JAMA Surgery | Original Investigation

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

Javier Ripollés-Melchor, MD; José M Ramírez-Rodríguez, PhD; Rubén Casans-Francés, PhD; César Aldecoa, PhD; Ane Abad-Motos, MD; Margarita Logroño-Egea, MD; José Antonio García-Erce, PhD; Ángels Camps-Cervantes, MD; Carlos Ferrando-Ortolá, PhD; Alejandro Suarez de la Rica, PhD; Ana Cuellar-Martínez, MD; Sandra Marmaña-Mezquita, MD; Alfredo Abad-Gurumeta, PhD; José M. Calvo-Vecino, PhD; for the POWER Study Investigators Group for the Spanish Perioperative Audit and Research Network (REDGERM)

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.

JAMA Surg. doi:10.1001/jamasurg.2019.0995
Published online May 8, 2019.

Invited Commentary
Supplemental content

Author Affiliations: Author affiliations are listed at the end of this article.

Group Information: The POWER Study Investigators Group for the Spanish Perioperative Audit and Research Network (REDGERM) appear at the end of the article.

Corresponding Author: Javier Ripollés-Melchor, MD, Infanta Leonor University Hospital, Madrid, Spain, Gran Vía del Este 80, 28031, Madrid, Spain (ripo542@gmail.com).

An 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.

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.

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 (NCT03012802). Ethics 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 EDC[21] 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, peri-

operative 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 definitions[24] (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

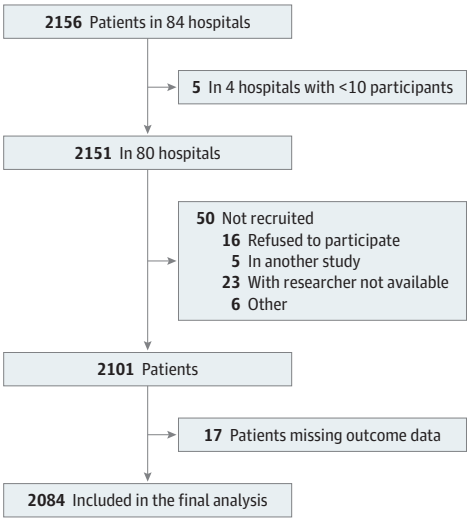
We analyzed outcomes depending on whether the patient belonged to an ERAS program as declared by the hospital where the intervention was performed. The discrete and continuous variables were described as number and percentage and median (interquartile range [IQR]) and their differences analyzed using 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

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-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).

Figure 1. STROBE Flow Diagram for Included Patients



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 = .04), and infection of uncertain origin (OR, 0.45; 95% CI, 0.2-0.99; P = .02); 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]; 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 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)

Table. Demographic and ERAS Adherence Data[a]

Characteristic	No. (%)			*P* Value
	Total (N = 2084)	ERAS (n = 1304)	No ERAS (n = 780)	
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)	.70
II	1153 (55.33)	718 (55.06)	435 (55.77)	
III	747 (35.84)	468 (35.89)	279 (35.77)	
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)	197 (15.11)	109 (13.97)	.52
Hypertension	1070 (51.34)	683 (52.38)	387 (49.62)	.24
Previous transfusion	108 (5.18)	69 (5.29)	39 (5)	.84
Hemoglobin, median (IQR), g/dL	13.2 (11.8-14.6)	13.2 (11.65-14.5)	13.3 (11.95-14.7)	.03[b]
Leukocytes, median (IQR), /μL	6880 (5577.5-8300)	6840 (5500-8300)	6920 (5680-8400)	.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[b]
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 (5.39)	72 (5.53)	40 (5.15)	.008[b]
Anterior rectum resection	490 (23.58)	305 (23.43)	185 (23.84)	
Intestinal reconstruction	150 (7.22)	106 (8.14)	44 (5.67)	
Hemicolectomy				
Left	168 (8.08)	102 (7.83)	66 (8.51)	
Right	582 (28.01)	361 (27.73)	221 (28.48)	
Sigmoidectomy	448 (21.56)	271 (20.81)	177 (22.81)	
Subtotal colectomy	59 (2.84)	39 (3.00)	20 (2.58)	
TEM	10 (0.48)	1 (0.08)	9 (1.16)	
Total colectomy	33 (1.59)	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 (59.24)	773 (59.32)	461 (59.10)	.07
Ostomy	501 (24.04)	322 (24.69)	179 (22.95)	.40
Analgesia				
Abdominal wall block	209 (10.03)	162 (12.42)	47 (6.03)	<.001 [b]
Epidural	642 (30.81)	455 (34.89)	187 (23.97)	
Intradural	84 (34.03)	55 (4.22)	29 (3.72)	
Intravenous	1149 (55.13)	632 (48.47)	517 (66.28)	
ERAS adherence				
Presurgical education	1346 (64.59)	977 (74.92)	369 (47.31)	<.001 [b]
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 [b]
Avoid fasting	1302 (62.48)	937 (71.86)	365 (46.79)	<.001 [b]
Carbohydrates preload	591 (28.36)	509 (39.03)	82 (10.51)	<.001 [b]
Avoid sedatives	1719 (82.49)	1147 (87.96)	572 (73.33)	<.001 [b]
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]

(continued)

Table. Demographic and ERAS Adherence Data[a] (continued)

Characteristic	No. (%) Total (N = 2084)	ERAS (n = 1304)	No ERAS (n = 780)	*P* Value
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]
ERAS 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.

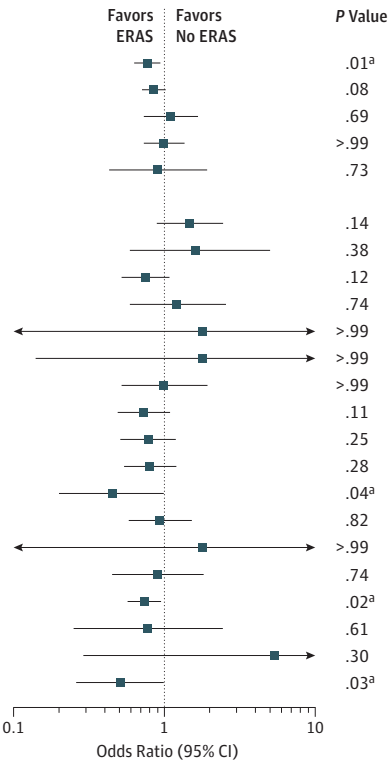
SI conversion factors: to convert albumin to grams per liter, multiply by 10; creatinine to micromoles per liter, multiply by 88.4; hemoglobin to grams per liter, multiply by 10; leukocytes to $\times 10^9$ per liters squared, multiply by 0.001.

[a] A complete definition of all ERAS item is presented in eTable 1 in the Supplement.

[b] Statistically significant.

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)	*P* Value
Moderate or severe complication	566 (27.16)	92 (7.06)	59 (7.56)	0.77 (0.63-0.94)	.01[a]
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)	.69
Reintervention	205 (9.84)	128 (9.82)	77 (9.87)	0.99 (0.73-1.36)	>.99
Mortality rate	35 (1.68)	21 (1.61)	14 (1.79)	0.9 (0.43-1.92)	.73
Type of moderate or severe complications					
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	1 (0.05)	26 (1.99)	13 (1.67)	1.2 (0.59-2.56)	.74
Cardiopulmonary edema	4 (0.19)	1 (0.08)	0	1.80 (0.07-44.15)	>.99
Deep vein thrombosis	45 (2.16)	3 (0.23)	1 (0.13)	1.8 (0.14-94.38)	>.99
Gastrointestinal bleeding	112 (5.37)	28 (2.15)	17 (2.18)	0.98 (0.52-1.93)	>.99
Infection (surgical site, superficial)	102 (4.89)	62 (4.75)	50 (6.41)	0.73 (0.49-1.09)	.11
Infection (surgical site, deep)	118 (5.66)	58 (4.45)	44 (5.64)	0.78 (0.51-1.19)	.25
Infection (surgical site, organ space)	30 (1.44)	68 (5.21)	50 (6.41)	0.8 (0.54-1.2)	.28
Infection (uncertain source)	82 (3.93)	13 (1)	17 (2.18)	0.45 (0.2-0.99)	.04[a]
Infection (bloodstream)	1 (0.05)	50 (3.83)	32 (4.1)	0.93 (0.58-1.52)	.82
Myocardial infarction	40 (1.92)	1 (0.08)	0	1.80 (0.07-44.15)	>.99
Pneumonia	309 (14.83)	24 (1.84)	16 (2.05)	0.9 (0.45-1.82)	.74
Paralytic ileus	16 (0.77)	174 (13.34)	135 (17.31)	0.74 (0.57-0.95)	.02[a]
Postoperative hemorrhage	3 (0.14)	9 (0.69)	7 (0.9)	0.77 (0.25-2.44)	.61
Pulmonary embolism	41 (1.97)	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)	.03[a]



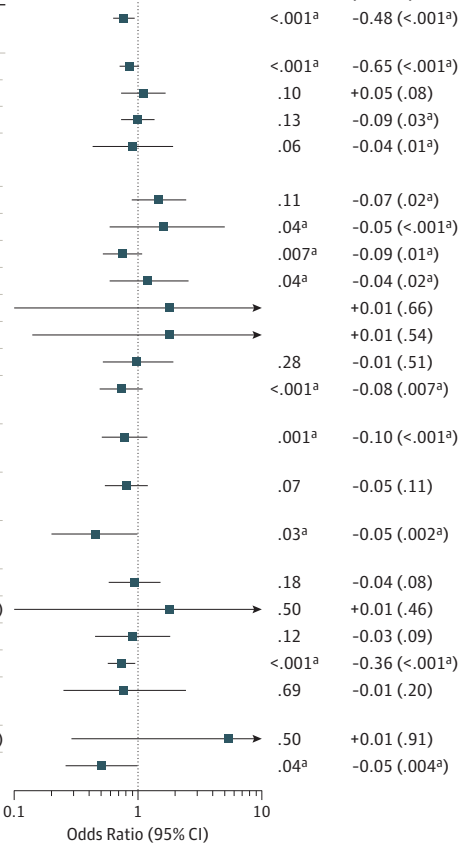
Moderate or severe complications and type of complication in all included patients and in patients with and without the Enhanced Recovery After Surgery (ERAS) protocol.

[a] Statistically significant.

(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,

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

Patients With at Least 1	Adherence >77.3% Q1 (n = 521)	Adherence >63.6% but <73.7% Q2 (n = 521)	Adherence >54.5% but <63.6% Q3 (n = 521)	Adherence <54.5% Q4 (n = 521)	Q1 vs Q4 Odds Ratio (95% CI)	Q1 vs Q4 *P* Value	Adherence Linear Fit (*P* Value)
Moderate or severe complication	84 (16.12)	147 (28.21)	163 (31.39)	183 (35.12)	0.34 (0.25-0.46)	<.001[a]	-0.48 (<.001[a])
Complication	143 (27.45)	212 (40.69)	247 (47.41)	277 (53.17)	0.33 (0.26-0.43)	<.001[a]	-0.65 (<.001[a])
Readmission	34 (6.53)	34 (6.53)	27 (5.18)	21 (4.03)	1.66 (0.95-2.9)	.10	+0.05 (.08)
Reintervention	35 (6.72)	33 (6.33)	39 (7.49)	34 (6.53)	0.63 (0.36-1.1)	.13	-0.09 (.03[a])
Mortality rate	3 (0.58)	8 (1.54)	13 (0.62)	11 (2.11)	0.27 (0.07-0.97)	.06	-0.04 (.01[a])
Type of moderate or severe complications							
Acute kidney injury	15 (2.88)	15 (2.88)	29 (5.57)	26 (4.99)	0.56 (0.29-1.08)	.11	-0.07 (.02[a])
Acute respiratory distress	0	3 (1.92)	10 (1.92)	9 (1.73)	0.05 (0.01-0.89)	.04[a]	-0.05 (<.001[a])
Anastomotic breakdown	22 (4.22)	31 (5.95)	42 (8.06)	44 (8.45)	0.48 (0.28-0.81)	.007[a]	-0.09 (.01[a])
Arrhythmia	2 (0.38)	8 (1.54)	19 (3.65)	10 (1.92)	0.2 (0.04-0.9)	.04[a]	-0.04 (.02[a])
Cardiopulmonary edema	0	1 (0.19)	0	0			+0.01 (.66)
Deep vein thrombosis	0	4 (0.77)	0	0			+0.01 (.54)
Gastrointestinal bleeding	8 (1.54)	15 (2.88)	8 (1.54)	14 (0)	0.56 (0.23-1.36)	.28	-0.01 (.51)
Infection (surgical site, superficial)	32 (6.14)	80 (15.36)	83 (15.93)	114 (21.88)	0.23 (0.15-0.35)	<.001[a]	-0.08 (.007[a])
Infection (surgical site, deep)	11 (2.11)	24 (4.61)	33 (6.33)	34 (6.53)	0.31 (0.15-0.62)	.001[a]	-0.10 (<.001[a])
Infection (surgical site, organ space)	21 (4.03)	31 (5.95)	31 (5.95)	35 (6.72)	0.58 (0.33-1.01)	.07	-0.05 (.11)
Infection (uncertain source)	3 (0.58)	5 (0.96)	10 (1.92)	12 (2.30)	0.25 (0.07-0.88)	.03[a]	-0.05 (.002[a])
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	0	0	3.01 (0.12-73.96)	.50	+0.01 (.46)
Pneumonia	4 (0.77)	11 (2.11)	14 (2.69)	11 (2.11)	0.36 (0.11-1.13)	.12	-0.03 (.09)
Paralytic ileus	32 (6.14)	80 (15.36)	83 (15.93)	114 (21.88)	0.24 (0.15-0.35)	<.001[a]	-0.36 (<.001[a])
Postoperative hemorrhage	2 (0.38)	2 (0.38)	8 (1.54)	4 (0.77)	0.5 (0.09-2.73)	.69	-0.01 (.20)
Pulmonary embolism	1 (0.19)	0	2 (0.38)	0	3.01 (0.12-73.96)	.50	+0.01 (.91)
Urinary tract infection	5 (0.95)	10 (1.92)	11 (2.11)	15 (2.88)	0.33 (0.12-0.91)	.04[a]	-0.05 (.004[a])



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

[a] Statistically significant.

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; and had a significant increase in patients in whom no antibiotic prophylaxis was performed (OR, 0.38; 95% CI, 0.14-1.03; *P* = .09) (**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%.

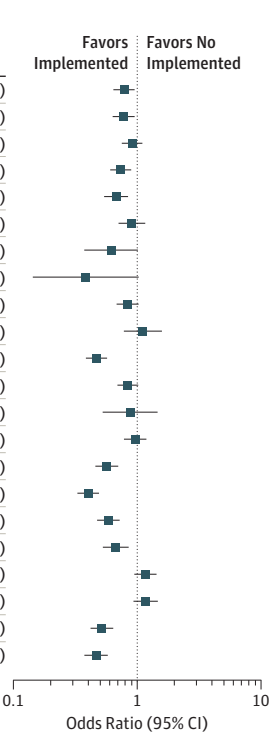
Hospital LOS was lower in the ERAS group compared with the non-ERAS group (7 [IQR, 5-12] vs 8 [IQR, 5-13] days; *P* < .001). Regarding the difference by adherence quartiles, Q1 presented a median LOS of 5 days, compared with 8 days in the lowest adherence group (eTable 3 in the Supplement). The survival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

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

Moderate to Severe Complications by ERAS Item	Implemented Event, No./ Total No. (%)	No Implemented Event, No./ Total No. (%)	Odds Ratio (95% CI)	P Value	Multivariate Estimated Outcome (P Value)
Presurgical education	352/1346 (26.15)	230/738 (31.17)	0.78 (0.64–0.95)	.02[a]	−0.05 (0.02[a])
Presurgical optimization	383/1453 (26.36)	199/631 (31.54)	0.78 (0.63–0.95)	.02[a]	−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)	.002[a]	−0.07 (0.002[a])
Carbohydrates preload	133/591 (22.50)	449/1493 (30.07)	0.67 (0.54–0.84)	<.001[a]	−0.08 (<0.001[a])
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	574/2068 (27.76)	8/16 (50.00)	0.38 (0.14–1.03)	.09	−0.04 (0.048[a])
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 (28.10)	45/173 (26.01)	1.11 (0.78–1.58)	.60	0.01 (0.56)
Laparoscopic approach	309/1371 (22.54)	273/713 (38.29)	0.47 (0.38–0.57)	<.001[a]	−0.17 (<0.001[a])
Avoid nasogastric tube	326/1231 (26.48)	256/853 (30.01)	0.84 (0.69–1.02)	.08	−0.04 (0.08)
Normothermia	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 (28.16)	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)	<.001[a]	−0.11 (<0.001[a])
Avoid urinary catheter	320/1450 (22.07)	262/634 (41.32)	0.40 (0.33–0.49)	<.001[a]	−0.20 (<0.001[a])
First 24-hour fluid balance <1500 mL	386/1544 (25.00)	196/540 (36.30)	0.59 (0.47–0.72)	<.001[a]	−0.11 (<0.001[a])
Postoperative multimodal analgesia	454/1717 (26.44)	128/367 (34.88)	0.67 (0.53–0.85)	.001[a]	−0.07 (<0.001[a])
Nutritional screening-support	406/1404 (28.92)	176/680 (25.88)	1.16 (0.95–1.43)	.16	+0.03 (0.15)
Normoglycemia	451/1572 (28.69)	131/512 (25.59)	1.17 (0.93–1.47)	.19	+0.03 (0.17)
Early mobilization	153/765 (20.00)	429/1319 (32.52)	0.51 (0.42–0.64)	<.001[a]	−0.13 (<0.001[a])
Early feeding	136/735 (18.64)	445/1349 (32.99)	0.47 (0.37–0.58)	<.001[a]	−0.15 (<0.001[a])



PONV indicates postoperative nausea and vomiting.

come 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 outcomes 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 patients[10]: less than 50% adherence, 13.1%; 75% to 90% adherence, 11.6%; and greater than 90% adherence, 9.3%. Gustafsson and colleagues[27] 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 colleagues[29] 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 the low adherence to protocols in the early postoperative phase[30] 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 studies[31] 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 goal-directed 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.

ARTICLE INFORMATION

Accepted for Publication: January 21, 2019.

Published Online: May 8, 2019. doi:10.1001/jamasurg.2019.0995

Author Affiliations: Department of Anaesthesia and Critical Care, Infanta Leonor University Hospital, Madrid, Spain (Ripollés-Melchor, Abad-Motos, Abad-Gurumeta); Universidad Complutense de Madrid, Madrid, Spain (Ripollés-Melchor, Abad-Motos, Abad-Gurumeta); Spanish Perioperative Audit and Research Network, Zaragoza, Spain (Ripollés-Melchor, Ramírez-Rodríguez, Casans-Francés, Aldecoa, Abad-Motos, Logroño-Egea, García-Erce, Ferrando-Ortolá, Suarez de la Rica, Calvo-Vecino); Grupo Español de Rehabilitación Multimodal. Enhanced Recovery After Surgery Spain Chapter, Zaragoza, Spain (Ripollés-Melchor, Ramírez-Rodríguez, Casans-Francés, Aldecoa, Abad-Motos, García-Erce, Ferrando-Ortolá, Suarez de la Rica, Cuellar-Martínez, Abad-Gurumeta, Calvo-Vecino); Department of General Surgery, Lozano Blesa University Hospital, Zaragoza, Spain (Ramírez-Rodríguez); Department of Anaesthesia and Perioperative Medicine. Lozano Blesa University Hospital, Zaragoza, Spain (Casans-Francés); Department of Anaesthesia and Perioperative Medicine, Río Hortega University Hospital, Valladolid, Spain (Aldecoa); Department

of Anaesthesia and Perioperative Medicine, Alava University Hospital, Alava, Spain (Logroño-Egea); Blood and Tissue Bank of Navarra, Servicio Navarro de Salud-Osasunbidea, Pamplona, Navarra, Spain (García-Erce); Anemia Working Group Spain, Barcelona, Spain (García-Erce); Department of Anaesthesia and Critical Care, Vall d'Hebrón University Hospital, Barcelona, Spain (Camps-Cervantes); Department of Anaesthesia and Perioperative Medicine, Hospital Clínic Universitat de Barcelona, Barcelona, Spain (Ferrando-Ortolá); Department of Anaesthesia and Critical Care, La Paz University Hospital, Madrid, Spain (Suarez de la Rica); Department of Anaesthesia and Critical Care, Hospital Universitario Central de Asturias, Oviedo, Spain (Cuellar-Martínez); Department of Anaesthesia and Perioperative Medicine, Hospital de Sant Joan Despí Moisès Broggi, Consorci Sanitari Integral, Barcelona, Spain (Marmaña-Mezquita); Department of Anaesthesia and Critical Care, Complejo Asistencial Universitario de Salamanca, Salamanca, Spain (Calvo-Vecino).

Author Contributions: Dr Ripollés-Melchor had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Concept and design: Ripollés-Melchor, Ramirez, Aldecoa, Camps-Cervantes, Marmaña-Mezquita, Abad-Gurumeta.
Acquisition, analysis, or interpretation of data: Ripollés-Melchor, Ramirez, Casans-Francés, Abad-Motos, Logroño.Ejea, García-Erce, Ferrando, Suarez-de-la-Rica, Cuellar-Martínez, Marmaña-Mezquita, Abad-Gurumeta, Calvo-Vecino.
Drafting of the manuscript: Ripollés-Melchor, Casans-Francés, Abad-Gurumeta.
Critical revision of the manuscript for important intellectual content: Ripollés-Melchor, Ramirez, Aldecoa, Abad-Motos, Logroño.Ejea, García-Erce, Camps-Cervantes, Ferrando, Suarez-de-la-Rica, Cuellar-Martínez, Marmaña-Mezquita, Abad-Gurumeta, Calvo-Vecino.
Statistical analysis: Ramirez, Casans-Francés.
Administrative, technical, or material support: Ripollés-Melchor, Abad-Motos, Marmaña-Mezquita.
Supervision: Ripollés-Melchor, Ramirez, Abad-Motos, Logroño.Ejea, García-Erce, Ferrando, Suarez-de-la-Rica, Cuellar-Martínez, Marmaña-Mezquita, Abad-Gurumeta, Calvo-Vecino.

Conflict of Interest Disclosures:
Dr Ripollés-Melchor reports personal fees from Edwards Lifesciences and Fresenius Kabi outside the submitted work. Dr García-Erce reports personal fees from Alexion, Amgen, Braun, Celgene, Ferrer, GSK, Inmucor, Jansen, Novartis, Octapharma, Sanofi, Sandoz, Terumo and Zambon; and personal fees and nonfinancial support from Vifor Pharma outside the submitted work.
Dr Suarez de la Rica reports personal fees from Baxter and MSD outside the submitted work. No other disclosures were reported.

Funding/Support: Support was provided solely from institutional and/or departmental sources. The Postoperative Outcomes within Enhanced Recovery After Surgery Protocol (POWER) study was supported by the Spanish Perioperative Audit and Research Network (REDGERM).

Role of the Funder/Sponsor: REDGERM had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Group Information: The POWER Investigators Group investigators are: *Study Chair:* Javier Ripollés-Melchor (Dept. Anesthesiology, Hospital Universitario Infanta Leonor, Madrid, GERM, RedGERM). *Study Co-Chair:* José Manuel Ramírez-Rodríguez (Dept. Surgery, Hospital Clínico Universitario Lozano Blesa, Zaragoza; GERM, RedGERM). *Steering Committee:* Ane Abad-Motos, César Aldecóa, Rubén Casans-Francés, Carlos Ferrando Ortolá, José Antonio García-Erce, Alejandro Suárez de la Rica, Manuel Ángel Gómez-Ríos, Ana Cuellar-Martínez (RedGERM), Alfredo Abad-Gurumeta, José María Calvo-Vecino. *Monitoring:* Alexia Bertone (independent). *Writing Committee:* Javier Ripollés-Melchor, José Manuel Ramírez-Rodríguez, Rubén Casans-Francés César Aldecóa, Ane Abad-Motos, Margarita Logroño-Egea, José Antonio García-Erce, Ángels Camps-Cervantes, Carlos Ferrando Ortolà, Alejandro Suárez de la Rica, Ana Cuellar-Martínez, Sandra Marmaña-Mezquita, Alfredo Abad-Gurumeta, José María Calvo-Vecino. *Complejo Asistencial Universitario de León:* Cristina Garcia Perez (principal investigator [PI]), Eva Higuera Míguelez, José Miguel Marcos Vidal, Maria Merino Garcia, Ana Belén Rubio López, Maria Esperanza Pascual Diez (Dept. of Anesthesiology). *Complejo Asistencial de Segovia:* Francisco Javier Garcia Miguel (PI) (Dept. of Anesthesiology). *Complejo Asistencial de Zamora:* Luis R. Cabezudo Sanjose (PI), Ruth Martínez Díaz, Sara Alegría Rebollo (Dept. General Surgery); José L. González Rodríguez (PI), M. Sol Vega Cruz, Gema Martínez Ragüés (Dept. Anestesia and Critical Care). *Complejo Universitario Asistencial de A Coruña:* Manuel Ángel Gómez-Ríos (PI), Eva Mosquera Rodríguez, Sara del Río Regueira (Dept. Anaesthesiology and Perioperative Medicine). *Complejo Hospitalario de Navarra, Pamplona:* Jose Ramón Perez-Valdivieso (PI), Marta Martin-Vizcaino (PI), Susana Hernandez-Garcia, Francisco Javier Yoldi-Murillo, Miguel Salvador-Bravo, Manuela Rubial-Alvare (Dept. Anaesthesiology), Fabiola Oteiza-Martinez, Enrique Balen Rivera (Dept. Surgery), Jose Antonio Garcia-Erce (Blood and Tissue Bank of Navarra), Ana Zugasti Murillo, Maria Estrella Petrina Jáuregui (Nutrition and Endocrinology Dept.). *Complejo Asistencial Universitario de Salamanca:* Domingo Bustos García (PI), José María Calvo-Vecino, María Pilar Sánchez Conde, Antonio Rodríguez Calvo, María Azucena Hernández Valero (Dept. Anesthesiology), María Angoso Clavijo, Luis Miguel González Fernández (Dept. Surgery), Miguel Angel Bravo Riaño, María Vanesa Arnes Muñoz (Dept. Nursery). *Complejo Hospitalario de Toledo:* Filadelfo Bustos Molina (PI), Daniel Paz Matín, Bárbara Vázquez Vicente, Lourdes González López, Conrado Mínguez Marín (Dept. Anesthesiology). *Complejo Hospitalario y Universitario de Pontevedra:* Susana Diz Jueguen (PI), Jaime Seoane Antelo, Julio Ballinas Miranda, Ester Carrera Dacosta, Erica Barreiro Domínguez, Alexandra Piñeiro Teijeiro, Raquel Sanchez Santos (Dept. General Surgery), Marina Varela Duran (PI), Pilar Diaz Parada (Dept. Anestesia and Critical Care). *Fundación Hospital del Espíritu Santo; Santa Coloma de Gramanet:* Aránzazu Calero-Lillo (PI), Manuel Ángel López-Lara, Salvador Muñoz-Collado, Juan Valverde-Sintas, Silvia Aznar-Puig, Daniel Troyano-Escribano (Dept. Colorectal Surgery). *Hospital 2 de Mayo, Barcelona:* Sandra Marmaña Mezquita (PI), Jesús Fernanz Antón (Dept. Anesthesia and Critical Care), Lucia Catot Alemany (Dept. General and Digestive Surgery). *Hospital Clínic Universitat de Barcelona:* Jaume Balust (PI), Marta Ubré (PI), Carlos Ferrando Ortolá, Graciela Martínez-Pallí (Dept. Anesthesiology), Ainitze Ibarzabal, Antonio M. Lacy (Dept. General and Digestive Surgery). *Hospital Clínico San Carlos, Madrid:* Rubén Sánchez Martín (PI), Karina Martins Cruz, Paula Pérez Jiménez (Dept. Anesthesiology). *Hospital Clínico Universitario Lozano Blesa, Zaragoza:* Rubén Casans-Francés (PI), Javier Longás (Dept. Anesthesiology). José Manuel Ramírez Rodríguez (PI), Manuela Elia (Dept. General and Digestive Surgery). *Hospital Clínico Universitario de Valencia:* Ana Mugarra Llopis (PI), Cristina Crisan, Estefanía Gracia Ferrándiz, Esther Romero Vargas, Marina Soro Domingo (Dept. Anesthesiology). *Hospital Clínico de Valladolid:* Rita Rodríguez Jiménez (PI, Blanca Prada Martin, Henar Muñoz Hernandez, Jose Ignacio Gómez Herrera, Sara Cocho Crespo, Sandra Fernández Caballero, Miguel Flores Crespo, Andrea Vázquez Fernández (Dept. Anesthesiology). *Hospital Comarcal de Inca:* Carlo Brugiotti (PI), Estefanía Ollé Sese (Dept. General Surgery). *Hospital Comarcal de Laredo:* Carla Rosario Houghton Acuña (PI), Marta López Doucil (Dept. Anesthesiology). *Hospital Comarcal de Vinaroz:* Ernesto-Ángel Tarazona-López (PI), Iván Bel Marcobal, Sonia González-Cogollor (Dept. Anesthesiology). *Hospital Costa del Sol, Marbella:* Manuel Llácer Pérez (PI), Alberto Arias-Romano, María Consolación Arrabal-Taborda, Mercedes Caballero-Domínguez, Rafael García-López, Julio Ontoria-Muriel, Antonio Vivó-Blasco (Dept. Anesthesiology). *Hospital Don Benito-Villanueva de la Serena:* Enrique Del Cojo Peces (PI), Jose María Tena Guerrero (PI), (Dept. Anesthesiology). *Hospital General Mateu Orfilia, Menorca:* Fernando Alcalde Matas (PI), Hernán Giordano (Dept. General Surgery). *Hospital General Universitario Gregorio Marañón, Madrid:* Jose M Perez Peña (PI), Luis Olmedilla Arnal, Pilar Benito Saz (PI), Elena Lopez Gil, Adela Ruiz Ortega, Sara Zapatero García (Dept. Anesthesiology), Emilio del Valle García (Dept. General Surgery). *Hospital General Universitario José María Morales Messeguer, Murcia:* Víctor Soria-Aledo (PI), Carmen V Pérez-Guarinos, Enrique Pellicer-Franco, Graciela Valero-Navarro, Mónica Mengual-Ballester, José Andrés García-Marín (Dept. Coloproctology). *Hospital General Universitario de Alicante:* Manuel Romero-Simó (PI), Ibán Caravaca-García (PI), Teresa Blasco-Segura, Carlos Felipe Campo-Betancourth, Rafael David Costa-Navarro (Dept. General and Digestive Tract Surgery, Colorectal Surgery Unit). *Hospital General Universitario de Castellón:* Laura Jordá Sanz (PI), María Isabel De Miguel Cabrera, José Miguel España Pamplona (Dept. Anesthesiology). *Hospital General Universitario de Ciudad Real:* Silvia Gil Trujillo (PI), Francisco Javier Redondo Calvo (PI), Víctor Baladrón Gónzalez, Remedios Moreno Ballesteros (Dept. Anesthesiology). *Hospital General Universitario de Elche:* José Luis Muñoz Rodes (PI), Elena Miranda (Dept. Anesthesiology). *Hospital General Universitario de Valencia:* Marta Roselló Chornet (PI), Lourdes Alós Zaragoza, Juan Catalá Bauset, María Ángeles Pallardo López, Noemí Almenara, Lorena Muñoz Devesa (Dept. Anesthesiology). *Hospital General de La Palma, Santa Cruz de Tenerife:* Benito Alcaide Pardo Dept. Surgery). *Hospital Nuestra Señora del Prado, Talavera de la Reina:* Pablo Gimeno Fernández (PI),

José Luis Gómez Agraz, Carla Iglesias Morales, Paola Berenice Ordoñez Enireb, Ana María Ríos Villalba, Joselvy Rodríguez Pinto, Sergio Sánchez Cortés (Dept. Anesthesiology). *Hospital Rafael Méndez, Lorca:* Mariano J. Tabares (PI), María Vicente Ruiz, Francisco González Sánchez, Antonio González Gil, Cristina García Zamora, Víctor Soriano Gimenez (Dept. Surgery). *Hospital Reina Sofía, Murcia:* José Manuel Muñoz Camarena (PI), Jorge Benavides Buleje (Dept. Surgery). *Hospital Rey Juan Carlos, Móstoles:* Juan Carlos Estupiñán-Jiménez (PI), Irene Portero-Larragueta (PI) (Dept. Anesthesiology), David Alias (Dept. Surgery). *Hospital Universitari Mútua Terrassa:* Carlos Maristany Bienert (PI), José Antonio Pardo López (Dept. Surgery). *Hospital Universitario 12 de Octubre, Madrid:* Álvaro Ramiro (PI), Pablo García, Arantza Martínez de Guereñu, Belinda Montalbán, Claudia Olea, David Benguría, Javier Silva, Adriana Calderón (Dept. 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Surgery). *Hospital Universitario Infanta Leonor, Madrid:* Ane Abad Motos (PI), Alfredo Abad Gurumeta, Norma Aracil Escoda, Eugenio Martínez-Hurtado, Beatriz Nozal Mateo, Elena Sáez Ruiz, Rut Salvachua Fernández, Javier Ripollés-Melchor (Dept. Anesthesiology), María Luisa de Fuenmayor Valera (Dept. Surgery), Elena Sánchez, Begoña Toribio (Dept. Nursery). *Hospital Universitario Insular de Gran Canaria:* Antonio Navarro-Sánchez (PI), José López-Fernández, Dácil Montesdeoca Cabrera, Francisco Javier Alcalá Serrano (Dept. Surgery). *Hospital Universitari i Politécnic La Fe, Valencia:* María José Alberola Estellés (PI), Óscar Díaz Cambronero, María Salomé Matoses Jaén (Dept. Anesthesia and Critical Care, Perioperative Medicine Research Group), María Dolores Ruiz Boluda (Dept. Anesthesia and Critical Care). *Hospital Universitario La Paz, Madrid:* Azahara-Sancho-de-Avila (PI), Sofia Diaz-Carrasco, Almudena-Martín-Martín, Alejandro Suarez-de-la-Rica, Rafael Uña Orejón, Emilio Maseda (Dept. 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Anesthesiology), Alma Blázquez Martin, Manuel Díez Alonso, Pilar Hernández Juara, José María Muguerza Huguet (Dept. Surgery). *Hospital Universitario Puerta de Hierro, Majadahonda:* María Macarena Barbero Mielgo (PI), Belén San Antonio San Román (PI), Laura Alonso Aguilar, Viktoria Molnar (Dept. Anesthesiology). *Hospital Universitario Puerta del Mar, Cádiz:* María Cristina Delgado Naviero (PI), Encarnación Meléndez Leal (Dept. Anesthesiology). *Hospital Universitario Quirón Madrid:* Virginia Cavero García (PI), África Fernández Sánchez, Daniela Andreína Cubek Quevedo, Rocío Díez Munar, Francisco Javier Blázquez Fernández de la Pradilla (Dept. Anesthesiology). *Hospital Universitario Ramón y Cajal, Madrid:* Ana B. Serrano (PI), Alberto Balvís, Alberto Berruezo, Elena Esparza, Inés de la Hoz, Ana Palavicini, Lucía Pereira, Ximena Vega, Judith de la Hoz, Gema Villanueva (Dept. Anesthesiology). *Hospital Universitario Río Hortega, Valladolid:* José-Ignacio Alonso-Fernández (PI), César Aldecoa Álvarez-Santullano (PI), Clara Bolaño Pérez, Teresa Villán González (Dept. Anesthesiology). *Hospital Universitario Sant Pau, Barcelona:* Astrid Batalla (PI), Gonzalo Azparren, Micaela Basttita, Mar Felipe, Luisa Cueva, Marta Giné, Ana M. Gómez-Caro, Inmaculada India, Santiago Piñol (Dept. Anesthesiology). *Hospital Universitario Son Espases:* Neus Esteve-Pérez (PI), Carlos Mora-Fernández, Ana Ferrer-Robles (Dept. Anesthesiology), Juan José Segura-Sampedro (PI), Natalia Alonso-Hernández (Dept. Surgery). *Hospital Universitario VallÓHebrón, Barcelona:* Angels Camps Cervantes (PI), Ivette Chocrón Da Prat, Carolina Caridad Coronado Silva, Héctor Duque Santos, Elena Esclapez Sempere, Patricia Galan Menéndez, Silvia Matarín Olmo, M. Pilar Tormos Pérez, Laura Villarino Villa (Dept. 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Surgery). *Hospital de Galdacano-Usansolo:* Aitor Landaluce Olavarria (PI), Izaskun Badiola, Marta Calvo, Unai De Andres, Vicente Portugal Porras, Bakarne Ugarte Sierra (Dept. Surgery). *Hospital de Igualada:* Ana Pedregosa Sanz (PI), Laura Perelló Cerdà (PI), Yobanys Rodríguez Téllez, Joanna Grössl Meleán (Dept. Anesthesiology), Xavier Viñas Truñén (Dept. Surgery). *Hospital de La Princesa, Madrid:* Enrique Alday Muñoz (PI) (Dept. Anesthesiology), Elena Bermejo Marcos (PI), Pedro Adolfo Alonso Casado, Francisco Alberto Gimeno Calvo, Ana Rodriguez Sánchez, Carmen Montes López (Dept. Surgery). *Hospital de Manacor:* Laura Álvarez Llano (PI) (Dept. Surgery). *Hospital de Manises:* María José Fas Vicent (PI), Juan Manuel Ortega Monzó (Dept. Anesthesiology). *Hospital de Mérida:* Gustavo Flores (PI), José Luis Tristancho (Dept. Anesthesiology). *Hospital de Sant Joan Despí Moisès Broggi, Consorci Sanitari Integral:* Sandra Marmaña Mezquita (PI), Montserrat Bayo Sans, M. Carmen Deiros Garcia, Jesús Fernanz Antón, María Lucía Gil Gómez, Lourdes Parra, Vanesa Tejedor de la Fuente (Dept. Anesthesiology), Carlos Jericó Alba (Dept. Internal Medicine), Núria Borrell Brau David Camacho Martín (Dept. Nursery), Jose Luís Ortiz de Zarate (Dept. Surgery). *Hospital de Viladecans:* Daniel López-Ruiz (PI), Vicens Rodriguez-Bustamante (Dept. Anesthesiology), M. Martinez-Vilalta (Dept. Surgery). *Hospital del Mar, Barcelona:* Daniel Amoros-Ruiz (PI), Marc Sadurni Sarda (Dept. Anesthesiology). *OSI Alto Deba:* Pablo Renedo-Corcóstegui (Dept. Anesthesiology).

Additional Contributions: Dr Julián Álvarez Escudero, president of the Spanish Society of Anesthesiology and Critical Care (SEDAR) provided noncompensated prerecruitment announcement of the study on the SEDAR website. Anestesiar (http://www.anestesiar.org) provided disinterested promotion of the study on Anestesiar website. Alejandro Bona Enguita serves as POWER website webmaster. No financial compensation was provided.

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