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Randomized Controlled Trial

Fast-Track Protocol *versus* Conventional Protocol for Colostomy Closure in Children: A Randomized Controlled Trial

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Keywords
Colostomy

Abbreviations
CP - Conventional protocol
ERAS - Enhanced recovery after surgery
FTP - Fast-track protocol

Abstract

Background: *Recent literature has focused on Enhanced Recovery After Surgery (ERAS) Programs or Fast Track Elements in peri-operative care of patients undergoing surgery. While fast-track surgery has been studied extensively in adult patients, studies in the pediatric age group are rather few. Existing few studies are disadvantaged by non-homogenicity of surgical procedures. For colonic surgeries, only early postoperative enteral feeding has been studied in detail. There are no randomized controlled trials that evaluate fast-track protocol in colonic surgery of children.*

Methods: *Thirty children with colostomy for different indications were randomized into two groups of 15 each. The control group had conventional protocol (CP) which included antegrade intestinal irrigation, conventional preoperative enemas postoperative nasogastric suction, placement of abdominal drains and slow commencement of oral feeds. The trial group followed the Fast Track protocol (FTP) that included parent and patient education, no bowel preparation, no prolonged pre-operative fasting, avoidance of routine placement of drains, tubes and catheters, immediate post-operative feeding, epidural anesthesia, immediate mobilization and limiting systemic opioids. The outcomes of two groups were compared.*

Results: *FTP leads to a significant decrease in post-operative pain, time taken to sit-up and stand, incidence of the overall complications and wound infection. However, it is associated with a significant increase in the rate of ileus. There is no significant difference between the two protocols as regard to the overall durations of hospital stay, return of bowel function, catheterization rate, readmission rate and time taken to walk and play.*

Conclusion*: Our study suggests that the conventional practice of bowel preparation, prolonged fasting, insertion of nasogastric tube and drain, systemic analgesia, delayed feeding, and post-operative bed rest are not mandatory in children undergoing colostomy closure. Fast-track protocol appears to be safe and effective.*

INTRODUCTION

Traditionally, colostomy closure involves mechanical bowel preparation with antegrade intestinal irrigation and conventional enemas.[1] Patients are kept fasting for long hours pre-operatively to prepare the bowel[2] as well as to decrease anesthesia-related aspiration pneumonitis.[3] Intra-operative drain placement below the fascia was advocated in the past.[2] All patients are routinely placed on nasogastric tube drainage with intravenous hydration. Oral feeds are begun slowly as the gastric dysmotility resolves.[4] Post-operative analgesia mainly consists of systemic (intravenous or oral) analgesia with opioids and non-steroidal anti-inflammatory drugs. All these measures are a hindrance for early ambulation that is prevented by multiple tubings attached to the patient.

Recent literature has focused on the use of *Enhanced Recovery Programs* or *Fast-Track Elements* in peri-operative care of the patients undergoing surgery. They include parent and patient education, no bowel preparation, no prolonged pre-operative fasting, minimally invasive surgical techniques, avoidance of routine placement of drains, tubes and catheters, immediate post-operative feeding, immediate mobilization as well as multimodal analgesia including loco-regional analgesia where feasible and limiting systemic opioid drugs.[5-7]

While fast-track surgery has been studied extensively in adult patients, studies in the pediatric age group are very few. Most of the in pediatric studies include a mixed variety of surgeries. For colonic surgeries, only early postoperative enteral feeding has been studied in detail. There have been no randomized controlled trials to evaluate fast-track colonic surgery in pediatric patients.

We aimed to assess the outcomes using a FTP for peri-operative management for colostomy closure in children and compare them with that of the conventional protocol (CP). We attempted to find out if the use of FTP leads to a decrease in hospital stay and other benefits such as reduced post-operative pain, early return of bowel and bladder function, ambulation and reduced morbidity.

MATERIAL AND METHODS

The study was conducted in a tertiary care centre of Pediatric Surgery in 2013-14. All children below 12 years of age and American Society of Anesthesiology class I and II, who are undergoing colostomy closure, were evaluated. Exclusion criteria included contraindications to neuroaxial anaesthesia (e.g. gross spinal anomaly, infection, or skin lesions over the back), distal loopogram showing disuse atrophy of colon in children having colostomy for more than 6 months and revision/redo of colostomy done for any cause. Those patients who met the necessary inclusion criteria were recruited in the study after institutional ethics committee clearance and the informed consent of parents and assent from children aged more than 7 years.

After going through a similar study[5] in adults done by Nanavati *et al*, the sample size was estimated to be four in either group to achieve a confidence level of 95% and a power of 80%. Sample size was calculated using the formula: $(1.645+0.84)^2$ X (sum of squares of standard deviation) / (square of the difference between the two means). However, we decided to recruit 15 patients in each group. Thirty such patients were chosen and were randomly divided into two groups using computer software (simple randomization) – 15 patients were managed using the conventional protocol (CP) and 15 patients were managed with fast-track protocol (FTP).

On the day of operation, all the patients (both groups) were taken-up as the first case in the morning and given general anesthesia. Fentanyl was given intravenously. Propofol, Isoflurane in Nitrous oxide and Oxygen and Vecuronium were used for anesthesia. The anastomosis was done with simple interrupted sutures (single layer) using polyglactin suture material.

The controls (CP group) were managed as per the conventional protocol for stoma closure that was being followed in our unit. Preoperative measures included mechanical bowel preparation with distal stoma washes and polyethylene glycol solution (1g/kg) with a glass of water given 16 hours before surgery. Solid diet and breast milk were restricted 16 hours before surgery; clear liquids were allowed up to 6 hours before surgery. Intraoperatively, a nasogastric tube was routinely placed and an intra-abdominal corrugated drain was placed. Post-operative measures included pain relief with opioids (Tramadol 1mg/kg/dose intravenously 8 hourly) and non-steroidal anti-inflammatory drugs (Paracetamol 15mg/kg/dose intravenously or orally three times a day). Ketorolac was used as a rescue analgesic (when pain score >6 despite administering the above mentioned analgesia), given intravenously (0.4mg/kg) SOS up to a maximum of three doses in a day. The nasogastric tube was removed after the return of bowel sounds and when the nasogastric aspirate turned non-bilious. A liquid diet was begun after the removal of the nasogastric tube. The drain was removed once soakage was less than one gauze piece in 24 hours. Intravenous fluids were given when the child was in nil by mouth.

Fast-track elements that were implemented in the cases (FTP group) included:

1. Pre-operative counseling of the parents and children.
2. Avoidance of mechanical bowel preparation.
3. Preoperative fasting of six hours for solids, four hours for breast milk and two hours for clear liquids.
4. Avoidance of prophylactic placement of nasogastric tube and abdominal drain.
5. Placement of an epidural catheter at L2-3 level (for sigmoid colostomy) or T9-10 level (for transverse colostomy). At the start of surgery, 0.25% bupivacaine was given. At the end of surgery, 30 μg/kg of morphine in 2-6ml of saline was given epiduraly. Adequate pain relief in the form of epidural morphine (30 μg/kg in 2-6ml of saline once a day) was given. Epidural catheter was kept *in situ* for 2 days after surgery. The patient was also given oral non-steroidal anti-inflammatory drugs (intravenous or oral syrup Paracetamol 15mg/kg three times a day). The rescue analgesia protocol was the same as was for the controls (CP group)
6. Early mobilization of patients in the post-operative period. Children were encouraged to sit-up on the evening of surgery and walk on postoperative day-1. They should be ambulated at least 4 times for 10 minutes each time on postoperative day-1. Parents of infants were encouraged to hold the baby upright for half an hour at least once on the evening of the day of surgery itself and at least 4 times on postoperative day-1.
7. Early enteral feeding within the first 24hr is started with sips and clear liquid diet on post-operative day-1 and solids on post-operative day-2. Exclusively breastfed infants fed on postoperative day-1. Intravenous fluids were given while the child was on nil-by-mouth.
8. Prevention of postoperative nausea and vomiting with antiemetic drugs (Ondansetron 0.1 /kg intravenously tds - max 4mg/day)

In case, there was any suspicion of an anastomotic leak or obstruction based on the clinical or hematological parameters, an ultrasound and X-ray abdomen (erect) were done. If the suspicion was confirmed, then the fast-track protocol was abandoned.

The criteria for discharge were the same for both groups: i.e. accepting a full diet, having passed flatus or feces and being able to carry out daily routine physical activity as per the age. All the patients were evaluated during their hospital-stay and were called for follow-up one week after discharge.

The primary outcome evaluated in patients in both groups was duration of hospital stay. The secondary outcomes included:

1. Pain on the evening of the days of surgery (at 9pm) and on the post-operative days 1 and 2 (at 9am). It was assessed using the FLACC Behavioral Pain Assessment Scale for children less than 4 years of age and the FACES Pain Scale for children 4 years and older.
2. Return of bowel function as assessed by auscultation of bowel sounds, asking for passage of flatus and/or feces and acceptance of diet.
3. Time at which child first voids urine spontaneously after surgery.
4. Readmission to the hospital, and the underlying reason(s).
5. Time at which the child returns to school or engages in playful activities (in children >1 yr).
6. Post-operative complications like vomiting, wound infection, wound dehiscence, paralytic ileus, anastomotic leak, obstruction, and itching (due to epidural analgesia)

Results between the two groups were compared by protocol–based analysis to see if there was any statistically significant difference in the above parameters. The quantitative variables were expressed as mean ± standard deviation (sd) and compared using the unpaired t-test/Mann-Whitney test. Qualitative variables were expressed as frequencies or percentages and compared using Chi-square/Fisher's exact test. Statistical Package for Social Sciences (SPSS) version-15.0 software was used for statistical analysis. Statistical significance was set at P <0 .05

RESULTS

The indications of colostomy in these 30 children included anorectal malformation (n=23), perineal injury (n=4) and bowel perforation (n=3). The cases and controls were age- and gender-matched with no statistical differences. The sigmoid colostomy was the commonest procedure followed by the transverse colostomy. Divided colostomy was slightly more common than the loop colostomy.

The primary duration of hospital stay (duration of hospitalization after first admission) (P= 0.282) and overall duration of hospital stay (including readmissions) (P= 0.119) did not differ significantly in the two groups. The pain scores on the day of surgery and post-operative days 1 and 2 were significantly lower for the FTP group as compared to the CP group (Table 1). The number of doses of rescue analgesia (ketorolac) required for the FT group was significantly lower than that needed for the CV group (Table 2).

Table 1: Pain Scores

Pain Score	Day 0	Day 1	Day 2
CP Mean ± SD	5.33 + 1.50	4.40 + 0.91	4.47 + 0.92
FTP Mean + SD	3.60 + 2.13	2.93 + 1.71	2.93 + 1.10
p-value	0.008*	0.003*	<0.001*

**Statistically significant (using unpaired t-test)*

Table 2: Number of Rescue Analgesic (Ketorolac) Doses Required

Number of rescue analgesic	CP (n=15)		FTP (n=15)	
	n	%	n	%
0	9	69	14	93
1	3	23	1	7
2	1	8	0	0
Mean ± SD	0.38 ± 0.65		0.07 ± 0.26	

p-value 0.046 (Statistically significant; Mann-Whitney test); CP - Conventional protocol; FTP - Fast-track protocol

Return of bowel function was earlier in the FTP than the CP group; but the difference was not statistically significant. Young children could not express passage of flatus and thus could only be recorded in 10 cases each group. Infants were on exclusive milk feeds; thus, acceptance of a solid diet could only be measured in 11 patients of the CP group and 13 of the FTP group.

In the CP group, the average times to removal of the nasogastric tube and the abdominal drain

were 49.87 (± 21.96) hrs and 2.53 (± 0.74) days respectively. None of the children was routinely catheterized intra-operatively. However, 1 patient in the CP group and 2 patients in the FTP group went into urinary retention and required catheterization post-operatively; catheters were removed on post-operative day-2.

Two of the patients in the CP group required readmission. One patient developed a fecal fistula that resolved on conservative management. This child required readmission for six days. The other child required readmission (3 days) for a wound infection that was managed with intravenous antibiotics and dressing.

The time taken to sit-up and stand was significantly lower in the FTP group as compared to the CP group.(Table 3) As some of the infants were too young to have physical mobility, data on sitting-up was available only in 11 children in the CP group and 14 in the FTP group. Similarly, time to standing was calculated in 9 children of the CP group and 13 of the FTP group. The mean time to start walking was almost the same in both groups. It was recorded for 10 children in the CP group and 13 in the FTP group. The time at which the child starts to engage in playful activities was also lower in the FTP group; however, the difference was not significant. The time to return to school was affected by many social factors. Many children with perforation and perineal injury had left school since the time of first surgery and would only be able to join school once the next academic year begins, thus the average time to return to school could not be measured.

There were 8 complications in the CP group and 6 in the FTP group (Table 4). There was a statistically significant increase in wound infections in the CP group and paralytic ileus in the FTP group. Wound infections were managed with dressings and intravenous antibiotics. Paralytic ileus was managed by delayed feeding. One patient in the FTP group had anastomotic leak that required re-exploration and repeat colostomy formation. The leak was detected before the discharge of the child and thus led to an increase in the duration of primary hospital stay. The patient with fecal fistula in the CP group required readmission but could be managed conservatively. The patient with colonic dysmotility required bowel washes in the postoperative period.

DISCUSSION

The primary duration of hospital stay and the overall duration of hospital stay (including readmissions) between the two groups were similar in the present study. These results cannot be compared with the results of the multiple studies done by Reismann et al[6,7] and Schukfeh et al[8], as they studied many different surgeries together and calculated the mean hospital stay due to all procedures. Thus they did not provide mean hospital stay for colostomy closure or bowel anastomosis. In the study by Sangkhathat et al[9] early enteral feeding after colostomy closure lead to significantly reduced post-operative stay, from an average of 6.1 days to 4.5 days. In our study, the mean postoperative stay for the FTP group was 4.33 days. Two out of the fifteen children in the FTP group were required to stay beyond post-operative day 5 (one was a case of an anastomotic leak who remained in hospital for 11 days, thus causing a skewed distribution and increase in the mean value). In the study by Mattioli et al[10], only 2 out of 46 required hospital stay beyond 5 days.

The mean pain scores were significantly lower in the FTP group (3.6, 2.93 and 2.93 for the day of surgery and postoperative days-1 and -2 respectively) compared to the CP group (5.33, 4.40 and 4.47 respectively). These results are better than those obtained by Reismann et al[6] where pain score during the immediate postoperative period was higher than 5 (4.2, 2.2, 2 for <4 years and 5.4, 4 and 2.3 for >4 years respectively). However, this study included a variety of surgeries and not just

Table 3. Return of Mobility

Time to activity	CP Mean ± SD	FTP Mean ± SD	p-value
Sits up (hr)	46.9 ± 24.9	14.6 ± 9.4	<0.001*
Stands (hr)	67.8 ± 29.3	23.2 ± 6.5	<0.001*
Walks (d)	3.4 ± 0.5	3.5 ± 5.0	0.493#
Plays (d)	7.0 ± 5.4	5.3 ± 3.8	0.168#

** Statistically significant, # Statistically not significant (using unpaired t-test), hr - hours, d - days. CP - Conventional protocol; FTP - Fast-track protocol*

Table 4: Incidence of various Complications

Complications	CP n (%)	FTP n (%)	P Value
Ileus	0 (0%)	3 (20%)	0.034*
Wound infection	5 (33%)	2 (13%)	0.008*
Anastomotic leak	0 (0%)	1 (7%)	0.155#
Vomiting	1 (6.6%)	0 (0%)	0.155#
Faecal Fistula	1 (6.6%)	0 (0%)	0.155#
Colonic dysmotility	1 (6.6%)	0 (0%)	0.155#

** Statistically significant, # Statistically not significant (using unpaired t-test), hr - hours, d - days. CP - Conventional protocol; FTP - Fast-track protocol*

colostomy closure. The children in the FTP group also required significantly lesser doses of rescue analgesia. This shows that preoperative counseling, epidural analgesia, the lack of drains and nasogastric tubes and active mobilization in the post-operative period lead to significant decrease in the pain scores. Only 1 child required removal of the epidural catheter on postoperative day-1 as it was blocked. Thus, insertion of epidural catheters is safe and effective even in young children and infants.

Return of bowel function was faster for the FTP group; however the difference was not statistically significant. In the FTP group, the mean time to tolerate liquid diet was 46.7 hrs and solid diet was 3 days. Flatus was passed in the meantime of 29 hrs and feces in 2.13 days. In the study by Mattioli et al[10] oral feeding and stool passage were achieved by post-operative day-1. In the study by Reismann et al[6], oral nutrition was achieved at a mean time of 15 hrs. However, this study included many surgeries which did not involve bowel handling, where it is possible to start feeds within a few hours of surgery. Sangkhathat et al[9] could achieve initiation of feeding within 19.7 hrs of surgery and full feeding by 45.5 hrs. Thus initiation of early feeding is feasible in the pediatric age group. Bowel function was also restored faster, probably owing to the avoidance of bowel preparation, initiation of early feeding, early mobilization and decreased pain in the FTP group.

Urinary retention is a known side-effect after epidural morphine administration. In our study, two patients of the FTP group and one of the CP group required catheterization due to urinary retention; however, this difference was not statistically significant. Thus, epidural morphine at a low dose of 30 μg/kg, does not cause significant urinary retention.

Two patients in the CP group required readmission, one for fecal fistula and one for wound infection (difference statistically not significant). This is in contrast to other studies of fast-track surgery in children[6,7,10] where readmissions were more amongst the fast-track patients.

The time taken to sit up and stand was significantly lower in the FTP group as compared to the CP group. The mean time to start walking was almost the same in both groups. The time at which the child starts to engage in playful activities was also lower in the FTP group; however, the difference was not significant. Reismann et al[6] could achieve mobilization in an average of 29.5 hrs, while in our study children were only walking after 3.46 days. This difference could be attributed to the fact that the former study included a variety of surgeries, some of which had faster convalescence than colostomy closure. It also could be attributed to cultural differences of the patient population. Many people still hold on to their traditional beliefs that strict bed rest is essential

for recovery after surgery. It was also observed that many children had not gone to school at all since the time of their previous illness (since the time of stoma formation). Thus they couldn't resume school immediately after surgery as many of them had lost one or two academic years and had to start school at the start of the forthcoming academic year.

The rate of complications was significantly higher for the CP group. There was a statistically significant increase in wound infections in the CP group and paralytic ileus in the FTP group. The increase in wound infections in the CP group may be related to the increase in stress response to surgery and the associated suppression of immunity. The increases incidence of ileus in the FTP group is probably related to the use of epidural morphine, which is known to decrease gastrointestinal motility.[3,5] One patient in the FTP group developed anastomotic leak that required re-exploration and repeat colostomy formation. The leak was detected before the discharge of the patient and thus led to an increase in the primary duration of hospital stay. In the CP group, vomiting, fecal fistula and colonic dysmotility were seen in one patient each. Reismann et al[7] defined complications associated with fast-track surgery as complications with a delay in diagnosis and treatment owing to early discharge. No such complications were seen in our study reported by Reismann et al.[6,7] In the study by Matioli et al [10] anastomotic leak and rectal pouch dehiscence was seen in one patient each. Thus, there were two complications among 46 patients. Our study thus replicates the complication rate of other studies.

Thus, in our study, the patients in the FTP group had a significant decrease in pain scores and need for rescue analgesia, a significantly shorter time to sit-up and stand and a significant decrease in overall complication rate. Patients in the FTP group had a significant decrease in wound infection and a significant increase in post-operative ileus (probably related to the use of epidural morphine). There was no significant differences in the duration of hospital stay, return of bowel function, need for catheterization, time taken to walk and play and readmission rate between the two groups. Thus, the entire gamut of traditional peri-operative care - including prolonged fasting, bowel preparation, use of drains and nasogastric tubes, intravenous analgesia and delayed feeding needs to be questioned. These measures are unnecessary even in the pediatric group of patients undergoing colonic surgeries. They increase the discomfort of the patient and do not lead to any significant improvement in results.

This study only included one type of surgery performed in the pediatric age group. More studies are required which evaluate the results in other abdominal surgeries too.

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