Original Article

Fast Track versus Conventional Perioperative Care Protocols in Paediatric Intestinal Stoma Closure – A Randomised Study

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Abstract

Background: It is still unclear to what extent fast-track (FT) surgery is applicable in paediatric surgery. The aim of the study was to compare the outcome between FT and conventional perioperative care protocols in paediatric intestinal stoma closure to assess the safety for future application. **Materials and Methods:** This study was a prospective randomised study. Twenty-six paediatric patients who underwent intestinal stoma closure from December 2019 to March 2021 were divided into two groups: group A, conventional methods and Group B FT protocol. The FT protocol included minimal pre-operative fasting, no pre-operative bowel preparation, no routine intraoperative use of nasogastric tube, drain tube, urinary catheter, early post-operative enteral feeding, early mobilisation, non-opioid analgesics and prophylactic use of anti-emetic. Total length of post-operative hospital stays and complications between these two groups were compared. **Results:** No significant differences were found between the two groups regarding anastomotic leak (nil in both groups), wound infection (7.7% in Group A vs. 0% in Group B; $P = 1.0$) and wound dehiscence (7.7% in Group A vs. 0% in Group B; $P = 1.0$). No significant differences were found in post-operative length of stay (median 5, interquartile range [IQR] 4–9 in Group A and median 6, IQR 4–7 in Group B, $P = 0.549$) and time to appearance of bowel function (passage of stool) (median 2 days in both groups; $P = 0.978$). **Conclusions:** FT surgery was comparable to the conventional method in terms of complication and thus can reduce unnecessary interventions.

Keywords: Enhanced recovery after surgery, fast-track protocols, hospital stay, intestinal stoma closure

Introduction

Fast-track (FT) surgery or enhanced recovery after surgery was aimed to avoid surgical stress and improve functional recovery and shorten hospital.[1-5] FT protocols include minimising pre-operative fasting, avoiding pre-operative bowel clearance, no routine use of drains, tubes and catheters, early post-operative oral feeding, early mobilisation and non-opioid multimodal analgesia.[6-9]

However, data on outcomes associated with the use of FT protocol in paediatric populations are limited.[10] Although FT surgery has been used for some procedures in children, such as appendectomy,[11-14] nephrectomy, pyelolithotomy and pyeloplasty;[15,16] there is considerable component variability in the studies performed in this area, and none utilised all the components.[17-20] The aim of the study was to determine the post-operative complication rate and length of stay (in hospital) (LOS) after applying FT protocol in paediatric intestinal stoma closure and compare it with conventional perioperative care protocol.

Materials and Methods

Study settings

It was a randomised study carried out in the department of paediatric surgery of authors' institute (blinded) from 1st December, 2019 to 6th March, 2021. The general objectives were to find out a better perioperative care protocol in paediatric intestinal stoma closure. The specific objectives were to compare the rate of anastomotic leak, wound

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infection and wound dehiscence between FT and conventional perioperative care protocol and to compare the total length of post-operative hospital stay between them. The study population was screened consecutively by the eligibility criteria to select the appropriate subjects for the trial and then the eligible subjects were randomly allocated in two treatment protocols. All patients who were admitted for elective intestinal stoma closure in this department ageing not more than 12 completed years were included. Patients were excluded if they had associated major congenital anomaly other than gastrointestinal (GI) pathology (e.g. congenital heart disease, urogenital malformation); conditions which might have an impact on the outcome of stoma closure, such as anal stenosis, anal stricture, rectal mucosal prolapse or retraction, retained aganglionic segment and extensive pre-operative soiling; stoma closure associated with other surgical procedure (s), such as abdominoperineal pull through, a two-stage procedure for Hirschsprung's disease (HD), malignant tumour of GI tract and had a history of tuberculous intestinal perforation were excluded.

Design

FT perioperative care protocol included minimal pre-operative fasting (for solids not more than 6 h and for liquid not more than 4 h), no mechanical bowel preparation, nasogastric (NG) decompression not more than 24 h, no urinary catheterisation or catheter for not more than 24 h, no abdominal drainage intraoperatively or removal of drain before 24 h, post-operative enteral intake within 48 h, post-operative enforced mobilisation within 24 h, use of non-opioid analgesia (i.e. ketorolac and paracetamol) and routine use of prophylaxis (i.e. ondansetron) for post-operative nausea and vomiting.[10,11,21] Conventional perioperative care protocol included long overnight fasting or fasting more than 6 h, mechanical bowel preparation in pre-operative period, perioperatively routine use of NG decompression which extends for more than 24 h, urinary catheterisation extending for more than 24 h, abdominal drainage for more than 24 h, post-operative enteral intake after 48 h, post-operative mobilisation after 24 h or according to patient's wish, use of opioid analgesia for pain management and medication for post-operative nausea and vomiting after the development of symptom.

Informed written consent was obtained from the legal relatives of the patients after a full explanation of the ultimate outcome, complications and purpose of the study. Eligible individuals were recruited consecutively and randomly assigned in 1:1 ratio (block size of two), with a computer-generated randomisation list, to one of the two treatment groups.

- Group A: Conventional perioperative protocol
- Group B: FT protocol.

All the operations were performed using a hand-sewn technique of anastomosis in single layers with 4-0 absorbable braided suture material in both groups. The antibiotic policy of the hospital was used for post-operative coverage uniformly for both groups. Patients were discharged when oral intake was adequate and pain was well controlled; patients passed flatus with or without stool; were able to ambulate independently and the wound condition was satisfactory.

All patients in both groups were followed up during their hospital stay and for 1 month after discharge to record outcomes. Post-operative complications and post-operative LOS were the main outcome variables.

Patients

A total of 30 patients were screened for eligibility, out of which 26 patients aged 12 years and below were enrolled in the study and were assigned randomly to conventional perioperative care protocol (Group A) or FT protocol (Group B) for intestinal stoma closure. Patients were followed up for 1 month following discharge to observe the outcomes. There was no lost to follow-up case and all of the enrolled 26 patients were included in the analysis.

Data analysis

Data were analysed using the Statistical Package for the Social Sciences, version-23 (SPSS-23, IBM, Chicago, Illinois, USA). The quantitative data were expressed as median (interquartile range [IQR]) or mean (±standard deviation) and range. Medians were compared between groups by Mann–Whitney *U*-test. Categorical variables were presented as number (percentage). The Pearson Chi-square or Fisher's exact tests were used, as appropriate, for between-group comparisons of categorical data. $P < 0.05$ were considered to be statistically significant.

Ethical statement

Voluntary consent was taken from the patient's legal guardian. All measures were taken to preserve the patient's anonymity and privacy. The patient's legal guardian was informed about the nature and purpose of the study. The study was approved by the ethical review committee of the authors' institute (blinded).

Results

There was no significant difference between the two groups with regard to age (median 1.58 years in Group A and 4.67 years in Group B, $P = 0.39$), sex (10 males and three

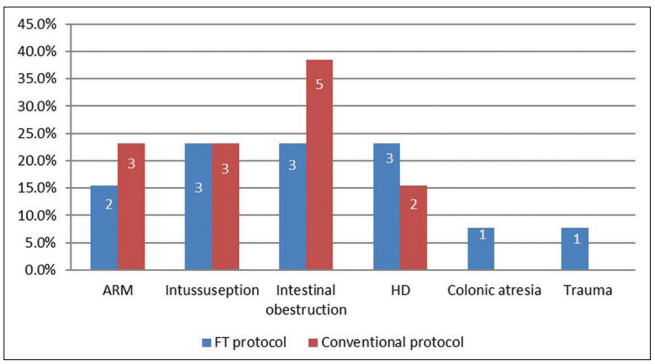


Figure 1: Primary diagnosis of the patients stratified by study groups. ARM: Anorectal malformation, HD: Hirschsprung's disease

females in both groups, $P = 1.0$) and weight (median 9 kg in Group A and 10 kg in Group B, $P = 0.08$). Table 1 describes the surgical characteristics of the patients.

The most common indication for stoma was an intestinal obstruction in eight patients (due to worm bolus, post-operative bands and adhesions, congenital bands and adhesions, appendicular perforation, midgut volvulus and malrotation), followed by intussusception (6), anorectal malformation (ARM) (5), HD (5), colonic atresia (1) and rectal trauma (1) [Figure 1].

Table 1: Surgical characteristics of the patients stratified by study groups

Surgical characteristics	Group-A (*n*=13), *n* (%)	Group-B (*n*=13), *n* (%)	*P*†
Type of operation			
Sigmoid colostomy closure	2 (15.4)	3 (23.1)	0.857*
Ileostomy closure	6 (46.2)	5 (38.5)	
Ileo-ascending stoma closure	2 (15.4)	1 (7.7)	
Transverse colostomy closure	3 (23.1)	4 (30.8)	
Type of stoma			
Loop	8 (61.5)	9 (69.2)	
Double-barreled	5 (38.5)	4 (30.8)	0.680*
Condition of stoma			
Uncomplicated	6 (46.2)	12 (92.3)	0.083*
Peristomal skin excoriation	5 (38.5)	1 (7.7)	
Prolapsed	1 (7.7)	0	
Retracted	1 (7.7)	0	
Duration of surgery (min)			
Median (IQR)	120 (83-135)	125 (98-150)	0.548**
Range	60-190	70-180	

†$P < 0.05$ was considered to be statistically significant. *P* values were obtained from *Chi-square tests or **Mann-Whitney *U*-test. Data are expressed as frequency (percentage) if not otherwise mentioned. Group A: Conventional perioperative care protocol and Group B: FT protocol. IQR: Interquartile range, FT: Fast track

Table 2: Comparison of post-operative complications between two groups

Type of complications	Group-A (*n*=13), *n* (%)	Group-B (*n*=13), *n* (%)	*P*†
Anastomotic leak	0	0	NA
Wound infection (superficial)	1 (7.7)	0	1.0
Wound dehiscence (partial)	1 (7.7)	0	1.0
Other complications			
Unspecified fever >48 h	5 (38.5)	2 (15.4)	0.782
Nausea and vomiting	2 (15.4)	2 (15.4)	1.0
Respiratory tract infection	3 (23.1)	1 (7.7)	0.641
Diarrhoea	1 (7.7)	0	1.0
Passage of blood per rectum	1 (7.7)	0	1.0
Ileus	1 (7.7)	0	1.0

†$P < 0.05$ was considered to be statistically significant. *P* values were obtained from Fisher's exact test. Data are expressed as frequency (percentage). Group A: Conventional perioperative care protocol and Group B: FT protocol. NA: Not applicable, FT: Fast track

Post-operative adverse events occurred in 5 (38.5%) patients in the FT protocol group compared to a total of 15 complications in 10 (76.9%) patients in the conventional protocol; in whom more than one complication was found in five patients [Table 2]. There was no anastomotic leak in any group. One case of wound infection and superficial wound dehiscence occurred, both of which were observed in Group A. Unspecified fever (>48 h) was the most frequent complication observed in the study followed by vomiting and respiratory tract infection. Other less frequently reported complications were passage of blood per rectum, ileus and diarrhoea, all observed only in Group A. However, none of the differences in complications rate between the two groups were statistically significant.

There was no significant difference in LOS days between groups (median 5, IQR 4–9 in Group A and median 6, IQR 4–7 in Group B, $P = 0.549$). The earliest and last time of appearance of bowel function was 1st post-operative day (POD) and 5th POD, respectively, in both groups. The median time was also similar in both groups (2 days). Statistically, no significant difference was observed between the two groups regarding the appearance of bowel function ($P = 0.978$). Post-operative period of up to 1 month was uneventful in the entire studied patients. None of the patients irrespective of study groups required readmission or reintervention.

Discussion

One of the primary goals of FT surgery protocol is to promptly return the patient to baseline function by maintaining pre-operative organ function and attenuating the neuroendocrine stress response after surgery. Many components comprise a typical enhanced recovery pathway, including avoidance of prolonged fasting and oral carbohydrate loading preoperatively, early mobilisation, early enteral nutrition and patient education. The present study was conducted to compare the FT protocol with that of conventional perioperative care protocol in paediatric patients who underwent stoma closure.

Regarding complications, there was an overall lower rate of complications in the patients with FT protocol compared to patients with the traditional group. About 38.5% of patients in the FT protocol group had some sort of complications compared to 76.9% of patients in the conventional protocol group. The reduction of the rates of post-operative complications in the FT group is likely to result from a combination of multimodal perioperative interventions, aiming to reduce metabolic response to surgery, to support the return of organ function and to preserve post-operative immune system.[22]

A total of nine individual FT elements were applied on the study group. This analysis of the present study showed that baseline confounding factors were comparable between the two groups in terms of age, sex, weight, operation type, stoma characteristics (type and condition), operative time and primary diagnosis of the patient. The majority of the patients in both groups had ileostomy closure (46.2% in

Group A vs. 38.5% in Group B, $P = 0.857$). However, Yadav *et al*. found sigmoid colostomy closure to be predominant in their study (42% in the FT group vs. 52% in the conventional group, $P = 0.445$).[22] It was probably because ARM was the predominant primary diagnosis in their study (51% in the FT group vs. 54% in the conventional group, $P = 0.799$); whereas, in this study majority of the primary diagnosis was an intestinal obstruction in Group A (38.5%) and HD, intussusceptions and intestinal obstruction in Group B (each of them was 23.1%). In this study, the majority of the stoma was loop variety (61.5% in Group A and 69.2% in Group B, $P = 0.680$) and most of their conditions were uncomplicated (46.2% in Group A vs. 92.3% in Group B, $P = 0.083$).

In this study, the median duration of the indwelling NG tube in Group A was 70 h, whereas, it was zero in Group B ($P < 0.001$). However, it was inserted in one patient in Group B after starting of oral fluids on the 2nd post-operative day, who had repeated bilious vomiting. It was a case of ileostomy closure who had a history of worm bolus obstruction. NG tube was kept for 18 h and later removed at 3rd POD. The subsequent post-operative period was uneventful in this patient. However, no statistically significant difference was found between the two groups regarding post-operative complications related to NG tube (e.g. vomiting, respiratory tract infection and ileus). In an randomized controlled trial (RCT), conducted by Gustafsson *et al.,* it was shown that the routine use of NG tube has no positive, but rather has a series of negative effects.[23] They stated that patients who had not received NG tubes tolerated oral intake earlier and routine NG decompression may unnecessarily delay the intake of important nutrition in the post-operative period. They also added that eliminating routine NG tube can prevent post-operative ileus. Nanavati and Prabhakar attributed their study to the fact that routine use of NG tubes postoperatively delays ambulation.[21] Rao *et al.* reported that pharyngolaryngitis and respiratory infections occurred less frequently if post-operative NG decompression was avoided.[24]

Group B did not receive abdominal drain routinely in the intraoperative period, whereas Group A received it routinely. The drain in Group A was removed only after the cessation of any exudates. However, there was one Group B patient who received an abdominal drain in the intraoperative period. It was a case of ileotransverse stoma closure with a history of worm bolus obstruction. There was extensive peristomal adhesion and some unexpected blood loss occurred during surgery. The drain was kept for 22.75 h. Jesus *et al.* conducted a Cochrane systematic review where they could not find any significant difference in outcomes, in terms of safety and effectiveness of routine drainage after stoma closure.[25] Browning *et al*. and Puleo *et al*. found in their respective studies that abdominal drains do not contribute to the early detection of anastomotic leaks; they impede ambulation, and may contribute to increased wound infection and a longer hospital stay.[26,27]

The start of oral fluids was attempted in all patients of Group B on the 1st post-operative day. All the patients except one tolerated that well and gradually increased fluid volume and consistency progressing into breastfeeding or semisolid food on the 2nd post-operative day according to their age. The patient who did not tolerate oral feeding and had repeated bilious vomiting after the start of oral fluids was kept nothing by mouth and a NG tube was inserted which was later removed after cessation of bilious suction on 2nd POD. Restart of oral fluids was initiated on the 2nd POD. On the contrary, post-operative enteral feeding in Group A had been delayed routinely up to the 3rd to 5th POD. A study on paediatric stoma closure conducted by Yadav *et al*. stated that they initiated the first sustained feed in the FT group at 28.5 ± 4.5 h, on the contrary; it was 153.8 ± 28.6 h in the conventional group ($P < 0.0001$).[23] They found a significant reduction in post-operative complications and hospital stay in the early feeding group. Feasibility, safety and effectiveness of early (within 24 h of operation) feeding in stoma closure has been found in several RCTs.[28-30] Stewart *et al*. demonstrated that radiologic and electrophysiologic studies indicated a return of small bowel function in 4–8 h post-incision, right colon function by 24 h and left colon function by 72 h.[31] It has been well established that any delay in the resumption of a normal oral diet after major surgery is associated with increased rates of infectious complications and delayed recovery.[16]

In this study, Group A showed statistically non-significant more post-operative respiratory tract infection, ileus and hospital stay than Group B which are also similar in different studies delayed mobilisation group. Haines *et al.* showed that lack of early mobilisation after abdominal surgery has been associated with an up to threefold increase in the likelihood of developing a pulmonary complication.[31] Basse *et al*. demonstrated that an aggressive structured mobilisation plan after bowel anastomosis leads to less ileus and shorter hospital stay.[32]

There were two patients from Group A who received antiemetic medication in their post-operative period due to nausea and vomiting, which was later omitted after cessation of the complaint. No significant difference was found between the two groups regarding post-operative nausea or vomiting (PONV). Fathy *et al*., Pearson and Hall, Nanavati and Prabhakar also provided prophylactic antiemetic to their FT group following stoma closure, but they also did not find any significant differences with the conventional group regarding PONV.[10,11,21]

Although no significant differences were found between the two groups regarding opioid-related complications (i.e. nausea, vomiting, ileus and respiratory tract infection). Kehlet and White demonstrated that opioid sparing reduces post-operative nausea, vomiting and pulmonary morbidity.[33,34] However, in this study, a significant difference was observed between groups regarding early post-operative mobilisation ($P < 0.001$). As opioid analgesia causes sedation, it was possible to mobilise Group B earlier because it received non-opioid analgesia. Kehlet and Wilmore showed that non-opioid analgesia is associated with early mobilisation.[5] They further added that it is also associated with a fast return of bowel function and

a reduction in LOS. However, this study did not find any significant differences between Groups A and B in terms of the appearance of bowel function and LOS.

In this study, the only patient who experienced wound infection (superficial) belongs to Group A (P = 1.0). It was a case of ileostomy closure and the incident was later managed by broad-spectrum antibiotics and regular drainage. It was speculated that this incident probably occurred due to poor nutritional status, which is commonly found among patients with an ileostomy. It was expected that long overnight fasting and delayed enteral feeding can deteriorate a patient's nutritional status which might lead to impaired wound healing among Group A patients. The study by Yadav *et al.* on paediatric stoma closure found a significant difference regarding wound infection between the two groups (6.5% in the early feeding group vs. 29% in the traditional feeding group; P = 0.02%).[22] There was no wound infection among 74 patients who underwent elective bowel anastomosis in a study conducted by Santos-Jasso *et al*.[35] No significant differences were also found by Fathy *et al*. regarding post-stoma-closure wound infection (13.3% in the FT group vs. 20% in the conventional group; P = 0.48).[10]

The study showed a higher trend of respiratory tract infection in the conventional perioperative care group compared to the FT group (23.1% vs. 7.1%), however, probably owing to the small sample size the difference was not statistically significant (P = 0.641). It was expected that the routine use of NG tube and late ambulation would be associated with more chest infection in the conventional group in the present study. Fathy *et al.* reported a higher rate of chest infection in the conventional protocol group compared to the FT protocol group (60% vs. 26.7%, P = 0.009).[10]

This study has some limitations. The sample size was small due to the COVID-19 pandemic situation, and some components of FT protocol were not chosen for this study (e.g. minimally invasive surgery, epidural analgesia). Due to the COVID-19 pandemic and lockdown situation some patients' guardians, who lived at distant places from Chattogram, did not want to go home even after fulfilling discharging criteria. They stayed in the hospital up to the 7th and 8th POD until their stitches were removed. It had a negative impact on post-operative LOS, especially on FT surgery patients.

Conclusion

The present study found no statistically significant differences between FT and conventional perioperative care protocol in pediatric intestinal stoma closure regarding postoperative complications and hospital stay. However, implementing FT protocol in pediatric intestinal stoma closure should be encouraged because of its aptitude to minimize patient suffering.

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Conflicts of interest

There are no conflicts of interest.

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