Original Research Article

Clinical evaluation of fast track protocol versus standard care in patients undergoing elective colorectal surgeries

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ABSTRACT

Background: Colo rectal surgeries are on the rise given colorectal carcinoma being the third most common cancer globally affecting more than 1 million people every year. Apart from carcinoma colo rectal surgeries are performed for severe inflammatory bowel diseases, strictures, diverticular diseases etc. The traditional approach to colo rectal surgery has been associated with high morbidity subjecting the patient to unnecessary preparations and prolonged hospital stay. Fast-track surgery consists of a protocol of evidence-based techniques to reduce surgical trauma and postoperative stress by minimizing pain, reducing complications, improving outcomes, and decreasing length of hospital stay while expediting recovery following elective procedures. Fast track protocols for colorectal surgery patients were developed to reduce physiological stress and postoperative organ dysfunction through optimization of perioperative care and recovery.

Methods: A total of 40 patients who are undergoing any elective colo-rectal surgeries will be included in the prospective study. Details regarding the age, sex and diagnosis were collected. Operative parameters and post-operative complications were recorded. Post-operative course in hospital and any deviation of normal post-operative course and its management is recorded and analyzed.

Results: The overall complication rates were significantly higher in the control group as compared to the Fast track group ($p < 0.05$). The duration of stay was found to be significantly shorter in the study group (mean 8.8 days Vs 11.7 days).

Conclusions: This evaluation provides strong evidence that the fast track approach is safe in colo-rectal surgeries and is not associated with increased incidence of complications. It results in significantly reduced duration of hospitalisation and reduction in overall cardio-pulmonary morbidity and complications.

Keywords: Fast track, Eras protocol, Colorectal surgeries

INTRODUCTION

Fast track surgery consists of a protocol of evidence-based techniques to reduce surgical trauma and postoperative stress by minimizing pain, reducing complications, improving outcomes, and decreasing length of hospital stay while expediting recovery following elective procedures.

The concept of fast-track surgery, also called enhanced recovery after surgery (ERAS) or multimodal surgery

involves using various strategies to facilitate better conditions for surgery and recovery in an effort to achieve faster discharge from hospital and more rapid resumption of normal activities after both major and minor surgical procedures, without an increase in complications or readmissions.¹ Fast-track programs originated in Denmark by Henrik Kehlet, and are now being taken up worldwide.

Fast track approach was developed with aim of improving outcomes in patients undergoing elective

colorectal surgeries. There is no fixed guidelines to this method and has several components which may or maynot be included in studies. Fast track protocol is designed based on the local conditions and patient input.

In the first half of 20th century; mortality from colorectal surgery often exceeded 20%, mainly due to sepsis. Modern surgical techniques and improved perioperative care have significantly lowered the mortality rate. Mechanical bowel preparation (MBP) is aimed at cleansing the large bowel of fecal content thus reducing morbidity and mortality related to colorectal surgery.

Studies have been carried out aimed to investigate the outcomes of colorectal surgery with and without MBPs, to avoid unpleasant side effects of MBP and also to design a protocol for preparation of a patient for colorectal surgery, Analysis of several parameters: gender, age, preoperative difficulties, tumor localization, operation performed, other organ infiltrations, mean time of surgery, length of hospital stay, postoperative complications and mortality was done in group with MBP versus group without MBP.

Mechanical bowel preparation (MBP) for elective colorectal surgery is not advantageous.² Furthermore; MBP is a time-consuming, expensive procedure and causes severe discomfort to the patient. More importantly, the application of MBP has been associated with serious complications in both healthy patients and patients with existing cardiac or renal disease, such as electrolyte and volume disturbances.³

The present study indicated that early oral feeding after elective colorectal surgery was not only well tolerated by patients but also affected the postoperative outcomes positively. Early postoperative feeding is safe and leads to the early recovery of gastrointestinal functions.

Also, early enteral nutrition after surgery can improve the nutritional status and immune functions of the patient.

METHODS

40 cases admitted between September 2014 to September 2016 under General surgery and allied departments for elective colo-rectal surgeries were included in the study.

Analyzing the outcomes

The two approaches to colo-rectal surgery will be assessed based on following parameters:

- Anastomotic leak
- Surgical site infection
- Post-operative recovery of bowel function
- Other complications: UTI, LRTI, dyselectrolytemia, MI etc.
- Cost distribution and age distribution

RESULTS

Demographics

Table 1: Age distribution.

		MBP			
		No bowel preparation		Bowel preparation done	
		n	%	n	%
Age_c	<40	4	20.0	4	20.0
	41-60	10	50.0	14	70.0
	>61	6	30.0	2	10.0

P=0.3, chi-square test

Figure 1: Age distribution.

Table 2: Mean age group.

	MBP						
	No bowel preparation			Bowel preparation done			p
	Mean	Median	SD	Mean	Median	SD	
Age	54.3	50.5	15.3	49.3	50.0	13.0	0.3

Table 3: Distribution of patients based on disease.

		MBP			
		No bowel preparation		Bowel preparation done	
		n	%	n	%
Diagnosis	Ca Anal canal	1	5.0	0	0.0
	Ca Ascending colon	8	40.0	3	15.0
	Ca Ascending colon+ Ca rectum	0	0.0	1	5.0
	Ca Caecum	3	15.0	0	0.0
	Ca Descending colon	0	0.0	1	5.0
	Ca hepatic flexure	0	0.0	1	5.0
	Ca Rectum	6	30.0	11	55.0
	Crohns disease	1	5.0	2	10.0
	Ileocaecal TB	0	0.0	1	5.0
	S/P LAR with colostomy	1	5.0	0	0.0

Table 4: Mean duration of stay in hospital.

	MBP						
	No bowel preparation			Bowel Preparation done			p
	Mean	Median	SD	Mean	Median	SD	
Duration of stay (days)	8.8	7.5	5.5	11.7	10.5	4.8	0.049

Figure 2: Types of surgery distribution.

The mean age of patients in FT group was 54.3 years and those of patients in control group were 49.3 years. There was no significant difference between the two groups in terms of age (Table 2).

Diagnosis and procedure done

As seen from Table 3 and Figure 2, most of the surgeries were performed for malignancy. 4 cases (10%) were operated for benign indications- three cases of Crohn's disease and one case of ileo-caecal tuberculosis.

Majority of cases included in the study involved major resections. Right hemicolectomy was the most commonly performed surgery.

Mann Whitney test

The average stay in hospital resulted shorter for the patients of the FT-Group (8.8 vs. 11.7 days; $p < 0.05$), as well as the median values (7.5 days range 1-23 after FT-Group; 10.5 days range 5-20 in the Control-Group). It is to underline that the causes of a longer stay in patients of the FT-Group were surgical site infections; and anastomotic leak in one case.

Overall hospital stay, with the same discharge criteria as in traditional care, is reduced by about 3-4 days. Most importantly, the decreased duration of paralytic ileus avoids discomfort, abdominal distension, impairment of pulmonary function, and insufficient oral nutrition.

Figure 3: Graphical representation of mean duration of stay in hospital.

Table 5: Type of anastomotic technique.

		MBP			
		No bowel preparation		Bowel preparation done	
		n	%	n	%
Type of anastomosis	Handsewn	6	30.0	3	15.8
	Stapling	14	70.0	16	84.2

P=0.3

Figure 4: Anastamotic technique.**Table 6: Duration of surgery.**

	Mean	Median	SD	Mean	Median	SD
Duration hours	3.12	3.00	1.36	3.33	3.00	1.22

P=0.7, independent t test.

Figure 5: Complication wise distribution.

Incidence of other complications were significantly higher in the control group ($p < 0.05$). These included ileus, wound dehiscence, LRTI etc.

One of the patients in C group had hypokalemia which required repeated corrections and monitoring. Also

The anastomotic technique did not have any significant effect on the study. It was thought that MBP will have the advantage of reducing the operating time. However, on statistical analysis, there was no significant difference seen in operating duration between the FT and Control groups. The types of resections in each of the groups were largely similar to avoid confounding factors.

Primary interest of this study was to observe the effect of omission of traditional practices such as MBP, prolonged fasting and delayed (>48 hours) removal of drains and tubes on two main outcomes-anastomotic leak and surgical site infections.

One patient in the FT group had anastomotic leak. However this patient had a confounding factor of hypoalbuminemia (1.8). Owing the small size of the study, this incidence of anastomotic leak was found to be statistically insignificant.

SSI incidence was found to be similar in both the study groups. This showed that MBP has no role in preventing SSI. Thus disproving age old beliefs of MBP preventing SSIs.

cardiopulmonary morbidity was seen in C group- two of the patients had sudden cardiac death.

Figure 6: Representation of cost.

There was no significant difference in the cost of hospitalization.

However this was inconclusive as variables such as type of ward chosen, laparoscopic/ open surgeries and loss of daily incomes were not taken into consideration.

Table 7: Complications of surgeries.

		MBP			
		No bowel preparation		Bowel preparation done	
		n	%	n	%
Complications	SSI	3	15.0	4	20.0
	Anastomotic leak	1	5.0	0	0.0
	Others	0	0.0	11	55.0

Table 8: Cost distribution.

	MBP					
	No bowel preparation			Bowel preparation done		
	Mean	Median	SD	Mean	Median	SD
Cost	58,300.00	60000.00	22,868.27	91,100.00	57,000.00	1,24,600.37

P=0.4

Table 9: Redo surgeries distribution.

		MBP			
		No bowel preparation		Bowel preparation done	
		n	%	n	%
Re-surgery	No	19	95.0	18	90.0
	loop ileostomy	1	5.0	0	0.0
	secondary suturing	0	0.0	2	10.0

P=0.9

Figure 7: Redo surgeries based on MBP versus without MBP.

Table 10: Distribution of patients based on early oral feeds and early drain removal.

	MBP						
	No bowel preparation			Bowel preparation done			P
	Mean	Median	SD	Mean	Median	SD	
Oral_feed_POD	1.90	2.00	0.91	3.33	3.00	1.08	<0.0001
Flatus_POD	2.20	2.00	0.52	3.39	3.00	1.50	0.003
Drain_removed_POD	2.58	2.50	0.67	7.17	6.50	2.57	<0.0001
Foleys_removed_POD	2.06	2.00	1.11	5.39	5.50	1.85	<0.0001
RT_removed_POD	1.54	1.00	0.88	3.00	3.00	1.11	0.001
mobilised_POD	2.10	2.00	0.85	5.00	4.00	1.64	<0.0001

One patient in FT group had to undergo re surgery-covering loop ileostomy was done for the patient with anastomotic leak.

Two patients in C group required secondary suturing under anesthesia.

These were not found to be statistically significant.

Patients in FT group were started orally within 48 hours (mean 1.9 days) and those in C group were started orally after 72 hours (mean 3.33 days). This was statistically significant. It was found to be clinically significant as well as the practice of early enteral feeding led to improved recovery, early regain of bowel function (2.2 days in FT group versus 3.39 days in C group).

Drains were avoided altogether in FT group (not used in 40% patients); or if used were removed early (mean 2.58 days). Drains were kept for average of 7.17 days in the Control group. Although this wide difference in practice of drain removal; there were no benefits found in C group. Thus, prolonged use drains were concluded to be an unnecessary and uncomfortable tradition.

Foleys catheter was removed at mean of 2.06 days in FT group and 5.36 days in C group. This was reflected in the duration taken to mobilize the patient post operatively (2.1 days in FT group versus 5 days in C group). This difference was significant and also had a huge impact in overall complication rates being higher in the control group of patients.

DISCUSSION

To our knowledge, this is the first prospective study evaluating the usefulness of fast track approach in elective colo-rectal surgeries, in our setup of patients.

Fast Track is an integrated multidisciplinary rehabilitation course aiming to optimize the peri-operative treatments involving in a synergistic way surgeon and anesthetist. The following measures may be requested: abolition of preoperative fasting (possibly replaced by a regulated diet and/or nutritional support), abolition of mechanical bowel preparation, administration of beta-blockers, antibiotic and anti-embolus prophylaxis, pre-operative pre-oxygenation, integrated anaesthesia, minimally invasive surgical access, intra-operative normothermia, limited perioperative fluid-therapy, early re-introduction of carbohydrates and post-operative re-feeding, absent or limited use of opioid analgesic drugs, excellent control of pain, abolition or limited use of drains, early removal of the nasogastric tube, early removal of the bladder catheter, early mobilization, short stay in hospital.⁴

The main field of application of this protocol is the colon-rectum surgery: the results analysed by several randomized surveys carried out in 2001-2016, are globally positive, even if there is a non-negligible evidence of early hospital re-admissions (up to 21%). It was remarked that the colon-rectum post-operative condition of ileum, nausea, pain and asthenia are the factors that determine the recovery timing and the duration of stay in hospital. This sequence is determined by the operation stress and by several iatrogenic factors,

such as improper analgesia, suspension of feeding, immobilization and invasive instrumentation (tube, catheter, drain). As a matter of fact, the operation stimulates the reply to stress (CO₂, vasoactive peptides, adrenocortical hormones and opiates) in relation to the entity of manipulation, inhibiting the intestine smooth muscle. Thus favoring an early mobilization of the patient and a reduced stay in hospital.

The use of local anaesthetic drugs in the epidural and subarachnoid areas mitigates the reaction from stress and the continuous infusion permits a better pain control, helping for an early mobilization of the operated patient, and reduces the inhibition of the gastro-colic motility that is typical of opioid drugs.⁵ Also in our survey the use of integrated anaesthesia guaranteed good results in most operated patients, also ensuring an effective pain control by means of a preventive, epidural analgesia and later on a systemic one. The perioperative normovolemic management, limited by us to 2000 cc. of balanced solution, demonstrated itself similarly effective in limiting stay in hospital and in helping recovery of gastro-intestinal function.⁶

It is finally to underline that for our patients we decided not to carry out the traditional intestinal preparation, and we did not observe any obstacle during the surgery operation.⁷ As a matter of fact, the intestinal mechanic preparation has been lately very debated as it was noticed that the use of polyethylene glycol or sodium phosphate may negatively affect the synthetic processes and the early post-operative healing and recovery.⁸

CONCLUSION

Growing demand for health care, rising costs, constrained resources, and evidence of variations in clinical practice have triggered interest in measuring and improving the quality of health care delivery. For a valuable quality assessment, relevant data on outcome must be obtained in a standardized and reproducible manner to allow comparison among different centers, between different therapies and within a center over time. Objective and reliable outcome data are increasingly requested by patients and payers (government or private insurance) to assess quality and costs of health care. Moreover, health policy makers point out that the availability of comparative data on individual hospital's and physician's performance represents a powerful market force, which may contribute to limit the costs of health care while improving quality.

The traditional care is followed by majority of surgeons. Fast Track approach allows omission of many outdated principles in colo-rectal surgery. However, we felt lack of acceptance among majority of surgeons.

Finally, a fast-track approach requires team effort of surgeon and anesthetist. Also, co-operation of the

hospital administration is needed in developing a short-stay package for elective colonic surgeries.

Therefore, the aim of the current study was 2-fold: first, to prove the lack of necessity for outdated procedures in colo-rectal surgeries, deriving from surgical complications based on our experience gained with the fast track approach; and second, to reduce the duration of hospitalization and its cost.

The results of our study confirm the applicability and safety of the “Fast Track Surgery”: compliance with the FT procedure has been good and morbidity occurrence in general has been limited. This “aggressive” approach has substantially modified the traditional methods that had been followed by us for many years and seems to permit a quicker patient discharge and therefore positive results for the patients and health care cost containment. We believe that if controls are carried out homogeneously and the number of patients observed is higher, rehabilitation programs will be consolidated, thus becoming a reference for all hospital units.

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Ethical approval: The study was approved by the institutional ethics committee

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