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ORIGINAL ARTICLE

Fast-track colorectal surgery: protocol adherence influences postoperative outcomes

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Abstract

Purpose This single-center prospective cohort study, conducted outside of a clinical trial, tried to identify the importance of each fast-track surgery procedure and protocol adherence level on clinical outcomes after colorectal surgery.

Methods From a prospectively maintained database, 606 patients who underwent elective laparoscopic or open colorectal resection within a well established fast-track surgery (FT) protocol, between 2005 and 2011, were identified. Univariate and multivariate analysis were performed to assess the relationship between each FT procedure with an adherence rate <100 % and the outcome variables (length of stay—LOS, 30-day morbidity and readmission rate). Patients were divided into four adherence level groups to FT procedures—100 %, 85–95 %,70–80 %, and <65 %. Each adherence group was compared with the other groups to evaluate differences in clinical outcome variables.

Results Group comparisons revealed that higher levels of FT protocol adherence corresponded to significantly improved LOS and morbidity rates. Readmission rates were only significantly different between the full fast-track pathway and the less implemented groups. Multivariate analyses revealed that the fast removal of bladder catheter positively influenced length of stay ($p<0.0001$) and 30-day morbidity ($p<0.0001$). Laparoscopy surgery, no drain positioning and enforced mobilization improved LOS ($p=0.027$, $p<0.0001$, $p=0.002$, respectively). Early solid feeding improved LOS ($p<0.0001$), morbidity ($p<0.0001$) and readmission rate ($p=0.011$).

Conclusion Postoperative outcomes after colorectal surgery are directly proportional to FT protocol adherence. The early removal of the bladder catheter and early postoperative solid feeding independently influenced the length of hospital stay and 30-day morbidity rates.

Keywords Fast-track colorectal surgery · Protocol adherence · Length of stay · Morbidity rate

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Introduction

Fast-track surgery (FT), also named enhanced recovery after surgery (ERAS), is defined as a multimodal pathway to reduce surgical stress using pain-free procedures with less organ dysfunction, less morbidity and improved recovery [1]. The ERAS Group recently outlined recommendations for the clinical perioperative care of patients undergoing elective colorectal surgery based on the best available evidence [2]; these recommendations include 20 standardized preoperative, intraoperative, and postoperative interventions. The safety of ERAS protocols has been demonstrated in several prospective studies [3–6], including six randomized trials [7–12]. The implementation of these recommendations in these randomized trials reduced overall complications in the ERAS group and decreased the length of hospital stay without increasing readmissions rates [13].

Unfortunately, the available data from high evidence or large cohort studies does not provide insight into the effect of protocol adherence or the implementation follow-up [13], and previous studies have demonstrated that the simple implementation of an ERAS protocol does not ensure improved results [14]. ERAS protocols are labor intensive and require a considerable allocation of resources, which complicates their implementation outside of clinical trials [15]. Two surveys have recently demonstrated that perioperative surgical routines deviate substantially from evidence based best practices [16, 17]. Another sound argument against the extremely strict structure of fast-track protocols is that not all of the fast-track elements are equally important and the exact influence of the number and type of interventions within an FT program remain unknown.

The present study, which was conducted outside of a clinical trial, tried to identify the importance of each fast-track procedure and protocol adherence level on clinical outcomes after colorectal surgery.

Methods

This research was designed as a single-center prospective cohort study. After institutional review board approval, we performed a query of a prospectively maintained divisional database to identify all patients (ASA grade I–IV) who underwent elective colorectal resection between January 1, 2005 and November 30, 2011 at our institution (a General Surgery Unit not specialized in Colorectal Surgery only at a high-volume, nonacademic tertiary care center). Exclusion criteria included patients who were medically unfit for surgery, had any non-elective admission or preoperative evidence of distant metastases, were aged less than 18 years and were pregnant. Patients who underwent operations during any time of year were considered to provide realistic results of the applicability of the fast-track protocol during routine clinical practice, and patients who underwent operations during the absence of the "Fast Track Research Team" (i.e., the authors of the present article) were not excluded.

Surgical interventions Three colorectal fellowship-trained surgeons performed or supervised open and laparoscopic procedures, and these surgeons were involved in all operations. Surgical interventions were conducted as described previously [18]. A right-sided hemicolectomy was performed through a right horizontal incision above the umbilicus (surgeon choice) in the open group. All other procedures were performed through a midline vertical incision that was extended as necessary. Laparoscopic right hemicolectomy with a total intracorporeal side-to-side anastomosis was performed using three 12-mm trocars in the left hemiabdomen. The specimen was extracted and protected by a plastic drape from a 3-cm Pfannestiel incision. A laparoscopic left hemicolectomy was executed using three 12-mm trocars in the right hemiabdomen, but we used a fourth 5-mm trocar for the anterior resection of the rectum (RAR). The colon was extracted from a 3-cm transverse laparotomy in the right abdomen. A loop ileostomy was executed at the end of low RARs using the 3-cm extraction laparotomy in the right hemiabdomen. A 19-French suction drain was positioned at the surgeon's discretion. The operating surgeon decided the suitability for laparoscopic-assisted resection on a case-by-case basis, depending on his/her practice or the patient's preference.

Fast-track surgery protocol Meetings with the entire staff were periodically conducted. We initially discussed each of the 14 elements of our FT program point-by-point, and we dedicated time to review our results every 2 weeks for the first 6 months, each month for 1 year, and subsequently every 6 months. The consent of all the professionals was obtained using this approach. A detailed protocol was prepared and distributed to all patients, department doctors (surgeons, anesthesiologists and nutritionists) and nurses to standardize the treatment as described previously [19]. ERAS interventions of our protocol included exhaustive preoperative counseling and a mechanical bowel preparation using a single dose of phosphate magnesium in patients who underwent rectal surgery. All patients were allowed clear liquids up to 4 h prior to surgery, and no premedication was administered. The nasogastric tube (NGT) was always removed at the end of surgery, and an active prevention of hypothermia was performed using a Bair Hugger and warmed intravenous fluids. Open surgery patients received a thoracic epidural catheter. All patients received 12 ml 0.5 % bupivacaine followed by 4 ml/h and an epidural dose of morphine (2 mg<70 years and 1 mg>70 years) intraoperatively. The epidural analgesia was continued during surgery and for 48 h with 0.25 % bupivacaine and morphine 0.05 mg/ml, 4 ml/h. Laparoscopic surgery patients received tramadol (300 mg), ketorolac tromethamine (90 mg) and ondansetron (10 mg) using an intravenous elastomeric infusion pump with a constant flow (2 ml/h) for 48 h. Both groups received Paracetamol (2 g) every 12 h. ketorolac Tromethamine (30 mg) was administered up to three times within 24 h when visual analog scale measurements were >50. The bladder catheter was removed from RAR patients on the second postoperative day in the absence of surgical complications. The bladder catheter was removed on the first postoperative day in all other cases. The suction drain was removed on the second postoperative day in the absence of surgical complications. Patients were mobilized to an armchair in the evening after the procedure; patients were mobilized to the bathroom and seated in an armchair for at least 4 h on the first postoperative day. Patients were allowed to drink water 3–6 h after the intervention and take a semiliquid diet on the first postoperative day. A solid diet was allowed on the second postoperative day. Patients were invited to walk out of the room and sit in an armchair for at least 8 h on the second postoperative day. Patients with respiratory illnesses or heavy smokers were provided with an incentive respiratory device during the postoperative period. An antithrombotic prophylaxis was administered twelveh prior to the intervention and continued until 30 days after discharge. An antibiotic (cephazolin 2 g and metronidazole 500 mg, i.v.) prophylaxis was administered 30 minutes prior to interventions and repeated after 3 h if necessary.

Discharge criteria Patients were dischargeable to their own home on the third postoperative day if they met the following criteria: absence of complications, taking at least three solid meals, stool canalization, autonomic mobilization and a need for only oral painkillers. All patients received clear instructions and the phone number of a doctor who was available 24 h per day. Patients who lived more than 100 km from the hospital were invited to remain near our department for at least 24 h. All patients visited the outpatient clinic after 8 days, and the histological response of their specimens was discussed. Patients were readmitted to our department in the event of fever, abdominal pain, or vomiting to study the possible presence of complications. All patients with colorectal cancer were introduced in an active multidisciplinary team conference (surgeon, oncologist, radiologist, endoscopist, nurses, and psychologist) for gastrointestinal cancer prior to the intervention, and all clinical management decisions were discussed regularly during weekly team meetings. The multidisciplinary team usually discussed the need for any adjuvant therapy 15 days after surgery, and the patients received psychological support if required. The patients were monitored for all of their other needs.

Statistical analyses Clinical outcome variables included the LOS, 30-day morbidity and readmission rates. Univariate analysis was initially performed to assess the relationship between each ERAS intervention with an adherence rate<100 % and the outcome variables. A univariate analysis was performed using the Mann–Whitney *U* test for continuous variables, and χ^2 was used for categorical variables. A multivariate analysis using binary logistic regression for categorical variables and linear regression of log transformed continuous variables was performed for all variables with a significant or near significant difference ($p<0.15$) in univariate analysis.

Adherence was calculated as the number of fulfilled interventions/14 (total number of preoperative and perioperative interventions), and patients were divided into four adherence groups—100 %, 85–95 %, 70–80 %, and <65 %. Each adherence group was compared with the other groups to evaluate differences in clinical outcome variables. Analyses were performed using the Mann–Whitney *U* test for continuous variables, and χ^2 was used for categorical variables. For all analyses, p values<0.05 were considered statistically significant, and all tests were two-sided. The results are reported as a median (range) or frequency (percent). Data were analyzed on an intention-to-treat basis. Data were tabulated in a Microsoft® Excel spreadsheet (Excel for Windows®; Microsoft Corporation, Redmond, Washington, USA) and processed using SPSS 16.0 for Windows® (SPSS, Chicago, Illinois, USA).

Measurement Two different authors independently reviewed demographics, treatment, and outcome variables for accuracy. The length of stay was defined as the number of nights spent in hospital after surgery plus the hospitalization period of patients who were readmitted within 30 days after surgery. Only morbidity in the first 30 days after surgery was considered, and this variable was usually verified in a follow-up telephone call or during outpatient clinic visits. The removal of the bladder catheter was considered fast if it occurred on postoperative day 1 for colonic surgery and postoperative day 2 for rectal surgery. Mobilization was defined as fast if the patient could remain out of bed for more than 8 h on the second postoperative day. The targets for liquid and solid diet tolerance were considered postoperative days 1 and 2, respectively. Due to the current lack of uniform consensus on the definition of conversion in laparoscopic colon surgery, we defined laparoscopic-converted colon resection as the abortion of the laparoscopic approach and the performance of a conventional abdominal incision for completion of the operation.

Results

During the study period, 606 patients who satisfied the inclusion criteria underwent elective colorectal surgery and followed the ERAS program: 153 patients underwent rectal resection and 453 patients had colonic surgery. Patient baseline characteristics and perioperative results are presented in Table 1, and postoperative results are presented in Table 2. One hundred percent compliance was registered for the majority of preoperative and intraoperative items, including preoperative counseling, preoperative feeding, bowel preparation only for extraperitoneal rectal surgery, no premedication use, no routine NG tube use, active hypothermia prevention, antithrombotic prophylaxis and antimicrobial prophylaxis; however, the absence of drain use (32.1 %) and laparoscopy/transverse incision (70.4 %) exhibited lower compliance rates. Postoperative items, such as target mobilization, liquid consumption on postoperative day 1, solid diet consumption on postoperative day 2 and early bladder catheter removal registered 68.6, 61.3, 54.1, and 72.2 % compliance, respectively. The overall median postoperative hospital stay was 6 days, and the readmission rate was 2.3 %. The median time to achieve the targeted mobilization was the second postoperative day. Liquid and solid diet tolerance occurred on the first and second postoperative days, respectively. The median time of bladder catheter removal was the second postoperative day. The postoperative complications rate in the first 30 days was 26.7 %; an 8.7 % rate of major surgical complications (3.3 % anastomotic leakages), 14.7 % rate of minor surgical complications and 8.7 % rate of non-surgical complications were registered.

Table 1 Baseline characteristics and perioperative results

	Patients (n=606)
Age (years)	70 (30–94)
Sex ratio (M/F)	357:249
ASA grade	
I	88 (14.5)
II	263 (43.4)
III	248 (40.1)
IV	7 (1.1)
BMI (kg/m^2)	
<24.9	399 (65.9)
>24.9	207 (34.1)
Comorbidity	367 (60.5)
Pulmonary	99 (18.3)
Cardiovascular	289 (47.7)
Renal	23 (3.8)
Diabetes	76 (12.5)
Liver	17 (2.8)
Cancer site	
Colon	453 (74.8)
Rectum	153 (25.2)
Pathology	
Cancer	517 (85.3)
Benign	89 (4.7)
Operations	
Right hemicolectomy	195 (32.1)
Transverse resection	12 (1.9)
Left flexure resection	9 (1.5)
Left hemicolectomy	205 (33.8)
Anterior resection	145 (23.9)
Hartmann procedure	26 (4.3)
Miles	8 (1.3)
Total colectomy	6 (1.0)
Laparoscopic operations and/or transverse incisions	427 (70.4)
Open conversion	34 (10.7)
Ileostomy	59 (9.7)
Drain positioning	471 (29)
Intraoperative complications	23 (3.8)
Spleen rupture	10 (1.5)
Other hemorrhage	8 (1.3)
No tumor finding	4 (0.7)
Colonic injury	1 (0.1)

Data are medians with ranges in parentheses for continuous variables. Data are numbers with percentages in parentheses for categorical variables

ASA American Society of Anaesthesiologists; *BMI* body mass index

Table 2 Short-term (30 days) outcomes

	Patients n=606
Postoperative stay	6 (3–56)
Readmission	14 (2.3)
Mobilization POD	2 (0–11)
First bowel movement POD	2 (0–13)
First flatus POD	2 (0–15)
First stool POD	4 (0–18)
Liquid diet toleration POD	1 (0–16)
Solid diet toleration POD	3 (0–21)
Drain removal POD	4 (0–30)
Bladder catheter removal POD	2 (0–22)
NGT tube reinsertion	60 (9.9)
Bladder catheter reinsertion	35 (5.8)
Analgesic administration (oral or IV) POD	2 (0–25)
Postoperative complications (n° of patients)	162 (26.7)
Surgical major	53 (8.7)
Surgical minor	89 (14.7)
Non surgical	72 (11.9)
Reintervention	27 (4.4)
Mortality	18 (2.9)

Data are medians with ranges in parentheses for continuous variables. Data are numbers with percentages in parentheses for categorical variables

POD postoperative day, *NGT* nasogastric tube

Influence of each ERAS intervention ERAS interventions with an adherence of 100 % were not examined. Univariate analyses revealed that LOS was highly influenced by all of the examined interventions (Table 3). The 30-day morbidity was influenced by the fast removal of bladder catheters, no drain positioning and early liquid and solid feeding. Readmission rates were only influenced by enforced postoperative solid feeding. Multivariate analyses revealed that the fast removal of bladder catheter independently influenced LOS (p<0.0001) and 30-day morbidity (p<0.0001). Laparoscopy surgery/transverse incision, no drain positioning and enforced mobilization influenced LOS (p=0.027, p<0.0001, p=0.002, respectively). Early solid feeding influenced LOS (p<0.0001), morbidity (p<0.0001) and readmission rate (p=0.011).

Influence of adherence rate Analyses demonstrated that the median length of hospital stay, 30-day morbidity rates and 30-day non-surgical morbidity rates were shorter with an increase in the number of ERAS interventions that were performed (Table 4). Group comparisons revealed that higher levels of ERAS protocol adherence corresponded to significantly improved LOS and morbidity rates. Readmission rates were only significantly different between the full fast-track pathway and the less implemented groups (70–80 % and <65 %).

Also in uncomplicated patients (Table 5) the analyses showed that higher levels of ERAS protocol adherence

Table 3 Univariate and multivariate analysis of postoperative outcomes per ERAS intervention

Evaluated intervention	Patients n=606	Length of stay	30-day morbidity	Readmissions
Laparoscopy/transverse incision				
Yes	427 (70.4)	6 (3–56)	105 (24.6)	8 (1.8)
No	179 (29.6)	9 (3–39)	57 (31.8)	6 (3.3)
p		<0.0001[a]	0.71	0.372
Use of drain				
Yes	195 (32.2)	8 (3–56)	124 (30.1)	9 (2.2)
No	411 (67.8)	5 (3–43)	38 (19.5)	5 (2.5)
p		<0.0001[a]	0.006	0.777
Early removal of bladder catheter				
Yes	441 (72.8)	6 (3–56)	92 (20.8)	11 (2.5)
No	165 (27.2)	9 (3–42)	70 (42.2)	3 (1.8)
p		<0.0001[a]	<0.0001[a]	1.000
Enforced mobilization				
Yes	416 (68.6)	6 (3–56)	103 (24.7)	8 (1.9)
No	190 (31.4)	8 (3–49)	59 (31.0)	6 (3.1)
p		<0.0001[a]	0.114	0.386
Enforced postoperative liquid feeding				
Yes	372 (61.4)	6 (3–56)	79 (21.2)	6 (1.6)
No	234 (38.6)	8 (3–43)	83 (35.4)	8 (3.4)
p		<0.0001	<0.0001	0.171
Enforced postoperative solid feeding				
Yes	322 (53.1)	5 (3–56)	60 (18.6)	2 (0.6)
No	284 (46.9)	8 (3–49)	102 (35.9)	12 (4.2)
p		<0.0001[a]	<0.0001[a]	0.005[a]

Data are medians with ranges in parentheses for continuous variables. Data are numbers with percentages in parentheses for categorical variables

$p<0.05$, statistically significant

[a]Statistically significant at multivariate analysis (look to the text for values)

corresponded to significantly improved LOS and postoperative outcomes.

Discussion

In this large single-center prospective cohort study of more than 600 patients we observed a clear relationship between the rate of adherence to the ERAS protocol after major colorectal surgery and clinical outcomes, which is similar to the conclusions of the only other similar study [20]. Higher rates of adherence corresponded to a reduction in length of hospital stay, 30-day morbidity, 30-day non-surgical morbidity and, if a full fast-track surgery pathway was followed, a reduction in readmission rates. The analysis of the uncomplicated

Table 4 Analysis of ERAS protocol adherence rate on clinical outcomes

Protocol adherence	Patients N=606	Length of stay	30-day morbidity	30-day non surgical morbidity	Readmissions
<65 %	105 (17.3)	10 (3–39)	42 (40)	15 (14.2)	4 (3.8)
70–80 %	170 (28.1)	8 (3–49)	56 (32.9)	16 (9.4)	4 (2.3)
85–95 %	223 (36.8)	6 (3–56)	50 (22.4)	14 (6.2)	6 (2.7)
100 %	108 (17.8)	4 (3–21)	14 (12.9)	6 (5.5)	0
100 % vs. 85–95 %		<0.0001	0.053	0.502	0.183
100 % vs. <65 %		<0.0001	<0.0001	0.002	0.052
100 % vs. 70–80 %		<0.0001	<0.0001	0.012	0.016
85–95 % vs. 70–80 %		<0.0001	0.022	0.024	1.000
85–95 % vs. <65 %		<0.0001	0.001	0.003	0.732
70–80 % vs. <65 %		<0.0001	0.246	0.486	0.416

Data are medians with ranges in parentheses for continuous variables. Data are numbers with percentages in parentheses for categorical variables

$p<0.05$, statistically significant

Table 5 Analysis of ERAS protocol adherence rate on clinical outcomes for patients without complications

Protocol adherence	Patients *N*=444	Length of stay	Solid diet tolerance	Mobilization	First bowel movement	First flatus	First stool
<65 %	63 (14.2)	9 (3-18)	5 (0-8)	3 (1-6)	3 (1-5)	4 (1-8)	5.5 (1-9)
70–80 %	94 (21.2)	7 (3-17)	4 (1-3)	2 (1-1)	2 (1-2)	3 (1-3)	5 (1-6)
85–95 %	173 (38.9)	5 (3-15)	2 (1-6)	1 (1-2)	1 (0-4)	2 (0-5)	4 (1-9)
100 %	114 (25.6)	4 (3-15)	2 (0-9)	1 (0-3)	1 (1-5)	2 (1-7)	3 (1-9)
100 % vs. 85–95 %		<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
100 % vs. <65 %		<0.0001	0.001	<0.0001	<0.0001	<0.0001	<0.0001
100 % vs. 70–80 %		<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	0.001
85–95 % vs. 70–80 %		<0.0001	<0.0001	0.041	0.005	<0.0001	0.028
85–95 % vs. <65 %		<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
70–80 % vs. <65 %		<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001

Data are medians with ranges in parentheses for continuous variables

$p<0.05$, statistically significant

patients (Table 5) can exclude that the non-adherence (<100 %) to the ERAS protocol (especially postoperative parameters such as not removing NGT or not tolerating solid food by the set date) was the result of complications (e.g., ileus or leak) as opposed to a cause for them or to worst outcomes.

The length of hospital stay is not a medically important outcome parameter. Therefore, the strongest argument for an independent association between overall adherence to the ERAS protocol and improved clinical outcomes supports the higher level of pathway adherence to reduce postoperative morbidity. The complexity of some ERAS programs, which can include up to 20 components, can limit their implementation [2]. Adherence to a median of 13 elements has been noted in specialized units, but just half of the ERAS pathway components have been observed in general units [21]. The adherence to a number of modalities in ERAS protocols is inconsistent and relatively low [14, 22, 23], and compliance with enhanced recovery programs remains poor [16, 24, 25]. These results confirm that the full implementation of fast-track surgery is challenging and difficult to achieve outside of clinical trials in which the selection of patients and sanitary staff is performed [15]. An ERAS program requires a dedicated multidisciplinary team with members who can abandon old paradigms and adopt new ideas. These reasons suggest that ERAS protocols are perceived as difficult to implement and enforce [14]. The present study observed optimal compliance with the pre- and intraoperative elements of the program, but protocol adherence decreased in the postoperative period, as noted previously [26]. It is not surprising that adherence to ERAS principles seemed most difficult during the immediate postoperative phase when the participation of nursing and junior medical staff is greatest and organizational changes are maximal [14]. Nursing and physician leadership are crucial elements for the initiation of an ERAS program because the identification of cultural barriers, common goal setting, careful planning and implementation, and continuous evaluation and re-education of the staff are required [20].

Randomized studies of the importance of the different ERAS components are lacking, and evaluations of the impact of each single intervention is difficult because the components influence each other and confound the interpretation [27]. The univariate analysis in this study revealed that the length of hospital stay was influenced by the majority of postoperative ERAS items, and multivariate analysis confirmed their independent influence. According to our previous study [18] and an important recent LAFA trial [28], laparoscopic surgery exerted an independent positive influence on LOS, but it failed to influence morbidity and readmission rates. However, the early removal of the bladder catheter [29] and early solid feeding [30] confirmed their independent influence on morbidity rates. These findings suggest that the combined effect of each single FT items in concert with the protocolized perioperative treatment improves outcomes. However, these postoperative variables are markers of protocol compliance and outcome. Therefore, a multivariate analysis of the outcome determinants that included these variables is likely confounded.

Several of our study results merit discussion. First, patients were assigned to open surgery or laparoscopy in an uncontrolled, nonrandomized manner, and this is a limitation. However, two authors independently obtained data to reduce the margin of error. This study was conducted at a tertiary referral center, and referral bias may limit the generalizability to smaller centers or centers without a similar level of complexity and volume of colorectal surgery. All members of our staff were well trained in the FT program, but a member of the “Fast-Track research team” (i.e. the authors of the present study) was not always present in the ward. This fact provided a realistic picture of the applicability of the fast-track protocol in routine clinical practice. Despite these potential biases, this study demonstrated clinically important results, and it is one of the largest studies to date that has quantified the impact of protocol adherence on postoperative outcomes.

In conclusion, this study demonstrated that postoperative outcomes after colorectal surgery are directly proportional to ERAS protocol adherence. The early removal of the bladder catheter and early postoperative solid feeding independently influenced the length of hospital stay and 30-day morbidity rates.

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