Original Article

Effectiveness of Subcutaneous Drain to Prevent Incisional Surgical Site Infection after Abdominal Surgery: A Randomized Controlled Trial

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Background: Surgical site infection (SSI) is a common complication after abdominal operation which may cause disability or mortality. One of the factors associated with SSI was the abdominal wall thickness ≥20 mm. Therefore, the drainage of collection within subcutaneous tissue may decrease SSI rate.

Objective: To compare SSI rate between patients with and without subcutaneous drain placement.

Materials and Methods: The present study was prospective randomized controlled trial that included patients with abdominal wall thickness of 20 mm. or more and that underwent major abdominal operation between October 2015 and January 2018. The enrolled patients were randomized into two groups, with and without subcutaneous drain. Demographic data, operative details, characteristics of wound, and SSI rate were collected. The statistical tests were Chi-square test for categorical data and t-test for numerical data.

Results: From 142 enrolled patients, 11 patients were excluded (four from death during follow-up and seven from incomplete data). Therefore, 138 were included and divided into 58 patients in the group with drain and 73 patients in the group without drain. The demographic data, operative time, subcutaneous thickness, and length of incision were not different. Regarding SSI, there was no significant difference between both groups (29.3% and 23.3%, p=0.44). Subgroup analysis within group of SSI patients, using drain showed significantly lower proportion of deep incisional SSI especially when subcutaneous thickness was 25 mm or more (18.8% and 53.8%, p=0.04) and estimated cut surface area of 4,500 mm^2 or more(8.3% and 50.0%, p=0.03).

Conclusion: Subcutaneous drain placement did not decrease overall SSI rate. However, this modality provided lower proportion of deep incisional SSI when SSI occurred especially in patients with thicker abdominal wall or larger cut surface area of surgical wound.

Keywords: Surgical site infection, SSI, Subcutaneous drain

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Surgical site infection (SSI) is one of the most common complication after abdominal operation and is associated with decreased quality of life, longer hospital stays, and higher cost of treatment. Moreover, this condition may cause disability or mortality. The incidence of this complication as reported in many studies was within range of 10% to 26.7%(1-4). The guideline for prevention of surgical site infection from Center for Disease Control and Prevention (CDC) in 1999 had classified surgical wound into four classes (clean, clean-contaminated, contaminated, and dirty-infected wound) as shown in Table 1, and also classified SSI into three types (superficial incisional SSI, deep incisional SSI, and organ/space SSI)(5). There had been many previously known factors associated with SSI including long operative time, malnutrition status, diabetes mellitus, obesity, and intraoperative blood transfusion. One of them was the obesity that usually associated with more thickness of abdominal wall at the site of surgical incision especially when it was 20

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Table 1. Criteria for defining a surgical site infection[5]

Superficial incisional SSI
Infection occurs within 30 days after the operation and infection involves only skin or subcutaneous tissue of the incision and at least one of the following:
1. Purulent drainage, 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 is deliberately opened by surgeon, unless incision is culture-negative.
4. Diagnosis of superficial incisional SSI by the surgeon or attending physician.
Do not report the following conditions as SSI:
1. Stitch abscess (minimal inflammation and discharge confined to the points of suture penetration).
2. Infection of an episiotomy or newborn circumcision site.
3. Infected burn wound.
4. Incisional SSI that extends into the fascial and muscle layers (see deep incisional SSI).
Note: Specific criteria are used for identifying infected episiotomy and circumcision sites and burn wounds.
Deep incisional SSI
Infection occurs within 30 days after the operation if no implant† is left in place or within 1 year if implant is in place and the infection appears to be related to the operation and infection involves deep soft tissues (e.g., fascial and muscle layers) of the incision and at least one of the following:
1. Purulent drainage from the deep incision but not from the organ/space component of the surgical site.
2. A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever (>38°C), localized pain, or tenderness, unless site is culture-negative.
3. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination.
4. Diagnosis of a deep incisional SSI by a surgeon or attending physician.
Notes:
1. Report infection that involves both superficial and deep incision sites as deep incisional SSI.
2. Report an organ/space SSI that drains through the incision as a deep incisional SSI.
Organ/space SSI
Infection occurs within 30 days after the operation if no implant is left in place or within 1 year if implant is in place and the infection appears to be related to the operation and infection involves any part of the anatomy (e.g., organs or spaces), other than the incision, which was opened or manipulated during an operation and at least one of the following:
1. Purulent drainage from a drain that is placed through a stab wound into the organ/space.
2. Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space.
3. An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination.
4. Diagnosis of an organ/space SSI by a surgeon or attending physician.

SSI=surgical site infection

mm or more[4,6]. This significantly related factor was reported in the previous study. A recent study showed that the wound closure with subcutaneous drain placement was effective for preventing incisional SSI in patients with thick subcutaneous fat in colorectal surgery[7]. Thus, the objective of the present study was to compare SSI rate between patients with and without drain intra-operatively placed within subcutaneous tissue at incision site during major abdominal surgery.

Materials and Methods

The present study was a prospective randomized controlled trial which included patients who underwent major abdominal operation between October 2015 and

January 2018 in Thammasat University Hospital. The inclusion criteria were age 18 to 80 years old, abdominal wall thickness of 20 mm or more measured on pre-operative computerized tomography (CT) scan, and intra-operatively measured length of incision of 10 cm or more. The patients without preoperative CT scan or with traumatic intra-abdominal injury as the indication of surgery, vulnerable patients, and immunocompromised patients were excluded from the study.

Patients who met the inclusion criteria were enrolled, informed and completed the consents, then randomized by minimization method and allocated into two groups, drain group and control group without drain. Prophylactic antibiotics were administered peri-operatively and aseptic techniques were followed as standard guideline for preventing SSI in every patients[5,8]. At the end of the operation, bleeding at subcutaneous fatty tissue was stopped and abdominal wall sheath was sutured with absorbable suture. The 12-Fr Radivac drain (Primed, Halberstadt, Germany), a small round straight tube with several side holes, was placed at the bottom of subcutaneous layer above abdominal wall sheath. Then, the skin incision was closed with staple. The tube drain was set to place at the corner of incision with a staple close to it and fixed to the skin with sticky tape and wound dressing. Then the external end of drain was connected to a closed negative-pressure collecting device. Patients in control group underwent the same procedure of wound closure except no drain placed within subcutaneous tissue. The dressing was opened on post-operative day 3 to inspect the surgical wound for sign of SSI following the definition of SSI proposed by CDC in 1999. In addition, the subcutaneous drain was removed at that time. If the wound had no sign of SSI, it would be reevaluated on day 7, 14, 21, and 30 post-operatively.

The demographic data (sex, age, underlying disease, history of smoking, body mass index (BMI), and pre-operative serum albumin level), detail of the operation (emergency or elective operation, type of operation, and operative time) and characteristic of surgical wound (length of wound and thickness of subcutaneous fat) were collected for analysis. Data were analyzed using Chi-square test for categorical data and student t-test for numerical data with significance at p-value smaller than 0.05. All statistical analyses were performed using IBM SPSS Statistics version 20.

Results

After the enrollment and randomization, there were 58 and 73 patients with and without drain, respectively. As shown in Table 2, the demographic data and types of operation were not significantly different.

About wound classification, there was no wound class 4 in the present study and wound class 2-3 had no difference between both groups. The other factors associated with SSI such as DM, smoking, pre-operative serum albumin, and operative time of these two groups were similar except BMI, which was higher in the drain group than the control group. The thickness of subcutaneous tissue at surgical wound in drain group was more than in control group, but not statistically significant. The wound length was also not different. The cut surface area was estimated using thickness multiplied by length and was similar between both groups.

SSI was detected in 34 patients of 131 enrolled patients, which was 25.9% of overall SSI rate. Comparing SSI rate between both groups, they were not significantly different as shown in Table 3. Regarding 34 patients with SSI, deep incisional SSI was in concern and analyzed further. Patients with drain had deep incisional SSI in 17.6%, which was much lower than the 41.2% of the other group without drain, however, the results were not statistically significant. The sub-group analysis was performed to select more specific group of patients with possibly associated factors as shown in Table 4 and Figure 1-3. There was no difference between both groups in sub-group of wound class 2-3, operation performed in emergency setting, or BMI of 25 kg/m^2 or more.

Following the inclusion criteria, all enrolled patients had size of surgical wound of 20 mm or more in depth and 100 mm or more in length. However, sub-group analysis was performed to define the result in more specific group such as patients with deeper or longer wound, larger cut surface area, or longer operative time. Figure 1 demonstrates comparison of SSI rate between both groups at many different cut points of several parameters. SSI rate did not seem to be reduced by placing subcutaneous drain comparing to control group. Interestingly, considering only in patients with SSI, drain group had significantly lower deep incisional SSI rate than without drain in patient with deeper wound and larger cut surface area. As demonstrated in Figure 2, the difference of proportion of deep incisional SSI in overall SSI between groups with and without drain was approximately 20% to 25%, which was statistically significant at some points, for example, when the thickness is 25 mm or

Table 2. Comparison of demographic data, relevant factors, and wound characteristics between both groups

	Drain group (n = 58)	Control group (n = 73)	p-value
Sex: male	65.5%	69.9%	0.60
Age (year), Mean±SD	59.95±14.52	60.46±12.58	0.83
DM	27.6%	24.7%	0.70
Smoking	25.9%	28.8%	0.71
Pre-operative albumin (g/dL), Mean±SD	3.36±0.69	3.46±0.46	0.36
BMI (kg/m^2), Mean±SD	26.44±5.25	23.85±3.50	<0.01
Type of operation			0.83
Colorectal	34.5%	39.7%	
Hepatobiliary-pancreas	41.4%	45.2%	
Esophagogastric	5.2%	2.7%	
Small bowel	10.3%	8.2%	
Soft tissue tumor	3.4%	1.4%	
Other	5.2%	2.7%	
Wound class 2-3	91.4%	95.9%	0.28
Emergency setting	20.7%	23.3%	0.72
Operative time (minute), Mean±SD	164.81±87.49	158.79±77.29	0.68
Wound characteristic, Mean±SD			
Thickness (mm)	33.21±13.85	29.79±7.51	0.09
Length (mm)	200.60±55.94	200.96±65.32	0.97
Estimated cut surface (mm^2)	6,766.6±3,852.5	6,039.9±2,674.8	0.21

SD=standard deviation; DM=diabetes mellitus; BMI=body mass index

Table 3. Comparison of overall SSI rate and proportion of deep incisional SSI in overall SSI

	Total number	Drain group % (n)	Control group % (n)	p-value
Overall SSI rate	131	29.3 (17/58)	23.3 (17/73)	0.44
Proportion of deep incisional SSI in overall SSI	34	17.6 (3/17)	41.2 (7/17)	0.13

SSI=surgical site infection

Table 4. Subgroup analysis by wound classification, emergency setting, and BMI

	Overall SSI rate, % (n)			Proportion of deep incisional SSI in overall SSI, % (n)		
	Drain group	Control group	p-value	Drain group	Control group	p-value
Wound class 2-3	30.2 (16/53)	24.3 (17/70)	0.46	18.8 (3/16)	41.2 (7/17)	0.16
Emergency setting	16.7 (2/12)	23.5 (4/17)	0.65	0.0 (0/2)	50.0 (2/4)	0.22
Overweight, BMI ≥25 kg/m^2	29.6 (8/27)	11.1 (2/18)	0.14	12.5 (1/8)	50.0 (1/2)	0.24

SSI=surgical site infection; BMI=body mass index

more or the cut surface area is 4,500 mm² or more. Concerning relationship between thickness and length of wound, the difference of proportion of deep incisional SSI in overall SSI in deeper and longer

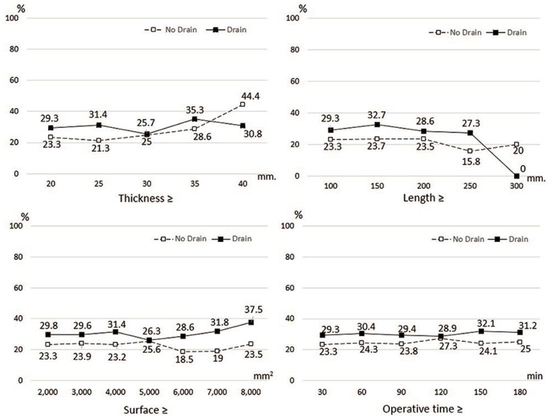

Figure 1. Subgroup analysis regarding subcutaneous thickness, wound length, cut surface area, and operative time comparing overall SSI rate between drain group and control group.

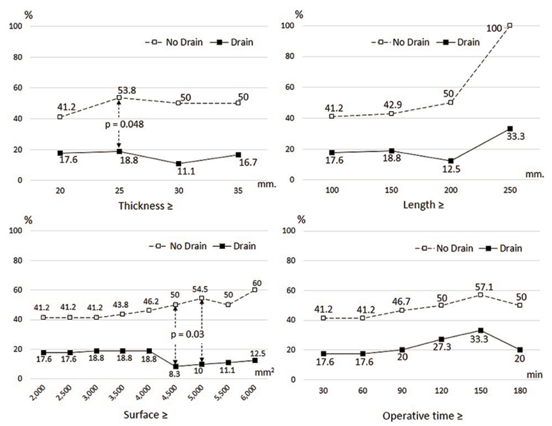

Figure 2. Subgroup analysis regarding subcutaneous thickness, wound length, cut surface area, and operative time comparing proportion of deep incisional SSI in overall SSI between drain group and control group.

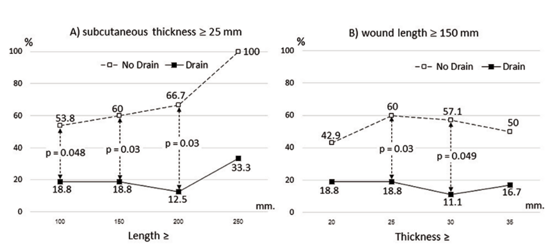

Figure 3. Subgroup analysis comparing proportion of deep incisional SSI in overall SSI between drain group and control group; subgroup of patients with (A) subcutaneous thickness ≥25 mm and (B) wound length ≥150 mm.

wound was apparently found by sub-group analysis as shown in Figure 3.

Discussion

There had been many risk factors previously known to be associated with SSI after major abdominal surgery. Subsequently, many methods were established in attempt to reduce post-operative SSI, for example, aseptic surgical technique and instrument, peri-operative antibiotic, local wound care, etc. Obesity was one of the important factors related to SSI. The mechanism was explained by reduced subcutaneous tissue oxygenation leading to wound hypoxia and eventually impaired healing. The other possible mechanism was inadequate tissue level of prophylactic antibiotics caused by different pharmacokinetics in obese patients(9). The thickness of abdominal wall subcutaneous tissue at surgical site had been also thought to be an important local factor associated with SSI. The more thickness of fatty tissue provided more space to develop seroma or hematoma, and finally infection. Thickness of subcutaneous fat was confirmed to be significantly related factor of post-operative SSI by Fujii et al(6) and Kwaan et al(10). Tongyoo et al reported thickness of 20 mm or more as one of the significant factors associated with SSI(4). Any modalities that were supposed to reduce the chance of serous collection within subcutaneous tissue should be very helpful to reduce SSI.

Fujii et al studied the effectiveness of subcutaneous drain in preventing SSI after colorectal surgery(7). They reported SSI rate at 14.3% and 38.6% in group with and without drain, respectively, which were significantly different. However, the comparison in the present study did not demonstrate the benefit of subcutaneous drain to reduce SSI. Surprisingly, SSI rate in the drain group was a little higher than the control group, but not significant. The explanation of this finding might be the significantly higher BMI of drain group. In addition, the subcutaneous thickness in the drain group was more than in the control group with almost significance. These higher proportion of obese patients and deeper subcutaneous tissue may provide unfavorable effect on the drain group more than on the control group at the first point.

Regarding surgical site infection, deep incisional SSI was more concerned than superficial infection due to higher morbidity and poorer quality of life. Placing a drain in the subcutaneous tissue seemed to be beneficial to reduce deep incisional SSI although SSI occurred. This advantage might be explained by the fact that surgeon usually placed a drain at the most dependent position of the space. In the present study, the drain was almost always placed at the deepest part of the subcutaneous tissue, just above the abdominal wall sheath. For that reason, drain would most properly work to drain serum and blood out of the deep space of surgical wound and subsequently reduce deep incisional SSI. In clinical implication, the favorable finding of lower proportion of deep incisional SSI in SSI patients by placing subcutaneous drain would be very helpful especially in patient with thicker subcutaneous and longer wound.

The present study had some limitation. The sample size was too small for sub-group analysis. There were too small groups of patients with deeper and longer surgical wound to make the statistical significance in more specific comparison. Because of the aforementioned condition, BMI of the drain group was higher than of the control group even though both groups were randomized. This limitation might affect the results of comparing SSI between both groups.

Conclusion

In the present study, subcutaneous drain placement did not decrease overall SSI rate. However, this modality provided lower proportion of deep incisional SSI when SSI occurred, especially in patients with thicker abdominal wall or larger cut surface area of surgical wound.

What is already known on this topic?

SSI is one of the clinically important post-operative complications of major abdominal surgery. Previous literature already defined many factors related to the increased incidence of SSI including more thickness of subcutaneous fatty tissue especially of 20 mm or more. Subsequently, there were few studies reported using subcutaneous drain to reduce incidence of SSI after major abdominal operations.

What this study adds?

This study demonstrated the potential benefit of the negative-pressure drain within subcutaneous fatty tissue of abdominal wall to provide lower proportion of deep incisional SSI in overall SSI especially in group of patients with thicker subcutaneous layer and longer operative incision.

Conflicts of interest

The authors declare no conflict of interest.

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