

In conclusion, this study supports that ERAS is associated with decreased LOS, improved pain control, and no additional complications than a traditional pathway. It validates the specific ERAS protocol implemented at a different site and shows that it is reproducible in hospitals with similar population of patients. This protocol would likely benefit all patients undergoing elective colorectal surgery. Future direction for this group is the description of the financial effect of ERAS implementation at MCJ and comparison with MCR.

Authors' Contributions All authors made substantial contribution to the conception and design of the work, as well as the acquisition, analysis, and interpretation of data. All authors were critically involved in drafting and revising this project for important intellectual content. Final approval of the version to be published was given by all authors, and they agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

 Table 3
 Outcome variable

 comparison between matched
 groups

Outcome Variable	No ERAS ^a $(n = 698)$	$\text{ERAS}^{\text{a}} (n = 698)$	P value
LOS, median (IQR), days	5 (4-7)	3 (2–5)	< .001
Re-admission in 30 days	42 (6.0)	55 (7.9)	.19
Reoperation	12 (1.7)	13 (1.9)	.83
Surgical site infection	50 (7.2)	58 (8.3)	.42
Anastomotic leakage	6 (0.9)	7 (1.0)	.65
Bleeding	45 (6.4)	27 (3.9)	.03

ERAS Implementation

ERAS enhanced recovery after surgery, IQR interquartile range, LOS length of stay

10

^a Values are presented as number and percentage of patients unless specified otherwise

Fig. 2 Change in LOS over time. Asterisk indicates that fourth quarter of 2016 included 5 patients from early October. ERAS indicates enhanced recovery after surgery; LOS length of stay

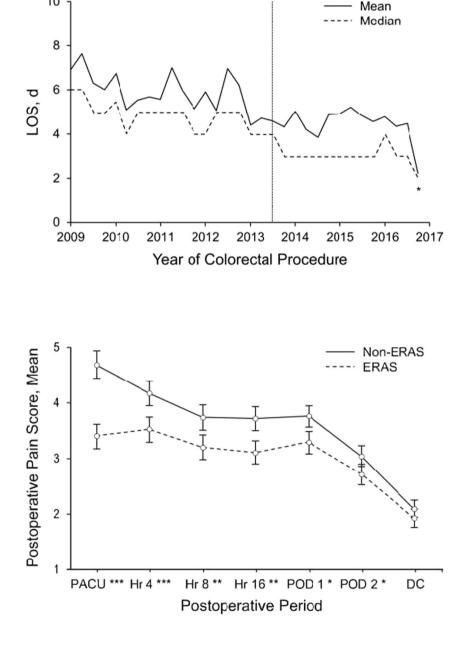


Fig. 3 Pain score of patient groups. Error bars indicate SD. *P < .05; **P < .01; ***P < .001. DC indicates hospital discharge; ERAS enhanced recovery after surgery, PACU postanesthesia care unit, POD postoperative day

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Compliance with ethical standards

The Mayo Clinic Institutional Review Board approved this retrospective study. This study followed the reporting guidelines of the Strengthening the Reporting of Observational Studies in Epidemiology.

Conflict of interest The authors declare that they have no conflict of interest.

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