

A PROSPECTIVE CASE STUDY: ASSOCIATION OF LOW SERUM ALBUMIN LEVEL AND LONGER INTERVAL TO CLOSURE WITH COMPLICATIONS RATE AFTER ILEOSTOMY CLOSURE

General Surgery

Dr Raj Kumar R Post Graduate Student, Mysore Medical College

Dr S Chandrashekar Associate Professor, Mysore Medical College

ABSTRACT

Background: A loop ileostomy is the stoma most constantly used to defunction an empty colon in order to safeguard a vulnerable distal anastomosis. Some cases have a trouble-free stoma, while others have recurring problems that may need another surgery. A temporary stoma, which has secured an anastomosis, may be closed as soon as the anastomosis is soundly healed. Early takedown, at around 2 weeks, is exercised by some surgeons but is technically more tough at this stage. A holdup of 6 – 8 weeks allows the stoma to mature and the planes around the stoma to become more defined. The further delay will also allow the case to get back nutritious and immunological status after a major operation, and will also reduce the danger of thromboembolic complications. However, the case has to learn to manage the stoma in order to return home. nonetheless, the morbidity and mortality associated with ileostomy reversal can not be overlooked. We assessed the possible danger factors for complications following ileostomy reversal. **Materials and methods:** All patients who underwent loop ileostomy closure between November 2019 and December 2021 at Krishna Rajendra Hospital, Mysore were identified. Medical records on patient characteristics, preoperative management, surgical techniques, postoperative management, chemotherapy/radiotherapy, and complications were retrospectively analyzed in a prospectively collected database. **Results:** A total of 84 patients underwent loop ileostomy closure. The overall complication rate was 25 % and one patient died. 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:

An enterocutaneous stoma is a controlled iatrogenic fistula. A stoma may be fashioned as an alternate outlet to the gastrointestinal tract after excision of all distal bowel or when restoration of continuity after a resection is contraindicated. Stomas are also used as a temporary or permanent diversion of the faecal channel from distal pathology or a healing anastomosis. A temporary stoma is generally a loop stoma that can be closed without a major laparotomy when it's no longer necessitated. A loop stoma may be left as a permanent stoma, but is more prone to complications.

Good stoma supervision is essential if the patient's preoperative quality of life is to be recovered. 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, but this is uncertain. A disc of skin and subcutaneous fat is removed. It's injudicious to bring a stoma out through a wound as the frequency of wound infection, parastomal herniation and problems with appliance fixation to irregular scarred skin are all increased. 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 (QoL). 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 November 2019 to December 2021 at Krishnarajendra Hospital 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 metronidazole plus ceftriaxone intravenous (IV) was the preferred 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
- Not willing to give consent

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 chemotherapy.

RESULT

Between November 2019 and December 2021, 84 patients underwent loop ileostomy closure in our center. The median age was 55 years (range, 21-85 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 (75.5%). 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

In an era of an expanding 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 hernia.

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' QoL, 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))	55 (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 (18.5e23)	33 (39)
• Overweight (23e25)	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)
Preoperative serum albumin level	
• <3.5 g/dL	102 (60-720)
• ≥3.5 g/dL	96 (60-180)
Hospital stay (days, median (range))	7 (5-34)

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

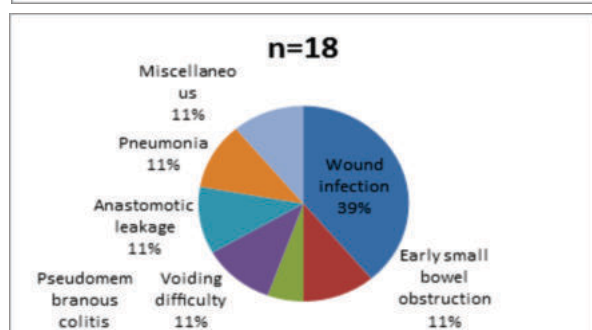
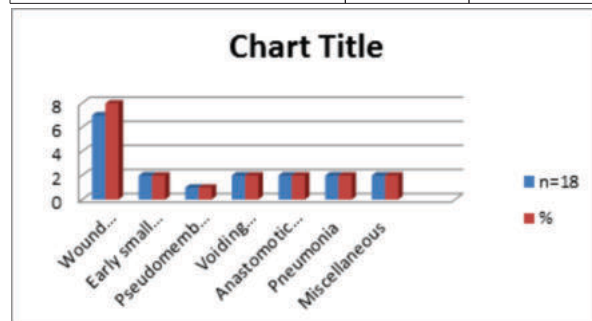


Table 4
Univariable analysis of factors associated with complications.

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, which creates 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.

REFERENCES

- 1) Baik, HyungJoo & Bae, Ki. (2020). Low albumin level and longer interval to closure increase the early complications after ileostomy closure. Asian journal of surgery. 44. 10.1016/j.asjsur.2020.09.007.
- 2) Fok, Chi & Fung, Derek & Kwok, Kam. (2021). Predictors of morbidity related to stoma closure after colorectal cancer surgery. Langenbeck's Archives of Surgery. 406. 10.1007/s00423-020-02054-z.

- 3) Yin, Tzu Chieh & Tsai, Hsiang-Lin & Yang, Ping-Fu & Su, Wei-Chih & Ma, Cheng-Jen & Huang, Ching-Wen & Huang, Ming-Yii & Huang, Chun-Ming & Wang, Jaw-Yuan. (2017). Early closure of defunctioning stoma increases complications related to stoma closure after concurrent chemoradiotherapy and low anterior resection in patients with rectal cancer. World Journal of Surgical Oncology. 15. 10.1186/s12957-017-1149-9.
- 4) Nassif, Mohammed & Trabulsi, Nora & Farsi, Ali & Al-shammakh, Sonds & Alghamdi, Ibtihal & Alshehrani, Esraa & Alotaibi, Shayma & Habeeb, Razan & Akeel, Nouf & Malibary, Nadim & Saleem, Abdulaziz & Kadi, Mai & Badahdah, Al-Mamoon. (2020). Factors affecting temporary stoma outcomes at a major Saudi University Hospital. International Surgery Journal. 7. 3604. 10.18203/2349-2902.isj20204658.
- 5) Fonseca AZ, Uramoto E, Santos-Rosa OM, Santin S, Ribeiro M Jr. COLOSTOMY CLOSURE: RISK FACTORS FOR COMPLICATIONS. Arq Bras Cir Dig. 2017;30(4):231-234. doi:10.1590/0102-6720201700040001
- 6) Waterland, Peter & Goonetilleke, Kolitha & Naumann, David & Sutcliffe, Mathew & Soliman, Faris. (2015). Defunctioning Ileostomy Reversal Rates and Reasons for Delayed Reversal: Does Delay Impact on Complications of Ileostomy Reversal? A Study of 170 Defunctioning Ileostomies. Journal of Clinical Medicine Research. 7. 685-689. 10.14740/jocmr2150w..
- 7) Sier, Maartje & Gelder, Linda & Ubbink, Dirk & Bemelman, Willem & Oostenbroek, R. (2015). Factors affecting timing of closure and non-reversal of temporary ileostomies. International journal of colorectal disease. 30. 10.1007/s00384-015-2253-3.
- 8) Malik, Tom & Lee, Matthew & Harikrishnan, Athur. (2018). The incidence of stoma related morbidity - A systematic review of randomised controlled trials. The Annals of The Royal College of Surgeons of England. 100. 1-8. 10.1308/rcsann.2018.0126.
- 9) Pan, Hong-Da & Peng, Yi-Fan & Wang, Lin & Li, Ming & Yao, Yun-Feng & Zhao, Jun & Zhan, Tian-Cheng & Gu, Jin. (2016). Risk Factors for Nonclosure of a Temporary Defunctioning Ileostomy Following Anterior Resection of Rectal Cancer. Diseases of the colon and rectum. 59. 94-100. 10.1097/DCR.0000000000000520.
- 10) Herlle, Florian & Sandra-Petrescu, Flavius & Weiss, Christel & Post, Stefan & Runkel, Norbert & Kienle, Peter. (2016). Quality of Life and Timing of Stoma Closure in Patients With Rectal Cancer Undergoing Low Anterior Resection With Diverting Stoma. Diseases of the Colon & Rectum. 59. 281-290. 10.1097/DCR.0000000000000545.