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ORIGINAL RESEARCH ARTICLE

Evaluation of the feasibility of an "enhanced recovery after surgery" protocol for older patients undergoing colon cancer surgery

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Abstract:

Objectives: The aim of this study was to evaluate the feasibility of a protocol for enhanced recovery after surgery (ERAS) for colon cancer in older patients. Methods: One hundred and fifty-nine patients enrolled in the ERAS group of our previous clinical study were divided according to age into an older group (n = 31; ≥80 years old) and a younger group (n = 128; <80 years old). We compared the two groups for clinical outcomes, including surgical complications, re-admission rates, and the time to discharge, based on criteria for hospital discharge. Compliance with each ERAS element was compared between groups. Results: Concomitant diseases were present in all older patients (100%), but only in 57.8% of the younger group (P < 0.0001). The preoperative risk grade according to the American Society of Anesthesiologists classification was significantly higher in the older group than in the younger group. The postoperative surgical complications and re-admission rates were not significantly different between groups. Discharge criteria were met three days after the operation. The median length of hospital stay was slightly longer in the older group (9 days, range 5-15) than in the younger group (8 days, range 4-41; P = 0.061). Compliance above 80% was observed for 13 ERAS items in the older group and 14 ERAS items in the younger group; thus, compliance with the ERAS protocol was equally feasible in both groups. Conclusions: For older patients undergoing colon cancer surgery, an ERAS protocol might be feasible with a high implementation rate of the elements in the protocol.

Keywords:

enhanced recovery after surgery, colon cancer, older patients

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Introduction

Enhanced recovery after surgery (ERAS) is an integrated, practical plan that comprises a series of items intended to promote recovery after surgery[1]. ERAS items include preoperative preparations, anesthesia, avoidance of intravenous fluid overload, early post-operative food intake, and early post-operative mobilization, etc. We previously performed a multi-institutional study to demonstrate the safety and efficacy of an ERAS protocol for patients undergoing colon cancer surgery[2]. That study gave rise to the question of whether this active peri-operative management might be equally useful for older patients, a population that has been increasing in recent years. Often, older patients have a high frequency of comorbid conditions, and they are at increased peri-operative risk. Indeed, the incidences of postoperative morbidity and mortality have been reported to increase progressively with advancing age[3]. It remains unclear whether an ERAS protocol, which requires active participation and may be perceived as quite aggressive, would also be suitable for delicate geriatric patients and whether this protocol might dispel the disadvantages of age in peri-operative settings.

Consequently, in the present study, we further analyzed our previous study by comparing the clinical outcomes between older and younger patients from the ERAS group[2].

Methods

Patients

All patients were over 20 years old with grade I or II physical status, based on The American Society of Anesthesiologists (ASA) classification. All patients had undergone elective surgery for colonic or rectosigmoid cancer, and they had participated in our previous prospective multi-institutional clinical study on ERAS, conducted from April 2011 to January 2014. Informed consent was obtained from all participating patients. The study was approved by the institutional review board at Osaka Saiseikai Senri Hospital, National Hospital Organization Osaka National Hospital, and Osaka Rosai Hospital. The above-mentioned study was conducted to compare clinical outcomes in patients who received an ERAS protocol with outcomes in patients that received conventional care. In the present study, we divided the patients in the ERAS group (n = 159) into age groups; the older group (n = 31) comprised patients ≥80 years old, and the younger group (n = 128) comprised patients <80 years old.

All operations were performed or supervised by board certified colorectal surgeons in one of the three above-mentioned hospitals during the study period. The inclusion criteria were as follows: white blood cell count ≥3000 cells/μl; platelet count ≥100,000 platelets/μl; serum aspartate aminotransferase (AST) or alanine aminotransferase (ALT) level ≤100 IU/μl; total bilirubin ≤2.0 mg/dl; and serum creatinine ≤1.5 mg/dl. Exclusion criteria were as follows: any preoperative emergency surgery or bowel obstruction; routine use of steroids; a history of cancer treatment with irradiation or chemotherapy; and previous laparotomy for any procedure other than appendectomy, oophorectomy, or cesarean section.

Table 1. Elements of the ERAS protocol.

preadmission education
No MBP for right-sided colectomy
preoperative CHL (2 h before surgery)
epidural anesthesia
intraoperative antimicrobial prophylaxis
avoidance of fluid overload (intraoperative-fluid <2000ml)
removal of NG tube upon intratracheal extubation
no drain
sitting position on the bed on the day of surgery
oral fluid intake on the day of surgery
ambulation on POD1
removal of urethral catheter on POD1
oral food intake on POD1
discontinuation of C.I.V. on POD1
use of chewing gum
oral nutrition supplement
routine postoperative laxative

ERAS: enhanced recovery after surgery; *MBP:* mechanical bowel preparation; *CHL:* carbohydrate liquid; *NG:* nasogastric; *POD1:* postoperative day 1; *C.I.V.:* continuous intravenous fluid

ERAS protocol

All patients were instructed to implement as many peri-operative routines as possible among those listed in the ERAS protocol (Table 1).

Prior to admission, patients received sufficient information on the ERAS protocol, including the discharge criteria. An isotonic, diluted elemental diet was administered about 2 h before the surgery to reduce preoperative thirst and hunger. The fluid regimens were designed to avoid intraoperative fluid overload in patients; thus, as a guide, 3 ml/kg/h was given in laparoscopic surgery and 5 ml/kg/h was given in open surgery. Intraperitoneal drains were as a rule not used. After surgery, on the same day, we took charge of removing the nasogastric tubes before intratracheal extubation; prompting the patient to assume a sitting position on the bed; and providing oral fluid intake. On the day following surgery, we also took charge of removing the urethral catheter to avoid interference with early ambulation after the operation. Mobilization was imposed on the patients by forcing them to leave the bed for several hours, starting on postoperative day 1 (POD1). When necessary, we provided proactive support with the aid of physical therapists. Oral food in-

take was started on POD1, and an oral nutrition supplement was recommended to the patients. Moreover, discontinuation of the nutrient infusion was considered for all patients on POD1.

Patient compliance for each individual ERAS element was calculated as the number of patients that complied with the element divided by total number of patients in each group. An ERAS protocol was considered accomplished when three conditions were met: (1) Food intake was initiated by the evening of POD1; (2) Intravenous fluid was discontinued on POD1; (3) Food intake was not discontinued after postoperative day 2 (POD2). The accomplishment rate was calculated as the number of patients who met these criteria divided by the total number of patients in each group.

On the other hand, patients were permitted to be discharged when they fulfilled the following criteria: (1) Pain was adequately relieved with non-opioid oral analgesia; (2) Food intake was normal and the patient had passed a bowel movement; (3) Daily life activities were recovered to the preoperative level.

Outcome measures

Outcome measures included the frequency of surgical and nonsurgical complications, categorized according to the Clavien-Dindo classification[4]. This provided the basis for calculating postoperative morbidity. Re-admission rates included incidents that occurred within 30 days of surgery. Mortality rates were based on deaths in the hospital and within 30 days after surgery. Clinical outcome measures included the day of the first flatus or stool; the time to commencing food intake; the duration of intravenous fluid requirement; the time to meeting the discharge criteria; the length of hospital stay (LOHS); the compliance rate for each element of the ERAS protocol; and the accomplishment rate for the full ERAS protocol.

Statistical analyses

Data analyses were performed with IBM SPSS version 22. Statistical comparisons of baseline characteristics of patients in each group were performed with the Student's *t*-test for age, Pearson's Chi-square test for the lesion site and stage, and Fisher's exact test for gender and concomitant diseases. All continuous data are presented as the median (range). Comparisons of clinical outcome variables and complication rates were performed with the Mann-Whitney *U*-test and Fisher's exact test, respectively. *P*-values less than 0.05 were considered significant.

Results

Patient demographics

The older group (n = 31) and younger group (n = 128) had similar gender ratios. The percentage of patients with ascending colon cancer was significantly higher in the older group than in the younger group. Stage I tumors were over-represented in the younger group, and stage II tumors were significantly over-represented in the older group. Among concomitant diseases, cardiac and vascular diseases including hypertension were more frequent in the older group than in the younger group. All the older patients (100%) had concomitant diseases and 57.8% of younger patients had concomitant diseases ($P < 0.0001$). The proportion of patients with ASA II grade was higher in the older group (12.9% for ASA I and 87.1% for ASA II) than in the younger group (45.3% for ASA I and 54.7% for ASA II; $P = 0.001$ for both; Table 2).

Clinical outcomes

There were no significant differences in clinical outcomes between groups. Laparoscopic surgery was performed in 93.5% and 97.7% of patients in the older and younger groups, respectively (Table 3). Median blood loss amounts were 0 (0-685) vs. 10 (0-1050) ml, operative times were 187 (100-327) vs. 203 (59-385) min, and intraoperative fluid administration volumes were 900 (280-1950) vs. 950 (280-2450) ml in the older and younger groups, respectively.

In both groups, oral food intake was resumed and postoperative intravenous fluids were discontinued the day after the operation. Most patients passed flatus within one day and passed stool within two days of the operation.

Discharge criteria were met three days after the operation in both groups. The median LOHS was slightly longer in the older group (9 days, range: 5-15) than in the younger group (8 days, range: 4-41), but the difference was not significant.

Complications

Postoperative surgical complications, including ileus, surgical site infection (SSI), anastomotic leaks, and anastomotic or intraperitoneal bleeding, are shown in Table 4. There were no significant differences between the older and younger groups. In total, three (9.7%) patients in the older group and 28 (21.9%) patients in the younger group had surgical complications ($P = 0.417$). Nonsurgical complications, such as respiratory, cardiovascular, hepatorenal disorders, urinary tract infection, deep vein thrombosis, and delirium, were not observed in either group. One patient with anastomotic bleeding in the older group and one patient with ileus in the younger group required re-admission within 30 days of surgery. Two patients in the younger group re-

Table 2. Baseline Characteristics of Patients in Older Group and Younger Group.

Characteristic	Older group (n = 31) Median (range) or percent (%)	Younger group (n = 128) Median (range) or percent (%)	*P*
Age, median (range)	83 (80-92)	68 (26-79)	
Gender			
Male	14 (45.1)	70 (54.7)	0.423
Female	17 (54.9)	58 (45.3)	
Site			
Cecum	5 (16.1)	23 (18.0)	1.000
Ascending	12 (38.7)	25 (19.5)	0.032
Transverse	3 (9.7)	16 (12.5)	1.000
Descending	1 (3.2)	10 (7.8)	0.693
Sigmoid	7 (22.6)	36 (28.1)	0.654
Rectosigmoid	3 (9.7)	16 (12.5)	1.000
Stage			
0	2 (6.5)	3 (2.3)	0.251
I	4 (12.9)	51 (39.8)	0.006
II	16 (51.6)	35 (27.3)	0.017
IIIa	6 (19.4)	24 (18.8)	1.000
IIIb	1 (3.2)	5 (3.9)	1.000
IV	0 (0)	4 (3.1)	1.000
unknown	0 (0)	6 (4.7)	
Concomitant disease			
Cardiac/hypertension	17 (54.8)	41 (32.0)	0.023
Respiratory	3 (9.7)	4 (3.1)	0.135
Liver	3 (9.7)	7 (5.4)	0.411
Kidney	2 (6.4)	2 (1.6)	0.171
Diabetes mellitus	3 (9.7)	18 (14.1)	0.768
Cerebral vascular	3 (9.7)	2 (1.6)	0.051
Total	31 (100)	74 (57.8)	<0.0001
ASA grade			
I	4 (12.9)	58 (45.3)	
II	27 (87.1)	70 (54.7)	0.001

ASA: American Society of Anesthesiologists

quired re-operations; one due to anastomotic leakage and the other due to a port site hernia.

Compliance

Compliance with each ERAS element in both groups is shown in Figure. 1. The ERAS protocol was well implemented in both groups. Among a total of 17 evaluated items, the compliance rate was over 80% for 13 items in the older group and for 14 items in the younger group. For two items, postoperative mobilization starting on POD1 and oral nutritional supplements, the rates of compliance were significantly lower in the older than in the younger group. The accomplishment rates for the ERAS protocol were 93.5% (29/31) in the older group and 85.9% (110/128) in the younger group. The protocol could not be accomplished by two patients in the older group due to ileus, and by 18 patients in the younger group due to ileus, anastomotic leakage, and anastomotic bleeding.

Discussion

The peri-operative strategy, ERAS, in colorectal surgery was proposed by Kehlet about 20 years ago, and currently it is practiced all over the world[5]. The traditional protocol for peri-operative care is practiced as follows: the intestinal tract is emptied with preoperative fasting; peri-operative fluid is managed with abundant intravenous fluid volume; and oral intake is resumed after the empirical confirmation of adequate intestinal peristalsis. We used to remove the urinary drainage tube following some ambulation, and we removed the peritoneal drainage tube when we were no longer concerned about postoperative bleeding and anastomotic leakage. In comparison, the ERAS protocol may be perceived as quite aggressive. It imposes a select, optimal fluid regimen, early oral feeding, exclusion of an unnecessary peritoneal drain, and urethral catheter removal on POD1 to avoid impairing independent mobility We omitted mechanical bowel preparations (MBPs) in right-sided colectomies because

Table 3. Clinical Outcomes in Patients That Followed the ERAS Protocol after Colorectal Cancer Surgery.

outcome	Older group (n = 31) Median (range) or number	Younger group (n = 128) Median (range) or number	*P*
Laparoscopic surgery / Open surgery (n)	29 / 2	125 / 3	0.251
Blood loss (ml)	0 (0-685)	10 (0-1050)	0.829
Operation time (min)	187 (100-327)	203 (59-385)	0.729
Intraoperative fluid (ml)	900 (280-1950)	950 (280-2450)	0.680
Oral food intake on POD1 (n)	29	116	0.658
Intravenous fluids discontinued on POD1 (n)	26	112	0.867
Time to first flatus (day)	1 (1-5)	1 (0-5)	0.346
Time to first stool (day)	2 (1-5)	2 (1-6)	0.856
Discharge criteria fulfilled on POD (day)	3 (2-14)	3 (2-39)	0.159
Postoperative hospital stay	9 (5-15)	8 (4-41)	0.061

ERAS: Enhanced recovery after surgery; *POD:* postoperative day

Table 4. Complications in Patients That Followed the ERAS Protocol after Colorectal Cancer Surgery.

	Older group (n = 31) n (%)	Younger group (n = 128) n (%)	*P*
Re-operation	0 (0)	2 (1.5)	1.000
Re-admission	1 (3.2)	2 (1.5)	0.481
Mortality	0 (0)	0 (0)	-
Morbidity	3 (9.7)	23 (18.0)	0.416
Ileus	2 (6.5)	7 (5.5)	0.688
Surgical site infection	0 (0)	5 (3.9)	0.584
Intraperitoneal infection	0 (0)	1 (0.7)	1.000
Anastomotic leakage	0 (0)	4 (3.1)	0.720
Anastomotic bleeding	1 (3.2)	7 (5.4)	1.000

MBPs have adverse effects due to dehydration, and they are associated with prolonged ileus after colonic surgery[6]. However, based on a risk-benefit analysis, we determined that MBPs were unavoidable in left-sided colectomies. Because solid stools often exist in the left colon, we reasoned that an MBP in left-sided colectomy would reduce the risk of anastomotic leakage and facilitate surgery on anastomoses with a circular stapler. In many cases in our study, epidural anesthesia was used to provide adequate pain relief without systemic use of opiates and to promote early return of gut function with a sympathetic block; however, this regional analgesic technique was in some institutions recently replaced with patient-controlled intravenous opioid administration[7].

In our previous study, the median LOHS was reduced by 5.5 days in the ERAS group compared with a conventional care group, without increasing the complication risk[2].

The number of older patients with colon cancer has increased, particularly in developed countries[8], and, accordingly, the number of colon cancer surgeries has also increased[9]. Older patients commonly have limited physical capacity and more comorbidities than younger patients, and thus they are at increased peri-operative risk[10]. Consequently, there is concern about the applicability of this active peri-operative management in the older population. This concern led us to compare outcomes between older and younger patients from our previous study.

Considering baseline characteristics, the site of colorectal cancer is known to be related to age; right-sided colonic cancers occur more often in older than in younger patients[3]. In the present study, we found that, apart from partial resections of the transverse colon, the older group had a higher rate of right-sided colectomies (58.0%; n = 18) than left-sided colectomies (35.5%; n = 11), but not the younger group (right: 44.4%; n = 55 vs. left: 55.6%; n = 69). Kwaan et al. reported that the surgical outcomes after colectomy for cancer were comparable in right-sided and left-sided resections, except for in the case of superficial SSI, which was less common in right-sided resections[11]. In our study, all three cases with surgical complications in the older group, despite the higher frequency of right-sided colectomies, had undergone left-sided colectomies. However, the difference was not significant. Also, the rate of overall morbidity in the younger group was similar between patients with right- and

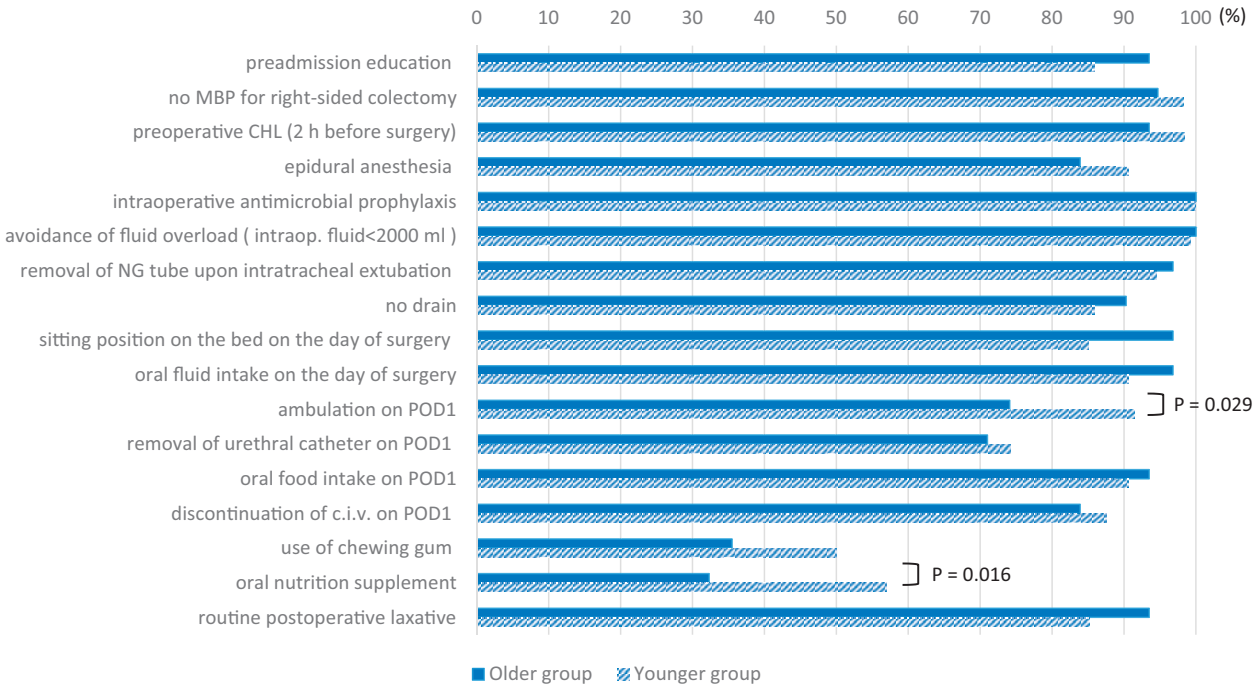

Figure 1. Compliance with each ERAS element. Compliance rates were over 80% for 13 items in the older group and for 14 items in the younger group. The rates of compliance for two items, postoperative mobilization starting on POD1 ($P = 0.029$) and oral nutritional supplements ($P = 0.016$), were significantly lower in the older group than in the younger group.
ERAS: enhanced recovery after surgery; *MBP:* mechanical bowel preparation; *CHL:* carbohydrate liquid; *NG:* nasogastric; *POD1:* postoperative day 1; *C.I.V.:* continuous intravenous fluid

left-sided colectomies (data not shown).

In addition, Frank et al. reported that locally advanced stage II colorectal tumors occurred in 34% of patients ≥80 years old compared with 28% of the younger group, but high tumor stages (III and IV) were not more frequently observed in the older group[12]. We observed a similar trend in the older patient group in our study.

As described in previous reports[3,12], patients in our study in the older group had significantly more comorbidities than in the younger group, particularly cardiac and vascular disease, including hypertension, and higher ASA grades. Despite adverse baseline conditions in the older group, we found no significant differences between the older and younger groups regarding complications, the rates of re-operation and re-admission, and bowel function recovery. Although a statistical difference (only 1 day) was not observed, the median LOHS tended to be longer in the older group than in the younger group ($P = 0.061$). These data demonstrated that the ERAS protocol was feasible for older patients.

A discrepancy existed between the time the patient was medically fit for discharge and the actual time of discharge. Most patients, and their families, were anxious to leave the hospital in the very early postoperative period. Moreover, the reimbursement system, which was based on a diagnostic procedure combination, discouraged from a hospital management point of view hospitals from substantially shortening the LOHS, which could generate vacant beds.

In a systemic review of 16 recent studies that investigated the ERAS protocol in older patients, Bagnall et al. found that ERAS could be safely applied to older patients to reduce complications and shorten the LOHS, but they suggested the necessity of further studies to evaluate adherence to ERAS protocols in older patients[13]. Consequently, in addition to safety and efficacy, we evaluated compliance with each ERAS element, and compared the results between older and younger patients from our previous study.

Few previous reports have investigated the impact of advanced age on adherence to the ERAS protocol. In a study that investigated enhanced recovery after colorectal surgery in patients below and over 65 years of age, Kisialeuski found a trend of less mobilization and longer administration of intravenous fluids for older patients[14]. Feroci found that, compared with younger patients, patients over 75 years old had longer hospital stays, higher morbidity, and higher mortality due to lower adherence to the ERAS protocol[15]. On the other hand, Slieker et al. reported that adherence to the ERAS protocol was similarly high in older and younger patients. Moreover, the older patients did not experience more complications, despite more comorbidities[16]. In their study, the median overall adherence was 78% in younger (<70 years) and 74% in older (≥70 years) patients.

In our study, the older group showed good compliance with the ERAS protocol. A compliance rate greater than 80% was observed for 13 out of 17 items in the older group, only one item less than in the younger group. To promote good compliance among older patients, all medical staff should explain the efficacy of each item, in plain language, and repeatedly, in the peri-operative period. The older group had low compliance for two items: postoperative mobilization starting on POD1; and oral nutritional supplements. In addition, older patients showed a lower rate of chewing gum than younger patients, although the difference was not significant. This trend might be related to the presence or absence of dentures. Adjusting these items to suit the specific conditions of older patients may improve compliance, which could lead to even better outcomes.

It should be noted that, in this study, no patient in the older group developed postoperative delirium, which was reported to occur in 10%-15% of older patients with colorectal cancer[17]. A bias may have been introduced with our inclusion criteria, which selected patients with a physical status of ASA grade I or II and sufficient intelligence to understand the content of this study. Therefore, the generalizability of our results might be limited to older patients in fit conditions. In practice, this protocol would be applicable to patients with laboratory data that has deviated somewhat from our inclusion criteria; however, close attention should be paid to renal dysfunction, which may worsen with relatively small amounts of intravenous fluid volumes, which are considered barely adequate in the protocol. This protocol may also be feasible and beneficial for patients with insufficient understanding, like those with dementia, about the purpose of procedures in the peri-operative period, like fasting, infusion, detention of drainage tubes, and so on.

This study demonstrated that an ERAS protocol might be feasible for older patients undergoing colon cancer surgery, and that older patients exhibit high adherence to most elements of the protocol.

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Conflicts of Interest

There are no conflicts of interest.

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