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Effect of Application of Subcutaneous Suction Drainage with Subcuticular Sutures for Wound Closure on the Incidence of Incisional Surgical Site Infection following Elective General Abdominal Surgery : A Randomized Controlled Trial

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Objective : The aim of this trial was to verify whether use of subcutaneous suction drainage with subcuticular sutures for wound closure might decrease the incidence of incisional surgical site infection (SSI) after general abdominal surgery.

Summary Background Data : The ideal method for wound closure following general abdominal surgery has not been established yet.

Methods : Patients were randomly assigned to receive either subcutaneous drainage with subcuticular sutures (drainage group) or subcutaneous sutures with skin stapling (control group). The primary end point was the incidence of incisional SSI within 30 days after surgery. This trial is registered with UMIN-CTR, number UMIN000003073.

Results : A total of 160 patients were randomly assigned to the drainage group (n＝81) or the control group (n＝79). Incisional SSI was observed in 12 patients (14.8 %) in the drainage group, and 15 patients (19.2 %) in the control group, with no significant difference between the two groups (P＝0.459). Subgroup analyses showed that the drainage method significantly reduced the incidence of SSIs in patients with diabetes mellitus (P＝0.048) and/or a subcutaneous fat pad thickness of ≥2.3 cm (P＝0.043).

Conclusion : Application of the subcutaneous drainage with subcuticular suture method for wound closure was not associated with any significant decrease in the incidence of incisional SSIs as compared to that of the conventional method. However, the drainage method might be beneficial for reducing the risk of SSIs in patients with diabetes mellitus and/or a subcutaneous fat pad thickness of ≥2.3 cm. *Shinshu Med J 63 : 91—101, 2015*

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Key words : subcutaneous drainage with subcuticular sutures, surgical site infection, general abdominal surgery, randomized open-label trial

I Introduction

Surgical site infection (SSI) is a common and serious complication encountered after surgery[1)], with reported incidence varying in the range of 5 % to 30 %[2)]. Development of SSI is associated with prolongation of the length of hospital stay, leading

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to increased medical costs[1]. Whereas several host-related risk factors that cannot be easily modified have been reported to predispose to the development of SSI[3][4], some surgical factors may also influence the risk[3][5], allowing room for surgeons to refine their surgical procedures.

Surgical textbooks teach that wound closure after abdominal surgery is performed by subcutaneous interrupted sutures to eliminate any dead space, followed by skin suture[6], or stapler skin closure for accurate approximation[7]. Since the last half of the 1990s, insertion of a subcutaneous drain, in an attempt to decrease the subcutaneous dead space by drainage of blood and serous fluids before the establishment of infection, has been reported to be beneficial to reduce the incidence of incisional SSI in obstetric/gynecologic surgery[8]–[10], colorectal surgery[11], and liver surgery[12]. Although randomized trials to verify its effect on the risk of SSI have been extensively conducted in the field of obstetric/gynecologic surgery[8]–[10], few studies conforming to the CONSORT statement on its effect have been reported in relation to general abdominal surgery[13]. In general abdominal surgery, Fujii et al.[11] and Tsujita et al.[12] reported the effectiveness of subcutaneous drainage on reducing incisional SSI, but these studies were retrospective. Kaya et al.[14] performed a randomized controlled trial, but they failed to confirm the effectiveness of the subcutaneous drainage method for preventing incisional SSI. Briefly, the subcutaneous drainage method has been considered to useful for preventing wound infection, but no randomized controlled trial demonstrates its effectiveness in general abdominal surgery. After elective general abdominal surgery, we use the conventional wound closure method, that is, subcutaneous sutures with skin stapling, and our incisional SSI rate is around 20 %. To further reduce this rate with a step-by-step approach, we decided to investigate the results of a newly introduced method, namely, subcutaneous drainage with subcuticular sutures, as compared to that of the conventional wound closure technique. This was the reason we designed this randomized controlled trial. In the current study, we tested the hypothesis that use of subcutaneous drainage with subcuticular sutures for wound closure can decrease the incidence of incisional SSI as compared to the conventional method, i.e., subcutaneous sutures with skin stapling after elective general abdominal surgery.

II Materials and Methods

A Patients

This was a single-center, randomized open-label trial conducted in Japan. The potential participants in this trial were patients scheduled to undergo elective clean-contaminated surgery, i.e., gastrointestinal surgery or hepatobiliary-pancreatic surgery with bilioenteric reconstruction for some benign or malignant diseases at Shinshu University Hospital. The inclusion criteria were : age between 20 and 80 years and American Society of Anesthesiologists score between 1 and 3. The exclusion criteria were : cases requiring emergency operation, those scheduled to undergo laparoscopic surgery, those requiring an identical skin incision to that for a previous abdominal surgery, those with uncontrolled diabetes mellitus, and those with a previous ileostomy or colostomy. The study protocol was approved by the institutional review board of the Shinshu University School of Medicine. An English-language summary of the protocol was submitted (registration ID : UMIN000003073) to the Clinical Trials Registry managed by the University Hospital Medical Information Network (UMIN) in Japan, which can be accessed commission-free on the internet (available at : http : //www.umin.ac.jp/ctr/index.htm). Written informed consent was obtained from all the participants.

B Randomization and masking

The participants were randomly assigned (1 : 1) to receive either subcutaneous suction drainage combined with subcuticular sutures (drainage group) or subcutaneous sutures with skin stapling (control group) for wound closure. The assignment was generated by an internet-accessed randomization system supported by the Internet Data and Information Center for Medical Research in the UMIN. The

randomization was performed by the minimization procedure taking into account the following stratification factors: presence or absence of diabetes mellitus (DM) requiring medication, body mass index (BMI <25 or ≥ 25 kg/m^2), and the scheduled operative procedure (with or without colostomy). The surgeons employed the assigned treatment, which was notified to them just before the abdominal closure. The patients and the principal surgeons, who were the outcome assessors, were not masked to the technique used in this trial.

C Procedure

In the control group, the subcutaneous tissue and skin were closed with interrupted sutures using absorbable monofilament suture material (PDS-II USP 2-0 ; Ethicon. Inc., Somerville, NJ, USA), and a skin stapler (HOGY skin stapler ; Covidien, Dublin, Ireland), respectively. The timing of staple removal was postoperative day 7.

In the drainage group, a subcutaneous suction drainage system (10Fr BLAKE Silicon drain ; Ethicon. Inc., Somerville, NJ, USA) was placed and brought out through a separate stab wound incision. The wounds were then closed with interrupted subcuticular sutures using absorbable monofilament suture material (PDS-II USP 4-0 ; Ethicon. Inc., Somerville, NJ, USA). All knots were buried in the wound. The subcutaneous drains were removed, in principle, on postoperative day 3.

Cefmetazole was administered intravenously at a dose of 1 g 30 min before the initial skin incision, and repeated every 8 hours during surgery, and additional antibiotics at a dose of 1 g per 12 h were administered for 3 days after operation. For patients undergoing preoperative biliary drainage and showing positive results of bile culture, the antimicrobial agent was selected according to the results of the bile culture. The skin of the abdomen was prepared with a povidone-iodine solution. After closure of the fascia with interrupted absorbable sutures of PDS-II USP 1 (Ethicon. Inc., Somerville, NJ, USA), the surgical incisions were irrigated with 500 ml of saline solution. The depth of the subcutaneous fat was measured from the fascia to the skin with a sterile ruler at the point of maximum thickness in the incision. The wounds were protected with a sterile dressing for 48 hours.

SSI was defined according to the criteria of the Centers for Disease Control and Prevention[15]. Infection control personnel monitored the development of SSI during the patient's hospital stay. The principal surgeons evaluated the presence or absence of SSI during the patient's hospital stay and at the follow-up visit on the 30th postoperative day in patients discharged within one month after surgery.

D Statistical analysis

The primary end point was the incidence of superficial or deep incisional SSI within 30 days after surgery. The secondary end points were the postoperative length of hospital stay and postoperative hospital cost.

A preliminary study in 33 patients undergoing conventional wound closure following gastrointestinal surgery showed that the incidence of incisional SSI was 21 %. Farnell et al. reported a wound infection rate of 4.4 % in patients treated by subcutaneous catheter drainage with subcuticular sutures for wound closure following clean-contaminated operation[16]. Taking these results into consideration, we hypothesized that the application of subcutaneous drainage combined with subcuticular sutures for wound closure, as compared to subcutaneous sutures and skin stapling, may decrease the incidence of incisional SSI by 15 %, that is, from 20 % to 5 %. The sample size required to detect a statistically significant difference by the two-tailed test with a type I error of 5 % and statistical power of 80 % was 76 patients per group, i.e., a total of 152 patients. Taking into account a potential dropout rate of 5 %, we set the target number of study subjects at 160. The projected accrual period was three years, and no interim analysis was performed.

We used the χ^2 test for analysis of the primary endpoint and the Mann-Whitney U test for analysis of secondary endpoints. The background characteristics and surgical outcomes in the two groups were compared using the χ^2 test or Fisher's exact test for categorical data and the t test or Mann-Whitney U

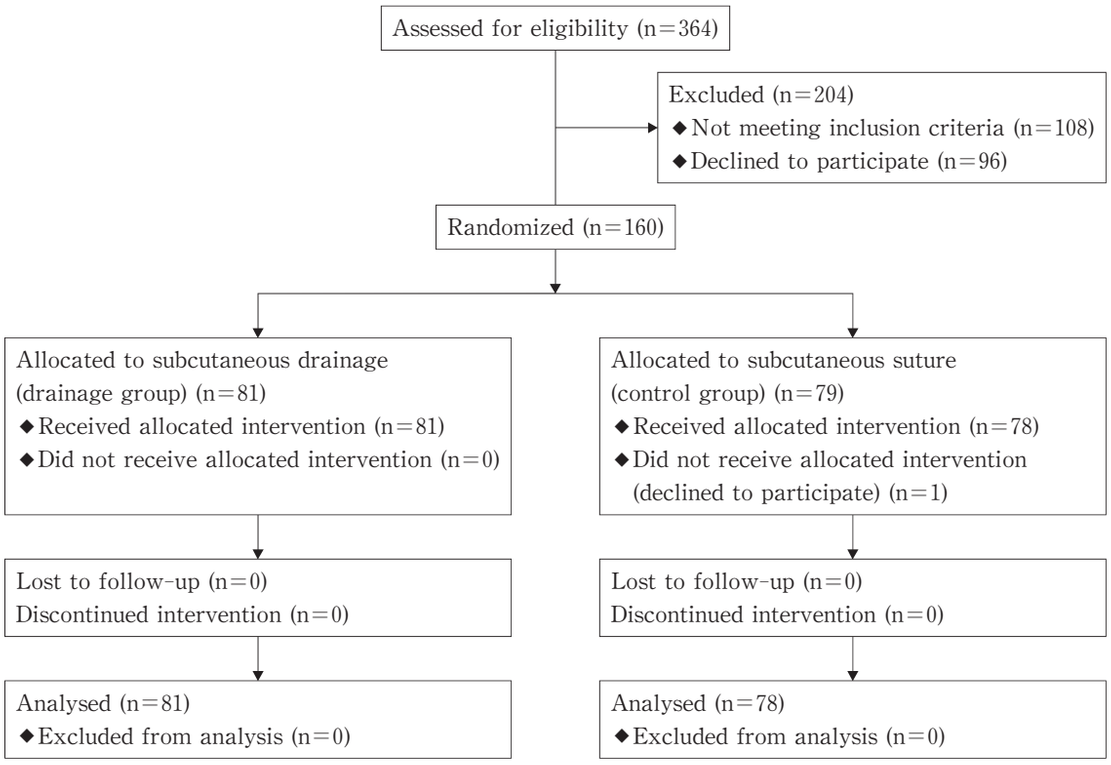

Fig. 1 Study flow diagram

test for continuous data. We conducted multivariate logistic regression analysis to assess risk factors associated with the occurrence of SSI. Variables to be entered into the regression analysis were chosen on the basis of the results of the univariate analysis ($P<0.10$) and consistency with the results of previous studies[3].

Subgroup analyses of the odds ratios were performed after stratifying the patients by their gender, age, BMI, presence/absence of DM, presence/absence of a history of smoking, presence/absence of a history of alcohol drinking, serum albumin level, operative time, and thickness of the subcutaneous fat pad. The median values were selected as the cutoff values for the continuous data, except for the patients' age (<60, 60–70, or ≥70 years).

All analyses were performed on an intention-to-treat basis. Statistical significance was defined as $P<0.05$. All analyses were performed using PASW Statistics 18 (SPSS, Chicago, IL).

Ⅲ Results

From April 2010 until November 2012, a total of 364 patients underwent elective gastrointestinal or hepatobiliary-pancreatic surgery at our Hospital. Of these, 96 patients declined to participate in this trial, and 108 patients were excluded because of the following reasons: scheduled to undergo laparoscopic surgery (n=65), requiring identical incision to that for previous abdominal surgery (n=34), and presence of previous ileostomy or colostomy (n=9). The remaining 160 patients in the intention-to-treat population were randomized to either the drainage group (n=81) or the control group (n=79). One patient who was assigned to the control group declined to be in the trial after the randomization. Finally, 159 patients were included for the follow-up assessment and their data were analyzed. The trial protocol is shown in **Fig. 1**. The patient characteristics and surgical outcomes (**Table 1**) were similar between the 2 groups.

The overall incidence of incisional SSI was 16.9 % in this trial. The incidence of incisional SSI was 14.8 % (95 % confidence interval (CI) 8.5–24.3 %) in the drainage group, as compared to 19.2 % (11.9–29.5 %) in the control group, with no significant

Table 1 Patients' characteristics and surgical outcomes

Characteristics	Drainage (n=81)	Control (n=78)	*P* value
Age (y)	67 (57–63)	68 (62–72)	0.347
Gender (male)	57 (70.4)	50 (64.1)	0.400
Body-mass index (kg/m²)	21.8 (20.5–24.0)	22.5 (20.2–24.2)	0.652
ASA score			0.657
1	44 (54.3)	37 (47.4)	
2	35 (43.2)	38 (48.7)	
3	2 (2.5)	3 (3.9)	
Diabetes mellitus	16 (19.8)	15 (19.2)	0.934
Smoking history	50 (61.7)	48 (61.5)	0.980
Alcohol history	41 (50.6)	36 (46.2)	0.573
Preoperative steroid use	3 (3.7)	2 (2.6)	1.000
Serum albumin (g/dL)	3.8 (3.5–4.2)	3.8 (3.5–4.1)	0.999
HbA1c (%)	5.9 (5.6–6.2)	5.9 (5.6–6.5)	0.836
Indication for operation			0.238
Malignant tumor	75 (92.6)	74 (94.9)	
Benign tumor	4 (4.9)	1 (1.3)	
Inflammatory bowel disease	1 (1.2)	0 (0)	
Others	1 (1.2)	3 (3.9)	
Operation			0.313
Gastrointestinal surgery	41 (50.6)	35 (44.9)	
+hepatectomy	1 (1.2)	1 (1.3)	
Colorectal surgery	24 (29.6)	18 (23.1)	
+hepatectomy	4 (4.9)	8 (10.3)	
+gynecological surgery	1 (1.2)	0 (0)	
Hepatectomy+bilioentelic anastomosis	9 (11.1)	13 (16.7)	
Pancreatoduodenectomy	1 (1.2)	3 (3.9)	
Colostomy	7 (8.6)	5 (6.4)	0.425
Type of incision			0.125
Midline	67 (82.7)	53 (67.9)	
J-shaped	10 (12.3)	16 (20.5)	
Midline+transverse	2 (2.5)	7 (9.0)	
Others	2 (2.5)	2 (2.6)	
Operative time (min)	342 (268–422)	353 (280–565)	0.142
Blood loss (ml)	230 (100–415)	250 (148–530)	0.226
Perioperative packed red blood cell transfusion	11 (13.6)	16 (20.5)	0.245
Antimicrobial prophylaxis			0.120
Cefmetazole	77 (95.1)	68 (87.2)	
Sulbactam/cefoperazone	2 (2.5)	1 (1.3)	
Imipenem/cilastatin	0 (0)	3 (3.9)	
Others	2 (2.5)	6 (7.7)	
Thickness of subcutaneous fat (cm)	2.4 (2.0–3.0)	2.2 (1.6–3.0)	0.647

ASA, American Society of Anesthesiologists' risk class.

Data are shown as number of patients (percentage) or median (interquartile range).

Table 2 Results of the primary and secondary endpoints and other postoperative outcomes

Outcome	Drainage (n=81)	Control (n=78)	*P* value
Primary endpoint			
Incisional surgical site infection	12 (14.8)	15 (19.2)	0.459
Superficial	10 (12.3)	14 (18.0)	
Deep	2 (2.5)	1 (1.3)	
Secondary endpoints			
Postoperative hospital stay, days	21 (16-25)	20 (16-28)	0.728
Postoperative hospital cost, $	14852 (12032-16930)	15326 (12736-21045)	0.087
Other postoperative outcomes			
Organ/space surgical site infection	4 (4.9)	7 (9.0)	0.316
Postoperative morbidity	27 (33.3)	28 (35.9)	0.734
Clavien-Dindo classification			0.517[a]
Grade V	0 (0)	0 (0)	
Grade IV	0 (0)	0 (0)	
Grade III	4 (4.9)	2 (2.6)	
Grade II	4 (4.9)	7 (9.0)	
Grade I	11 (13.6)	13 (16.7)	
Additional antibiotics use	14 (17.3)	13 (16.7)	0.918

Data are shown as number of patients (percentage) or median (interquartile range).
[a]Analysis comparing ≤Grade II and ≥Grade III.

difference between the groups ($P=0.459$) (**Table 2**). The median postoperative length of hospital stay, the median postoperative hospital costs, and other operative outcomes were comparable between the groups (**Table 2**).

The multivariate analysis failed to identify any variables significantly associated with the development of postoperative incisional SSI, however, there was a tendency toward a higher risk of incisional SSI in patients with DM than in those without (adjusted odds ratio 2.581, 0.945-7.051, $P=0.064$) (**Table 3**).

Subgroup analyses showed that the drainage method significantly reduced the incidence of SSIs in patients with DM (OR: 0.163, 95 % CI: 0.027-0.983, $P=0.048$) and/or a subcutaneous fat pad thickness of ≥2.3 cm (0.321, 0.107-0.964, $P=0.043$) (**Fig. 2**).

Ⅳ Discussion

The aim of this trial was to clarify the effect of the application of subcutaneous suction drainage with the subcuticular suture method for wound closure on reducing the incidence of incisional SSI after general abdominal surgery[13]. This trial failed to confirm the superiority of the subcutaneous drainage with subcuticular suture method over the subcutaneous suture with skin stapling method, a result that was in line with previous reports[14)-20)]. A few retrospective studies have reported the effectiveness of subcutaneous drain placement for preventing incisional SSI in general abdominal surgery. It is difficult to clearly define the reasons for the discrepancy in the results between our trial and the previous studies, but the following may be considered. The participants in our trial differed from those in previous studies. The potential participants in our study included those scheduled to undergo elective hepatobiliary-pancreatic surgery with bilioenteric reconstruction (23.9 % of all cases). Previous studies included only patients receiving colorectal surgery[11], or hepatectomy[12], with a shorter operative time than in our study.

The reported incidence of incisional SSI varies widely according to the type of operation: around 5 % for gastric cancer surgery[21)22)], 10-26 % for colorectal surgery[1)23)], and 14-16 % for general abdominal surgery[24)25)]. The overall incidence of incisional SSI of 16.9 % in this trial was comparable to previously reported figures[24)25)]. Surprisingly, we

Table 3 Multivariate analysis of risk factors for incisional surgical site infection

Variables	n	Odds ratio (95 % CI)	*P* value	Adjusted odds ratio[a] (95 % CI)	*P* value
Wound closure method					
Drainage	81	0.703 (0.318–1.679)	0.460	0.657 (0.269–1.603)	0.356
Control	78	1		1	
Gender					
Male	107	0.966 (0.401–2.327)	0.939	0.685 (0.173–2.715)	0.590
Female	52	1		1	
Age					
≥70	61	0.660 (0.227–1.923)	0.447	0.547 (0.168–1.787)	0.248
60–69	55	1.094 (0.397–3.012)	0.862	0.906 (0.302–2.712)	0.860
<60	43	1		1	
Body-mass index					
≥25 kg/m²	26	2.082 (0.775–5.593)	0.146	1.720 (0.559–5.289)	0.344
<25 kg/m²	133	1		1	
Diabetes mellitus					
Present	31	2.500 (0.994–6.285)	0.051	2.581 (0.945–7.051)	0.064
Absent	128	1		1	
Smoking history					
Present	98	1.300 (0.543–3.112)	0.556	1.133 (0.296–4.335)	0.856
Absent	61	1		1	
Alcohol history					
Present	77	1.179 (0.515–2.701)	0.696	1.393 (0.464–4.181)	0.554
Absent	82	1		1	
Serum albumin					
>3.5 g/dl	109	1.380 (0.542–3.515)	0.499	1.224 (0.449–3.342)	0.693
≤3.5 g/dl	50	1		1	
Operative time					
≥6 h	77	1.411 (0.614–3.245)	0.417	1.219 (0.495–3.002)	0.667
<6 h	82	1		1	
Thickness of subcutaneous fat					
≥2.3 cm	82	2.125 (0.890–5.072)	0.089	1.647 (0.616–4.402)	0.320
<2.3 cm	77	1		1	

95 %CI, 95 % confidence interval.

[a]Adjusted for wound closure method, gender, age, body-mass index, diabetes mellitus, smoking history, alcohol history, serum albumin, operative time, or thickness of subcutaneous fat.

observed a higher-than-expected rate (14.8 %) of incisional SSI in the patients in whom the subcutaneous drainage with subcuticular suture method was used for wound closure, which was comparable with some previously reported rates[18)–20)], but higher than others[14)16)]. Farnell et al.[16)] reported a lower incidence of incisional SSI in their study. However, their trial design and type of subcutaneous drain were different from those in our study, so it is difficult to compare the results of their study directly to ours. Kaya et al.[14)] also reported a lower incidence of incisional SSI of subcutaneous drainage group in their randomized controlled trial (5.7 %) than ours (14.8 %). However, there were several divergent elements between these studies. The patients' characteristics in their study showed a younger (54 vs 67 years old) and lower rate of male patients (51 % vs 70 %), a shorter operation time (within 4 hours in 96 % of all patients vs 19 %), and a shorter duration of preoperative hospital stay (2.9 vs 7.9 days), compared to our study. All these factors have been recognized as risk factors for incisional SSI[15)], and that was considered to be the reason for the discrepancy in the results between our trial and the previous study.

Previous studies have documented the following

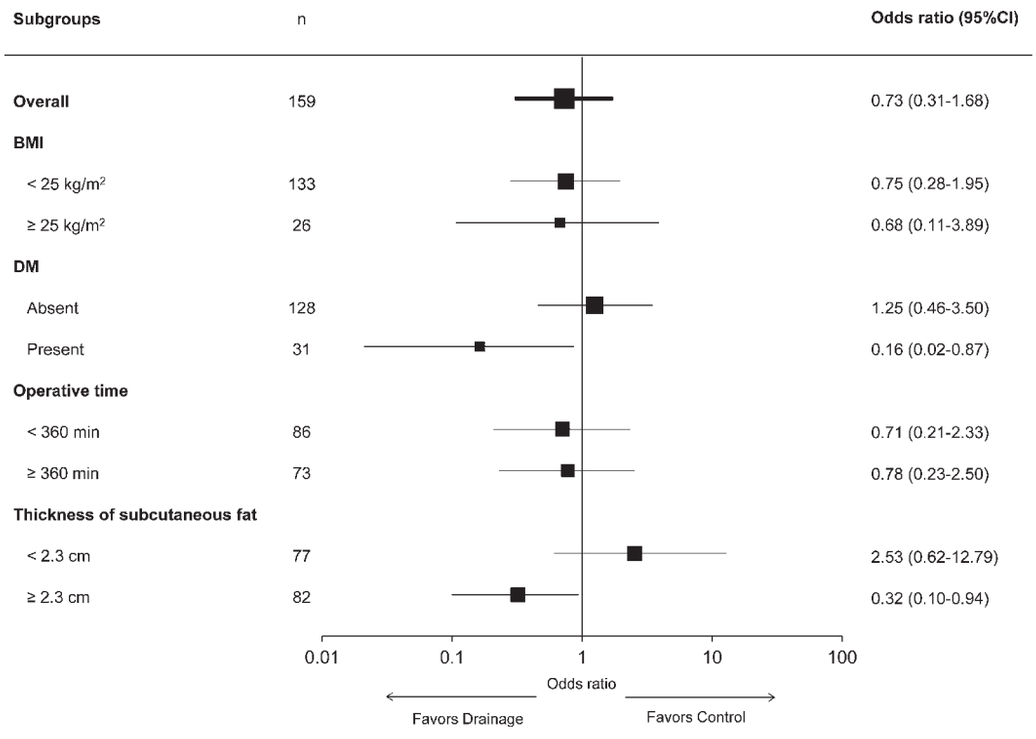

Fig. 2 Subgroup analyses

as risk factors for SSI : obesity[4)23)], weight loss[3)], presence of DM[3)], packed red blood cell transfusion[3)5)], and operation time[26)]. Consistent with these, the multivariate analysis in this study identified a tendency toward a higher risk of incisional SSI in patients with DM than in those without, although the difference did not reach statistical significance. The subgroup analyses showed that the investigated method for wound closure (subcutaneous suction drainage with subcuticular sutures) was associated with a marginal reduction in the incidence of SSIs in patients with the aforementioned risk factors, such as DM and/or a subcutaneous fat pad thickness of ≥2.3 cm, suggesting the potential benefits of adopting this method in such patient subgroups.

In the present study, cefmetazole was the predetermined prophylactic antibiotic for all enrolled patients, except for those undergoing preoperative biliary drainage and showing positive results of bile culture, for whom the antimicrobial agent was selected according to the results of the bile culture. Routine administration of cefmetazole for such patients would be ethically unacceptable because contamination of the operative field by infected bile has been suggested to be associated with an increased rate of postoperative infectious complications[27)].

The strengths of this study include the randomized design, high participant retention rate for 2.5 years and zero loss to follow-up rate with systematic assessment of the incidence of SSI. However, our study had several limitations. First, the disease distribution in the participants in the trial was heterogeneous ; inclusion of different surgical procedures might have treated a risk of overlooking the beneficial effect of the trial method. Secondly, unmasked assessment of the primary endpoint could have impaired the internal validity. In the present trial, the diagnosis of SSI was made under the monitoring of the infection control personnel, however it was difficult to mask the assigned method for the outcome assessors, because the staples used in the control group could be easily identified. Thirdly, despite our best efforts to obtain relevant data to calculate sample size during the study design phase, our trial might have been underpowered to detect differences in the primary endpoint.

In our study, subgroup analysis showed that sub-

cutaneous drainage reduced the incidence of incisional SSIs in patients with DM and/or a subcutaneous fat pad thickness of ≥2.3 cm. DM is considered a risk factor for SSI[3] because of protracted wound healing and increased susceptibility to infection. Obesity also has traditionally been considered a risk factor for incisional SSI[4)23)]. It is a well-known fact that wounds with large areas of dead space remain hypoxic and heal poorly, therefore the greater the subcutaneous fat thickness, the greater the ischemic insult. Subcutaneous drainage can decrease the subcutaneous dead space by drainage of blood and serous fluids before the establishment of infection, which leads to a reduced risk of incisional SSI. Fujii et al.[11)] reported that the subcutaneous drain is effective for preventing incisional SSI in patients with thick subcutaneous fat in colorectal surgery in their retrospective study. So, another randomized trial including only participants who have risk factors for incisional SSI, such as those with DM and/or a thick subcutaneous fat pad, may demonstrate the effectiveness of subcutaneous drainage for preventing incisional SSI.

In conclusion, application of subcutaneous drainage with the subcuticular suture method for wound closure was not associated with any significant decrease in the incidence of incisional SSIs as compared to that of conventional subcutaneous suture with the skin stapling method. However, the results of subgroup analyses suggested that the drainage method might be beneficial for reducing the risk of SSIs in patients with DM and/or a subcutaneous fat pad thickness of ≥2.3 cm.

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Conflict of Interest

The authors declare that they have no conflict of interest.

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