


A randomized controlled trial of subcutaneous closed-suction Blake drains for the prevention of incisional surgical site infection after colorectal surgery

Jun Watanabe¹  · Mitsuyoshi Ota² · Makoto Kawamoto¹ · Yago Akikazu¹ · Yusuke Suwa¹ · Hirokazu Suwa² · Masashi Momiyama³ · Atsushi Ishibe³ · Kazuteru Watanabe³ · Hidenobu Masui¹ · Kaoru Nagahori¹

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Abstract

Background The effects of subcutaneous closed-suction Blake drain for preventing incisional surgical site infections (SSIs) after colorectal surgery have never been evaluated in a randomized controlled trial (RCT). Thus, we performed a RCT to evaluate the clinical benefits of using a subcutaneous closed-suction Blake drain in patients undergoing colorectal surgery.

Method Consecutive patients who underwent colorectal surgery were enrolled in this study. Patients were randomly assigned to the subcutaneous closed-suction drainage arm or the control (no subcutaneous drainage) arm. The primary endpoint was incidence rate of incisional SSIs. And, we performed logistic regression analysis to detect predictive factors for incisional SSIs after colorectal surgery.

Results From November 2012 to September 2014, a total of 240 patients were enrolled in this study. One-hundred-seventeen patients who were treated by the control arm and 112 patients by the subcutaneous drainage arm were judged to be eligible for analysis. The incidence of incisional SSIs rate was 8.7 % in the overall patients. The incidence of incisional SSIs rate was 12.8 % in the control arm and 4.5 % in the subcutaneous drainage arm. There was significantly reduction

of the incidence in the subcutaneous drainage arm than in the control arm ($p = 0.025$). Logistic regression analysis demonstrated that thickness of subcutaneous fat >3.0 cm, forced expiratory volume in 1 s as percent of forced vital capacity (FEV1.0 %) >70 %, and subcutaneous drain were independent predictors of postoperative incisional SSIs ($p = 0.008$, $p = 0.004$, and $p = 0.017$, respectively).

Conclusion The results of our RCT suggest that a subcutaneous Blake drain is beneficial for preventing incisional SSIs in patients undergoing colorectal surgery.

Keywords Subcutaneous drain · Closed-suction drain · Colorectal cancer · Surgical site infection · Risk factor

Introduction

Surgical site infections (SSIs), including wound infection (incisional SSI), are still a major problem in general surgery. The morbidity, increased length of stay, delay in further treatment (adjuvant chemotherapy or radiation), and the significant psychological effects on patients have been well demonstrated in the literature [1]. Despite the execution of such preventive strategies as preoperative antibiotic prophylaxis [1] and anti-septic skin cleansing [1], SSI rate remains above 15 % after general abdominal surgery in prospective trials [2, 3]. Moreover, the incidence of SSIs after colorectal surgery has been reported to be as high as 20 % and up to 32 % from randomized controlled trials (RCTs) [2, 3].

In colorectal surgery, endogenous pathogens from the patient's gastrointestinal tract cause incisional SSI [1] and the existence of fluid collection in subcutaneous layer is thought to encourage bacterial growth, resulting in increased SSIs [4]. It was proposed that clearing contaminated secretions from the

✉ Jun Watanabe
nabe-jun@comet.ocn.ne.jp

¹ Department of Surgery, Yokosuka Kyosai Hospital, 1-16 Yonegahama street, Yokosuka 238-8558, Japan

² Department of Surgery, Gastroenterological Center, Yokohama City University, Yokohama, Japan

³ Department of Gastroenterological Surgery, Yokohama City University Graduate School of Medicine, Yokohama 236-0004, Japan

wound might reduce the incidence of surgical site infection [5]. Insertion of subcutaneous closed-suction Blake drain removes fluids from the subcutaneous layer in the early post-operative phase before they become infected, resulting in a reduction of incisional SSIs.

Recently, two RCTs have examined subcutaneous closed-suction drainage systems as a means to prevent incisional SSIs in digestive surgery, but these studies were not found effective in preventing SSIs [6, 7]. In a subgroup analysis of one RCT, in patients with colorectal malignancies and lower abdominal incisions, this drainage system was found effective [7].

The effects of subcutaneous closed-suction Blake drain for preventing incisional SSIs after colorectal surgery have never been evaluated in a RCT. Thus, we performed a RCT to evaluate the clinical benefits of using a subcutaneous closed-suction Blake drain in patients undergoing colorectal surgery.

Materials and methods

Patients

This study was approved by the Ethics Advisory Committee of Yokosuka Kyosai Hospital before initiation and was registered in the UMIN Clinical Trials Registry as UMIN000010281 (<http://www.umin.ac.jp/ctr/index.htm>). Consecutive patients who underwent colorectal surgery in the Department of Surgery, Yokosuka Kyosai Hospital, were enrolled in this study. The inclusion criteria were ages over 20 years. The exclusion criteria were appendectomy, hernia repair surgery, laparoscopic operation without additional skin incision, re-do operations before the end of wound healing of the primary operation, history of radiotherapy in lower abdomen, and emergency operation. The procedure used during this study was explained, and written informed consent was obtained from all of the patients.

Randomization and masking

Patients were randomly assigned to the subcutaneous closed-suction drainage group or the control group using minimization method according to location (colon/rectum). The allocation procedure was not masked from investigator or patients.

Procedure

Three consultant surgeons who specialized in colorectal open surgery and one consultant surgeon who were specialized in colorectal laparoscopic surgery involved in this study. Each consultant surgeons had performed 200 or more open colorectal surgery, respectively. Moreover, one consultant laparoscopic surgeon was qualified by an Endoscopic Surgical

Skill Qualification System of the Japan Society for Endoscopic Surgery [8].

Skin incision was performed with a scalpel; subcutaneous fat and linea alba were dissected by electrical cautery. During the operation, wound protection was achieved by a dual-ring drape device. Wound closure was done using 1-Vicryl® for the fascia layer and 4-0 PDS® subcuticular sutures for the skin. Prophylactic intra-operative wound irrigation with 1000 ml saline was routinely performed before skin closure. Subcutaneous closed-suction drains were inserted if the patient was randomized in the subcutaneous drainage group. In these cases, 15-Fr silicon flexible drains (Blake drains, Ethicon, Somerville, NJ, USA) were used for the drainage tube. The exit of the drains was separate from the incisions. The device was connected to a low pressure (40–80 mmHg), continuous aspiration reservoir to allow the full length of the wound to be drained. Drains were removed on the fifth day after operation.

The prophylactic antibiotic regimens were performed as follows: flomoxef sodium was injected intravenously within 30 min before skin incision. In patients who underwent operations lasting longer than 3 h, flomoxef sodium was injected intravenously every 3 h, as recommended by the CDC guidelines [1].

Diagnosis of incisional SSIs

All patients were monitored for postoperative incisional SSIs, which were included superficial and deep SSIs. The surgeons performed a physical examination every day from the operating day until discharge. After hospital discharge, all patients were followed at the hospital as an outpatient on day 14 and day 30.

The diagnosis of SSI was based on the definition of the CDC guideline: (1) purulent discharge with or without laboratory confirmation from the superficial incision; (2) organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision; (3) at least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat and superficial incision are deliberately opened by surgeon, unless incision is culture-negative; and (4) diagnosis of superficial SSI by the surgeon or attending physician. According to these definition, incisional SSIs were defined as such findings occurring within 30 day after surgery. The severity of SSIs was assessed by the Common Terminology Criteria for Adverse Events (CTCAE) version 4.0. Each SSI was diagnosed and confirmed by a surgeon other than patient's primary surgeon.

Statistical analysis

The primary endpoint for this study was incidence rate of incisional SSIs. It was calculated that 95 patients would be

required in this study to demonstrate a reduction in incidence rate of SSI from 15 to 5 % at the 5 % significance level with power of 80 %. The data were presented as a mean and standard deviation or as a median and variance. Statistical analysis was performed using the SPSS statistical software (SPSS Inc., Chicago, USA). Differences between categorical variables were tested with Pearson's chi-squared test. Differences between continuous variables were tested with the Mann-Whitney U test. Probability (p) values were considered to be statistically significant at a level of $p < 0.05$. And, we performed logistic regression analysis to detect predictive factors for incisional SSIs after colorectal surgery.

Results

From November 2012 to September 2014, a total of 240 patients were enrolled in this study. Patients were randomized to the control arm (120 patients) and the subcutaneous drainage arm (120 patients). After randomization, three patients marked a deviation from study protocol which was treated by the control arm. These three patients could not be followed at the hospital as an outpatient on day 30 because of changing hospital. Six patients marked a deviation from study protocol, and two patients delayed surgery, which was treated by the subcutaneous drainage arm. Of these six patients, three patients could not be followed at the hospital as an outpatient on day 30 because of changing hospital. One patient did not

undergo colorectal surgery because tumor location was ileum. One patient underwent laparoscopic operation without additional skin incision. In one patient, subcutaneous drain was not inserted. Therefore, 117 patients who were treated by the control arm and 112 patients who were treated by the subcutaneous drainage arm were judged to be eligible for analysis (Fig. 1). The clinicopathological characteristics of 229 patients are presented in Table 1. Baseline factors were well balanced between the arms. Surgical procedure and outcomes are summarized in Table 2. Operation time, blood loss, wound length, thickness of subcutaneous fat, and laparotomy rate were similar between the control arm and subcutaneous drainage arm.

The incidence of incisional SSIs

The incidence of incisional SSIs rate was 8.7 % (20/229) in the overall patients. The incidence of incisional SSIs rate was 12.8 % (15/117) in the control arm and 4.5 % (5/112) in the subcutaneous drainage arm. There was significantly reduction of the incidence in the subcutaneous drainage arm than in the control arm ($p = 0.025$). The incidence of superficial SSIs in the subcutaneous drainage arm was significantly smaller than in the control arm (control arm 10.3 % (12/117) and subcutaneous drainage arm 3.6 % (4/112); $p = 0.047$). The incidence of incisional SSIs over grade 3 rate was 1.7 % (2/117) in the control arm and 0 % (0/112) in the subcutaneous arm (Table 3).

Fig. 1 CONSORT diagram

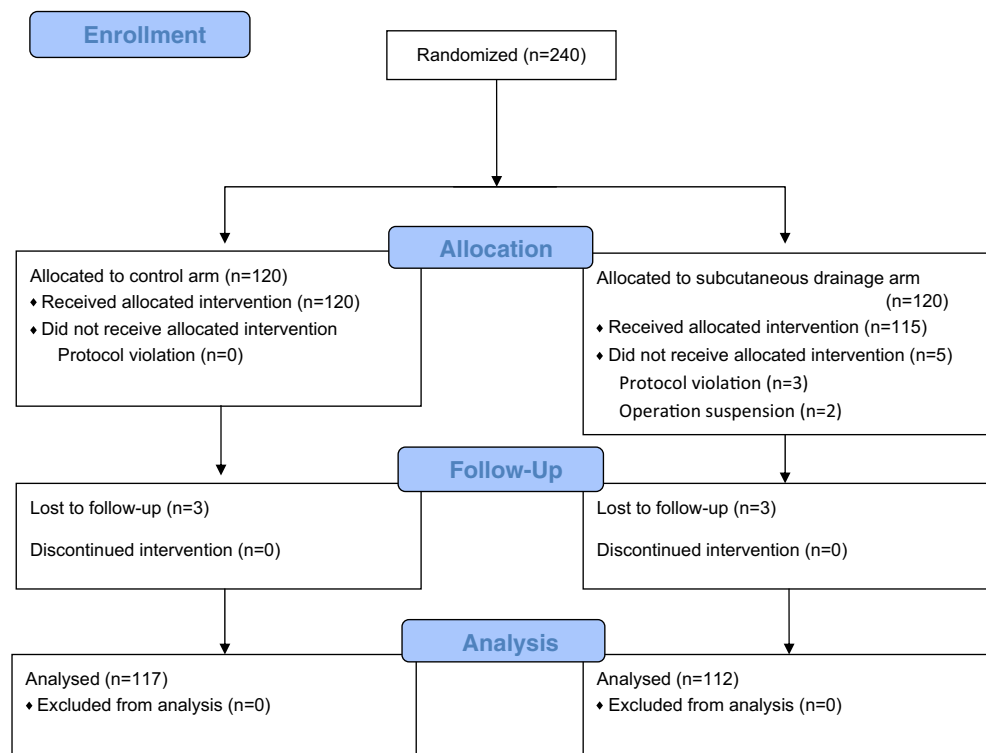


Table 1 Clinicopathological characteristics

| Variable | Control arm (<i>n</i> = 117) | Subcutaneous drainage arm (<i>n</i> = 112) | <i>p</i> value |
|---------------------------------|----------------------------------|---|----------------|
| Age, mean ± SD | 70.4 ± 11.7 | 71.4 ± 10.5 | 0.520 |
| Gender, male/female | 74/43 | 61/51 | 0.182 |
| BMI, mean ± SD | 22.3 ± 3.54 | 21.7 ± 3.45 | 0.176 |
| Smoking, -/+ | 64/53 | 63/49 | 0.894 |
| ASA score, 1–2/3–4 | 108/9 | 98/14 | 0.274 |
| DM, absence/presence | 92/25 | 90/22 | 0.870 |
| COPD, absence/presence | 111/6 | 108/4 | 0.749 |
| Steroids, absence/presence | 115/2 | 107/5 | 0.272 |
| Albumin, mean ± SD | 3.77 ± 0.68 | 3.70 ± 0.73 | 0.492 |
| Lymphocyte, mean ± SD | 1596 ± 580 | 1551 ± 626 | 0.575 |
| FEV1.0 %, mean ± SD | 74.5 ± 10.9 | 73.9 ± 9.2 | 0.642 |
| Location, colon/rectum | 102/15 | 98/14 | 0.994 |
| Malignancy, benign/malignant | 7/110 | 6/106 | 0.838 |
| Stage, 0–1/2/3/4 | 23/39/34/14 | 17/34/34/21 | 0.497 |

BMI body mass index, *ASA* American Society of Anesthesiologists, *FEV1.0 %* forced expiratory volume in 1 s as percent of forced vital capacity

Predictive factors for incisional SSIs

Based on univariate analysis, thickness of subcutaneous fat >3.0 cm, forced expiratory volume in 1 s as percent of forced vital capacity (FEV1.0 %) <70 %, and subcutaneous drain significantly predicted postoperative incisional SSIs (Table 4). Moreover, logistic regression analysis demonstrated that thickness of subcutaneous fat >3.0 cm, FEV1.0 % >70 %, and subcutaneous drain were independent predictors of postoperative incisional SSIs ($p = 0.008$, $p = 0.004$, and $p = 0.017$, respectively).

Discussion

Usefulness of subcutaneous drain for wound infection has been reported mainly in the obstetrics and gynecological region. Among prospective RCTs of obstetrics and gynecological region [9, 10], cholecystectomy [11], and gastrointestinal region [6, 7] ever reported, it has been reported that subcutaneous drain has no effect for reduction of wound infection in the obstetrics and gynecological region as a result of meta-analysis including RCT [12]. In consideration of a low occurrence rate of wound infection during surgery of obstetrics and gynecological region ranging from 3.8 to 10.0 % even in high-risk group [12], effect of intervention by subcutaneous drain is believed to be poor.

It has been reported on effects of subcutaneous drain on wound infection also in gastrointestinal region. Some

retrospective studies have reported that subcutaneous drain reduces wound infection in case of colorectal surgery [13], hepatectomy [14], and closure of ileostomy [15], which have high risk of wound infection. With two reports of prospective RCTs ever made, on the other hand, Baier PK et al. have reported that no usefulness of subcutaneous drain on wound infection was not recognized in 200 cases of gastrointestinal surgeries [6]. In addition, Kaya E. et al. have reported that usefulness of subcutaneous drain was not recognized in 402 cases of gastrointestinal surgeries but that it significantly reduced wound infection in colorectal malignancies and lower abdominal incisions as a result of subgroup analysis [7]. It is controversial in gastrointestinal region whether subcutaneous drain is useful for wound infection prevention. SSI occurrence rate is still at high level as a report has indicated that incisional SSI occurrence rate in colorectal surgery exceeds 20 % [2, 3]. From those described above, it is believed that subcutaneous drain is likely to be useful as long as it is indicated limitedly to cases with high risk of wound infection occurrence such as colorectal surgeries. Without any report ever made on prospective RCT performed only for colorectal surgery using a closed-suction Blake drain for subcutaneous area, this report is the first one in such setting with a result that subcutaneous drain placement significantly reduces wound infection.

Problem in postoperative subcutaneous tissue is that suture of subcutaneous fat is easy to cause tissue necrosis, but dead space is formed subcutaneously if it is not sutured [16]. With a formation of seroma by effusion and blood retained in the dead space, such environment is believed to be formed that

Table 2 Surgical procedure and outcomes

| Variable | Control arm (<i>n</i> = 117) | Subcutaneous drainage arm (<i>n</i> = 112) | <i>p</i> value |
|---|----------------------------------|---|----------------|
| Surgical procedure | | | |
| Ileocolic resection | 13 (11.1 %) | 12 (10.7 %) | 0.912 |
| Right hemicolectomy | 31 (26.5 %) | 25 (22.3 %) | |
| Partial colectomy (transverse colon) | 3 (2.6 %) | 8 (7.1 %) | |
| Left hemicolectomy | 6 (5.1 %) | 10 (8.9 %) | |
| Partial colectomy (descending colon) | 5 (4.3 %) | 3 (2.7 %) | |
| Sigmoidectomy | 31 (26.5 %) | 27 (24.1 %) | |
| High anterior resection | 11 (9.4 %) | 11 (9.8 %) | |
| Low anterior resection | 14 (12.0 %) | 13 (11.1 %) | |
| Hartmann | 1 (0.9 %) | 1 (0.9 %) | |
| Rectal amputation | 1 (0.9 %) | 1 (0.9 %) | |
| Subtotal colectomy | 1 (0.9 %) | 1 (0.9 %) | |
| Operating time (min), mean ± SD | 239 ± 95.8 | 235 ± 83.8 | 0.756 |
| Blood loss (ml), mean ± SD | 209 ± 359 | 235 ± 384 | 0.589 |
| Wound length (cm), mean ± SD | 11.5 ± 7.10 | 12.1 ± 6.58 | 0.528 |
| TSF (cm), mean ± SD | 1.70 ± 0.66 | 1.72 ± 0.73 | 0.584 |
| Body temperature (°C), mean ± SD | 36.0 ± 0.58 | 36.0 ± 0.66 | 0.603 |
| Approach, open/laparoscopic | 70/47 | 75/37 | 0.276 |
| Stoma, absence/presence | 99/18 | 87/25 | 0.236 |
| Wound classification, II/III | 117/0 | 112/0 | – |
| Abdominal drain, absence/presence | 51/66 | 52/60 | 0.692 |
| Postoperative complication | | | |
| Total | 35 (30.0 %) | 36 (32.1 %) | 0.716 |
| ≥Grade III | 9 (7.7 %) | 9 (8.0 %) | 0.923 |
| Anastomotic leakage | 3 (2.6 %) | 3 (2.7 %) | 0.957 |
| Anastomotic bleeding | 0 (0 %) | 1 (0.9 %) | 0.306 |
| Small-bowel obstruction | 3 (2.6 %) | 4 (3.6 %) | 0.658 |
| Lymphorrhoea | 1 (0.9 %) | 1 (0.9 %) | 0.975 |
| Urinary | 3 (2.6 %) | 1 (0.9 %) | 0.335 |
| Pneumonia | 1 (0.9 %) | 2 (1.8 %) | 0.536 |
| Mortality | 0 (0.0) | 0 (0.0) | – |

TSF thickness of subcutaneous fat

bacteria contaminated during surgery is easy to proliferate [12, 13]. It is believed that incisional SSI may be reduced by removing effusion and blood that would induce proliferation of bacteria earlier after surgery before infection by placing a subcutaneous drain. Moreover, it is believed that wound healing is enhanced advantageously by promoting division and proliferative capacity of fibroblast cells as well as enhancing blood flow and granulation assisted by suction effect [17]. However, it is required to pay attention to the period of placement because placement of drain as a foreign matter on the subcutaneous tissue may cause retrograde infection with a risk that the drain itself could work as a culture if the placement continued for a long period of time [18]. Wound infection is often developed from day 5 on after surgery [3]. In the present

study, median value of wound infection development timing was day 8 after surgery. In postoperative negative-pressure incision therapy, period of placement execution after surgery is for 5 days or longer [19–21]. Therefore, as incisional SSI may not be prevented if subcutaneous drain was removed within 72 h since its placement [6, 7], the day of subcutaneous drain removal was set at day 5 after surgery in this study. As the result, incisional SSI occurrence rate became significantly smaller to 4.5 % in subcutaneous drainage arm compared with control arm. Further, any case was not recognized that developed incisional SSI based on retrograde infection caused by 5 days of placement.

In reports ever made, drains with multiple side holes have been used such as Redon drain [6], Redi-vac [9], and Jackson-

Table 3 Incidence of incisional SSIs

| Variable | Control arm (n = 117) | Subcutaneous drainage arm (n = 112) | p value |
|------------------------------------|--------------------------|---|---------|
| Superficial SSIs | 12 (10.3 %) | 4 (3.6 %) | 0.047 |
| Deep SSIs | 3 (2.6 %) | 1 (0.9 %) | 0.335 |
| Incisional SSIs | | | |
| Total | 15 (12.8 %) | 5 (4.5 %) | 0.025 |
| \geq Grade 3 | 2 (1.7 %) | 0 (0.0 %) | 0.165 |
| Date of onset, median (range) | 8 (2–30) | 8 (5–10) | 0.933 |
| Bacterial test of wound (positive) | 13 (11.1 %) | 5 (4.5 %) | |
| <i>Enterococcus faecalis</i> | 6 | 3 | |
| <i>Enterococcus avium</i> | 2 | 0 | |
| <i>Enterobacter cloacae</i> | 2 | 1 | |
| <i>Bacteroides</i> sp. | 2 | 3 | |
| <i>Clostridium difficile</i> | 1 | 1 | |
| <i>Pseudomonas aeruginosa</i> | 3 | 1 | |
| <i>Staphylococcus epidermidis</i> | 5 | 2 | |
| MRSA | 0 | 1 | |

Pratt [10, 22]. Such drains may damage adipose tissues by a strong negative pressure from small suction holes [14]. Since this small hole is easily clogged if adipose tissue got stuck in the hole, it is possible that subcutaneous area is not drained evenly. While there is a report using a Penrose drain [23], open drain is not recommended from a perspective of retrograde infection. So, in this study, we used silastic closed-suction Blake drain with four channels along the sides with a solid core center. This drain prevents effusion from the full length of the wound through a slit, without causing tissue damage [18].

In this study, in the multivariate analysis, thickness of subcutaneous fat >3.0 cm, FEV1.0 % <70 %, and subcutaneous drain correlated with incisional SSIs. A lot of reports have been made up to now on obesity as the risk factors of wound infection [24, 25]. According to Lee et al., abdominal subcutaneous fat thickness measured by CT scanning was significantly thicker in SSI onset group in a study for 655 cases of patients who experienced median abdominal laparotomy; they reported that abdominal subcutaneous fat thickness is an independent risk factor of superficial SSI [26]. Fujii et al. have

Table 4 Predictive factors for incisional SSIs

| Factors | Univariate analysis Relative risk (95 % CI) | p value | Multivariate analysis Relative risk (95 % CI) | p value | |
|-----------------------|---|----------------------|---|----------------------|-------|
| Gender | Male/female | 1.194 (0.474–3.005) | 0.707 | | |
| Age | $>75/<75$ | 1.783 (0.708–4.488) | 0.215 | | |
| DM | Yes/no | 0.662 (0.186–2.360) | 0.522 | | |
| ASA | 3/2–1 | 1.668 (0.449–6.187) | 0.702 | | |
| BMI | $>25/<25$ | 1.287 (0.405–4.087) | 0.668 | | |
| Alb | $>4.0/<4.0$ | 0.432 (0.151–1.233) | 0.083 | | |
| TSF | $>3.0/<3.0$ | 4.500 (1.286–15.748) | 0.011 | 6.224 (1.605–24.135) | 0.008 |
| Approach | Laparoscopic/open | 0.720 (0.266–1.950) | 0.516 | | |
| Operative time | $>180/<180$ | 1.098 (0.381–3.161) | 0.862 | | |
| Blood loss | $>100/<100$ | 1.307 (0.520–3.285) | 0.568 | | |
| Stoma | Yes/no | 1.500 (0.514–4.379) | 0.456 | | |
| FEV% | $>70/<70$ | 3.508 (1.379–8.925) | 0.006 | 4.216 (1.570–11.325) | 0.004 |
| Benign | Malignant/benign | 3.175 (0.808–12.500) | 0.111 | | |
| Subcutaneous drain | Yes/no | 0.318 (0.111–0.906) | 0.025 | 0.257 (0.085–0.781) | 0.017 |

also reported on 152 cases of patients who received elective colorectal surgery that abdominal subcutaneous fat thickness was an independent risk factor of SSI occurrence as a result of multivariate analysis [25]. In addition, a volume less than 70 % of FEV 1.0 % was proved to be an independent risk factor in this study, whereas Segal CG et al. [27]. and Moghadamyeghaneh Z et al. [28] have reported COPD as a risk factor of superficial SSI and wound dehiscence, respectively. With a lot of reports that smoking is an independent risk factor for surgical site infection occurrence [29, 30], reduction in FEV 1.0 % may have been affected by smoking in the past. From the results of this study, it is suggested that thickness of subcutaneous fat and reduction in FEV 1.0 % work as useful indicators of incisional SSI occurrence.

One limitation of this study is that it was performed within a single specialized institution. Thus, further studies of multi-institutions and a larger population are needed to confirm our findings and to determine recommendations for the routine use of a subcutaneous drain in colorectal surgery.

In conclusion, the results of our randomized controlled trial suggest that a subcutaneous Blake drain is beneficial for preventing incisional SSIs in patients undergoing colorectal surgery, and logistic regression analysis demonstrates that thickness of subcutaneous fat >3.0 cm, FEV% >70 %, and subcutaneous drain were independent predictors of postoperative incisional SSIs.

Compliance with ethical standards

Conflict of interest Jun Watanabe, Mitsuyoshi Ota, Yusuke Suwa, Atsushi Ishibe, Kazuteru Watanabe, Hidenobu Masui, Kaoru Nagahori, and Itaru Endo have no conflicts of interest or financial ties to disclose.

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