Original Research Article

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Early takedown of a defunctioning ileostomy, is there a downside? – a prospective analysis from Rural Bengal

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ABSTRACT

Background: Since the pilot study in 2002, many studies have evaluated the feasibility of an Early Ileostomy takedown by 2 weeks, thus decreasing the stoma related morbidity. However, in a developing country like India, this paradigm shift is still debatable. Our study from a tertiary teaching rural hospital in Bengal evaluates the feasibility of Early takedown by 2 weeks and compares it to a more accepted concept of Ileostomy takedown by 8-10 weeks.

Methods: This prospective longitudinal comparative study conducted from February 2018 to July 2019, in our institute. Sample size was calculated to be 30 in each group. The early closure went a takedown at 2 weeks and the delayed closure underwent a takedown by 8-10 weeks. Data was analysed with Fischer's exact or Chi square test, student's t test. A p value of 0.05 was significant.

Results: Our set of rural patients, had more stoma related complications due to lack of stoma care (13.33% vs 3.33%, EC vs DC). Intraoperative adhesions (26 vs 12, p=0.0004) significantly increased operative time (126.1667±27.5895 vs 86.0000±34.2506, EC vs DC, p<0.001), leading to post-operative complications hence, the Length of hospital stay was more in the early subset (17.9667±6.9851 vs 11.2000±4.0548, EC vs DC, p<0.001).

Conclusions: An early takedown of a defunctioning ileostomy, may be a technically difficult procedure to perform, has more post-operative complications and is discouraged, in our opinion.

Keywords: Ileostomy, Defunctioning, Loop, Stoma, Reversal, Takedown

INTRODUCTION

A "defunctioning" ileostomy is often used as a temporary method of faecal diversion in surgeries of the colon that include a distal colonic anastomosis. Such a stoma prevents anastomotic leak and peritonitis from the index surgery. A few surgeons perform proximal defunctioning colostomies but a defunctioning Ileostomy has as clear set of advantages, there is less chances of stoma prolapse and it is easy to restore without compromising the vascular arcade. Although there are minor differences between a defunctioning and loop ileostomy, for the sake of simplicity they are considered synonymous in this study. The timing of reversal of these defunctioning stomas have been a matter of debate. The Western world

has seen an increased number of reversals within a week of the index operation, since the pilot study conducted by Bakx et al in 2002 showed the feasibility of reversal by 11 days without any significant morbidity.² However, the situation seems to be more dubious, with skepticism to deviate from the traditional teaching, of performing the stoma takedown after the "window of doom" (from 10 days to 6 weeks) in a developing country, among the rural population where there is a lack of research and an expert consensus.

Our study attempts to identify the indications of constructing a defunctioning ileostomy, the complications associated with the stoma and to compare the outcomes of an early takedown of these stomas by 2 weeks of the

index surgery, to a more traditionally accepted duration of 8-12 weeks. This study is set amidst a rural Indian population, in our teaching institution in Bengal.

METHODS

This prospective longitudinal comparative study was undertaken in the Department of General Surgery of Bankura Sammilani Medical College and Hospital over a duration of 18 months from February 2018 to July 2019, after obtaining an Ethical clearance from the Institutional Ethical Committee, according to the ethical standards for conducting experiments on human subjects and in accordance to the Declaration of Helsinki 1975, revised in 2013.

Sample size

The sample size was calculated with a total of 60 patients with 30 patients in each group.

Inclusion criteria

Inclusion criteria were 1) patients with loop or defunctioning ileostomies 2) age (18-70 years) 3) medically fit for an ileostomy reversal 4) grade I-III peritoneal contamination

Exclusion criteria

Exclusion criteria were 1) age>70 2) irreversible stoma 3) cardio respiratory risk 4) anastomotic leak 5) persisting enterocutaneous fistula 6) abdominal wound dehiscence 7) grade IV peritoneal contamination 8) patient denial

Subject allocation and assignment into groups

Of the 246 patients with Ileostomies, 96 patients had loop or defunctioning Ileostomies. Among these patients those satisfying our inclusion criteria were included in the study while those who fell in the exclusion criteria were rejected. Using the above-mentioned technique of sampling a total of 60 patients were included with 30 in each arm of the study. The participants were included only after obtaining a written consent to participate in the study. Patients were randomly assigned into the Early and Delayed group using simple random number tables. The socio-demographic, comorbidities and details of the index surgery and stoma related complications were documented as descriptive data.

The Early subset of the study arm underwent a takedown by 2 weeks and the delayed subset underwent a takedown by 8-12 weeks. The post-operative course was observed and the results in between the two groups were compared. The primary endpoint of this study was the end of a successful follow up of the patients six months after the stoma reversal. (Figure 1).

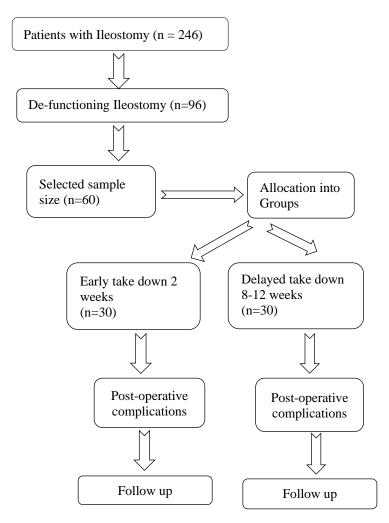


Figure 1: A summary of the study.

Surgical technique of ileostomy takedown

The prerequisites to the Ileostomy takedown constituted blood investigations, electrolytes. A distal loop-o-gram was performed prior to takedown to check the patency of the distal anastomosis and the presence of any leaks. All out patients were given mechanical bowel preparation prior to takedown (Figure 1).



Figure 1: Distal colonic contrast study to evaluate for distal patency.

The surgical procedure of takedown commenced was carried out by the consultant surgeon, and the primary researcher observed the procedure. A circumferential incision was made around the Ileostomy after taking muco-cutaneous stay sutures. After deepening the incision to the rectus sheath, adhesions around the bowel were gently dissected, while simultaneously mobilizing the bowel. A certain number of cases, that posed significant difficulty to mobilize the bowel with a circumferential incision, and those which suffered an inadvertent enterotomy or haemorrhage from the mesentery were converted to a formal Laparotomy. The margins of the stoma were refashioned by truncating the proximal end of the Ileostomy spigot and a hand sewn anastomosis was performed using 3-0 Silk sutures, (SILKUS®, Lotus) on the fresh margins of the bowel using a single layer extramucosal technique. The completed anastomosis was checked for patency and returned back to the peritoneal cavity. The rectus sheath was closed with 1-0 loop Polydioxanone. (MASS®, Lotus) The wound was closed in a linear fashion and the skin was closed with 2-0 Monofilament Polyamide sutures (NYLUS®, Lotus), after wound lavage (Figure 2, $3).^{4}$

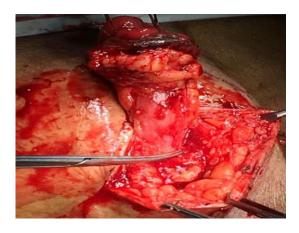


Figure 2: Loop ileostomy being mobilized after a circumferential incision around the stoma.

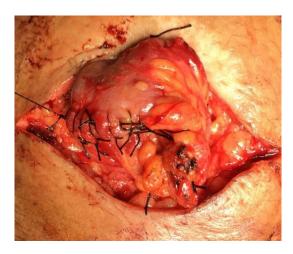


Figure 3: Completed Anastomosis, using a single layer extra mucosal technique after refashioning the edges.

Data collection

Pre-designed questionnaires were used to document the preoperative, perioperative and post-operative data and the results were tabulated in Microsoft Excel 2016.

Statistical analysis

The data was analyzed by SPSS (version 24.0; SPSS Inc., Chicago, IL, USA) and Graph Pad Prism version 5. Data had been summarized as mean and standard deviation for numerical variables and count and percentages for categorical variables. Categorical variables were compared with the Fischer's exact or Chi square test. Continuous variables were evaluated for normality. The unpaired Student's t test was used to compare two continuous variables, depending on the normality of distribution. The null hypothesis was rejected when the P value was greater than 0.05. Thus, a p value≤0.05 was considered for statistically significant.

RESULTS

A total of 60 subjects segregated into two groups of 30 subjects each were analysed. We had no patient dropouts during the course of this study. Descriptive data included assessment of the mean age which was 44.7667±12.4946 vs 44.7333±14.4650 (EC vs DC) respectively. There was a slight male predisposition in both groups 16 vs 24 (EC vs DC). Pre-operative co-morbidities included assessment of history of Chronic Obstructive Pulmonary Disease, Diabetes, Ischemic heart Disease and Renal Disease. Diabetes Mellitus seemed to be the predominant coexisting comorbidity, 8 vs 10 (26.67% vs 33.33%) among the two groups EC vs DC (Table 1).

Table 1: A comparison between demographic and comorbidities between the two groups.

Parameters	Early closure (n=30)	Delayed closure (n=30)
Age (Mean±SD)	44.7667± 12.4946	44.7333± 14.4650
Sex distribution (Female, Male)	6.16	14.24
Comorbidities		
COPD	3 (30%)	5 (16.67%)
Diabetes mellitus	8 (26.67%)	10 (33.33%)
Ischemic heart disease	2 (6.67%)	0
Renal disease	1 (3.33%)	0
Others	1 (3.33%)	2 (6.67%)

The index operation mandating the construction of the ileostomy was due to colorectal cancer, which included low anterior resections (36.67% vs 26.67%), ultra-low anterior resections (10% vs 10%), for EC vs DC respectively. Other indications included irritable bowel

disease like ulcerative colitis that included 2 cases in the early group. 1 patient in the early group had familial adenomatous polyposis coli, who were managed by a proctocolectomy. Apart from these emergency exploratory laparotomies for colorectal traumata were (6.67% vs 3.33%), Ileal perforations (20% vs 36.67%) and Intestinal obstructions were (16.67% vs 23.33%), in the EC vs DC groups respectively.

The type of anastomosis of the index surgeries included Colo-colic (6.67 % vs 16.67%), Colo rectal (50 % vs

26.67%), colo-anal (36.67 % vs 56.67%) and ileo anal (6.67% vs 0%), in the EC vs DC groups. A combination of both hand-sewn (90% vs 83.33%) and stapled anastomosis (10 % vs 16.67 %), in the subgroups EC vs DC were performed in the index surgeries. The patients with colorectal cancer (56.67 % vs 53.33 %, EC vs DC) were subjected to chemoradiation and those with irritable bowel disease, receiving steroids or immunosuppressive therapy was (6.67 % vs 0%, EC vs DC) (Table 2).

Table 2: Comparison between the index surgery between the two groups.

Parameters	Early closure (n=30)	Delayed closure (n=30)			
Indications for Ileostomy (Index Surgery)					
Low anterior resection	11 (36.67)	8 (26.67)			
Ultra-low anterior resection	3 (10)	3 (10)			
Intersphinteric resection	3 (10)	5 (16.67)			
Intestinal obstruction	5 (16.67)	7 (23.33)			
Colorectal trauma	5 (16.67)	7 (23.33)			
Total proctocolectomy with ileo-anal anastomosis	2 (6.67)	0			
Total proctocolectomy with ileoanal pouch	1 (3.33)	0			
Type of distal anastomosis (index surgery)					
Colo - colic	2 (6.67)	5 (16.67)			
Colo- rectal	15 (50)	8 (26.67)			
Colo-anal	11 (36.67)	17 (56.67)			
Ileo-anal	2 (6.67)	0			
Stapled or hand sewn (index surgery)					
Stapled	27 (90)	25 (83.33)			
Hand Sewn	3 (10)	5 (16.67)			
Pre stoma reversal treatment					
Chemo-radiotherapy	17 (56.67)	16 (53.33)			
Steroids and immunosuppressant	2 (6.67)	0			

Figures in parenthesis are in percentages.

Table 3: Comparison of the defunctioning stoma and related complications between the two groups.

Parameters	Early closure (n=30)	Delayed closure (n=30)			
Stoma care					
Yes	4 (13.33)	1(3.33)			
No	26 (86.67)	29 (96.67)			
Stoma related complications					
Skin excoriation	14 (46.67)	17 (56.67)			
Stoma prolapse	2 (6.67)	6 (20)			
Stoma retraction	1 (3.33)	3 (10)			
Muco-cutaneous dehiscence	3 (10)	1 (3.33)			
High output stoma	8 (26.67)	2 (6.67)			
Blocked stoma	0	1 (3.33)			
Parastomal hernia	2 (6.67)	0			

Figures in parenthesis are in percentages.

Since our patients belong to a rural population, knowledge and execution of stoma care was very less.

(13.33% vs 3.33%, EC vs DC), which culminated in various stoma related morbidities, such as skin excoriation (46.67 % vs 56.67%), stoma prolapse (6.67% vs 20%), Stoma Retraction (3.33% vs 10%), mucocutaneous dehiscence (10% vs 3.33%), high output stoma (26.67% vs 6.67%), blocked stoma (0 % vs 3.33%) and parastomal hernias (6.67% vs 0 %), in the EC vs DC groups respectively (Table 3).

Intraoperatively, during the Ileostomy takedown, adhesions were higher in the EC group (26 vs 12) and the results was statistically significant (P= 0.0004). The Mean operative time was more in EC compared to the DC group, (126.1667 \pm 27.5895 vs 86.0000 \pm 34.2506) which was also statistically significant (P <0.0001). Only 3 cases in the EC group vs 1 in the DC group required conversion to Laparotomy due to intraoperative difficulty due to inadvertent bowel injury and intraoperative haemorrhage. (P= 0.3006).

An early ileostomy closure isn't without complications. Post-operative complications included Superficial wound infection (12 vs 9, in EC vs DC, P=0.5889), Wound

dehiscence (4 vs 1, in EC vs DC, P= 0.3533), anastomotic leak (3 vs 1, in EC vs DC, P=0.6120), entero-cutaneous fistula (1 vs 0, in EC vs DC, P=0.3132), post-operative ileus (11 vs 8, in EC vs DC, P=0.5796), subacute intestinal obstruction (5 vs 2, in EC vs DC, P=0.4238),

incisional hernia (2 vs 0, in EC vs DC, P=0.4915), sepsis (3 vs 1, in EC vs DC, P=0.6120). None of them are statistically significant. These results are summarized in Table 4.

Table 4: Intraoperative and post-operative comparison between the two groups.

Parameters	Early closure (n=30)	Delayed closure (n=30)	P value
Intra operative			
Adhesions	21	14	0.0667
Mean operative time (mins)	126.1667 ± 27.5895	86.0000 ± 34.2506	p<0.0001
Conversion to laparotomy	3	1	0.3006
Post-operative	•		
Superficial wound infection	12	9	0.5889
Wound dehiscence	1	4	0.3533
Anastomotic leak	1	3	0.6120
Entero-cutaneous fistula	0	1	0.3132
Post-operative ileus	8	11	0.5796
Subacute intestinal obstruction	2	5	0.4238
Incisional hernia	2	0	0.3132
Sepsis	0	2	0.4915

The mean length of stay in the hospital in days were 17.9667±6.9851 vs 11.2000±4.0548, in the EC vs DC, where, p<0.001 and was statistically significant. These has been represented in (Figure 4), which shows an increased hospitalization among the subset of patients undergoing and early closure (Figure 4).

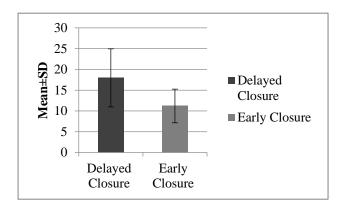


Figure 4: Length of hospital stay.

DISCUSSION

The pilot study by Bakx et al in 2002 showed the feasibility of a less morbid defunctioning ileostomy takedown by 11 days.² Many surgeons, in their studies and researchers in their systematic reviews have since then evaluated an intervention that tried to cut short the stoma bearing duration for the patient. It is imperative to understand that a stoma definitely has psychological and sexual shortcomings and since these stomas would be constructed for temporary faecal diversion they would be unnecessary after they have served their purpose.^{5,6} A persistent stoma may cause renal implications as stated

by Gessler et al, Menegaux et al confirmed that a high output stoma demands an early closure. ^{7,8} However, there is no consensus regarding the actual time period for reversal of stomas. An extremely early intervention may be a bane altogether. The role of an early takedown has been best studied in patients with a distal colonic anastomosis like complicated low or ultralow anterior resections, in rectal cancer or in cases of ulcerative colitis after proctocolectomy. ⁹⁻¹⁶ They seem to be more cost effective. ¹⁷ Recent studies have shown the feasibility of laparoscopic reversal with minor complications. ¹⁸ There seems to be no difference between staplers and hand sewn anastomosis, but stapled bowel opens faster. ¹⁹ Further more educated people opt for early reversal. ²⁰

Our institute is a high-volume tertiary care center that caters to the rural population of Bengal and hence most of our patient's harboring the disease present late, due to lack to knowledge and paucity of their caregivers to attend the hospital in definite time. This study focused on the implications and feasibility of early reversal of Ileostomies in selected groups of patients. Most of our patients come from the rural population and hence the stoma related complications are on the rise. They do not seek prompt medical attention and care for their stomas. Most of them suffer from stoma related complications, majority of them being poor peristomal skin care. Residents in training perform a high volume of Emergency surgeries hence the technical correctness of a stoma is also questionable. The morbidity with the stoma is the primary reason for undertaking an Early Closure, which is in according to Alves et al and Jordi-Galais et al.5,6 High output stomas mandated a prompt takedown, which is consistent to the study as described by Menegaux et al.8 Hence an early takedown would be beneficial to such patients.

The Early closure of a defunctioning stoma significantly decreases the patient's time and burden with the stoma but it does come with its set of complications. There is a risk of intraoperative adhesions. (26 vs 12, p=0.0004), is a risk that discourages an Early Reversal. Previous studies have however shown its feasibility, hence here the skill of the surgeon is of foremost importance. Intraoperative difficulties result in prolonged operating time (126.1667±27.5895 vs 86.0000±34.2506, p<0.0001) and may add to the post-operative morbidity. They also culminate in postoperative Ileus and Subacute bowel obstruction. Patients with colorectal cancer are often subjected to chemo radiation and those with ulcerative colitis may use corticosteroids or biologics that may affect the intraoperative and post-operative course of these patients.21 These add to an increased rate of wound infection, anastomotic leaks, sepsis and enterocutaneous fistulae. The results of individual postoperative complications are not significant in our study. They eventually lead to a significant amount of hospitalization (17.9667±6.9851 vs 11.2000±4.0548, p<0.001), which is contradicts the results of the EASY trial. 12-14

Our study has a few shortcomings. The cost analysis and evaluation of the quality of life may be the limitations of our study because, our institute provides all the necessary drugs and equipment without any charge. Majority of the patients in this study are rural, and have an erratic follow up. Although none of our patients were lost to follow up, due to their erratic nature of presentation to follow up clinics, but it proved to be difficult to maintain their data for the researchers. Furthermore, the study includes a small group of patients. A larger subset and the inclusion of data from other institutions may increase the complications further and throw light to the limitations of our study. All of our Ileostomy reversals were hand sewn, hence the merit of a stapled anastomosis was not evaluated. Wound complications may be an institutional concern. Further studies like the recent easy trial if conducted in a large scale including many institutions, in India may shed more light on different perspectives of Ileostomy reversals.

CONCLUSION

It is clear from our study that the subset of patients undergoing an Early ileostomy closure, may need a longer operative time due to intraoperative adhesions, the post-operative complications are on the higher side thus prolonging the duration of hospital stay. Since, expert consensus (level I) Indian data is lacking. Future studies on this debate may determine the fate of this technique in a rural Indian set-up.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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