Original Article

Fast-track improves post-operative nutrition and outcomes of colorectal surgery: a single-center prospective trial in China

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Fast-track (FT) has been shown to enhance post-operative recovery. The aim of this study was to compare the effects of FT and traditional nutrition on post-operative rehabilitation, as well as evaluate the feasibility of applying FT in nutrition management of colorectal surgery. A prospective and randomized controlled trial was performed. This study included 464 patients who underwent colorectal surgery. The patients were randomly assigned into an FT group and a traditional group. The nutritional risk screening (NRS 2002) score, post-operative recovery index and surgical complications were compared between the FT and traditional groups. The NRS 2002 score in the FT group was better than the traditional group (p<0.05). Serum indicators for nutrition (HGB, ALB, A/G) and immune function (lymphocyte rate [LYMPH%], IgA, and CD4+) in the FT group were superior to those in the traditional group (p<0.05) on post-operative day 5. The first time to aerofluxus, defecation, oral intake and ambulation in the FT group was shorter when compared to the traditional group (p<0.05). The complication incidence was significantly lower in the FT group than in the traditional group (p<0.05). In particular, the occurrence rate of anastomotic leakage was higher in the traditional group than in the FT group (0.5% vs 2.8%, p<0.05). Taken together, these data suggest that FT management can improve the nutritional condition and outcomes of colorectal surgical patients.

Key Words: fast-track, nutrition, post-operative, colorectal, prospective

INTRODUCTION

Fast-track (FT) programs, also known as enhanced recovery programs,[1] are a series of managements to reduce surgical damage and complications. Based on patient physiopathological changes during the peri-operative period, the application of FT has led to shorter hospital stays and recovery times.[2,3] In recent years, FT has been widely applied in colorectal surgery patients to promote peri-operative and post-operative recovery. However, few studies have investigated the effects of FT on Chinese patients undergoing colorectal surgery.

In China, patients with colorectal cancer exhibit several unique characteristics. First, early symptoms are usually neglected by the patients. Consequently, most patients are diagnosed with advanced colorectal cancer upon their first visit to the hospital. Second, most of these patients are malnourished, and even cachectic. Advanced stages of colorectal cancer can affect post-operative recovery[4] and can lead to immune dysfunction, delays in wound healing, intestinal wall swelling and increased traumatic-stress. Therefore, we postulated that FT could help improve the nutritional status of patients following colorectal surgery. Here, we performed a prospective study to evaluate the effects of FT on the recovery and nutritional condition of patients undergoing colorectal surgery.

MATERIALS AND METHODS

Patients

Patients over 18 years old were enrolled at the Center of Gastroenterology Surgery, West China Hospital, Sichuan University. Patients were enrolled in the study if they were histologically diagnosed with colorectal cancer by enteroscope and underwent colorectal surgery. Patients with metabolic diseases, immunological diseases, ileus, enterobrosis, chronic enteritis or fever were excluded from this study. In addition, patients with severe diarrhea, pleural or abdominal fluid, liver function failure or cardiopulmonary insufficiency (ASA grade IV) were excluded.

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Table 1. Comparison of Fast-Track (FT) and traditional management protocols

	FT management	Traditional management
Pre-operative	● pre-operative assessment, counseling and FT management education ● free diet, but limitation of fibers ● fast solid food before 6 h and liquid food (without milk or beverage with fat) before2 h nil by mouth ● patients are not received mechanical bowel preparation, only oral intestinal cleaner 12 h pre-operation can be accepted, but no need of liquid stool. ● receive single-dose antibiotic prophylaxis, (1.5 g cefuroxim, Zinacef, and 0.5 g metronidazol, Clont) at induction of anaesthesia.	● nasogastric tube and urinary catheter were routine ● pre-operative fasting at least 8h ● orthograde mechanical bowel preparation
Intraoperative	● continuous epidural anesthesia ● right-sided colon resection via a T6-T7 level catheter; sigmoidectomy with a 9-T10 level catheter; rectectomy via a L1-L4 level catheter ● if chosen general anesthesia, enough dose in first injection ● minimally invasive techniques ● prevention of hypothermia, keeping the intra-operative core temperature at 36 ±0.5°C	● general anesthesia ● open surgery ● 34.7±0.6°C
Post-operative	Post-operative day 1: ● for non-hypovolemia patients, give fluid restriction to 1500 ml/kg·d ● with or without nasogastric tube in after 12 h ● remove urinary catheter for patients received colon and upper segment of rectum surgery ● without or remove drainage tube in 24h ● early oral feeding of water or tea at 12 h, use of EN emulsion (Fresubin®), 50% of total dose in 24 h (Total energy: 25-30 kcal/kg·d) ● early activities mobilized in bed at 6 h, spend 2 h out of bed on the day of surgery and 6 h per day until discharge ● regular pain control by a PCA (patient-controlled analgesia) pump 96 ml/2 ml/hr, opioid-sparing multimodal analgesia, including oral paracetamol, non-steroidal anti-inflammatory drugs, gabapentanoids ● no regular parenteral nutrition support Post-operative day 2: ● fluid restriction to 1000 ml/kg·d ● remove urinary catheter for rectal lower segment ● walk around ward in 24h~48 h, and go to bathroom ● keeping urinary catheter in for 1-3 days ● 100% total dose of EN in 48 h. (Total energy was 25-30 kcal/kg·d) Post-operative day 3-5: ● fluid restriction to 500 ml/d ● discharge with criteria: oral drug analgesia, solid diet and no fluid transfusion	● nasogastric tube remain ● nil by mouth until flatus, sips of water if bowel passage ● mobilization of the patients from post-operative day 1 ● transfuse fluid for patients about 3000 ml/kg·d until intake food ● TPN (Kabiven TM PI) by PICC or CVC, 1-2 ml/kg·d, 50% of total dose in 24h, total dose in 48h. ● oral feeding after aerocluxus, (Total energy was 25-30 kcal/kg·d) ● continuous epidural anaesthesia for 2-3 days ● consider the removal of the urinary catheter at post-operative days 3–5 on the basis of the patient's need

Measurements

Patients were randomized by a computer and assigned into a FT group, which was managed with FT programs during the peri-operative period, or a traditional group, which served as the control group. FT management included preoperative, intra-operative and post-operative protocols, while patients in the traditional group were treated by a standard established procedure (Table 1). Patients in both groups received the same amount of energy (25-30 kcal/kg·d) following surgery, but via different methods. The patients and/or the patients' family provided informed consent before the study. The study complied with the provision of the Declaration of Helsinki and was approved by the Chinese Clinical Trial Registry (ChiCTR) (registration number ChiCTR-TRC-12001948).

The treatment team and the patients' families were not blinded to the study. In addition, the data collectors were not involved in the clinical management of patients to ensure statistical validity and reliability. All surgeries were performed by the same team of surgeons, and the patients were treated and nursed by the same treatment team during the peri-operative period. Post-operative complications were based on patient complaints and clinical symptoms.

The nutrition condition of the patients was evaluated one day before surgery and 5 days following the operation based on the nutritional risk screening 2002 score (NRS2002), according to the Chinese Society of Parenteral and Enteral Nutrition (CSPEN) and the European Society of Parenteral and Enteral Nutrition (ESPEN).[5]

The first step to determine the NRS2002 score was primary screening, which consisted of four questions to demonstrate the patients' nutritional condition. The second step was final screening, which evaluated nutritional status and damage of malnutrition. The disease severity score, nutritional damage and age contributed to the total score. Disease severity was graded 1-3 based on metabolic needs and nutritional requirements. Nutritional damage was based on BMI, recent weight loss, and intake change. Patients with a total score >3 were considered to have nutritional risks and required nutritional support. The patients were assessed at post-operative days 4-6 with a questionnaire, and their height and weight were measured with a RGZ-120-RT weight/height machine (accuracy rating: 0.2 kg and 0.2 cm, respectively, Xi Heng Measuring Insturments Company, Wuxi, Jiangsu).

Serum indicators were measured 1 day before surgery and 5 days following the operation. Nutrition responses were evaluated based on the serum levels of HGB, TP, ALB, PA and A/G. Immune function was evaluated based on the Lymphocyte rate (LYMPH%) and serum levels of IgA, IgM, CD4+ and CD8. The first time to aerofluxus, defecation, oral intake and ambulation, and the length of hospital stay after surgery were recorded. Patient complications, including anastomotic bleeding, wound infection, lung infection, anastomotic leakage, ileus and uroschesis, were assessed according to the Physiological and Operative Severity Score for the Enumeration of Mortality and Morbidity (POSSUM) scale.

Statistical analysis

Data were analyzed by SPSS17.0 (SPSS *Inc* Chicago, Illinois) and expressed as mean±SD. Patient age and the rehabilitation indicators in the FT and traditional groups were compared and analyzed by Mann-Whitney U-tests (non-normal distribution). NRS2002 scores between the two groups were analyzed with the Wilcoxon test (non-normal distribution) or with Student's t-tests (normal distribution). The chi-square test or Fisher's exact test was used to evaluate frequency data. $p<0.05$ was considered statistically significant.

RESULTS

From January 2011 to February 2012, 445 of the 464 enrolled patients completed the study, including 208 patients in the FT group and 237 in the traditional group.

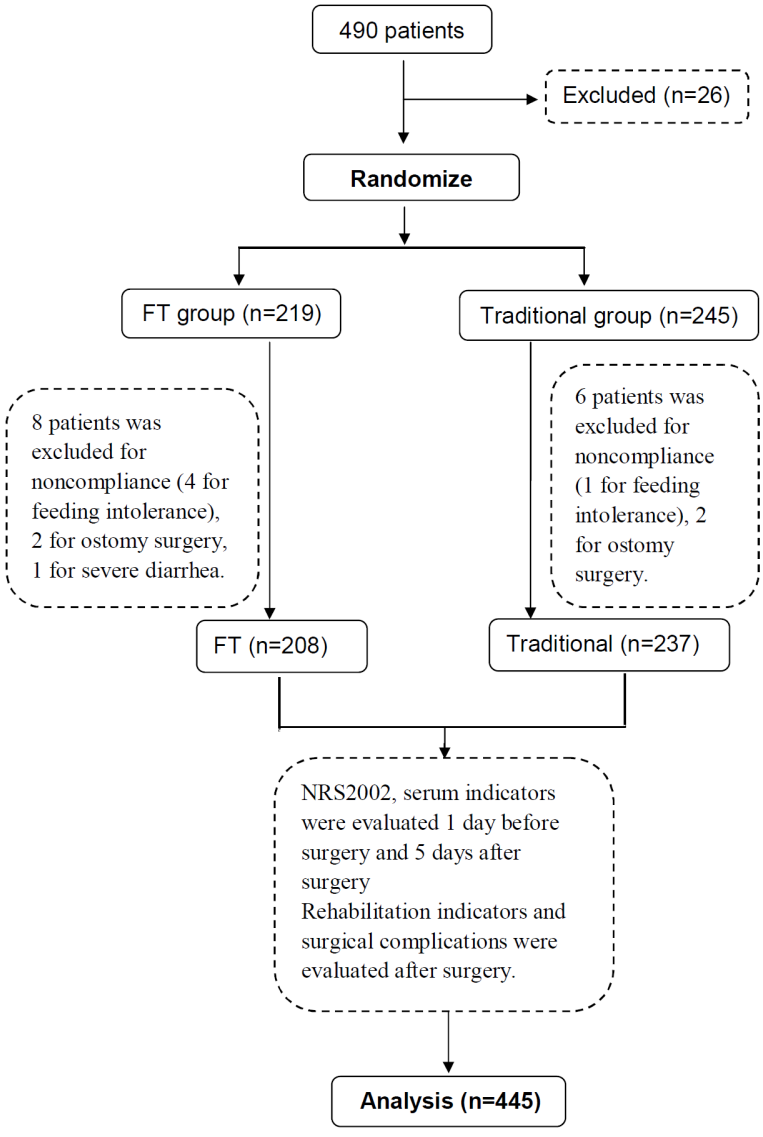

Figure 1. CONSORT diagram

Table 2. Baseline characteristics of the two groups

	Fast track group (n=208)	Tradition group (n=237)	*p*
Gender			
Men	128 (61.5%)	142 (59.9%)	0.771
Women	80 (38.5%)	95 (40.1%)	
Age (year, mean±SD)	57.7±12.0	60.0±12.8	0.453
Position			
Right hemicolon	44 (21.2%)	69 (29.1%)	0.126
Left hemicolon	36 (17.3%)	32 (13.5%)	
Rectum	128 (61.5%)	136 (57.4%)	
TNM stage			
I	60 (28.9%)	75 (31.6%)	0.522
II	148 (71.1%)	162 (68.4%)	
Degree of differentiation			
Well	9 (4.3%)	12 (5.1%)	0.530
Moderate	111 (53.4%)	137 (57.8%)	
Poor	88 (42.3%)	88 (37.1%)	
Histological type			
Adenocarcinoma	167 (80.3%)	182 (76.8%)	0.668
Mucinous adeno-carcinoma	31 (14.9%)	42 (17.7%)	
Other	10 (4.8%)	13 (5.5%)	
ASA classification			
I	21 (10.1%)	20 (8.4%)	0.819
II	142 (68.3%)	163 (68.8%)	
III	45 (21.6%)	54 (22.8%)	

Table 3-1. NRS2002 scores in the two groups

Group	N	Difference value (Postoperative day 5- Preoperative 1d)	*p*
Fast track	208	-1.44±1.03	
Tradition	237	-0.21±0.85	0.018

Table 3-2. Subgroup analysis of NRS2002 scores

Score of NRS2002	Fast track group (n=208)	Tradition track group (n=237)	*P*
0-2	121 (58.2)	107 (45.1)	0.006
≥3	87 (41.8)	130 (54.9)	

Among the patients, 4 patients underwent ostomy and one patient had severe diarrhea. Fourteen cases were excluded due to noncompliance. The study protocol is shown in the CONSORT diagram (Figure 1). The patients' baseline information, including age, gender, tumor location, tumor type, TNM stage and differential degree, are shown in Table 2.

Most of the tumors were Stage II located in the rectum, and the predominant tumor type was adenoma. In general, baseline information was not significantly different between the two groups. In contrast, the NRS2002 score in the FT group was superior to the traditional group ($p<0.05$, Table 3). In addition, the serum indicators of nutrition (HGB, ALB, A/G, PA) and immune function (LYMPH%, IgA, CD4+) in the FT group were superior to those in the traditional group ($p<0.05$, Table 4). The first time to aerofluxus, defecation, oral intake and ambulation in the FT group was shorter when compared with the traditional group ($p<0.05$). Furthermore, the length of hospitalization post-operation was longer in the traditional group than in the FT group, but the difference was not statistically significant. Finally, a lower complication rate was observed in the FT group ($p<0.05$; Table 6), and the anastomotic leakage occurrence rate was higher in the traditional group than in the FT group (0.5% vs 2.8%, $p<0.05$).

DISCUSSION

In this study, we demonstrated that patients in the FT group had significant nutritional improvement, post-operative recovery and less surgery complications compared to the traditional group. These results indicate that FT, as a peri-operative management strategy, can effectively promote the recovery of colorectal cancer patients and reduce the surgical complications following colorectal surgery.

FT is an advanced nutritional support strategy. As described by Wind,[6] FT provides appropriate preoperative nutritional support, reasonable pre-operative fasting and bowel preparation times, early post-operative enteral feeding, the application of laxatives to promote early gastrointestinal peristalsis, and shorter or no indwelling stomach tubes. The nutritional support methods in our study were based on these principles. In this study, patients in the traditional group stopped eating solid food for 12 hours and stopped drinking for 8 hours before surgery, with the aim to prevent aspiration. We suspected that conventional preoperative fasting could aggravate the psychological burden of patients and that the lack of energy consumption could produce post-operative insulin resistance. Some small-scale randomized controlled trials have also shown that eating small amounts of carbohydrates before surgery can help promote early recovery of bowel function and reduce the length of hospital stay.[7-9] Therefore, in this study, patients in the FT group underwent 6 hours of fasting and 2 hours of water deprivation before surgery. Patients in the traditional group underwent mechanical enema, while patients in the FT group received oral laxatives 12 hours before surgery. In addition, oral feeding was started following anal exhaust in the traditional group and 24 hours after operation in the FT group. The tolerance of patients for early feeding is based on the recovery of gastrointestinal function, and enteroparalysis mainly depends on the recovery of the colon's motor function.[10] In addition, early feeding or chewing movements can stimulate gastrointestinal neurohormonal release.[11] Thus, in this study, we hypothesized that early feeding would not cause enteroparalysis. More importantly, we adjusted the total energy intake and proportion of liquid infusion for patients in the FT and traditional groups in order to compare between the two groups.

The results showed that the serum indicators of the FT group were better than in the traditional group. We speculated that FT could reduce or partially block patient stress through nutritional support, as well as increase recovery time. Fast Track can effectively reduce sensory nerve input, which causes the hypothalamic paraventricular nucleus to release corticotropin hormone and activate the hypothalamic-pituitary-adrenal axis (HPA). In addition, FT can effectively slow down the speed and extent of catabolism to help reduce the stress response.

The results of this study are consistent with several previous studies. For example, our study demonstrated that patients who underwent colorectal surgery had a high nutritional risk, with 217/455 patients (48.8%) NRS2002

Table 4. Serum indicators in the two groups

	Fast track group (n=208)		Tradition group (n=237)	
	Pre-operative day 1	Post-operative day 5	Pre-operative day 1	Post-operative day 5
Nutrition indicators				
HGB (g/L)	136±11.3	133±15.7*	135±13.6	125±14.9
TP (g/L)	65.4±5.03	66.2±5.29	64.9±4.38	62.0±5.31
ALB (g/L)	43.1±5.87	41.2±5.52*	42.7±5.09	36.1±4.41
PA (mg/L)	151±48.9	227±58.4*	153±50.3	155±50.2
A/G	1.65±0.32	1.55±0.27*	1.69±0.50	1.38±0.21
Immune function indicators				
Lymphocyte rate (LYMPH%)	32.4±6.87	31.5±7.70*	31.7±7.93	20.3±6.38
IgA	2.12±0.73	2.97±0.79*	2.27±0.88	2.03±0.98
IgM	1.54±0.48	1.81±0.68	1.61±0.55	1.51±0.58
CD4+ (%)	45.3±6.76	46.1±7.16*	44.9±7.22	39.2±5.38
CD8+ (%)	29.4±6.87	31.0±5.94	28.4±6.54	31.6±6.24

Note: HGB-Haemoglobin; TP-TotalProtein; ALB-Albumin; PA-pre-albumin; A/G: Albumin/ Globulin; IgA-Immunoglobulin A; IgM-Immunoglobulin M.
* $p<0.05$ compared to Tradition group.

Table 5. Rehabilitation indicators in the two groups

	Fast track group (n=208)	Tradition group (n=237)	*p*
Rehabilitation indicators			
First aerocluxus (d, mean±SD)	3.71±1.14	4.26±1.52	0.033
First defecation (d, mean±SD)	4.84±1.59	5.83±2.05	0.011
First intake (d, mean±SD)	3.27±1.57	5.27±2.60	<0.001
First ambulation (d, mean±SD)	3.70±1.65	5.40±2.29	0.000
Length of hospitalization post-operation (d, mean±SD)	8.54±3.18	9.62±3.83	0.080

scoring over 3. This is similar to the ratio reported by Orrevall *et al* [12] In addition, patients in the FT group had an increased NRS2002 score following surgery. Guo's study showed that 39.8% of their patients had an increased score.[13]

However, there are some significant advantages of this study when compared to other studies. First, our study was prospective after randomization. We enrolled patients in strict accordance with pathological staging for colorectal cancer, as well as regulated the same surgical procedure to control bias. Second, we selected the quantitative nutrition indicator NRS2002 scale as the main index. The reliability and validity of NRS2002 has been confirmed in previous studies.[14] In addition, to assess the efficacy and safety of FT, other immunological parameters, post-operative recovery indicators and the incidence of complications were chosen as secondary indices.

Interestingly, the length of hospital stay was not different between the two groups, which is inconsistent with other studies.[15,16] This may have been due to the traditional values of our patients. Some patients in China are willing to stay in the hospital even though they have recovered. Therefore, further efforts are needed to improve the recognition of FT programs by patients and to establish a hospital-community-home nursing model to fully implement FT programs. However, when to provide nutritional support and how to control this progress need to be further investigated.

In summary, we conducted a prospective study on the post-operative nutritional risk and outcomes of patients undergoing colorectal cancer surgery. We found that the nutritional support of FT was more effective than the traditional nutritional support strategy in improving immune function, accelerating post-operative rehabilita-tion and reducing surgical complications in colorectal surgery patients. This study provides direct evidence for the efficacy and safety of FT and suggests that FT could be a valuable method for peri-operative nutritional support in colorectal surgery patients.

Limitations

There are a few limitations to this study. First, this is a single-center study, and thus multicenter studies are needed to further evaluate the effect of FT on colorectal

Table 6. Surgical complications in the two groups

	Fast track group (n=208)	Tradition group (n=237)	*p*
Complications post-operation			
Yes	18 (8.7)	47 (19.8)	0.001
No	190 (91.3)	190 (80.2)	
Anastomotic bleeding, n (%)	2 (1.0)	7 (3.0)	0.184
Anastomotic leakage, n (%)	1 (0.5)	9 (2.8)	0.023
Wound infection, n (%)	5 (2.4)	10 (4.2)	0.290
Pulmonary infection, n (%)	1 (0.5)	5 (2.1)	0.222
Intestinal obstruction, n (%)	1 (0.5)	7 (3.0)	0.072
Urinary retention, n (%)	8 (3.8)	9 (3.8)	0.979
Mortality, n (%)	0 (0)	0 (0)	/

surgery outcomes. Second, additional nutritional markers, such as transferrin, should be monitored. In addition, feeding intolerance following FT requires further investigation.

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AUTHOR DISCLOSURES

None.

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Original Article

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加速康复外科改善结直肠癌患者术后营养状态及临床效果：中国的一项单中心、前瞻性研究

研究证明加速康复外科能够促进手术患者康复。本研究的目的是比较加速康复外科流程与传统流程下的营养支持对患者术后康复的影响，同时探究加速康复外科流程在结直肠手术患者营养支持方案中的临床适用性。本研究前瞻性地纳入 464 例结直肠癌手术患者，随机分为加速康复外科流程组(FT 组)和传统流程组。终点指标为 NRS2002，术后康复指标，术后并发症。FT 组 NRS2002 评分低于传统流程组(p<0.05)；FT 组血红蛋白，白蛋白，白球比及淋巴细胞比率、IgA、CD4+等指标在术后第 5 天均优于传统流程组(p<0.05)；FT 组首次排气、排便、经口进食及下床活动时间短于传统流程组(p<0.05)；FT 组的并发症发生率低于传统流程组(p<0.05)；传统流程组的吻合口瘘发生率高于 FT 组(2.8%比上 0.5%，p<0.05) 。综上所述，本研究表明加速康复外科能够改善结直肠癌术后患者的营养状态及临床效果。

关键词：加速康复外科、营养、术后、结直肠癌、前瞻性