

Fast-track versus conventional protocol in colon cancer surgery

Kolon kanseri cerrahisi sonrası konvansiyel ve hızlı iyileşme protokolünün karşılaştırılması

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ABSTRACT

Objective: The fast-track surgery (FTS) protocol is focused on achieving a faster recovery and decreasing morbidity with the use of anesthesia, analgesia, decreased surgical stress, fluid treatment, minimally invasive surgery, nutrition, and mobilization.

Material and Methods: This study was conducted in the General Surgery Department at Vakıf Gureba Training and Research Hospital. Ninety-one operated colon cancer patients who underwent surgery between January 2005 and December 2010 were enrolled in the study. They patients were divided into two groups, the Conventional group (Group 1: 20 males, 15 females) and Fast-Track Surgery group (Group 2: 37 males, 19 females).

Results: The morbidity rate in Group 1 was 51.4% and was 25% in Group 2 (p=0.01). The mortality rate for Groups 1 and 2 were 22.9% and 3.6%, respectively (p=0.004). The mean length of stay in the hospital was 15.6±14.4 days for Group 1 and 8.4±7.1 days for Group 2.

Conclusion: The FTS protocol was researched previously by several studies, but the existence of all three parameters (morbidity, mortality, and length of stay in the hospital) in one study is rarely found. The use of the FTS protocol for patients with colon cancer can decrease the morbidity, mortality, and length of stay in the hospital.

Key Words: Colon cancer, conventional protocol, fast-track protocol

ÖZET

Amaç: Hızlı iyileşme protokolü anestezi, analjezi, azaltılmış cerrahi stres, sıvı desteği, minimal invaziv girişimler, beslenme ve mobilizasyon kullanılarak, hızlı iyileşmeye ve morbiditenin düşürülmesini sağlamaya yoğunlaşmıştır.

Gereç ve Yöntemler: Çalışmamız Vakıf Gureba Eğitim ve Araştırma Hastanesi, Genel Cerrahi bölümünde yapıldı. Ocak 2005-Aralık 2010 arası cerrahi tedavi görmüş opere 91 kolon kanseri hastası çalışmaya alındı. Doksan bir hasta konvansiyonel tedavi (Grup 1: 20 erkek, 15 kadın) ve hızlı iyileşme protokolü (Grup 2: 37 erkek, 19 kadın) uygulanan olmak üzere 2 gruba ayrıldı.

Bulgular: Morbidite oranı Grup 1'de %51,4 iken, Grup 2'de %25 bulundu (p=0,01). Mortalite oranları Grup 1 ve 2 için sırasıyla, %22,9 ve %3,6 idi (p=0,004). Grup 1 için ortalama hastanede yatış süresi 15,6±14,4 gün, Grup 2 için 8,4±7,1 gün olarak saptandı.

Sonuç: Hızlı iyileşme protokolü daha önce çeşitli çalışmalarda araştırılmış olmasına rağmen, 3 parametrenin (morbidite, mortalite ve hastanede yatış süresi) beraber olduğu tek bir çalışma nadir bulunmaktadır. Hızlı iyileşme protokolü kolon kanserli hastalarda morbidite, mortalite ve yatış süresini azaltmaktadır.

Anahtar Kelimeler: Kolon kanseri, konvansiyonel protokol, hızlı iyileşme protokolü

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INTRODUCTION

Colon cancers are widespread in the world, especially in North America, Western Europe, Scandinavia, New Zealand, and Australia, and they are responsible for 10% of all cancer deaths. Easy accessibility to health organizations, community awareness through mass media, dissemination of screening programs due to executed health policy, and improvements in technology have helped to diagnose colon cancer at an early stage (1).

In the last century, the standard treatment modalities of the postoperative colon surgery period have included long-term restrictions to enteral feeding, total parenteral nutrition, long-term nasogastric tubes, Foley catheters, and abdominal drains (2). Evidence-based studies have shown that changing these conventional approaches for patient care may hasten recovery, thereby reducing complications and the length of hospital stay. Different from the conventional approach, these multidirectional approaches are called fast-track surgery (FTS) (3-6). Fast-track surgery is focused on achieving a faster recovery and decreasing morbidity by the use of anesthesia, analgesia, decreased surgical stress, fluid treatment, minimally invasive surgery (MIS), nutrition, and mobilization (7, 8). Fast-track surgery indirectly affects health expenditures, which is a benefit; however, this is not its purpose. The primary purpose of FTS is to decrease complications and obtain better results, which indirectly leads to reduced costs (9).

In this study, the postoperative morbidity, mortality, and length of hospital stay were compared using the FTS protocol and conventional treatment.

MATERIAL AND METHODS

Ninety-one colon cancer patients operated between January 2005 and December 2010 in the General Surgery Department at the Vakif Gureba Training and Research Hospital were included in this retrospective study. The principles of FTS were identified as follows: detailed informed consent of the patients; elective respiratory physiotherapy education; preoperative high carbohydrate and protein diet; no bowel cleansing; MIS, effective treatment of postoperative symptoms such as pain, nausea, and vomiting; early removal of the nasogastric tube and Foley catheter; early mobilization; and early enteral feeding. Patients were divided into two groups, with Group 1 as the Conventional group (n=35) and Group 2 as the FTS group (n=56). The selection of patients for each group depended on the patients' decision.

This study was conducted according to the Declaration of Helsinki and local approval was obtained from Vakif Gureba Training and Research Hospital. Informed consent was obtained from all patients.

The basic principal was to educate the patients and their relatives before the operation. The education was provided through visual materials showing the formation of the disease, the treatment modalities, and the requirements to hasten the recovery period. For malnourished patients, high protein and carbohydrate content feeding solutions were given preoperatively. Patients were also advised to exercise to improve their physical conditions with activities such as walking and climbing stairs. Triflow ball exercises were performed with the help of a respiratory physiotherapist to increase the lung capacity. Without cleansing the bowel, the patients were fed fiber-free diets 3-4 days prior to surgery. All patients were instructed to continue to undergo the procedures postoperatively that they had undergone preoperatively so that all patients were included in the interactive self-treatment. Due to this, the motivation of the patients was high. A thoracic epidural catheter was inserted by the anesthesia team preoperatively to provide for postoperative pain control.

On the first postoperative day, nasogastric tubes and Foley catheters from all patients were removed, and enteral water feeding was initiated. Shortly thereafter, a nurse provided assistance with long-distance walking. Later in the day, bedside respiratory physiotherapy and a liquid diet with enteral feeding were initiated. Parenteral fluid restriction was initiated on the first postoperative day for all patients. Nausea and vomiting were controlled by intravenous drugs.

On the second postoperative day, the epidural catheters were removed and analgesia was provided by oral or intravenous nonsteroidal anti-inflammatory drugs. The previous drugs and those for nausea and vomiting were administered via the enteral route, and the high protein, no fiber, semisolid diet continued. The number of respiratory physiotherapy sessions and the walking distance were increased. The parenteral fluid replacement was stopped.

On the third postoperative day, a low fiber semisolid diet was initiated, and the drains were removed if there were no complications. On the fourth day, barring complications, a low fiber, normal diet was initiated, and the number of respiratory phys-

Table 1. Parameters in the FTS protocol

Mortality
Morbidity
Re-hospitalization
Length of stay in the hospital (first hospitalization)
Total length of stay in the hospital
Result of a minimum 30-day follow-up
Preoperative preparation
Preoperative feeding
Prebiotics
No premedication
No bowel cleansing
Fluid restriction
Perioperative high dose O ₂ administration
Prevention of hypothermia
Epidural analgesia
Minimally invasive/transverse incisions
No routine usage of a nasogastric tube
No usage of drains
Mandatory postoperative mobilization
Mandatory postoperative enteral feeding
No usage of systematic morphine
Standard laxatives
Early removal of Foley catheter

iotherapy sessions and the walking distance were increased to those of the preoperative period. Assuming no complications arose, the patients were discharged 5 days after the surgery.

Low-molecular-weight heparin was initiated in all patients on the preoperative day and was administered continuously for the first month. If there were no complications, antibiotherapy was only administered prophylactically.

The main component of MIS was laparoscopic surgery. In this procedure four or five trocars (5–15 mm) were used. Anastomoses were created extracorporeally, and the ultimate incision length was 4 cm during the MIS. For right colon tumors, right hemicolectomy was performed, for transverse colon tumors, extended right or left hemicolectomy was performed, for left colon tumors, left hemicolectomy was performed, and for sigmoid colon tumors, anterior resection was performed. The parameters used for FTS in this study are shown in Table 1.

Statistical Analysis

Data of all patients (reports for the clinical visits, type of operations, and pathological) were obtained retrospectively. The evaluation of and statistics for the dataset were calculated using Statistical Package for the Social Sciences (SPSS Inc., Chicago, IL, USA) 15.0 program. A Kolmogorov-Smirnov test with Lilliefors Significance Correction was used to measure the compliance of the data with a normal distribution. For statisti-

Table 2. The demographics of patients

		Group 1	Group 2	Total
Sex	Female	15	19	34
	Male	20	37	57
Age	Mean	71.2±9.3	54.95±4.2	61.2±13.9
Comorbidities	DM	10	5	15
	COPD	8	9	17
	HT	11	5	16
	CHF, CAD	18	12	30
	Miscellaneous	15	13	28
Stages	0	0	2	2
	1	2	24	26
	2	3	10	13
	3	15	19	34
	4	15	1	16

DM: diabetes mellitus; COPD: chronic obstructive pulmonary disease; HT: hypertension; CHF: congestive heart failure; CAD: coronary artery disease

cal comparisons, a parametric Student t-test was used for normally distributed data, and a nonparametric Mann–Whitney U-test was used for data that significantly differed from a normal distribution. For dichotomous data comparisons, Fisher's exact test and chi-square test were used. A 95% confidence interval combined with a p-value of <0.05 was considered statistically significant.

RESULTS

A total of 91 colon cancer patients (57 males and 34 females) were evaluated. Group 1 (Conventional) was composed of 20 males and 15 females and Group 2 (FTS) was composed of 37 males and 19 females. The mean age of the patients was 61.2±13.9 years (range: 25–90 years). Two (2.2%) patients were classified as stage 0, 26 (28.5%) as stage 1, 13 (14.3%) as stage 2, 34 (37.3%) as stage 3, and 16 (17.6%) as stage 4. Majority of patients had right colon tumors (32; 35.1%). Twenty-five (27.4%) patients had left and 25 (27.4%) had sigmoid colon tumors. The remaining nine (10.1%) had transverse colon tumors. The demographics of patients are shown in Table 2. During the postoperative follow-up period, 32 (35.1%) patients experienced morbidity with complications of wound infections, intra-abdominal infections, prolonged ileus, wound detachments (fascial dehiscence), and pulmonary embolism.

In Group 1, four patients had intra-abdominal infections due to anastomosis leakage, four had wound infections, three had prolonged ileus, two had wound detachments, and one had a pulmonary embolism. Of the four patients with intra-abdominal infections, one underwent reoperation for colostomy but died of intra-abdominal sepsis. Another patient died from intra-abdominal sepsis due to anastomosis leakage.

In Group 2, two patients had intra-abdominal infections due to anastomosis leakage, nine had wound infections, two had prolonged ileus, and one had a wound detachment. One patient with anastomosis leakage underwent colostomy, and the other underwent ileostomy. Both patients were discharged 20

Table 3. Distribution of morbidity

	Morbidity				Total	
	Positive n	(%)	Negative n	(%)	n	(%)
Group 1	18	51.4	17	48.6	35	100.0
Group 2	14	25	42	75	56	100.0
Total	32	35.2	59	64.8	91	100.0

Table 4. Distribution of mortality

	Mortality				Total	
	Exitus n	(%)	Alive n	(%)	n	(%)
Group 1	8	22.9	27	77.1	35	100.0
Group 2	2	3.6	54	96.4	56	100.0
Total	10	11.0	81	89.0	91	100.0

days after the operation. There was no mortality due to complications in Group 2.

The morbidity rate in Groups 1 and 2 were 51.4% and 25%, respectively (Table 3), which were significantly different ($\chi^2=6.598$; $p=0.01$).

Eight patients died in Group 1: two from intra-abdominal sepsis due to anastomosis leakage, one from a pulmonary embolism, two from metastatic disease, and three from pancytopenia due to chemotherapy. In Group 2, one patient died from aggravating AIDS (the patient was HIV+) and one died from an intra-abdominal infection caused by anastomosis leakage at the gastric site (the patient had undergone both colon and gastric resections because of a locally advanced tumor).

The mortality rates for the Conventional and FTS groups were 22.9% and 3.6%, respectively (Table 4), which were significantly different ($\chi^2=8.190$; $p=0.004$).

The mean length of stay in the hospital for Groups 1 and 2 were 15.6±14.4 days and 8.4±7.1 days, respectively. The length of stay in the hospital for Group 2 was significantly shorter than that for Group 1 ($p<0.001$).

DISCUSSION

Colon cancers are one of the most common cancers in developing and developed countries. Many positive discoveries have been made regarding colon cancer recently, such as a better understanding of the etiologies, an improvement in the diagnostic tools, optimization of surgical treatment, new adjuvant treatments, and learning the importance of a multidisciplinary approach. The morbidity and mortality of surgery has decreased with parallel improvements in laparoscopic surgery, technological progress, and better intensive care units. But the dependency of patients on hospitals and the health sector from birth to death has increased with progress in treatments. This situation negatively affects limited economic sources, the number of hospital beds, and the time spent on treatment. According to the cost-effectiveness principal, short treatment times, spending a minimum of economic resources,

and treatment without an increase in morbidity and mortality are the most logical solutions.

The basic steps of the FTS protocol are early enteral feeding, effective pain control, an MIS approach, and early mobilization of the patient. The FTS protocol includes perioperative care, and both principles accelerate the postoperative recovery and decrease intense stress responses. For elective colon surgery, a multimodal FTS protocol was improved by controlling factors that inhibit early discharge. By accelerating the recovery, increasing mobilization, and arranging for home care, it is possible to decrease complications and administer analgesia and parenteral fluids (3, 10-15). Previous studies employing this multimodal FTS protocol reported that the postoperative ileus and length of stay in the hospital were shortened by sustained epidural analgesia, early enteral feeding, and mandatory mobilization with *sisaprid* and laxative usage (10). Recent randomized studies comparing open versus laparoscopic colectomies reported that this procedure can be safely applied to all risk-group patients (16, 17). At the same time, results such as a low morbidity rate, less pain, faster recovery times, and shorter lengths of stay in the hospital were found (16, 18, 19). In a study consisting of 60 elderly or high-risk consecutive patients who had undergone laparoscopic colon resections using the FTS protocol, it was determined that patients could be mobilized within a minimum of 8 h on the second postoperative day, the mean length of stay in the hospital was 2.5 days, and they defecated within 3 postoperative days (20). In another study comparing open colon resection using the FTS protocol and the conventional protocol, the length of stay in the hospital and costs were decreased with the FTS protocol (21).

In our study, the control of patient analgesia in the FTS group during the postoperative period was provided by the insertion of an epidural catheter preoperatively by the anesthesia team. With the use of sufficient analgesia, the Foley catheter was removed, and the patients could be mobilized on the first postoperative day. The self-confidence of the patients was high because of receiving sufficient analgesia. This high self-confidence of the patients triggered a more willing mobilization. Similarly, high self-confidence directly affects immunity, and thus rapid recoveries were observed (22). On the other hand, the respiratory exercises without sufficient analgesia were difficult to perform for the patients. This caused more respiratory problems, thus increasing the morbidity and mortality, and consequently, increasing the length of stay in the hospital.

In an extensive systematic review by Wind et al. (23), there were six studies consisting of three randomized (24-26) and three controlled clinical studies (12, 27, 28). These studies were published between 1998 and 2005, and a total of 512 patients were included. Using the FTS protocol, the length of stay in the hospital for the first hospitalization was shortened by approximately 1-6 days, and the total time of hospitalization was significantly shorter (12, 24, 25, 27-29). In addition, there was no significant difference in the re-hospitalization rate between the two groups, although a trend toward re-hospitalization was higher in the Conventional group (12, 24, 25, 27-29). In our study, re-hospitalization rates in the early period were not determined for the groups. However, after discharge all patients recalled to control, effectivity of analgesia was asked, whether insufficient analgesia was thought, consultation was

performed to the algology department. Regular treatment for pain control was provided for all patients. Shortened hospitalization times increase the number of empty beds and decrease nosocomial infections. When the hospitalization period increases at FTS group, nosocomial infection risk increases. Because of this, antibiotherapy must be started as prophylaxis. In our study, the mortality rate and mean length of stay of the Conventional group were high compared with those reported in other studies (12, 24, 25, 27-29). This may have been due to higher stage and older patients in the Conventional group.

A recent meta-analysis by Spanjersberg et al. (30) revealed a reduction in overall complications with the use of the FTS protocol; however, the major complications were not reduced. In studies originating in Europe, the postoperative complication rate after an open colectomy for colorectal cancer can increase up to 25%-35% and the length of stay in the hospital can be up to 14 days for laparoscopic surgery and up to 21 days for conventional surgery (31, 32). In a study comparing the FTS protocol and conventional treatment for open colorectal surgery, the morbidity of the FTS patient group was less than that of the Conventional group (21% versus 49%), and the length of stay in the hospital for the FTS group was significantly shorter than that of the Conventional group (5 days versus 9 days) (33).

In our study, the morbidity of the FTS group was significantly less than that of the Conventional group, with wound infection being the major morbidity in both groups. This may be due to the presence of comorbid diseases in the patients of both groups and because many patients in both groups were at advanced stages. The mortality of the FTS group was significantly less than that of the Conventional group, and the length of stay in the hospital may affect the morbidity and thus the mortality. With a longer stay, the conventional group may be more sensitive to hospital infections (34). A shorter time to resume normal activities can also reduce cardiovascular morbidities in the FTS group (35). In the present study, only 11 patients had MIS (laparoscopic surgery), and the number of patients in the FTS group was not sufficient to compare the morbidity, mortality, and length of stay in the hospital. A large series of studies is warranted to determine the effectiveness of applying MIS to the FTS protocol.

In a review (36) investigating early enteral feeding after open colorectal surgery, 15 clinical studies and 1352 patients were examined. Early enteral feeding was tolerated by 86% of the patients, and it did not increase morbidity but shortened the hospitalization time. Thus, they recommended early enteral feeding for patients who had undergone open colorectal surgery. In another study (22), it was determined that the FTS protects cellular immunity and thereby facilitates the time for normalization of gastrointestinal functions, shortening the hospitalization time (6.7 days versus 9.7 days). Postoperative ileus, first defecation time, and transit time to solid foods decreased in the FTS group (7).

In our study, prolonged ileus was noted in three patients in the Conventional group and in two patients in the FTS group. The transit time to solid foods in the FTS group as one of the method modalities was 2 to 3 postoperative days. Not performing a preoperative bowel cleansing, only restricting fiber in the diet,

and an early transition time to solid foods decreased the time to first defecation in the FTS group compared with the Conventional group. This was the reason for more prolonged ileus in the conventional group.

The FTS protocol is implemented by a team consisting of an anesthetist, a surgeon, a dietitian, a physiotherapist, a nurse, and the hospital staff. On vacation, a sufficient number of members of this team should be actively working (12), and the number of trained members of the team must be sufficiently high to perform FTS on these days. The team consisting of an anesthetist, a surgeon, a nurse, and the ward staff actively worked on vacation days.

In some studies, solid food tolerance, defecation, and analgesia by oral analgesics are the required criteria for discharging patients (24, 25, 29). In another similar study, normal body temperature, a normally functioning gastrointestinal system, and tolerance to enteral feeding were the criteria for discharging patients (28). In this study, the criteria for discharging patients were the toleration of solid food, complete mobilization, defecation, and effective pain control with oral analgesics. It was explained to the patients and their relatives who were afraid of the early discharge that an early adjustment to normal life will lead to a faster recovery. Consultation through phone 24 h/day was also available if required. This option may have increased their self-confidence and eased the early discharge. Decreases in both the length of stay in the hospital and morbidity and increases in the number of empty beds, also decreased the healthcare costs. This was not the purpose of the FTS protocol, but it was an indirect gain.

CONCLUSION

The FTS protocol was researched previously by several studies, but the existence of all three parameters (morbidity, mortality, and length of time spent in the hospital) in one study is rarely found. Employing the FTS protocol for patients with colon cancer decreases the morbidity, mortality, and length of stay in the hospital.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Vakıf Gureba Training and Research Hospital.

Informed Consent: Written informed consent was obtained from patients who participated in this study.

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