A combination of subcuticular sutures and subcutaneous closed-suction drainage reduces the risk of incisional surgical site infection in loop ileostomy closure

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A brief title Wound closure method to prevent SSI in loop ileostomy closure

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Abstract

Purpose The purpose of this study was to evaluate the effectiveness of a wound closure method using a combination of subcuticular sutures and subcutaneous closed-suction drainage (SS closure) for preventing incisional surgical site infection (SSI) in loop ileostomy closure.

Methods A total of 178 consecutive patients who underwent loop ileostomy closure at Nara Medical University Hospital between 2004 and 2018 were retrospectively assessed. The patients were divided into two groups: the conventional skin closure (CC) group from 2004 to 2009 (75 patients) and the SS closure (SS) group from 2010 to 2018 (103 patients). Incidence of incisional SSI was compared between the two groups, and factors associated with incisional SSI were examined by univariate and multivariate analysis.

Results Incisional SSI occurred in 7 cases (9.3%) in the CC group but was significantly reduced to only 1 case (0.9%) in the SS group (p=0.034). In univariate analysis, hemoglobin levels, serum creatinine levels, and SS closure were associated with incisional SSI. SS closure was the only independent preventive factor for incisional SSI by multivariate analysis (HR=0.24, p=0.011).

Conclusion The combination of subcuticular sutures and subcutaneous closed-suction drainage may be a promising way of preventing incisional SSI in loop ileostomy closure.

Introduction

Diverting loop ileostomy is commonly performed to protect a downstream anastomotic site in colorectal surgery, such as anal-preserving operation for rectal cancer and inflammatory bowel disease (IBD) [1, 2]. Closure of loop ileostomy is a minor operation, but the complication rate is high, with complications reported in up to 41% of cases [3–5]. Incisional surgical site infection (SSI) is one of the most common complications after ileostomy closure, with an incidence rate of 3.1%–40% [6–8]. Although incisional SSI is not a lethal complication, it increases medical costs, prolongs hospital stay, and reduces the patient quality of life (QOL) [9]. Several techniques for skin closure have been attempted to reduce the risk of incisional SSI, including secondary closure of the skin [10], subcutaneous purse-string suture [11, 12], negative-pressure wound therapy (NPWT) [13], and subcuticular sutures.

Subcuticular sutures have several advantages for wound closure, including cosmetic benefits, convenient wound management without the need for suture removal, and maintenance of the subcutaneous blood flow [14–16]. An additional benefit of this suturing technique is that it is associated with a reduced incidence of incisional SSI. This was first proven in clean operations, such as cardiovascular and orthopedic surgeries, and subsequently in the clean-contaminated wounds of gynecological surgeries [17–19]. Since then, subcuticular sutures have been introduced for stoma closure, which is a contaminated surgery, and the incisional SSI incidence is now significantly lower than that for conventional transdermal sutures, although the incidence remains high at 11.1% [20]. Subcuticular sutures, when used alone for skin closure after stoma resection, were thought to have the potential disadvantage of retaining the infectious fluid in the dead space created in the subcutaneous tissue. Indeed, a retrospective study and a randomized controlled trial (RCT) demonstrated the need for a subcutaneous suction drain in conventional ileostomy closures [14, 21]. However, combining subcutaneous drainage with subcuticular sutures may overcome this disadvantage associated with subcuticular sutures.

To reduce the incisional SSI incidence in stoma closure, we introduced a wound closure method using a combination of subcuticular sutures and subcutaneous closed-suction drainage (SS closure) for loop ileostomy closure from January 2010 and have been using this procedure ever since. The purpose of this study was to evaluate the effectiveness of SS closure for preventing incisional SSI in loop ileostomy closure.

Patients and methods

Consecutive patients who underwent loop ileostomy closure in Nara Medical University Hospital between January 2004 and December 2018 were retrospectively assessed. Patients from 2004 to 2009 received conventional skin closure (CC group), and those from 2010 to 2018 received skin closure with a combination of subcuticular sutures and subcutaneous suction drainage (SS group). The patient characteristics and surgical outcomes, including the incidence of incisional SSI, were compared between the two groups. In addition, the clinicopathological factors were analyzed to identify the risk or preventive factors for incisional SSI after loop ileostomy closure using univariate and multivariate analyses. In this study, diabetes mellitus was defined as a diagnosis of diabetes mellitus and being treated with insulin or oral medications.

This study was approved by the ethics committee of Nara Medical University (No. 2372). All patients gave their informed consent for the use of their anonymized data via an opt-out method. Patients consent to participate was obtained through an opt-out method.

Preoperative management

Patients ate regular diet until dinner the day before surgery. No pretreatment was performed. Antibiotics were administered as 1 g of cefmetazole sodium once immediately before (30 minutes) the skin incision, once on the day after surgery, and twice on the next day with a 12-h interval.

Surgical techniques

A summary of the surgical procedure is shown in Fig. 1 and the supplementary video is given in the animation (Online Resource 1). First, we gently removed the stoma pouch using a remover. Before the skin incision, we gently scrubbed around a diverting ileostomy with weakly acidic soap to remove dirt and pouch glue from the skin. After scrubbing the skin, the ileostomy was first temporarily closed with a purse-string suture in a semi-clean operation. Subsequently, the skin was incised in a leaf shape around the circumference while maintaining a distance of 5 mm from the mucocutaneous junction. The incised skin was inverted with dense sutures to cover the intestinal mucosa and prevent bacterial contamination, and the semi-clean procedure was finished. The skin was then disinfected with povidone iodine, and clean procedures were started.

The closed ileostomy was pulled from the abdominal wall with supporting thread. The subcutaneous fat, rectus fascia, and peritoneum were peeled from the intestinal wall and the intestine was removed from the abdominal wall. Then, the wound edge was fitted with a wound protection device and covered with a sterile cloth to prevent contamination of the wound as much as possible. After performing partial resection of the small intestine, intestinal anastomosis was performed by hand-sewn anastomosis or instrumental anastomosis (functional end-to-end anastomosis) at the discretion of the surgeon. We exchanged surgical instruments and gloves for fresh ones.

The peritoneum and rectus fascia were closed using 0 PDS II (Ethicon, New Brunswick, NJ, USA). We carefully washed the subcutaneous tissue of the wound with saline. In the SS group, we placed a closed-suction drain (J-Vac drainage system; Johnson & Johnson Co., New Brunswick, State of New Jersey, USA), at the subcutaneous layer, and the skin was closed using 4/0 PDS II (Ethicon) with subcuticular sutures (Fig. 1). In the CC group, the skin was closed with interrupted transdermal sutures using 2/0 non-absorbable suture materials. Subcutaneous closed-suction drainage was not used.

Postoperative management

Disinfection was not performed after surgery. The subcutaneous closed-suction drain was removed on the third day after surgery. In order to keep the wound clean, a shower bath was recommended from the fourth day. After confirming that there were no postoperative complications, the patient was discharged roughly one week later.

The diagnosis of incisional SSI

Incisional SSI was defined as the presence of cellulitis or purulent discharge, with or without positive bacterial growth, within 30 days after the operation [22]. The surgical wounds were routinely observed and evaluated by the surgical team until discharge and at the first outpatient examination by the outpatient surgeon.

Statistical analyses

The data presented were analyzed using the Pearson's chi-square and Fisher's exact tests. For continuous variables, data were expressed as the median (range). The Mann-Whitney U-test was used for statistical comparisons of different groups. $p < 0.05$ was considered to indicate a statistically significant difference. All of the tests were performed using the SPSS statistics software program, version 25 (SPSS Inc., Chicago, IL, USA).

Results

Characteristics of the patients with loop ileostomy closure

A total of 178 consecutive patients were enrolled in the study. The CC group had 75 patients, and the SS group had 103 patients. Table 1 shows the characteristics of the patients with loop ileostomy closure. There were no significant differences in the age, gender, body mass index, or primary disease for loop ileostomy creation between the two groups. Regarding underlying disease, the proportion of patients with diabetes was significantly higher in the SS group than in the CC group (6.6% vs. 15.5%, p=0.045). The proportion of patients with steroid use was also significantly higher in the SS group than in the CC group (0% vs. 8.7%, p=0.006).

Surgical outcomes

Table 2 shows the surgical outcomes between two groups. There were no significant differences in the operation time, days of hospital stay, or total postoperative complication rate between the two groups. Blood loss was significantly greater in the SS group than in the CC group (15 ml vs. 30 ml, p=0.025). Regarding the anastomotic procedure, the CC group had a higher rate of hand-sewn sutures (94.6%), while the SS group had a higher rate of instrumental anastomosis (functional end to end anastomosis, 53.3%) (p=0.031). SSI occurred in 7 cases (9.3%) in the CC group but was significantly reduced to only 1 case (0.9%) in the SS group (p=0.034).

Factors associated with development of incisional SSI

Table 3 shows the factors associated with the development of incisional SSI after loop ileostomy closure. From a univariate analysis, the hemoglobin level (<10 g/dL) (hazard ratio [HR]=10.1, p=0.011) and serum creatinine level (>1 mg/dL) (HR=4.77, p=0.035), as well as subcuticular sutures with subcutaneous closed-suction drainage (HR=0.06, p=0.002) were extracted as significant factors associated with the development of incisional SSI. A multivariate analysis further indicated that a combination of subcuticular sutures and subcutaneous closed-suction drainage was the only independent preventative factor for the development of SSI (HR=0.24, p=0.011).

Discussion

Kobayashi et al. first reported the preventive effect of incisional SSI with subcuticular sutures alone in stoma closure. In that report, the incidence of incisional SSI was reduced from 37.5% in the conventional method to 11.1% in the subcuticular sutures [20]. It was considered that the subcuticular sutures contributed to the decrease in the SSI incidence because it maintained good blood flow in the skin and also accurately repaired the skin structure [23]. However, due to the formation of subcutaneous dead space in which exudate accumulates, skin closure with subcuticular sutures alone had been shown to have limitations in the prevention of SSI.

To address this subcutaneous dead space, a subcutaneous closed-suction drain insert was introduced. Kanamaru et al. introduced a combination of subcuticular sutures and subcutaneous suction drain for total cystectomy and reduced the incision SSI rate from 31.8% to 0% [24]. Watanabe et al. also used this method for colorectal surgery to reduce the incidence of SSI from 12.8% to 4.5% [25]. Regarding the usefulness of this method in stoma closure, Yoshimatsu et al. reported a low SSI incidence of 2% [26]. However, this report was a single-arm, retrospective study of various stomas, including colostomy and ileostomy. Thus far, there have been no reports on the superiority of this method over the conventional method and its position in SSI prevention. Although our study is a single-center, retrospective study, it is the first report comparing this method with conventional methods for the prevention of incisional SSI in stoma closure. In particular, limiting the surgical procedure to loop ileostomy closure made extraction of factors related to incisional SSI more accurate.

Our results show that SS closure resulted in a significantly lower incisional SSI rate than CC closure, despite disadvantageous background factors, such as diabetes mellitus and steroid use, and increased intraoperative blood loss. Regarding the intraoperative blood loss, the SS group was considered to include many complicated cases with severe adhesion, according to the medical record review. This fact may also be associated with the relatively high incidence of ileus in the SS group, although there was no statistically significant difference between the groups. The incidence of SSI in the CC group was 9.3%, which was relatively low. We have long been making efforts to prevent incisional SSI. For instance, we exchanged all surgical tools and gloves before closing the stoma hole prior to ileostomy excision in both the CC and SS groups. We also ensured the wound is kept clean by washing with at least 500 ml of saline during the procedure. Our data suggested that these radical precautions reduced the incidence of incisional SSI to 9.3%, even with the conventional skin closure method. For further improvement, we have introduced the SS closure technique. As a result, SS closure was found to be the only independent factor for preventing the development of SSI. The incidence of incisional SSI was reduced to only 1 (0.9%) among 103 consecutive cases over 9 years. These results indicate that SS closure has a strong preventive power against incisional SSI on ileostomy closure. The incidence of incisional SSI of 0.9% is one of the lowest ever reported for ileostomy closure.

In addition to subcuticular sutures, various attempts have been made to prevent incisional SSI in ileostomy closure, including secondary wound closure, purse-string skin sutures, and NPWT. Hackam et al. reported that delayed primary or secondary wound closure could reduce the rate of incisional SSI in stoma closure from 41% to 15% [10]. However, the superiority of secondary wound closure was no longer recognized when the incidence of incisional SSI of primary closure was reduced by 10% through various efforts [27].

Purse-string sutures are an attractive wound management method because they are simple, and the final wound scar is small [11, 12]. A recent RCT comparing purse-string closure and linear closure for ileostomy closure showed that the incisional SSI rates were 8% vs. 30% (p=0.03) [28]. A meta-analysis showed that the SSI rates were 6% vs. 29% (p <0.00001) [29]. Certainly, the superiority of purse-string closure has been statistically shown; however, the SSI rates in the linear closure group were unacceptably high (21.9%–38.7%) [28, 29]. In the present study, the incidence of SSI was as low as 9.3%, even in the CC group. Therefore, it is possible that the meta-analysis were collections of RCTs performed at institutions where the linear closure procedures had not been sufficiently mature. In addition, purse-string closure has the disadvantage of exudate from the wound persisting for a long time, with wound dressing required. In our SS method, the subcutaneous drain was removed by 72 h after surgery, and subsequent wound dressing became unnecessary.

The advantages of NPWT have been demonstrated in several damaged animal models [30]. NPWT was confirmed to increase the expression of vascular endothelial growth factor (VEGF) and fibroblast growth factor-2 (FGF-2) in damaged tissue. Therefore, NPWT can help promote vascularization within hypoxic tissue and may accelerate wound healing [31]. However, the findings of NPWT in ileostomy closure are still limited. One RCT showed no benefit of adding NPWT to purse-string sutures in ileostomy closure in patients with ulcerative colitis [13]. An RCT is currently being planned to clarify whether or not NPWT promotes wound healing after stoma reversal [32].

The present study's SSI rate of 0.9% in ileal stoma closure by the SS method is excellent among previously reported data. However, this study has several limitations. First, it was a retrospective, single-center study and could not be a highly evidential study. Second, other endpoints, such as cost effectiveness and cosmetic results, were unable to be evaluated by the present data. We believe that these issues need to be further investigated through a well-designed, randomized trial in the future.

In conclusion, the combination of subcuticular sutures and subcutaneous closed-suction drainage may be a promising procedure for preventing incisional SSI in loop ileostomy closure.

Disclosure

Conflict of interest: Kohei Fukuoka and other co-authors have no conflict of interest.

Ethical Statements: The protocol for research project was approved by the Ethics Committee of the institution (No. 2372) and it conforms to the provisions of the Declaration of Helsinki.

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Figure legends

Fig. 1 Procedures of SS closure. **a** The stoma is washed with foam. **b** The stoma exits are closed with purse-string sutures. The skin around the stoma is incised into a leaf shape with a scalpel. **c** The mucosa of the stoma is inverted and covered by the skin. **d** The ileum is gently peeled off when the stoma is removed from the abdominal wall. **e** A wound protector is attached to the wound edge. **f** The ileum is anastomosed with hand-sewn or functional end-to-end anastomosis. **g** A closed suction drain is inserted subcutaneously. **h** the skin is closed with subcuticular sutures using 4-0 monofilament absorbent thread.

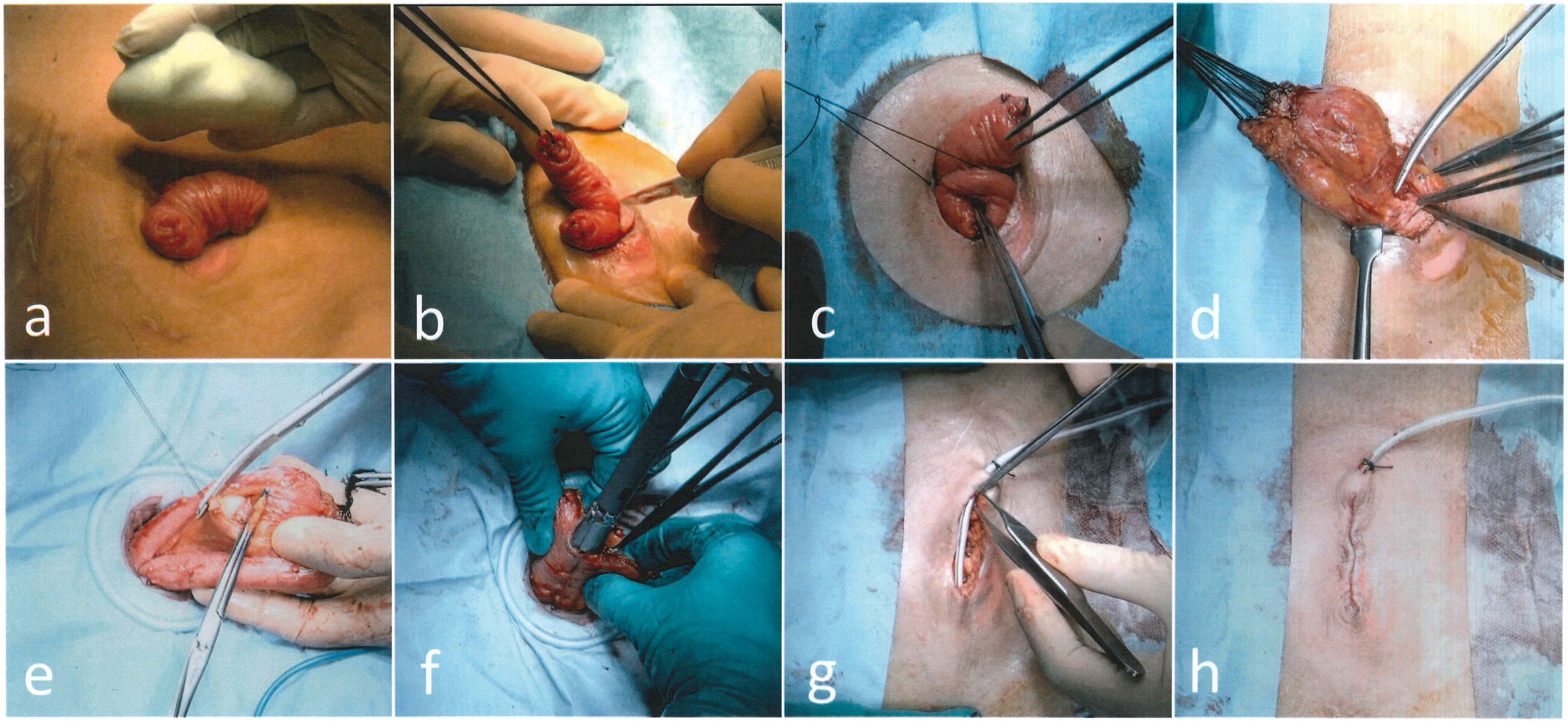
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Table 1. Demographics and perioperative characteristics of the two groups

	CC group	SS group	
Characteristic (%) or median (range)	N=75	N=103	*p* value
Gender			0.442
Male	48 (64%)	62 (60.1%)	
Female	27 (36%)	41 (39.9%)	
Age (years)	57 (17–81)	56 (13–79)	0.928
Body mass index (kg/m^2)	21.8 (16.4–29.3)	21.4 (15.5–28.4)	0.673
Disease			
Colorectal cancer	43 (57.3%)	56 (54.3%)	0.823
IBD	23 (30.6%)	32 (31.0%)	0.834
Carcinoid	3 (4%)	3 (2.9%)	0.798
Others	6 (8%)	9 (8.7%)	0.932
Medical history			
Hypertension	10 (13.3%)	21 (20.3%)	0.209
Diabetes mellitus	5 (6.6%)	10 (15.5%)	0.045*
Cardiovascular disease	2 (1.9%)	7 (6.7%)	0.167
Steroid used	0 (0%)	9 (8.7%)	0.006*

IBD Inflammatory bowel disease, *CC* conventional skin closure, *SS* a combination of subcuticular sutures and subcutaneous closed-suction drainage

*p<0.05

Table 2. Surgical outcomes of the two groups

	CC group	SS group	
Characteristic (%) or median (range)	N=75	N=103	*p* value
Operation time (minutes)	118 (56–242)	117 (54–340)	0.723
Blood loss (ml)	15 (0–140)	30 (0–405)	0.025*
Days of hospital stay (days)	12 (7–75)	9 (6–35)	0.878
Anastomosis procedure			0.031*
Hand sewn	71 (94.6%)	48 (46.6%)	
FEEA	4 (5.3%)	55 (53.3%)	
Complication	13 (17.3%)	18 (17.4%)	0.438
Ileus	6 (8%)	14 (13.6%)	0.140
Anastomotic leakage	0 (0%)	1 (0.9%)	1.000
Anastomotic bleeding	1 (1.3%)	1 (0.9%)	1.000
Incisional SSI	7 (9.3%)	1 (0.9%)	0.034*

CC conventional skin closure, *SS* a combination of subcuticular sutures and subcutaneous closed-suction drainage, *FEEA* Functional end-to-end anastomosis, *SSI* surgical site infection

*p<0.05

Table 3. Results of univariate and multivariate analyses for incisional SSI risk in loop ileostomy closure

	Univariate		Multivariate	
Variables	HR (95% CI)	*p* value	HR (95% CI)	*p* value
Male sex	0.74 (0.15–3.88)	0.731		
Age ≥65 years old	0.61 (0.05–3.31)	0.721		
BMI ≥25	0.37 (0.01–2.96)	0.689		
Cardiovascular disease	3.83 (0.35–23.4)	0.142	1.01 (0.08–11.9)	0.993
Diabetes mellitus	3.15 (0.47–16.1)	0.125	3.39 (0.47–24.4)	0.225
Hypertension	1.21 (0.11–6.69)	0.686		
Malignant disease	2.02 (0.37–20.5)	0.492		
Steroid	NA	1.000		
Hemoglobin <10 g/dL	10.1 (1.41–59.8)	0.011*	3.75 (0.53–24.4)	0.181
Creatinine ≥1 mg/dL	4.77 (0.88–23.8)	0.035*	2.32 (0.43–12.3)	0.324
Serum albumin <3.5 g/dL	3.29 (0.36–19.7)	0.175		
Blood loss ≥100 ml	1.71 (0.03–14.7)	0.486		
Operative time ≥180 min	1.25 (0.23–6.03)	0.743		
FEEA	0.21 (0.04–1.67)	0.262		
SS closure	0.06 (0.01–0.49)	0.002*	0.24 (0.08–0.73)	0.011*

SSI surgical site infection, HR hazard ratio, *CI* Confidence interval, *BMI* body mass index, *FEEA* functional end-to-end anastomosis, *SS closure* a combination of subcuticular sutures and subcutaneous closed-suction drainage

*p<0.05