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Association Between Use of Enhanced Recovery After Surgery Protocol and Postoperative Complications in Colorectal Surgery The Postoperative Outcomes Within Enhanced Recovery After Surgery Protocol (POWER) Study

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IMPORTANCE Enhanced Recovery After Surgery (ERAS) care has been reported to be associated with improvements in outcomes after colorectal surgery compared with traditional care.

OBJECTIVE To determine the association between ERAS protocols and outcomes in patients undergoing elective colorectal surgery.

DESIGN, SETTING, AND PARTICIPANTS The Postoperative Outcomes Within Enhanced Recovery After Surgery Protocol (POWER) Study is a multicenter, prospective cohort study of 2084 consecutive adults scheduled for elective colorectal surgery who received or did not receive care in a self-declared ERAS center. Patients were recruited from 80 Spanish centers between September 15 and December 15, 2017. All patients included in this analysis had 1 month of follow-up.

EXPOSURES Colorectal surgery and perioperative management were the exposures. Twenty-two individual ERAS items were assessed in all patients, regardless of whether they were included in an established ERAS protocol.

MAIN OUTCOMES AND MEASURES The primary study outcome was moderate to severe postoperative complications within 30 days after surgery. Secondary outcomes included ERAS adherence, mortality, readmissions, reoperation rates, and hospital length of stay.

RESULTS Between September 15 and December 15, 2017, 2084 patients were included in the study. Of these, 1286 individuals (61.7%) were men; mean age was 68 years (interquartile range [IQR], 59-77). A total of 879 patients (42.2%) presented with postoperative complications and 566 patients (27.2%) developed moderate to severe complications. The number of patients with moderate or severe complications was lower in the ERAS group (25.2% vs 30.3%; odds ratio [OR], 0.77; 95% CI, 0.63-0.94; P = .01). The overall rate of adherence to the ERAS protocol was 63.6% (IQR, 54.5%-77.3%), and the rate for patients from hospitals self-declared as ERAS was 72.7% (IQR, 59.1%-81.8%) vs non-ERAS institutions, which was 59.1% (IQR, 50.0%-63.6%; P < .001). Adherence quartiles among patients receiving the highest and lowest ERAS components showed that the patients with the highest adherence rates had fewer moderate to severe complications (OR, 0.34; 95% CI, 0.25-0.46; P < .001), overall complications (OR, 0.33; 95% CI, 0.26-0.43; P < .001), and mortality (OR, 0.27; 95% CI, 0.07-0.97; P = .06) compared with those who had the lowest adherence rates.

CONCLUSIONS AND RELEVANCE An increase in ERAS adherence appears to be associated with a decrease in postoperative complications.

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Supplemental content

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Corresponding Author: Javier Ripollés-Melchor, MD, Infanta Leonor University Hospital, Madrid, Spain, Gran Vía del Este 80, 28031, Madrid, Spain (ripo542@gmail.com). n estimated 310 million patients undergo surgery worldwide each year. ¹ The International Surgical Outcomes Study reported that, globally, 26.8% of patients who underwent major surgery had postoperative complications, and 24.3% of those who underwent low abdominal surgery developed complications. ² These findings are similar to those of a previous study. ³ Postoperative complications after major surgery have been shown to increase the length of stay (LOS), cost, and mortality. ⁴ · 6 Moreover, the presence of postoperative complications after colorectal surgery was associated with decreased long-term survival, independent of patient, disease, and treatment factors. ³

Enhanced Recovery After Surgery (ERAS) protocols or enhanced recovery pathways (ERPs) have become prevalent in colorectal surgery. These programs combine use of a multidisciplinary team, protocolization of perioperative management, and patient education.⁷

Single-center studies, ^{8,9} multicenter observational studies, ¹⁰⁻¹² and meta-analyses ¹³ have reported that the application of a perioperative ERP is associated with improvements in postoperative outcomes. Many of the components of the ERP could be considered as standard care ¹⁴; nevertheless, there are still barriers for its full implementation, ¹⁵ despite health systems recommendations. ¹⁶ Adherence to the individual items that make up an ERP in the perioperative period has been associated with improvements in postoperative outcomes, ^{10,17} including with reductions in postoperative complications and LOS. ^{18,19}

Although there is evidence that demonstrates the effectiveness of the ERP,¹² to our knowledge, there are no large case series of patients showing better postoperative outcomes in centers that perform ERP successfully compared with centers that have the same adherence rates to individual components that make up an ERP as a whole, even though a predefined ERP is not performed. Moreover, there is uncertainty regarding the relative benefit from each component of an ERP.

Therefore, the aim of this study was to characterize the management strategies for treatment in patients who underwent elective colorectal surgery in Spain, including centers with and those without an established ERP, and analyze the association between the individual elements of the ERAS protocols and postoperative complications.

The primary end point of the study was the incidence of moderate to severe postoperative complications within 30 days after surgery. Secondary end points were ERAS adherence, readmissions, reoperations, hospital length of stay, mortality, and the occurrence of postoperative complications.

Methods

Study Design and Participants

The Postoperative Outcomes Within Enhanced Recovery After Surgery Protocol (POWER) study was a prospective, 2-month, multicenter cohort study. The study was approved by the Instituto Aragonés de Ciencias de la Salud Ethics Committee, Zaragoza, Spain and by the Spanish Medical Agency, and was registered prospectively (NCTO3012802). Ethics

Key Points

Question Are the complications after colorectal surgery frequent and are the complications associated with Enhanced Recovery After Surgery protocols?

Findings In this cohort study of 2084 patients, 566 patients presented with moderate to severe complications. Patients receiving care at a facility that had greater adherence to the Enhanced Recovery After Surgery items had a lower number of postoperative complications, regardless of whether the center had an established Enhanced Recovery After Surgery protocol.

Meaning An increase in adherence to the Enhanced Recovery After Surgery protocol appeared to be associated with a decrease in postoperative complications; thus, a high adherence rate to the Enhanced Recovery After Surgery protocol is recommended in the management of care for patients undergoing colorectal surgery.

committees or institutional review boards at each site reviewed and approved the protocol. Written informed consent was obtained for patients to take part in the study when required by local ethics committees. Participants did not receive financial compensation.

This study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline for cohort studies. ²⁰ Hospital and investigator participation were facilitated through the Spanish Perioperative Audit and Research Network, which was established by the Grupo Español de Rehabilitación Multimodal. All Spanish hospitals were invited to participate, regardless of the number of beds and the existence of an ERP protocol.

Procedures

All consecutive adult (>18 years) patients undergoing elective primary colorectal surgery with a planned overnight stay were included during a single period of 2 months of recruitment between September 15 and December 15, 2017, in all participating centers. Each patient was followed up for 30 days after surgery. The follow-up was performed through hospital and primary care medical records.

Data were collected using Castor EDC²¹ and deidentified before entry into a secure, internet-based electronic case record form designed specifically for POWER, which incorporated automated checks for plausibility, consistency, and completeness.

The centers were considered ERAS centers if they had received specific training in ERAS provided by the Grupo Español de Rehabilitación Multimodal and declared having a multidisciplinary ERAS team and an ERAS protocol established and approved in their center. Data describing perioperative care facilities including the ERP application were collected for each patient. Individual data on 22 ERP items were collected prospectively for each included patient. The definition of the individual ERP components was based on the guidelines of the Enhanced Recovery After Surgery Society in colorectal surgery^{22,23} (eTable 1 in the Supplement). Data included patient characteristics (American Society of Anesthesiologists

grade, age, sex, smoking status, body mass index, and comorbidities), procedure performed, surgical approach, perioperative interventions, ERP items, adherence, and outcomes (including postoperative complications, time to achieve targeted mobility, total LOS, and 30-day mortality). Complications were defined and graded as mild, moderate, or severe as described by European Perioperative Clinical Outcome definitions²⁴ (eTable 2 in the Supplement) and were included if they occurred within 30 days after surgery. Data were censored at 30 days following surgery for patients who remained in the hospital. Data validation was conducted by the principal investigator at each site.

Outcomes

The primary outcome was the number of patients with 30-day in-hospital moderate to severe postoperative complications. Secondary outcome measures included ERP adherence, mortality, readmission, reoperation rates, and hospital LOS.

Statistical Analysis

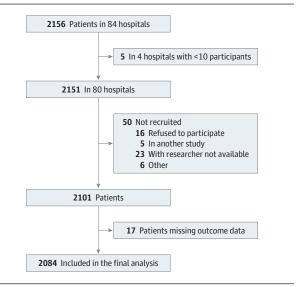
We analyzed outcomes depending on whether the patient belonged to an ERAS program as declared by the hospital where the intervention was performed. The discrete and continuous variables were described as number and percentage and median (interquartile range [IQR]) and their differences analyzed using the Fisher exact or Pearson and Wilcoxon rank sum tests. Subsequently, we repeated the analysis, subdividing all of the sample into quartiles according to the adherence rate to ERAS items (regardless of whether the patients belonged to a self-declared ERAS hospital), and comparing the quartiles of higher and lower adherence and calculating a linear fit of the adherence with the variable under study. Next, we analyzed the moderate or severe complication rate for each of the ERAS items using the Fisher exact test and performed a multivariate analysis to study the association between the rate of each of the items and the clinical and demographic variables. In addition, we applied the Kaplan-Meier test to determine whether there were differences in hospital length of stay (LOS) depending on the patient's inclusion in an ERAS program or the ERAS adherence quartile. To avoid errors by multiple comparisons, we calculated the respective q value for each P value to maintain a false discovery rate below 5%.25 We considered comparisons in which P value and q value were below .05 as being statistically significant.

Results

Participants 4 8 1

Data describing 2084 patients were collected in 80 Spanish hospitals (**Figure 1**). Of these, 1286 individuals (61.7%) were men; mean age was 68 years (IQR, 59-77). Other characteristics are shown in the **Table**. In accordance with the statistical analysis plan, patients from centers that recruited fewer than 10 patients were excluded from the analysis. According to the hospitals where the surgery was performed, 1304 patients (62.5%) were included in ERAS programs (**Figure 2**). The ERAS and non-

Figure 1. STROBE Flow Diagram for Included Patients



ERAS groups showed demographic differences in the presence of congestive heart failure; hemoglobin, albumin, and creatinine levels before surgery; and cancer being the reason for surgery (Table).

Outcome Data

A total of 879 patients (42.2%) developed postoperative complications, and 566 patients (27.2%) developed complications graded as moderate or severe. The number of patients with moderate to severe complications was lower in the ERAS group (25.2% vs 30.3%; odds ratio [OR], 0.77; 95% CI, 0.63-0.94; P=.01) but not in terms of overall complications, readmission, reoperation, or mortality rate (Figure 2). In terms of type of complications, the ERAS group had a reduction in rates of paralytic ileus (OR, 0.74; 95% CI, 0.57-0.95; P=.02), urinary tract infection (OR, 0.51; 95% CI, 0.26-0.99; P=.03), and infection of uncertain origin (OR, 0.45; 95% CI, 0.2-0.99; P=.04); no significant differences were found for other specific complications (Figure 2).

ERAS Adherence and Outcome Data

The overall adherence rate to the ERAS protocol components was 63.6% (IQR, 54.5%-77.3%), with the rate for facilities self-declared as ERAS being 72.7% (IQR, 59.1%-81.8%) vs 59.1% (IQR, 50.0%-63.6%) at non-ERAS facilities (P < .001). In terms of adherence to each item, no differences were found in the rate of presurgical optimization, antithrombotic and antibiotic prophylaxis, laparoscopic approach, and no use of nasogastric tube; adherence was greater with other factors in the ERAS environment, for example, presurgical education (74.92% [977 of 1304] vs 47.31% [369 of 780]; P < .001), avoidance of fasting (71.86% [937 of 1304] vs 46.79% [365 of 780]; P < .001), carbohydrates preload (39.03% [509 of 1304] vs 10.51% [82 of 780]; P < .001), avoidance of drainage (38.65% [504 of 1304] vs 28.21% [220 of 780]; P < .001) or avoidance of urinary catheterization (72.85% [950 of 1304] vs 64.1% [500 of 780];

	No. (%)				
Characteristic	Total (N = 2084)	ERAS (n = 1304)	No ERAS (n = 780)	P Valu	
Age, median (IQR), y	68 (59-77)	68 (59-77)	69 (60-77)	.78	
Men	1286 (61.7)	797 (61.12)	489 (62.69)	.49	
BMI, median (IQR)	26.68 (24.07-29.71)	26.67 (24.02-29.38)	26.76 (24.16-30.12)	.17	
ASA classification					
I	129 (6.19)	86 (6.60)	43 (5.51)		
II	1153 (55.33)	718 (55.06)	435 (55.77)	.70	
III	747 (35.84)	468 (35.89)	279 (35.77)	/0	
IV	55 (2.64)	32 (2.45)	23 (2.95)		
Smoking	399 (19.15)	251 (19.25)	148 (18.97)	.91	
Diabetes	454 (21.79)	292 (22.39)	162 (20.77)	.41	
Congestive heart failure	129 (6.19)	96 (7.36)	33 (4.23)	.005 ^b	
Coronary artery disease	190 (9.12)	127 (9.74)	63 (8.08)	.21	
Cirrhosis	29 (1.39)	20 (1.53)	9 (1.15)	.57	
Metastasis	188 (9.02)	111 (8.51)	77 (9.87)	.31	
Stroke	118 (5.66)	71 (5.44)	47 (6.03)	.63	
COPD	306 (14.68)			.52	
Hypertension	1070 (51.34)	683 (52.38)	387 (49.62)	.24	
Previous transfusion	108 (5.18)			.84	
Hemoglobin, median (IQR), g/dL	13.2 (11.8-14.6)	13.2 (11.65-14.5) 13.3 (11.95-14.5)		.03 ^b	
Leukocytes, median (IQR), /µL	6880 (5577.5-8300)	6840 (5500-8300)		.12	
Albumin, median (IQR), g/dL	4.1 (3.8-4.4)	4.1 (3.7-4.3)	4.2 (3.8-4.5)	<.001	
Creatinine, median (IQR), mg/dL	0.84 (0.71-1)	0.85 (0.72-1)	0.81 (0.7-1)	.04 ^b	
Surgical procedure					
Abdominoperineal amputation	112 (5.37)	72 (5.52)	40 (5.13)		
Anterior rectum resection	490 (23.51)	305 (23.39)	185 (23.72)		
Intestinal reconstruction	150 (7.22)	106 (8.14)	44 (5.67)		
Hemicolectomy					
Left	168 (8.06)	102 (7.82)	66 (8.46)		
Right	582 (27.93)	361 (27.68)	221 (28.33)	.008b	
Sigmoidectomy	448 (21.50)	271 (20.78)	177 (22.69)	.000	
Subtotal colectomy	59 (2.83)	39 (2.99)	20 (2.56)		
TEM	10 (0.48)	1 (0.08)	9 (1.16)		
Total colectomy	33 (1.58)	25 (1.92)	8 (1.03)		
Transverse colectomy	26 (1.25)	20 (1.54)	6 (0.77)		
Oncologic surgery	1777 (85.27)	1092 (83.74)	685 (87.82)	.01 ^b	
Laparoscopic approach	1234 (59.21)	773 (59.28)	461 (59.10)	.07	
Ostomy	501 (24.04)	322 (24.69)	179 (22.95)	.40	
Analgesia	301 (24.04)	322 (24.09)	179 (22.93)	.40	
	200 (10 02)	162 (12 42)	47 (6.02)	. 001	
Abdominal wall block	209 (10.03)	162 (12.42)	47 (6.03)	<.001	
Epidural	642 (30.81)	455 (34.89)	187 (23.97)		
Intradural	84 (4.03)	55 (4.22)	29 (3.72)		
Intravenous	1149 (55.13)	632 (48.47)	517 (66.28)		
ERAS adherence	4246/	0== (= 4 :	260 (47 5 ::)		
Presurgical education	1346 (64.59)	977 (74.92)	369 (47.31)	<.001	
Presurgical optimization	1453 (69.72)	921 (70.63)	532 (68.21)	.26	
Avoid bowel preparation	1067 (51.2)	743 (56.98)	324 (41.54)	<.001	
Avoid fasting	1302 (62.48)	937 (71.86)	365 (46.79)	<.001	
Carbohydrates preload	591 (28.36)	509 (39.03)	82 (10.51)	<.001	
Avoid sedatives	1719 (82.49)	1147 (87.96)	572 (73.33)	<.001	

(continued)

Table. Demographic and ERAS Adherence Data^a (continued)

	No. (%)				
naracteristic	Total (N = 2084)	ERAS (n = 1304)	No ERAS (n = 780)	P Value	
Antithrombotic prophylaxis	2016 (96.74)	1265 (97.01)	751 (96.28)	.38	
Antibiotic prophylaxis	2068 (99.23)	1295 (99.31)	773 (99.1)	.61	
Standardized anesthesia protocol	1447 (69.43)	1023 (78.45)	424 (54.36)	<.001 b	
PONV prophylaxis	1911 (91.7)	1243 (95.32)	668 (85.64)	<.001 b	
Laparoscopic approach or minimal incision in open surgery	1371 (65.79)	860 (65.95)	511 (65.51)	.85	
Avoid nasogastric tube	1231 (59.07)	790 (60.58)	441 (56.54)	.07	
Normothermia	2012 (96.55)	1272 (97.55)	740 (94.87)	.002 ^b	
Goal-directed fluid therapy	635 (30.47)	519 (39.8)	116 (14.87)	<.001 ^b	
Avoid drainage	724 (34.74)	504 (38.65)	220 (28.21)	<.001 ^b	
Avoid urinary catheterization	1450 (69.58)	950 (72.85)	500 (64.1)	<.001 ^b	
First 24-h fluid balance <1500 mL	1544 (74.09)	1061 (81.37)	483 (61.92)	<.001 ^b	
Postoperative multimodal analgesia	1717 (82.39)	1131 (86.73)	586 (75.13)	<.001 ^b	
Perioperative nutritional screening, support	1404 (67.37)	840 (64.42)	564 (72.31)	<.001 ^b	
Normoglycemia	1572 (75.43)	1072 (82.21)	500 (64.1)	<.001 ^b	
Early mobilization	765 (36.71)	631 (48.39)	134 (17.18)	<.001 ^b	
Early feeding	735 (35.27)	620 (47.55)	115 (14.74)	<.001 ^b	
RAS protocol, median (IQR), % adherence	63.6 (54.5-77.3)	72.7 (59.1-81.8)	59.1 (50-63.6)	<.001 ^b	

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); COPD, chronic obstructive pulmonary disease; ERAS, Enhanced Recovery After Surgery; IQR, interquartile range; PONV, postoperative nausea and vomiting; TEM, transanal endoscopic microsurgery.

SI conversion factors: To convert albumin to grams per liter, multiply by 10; creatinine to micromoles per liter, multiply by 88.4; hemoglobin to grams per liter, multiply by 10; leukocytes to ×10⁹ per liters squared, multiply by 0.001.

Figure 2. Postoperative Outcomes

Patients With at Least 1	Total (N=2084) Events, No. (%)	ERAS (n = 1304) Events, No. (%)	No ERAS (n = 780) Events, No. (%)	Odds Ratio (95% CI)	Favors ERAS	Favors No ERAS	P Value
Moderate or severe complication	566 (27.16)	329 (25.2)	237 (30.4)	0.77 (0.63-0.94)	- -		.01a
Complication	879 (42.18)	531 (40.72)	348 (44.62)	0.85 (0.71-1.02)	-		.08
Readmission	116 (5.57)	75 (5.75)	41 (5.26)	1.1 (0.73-1.67)		-	>.99
Reintervention	205 (9.84)	128 (9.82)	77 (9.87)	0.99 (0.73-1.36)	-	<u> </u>	>.99
Mortality rate	35 (1.68)	21 (1.61)	14 (1.79)	0.9 (0.43-1.92)			.73
Type of moderate or severe complication	1S						
Acute kidney injury	85 (4.08)	60 (4.6)	25 (3.21)	1.46 (0.89-2.45)	-	-	.14
Acute respiratory distress	22 (1.06)	16 (1.23)	6 (0.77)	1.6 (0.59-5.02)			.38
Anastomotic breakdown	139 (6.67)	78 (5.98)	61 (7.82)	0.75 (0.52-1.08)	_		.12
Arrythmia	39 (1.87)	26 (1.99)	13 (1.67)	1.2 (0.59-2.56)		-	.74
Cardiopulmonary edema	1 (0.05)	1 (0.08)	0	1.80 (0.07-44.15)	•	-	→ >.99
Deep vein thrombosis	4 (0.19)	3 (0.23)	1 (0.13)	1.8 (0.14-94.38)		-	→ >.99
Gastrointestinal bleeding	45 (2.16)	28 (2.15)	17 (2.18)	0.98 (0.52-1.93)			>.99
Infection (surgical site, superficial)	112 (5.37)	62 (4.75)	50 (6.41)	0.73 (0.49-1.09)		<u> </u>	.11
Infection (surgical site, deep)	102 (4.89)	58 (4.45)	44 (5.64)	0.78 (0.51-1.19)		<u> </u>	.25
Infection (surgical site, organ space)	118 (5.66)	68 (5.21)	50 (6.41)	0.8 (0.54-1.2)	_	 -	.28
Infection (uncertain source)	30 (1.44)	13 (1)	17 (2.18)	0.45 (0.2-0.99)			.04ª
Infection (bloodstream)	82 (3.93)	50 (3.83)	32 (4.1)	0.93 (0.58-1.52)	_	_	.82
Myocardial infarction	1 (0.05)	1 (0.08)	0	1.80 (0.07-44.15)	•	-	→ >.99
Pneumonia	40 (1.92)	24 (1.84)	16 (2.05)	0.9 (0.45-1.82)			.74
Paralytic ileus	309 (14.83)	174 (13.34)	135 (17.31)	0.74 (0.57-0.95)			.02a
Postoperative hemorrhage	16 (0.77)	9 (0.69)	7 (0.9)	0.77 (0.25-2.44)			.61
Pulmonary embolism	3 (0.14)	3 (0.23)	0	5.40 (0.29-100.4)		-	→ .30
Urinary tract infection	Total (n = 2084)	19 (1.46)	22 (2.82)	0.51 (0.26-0.99)			.03a
					0.1	1 io (95% CI)	10

Moderate or severe complications and type of complication in all included patients and in patients with and without the Enhanced Recovery After Surgery (ERAS) protocol.

P < .001) (Table). The ERAS group also had less use of intraoperative fluids (1500 mL [IQR, 1000-2000] vs 1500 mL [IQR,

1185-2100]; *P* < .001), less time to ambulation (24 hours [IQR, 20-48] vs 30 hours [IQR, 24-48]; *P* < .001) and oral intake (20

^a A complete definition of all ERAS items is presented in eTable 1 in the Supplement.

 $^{^{\}rm b}\!$ Statistically significant.

^a Statistically significant.

Adherence Adherence Adherence >63.6% but >54.5% but Adherence 01 vs 04 Adherence >77.3% <73.7% <63.6% <54.5% Odds Ratio Favors Favors 01 vs 04 Linear Fit Patients With at Least 1 Q1 (n = 521) Q2 (n = 521) Q3 (n = 521)Q4(n=521)(95% CI) 01 04 P Value (P Value) Moderate or severe 84 (16.12) 147 (28.21) 163 (31.29) 183 (35.12) 0.34 (0.25-0.46) <.001a -0.48 (<.001a) complication 212 (40.69) 247 (47.41) 277 (53.17) 0.33 (0.26-0.43) <.001a -0.65 (<.001a) Complication 143 (27.45) Readmission 34 (6.53) 34 (6.53) 27 (5.18) 21 (4.03) 1.66 (0.95-2.9) .10 +0.05 (.08) -0.09 (.03^a) Reintervention 35 (6.72) 33 (6.33) 39 (7.49) 34 (6.53) 0.63 (0.36-1.1) .13 13 (2.50) 0.27 (0.07-0.97) -0.04 (.01a) 3 (0.58) 8 (1.54) 11 (2.11) .06 Mortality rate Type of moderate or severe complications 15 (2.88) 29 (5.57) 26 (4.99) 0.56 (0.29-1.08) -0.07 (.02a) Acute kidney injury 15 (2.88) .11 Acute respiratory distress 3 (1.92) 10 (1.92) 9 (1.73) 0.05 (0.01-0.89) .04a -0.05 (<.001a) 0 Anastomotic breakdown 22 (4.22) 31 (5.95) 42 (8.06) 44 (8.45) 0.48 (0.28-0.81) .007a -0.09 (.01a) 19 (3.65) 0.2 (0.04-0.9) -0.04 (.02a) Arrhythmia 2(0.38)8(1.54)10 (1.92) .04a +0.01 (.66) 0 1(0.19)0 Cardiopulmonary edema 0 0 4 (0.77) 0 +0.01 (.54) Deep vein thrombosis 8 (1.54) 14 (2.69) 0.56 (0.23-1.36) Gastrointestinal bleeding 8 (1.54) 15 (2.88) .28 -0.01 (.51) Infection (surgical site, 32 (6.14) 80 (15.36) 83 (15.93) 114 (21.88) 0.23 (0.15-0.35) <.001a -0.08 (.007a) superficial) 0.31 (0.15-0.62) .001a -0.10 (<.001a) Infection (surgical site, 11 (2.11) 24 (4.61) 33 (6.33) 34 (6.53) deep) .07 Infection (surgical site, 21 (4.03) 31 (5.95) 31 (5.95) 35 (6.72) 0.58 (0.33-1.01) -0.05(.11)organ space) Infection (uncertain 3 (0.58) 5 (0.96) 10 (1.92) 12 (2.30) 0.25 (0.07-0.88) .03a -0.05 (.002a) source) Infection (bloodstream) 14 (3.65) 19 (3.65) 26 (4.99) 23 (4.41) 0.6 (0.3-1.18) .18 -0.04 (.08) Myocardial infarction 1 (0.19) 0 3.01 (0.12-73.96) .50 +0.01 (.46) 4 (0.77) 11 (2.11) 14 (2.69) 11 (2.11) 0.36 (0.11-1.13) .12 -0.03 (.09) Pneumonia Paralytic ileus 32 (6.14) 80 (15.36) 83 (15.93) 114 (21.88) 0.24 (0.15-0.35) <.001 -0.36 (<.001a) 8 (1.54) 0.5 (0.09-2.73) Postoperative 2(0.38)2 (0.38) 4(0.77).69 -0.01(.20)hemorrhage 3.01 (0.12-73.96) 1 (0.19) 0 2 (0.38) 0 +0.01 (.91) Pulmonary embolism > 50 Urinary tract infection 5 (0.96) 10 (1.92) 11 (2.11) 15 (2.88) 0.33 (0.12-0.91) .04a -0.05(.004a)0.1 10

Figure 3. Postoperative Outcomes and Enhanced Recovery After Surgery (ERAS) Adherence

 $Postoperative\ moderate\ to\ severe\ complications\ in\ all\ included\ patients\ depending\ on\ the\ quartile\ (Q)\ of\ adherence\ to\ the\ ERAS\ protocol.$

hours [IQR, 6-26] vs 26 hours [IQR, 24-48]; P < .001), and shorter LOS (7 days [IQR, 5-12] vs 8 [IQR, 5-13]; *P* < .001) (eTable 3 in the Supplement). Among the highest adherence quartile (Q1) and lowest adherence quartile (Q4) of ERAS items, Q1 also had a decrease in the rate of moderate to severe complications (OR, 0.34; 95% CI, 0.25-0.46; P < .001), overall complications (OR, 0.33; 95% CI, 0.26-0.43; P < .001), and mortality (OR, 0.27; 95% CI, 0.07-0.97; P = .06), compared with Q4, as well as acute kidney injury (OR, 0.56; 95% CI, 0.29-1.28; P = .11), acute respiratory distress syndrome (OR, 0.05; 95% CI, 0.01-0.89; P = .04), anastomotic breakdown (OR, 0.48; 95% CI, 0.28-0.81; *P* = .007), arrhythmia (OR, 0.2; 95% CI, 0.04-0.9; P = .04), and superficial (OR, 0.23; 95% CI, 0.15-0.35; P < .001) and deep surgical site (OR, 0.31; 95% CI, 0.15-0.62; P = .001) infection (Figure 3), together with higher postsurgical levels of hemoglobin (11.6 g/dL [IQR, 10.4-12.9] vs 11.4 g/dL [IQR, 10.3-12.8]; *P* < .001 [to convert to grams per liter, multiply by 10]). The linear fit of the variables against ERAS adherence confirmed the differences between Q1 and Q4 (eFigure in the Supplement).

Multivariate analysis of ERAS items showed a statistically significant reduction of moderate to severe complications in patients who had undergone laparoscopic surgery (OR, 0.47; 95% CI, 0.38-0.57; *P* < .001), presurgical education (OR, 0.78; 95% CI, 0.64-0.95; P = .02) or optimization (OR, 0.78; 95% CI, 0.63-0.95; P = .02); carbohydrate preload had been implemented (OR, 0.67; 95% CI, 0.54-0.84; P < .001), had avoided fasting (OR, 0.73; 95% CI, 0.60-0.89; P = .002), surgical drainage tubes (OR, 0.56; 95% CI, 0.46-0.70; P < .001), or urinary catheters (OR, 0.40; 95% CI, 0.33-0.49; P < .001); had a fluid balance of less than 1500 mL in the first 24 hours (OR, 0.59; 95% CI, 0.47-0.72; *P* < .001); and had been mobilized (OR, 0.51; 95% CI, 0.42-0.64; *P* < .001) and fed (OR, 0.47; 95% CI, 0.37-0.58; P < .001) early (**Figure 4**). Higher levels of albumin (-0.08; 95% CI, -0.13 to -0.04; *P* < .01) and hemoglobin (-0.07; 95% CI, -0.12 to -0.03; P < .01) were associated with a lower incidence of moderate and severe complications (eTable 4 in the Supplement). It was not necessary to censor any *P* value after the multiple comparison study to adjust the false discovery rate to 5%.

Odds Ratio (95% CI)

^a Statistically significant.

Implemented No Implemented Multivariate Moderate to Severe Odds Ratio Favors : Favors No Estimated Outcome Event. No./ Event. No./ Complications by ERAS Item Total No. (%) Total No. (%) (95% CI) Implemented Implemented P Value (P Value) 352/1346 (26.15) 230/738 (31.17) 0.78 (0.64-0.95) .02a -0.05 (0.02a) Presurgical education Presurgical optimization 383/1453 (26.36) 199/631 (31.54) 0.78 (0.63-0.95) .02a -0.05 (0.02^a) Avoid bowel preparation 288/1067 (26.99) 294/1017 (28.91) 0.90 (0.75-1.10) .35 -0.02 (0.33) Avoid fasting 333/1302 (25.58) 249/782 (31.84) 0.73 (0.60-0.89) .002a -0.07 (0.002a) -0.08 (<0.001a) Carbohydrates preload 133/591 (22.50) 449/1493 (30.07) 0.67 (0.54-0.84) <.001a Avoid sedatives 474/1719 (27.57) 108/365 (29.59) 0.90 (0.71-1.16) .44 -0.02 (0.44) Antithrombotic prophylaxis 556/2016 (27.58) 26/68 (38.24) 0.62 (0.37-1.01) .07 -0.04 (0.05) Antibiotic prophylaxis -0.04 (0.048a) 574/2068 (27.76) 8/16 (50.00) 0.38 (0.14-1.03) .09 Standarized anesthesia protocol 388/1447 (26.81) 194/637 (30.46) 0.84 (0.68-1.03) .09 -0.04 (0.09) PONV prophylaxis 537/1991 (26.97) 45/173 (26.01) 1.11 (0.78-1.58) .60 0.01 (0.56) 309/1371 (22.54) -0.17 (<0.001a) Laparoscopic approach 273/713 (38.29) 0.47 (0.38-0.57) <.001a Avoid nasogastric tube 326/1231 (26.48) 256/853 (30.01) 0.84 (0.69-1.02) .08 -0.04 (0.08) 560/2012 (27.83) 22/72 (30.56) 0.88 (0.53-1.46) .60 -0.01 (0.61) Goal-directed fluid therapy 174/635 (27.40) 408/1041 (39.19) 0.96 (0.78-1.19) .75 -0.01 (0.72) Avoid drainage 151/724 (20.86) 431/1360 (31.69) 0.56 (0.46-0.70) <.001a -0.11 (<0.001a) Avoid urinary catheter 320/1450 (22.07) 262/634 (41.32) 0.40 (0.33-0.49) $<.001^{a}$ -0.20 (<0.001a) First 24-hour fluid balance <1500 mL 386/1544 (25.00) 196/540 (36.30) <.001a -0.11 (<0.001a) 0.59 (0.47-0.72) Postoperative multimodal analgesia 454/1717 (26.44) 128/367 (34.88) -0.07 (<0.001a) 0.67 (0.53-0.85) .001a Nutritional screening-support 406/1404 (28.92) 176/680 (25.88) 1.16 (0.95-1.43) .16 +0.03 (0.15) 451/1572 (28.69) 131/512 (25.59) 1.17 (0.93-1.47) .19 +0.03 (0.17) Normoglycemia Early mobilization 153/765 (20.00) 429/1319 (32.52) 0.51 (0.42-0.64) <.001a -0.13 (<0.001a) -0.15 (<0.001a) Early feeding 136/735 (18.50) 445/1349 (32.99) 0.47 (0.37-0.58) < 001a Odds Ratio (95% CI)

Figure 4. Moderate to Severe Complications by Enhanced Recovery After Surgery (ERAS Items)

PONV indicates postoperative nausea and vomiting.

Hospital LOS was lower in the ERAS group compared with the non-ERAS group (7 [IQR, 5-12] vs 8 [IQR, 5-13] days; P < .001). Regarding the difference by adherence quartiles, Q1 presented a median LOS of 5 days, compared with 8 days in the lowest adherence group (eTable 3 in the Supplement). The survival study confirmed the findings of hospital LOS (eFigure in the Supplement).

Discussion

This prospective observational study examined the postoperative outcomes in scheduled colorectal surgery, and the outcome associated with 22 evidence-based care components of an ERP in 80 Spanish centers and more than 2000 patients without limiting the inclusion of patients to centers with an established ERP.

A 2011 Cochrane review found that ERPs were associated with a reduction in overall complications and LOS compared with conventional perioperative care. ²⁶ The POWER study suggests that having a defined ERP is not associated with improvements in the postoperative outcomes; nevertheless, regardless of whether a particular patient is involved in an established ERP, high adherence to the ERP individual components was associated with a decrease in postoperative complications and LOS.

In centers with a well-established ERP, an association between dose effect and protocol adherence and patient out-

comes has been suggested: the more that protocol components are applied, the better the patient outcomes. ^{9,27,28} A negative association was shown between adherence and the development of complications in an international data set at 13 centers at different stages of ERAS adoption including more than 2000 patients¹⁰: less than 50% adherence, 13.1%; 75% to 90% adherence, 11.6%; and greater than 90% adherence, 9.3%. Gustafsson and colleagues²⁷ showed that, in facilities with 70% or more adherence to ERAS components, the risk of 5-year cancer-specific death was lowered by 42% compared with the risk in facilities with less than 70% adherence. Nevertheless, to our knowledge, it has not been demonstrated that adherence to an ERAS protocol in centers that do not carry out the items in a predefined manner was associated with improvements in outcomes.

Adherence to the ERP affects all perioperative periods. Some of the items demonstrate high adherence in all facilities, such as the laparoscopic approach, antibiotic prophylaxis, antithrombotic prophylaxis, and avoidance of a nasogastric tube; in our sample, these items can be considered as standard care. However, there are other items with low adherence (<50%) in both ERAS and non-ERAS settings. After retrospectively analyzing 2876 patients in an ERP in colorectal surgery, Aarts and colleagues²⁹ found that only 20.1% of the patients received care that fulfilled all the phases of the ERP. The poorest adherence rate was for postoperative interventions (40.3%) that were independently associated with an increase in optimal recovery. This finding confirms reports on

^a Statistically significant.

the low adherence to protocols in the early postoperative phase³⁰ and is consistent with the adherence found in the POWER trial for these items. In addition, we found that 2 items—early feeding and early mobilization—were independently associated with a decrease in moderate to severe postoperative complications. Randomized studies³¹ and observational studies^{32,33} demonstrated that early feeding (<24 hours postoperatively) accelerated gastrointestinal recovery and decreased the rate of complications and the LOS.^{31,34} We found that the average initial oral feeding was given less than 24 hours postoperatively only in the quartile of highest adherence of the ERP (adherence >77%), suggesting that a direct intervention that allows the early initiation of oral feeding was performed exclusively in specialized centers.

This study additionally supports the use of laparoscopic resection within an ERAS program as an independent factor associated with improved outcomes. Similar to previous studies, ^{10,19} in the multivariate analysis of our cohort, the use of laparoscopy was independently associated with a reduction of complications by 17%.

There are reasons to believe that all components of the ERAS program work synergistically.³⁵ In addition, when analyzing the association between individual items and postoperative complications, it may be possible that some of the ERAS items may influence each other, which causes difficulties in interpretation. For example, we did not find that the use of goaldirected hemodynamic therapy reduces postoperative complications, although maintaining a fluid balance less than 1500 mL on the first postoperative day was independently associated with the decrease in complications. The lack of protocolization of goal-directed hemodynamic therapy, as well as the lack of evaluation of the implementation of goal-directed hemodynamic therapy may explain these results. As with performing ERP, affirming that goal-directed hemodynamic therapy is conducted is not enough; after all, avoiding volume overload has been shown to reduce complications in multiple studies.^{8,19}

Strengths and Limitations

This study had several strengths compared with prior studies. The first of these is the large number of consecutive patients enrolled. Only 50 eligible patients during the study period were not included, significantly reducing the risk of selection bias, allowing a representative cross-section of the population to be analyzed. Second, unlike other studies including a similar number of patients, we conducted a prospective study, with a case report form specifically designed for the study and with a 2-month recruitment period; another study analyzed data for periods as long as 5 years. ¹⁰ The changes produced in the perioperative treatment of the patients, clinical experience of the surgeons, and even in the ERAS guidelines, result in the patients not being comparable during such a long period of recruitment. ¹⁰

Furthermore, postoperative complications were analyzed, including centers with ERP and those without ERP, but in which the individual components of the ERP were assessed in all the patients included in the study. Despite a few

randomized clinical trials, to date, auditing of ERAS has been largely performed in a manner similar to intention-to-treat analysis, such that only the treatment assignment (pre-ERAS vs ERAS) was relevant, ⁸ or in large databases including only patients in ERAS centers. ¹⁰⁻¹² These types of studies obtained the same conclusions: the application of ERAS, and especially a high adherence to the protocols improve the postoperative outcomes. Because many of the individual items that make up the ERP should be considered as standard care, we decided to include centers with and without ERPs. We found that patients who receive care in settings with high adherence to the ERP had fewer postoperative complications and shorter LOS; however, this was independent of the existence of an ERP in a certain center.

The POWER study has some limitations. Because care was not randomly assigned, there may be residual confounding from either measured or unmeasured variables. Furthermore, although we defined all ERAS items in the POWER protocol, we cannot rule out measurement errors or misclassification on the part of the researchers, especially in some elements of the ERP, such as fluid balance in the first 24 hours, which implied more complex measurements and in which there could be a lack of information in the patients' medical records. In addition, the current recommendations on some items are different from those that we used; for example, we defined the avoidance of mechanical bowel preparation as part of adherence to the ERP, 22,23 while the most recent guidelines recommend performing it. 35 Therefore, it is possible that when reversing the definition of the item, the results may be different. However, there are interrelated items: we have found that avoiding urinary catheterization and surgical drains was associated with a reduction of complications by 20% and 11% in the multivariate analysis respectively; however, it is possible that both the presence of a urinary catheter and the insertion of surgical drains were directly related to the patients who presented complications, as a measure of treatment or prophylaxis. Further studies are necessary to evaluate the effect of ERP on longer-term outcomes, especially functional and cognitive ability after surgery.

Conclusions

This study suggests that ERP in colorectal surgery is not fully applied in daily clinical practice. In addition, there are certain elements of the ERP that have low adherence, even in specialized ERAS centers. Postoperative recovery is mainly associated with the minimally invasive surgical approach and the postoperative components, such as early oral intake and early ambulation. Therefore, adherence to these items is recommended to be mandatory in future ERAS programs. The POWER study shows that having a protocol is not enough to improve outcomes, but an increase in adherence to ERAS items is associated with a decrease in postoperative complications; therefore, continuous auditing of adherence to ERAS and postoperative outcomes is essential.

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