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Research Article

Surgical site infection reduction bundle in stoma closure: A retrospective cohort study

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ABSTRACT

Introduction: Advances in minimally invasive surgeries and pre-operative treatments allow the preservation of anal function through lower anastomosis in patients with rectal cancer, often necessitating temporary diverting stomas owing to the risk of anastomotic leakage. Stoma closure is associated with a high rate of surgical site infections (SSIs). Various measures, including purse-string skin sutures and negative-pressure wound therapy, have been implemented, and some guidelines recommend purse-string skin sutures as the standard method of stoma closure. However, at our institution, we used linear skin closure with an SSI reduction bundle. This study describes our stoma closure method and retrospectively analyses surgical outcomes.

Materials and Methods: This retrospective study included patients aged ≥ 20 years who underwent loop stoma closure using linear skin sutures at our institution between January 2006 and March 2021. Our protocol emphasises the following: (1) pre-operative oral anti-microbials, (2) a surgical technique that distinctly separates clean and contaminated regions, and (3) wound closure to eliminate dead space. We evaluated the surgical outcomes, including the incidence of SSIs and other post-operative complications.

Results: Ninety-two patients (53 men, 39 women; mean age, 59.4 years) underwent loop stoma closure. SSIs occurred in two patients (2.2%). No risk factors for SSIs were identified.

Conclusion: In our department, the incidence of SSIs after linear skin closure of stomas was low. Adherence to proper infection prevention practices can effectively mitigate SSIs, even with linear skin closure.

1. Introduction

Minimally invasive surgeries and pre-operative treatments have enabled the preservation of anal function in patients with rectal cancer who previously required permanent stoma procedures such as low and very low anterior and inter-sphincteric resections. However, temporary diverting stomas are often created due to the risk of anastomotic leakage. Stoma closure reportedly results in a high rate of surgical site infections (SSIs), with rates as high as 40% for linear skin closure [1]. Various strategies have been used to prevent SSIs, including purse-string skin sutures [2] and negative-pressure wound therapy (NPWT) [3].

Some guidelines recommend purse-string skin sutures as the standard method for stoma closure [4]. A recent meta-analysis reported a lower incidence of SSI with purse-string than with linear skin closures [2]. However, these procedures are burdensome for patients, such as the necessity for outpatient visits due to prolonged wound healing in purse-string skin sutures and the need to wear a device in NPWT-assisted closure.

At our institution, stoma closure is performed using an SSI reduction bundle in conjunction with linear skin closure, which yields satisfactory results. In this study, we aimed to describe our stoma closure procedure and retrospectively analyse surgical outcomes, including the proportion

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Abbreviations: SSIs, surgical site infections; NPWT, negative-pressure wound therapy; BMI, body mass index.

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of SSIs and other post-operative complications.

2. Methods

2.1. Study design and patients

This retrospective cohort study included patients aged ≥ 20 who underwent loop stoma closure with linear skin sutures at the National Hospital Organisation Kyoto Medical Centre between January 2006 and March 2021. Loop stoma closures are primarily performed following rectal cancer surgery with a diverting stoma, such as a low anterior resection. The sample size was determined based on the number of cases during the study period. Data were retrospectively obtained from the electronic medical records. Patients who required concurrent resection of lesions, such as those due to malignancy or diverticula, or those who simultaneously underwent additional intra-abdominal procedures were excluded. The study design and preparation of the original manuscript were performed according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Reporting Guidelines (Supplementary Table).

The outcomes evaluated included operative time, blood loss, post-operative hospital stay, number of days from stoma operation to closure, and post-operative complications (SSIs, anastomotic leakage, wound dehiscence, bowel obstruction, or incisional hernia). SSI was defined according to the criteria of the Centres for Disease Control and Prevention/National Healthcare Safety Network [5]. The presence of SSIs was monitored by the surgical team during the hospital stay and at the first follow-up outpatient visit.

2.2. Procedure for stoma closure

The critical aspects of our stoma closure method are the preoperative and surgical procedures.

No mechanical preparations were performed before surgery. Patients were provided a low-residue diet and administered oral kanamycin and metronidazole the day before surgery. Cefmetazole sodium was administered intravenously immediately before the surgery.

We attempted to distinguish between the clean and contaminated regions during surgical procedures. The skin was initially cleaned with alcohol swabs and alcohol-based sanitisers, followed by disinfection of the surgical field with a 10% povidone-iodine solution, which was then covered with a non-woven sterile drape. At the start of the surgery, a spindle-shaped incision was made in the peristomal skin along the stoma-skin junction. The inverted bowel was straightened after separation from the subcutaneous tissue, and the stoma intestine was anastomosed using a continuous monofilament absorbable thread for provisional suture closure. All surgical preparations were repeated to maintain a clean operative field, including disinfecting the skin with 10% povidone-iodine solution, changing sterile gloves, gowns, and surgical instruments, and covering with a new sterile surgical drape. Subsequently, the temporarily closed intestines were resected, and functional end-to-end anastomosis was performed again, with full awareness of the distinction between the clean and contaminated regions. No wound protectors were used. The wound was closed by interrupted fascia suturing with a monofilament suture (using standard monofilament from 2005 to 2013, and anti-bacterial monofilament from 2014), followed by washing the subcutaneous space with 1 L saline solution. Vertical mattress sutures were used for skin closure to reduce the dead space. In cases of parastomal hernia, the hernia sac was excised, and efforts were made to eliminate any remaining dead space by employing a vertical mattress suture and a linear closure method identical to that used in non-hernia cases.

This section provides an overview of the surgical procedures. In all cases, the procedures were standardised and performed or supervised by an expert surgeon. The surgical procedures are summarised in Videos 1, 2, 3, and 4. These are four intraoperative videos filmed at triple speed.

2.3. Patient follow-up protocol

In all cases, the first outpatient visits were made within 1 month after surgery, and all patients were instructed at the time of discharge to visit our outpatient clinic instead in case of any problems, such as redness around the wound. After the initial outpatient visit, in cases of malignant disease, physical examination and imaging tests were continued according to the follow-up procedures for the disease.

2.4. Statistical analysis

Statistical analyses were performed using JMP Pro (version 16.2.0, SAS Institute, Cary, NC, USA). Statistical significance was set at P < 0.05. significant. Risk factors were examined using Fisher's exact test, and 95% confidence intervals (CIs) for relative risk ratios were calculated. Patients were stratified for risk factor analysis as follows: older or younger than 75 years, operating time longer or shorter than the average time, and more or less than 180 d from stoma operation to closure. Three body mass index (BMI) categories were established: $> 30 \text{ kg/m}^2$ (obese), $< 18 \text{ kg/m}^2$ (underweight), and $18-30 \text{ kg/m}^2$ (normal).

2.5. Ethics

To ensure ethical compliance, a study summary, including its purpose, content, and contact information, was posted on the hospital website, allowing participants to opt-out. The Kyoto Medical Centre Ethics Review Committee approved this study (approval number 21–004).

3. Results

3.1. Patient characteristics

The patient flowchart is shown in Fig. 1. Between January 2006 and March 2021, 105 linear loop stoma closures were performed. Of these, 92 patients were examined after excluding 13 who were disqualified for concomitant lesion resection or additional procedures. The patient characteristics are detailed in Table 1. Of the 92 patients, 53 (57.6%) were male and 39 (42.4%) were female, with a mean age of 59.4 years. Diabetes mellitus was present in 14.1% of patients, and over 70% of the diseases that required a stoma were malignant.

3.2. Outcomes

Table 2 shows surgical outcomes and post-operative complications. The median operative time was 104.5 min, blood loss was 15 mL, post-operative hospital stay was 9 d, and duration from stoma operation to closure was approximately 6 months. The median follow-up duration after surgery was > 3 years.

SSIs occurred in 2.2% (n=2) of the patients, with no SSIs reported since 2011. Bowel obstruction and incisional hernias were uncommon, occurring in 6.5% and 3.3% of the patients, respectively. Only one case of wound dehiscence occurred after suture removal, and no SSIs related to wound dehiscence were observed.

3.3. Risk factor analyses

Risk factor analyses were performed to determine the occurrence of SSIs associated with each factor. However, no risk factors were identified in the present study (Table 3).

3.4. SSI cases

The two SSI cases are listed in Table 4. Ileostomies were performed in patients with a history of smoking. However, none of the patients had a history of diabetes or steroid use.

105 cases who underwent linear loop stoma closure

13 cases excluded due to concurrent lesion resections

9 cases: colorectal resection 2 cases: hepatobiliary resection 2 cases: other procedures*

92 cases included in analysis

*: includes ileostomy recreation and gastrostomy procedure.

Fig. 1. Patient flowchart of the study.

Table 1 Patient characteristics in this study.

| | | All cases $(n = 92)$ |
|---------------------------|-----------|----------------------|
| Age(mean ± SD) | | 59.4 ± 13.5 |
| Sex | Male | 53 (57.6%) |
| | Female | 39 (42.4%) |
| Body mass index | <18 | 11 (12.0%) |
| | >30 | 3 (3.3%) |
| Stoma type | Ileostomy | 84 (91.3%) |
| | Colostomy | 8 (8.7%) |
| Parastomal hernia | | 7 (7.6%) |
| Diabetes mellitus | | 13 (14.1%) |
| Steroid use | | 6 (6.5%) |
| Malignancy | | 66 (71.7%) |
| Smoking history | | 51 (55.4%) |
| Preoperative chemotherapy | | 29 (31.5%) |
| ASA-PS | 1 | 38 (41.3%) |
| | 2 | 49 (53.3%) |
| | 3 | 5 (5.4%) |

SD: standard deviation.

ASA-PS: American Society of Anesthesiologists physical status.

Table 2Operative outcomes including postoperative complications.

| | | All cases $(n = 92)$ | |
|--|-------------|----------------------|--|
| Operative time (min) | | 104.5 [60–195] | |
| Bleeding (ml) | | 15 [0–160] | |
| Postoperative hospital stay (days) | | 9 [2–39] | |
| Time to stoma closure(days) | | 173 [5–1711] | |
| Follow-up duration after surgery(days) | | 1269 [20-4717] | |
| SSI | Incisional | 2 (2.2%) | |
| | Organ/space | 0 (0%) | |
| Anastomotic le | eakage | 0 (0%) | |
| Wound dehiscence after suture removal | | 1 (1.1%) | |
| Bowel obstruction | | 6 (6.5%) | |
| Incisional hernia | | 3 (3.3%) | |

Continuous variables are described as median (range).

SSI: Surgical site infection.

4. Discussion/Conclusion

The incidence of SSIs after stoma closure was 2.2% at our institution. This outcome may be attributed to the pre-operative strategies and surgical procedures. As part of the pre-operative procedure, an enteral

Table 3Univariate analysis of risk factors for surgical site infection (SSI).

| | | Cases with SSI/total (%) | RR | RR 95%CI | P value |
|-------------------|-----------|--------------------------------|------|-----------|------------|
| Sex | Men | 1/53 | ref | ref | 1.0 |
| | Women | 1/39 | 1.36 | 0.09-21.1 | |
| Age | ≦75 y.o. | 2/84 | ref | ref | 1.0 |
| J | >75 y.o. | 0/8 | 0 | 0-NA | |
| Time to stoma | ≦180 days | 2/48 | ref | ref | 0.50 |
| closure | >180 days | 0/44 | 0 | 0-NA | |
| Preoperative | No | 2/63 | ref | ref | 1.0 |
| chemotherapy | Yes | 0/29 | 0 | 0-NA | |
| Stoma site | Ileostomy | 2/84 | ref | ref | 1.0 |
| | Colostomy | 0/8 | 0 | 0-NA | |
| Parastomal hernia | No | 2/85 | ref | ref | 1.0 |
| | Yes | 0/7 | 0 | 0-NA | |
| Malignancy | No | 1/26 | ref | ref | 0.49 |
| | Yes | 1/66 | 0.39 | 0.03-6.1 | |
| Diabetes mellitus | No | 2/79 | ref | ref | 1.0 |
| | Yes | 0/13 | 0 | 0-NA | |
| Smoking history | Yes | 2/51 | ref | ref | 0.50 |
| | No | 0/41 | 0 | 0-NA | |
| Steroid use | No | 2/86 | ref | ref | 1.0 |
| | Yes | 0/6 | 0 | 0-NA | |
| ASA-PS | 2 | 1/49 | ref | ref | ref |
| score | 1 | 1/49 | 1.29 | 0.08-20.0 | 1.0 |
| | 3 | 0/5 | 0 | 0-NA | 1.0 |
| Body mass index | 18-30 | 2/78 | ref | ref | ref |
| | <18 | 0/11 | 0 | 0-NA | 1.0 |
| | >30 | 0/3 | 0 | 0-NA | 1.0 |
| Operative time | >106 min | 2/42 | ref | ref | 0.21 |
| | ≦106 min | 0/50 | 0 | 0-NA | |

SSI: surgical site infection; RR: risk ratio; CI: confidence interval; y.o.: years old;. ASA-PS: American Society of Anesthesiologists physical status; ref: reference; NA: not applicable.

diet, a low-residue diet for pre-operative therapy, is designed to reduce digestive tract contents while allowing patients to continue their oral intake. Based on the findings of a multicentre randomised controlled trial conducted at our hospital [6], in which oral anti-microbials before colorectal resection reduced the incidence of SSI, oral antibiotics were also used for stoma closure. The reason for using "colorectal" antibiotics in ileostomy closure is that a previous study showed that the number of bacteria increases as one proceeds towards the terminal ileum, reaching a similar quantity in the colon [7]. As the number of bacteria in the

Table 4Details of surgical site infection (SSI) cases.

| | Case1 | Case2 |
|--------------------------------------|-----------|-----------|
| Sex | Male | Female |
| Age (y.o.) | 52 | 62 |
| Operative year | 2007 | 2010 |
| Time to stoma closure (days) | 110 | 28 |
| Preoperative chemotherapy | No | No |
| Stoma site | Ileostomy | Ileostomy |
| Parastomal hernia | No | No |
| Malignancy | Yes | No |
| Diabetes mellitus | No | No |
| Smoking history | Yes | Yes |
| Steroid use | No | No |
| ASA-PS score | 1 | 2 |
| Body mass index (kg/m ²) | 19.6 | 18.0 |
| Operative time (min) | 139 | 116 |

SSI: surgical site infection; y.o.: years old;.

ASA-PS: American Society of Anesthesiologists physical status.

terminal ileum and colon is almost the same, using the same anti-microbial agent before colorectal surgery is reasonable. However, pre-operative mechanical bowel preparation is avoided because it can lead to pre-operative dehydration and an increased risk of SSIs owing to higher intra-operative stoma drainage.

In this article, we describe this surgical technique. We focused on tightly closing the fat tissue directly above the fascia to secure the closure of the subcutaneous fat layer with a vertical mattress stitch because we believe that the cornerstone of skin suturing is the elimination of dead space. A previous study showed that suturing just above the fascia with a long needle decreased the incidence of SSIs and minimised dead space in SSI incidence reduction [8].

Distinguishing between clean and contaminated regions is vital for preventing SSIs. The World Health Organization recommends exchanging surgical tools for procedures involving instrument contamination. However, demonstrating the efficacy of this strategy is challenging [9]. Our concept is supported by a recent randomised controlled trial in which exchanging gloves and instruments prior to abdominal wall closure may have lowered the risk of SSIs [10]. Our findings imply that these pre-operative procedures and surgical techniques reduce the SSI rates to a sufficiently low level.

Our institution implemented the procedure in 2006. Because of the extensive education provided to trainees, our practices are now more closely based on the concept of infection prevention. Fundamental procedures became stricter, subsequently accompanied by changes in the composition of supervisory teams. Since 2011, the incidence of SSIs has been zero. These results suggest that proficiency in this technique is important for reducing the incidence of SSIs.

Purse-string closure has emerged as an effective method to avoid SSIs during stoma closure. A recent meta-analysis revealed that, compared to linear skin closure, purse-string closure could reduce the incidence of SSIs [2]. However, the overall incidence of SSIs with linear sutures in the meta-analysis was >20%, which was considerably higher than that observed in our study. With this method, purse-string suturing may be unnecessary.

More recent attempts have been made to employ NPWT [3], which is regarded as a precautionary strategy for wound healing based on the anticipation of an SSI. However, purse-string sutures with NPWT are aimed at secondary healing, which is fundamentally different from simple linear closure.

In this study, patients had a relatively extended post-operative hospital stay. This is because almost all patients were hospitalised until the sutures were removed to check for infection, and some post-rectal resection patients were hospitalised to control defaecation because of complaints of frequent bowel movements.

Our study had three limitations. First, this was a retrospective descriptive study rather than a comparative study. Second, due to the

small number of SSI cases, multivariate risk factors analysis was impossible. Instead, univariate analyses were repeatedly conducted, which may have resulted in issues of multiplicity. Third, only a few patients in this study were obese, with only 3.3% having a BMI of 30 or higher. All the patients in this study were consecutive. Notably, a significant proportion of the population in Japan is slim. For instance, a study conducted using a Japanese clinical database reported that only 10.7% of the patients had a BMI of $\geq\!25$ [11]. Based on this study, it is not surprising that the percentage of patients with a BMI of $\geq\!30$ is as low as 3.3%.

In our department, the incidence of SSIs following stoma closure with linear suture closure is sufficiently low to imply that emphasising fundamental infection prevention strategies is necessary to lower the rate of SSIs and that even linear suture closure performed under such strategies could prevent SSIs.

Statement of ethics

Study approval statement (Ethical review board)

This study protocol was reviewed and approved by the Kyoto Medical Centre Ethics Review Committee (approval number: 21–004).

Consent to participate statement

The requirement for written informed consent was waived by the Institutional Review Board.

Funding sources

The authors declare that there are no sources of funding.

Data availability

The data that support the findings of this study are not publicly available because they contain information that could compromise the privacy of research participants; however, the data can be availed from the corresponding author upon reasonable request.

CRediT authorship contribution statement

Kentaro Goto: Writing – review & editing, Writing – original draft, Methodology, Formal analysis, Data curation. Ryo Matsusue: Writing – review & editing, Writing – original draft, Supervision, Conceptualization. Kanako Degawa: Writing – review & editing, Formal analysis, Data curation. Akimori Miki: Writing – review & editing, Formal analysis, Data curation. Hiroki Nakanishi: Writing – review & editing, Formal analysis, Data curation. Hiroki Hata: Writing – review & editing, Writing – original draft. Masato Narita: Writing – review & editing, Writing – original draft. Takashi Yamaguchi: Writing – review & editing, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.sipas.2025.100277.

Video 1 (stomaclosure_1.mov): Cleaning and sterilisation of the area around the stoma. The area was sterilised and draped after thoroughly cleaning with gauze and alcohol-coated cotton or alcohol gel.

Video 2 (stomaclosure_2.mov): Temporary closure of the stoma. After incision of the peristomal skin, the intestinal tract was detached from the surrounding skin and inverted for temporary suturing.

Video 3 (stomaclosure_3.mov): Rewiping and resterilisation after temporary suture closure. The surgical field was cleaned and resterilised, and a new drape was deployed.

Video 4 (stomaclosure_4.mov): Anastomosis, resection of the temporarily closed bowel, and wound closure. The surgical procedure was performed with the surgeon cognizant of the distinction between clean and contaminated regions. After fascial closure, subcutaneous lavage and skin closure were performed with vertical mattress linear sutures to ensure no dead space.

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