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Impact of laparoscopy on adherence to an enhanced recovery pathway and readiness for discharge in elective colorectal surgery: Results from the PeriOperative Italian Society registry

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Abstract

Introduction Previous studies reported that laparoscopic surgery (LPS) improved postoperative outcomes in patients undergoing colorectal surgery within an enhanced recovery program (ERP). However, the effect of minimally invasive surgery on each ERP item has not been clarified, yet. The aim of this study is to assess the impact of LPS on adherence to ERP items and recovery as measured by time to readiness for discharge (TRD).

Methods Prospectively collected data entered in an electronic Italian registry specifically designed for ERP were reviewed. Patients undergoing elective colorectal surgery were divided into three groups: successful laparoscopy, conversion to open surgery, primary open surgery. Adherence to 19 ERP elements and postoperative outcomes were compared among groups. Multivariate regression analysis was used to identify whether LPS had an independent role to improve ERP adherence and postoperative outcomes.

Results 714 patients (successful LPS 531, converted 42, open 141) underwent elective colorectal surgery within an ERP. Epidural analgesia was used in the 75.1% of open group patients versus 49.9% of LPS group patients ($p=0.012$). After surgery, oral feeding recovery, i.v. fluids suspension, removal of both urinary and epidural catheters occurred earlier in the LPS group both in the overall series and in uneventful patients only. Mean TRD and length of hospital stay were significantly shorter in the LPS group ($p<0.001$ for both). Overall morbidity rate was 18.7% in the LPS group versus 32.6% in the open group ($p=0.001$). At multivariate analysis, LPS was significantly associated to an increased adherence to postoperative ERP items, a shorter TRD, and a reduced overall morbidity, whereas rectal surgery and new stoma formation impaired postoperative recovery.

Conclusions The present study showed that a successful laparoscopic procedure had an independent role to increase the adherence to postoperative ERP and to improve short-term postoperative outcome.

Keywords Enhanced recovery pathway · Colorectal surgery · Laparoscopy · Postoperative complications · Time to readiness for discharge · Length of hospital stay

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In the last decade, enhanced recovery pathways (ERP) have been associated with a substantial reduction of postoperative complications, length of hospital stay (LOS), and hospital costs in patients undergoing elective colorectal

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surgery [1–5]. Benefits of fast-track were firstly demonstrated in open surgery [6] and laparoscopic approach was originally not included in the enhanced recovery after surgery (ERAS) pathway [7]. Further studies showed additional benefits on short-term postoperative outcome when ERP was combined with minimally invasive surgical technique [8–11]. However, the majority of published series had some limitations. In fact, ERPs were not fully applied, and compliance to the pathway was partially reported. In our recent study, focusing on the effect of ERP in elderly and high-risk patients, a multivariate analysis showed that laparoscopic surgery (LPS) was associated with an increased overall adherence to ERP [12]. However, the specific impact of LPS on each ERP element needs to be elucidated.

The aim of this study is to assess the impact of LPS on the adherence to ERP items and on time to readiness for discharge in a large series of patients undergoing elective colorectal surgery.

Methods

A retrospective analysis of prospectively collected data was carried out in an unselected series of patients undergoing elective colorectal surgery in 13 Italian hospitals affiliated with the PeriOperative Italian Society (POIS). All patients received an extensive ERP pathway, which was defined with active contribution from the ERAS® Society. Since ERAS pathway did not include laparoscopic approach, the decision to perform open or minimally invasive surgery was left to first surgeon.

Demographics, patient comorbidities, preoperative and intraoperative parameters, adherence to ERP items, early recovery variables, and short-term postoperative outcomes have been obtained from the specifically designed POIS database.

Primary endpoints of the study were adherence to ERP items and time to readiness for discharge (TRD). Adherence to each of the 19 ERP items was defined as the successful completion of a planned intervention as described in previous studies [12, 13] (Supplemental Table). Overall adherence for each patient was calculated as the total number of ERP elements to which the patient was adherent. TRD was defined from a previous consensus as the time to achieve standardized discharge criteria [14]. 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 endpoints were overall postoperative morbidity and primary LOS.

According to a previous study, criteria to identify postoperative complications were a priori defined [15]. Postoperative complications were graded according to Clavien–Dindo classification [16]. Complications graded as III to 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

Descriptive data are reported as mean (standard deviation), or median (25th–75th percentile), otherwise specified. Normality was assessed by inspection of frequency histograms.

The cohort was divided into three groups: LPS (i.e., patients in which a laparoscopic procedure was successfully completed), open (i.e., patients who underwent upfront open surgery), and conversion (i.e., patients who need a conversion from laparoscopy to open surgery). Intent-to-treat analysis (converted patients were included in the LPS group) and per protocol analysis (converted patients were included in the open group) were also carried out. A subgroup analysis comparing patients with an uneventful postoperative course versus postoperative complicated patients was also performed.

The groups were compared using Chi-square test for categorical data, and Student's *T* test, Mann–Whitney U test, ANOVA, and Kruskal–Wallis tests for continuous data, as appropriate. Multivariate regression analyses were performed to identify factors independently associated with overall morbidity, TRD, and pathway adherence. As TRD was not normally distributed, these data were log-transformed.

Statistical analyses were performed using STATA® version 13.1 software (StataCorp, College Station, TX, USA). All statistical tests were two-sided, a "*p*" value <0.05 was considered to indicate statistical significance.

Results

Seven hundred and thirty patients underwent elective colorectal surgery during the study period. Sixteen (2.2%) patients were excluded from the study because of missing data, thus a total of 714 patients were included in the analysis. LPS was successfully completed in 531 patients, 42 patients needed to be converted to open surgery, 141 patients received primary open surgery. No significant difference about the rate of patients who received LPS was found among the hospitals involved in the study.

Table 1 reports demographics, preoperative variables, and compliance for preoperative ERP items. Patients in

Table 1 Preoperative variables and compliance to ERP

	LPS ($n=531$)	Open ($n=141$)	Conversion ($n=42$)	p value
Age (years)	67.0 (11.5)	70.8 (10.7)	67.7 (12.3)	0.001
Men	288 (54.2%)	73 (51.8%)	30 (71.4%)	0.494
ASA score III–IV	192 (36.1%)	51 (36.2%)	18 (42.9%)	0.843
Hemoglobin (g / L)	13.1 (2.0)	12.3 (1.9)	13.0 (1.6)	<0.001
Diabetes	55 (10.4%)	28 (19.8%)	9 (21.4%)	0.012
Weight loss >10%	5 (0.9%)	2 (1.4%)	0	0.707
Cancer	452 (85.2%)	127 (90.0%)	38 (90.5%)	0.899
Neoadjuvant CT-RT	30 (5.8%)	15 (10.6%)	2 (4.8%)	0.132
Obesity (BMI>30)	53 (10.0%)	18 (12.8%)	8 (19.0%)	0.238
Preadmission counseling	516 (97.2%)	138 (97.9%)	40 (95.2%)	0.994
No oral bowel preparation	453 (83.5%)	117 (83.0%)	37 (88.1%)	0.968
CHO loading	424 (79.8%)	122 (86.5%)	29 (69.0%)	0.683

Data are number of patients (%) or mean (standard deviation)

ASA American Society of Anesthesiologists, *BMI* body mass index, *CHO* carbohydrate

the open group were slightly older than those in the other two groups. Diabetes was less frequent in the LPS group, while preoperative hemoglobin level was lower in the open group. No significant difference among groups was found for other variables and preoperative compliance. All patients received antibiotic and antithrombotic prophylaxis.

Table 2 reports operative variables and adherence to intraoperative ERP items. In all three groups, the majority of patients had an abdominal drain. Epidural analgesia was significantly more used in the open group, while no difference among groups was found for the amount of fluids given. Open surgery was associated with a higher transfusion rate, mainly due to lower preoperative hemoglobin level rather than higher intraoperative bleeding.

Table 3 reports adherence to seven postoperative ERP elements. Most patients had the nasogastric tube removed at the end of surgery, with a low repositioning rate. Oral feeding recovery, i.v. fluids suspension, removal of epidural, and urinary catheters occurred earlier in the LPS group. In all three groups, the vast majority of patients mobilized on postoperative day 1. Prokinetics were used in 99 (18.6%) patients of the LPS group and in 42 (22.9%) patients who had an open procedure ($p=0.207$). In the overall series, the percentage of patients who met less than four postoperative items was 14% in the LPS group, 62% in the conversion group, and 44% in the open group ($p<0.001$). Limiting the analysis to uneventful patients only, the percentage of those who met less than four postoperative items was 10% in the

Table 2 Operative variables and compliance to ERP

	LPS ($n=531$)	Open ($n=141$)	Conversion ($n=42$)	p value
Duration of surgery (min)	205 (75)	187 (70)	240 (93)	<0.0001
Operative blood loss (mL)	77 (89)	78 (110)	143 (145)	<0.0001
Transfused patients	34 (6.4%)	21 (14.9%)	3 (7.1%)	0.012
Right colectomy	168 (31.6%)	60 (42.5%)	5 (11.9%)	
Left colectomy	136 (25.6%)	20 (14.2%)	17 (40.5%)	
Transverse resection	101 (1.9%)	7 (5.0%)	2 (4.8%)	
Sigmoid resection	78 (14.7%)	14 (9.9%)	5 (11.9%)	
Rectum resection	131 (24.7%)	34 (24.1%)	13 (31.0%)	
Total colectomy	8 (1.5%)	6 (4.2%)	0	
Stoma	58 (10.9%)	35 (24.8%)	9 (21.4%)	0.001
Epidural	265 (49.9%)	106 (75.1%)	23 (54.7%)	0.022
PONV prophylaxis	362 (68.2%)	131 (92.9%)	32 (76.2%)	0.083
Intraop. warming	522 (98.3%)	137 (97.2%)	40 (95.2%)	0.914
Intraop. fluids (mL / kg / h)	8.1 (5.1)	7.7 (6.0)	8.6 (5.2)	0.572
Resection site drainage	350 (65.9%)	93 (66.0%)	35 (83.3%)	0.612

Data are number of patients (%) or mean (standard deviation)

LPS group, 53% in the conversion group, and 39% in the open group ($p < 0.001$).

Table 4 reports short-term postoperative outcome. In the overall series, postoperative mortality was 0.3%, major morbidity 5.0%, and overall morbidity 21.1%. Median TRD and LOS were 4 (3–6) and 6 (4–7) days, respectively. The open group had higher overall morbidity, while the LPS group had shorter TRD and LOS. The reduction of respiratory complications was barely significant in the LPS group. No difference among groups was found in mortality, major complications, anastomotic leak, reoperation, and readmission rates. In both intent-to-treat and per protocol analyses morbidity, TRD, and LOS were significantly reduced in the LPS group ($p < 0.001$ for all variables).

Table 5 shows that LPS allowed to meet earlier all discharge criteria. No difference was found comparing open and converted groups. Multivariate regression analyses showed that LPS had an independent role to increase adherence to postoperative enhanced recovery pathway, to

Table 3 Postoperative compliance to ERP

	LPS ($n=531$)	Open ($n=141$)	Conversion ($n=42$)	p value
No NGT	0.1 (0.4)	0.6 (1.8)	0.3 (0.8)	<0.001
Repositioning	37 (7.0%)	22 (15.6%)	3 (7.1%)	0.014
Oral liquids (day)	0.4 (0.8)	1.2 (2.1)	1.0 (1.0)	<0.001
Solid food (day)	1.5 (1.1)	2.6 (2.5)	3.4 (3.9)	<0.001
Stop i.v. fluids (day)	1.9 (1.8)	3.7 (3.6)	3.6 (2.8)	<0.001
Restart i.v. fluids	66 (12.5%)	16 (11.2%)	2 (4.8%)	0.393
Urinary catheter removal (day)	1.4 (1.7)	2.3 (2.1)	2.5 (2.4)	<0.001
Epidural catheter removal (day)	2.6 (1.1)	3.7 (1.7)	3.3 (1.1)	<0.001
Mobilization POD 1 (min out of bed)	426 (793)	454 (674)	231 (446)	0.227

Data are number of patients (%) or mean (standard deviation)

NGT nasogastric tube, *POD* postoperative day

Table 4 Postoperative outcome parameters

	LPS ($n=531$)	Open ($n=141$)	Conversion ($n=42$)	p value
30-day overall morbidity	99 (18.7%)	46 (32.6%)	6 (14.3%)	<0.001
Major complications (Dindo III–V)	29 (5.5%)	6 (4.2%)	1 (2.4%)	0.632
Anastomotic leak	17 (3.2%)	8 (5.7%)	2 (4.8%)	0.402
Abdominal abscess	8 (1.5%)	6 (4.2%)	1 (2.4%)	0.143
Wound infection	13 (2.5%)	6 (4.2%)	2 (4.8%)	0.433
Respiratory complications	8 (1.5%)	6 (4.2%)	2 (4.8%)	0.088
Urinary tract infection	6 (1.1%)	3 (2.1%)	0	0.491
Reoperation	25 (4.7%)	9 (6.4%)	1 (2.4%)	0.559
30-day mortality	1 (0.2%)	1 (0.7%)	0	0.549
Length of hospital stay (days)	5.7 (3.1)	8.7 (4.5)	9.1 (10.9)	<0.001
Time to readiness for discharge (days)	4.5 (2.5)	7.1 (4.2)	7.5 (11.1)	<0.001
Readmission	12 (2.3%)	1 (0.7%)	1 (2.4%)	0.498

Data are number of patients (%) or mean (standard deviation)

Table 5 Meeting discharge criteria

	LPS ($n=531$)	Open ($n=141$)	Conversion ($n=42$)	p value
Food intake	2.5 (1.7)	3.8 (3.5)	4.0 (3.8)	<0.001
Bowel function	2.8 (1.6)	3.4 (1.9)	4.6 (3.6)	<0.001
Pain control (oral drugs)	3.0 (1.6)	3.8 (2.1)	4.4 (3.0)	<0.001
Self-care	2.8 (2.1)	4.3 (3.0)	5.9 (11.3)	<0.001
No morbidity evidence	4.5 (2.5)	7.2 (4.1)	7.3 (11.1)	<0.001
Patient agreement	5.3 (2.8)	8.3 (4.3)	8.9 (10.9)	<0.001

Data are reported as mean (standard deviation) of postoperative day when discharge criteria were met

shorten TRD, and to reduce 30-day postoperative morbidity (Table 6).

Discussion

The present study shows that LPS had a key role to improve adherence to postoperative ERP in both the overall series and the subgroup of uneventful patients. Moreover, LPS had an independent role to reduce overall morbidity and to shorten time to readiness for discharge and length of hospital stay.

Although LPS was not included in the first ERAS pathways [7], previous studies have reported advantages when minimally invasive surgical technique has been combined with ERP. In the LAFA randomized trial, Vlug et al. reported that the combination of fast-track and LPS was the best perioperative strategy in patients undergoing elective colorectal surgery [8]. When ERP and conventional perioperative care were compared in patients receiving LPS, ERP yielded earlier recovery of gut function, lower use of opioids, and earlier discharge without reducing overall and major morbidity [17–19]. Similarly, LPS improved short-term postoperative outcome in comparison with open approach when both groups received the same enhanced recovery protocol [9–11]. In a multicenter RCT including 204 patients receiving ERP, Kennedy et al. [11] found a 2-day reduction of LOS in the LPS group; however, no other difference in short-term outcome parameters was found comparing LPS and open surgery. In a systematic review and meta-analysis including five RCTs with a total of 598 patients, Zhuang et al. [9] reported that LPS shortened LOS and reduced the number of postoperative complications, but not the number of complicated patients. In another systematic review and meta-analysis including three RCTs and six comparative controlled trials, Spanjersberg et al. [10] found that LPS shortened LOS and reduced postoperative overall morbidity. In both meta-analyses, the quality of the included studies was suboptimal, the compliance to ERP 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 LPS can facilitate a fully adherence to ERP and can furtherly improve patients' recovery.

Results from the ERAS Society® Registry showed that LPS reduced postoperative complication rate and shortened LOS; however, the specific impact of LPS on each ERAS item was not reported [20]. In the present study, LPS was associated to a better compliance to postoperative ERP in the subgroup of uneventful patients, suggesting that the impact of minimally invasive surgery was independent from the reduction of overall morbidity rate. At multivariate analysis, both rectal surgery and new stoma formation had an independent negative impact on ERP adherence, TRD, and overall morbidity, while older age only prolonged TRD.

LPS allowed to meet earlier all discharge criteria and this translated in a 3-day shorter TRD than in the open group. The same difference was found in the intent-to-treat analysis when converted patients were included in the LPS group. The mean LOS in the overall series was longer when compared to early fast-track experiences in colorectal surgery [21, 22]; however, it could reflect a more careful discharge policy to minimize the risk of hospital readmission.

Focusing on postoperative morbidity, the most relevant reduction in the LPS group occurred for pulmonary complications. This might reflect the beneficial effects of fluid restriction, adequate pain control, and early mobilization [3, 23, 24]. Both compliance to postoperative ERP and postoperative outcome parameters were comparable between converted and open group. This is consistent with previous studies that did not find either higher morbidity or longer LOS comparing converted and open surgery patients [17, 25].

Although all centers were invited to submit consecutive elective patients, a potential selection bias cannot be ruled

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	Multivariate models		
Variables	Beta[‡] / OR[†]	95% CI	*p* value
Time to readiness for discharge			
Older age	0.077[‡]	0.02–0.14	0.012
Male gender	0.061[‡]	0.00–0.12	0.046
Surgical approach			
Open	0.425[‡]	0.35–0.50	<0.001
Conversion to open	0.278[‡]	0.16–0.40	<0.001
Rectal surgery	0.129[‡]	0.06–0.20	<0.001
ERAS pathway overall adherence			
ASA score ≥3	−0.129[‡]	−0.16 to −0.10	<0.001
Surgical approach			
Open	−0.023[‡]	−0.06–0.01	0.211
Conversion to open	−0.145[‡]	−0.20–0.86	<0.001
New stoma formation	−0.161[‡]	−0.20 to −0.12	<0.001
30-day morbidity			
Surgical approach			
Open	2.053[†]	1.35–3.13	0.001
Conversion to open	0.564[†]	0.23–1.38	0.209
New stoma formation	1.980[†]	1.24–3.17	0.004

All multivariate models were adjusted for age and gender

[†]OR Odds Ratio for multivariate logistic regression

[‡]Beta coefficient for multivariate linear regression

out. However, the wide range of age and comorbidities of the included cohort would indicate a small likelihood of selectivity. Moreover, the rate of patients with ASA score III–IV was the same in LPS and open groups. A possible limitation of this study is that patients of the open surgery group were older and had a higher rate of new stoma formation which could reflect more complex rectal surgery in comparison with LPS patients. However, multivariate analysis showed that laparoscopic surgery had an independent role to improve postoperative recovery. Strengths of the present study include a specifically designed database to capture adherence to each ERP item and the individual assessment of standardized criteria to identify the time to readiness for discharge.

In conclusion, patients of the open group were older and had a higher rate of new stoma formation. However, multivariate analysis showed that LPS had an independent role to increase the adherence to postoperative enhanced recovery protocol and to improve short-term postoperative outcome. Therefore, we suggest that minimally invasive surgery should integrate an enhanced recovery pathway.

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Compliance with ethical standards

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