

Enhanced Recovery Program in High-Risk Patients Undergoing Colorectal Surgery: Results from the PeriOperative Italian Society Registry

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Abstract

Background Enhanced recovery after surgery (ERAS) pathways represent the optimal approach for patients undergoing colorectal surgery. Elderly or low physical status patients have been often excluded from ERAS pathways because considered at high risk. The aim of this study is to assess the adherence to ERAS protocol and its impact on short-term postoperative outcome in patients with different surgical risk undergoing elective colorectal resection.

Methods Prospectively collected data entered in an electronic Italian registry specifically designed for ERAS were reviewed. Patients were divided into four groups according to age (70-year-old cutoff) and preoperative physical status as measured by the ASA grade (I–II vs. III–IV). Adherence to 18 ERAS elements and postoperative outcomes were compared between groups. Regression analysis was used to identify independent factors associated with improved outcomes.

Results Eleven Italian hospitals reported data on 706 patients undergoing elective colorectal surgery within an ERAS protocol. Patients with low physical status had reduced adherence to preoperative carbohydrate loading, epidural analgesia, PONV prophylaxis, and early urinary catheter removal. No difference was found between groups for adherence to other perioperative elements. Major complications occurred in 37 (5.2 %) patients without significant differences among groups ($p = 0.384$). Median (IQR) time to readiness for discharge (TRD) was 4 (3–6) days, length of hospital stay (LOS) was 6 (4–7) days, and both were significantly shorter by only 1 day in the groups of younger patients ($p < 0.001$). At multivariate analysis, laparoscopy increased adherence to ERAS items and reduced TRD, LOS, and morbidity. A high ASA grade was significantly associated with lower adherence, whereas older age significantly prolonged TRD and LOS.

Conclusion ERAS pathway can be safely applied in elderly and low physical status patients yielding slight differences in postoperative morbidity and time to recover. Laparoscopy was independently associated with increased adherence to ERAS protocol and improved short-term postoperative outcome.

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Introduction

Elderly patients carry higher comorbidity, frailty, and social care requirements following surgery, requiring specific strategies to optimize postoperative recovery [1, 2]. Elderly should benefit more from enhanced recovery programs which have been shown to reduce perioperative stress, minimize postoperative organ dysfunction, and improve short-term outcomes following elective colorectal surgery [3–8]. However, in most RCTs comparing enhanced recovery after surgery (ERAS) pathways to traditional care, elderly represented a small proportion of the recruited patients. Doubts were raised about the ability of elderly to fully comply with ERAS protocols [9].

A recent systematic review reported that ERAS protocol can be safely applied in patients over 65 years old, allowing a reduction in postoperative morbidity and shortening length of hospital stay compared to traditional care [10]. However, few data have been reported about the compliance of elderly with ERAS components and such analyses were not adjusted for possible comorbidities. Still unanswered questions are whether elderly or high-risk patients are able to fully adhere to ERAS protocol and whether they can benefit at the same extent as younger and lower-risk patients.

The aim of this study is to assess the compliance to ERAS protocol and its impact on short-term postoperative outcome in patients with different surgical risk undergoing elective colorectal surgery.

Methods

This study is reported according to the STROBE guidelines for the conducting and reporting of observational cohort studies [11].

Study design

This is a review of a prospectively collected database including patients undergoing elective colorectal surgery in 11 Italian hospitals affiliated with the PeriOperative Italian Society (POIS) between January 2014 and June 2015. All centers treated patients within a common and extensive ERAS pathway which was defined with active contribution from the ERAS[®] Society and applied in all unselected patients. Before the start of the study, all hospitals had been involved in a pathway implementation program led by the POIS.

Data collection

All data were collected prospectively through a standardized electronic spreadsheet, which was used to record about

90 variables per patient. Every three months, the spreadsheet containing data collected in that time period was submitted to a web-based password-protected data center, managed by the POIS (www.italianperioperativeprogram.it) where all files were merged. Data collected included demographics, patient comorbidities, preoperative and intraoperative parameters, adherence to ERAS items, early recovery variables, and short-term postoperative outcomes.

Outcome measures

The primary end point of the study was time to readiness for discharge (TRD), which is defined as the time (i.e., number of postoperative days) to achieve standardized discharge criteria. TRD represents a validated measure of postoperative recovery in colorectal surgery as defined by a previous consensus [12]. Discharge criteria were the following: no clinical or laboratory evidence of postoperative complications or untreated medical problems; good pain control with oral analgesics; adequate oral food intake with no need for intravenous infusion support; recovered mobilization; and recovery of bowel function defined as passage of flatus.

Secondary end points were adherence to ERAS pathway items, postoperative morbidity, and primary length of hospital stay (LOS). Adherence was defined as the successful completion of a planned intervention (e.g., a patient expected to mobilize out of bed on POD 1 actually sits in a chair out of bed). Table 1 reports the definition of adherence to 18 ERAS elements adopted in the study. Overall adherence was calculated as the sum of elements among the 18 milestones reported to which the patients was adherent. According to previous studies, criteria to identify postoperative complications were a priori defined [13]. Postoperative complications were graded according to Clavien–Dindo classification [14]. Complications graded as III–V were considered as major. Follow-up for postoperative outcomes was carried out for 30 days after hospital discharge. Hospital readmission for any postoperative complication occurring within 30 days after discharge was also recorded.

Statistical analysis

A complete case analysis was performed, excluding patients with missing data for age, ASA score, or the outcomes of interest. Statistical analyses were performed using STATA[®] version 13.1 software (StataCorp, College Station, TX, USA). Descriptive data are reported as mean (\pm standard deviation), or median (25th percentile–75th percentile), otherwise specified. Normality was assessed by inspection of frequency histograms.

To compare outcomes between high and lower surgical risk patients, the cohort was divided into four groups according to age and preoperative physical status as measured by the

Table 1 Perioperative care ERAS interventions and definition of compliance

ERAS intervention	Definition of compliance
Preoperative	
Preadmission education	Patient received preoperative multidisciplinary counseling.
No mechanical bowel preparation	No preoperative oral solution for bowel cleansing.
Carbohydrate loading	Intake of a preoperative maltodextrin-based drink.
No long-acting sedation	No long-acting sedating medication used before surgery.
Intraoperative	
Antibiotic prophylaxis	Antibiotic prophylaxis completed prior to surgical incision
Epidural analgesia	Thoracic epidural analgesia prolonged until POD 3
Avoid fluid overload	Intraoperative fluid infusion rate <6 ml/kg/h
PONV prophylaxis	Multimodal pharmacologic prophylaxis administered
No abdominal or pelvic drainage	No resection-site drainage used
Active warming	Active patient warming during surgery
Thromboembolic prophylaxis	Thromboembolic disease prophylaxis with low-molecular-weight heparin.
Avoidance of nasogastric tube	Nasogastric tube removed at the end of surgery
Postoperative	
Opioid-sparing multimodal analgesia	Use of opioid-sparing analgesic strategies
Oral liquids on POD 0	Patient receives oral liquids on the day of surgery postoperatively
Solid diet on POD 1	Patient receives solid food starting on POD 1
Early mobilization out of bed	Patient mobilized out of bed within the first 24 h after surgery.
Early termination of IV fluid infusion	Termination of intravenous fluid infusion by POD 2.
Early removal of urinary catheter	Removal of urinary catheter by POD 1.

POD postoperative day, PONV postoperative nausea and vomiting, IV intravenous

American Society of Anesthesiologists (ASA) score, as follows. Group 1: young patients (age < 70 years) and high physical status (ASA grade I–II); group 2: elderly patients (age ≥ 70 years) and high physical status (ASA grade I–II); group 3: young patients (age < 70 years) and low physical status (ASA grade III–IV); group 4: elderly patients (age ≥ 70 years) and low physical status (ASA grade III–IV). The four groups were compared using Chi-square test for categorical data, and Mann–Whitney *U* test, ANOVA, and Kruskal–Wallis tests for continuous data, as appropriate. Univariate and multivariate linear (for continuous outcomes) or logistic (for binary outcomes) regression analyses were performed to identify factors independently associated with TRD, LOS, pathway adherence, and postoperative morbidity. As TRD and LOS were not normally distributed, these data were log-transformed.

All statistical tests were two-sided, and a “*p*” value <0.05 was considered to indicate statistical significance.

Results

Seven-hundred and twenty-two patients underwent elective colorectal surgery in eleven hospitals during the study period. Sixteen (2 %) patients were excluded from the

study because of missing data; thus, a total of 706 patients were included in the analysis.

Table 2 reports demographics, preoperative, and operative variables in the four groups. Preoperative hemoglobin levels were lower in the elderly, diabetes was more frequent in patients with a low physical status, and obesity was more common in the group of young patients with an ASA score III–IV. No difference was found in type of disease, length of preoperative stay, use of laparoscopic approach, and intraoperative blood loss.

Patients were adherent to a median 11 (9–12) ERAS elements. Median overall adherence was significantly lower in patients with low preoperative physical status ($p < 0.001$): 61 % (56–72) in group 1, 66 % (56–72) in group 2, 56 % (50–61) in group 3, and 56 % (44–67) in group 4. All patients received multidisciplinary counseling, antibiotic and antithrombotic prophylaxis, and intraoperative active warming. Table 3 reports compliance to other ERAS elements. Most patients did not receive oral bowel preparation, while only a minority had no premedication and no abdominal drain. Both low physical status patient groups had lower adherence to preoperative carbohydrate loading, postoperative nausea and vomiting prophylaxis, and thoracic epidural analgesia. Intraoperative fluid administration was higher with increasing age and ASA

Table 2 Demographics, preoperative, and intraoperative variables

	ASA I–II, <70 (n = 279)	ASA I–II, ≥70 (n = 167)	ASA III–IV, <70 (n = 98)	ASA III–IV, ≥70 (n = 162)	p value
Age (years)	58.1 (9)	77 (4.6)	62.9 (5.7)	78 (5.3)	<0.001
Male gender	146 (52 %)	81 (48 %)	59 (60 %)	99 (61 %)	0.069
ASA score	I: 77 (28 %) II: 202 (72 %)	I: 15 (9 %) II: 152 (91 %)	III: 86 (88 %) IV: 12 (12 %)	III: 143 (88 %) IV: 19 (12 %)	<0.001
Hemoglobin (g/L)	13.2 (1.8)	12.6 (1.9)	13.5 (2.1)	12.2 (2.0)	<0.001
Diabetes	18 (6 %)	22 (13 %)	18 (18 %)	34 (21 %)	<0.001
Cancer	227 (82 %)	149 (89 %)	87 (89 %)	143 (88 %)	0.054
Neoadjuvant CT–RT	22 (8 %)	7 (4 %)	9 (9 %)	10 (6 %)	0.308
Obesity	36 (13 %)	14 (8 %)	20 (20 %)	11 (7 %)	0.004
Preop stay (days)	1 (0–1)	1 (0–1)	1 (1–1)	1 (0–1)	0.475
Operative blood loss (mL)	50 (0–100)	50 (0–100)	50 (0–100)	70 (0–100)	0.773
Laparoscopy	208 (76 %)	122 (73 %)	76 (78 %)	114 (71 %)	0.597
Right colectomy	79 (28 %)	65 (39 %)	23 (24 %)	68 (42 %)	
Left colectomy	126 (45 %)	62 (37 %)	44 (45 %)	48 (30 %)	
Rectal resection	71 (25 %)	35 (21 %)	28 (29 %)	43 (27 %)	0.564
Total colectomy	3 (1 %)	5 (3 %)	3 (3 %)	3 (2 %)	
New stoma	36 (13 %)	19 (11 %)	20 (20 %)	25 (15 %)	0.191

ASA American Society of Anesthesiologists

Data are number of patients (%) or mean (standard deviation) or median (25th percentile–75th percentile)

score. Most patients had the nasogastric tube removed at the end of surgery, and the rate of tube repositioning was low in all groups. No difference among groups was found for oral feeding recovery, timing of IV fluid suspension, and removal of epidural catheter. Removal of urinary catheter occurred later in both ASA III and IV groups, and IV fluid restart was less frequent in group 1. The large majority of patients mobilized on POD 1, but time spent out of bed was significantly shorter in elderly patients.

Table 4 reports short-term postoperative outcome in the four groups. In the overall series, major morbidity was 5.2 % and mortality 0.3 %. Median TRD and LOS were 4 (3–6) and 6 (4–7) days, respectively. No difference was found in the four groups regarding mortality, major complications, respiratory complications, urinary tract infection, and reoperation rates. Anastomotic leak was significantly more common in patients with a low versus high physical status (5.8 vs. 2.7 %, $p = 0.037$). Group 1 had both the lowest transfusion and overall morbidity rates, while group 3 had the highest surgical site infection rate.

Table 5 shows the median postoperative day when patients reached standardized discharge criteria. Both TRD and LOS were a 1 day longer in the two elderly groups, whereas ASA score had no impact on TRD and LOS.

Table 6 includes the results of multivariate regression analyses for postoperative outcomes. Older age significantly prolonged TRD by 10 % and LOS by 12 %. Rectal

surgery was also associated with prolonged TRD and LOS, while laparoscopic surgery significantly reduced both TRD and LOS by 41 %. A low preoperative physical status and fashioning a new stoma were significantly associated with reduced adherence to the ERAS elements, while laparoscopy was associated with increased adherence. Elderly patients and those with a new stoma were more likely to develop a postoperative complication, while laparoscopy represented a protective factor for morbidity.

Discussion

The present study shows that elderly patients did not require a specifically tailored ERAS protocol, while adherence to ERAS elements was slightly lower in patients with a low preoperative physical status. No significant increase in postoperative mortality and major complications in the elderly and high ASA score patients was found. A 1-day difference in time to readiness for discharge and length of hospital stay was found comparing younger versus elderly, also when patients were stratified according to ASA grade. Multivariate analysis showed that the laparoscopic approach was associated with increased adherence to ERAS postoperative pathway and improved short-term postoperative outcomes.

Table 3 Adherence to ERAS elements in the four groups

	ASA I–II, <70 (n = 279)	ASA I–II, ≥70 (n = 167)	ASA III–IV, <70 (n = 98)	ASA III–IV, ≥70 (n = 162)	p value
No oral bowel prep.	236 (85 %)	151 (91 %)	74 (76 %)	138 (85 %)	0.009
CHO loading	232 (83 %)	145 (87 %)	70 (71 %)	119 (73 %)	0.001
No premedication	104 (37 %)	66 (40 %)	34 (35 %)	64 (40 %)	0.846
Epidural anesthesia	187 (67 %)	101 (61 %)	32 (33 %)	70 (43 %)	<0.001
PONV prophylaxis	240 (86 %)	147 (88 %)	40 (41 %)	99 (61 %)	<0.001
Intraop. fluids mL	1500 (1500–2450)	1600 (1050–2000)	2000 (1500–2500)	1900 (1500–2500)	0.391
mL/kg/h	6.5 (4.6–9.9)	7.2 (4.8–10.1)	8.0 (5.9–10.4)	8.9 (6.1–12.6)	<0.001
No abdominal drain	111 (40 %)	62 (37 %)	11 (11 %)	51 (31 %)	<0.001
No NGT	261 (94 %)	153 (92 %)	90 (92 %)	148 (92 %)	0.857
Reinsertion	16 (6 %)	21 (13 %)	7 (7 %)	15 (9 %)	0.085
Oral liquids POD 0	169 (61 %)	94 (56 %)	64 (65 %)	92 (57 %)	0.440
Solid food POD 1	169 (61 %)	86 (52 %)	66 (67 %)	93 (57 %)	0.069
Stop IV POD 2	199 (71 %)	117 (70 %)	78 (80 %)	108 (67 %)	0.166
IV fluids restart	20 (7 %)	24 (14 %)	15 (15 %)	20 (12 %)	0.046
Urinary catheter removal POD 1	224 (80 %)	131 (78 %)	58 (59 %)	101 (62 %)	0.001
Epidural catheter removal POD 3	150/186 (81 %)	78/100 (78 %)	21/30 (70 %)	52/79 (75 %)	0.539
Mobilization POD 1 (min)	180 (60–240)	120 (60–240)	180 (60–240)	120 (60–180)	0.006
Mobilization POD 1	247 (89 %)	159 (95 %)	85 (87 %)	140 (86 %)	0.088

Data are number of patients (%) or median (25th percentile–75th percentile)

Table 4 Postoperative morbidity and mortality in the four groups

	ASA I–II, <70 (n = 279)	ASA I–II, ≥70 (n = 167)	ASA III–IV, <70 (n = 98)	ASA III–IV, ≥70 (n = 162)	p value
30-Day mortality	1 (0 %)	0	0	1 (1 %)	0.702
Overall complications	52 (19 %)	54 (32 %)	30 (31 %)	44 (27 %)	0.006
Major complications	10 (4 %)	10 (6 %)	8 (8 %)	9 (6 %)	0.384
Surgical site complications	30 (11 %)	5 (3 %)	17 (17 %)	10 (6 %)	<0.001
Respiratory complications	5 (2 %)	3 (2 %)	3 (3 %)	3 (2 %)	0.887
Urinary tract infections	5 (2 %)	2 (1 %)	1 (1 %)	3 (2 %)	0.907
Blood transfusions ^a	13 (5 %)	20 (12 %)	10 (10 %)	22 (14 %)	0.021
Reoperation	10 (4 %)	10 (6 %)	7 (7 %)	7 (4 %)	0.458
30-Day hospital readmission	3 (1 %)	7 (4 %)	2 (2 %)	1 (1 %)	0.064

Data are number of patients (%)

^a Refers to intraoperative or postoperative blood transfusions

Advanced age and low preoperative physical status as measured by ASA score have traditionally been associated with increased mortality following colorectal surgery [15, 16]. Moreover, elderly with relevant comorbidities are expected to suffer from higher postoperative morbidity rate and longer recovery with increasing hospital and social costs.

In the last decade, ERAS pathways have been associated with a substantial reduction in both morbidity rate and LOS after elective colorectal surgery with no increase in hospital readmission rates [6–8]. In a large cohort of patients from the International Registry of ERAS Society, the increasing

compliance with the enhanced recovery program was independently associated with better outcomes following elective colorectal surgery [17]. The reduction in surgical stress by the application of ERAS protocol might be highly effective in the elderly who could benefit more from a less invasive perioperative care pathway. Unfortunately, RCTs published so far included a limited amount of elderly patients; therefore, a reliable analysis of the compliance to ERAS protocols and its impact on short-term postoperative outcomes in the elderly is difficult to derive [18–20].

In a systematic review, Bagnall and coll. reported that ERAS pathway is safe and feasible in patients over 65 and

Table 5 Meeting criteria for discharge

	ASA I–II, <70 (n = 279)	ASA I–II, ≥70 (n = 167)	ASA III–IV, <70 (n = 98)	ASA III–IV, ≥70 (n = 162)	p value
Food intake	2 (1–3)	3 (2–4)	2 (2–3)	2 (2–4)	0.071
Bowel function	3 (2–4)	3 (2–4)	3 (2–4)	3 (2–4)	0.118
Pain control with oral analgesics	3 (2–4)	3 (2–4)	3 (2–4)	3 (2–4)	0.671
Ability to mobilize and self-care	3 (2–4)	3 (2–4)	2 (1–3)	3 (2–4)	<0.001
No morbidity evidence	4 (3–5)	5 (4–6)	4 (3–5)	4 (3–6)	<0.001
Time to readiness for discharge (days)	4 (3–5)	5 (4–6)	4 (3–5)	5 (3–6)	0.006
Length of hospital stay (days)	5 (4–7)	6 (5–8)	5 (4–7)	6 (4–7)	0.003

Values are median postoperative days (25th percentile–75th percentile)

Table 6 Multivariate regression models for independent factors associated with time to readiness for discharge, overall adherence to ERAS pathway, 30-day morbidity

Outcome measure Variables	Multivariate models		
	Beta ^a /OR ^b	95 % CI	p value
Time to readiness for discharge			
Older age	0.102 ^a	0.03 to 0.15	0.004
Male gender	0.058 ^a	−0.01 to 0.11	0.086
Laparoscopic approach	−0.408 ^a	−0.48 to −0.34	<0.001
Rectal surgery	0.133 ^a	0.06 to 0.20	<0.001
Length of primary hospital stay			
Older age	0.117 ^a	0.05 to 0.18	<0.001
Laparoscopic approach	−0.405 ^a	−0.48 to −0.33	<0.001
Rectal surgery	0.157 ^a	0.09 to 0.23	<0.001
ERAS pathway overall adherence			
ASA score ≥ 3	−1.031 ^a	−1.35 to −0.71	<0.001
Laparoscopic approach	0.877 ^a	0.52 to 1.24	<0.001
New stoma formation	−1.579 ^a	−2.03 to −1.13	<0.001
30-Day morbidity			
Older age	1.489 ^b	1.06 to 2.10	0.023
Laparoscopic approach	0.590 ^b	0.41 to 0.86	0.006
New stoma formation	1.844 ^b	1.17 to 2.90	0.008

^a Beta coefficient for multivariate linear regression

^b Odds ratio for multivariate logistic regression

it improves short-term postoperative outcome when compared to conventional perioperative care [7]. However, the quality of the included studies was suboptimal, the number of elderly patients recruited was low, the compliance to the ERAS protocol was only partially reported, and the analysis was not adjusted for ASA grade, comorbidity, or type of surgery. Therefore, the authors advocated the need for further studies to clarify whether elderly can fully adhere to ERAS protocol and may derive the same benefit as younger patients. In the present study, data about adherence to ERAS items have been prospectively collected in all

patients and the analysis has been adjusted for relevant predictors such as age, ASA grade, and type of surgery. Moreover, 70 years old was adopted as threshold to identify elderly patients, as reported in a recent publication [21].

In our series, elderly patients did not show a substantially worse compliance to ERAS protocol when compared with younger. The postoperative pathway was fully applied in the elderly including the early resumption of oral feeding; therefore, no specifically tailored ERAS protocol should be designed for elderly. High ASA grade was associated with reduced use of epidural analgesia and increased intraoperative fluid infusions.

Within the ERAS pathway, neither advanced age nor high ASA grade was associated with higher postoperative mortality and major complication rates, while a 1-day-longer TRD and LOS were found in elderly compared with younger patients. Since the discharge policy was the same regardless of age, elderly required one day longer to meet discharge criteria. The mean LOS in the overall series was longer when compared to previous fast-track experiences in colorectal surgery [22, 23]; however, it could reflect a careful discharge policy to minimize the risk of hospital readmission. In fact, patients requiring hospital readmission within 30 days were less than 5 %, which is considerably lower than recently reported series in established ERAS centers where LOS is shorter [24]. The present study confirmed that laparoscopic approach had an independent role in increasing the adherence to the ERAS protocol, reducing postoperative morbidity, and shortening hospital stay [17, 25, 26].

Focusing on single postoperative complications, both pulmonary and urinary infection rates were very low and no difference between elderly and younger patients was found. This might reflect the beneficial effects of fluid restriction, adequate pain control, early mobilization, and early removal of bladder catheter [6, 27, 28]. Moreover, the early recovery of oral feeding did not increase the risk of aspiration pneumonia or anastomotic leak in elderly.

Elderly patients with an ASA grade III–IV who were potentially the subgroup with the lowest compliance and highest surgical risk had 1-day delay in bladder catheter removal and the shortest time of postoperative mobilization. Noteworthy, the lowest morbidity rate and the shortest LOS were found in the younger patients with ASA grade I–II who had the lowest intraoperative fluid infusion and perioperative blood transfusions as well they had the lowest incidence of diabetes. The highest surgical site infection rate was found in the elderly patients with ASA grade I–II who had the highest incidence of obesity and the lowest rate for epidural analgesia.

A limitation of this study is the potential selection bias, despite all centers have been invited to submit consecutive elective patients. However, the wide range of age and comorbidities of the included cohort would indicate a small likelihood of selectivity. Furthermore, only a small number of patients were excluded due to missing data. Hospitals participating in this study could differ for the stage of ERAS pathway implementation and specific ERAS elements, and this might explain the different levels of compliance to some elements of the protocol. Strengths of the present study include a specifically designed database to capture adherence to ERAS pathway elements and the use of a validated indicator of short-term recovery, such as time to readiness for discharge [12].

In conclusion, the present study shows that elderly patients did not require a specifically tailored ERAS protocol. No significant increase in postoperative mortality and major complications in the elderly and high ASA grade patients was found. A small difference between time to readiness for discharge and length of hospital stay was found comparing younger versus elderly, also when patients were stratified according to ASA grade. Multivariate analysis showed that laparoscopic approach improved both adherence to ERAS postoperative pathway and short-term postoperative outcome.

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