



DECIDING FACTORS OF SUCCESSFUL ILEOSTOMY CLOSURE: A PROSPECTIVE STUDY

General Surgery

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ABSTRACT

Background A loop ileostomy is done to safeguard a vulnerable distal anastomosis. Post-operative period of these patients might have a trouble-free stoma, or stoma related complications. A temporary stoma is usually created for diversion and closed as soon as the distal anastomosis is functional. Few surgeons opt for early closure of such loop ileostomy which may lead to stoma related complications. Holding up a stoma for 6 – 8 weeks allows the stoma to mature and the planes around the stoma to become more defined. The delay will allow the case to get back nutritious and immunological status after a major operation, and will also reduce the danger of thromboembolic complications. However, self-care of stoma might be challenging for the patient after discharge. This should always be considered in case further delay after the maturation of stoma and resolution of pathology may lead to complications related to malnutrition. We assessed the possible contributing factors for complications following ileostomy reversal. **Materials and methods:** All patients who underwent loop ileostomy closure between November 2020 and April 2022 at Vinayaka Mission's Medical College and Hospital, Karaikal. Medical records on patient characteristics, preoperative management, surgical techniques, postoperative management, chemotherapy/radiotherapy, and complications were retrospectively analyzed in a prospectively collected from database. **Results:** A total of 84 patients underwent loop ileostomy closure. The overall complication rate was 25 %. The two most common complications were wound infection (18%) and small bowel obstruction (3.9%). In univariable and multivariable analyses, closure technique or chemotherapy did not affect the outcome, but low serum albumin <3.5 g/dL and longer interval to ileostomy closure were independent contributing factors for morbidities of ileostomy closure. **Conclusion:** Closure approach or chemotherapy didn't affect the complication of ileostomy closure. Nevertheless, serum albumin <3.5 g/dL and a longer interval to ileostomy closure were identified as risk factors for morbidity of ileostomy closure. These two factors should be corrected and planned before ileostomy closure.

KEYWORDS

INTRODUCTION:

A stoma can be defined as a controlled iatrogenic fistula that is fashioned as an alternate drainage to the gastrointestinal tract. Stomas are used as a temporary or permanent diversion of the fecal channel from distal pathology or a healing anastomosis. A temporary stoma is usually a loop stoma that can be closed without a major laparotomy when it's no longer necessitated. It can be left as a permanent stoma, but is more prone to complications.

Appropriate stoma supervision is essential if the patient's preoperative recovery. A stoma is usually brought out through the rectus sheath a few centimeters either above or below the umbilicus. More lateral stomas were supposed to be associated with a higher frequency of incisional hernia. A disc of skin and subcutaneous fat is removed. Stoma-related complications such as dehydration, electrolyte imbalance, parastomal hernia, and cellulitis caused by peristomal infection have harmful effects on patients' health and quality of life. Recent findings suggest that early closure of ileostomy from the index operation is helpful to patients, with comparable postoperative and lower stoma-related complication rates. On the other hand, other studies indicate that early ileostomy closure is significantly associated with complications.

Thus, this study focus is whether operation interval and other clinicopathologic parameters are risk factors of postoperative complications of Ileostomy closure (IC)

MATERIALS AND METHODS:

All patients who underwent loop IC between november2020 to April 2022 at Vinayaka mission's medical college and Hospital, Karaikal were enrolled in this study.

Patient demographics and clinicopathological variables were retrospectively assayed in a prospectively collected database. Prior to ileostomy closure, all cases witnessed a water-soluble contrast enema study to assure the integrity and patency of colorectal anastomosis. Patients were administered prophylactic antibiotics with bowel preparation in all cases. All operations were additionally performed or supervised by the experienced surgeons.

Inclusion criteria:

Patients admitted for ileostomy loop closure who meet the following

criteria will be eligible to participate in the study:

- Aged 18 years and older.
- Able to provide informed consent.
- ASA I and II (American Society of Anesthesiologists).
- No anastomotic leak proven on preoperative water-soluble enema.

Exclusion criteria:

Patients admitted for ileostomy loop closure who meet the following criteria will be excluded from the study:

- Immunosuppression
- Therapeutic anticoagulation
- Previous proctocolectomy
- Previous ileal pouch anal anastomosis
- Postoperative antibiotics were prescribed for infective complications. The timing of IC was decided by the surgeon depending on the patient's ongoing chemotherapy status, nutrition status, or whether the patient had complications. Adjuvant chemotherapy patients were planned for IC after the completion of the same.

RESULT

Between November 2020 and April 2022, 84 patients underwent loop ileostomy closure in our hospital. The median age was 56 years (range, 18-75 years), with 52 male (61.9%). The primary diagnoses were rectal cancer (50, 60%), left colon cancer (15, 18%), ovarian cancer (4, 5%), familial adenomatous polyposis (2, 1.8%), diverticular disease (1, 0.8%), Crohn's disease (1, 0.8%), and other conditions (11, 13%). The previous types of surgeries included low anterior resection (48, 57%), coloanal anastomosis (13, 15%), left hemicolectomy (6, 7%), total or subtotal colectomy (3, 4%), Hartmann's repair (4, 5%), and others (10, 12%). ASA score 2 was the most common, with 63 patients (75. %). Sixteen (16.4%) patients had diabetes mellitus (DM), and 21 patients (10.5%) were smokers at the time of operation. Twenty-five patients (30%) received preoperative concurrent chemoradiotherapy.

Before ileostomy closure, 51 (61%) patients underwent adjuvant chemotherapy. The mean interval from ileostomy creation to closure was 102 days (range, 60-720 days). The median operation time was 96 min (range, 60-180 min). The median length of hospital stay after ileostomy closure was seven days (range, 5-34 days). Patient demographics are summarized in Table 1.

There were 18 patients (23.7%) with postoperative complications, with Clavien-Dindo classification I being the most common (11 patients). Two patients had a Clavien-Dindo classification of III-V (Table 2). The most common complications were wound infection (41, 11.6%); Clostridium difficile infection was found in six patients (1%), of whom two (2%) had anastomotic leakage that required reoperation. One patient (6%) died of small bowel obstruction and consequent surgeries and complications.

DISCUSSIONS

Now a days there is an increase in number of anal sphincter- saving surgeries using minimally invasive approaches, ileostomy creation and IC have become a critical part of the surgery in order to reduce the morbidity and mortality associated with anastomotic leakage. Hence, to enhance surgical results, additional studies are needed to probe the risk factors associated with complications following IC.

In a nationwide retrospective study that used data from the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) with 5401 cases who underwent IC, the complication and mortality rates were 17.7 and 0.6, respectively, with the most common complication being wound infection (6.7). In our 84 cases, the morbidity rate was 21 and mortality rate was 0.7, which is similar with rates reported in other studies, in which morbidity ranged from 5 to 40, and mortality ranged from 0 to 4.

The most common complication in our study was wound infection (8), the incidence was analogous to those in other studies, in which wound infection ranged from 3.8 to 12.9. Other complications, such as early small bowel obstruction, voiding difficulty, anastomotic leakage and pneumonia, were reported in our study with rates also comparable to other studies.

The frequency of serious complications, such as anastomotic leakage, 2, which was lower than the reported incidence rate, which is 3 to 4. Since wound infection is a well-known threat factor for incisional hernia, it can be induced that the wound infection cases in our study may also have incisional hernia; therefore, reduction of wound infection may also reduce the number of incisional hernias. Still, because this study investigated the short-term postoperative complications, incisional hernia wasn't one of the factors. Numerous attempts have been made to identify the possible threat factors for postoperative complications after IC. Still, there are no definite factors that are attributable to the complications.

In this study, we establish that hypoalbuminemia was the strongest independent threat factor for IC complications (preoperative serum albumin 8.5 weeks, and shorter intervals could affect in an increased risk of postoperative complications (sensitivity, 88; specificity, 44). Recent interest in early closure reflects patients' poor QoL and stoma-related complications. The authors suggest that, considering this study's results and patients', it seems reasonable to consider early IC.

The effects of chemotherapy on surgical complications remain controversial. Chemotherapy may interrupt the healing process, which makes surgeons delay IC if the patient undergoes adjuvant chemotherapy. Still, recent findings suggest that this may not always be the case; there's no conclusive evidence that chemotherapy impairs healing.

In our study, cases who entered chemotherapy mostly underwent 5-fluorouracil based chemotherapy; therefore, adjuvant chemotherapy wasn't a significant threat factor. Nonetheless, chemotherapy, such as doxorubicin, is a well-known factor that inhibits wound healing. Therefore, depending on the types of chemotherapy used in patients, there may be an increase in complication rates, but further studies are demanded to validate this.

Surgical technique is a crucial threat factor for surgical complications in numerous studies. In our study, stoma closure using handsewn end-to-end anastomosis with resection was conducted on 58 cases; handsewn end-to-end anastomosis without resection was conducted on 14, and staples were used on 12 cases. The anastomosis approach wasn't a threat factor for morbidity in our study.

Table 1
Patient Demographics

Clinical characteristics	Total number of patients n=84, (%)
Age (years, median (range))	56 (18-75)
Sex	
• Male	52 (61.9)
• Female	32 (38.1)
Types of disease	
• Rectal cancer	50 (60)
• Left colon cancer	15 (18)
• Ovarian cancer	4 (5)
• Familial adenomatous polyposis	2 (2)
• Diverticular disease	1 (1)
• Crohn's disease	1 (1)
• Others	11 (13)
Previous types of surgery	
• Low anterior resection	48 (57)
• coloanal anastomosis	13 (15)
• Left hemicolectomy/anterior resection	6 (7)
• Total/subtotal colectomy	3 (4)
• Hartmann's repair	4 (5)
• Miscellaneous	10 (12)
BMI (Asian guideline) (kg/m ²)	
• Underweight (<18.5)	10 (12)
• Normal weight (18.5-23)	33 (39)
• Overweight (23-25)	21 (25)
• Obese (≥25)	20 (24)
ASA Score	
1	11 (13)
2	63 (75)
3	10 (12)
Smoking history	
• Yes	21 (25)
• No	63 (75)
Comorbidities	
• Yes	40 (48)
• No	44 (52)
Diabetes mellitus	
• Yes	16 (19)
• No	68 (81)
Preoperative concurrent chemoradiotherapy	
• Yes	25 (30)
• No	59 (70)
Adjuvant chemotherapy	
• Yes	51 (61)
• No	33 (39)
Closure technique	
• Handsewn with resection	58 (69)
• Handsewn without resection	14 (17)
• Stapled	12 (14)

Table 2
Clavien-dindo Classification of Complications

Clavien-Dindo classification	n=18	%
1	11	61
2	4	22
3	2	11
4	0	0
5	1	6

Table 3
Breakdown of complication types

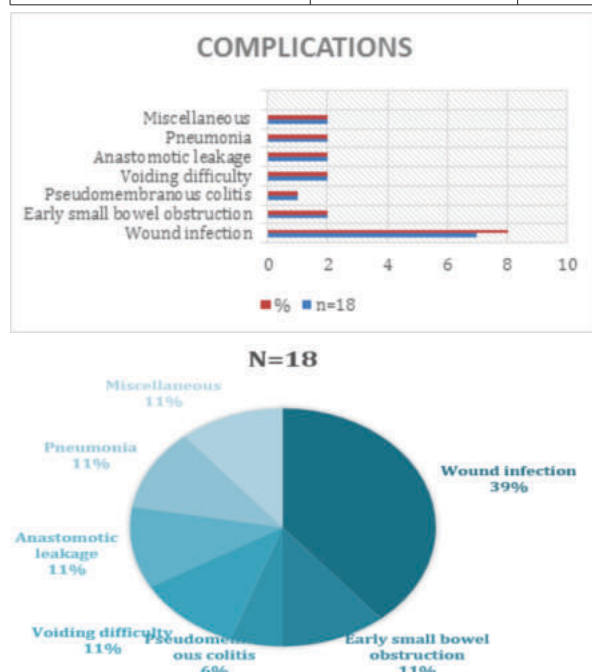
Type of complication	n=18	%
Wound infection	7	8
Early small bowel obstruction	2	2
Pseudomembranous colitis	1	1
Voiding difficulty	2	2
Anastomotic leakage	2	2
Pneumonia	2	2
Miscellaneous	2	2
Total	18	21

Table 4
Univariable analysis of factors associated with complications.

Factors	P
Age	0.4215
Male sex	0.5400
BMI (Body Mass Index)	0.1108
ASA (American Society of Anesthesiologist)	0.2490
Smoking	0.7259
Co morbidities	0.1980
Diabetes mellitus	0.0698
Underlying pulmonary disease	0.0734
Preoperative chemoradiotherapy	0.2029
Postoperative adjuvant chemotherapy	0.2217
Ileostomy closure technique	0.6500
Serum albumin level <3.5 g/dL	0.0002
Time to ileostomy closure (cutoff: 116.5 days), days	0.0049
Operative time	0.3459

Table 5 Multivariable analysis of factors associated with complications

Factors	Odds Ratio (95% CI)	P value
Serum albumin level < 3.5 g/dL	7.123	<0.0005
Time to ileostomy closure (cutoff: 116.5 days), days	1.952	<0.01



Limitations:

The limitations of this study include its retrospective nature and small sample size. The timing and approach of closure may be reflections of the surgeon's preference, leading to a selection bias. Still, this study has value in supporting hypoalbuminemia and late closure as possible strong risk factors of early morbidity in ileostomy closure. Thus, surgeons should emphasize the significance of nutrition to prevent preoperative hypoalbuminemia reflecting the patient's nutritive status and perform early closure no later than four months after surgery, if possible, to further reduce the morbidity rates of IC. Large prospective randomized multicenter studies are demanded to validate these findings.

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