

Complications Following Early and Delayed Ileostomy Closure: An Interventional Study

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ABSTRACT

Introduction: Ileostomy is used frequently now-a-days for various surgical conditions. Patients with ileostomies face several problems like physiological, psychological and social problems. Moreover, a stoma can also lead to different complications. Surgeries for reversal of stomas can also lead to different complications, leading to increased morbidity and mortality.

Aim: To find significant differences, if any, in morbidity and mortality between patients of early and delayed ileostomy closure.

Materials and Methods: In this interventional study, 100 patients were recruited into two groups of i.e., 40 in early ileostomy closure group and 60 in the delayed ileostomy closure group. Their baseline characteristics were compared to find out the comparability between the two groups. The patients were followed-up over a period of time to find out complications such as skin excoriation, wound dehiscence, wound infection, anastomotic leakage, faecal fistula etc. Student's t-test was applied for continuous variables and for discrete variables, Chi-square test was applied to find out whether there was any

statistically significant difference between the two groups. A p-value < 0.05 was considered significant.

Results: Out of total 40 patients, in the early closure group 5 (12.5%) of patients closure group developed skin excoriation, whereas 10 (25%) developed wound infection and 10% of the patients developed incisional hernia. Skin excoriation amongst delayed closure group was noticed in 21 (35%), wound infection in 6 (10%) and Incisional hernia in 1 (1.7%) patient. Skin excoriation was significantly less among early closure group with an OR of 0.27 (0.09-0.78). Duration of stay in the hospital was significantly less among the early closure group (24.92±5.12) days compared to the delayed closure group (41.43±12.29) days (p<0.001). One patient expired due to sepsis after on 13th postoperative day, who was in the delayed closure group.

Conclusion: Skin excoriation was significantly less amongst the patients of the early ileostomy group. Hence, early ileostomy closure can reduce the complications of ileostomy and the duration of carrying the ileostomy.

Keywords: Wound excoriation, Infection, Incisional hernia, Morbidity, Postoperative complications, Wound infection

INTRODUCTION

There are several surgical indications for which ileostomy is performed. Ileostomy may be performed to prevent the spread of peritonitis in case of anastomosis leakage, in emergency cases with peritoneal contamination for faecal diversion or for protecting an rectal anastomosis etc. Patients who have undergone ileostomies, suffer a variety of issues; which includes maintain the seal due to the stoma's poor location or configuration. They also have to deal with the issues of gas control and odor. These problems can be managed by maintaining strict hygiene, paying close attention to the diet and drugs they consume and using a variety of deodorants [1].

Stoma prolapse, stoma retraction, parastomal hernia, excoriation of skin are some of the major complications related to stoma. Majority of these complications necessitate quick attention and may even warrant revision surgery. Not only the patient but the society also bear the burden of the stoma. It has a negative physiological and psychological impacts along with social ramifications. Ileostomy patients must adapt to the new body image, new lifestyle and changes in everyday routines [2]. In a Questionnaire survey of 76 patients with temporary stomas indicated that the stoma had a social impact on more than half of the patients, and that 12% were entirely isolated [3].

A prospective study over four years on rectal cancer patients found that construction of stoma usually worsens the quality of life while stoma closure resulted in an increase in quality of life [4]. Temporary ileostomy reversal may lead to complications. Which require reoperation followed by major complications. Major complications may vary from 0 to 7-9% and minor complications vary from 4-5% to 30% [5].

Several preliminary studies suggest, however, that it is possible to reduce the complication rate in selected patients by closing a temporary ileostomy within 2 weeks after creation [6]. For quite some time, the conventional idea of when to close a temporary ileostomy has been a point of contention [7]. Stoma reversal may cause complications requiring re-operation, and a literature review concluded that there is wide variation from no cases to as much as 14%-17%, where the presence of inflammatory bowel disease is a risk factor [6].

A retrospective study, however, had a mortality of 1% for temporary colostomy and around 5% for temporary ileostomy, which is very high [8]. It was also seen that early reversal of stoma was not associated with increased morbidity and mortality [3]. In a randomized controlled study including 190 study subjects, the stoma was closed after 8 days in the intervention group and they were compared to a control group, where the stoma closure was done after 60 days. The study found no statistically significant differences in the number of complications, whereas length of hospital stay was prolonged for the late closure group. Patients in the late reversal group had more complications related to small bowel obstruction and medical complications [9].

A small randomised study investigated the impact of early closure (9 days postoperatively) of ileostomy in 36 preoperatively selected patients. The study showed that length of hospital stay in the early intervention group was much shorter [10]. So, the present study was aimed to find any significant difference in morbidity and mortality in patients of early and delayed ileostomy closure.

MATERIALS AND METHODS

This interventional study was conducted among 100 patients who were admitted through Outpatient Department (OPD) and Emergency Department who required temporary ileostomy in the Department of General Surgery of Calcutta National Medical College Kolkata, West Bengal, India, from March 2012 to February 2013. Ethical clearance was taken from Institutional Ethics Committee (IEC) (CNMC/ETHI/35). Patients were included in the study after taking their written informed consent.

Early ileostomy closure was defined as closure of the ileostomy wound within 2 weeks of creation and delayed closure was defined as 10-12 weeks after ileostomy creation [11]. Patients were followed-up for surgical complications every week for first 6 weeks following closure and then at 12 weeks and 6 months.

Inclusion criteria: Patients with a temporary ileostomy of diverse aetiology, those physically and mentally fit to undergo surgery within two weeks and patients with stage I to stage III peritoneal contamination according to Modified Hinchey classification [12] system during primary surgery were included in the study.

Exclusion criteria: Patients whose stoma is not reversible, those who developed abdominal wall dehiscence after primary operation or patients with tubercular perforation, communicative problems and those with clinical stage IV peritoneal contamination were excluded from the study.

Total sample of 100 patients were included on the basis of inclusion and exclusion criteria and were divided into early ileostomy closure group (n=40 patients) and delayed ileostomy closure group (n=60 patients) based on their clinical profile.

Before intervention each patient underwent distal loopogram (distal segment contrast) study. This was to evaluate any distal obstruction. Apart from those routine investigations like haemoglobin, electrolytes, serum proteins, chest X-ray, blood urea, serum creatinine etc., were performed to assess fitness and risk of surgery. All the patients were offered a clear liquid diet the night before surgery. Prior to the day of operation each patient underwent mechanical bowel preparation with polyethylene glycol. These patients in the postoperative period were observed in the general wards. Nasogastric decompression using a nasogastric tube was not routinely used except in those patients presenting with abdominal distension or persistent vomiting. All the patients were offered intravenous solutions and antibiotics (2nd generation cephalosporin and metronidazole). Oral allowance and oral medication was soon added instead of parenteral medication with resumption of bowel sounds. All complications diagnosed within the first 30 days after surgery were included in the present study as morbidity, including those specifically related to the operative procedure.

STATISTICAL ANALYSIS

Statistical analysis was done using Microsoft excel and Statistical Package for Social Sciences (SPSS) version 20.0 (IBM, Armonk, New York, USA). As there was no proper randomisation of the study subjects, the characteristics of patients of two groups were compared to find out whether there were any significant differences between two groups of patients. For continuous variables, Student's t-test was applied and for discrete variables, Chi-square test was applied. The criterion for statistical significance was set at p-value 0.05.

Analysis	Skin excoriation		Wound infection		Wound dehiscence		Anastomotic leak		Faecal fistula		Intestinal obstruction		Incisional Hernia	
	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Early ileostomy (n=40)	5 (12.5)	35 (87.5)	10 (25)	30 (75)	2 (5)	38 (95)	1 (2.5)	39 (97.5)	1 (2.5)	39 (97.5)	3 (7.5)	37 (92.5)	4 (10.0)	36 (90.0)
Delayed ileostomy (n=60)	21 (35.0)	39 (65.0)	6 (10)	54 (90)	5 (8.3)	55 (91.7)	4 (6.7)	56 (93.5)	2 (3.3)	58 (96.7)	5 (8.3)	55 (91.7)	1 (1.7)	59 (98.3)
p-value	0.023*		0.084		0.810		0.645		1.000		1.000		0.154	
OR	0.27		3		0.58		0.36		0.74		0.89		6.56	
95% CI of OR	0.09-0.78		0.99-9.07		0.11-3.14		0.04-3.34		0.07-8.49		0.20-3.96		0.70-60.97	

[Table/Fig-3]: Comparison of surgical complications among both group of study subjects (n=100). Values in parenthesis indicate percentages; * Indicates statistical significance; OR: Odd's ratio; CI: Confidence interval; p-value<0.05 considered significant

RESULTS

Total of 100 subjects were analysed, mean age of the study subjects were 45.84±12.82 years. Enteric perforation was the most common cause (57%) for which ileostomy was performed followed by colorectal cancer (32%) [Table/Fig-1].

Variables	Frequency (n)	
Age group (in years)	15-25	6
	>25-35	17
	>35-45	22
	>45-55	24
	>55-65	23
	More than 65	8
Gender	Male	64
	Female	36
Indication for ileostomy	Enteric Perforation	57
	Trauma	8
	Inflammatory Bowel Disease	3
	Colorectal Cancer	32
Peritonitis	Grade I	27
	Grade II	31
	Grade III	10
	No peritonitis	32

[Table/Fig-1]: Characteristics of study subjects (n=100). Grade I: Pericolic abscess; Grade II: Distant or complex abscess associated with fistula; Grade III: Generalised purulent peritonitis

Majority of the patients with grade II peritonitis (64.5%) was in the delayed closure group. But this difference was statistically non significant [Table/Fig-2]. Among the study subjects, 6 patients had stoma prolapse and 2 had stoma retraction. All of them were included in the delayed closure group. But it was not found to be statistically significant [Table/Fig-2].

Variables	Early closure (n=40)	Delayed closure (n=60)	p-value	
Mean age (years)	43.65±13.18	47.30±12.47	0.164*	
Operative time (minutes)	76.38±17.13	78±22.28	0.682*	
Gender	Male	30 (46.9)	34 (53.1)	0.061†
	Female	10 (27.8)	26 (72.2)	
Aetiology	Enteric Perforation	22 (38.6)	35 (61.4)	0.203†
	Trauma	6 (75.0)	2 (25.0)	
	IBD	1 (33.3)	2 (66.7)	
	Colorectal cancer	11 (34.4)	21 (65.6)	
Grade of peritonitis (N=68)	Grade I	13 (48.1)	14 (51.9)	0.547†
	Grade II	11 (35.5)	20 (64.5)	
	Grade III	5 (50.0)	5 (50.0)	
Stoma prolapse	Present	0	6 (100.0)	0.078†
	Absent	40 (42.6)	54 (57.4)	
Stoma retraction	Present	0	2 (100.0)	0.515†
	Absent	40 (40.8)	58 (59.2)	

[Table/Fig-2]: Comparison of baseline characteristics of two groups of patients (n=100). *Student's t-test was used to determine p-value; †Chi-square test was applied; IBD: Inflammatory Bowel Disease; n=32 had no peritonitis

On comparing different surgical complications amongst the subjects of both the groups, it was seen that skin excoriation was significantly less among early closure group with an OR of 0.27 (0.09-0.78) [Table/Fig-3].

Duration of stay in the hospital was significantly less among the early closure group (24.92±5.12) days compared to the delayed closure group (41.43±12.29) days ($p < 0.001$). One patient expired due to sepsis after 13th postoperative day, who was in the delayed closure group.

DISCUSSION

In the current study it was found that, baseline characteristics of the two groups were similar and there was no statistically significant difference among them. When they were compared for complications following surgery, skin excoriation was significantly less among the early closure group, ($p = 0.023$). In emergency situation, loop ileostomy is a life saving operation. To safeguard the distal anastomosis following a colorectal surgery, temporary loop ileostomies are created [13]. As it is easier to create loop ileostomies, they are favored by majority of the surgeons [14].

Usually, intestinal continuity is restored after 8-12 weeks. In the meantime, one-fourth of the patients suffer from different complications due to stoma with negative impact on the quality of life of the patients [10,15]. There is an argument regarding the time interval between creation of ileostomy and closure. When tried too early, patients who may not have recovered effectively from primary surgery will have an edematous stoma [9,16]. If the closure is performed too late, adhesions may become an issue.

Different studies have reported that complications following ileostomy closure varies between 10 to 30%. [17-25]. It was also found that, ileostomy closure associated with restorative proctocolectomy was associated to higher complications compared to closure associated with coloanal or low colorectal anastomoses [17-22]. Van de Pavoordt HD et al., and Phang PT et al., reported complication rates of 17% and 28% respectively [17,25]. For most of the complications, the current study found no statistically significant difference between the two groups.

In the current study, patients with delayed closure were found to have more complications related to stoma e.g., stoma prolapse was found in around 12% of subjects of delayed closure group. In comparison no cases of stoma prolapse was found in the early closure group. Whereas, one-third of the patients of delayed closure group was found to have retraction of stoma in comparison to none in early closure group although the difference recorded were statistically insignificant. Skin excoriation was found to be more common (35%) in the delayed closure group in comparison to the study subjects in the other group, and the difference was statistically significant ($p = 0.023$).

The current study found that, one-fourth of the patients in the early ileostomy closure group had ileostomy wound site infection, which was higher than the delayed closure group, but the difference was no significant statistically. Nelson T et al., also showed that wound infection was more in early closure group (32%) compared to delayed closure group (18%), although it was not statistically significant [26]. Similarly, Alves A et al., found that surgical site complications are more common in early closure group [9]. Velmahos GC et al., also showed slightly higher wound infection in early closure group (16.7%) compared to late closure group (10.0%) [27]. Fukudome I et al., also found that wound infection was more in early closure group (17.6%) compared to delayed closure group (5.6%) [28]. Sarawgi M et al., found that wound infection was also more common in the early closure group [29].

In the current study, anastomotic leak was less in the early ileostomy closure group (2.5%) in comparison to the delayed ileostomy closure

group (6.7%). Anastomotic leakage was also less in the early closure group in the study done by Alves A et al., [9]. Velmahos GC et al., also found that, early closure was not associated with increased risk of anastomotic leakage [27].

No significant differences were found in cases of intestinal obstruction in between the groups which corroborates with the findings of Alves A et al., [9] Similarly, Velmahos GC et al., also showed that there was no significant difference between the two groups regarding occurrence of anastomotic leakage [27]. No cases anastomotic leakage was recorded by Sarawgi M et al., [29]. Khan N et al., found anastomotic leakage in 5.8% cases of early closure, but Ali SM et al., reported anastomotic leakage in 4.5% cases of early closure group which is higher than the current study (2.5%) [30,31]. In a systemic review Farag S et al., found that the risk of anastomotic leakage and other postoperative complications were similar in both the groups [32].

Omundsen M et al., also reported significantly more cases of wound infection in the early closure group. But other complications were similar in both groups [33]. In a meta-analysis done by Menahem B et al., wound infection was significantly more in the early closure group, but no significant difference between occurrences of anastomotic leakage was found [34]. Unfortunately, one patient expired due to sepsis after on 13th postoperative day, who was in the delayed closure group.

During follow-up, incidence of incisional hernia was studied and it was found to be higher in early closure group (10%), but not statistically significant ($p = 0.154$). Faecal fistula was found in 2.5% of cases in the early closure group, which similar to the findings of Kumar B and Mishra PK (2.8%) [35].

In the current study, length of hospital stay was significantly less in the early closure group similar to the findings of Menegaux F et al., but Farag S et al., did not report any statistically significant difference in length of hospital stay between two groups [10,32].

Limitation(s)

The study was done only on 100 cases due to constraints of time and manpower. Randomisation of study subjects between two groups could not be done. So, there is a chance that some confounding factors may have affected the results of the study.

CONCLUSION(S)

Early ileostomy closure within two weeks does not lead to significantly higher morbidity compared to the delayed ileostomy closure. Hence routinely assigning patients with temporary loop ileostomy for early closure may lead to improved quality of life of the patient and well-being of the patient. The standard practice of prolonged stoma care of patients should be customized. Further studies and researches evaluating disease specific outcomes of closure are needed in future.

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