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Original Article

Fast-track Protocol versus Conventional Protocol on Patient Outcome: A Randomized Clinical Trial

Sandhya P Iyer, Zeeshan Kareem

Department of General Surgery, Lokmanya Tilak Municipal Medical College and Lokmanya Tilak Municipal General Hospital, Sion, Mumbai, Maharashtra, India

Abstract

Background: The aim of this study is to compare fast-track methodology with traditional methods of surgical care in achieving better patient outcome, and ensuring a timely discharge from the hospital, and also note the factors that are responsible for a delayed discharge from the hospital. **Materials and Methods:** One hundred patients undergoing elective surgeries were randomly allocated into fast-track and traditional protocol of perioperative care. Patients who underwent fast-track protocol (FTP) were started on early oral feeding and were encouraged for early discharge, while the others were made to follow the traditional method of recovery. The gastrointestinal functions, postoperative complications and hospital stay time were recorded. The results were tabulated and analyzed. **Results:** Early feeding was well tolerated by all the patients in the "fast track" group, while the patients in the control group had increased number of "nil by mouth" days, and this result was statistically significant. Ambulation was started earlier in the case group as compared to the controls, and the mean period of starting of ambulation was statistically significant, in the cases as compared to the controls. The patients in the case group had an earlier discharge from the hospital, as compared to the control group. The most common reason for a delay in discharge from the hospital, in either group, was seen to be inadequate pain relief postoperatively. **Conclusion:** The FTP can significantly shorten the postoperative hospital stay after elective surgery, as compared to the traditional protocol.

Keywords: *Enhanced recovery, fast-track surgery, length of stay, peri-operative care*

Introduction

Enhanced recovery after surgery (ERAS) was a concept propagated by Professor Henrik Kehlet in the 1990s. ERAS protocols or "fast track surgery" are multimodal perioperative care pathways designed to achieve early recovery after surgical procedures, by maintaining preoperative organ function and reducing the stress response following surgery.[1] ERAS interventions focus on those key factors that usually keep patients in hospital and make them dependent on drugs and specialist assistance following uncomplicated surgery. Pillars of ERAS protocols cover all the perioperative phases by removing or decreasing the influence of such factors and promoting good habits that favor the recovery of physiological function.[2]

Although the ERAS protocol has been in practice in various countries and hospitals, it is still not very widely followed in our country. This is due to many surgeons preferring to opt for traditional methods, rather than adopting the new evidence-based protocols. This study applied the "fast track" protocol on elective surgeries, and the results showed that such a protocol can be routinely applied and significantly improved postoperative recovery in these patients.

Address for correspondence: Dr. Zeeshan Kareem, 3/103, AROMA, Opposite Oshiwara police Station, Link Road, Andheri (West), Mumba - 400 053, Maharashtra, India. E-mail: zeeshankareem570@gmail.com

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Materials and Methods

A prospective randomized controlled study was carried out at a Municipal General Hospital in Mumbai, India, over a period from June, 2015 to December, 2016 over one hundred patients undergoing elective surgery. The approval of the Institutional Ethics Committee was taken before commencement of this trial and written informed consent was taken from the patients.

The patients were divided, after recording baseline parameters, by stratified randomization on the basis of the type of surgery required, into case and control groups. They were subjected to "fast track" and traditional protocols of perioperative care and postoperative recovery.

Patients included in our study were between the age group of 12–70 years of either sex and underwent the following elective surgeries:

1. Laparoscopic appendectomy
2. Laparoscopic hernia repair
3. Laparoscopic cholecystectomies
4. Stoma closure
5. Open cholecystectomies
6. Modified Puestow's surgeries.

Patients with comorbid conditions such as hypertension, diabetes mellitus, etc., and those undergoing emergency surgeries were excluded from the study.

The patients were seen in the outpatient department, relevant clinical history, and examination was done. The patients were counseled about the procedure and postoperative course in full detail. Once the patients were admitted for the elective procedure, basic blood investigations required for anesthesia fitness were performed and values recorded.

The differences between the fast-track protocol (FTP) and the conventional care protocol followed at our center are shown in Table 1.

Patients in both the groups were given anesthesia either in the form of general anesthesia, or spinal anesthesia. The operative details were noted and intraoperative complications, if any, were also noted that could affect the postoperative course of the patients.

Variables studied in the postoperative period have been described in Tables 2 and 3. The discharge criteria used for all patients were uniform, i.e., when oral intake was adequate, pain was minimal or absent, the patient could pass urine, at least flatus with or without stool, was able to ambulate independently and the wound condition was satisfactory. Patients were followed up after discharge at an interval of 10 and 21 days to check for wound status and then for 3 months to look for any complications or readmissions.

Table 1: Protocols applied to the two groups

	Fast-track protocol	Conventional protocol
Preoperative period	Complete information about the protocol was given and consent taken Minimal Starvation period (8 h for solids and 6 h for liquids). Patients undergoing stoma closure were not given solids for a period of 24 h before surgery Mechanical bowel preparation was avoided in all cases A 100 g oral carbohydrate drink was given to the patient to be consumed along with other clear liquids up to 6 h before surgery	Overnight starvation was followed (10 h for solids as well as liquids). Patients undergoing stoma closure were not given solids for a period of 24 h before surgery Mechanical bowel preparation was given only to stoma closure cases No oral carbohydrate drink was given
Operative period	Elective use of abdominal drains, urinary catheters and nasogastric decompression, only when absolutely essential Strictly avoiding overhydration	Routine use of abdominal drains, urinary catheters and nasogastric decompression Liberal hydration
Postoperative period	Early enforced mobilization Early enteral nutrition Early removal of all drains, catheters, and tubes	No enforced mobilization Enteral nutrition given once bowel motility restored Removal of all drains, catheters, and tubes done when markers of bowel motility are observed

Data analysis

Continuous variables were summarized by group using summary statistics (number of observations, mean and standard deviation with range of minimum and maximum). Categorical data were summarized by treatment group using frequencies and percentages. Continuous variables and other efficacy variables such as mean period of discharge, return of motility, ambulation and mean period of removal of tubes, drains and catheters were compared using Student's *t*-test. All the statistical tests were interpreted at

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5% level of significance. The relevant measures have been shown in Tables 1-6.

Results

A total of 100 patients participated in the study, which were equally divided into case and control groups. The median age of the study population was 35 years, with a minimum of 18 years and maximum of 65 years. The diagnosis of the patients in the study population was as shown in Table 4. The baseline hematologic and biochemical parameters in the study population are as shown in Table 5. The procedures both groups underwent are shown in Table 6.

The details of the postoperative events are as shown in Table 2. This table highlights details of analgesia administered, duration of catheter, nasogastric tube, abdominal drain, day of starting enteral nutrition, day of passage of flatus and stools, day of discharge decided, and the day of actual discharge.

In terms of analgesia postoperatively, the aim was to achieve a tolerable or minimal level of pain with respect to patient perception. The requirement of parenteral analgesia was seen more in the control group.

All the patients in the study population were catheterized intraoperatively, irrespective of the type of anesthesia administered. Removal of the urinary catheters was done on different days for both the groups.

With respect to nasogastric tube insertion, all the patients underwent tube insertion during surgery in

Table 2: Postoperative details of both the groups

Parameter	Cases	Controls	*P*
Period of analgesia (mean period in days)			
Parenteral	1.08±0.34	2.02±0.47	0.000*
Oral	1.18±0.44	1.48±0.65	0.008*
Urinary catheterization (mean period in days)	0.00±0.00	1.08±0.34	0.000*
Ryle's tube (mean period in days)	0.00±0.00	1.42±0.575	0.000*
Abdominal drain (mean period in days)	1.09±0.426	2.35±0.522	0.000*
Starting of feeds (mean period of days)	0.00±0.00	1.48±0.544	0.000*
Starting of ambulation (mean period of days)	1.02±0.14	1.56±0.50	0.000*
Return of motility markers (mean period of days)			
Flatus	1.04±0.19	1.92±0.75	0.000*
Stools	1.66±0.59	2.56±0.70	0.000*
Day of discharge decided (mean period of days)	1.54±0.97	2.78±1.11	0.000*
Day of actual discharge (mean period of days)	2.38±0.94	3.56±0.90	0.000*

*Significant, by students *t*-test

Table 3: Reasons for delay in discharge in both groups

Reasons for delay in discharge	Cases	Controls
Charges	2	2
Distance	11	10
Inadequate pain relief	20	16
Relatives	2	3
Wound infections	2	1
Housing	1	3
Respiratory ailments	0	1
Distance/other systemic complications	0	1
Government schemes/wound infections	0	1
Housing/distance	4	2
Housing/distance/charges	0	1
Distance/inadequate pain relief	1	0
Distance/relatives	1	0
Housing/inadequate pain relief	1	0
Other systemic complications	0	1
Total	45	42

Table 4: Diagnosis of the patients in the study population

Diagnosis	Number of patients
Chronic cholecystitis	71
Chronic cholecystitis with choledocholithiasis	2
Chronic pancreatitis	2
Left inguinal hernia	1
Right inguinal hernia	4
Stoma closure	16
Recurrent appendicitis	3
Subacute intestinal obstruction	1
Total	100

Table 5: Laboratory parameters

Lab parameter	Mean value (X±SD)		*P*
	Cases (50)	Controls (50)	
Hemoglobin	13.05±1.99	12.50±1.81	0.154 (NS)
TLC	7537±2181.80	7274±2047.08	0.535 (NS)
Platelet count	280,640±63,286.44	263,340±101,370.53	0.309 (NS)
Creatinine	0.91±0.24	0.81±0.18	0.060 (NS)
Total bilirubin	0.65±0.23	0.59±0.13	0.153 (NS)
Total proteins	6.90±0.57	6.86±0.59	0.708 (NS)
Serum albumin	3.76±0.39	3.72±0.48	0.616 (NS)
RBS	95.58±17.13	97.48±14.89	0.555 (NS)

By students *t*-test. NS: Not significant, TLC: Total leukocyte count, RBS: Ribosome binding site, SD: Standard deviation

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Table 6: Surgeries performed in the study population

Procedure planned	*n*	Cases	Controls
Diagnostic laparoscopy	1	0	1
Laparoscopic appendectomy	3	3	0
Laparoscopic cholecystectomy	71	36	35
Laparoscopic right inguinal hernia repair	4	4	0
Laparoscopic left inguinal hernia repair	1	0	1
Open cholecystectomy	2	1	1
Stoma closure	16	4	12
Modified puestow procedure	2	2	0
Total	100	50	50

both the groups. All the patients in the case group had their nasogastric tubes removed either immediately postoperatively or on the evening of surgery itself.

With respect to abdominal drain placement, in the case group, abdominal drains were placed selectively in 43 patients out of the 50, and all the patients had their drains removed on the 1st postoperative day, except for the Modified puestow's surgeries, where they were removed on the 3rd postoperative day. In the control group, out of the 50 patients, 49 had abdominal drains placed during surgery, which were removed when the output reduced to <20 ml.

With respect to starting of feeds, all the patients in the case group were started on sips and liquid diet after removal of the nasogastric tube on the evening of the surgery itself. Soft or solid diet was started on the 1st postoperative day for all these patients.

Ambulation in the postoperative period was also different in both the groups. The day of discharge, as decided by the clinician, was recorded in terms of postoperative days. The patient was deemed fit to be discharged when the discharge criteria set out by the study were met. The mean day of discharge, as decided by the clinician, in both the groups is as shown in Table 2. However, the day each patient actually went discharge was different in both the groups. This disparity was due to several factors that prevented the patient to be discharged from the hospital, leading to prolonged hospital stay. Hence, the day of actual discharge from the hospital was important, as it gave us an indication of the mean duration of hospital stay in each group.

The reasons for a delay in the discharge, as seen in both the groups, are as shown in Table 3.

Out of the 50 cases, 5 of the patients were discharged on time whereas, out of the 50 controls, 8 of the patients were discharged on time. The most common reasons for a delay in discharge were inadequate pain relief and distance in both the groups.

Discussion

FTPs or enhanced recovery programs are treatment protocols made with adherence to evidence-based principles. There have been many studies on the effect of FTP on colorectal surgeries[3] as well as colostomy closures.[4] Our study tests the efficacy of the FTP and seeks for results in terms of hospital stay as the final outcome measure and looks for reasons that lead to a delay in discharge from the hospital.

In our study, the two groups were found comparable in terms of demographic data such as age and sex, baseline biochemical, and hematologic parameters. Studies have demonstrated that even though advanced age is not a contraindication for applying FTPs, care must be exercised and protocols modified for the elderly.[5]

In the studies previously conducted on these protocols, most of them were on colorectal surgery, in which cases most common indication was malignancy of the distal gastrointestinal tract.[6] Our study, however, concentrated on applying FTPs for patients planned for minimally invasive surgeries, i.e., laparoscopic procedures, as well as stoma closure surgeries and modified Puestow's surgeries.

The importance of a preoperative diet plan and exercise regimen has been shown by several clinical trials worldwide.[1] The nutritional status in our study was mainly judged by the measurement of blood hemoglobin and serum albumin levels. The mean levels of both the measurements were not significantly different in both the groups. Lohsiriwat *et al*.[7] from Thailand have demonstrated that hypoalbuminemia, which is a level <3.5 g/dl, is associated significantly with a poor surgical outcome. A preoperative carbohydrate drink was given to all the patients in the case group, having 100 g of glucose powder to be consumed with water. In addition, reduced preoperative fasting period was advised. Noblett *et al*.[8] have demonstrated that oral carbohydrate loading is associated with shorter hospital stays. In addition, trials evaluating mechanical bowel preparation in elective surgery either show no benefit or rather a deleterious effect of mechanical bowel cleaning.[9] In our study, in the cases, all the patients requiring anastomosis, i.e., stoma closure surgeries as well as modified Puestow's surgeries, were not given any bowel preparation and the patients did not have any anastomotic leaks and/or wound infections.

A study has also shown that a 2 h preoperative fasting for clear liquids and a 6 h fast for solids is sufficient and is not associated with any increase in complications.[10] In our study, the preoperative fasting for clear liquids was kept to 6 h in the case group by consensus of the

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surgeon anesthetist team. An important consideration was the minimization of incision size and use of minimally invasive techniques in fast-track surgery. Use of minimal incisions in open surgeries and minimally invasive surgery causes minimal interruption of physiology. In our study, there was an equal distribution of surgical techniques in either group.

The multimodal approach to analgesia offers better pain relief in the immediate postoperative period. In our study, the mean period for administration of parenteral as well as oral analgesia was more in the control group than the cases, and the difference was statistically significant. Many studies have shown that pain remains the most common reason for delaying discharge after ambulatory surgery.[11]

As the FTP especially focuses on early ambulation and discharge, an important consideration is to be given to the use of drains, tubes, and catheters in the perioperative period. Browning *et al*.[12] have demonstrated that the prolonged use of drains, tubes, and catheters impede ambulation and result in lesser out of bedtime even when ambulation has begun. Hence, selective, rather than routine use should be preferred. The patients in the case group had a shorter average duration with catheter, abdominal drain, and nasogastric tube *in situ*, as compared to the controls, and this difference was seen to be statistically significant. Nelson *et al*.[13] concluded that routine nasogastric decompression after abdominal surgery does not hasten recovery from ileus and should be avoided. Similarly, the routine use of abdominal drains should also be avoided in a fast track program.[14]

Studies have suggested that early enteral feeding is either beneficial or has no significant adverse effects other than a slightly increased incidence of vomiting.[15] In our study, in the case group, all the patients were started on liquids on the evening of surgery itself, without any exceptions. A gradual transition to solid diet was done if liquids were well tolerated overnight. There were no complications seen on starting feeds early. The mean duration of starting feeds in the cases was 1.02 days, while in the control group it was 1.56 days, and this difference between both the groups was statistically significant.

With respect to ambulation, in our study, we had considered the day on which patient spent at least 10 min out of bed as the day of ambulation. The average time taken for the patients in the control group to mobilize was more as compared to the cases, and the difference was statistically significant. Henriksen *et al*.[16] have demonstrated that enforced ambulation is significantly associated with decreased hospital stay.

The final outcome measure of this study was in terms of the day on which the patient could be discharged. Reasons for delay in the discharge from the hospital were also noted. The average duration of stay in the hospital was longer for the control group (3.56 days) as compared to the cases (2.38 days), difference being statistically significant. Earlier discharge from the hospital has a lot of advantages, both to the patient and to the hospital. It reduces the incidence of nosocomial infections such as surgical site infections. It saves considerable amount of health-care cost to the patient. It promotes a sense of well-being in the patient and allows for early reintegration of the patient into society.[17] At the hospital level, it increases patient turnover and reduces costs for the hospital and is especially beneficial to the public sector hospitals. In our study, inadequate pain relief and distance from the hospital to the patient's residence were the major factors that prevented the patients from being discharged on time, thus increasing duration of hospital stay, as well as reducing the patient turnover for the hospital. If managed properly, these factors could be prevented and an adequate discharge time ensured for each patient so that the costs of healthcare can be reduced.

Conclusion

The FTP is an amalgamation of several evidence-based interventions which when put together, form a patient management protocol that is safe and has excellent results in terms of facilitating an early yet appropriate discharge from the hospital setting without increase in the complications.

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Conflicts of interest

There are no conflicts of interest.

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