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Original

Subcutaneous Closed Suction Drainage in Elective Open Surgery for Colorectal Cancer Lowers the Incidence of Seroma

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Background: This study was conducted to clarify whether subcutaneous closed suction drainage acts as prophylaxis against incisional surgical site infection (SSI) in patients undergoing elective surgery for colorectal cancer. **Methods:** Eighty-one patients with colorectal cancer treated between February 2012 and March 2016 were assigned to subcutaneous drainage (39 patients) or no subcutaneous drainage (42 patients). The subcutaneous drain was removed 72 hours after surgery or if the discharge was ≤20 ml/day. The diagnosis of SSI was in strict accordance with the Centers for Disease Control and Prevention guidelines. The primary study outcome measure was the incidence of seroma. **Results:** The incidence of SSI (10.2% and 7.1% in the subcutaneous drainage group and non-drainage group, respectively) did not differ significantly (p = 0.618). However, seroma was detected in 8 (20.5%) patients in the subcutaneous drainage group and 19 (45.2%) patients in the non-drainage group (p = 0.017). Patient characteristics and perioperative variables were analyzed in relation to seroma formation. The postoperative day 3 glucose level and subcutaneous drainage were shown to independently influence seroma formation. **Conclusion:** Subcutaneous drainage appears to enhance wound healing and reduce the risk of seroma formation. Further RCTs are required with larger sample sizes to clarify the efficacy of subcutaneous drainage on SSI.

Key Words: subcutaneous drainage, closed suction drainage, colorectal cancer, surgical site infection

Introduction

Subcutaneous drainage has been advocated for preventing incisional surgical site infection (SSI)[1)~3)] after open colorectal surgery[4)]. Controversy remains, but many investigators have reported the effectiveness of subcutaneous drainage in cases of inflammatory bowel disease and cases of contaminated surgery[5)6)]. Eradication of dead space at the surgical site is the basic principle of surgical closure of the abdominal wall. This prevents pooling of serum and blood, which in turn reduces the risk of infection. In days past, subcutaneous suture was performed, but the presence of foreign bodies (i.e., sutures, charred tissue, necrotic debris) increases the risk of SSI from low levels of bacteria[7)]. Recent studies have confirmed the superiority of non-suture over suture of subcutaneous tissue[8)].

Various risk factors for postoperative wound infections have been reported, including stoma reversal, prolonged operation time, a high degree of contamination, obesity, and diabetes[9)]. The number of patients with these risk factors is increasing. Therefore, we conducted a study of the effectiveness of subcutaneous closed suction drainage for prevention of incisional SSI after elective open colorectal surgery. The primary study question was whether such drainage prevents seroma leading to SSI.

Materials and Methods

1. Subjects

This retrospective study included 81 patients in

Table 1 Patient characteritics per study group

	Non-drainage group (n = 42)	Drainage group (n = 39)	p value
Age (years)	67.1 ± 12.2	65.4 ± 13.4	0.720
Sex ratio (M : F)	16 : 26	22 : 17	0.024
Height (cm)	159 ± 7.6	160 ± 11.3	0.366
Weight (kg)	56.7 ± 11.9	61.3 ± 12.7	0.070
BMI (kg/m2)	22.4 ± 4.0	23.6 ± 2.9	0.125
Tumor location (C : A : T : D : S : R)	(4 : 5 : 6 : 0 : 11 : 16)	(5 : 6 : 3 : 1 : 12 : 12)	0.183
Tumor stage (0/I/II/IIIa/IIIb/IV)	(3/10/13/12/2/2)	(3/5/13/12/4/2)	0.932
ASA score (1 : 2 : 3)	(12 : 23 : 7)	(10 : 27 : 2)	0.608
Diabetes (n)	3	6	0.238
Total parenteral nutrition (n)	0	0	—
Depth of subcutaneous tissue (mm)*	15.2 ± 5.9	16.5 ± 4.8	0.275
Pre-operative hemoglobin level (g/dL)	12.2 ± 1.9	12.4 ± 1.4	0.432
Pre-opertive total protein level (g/dL)	6.43 ± 0.54	6.71 ± 0.53	0.989
Pre-operative albumin level (g/dL)	3.95 ± 0.61	3.98 ± 0.49	0.572
Pre-operative glucose level (g/dL)	112.6 ± 27.8	109.9 ± 32.2	0.344
Pre-operative CRP level (mg/dL)	0.36 ± 0.52	0.81 ± 1.67	0.944

BMI = body mass index; Tumor location: C = cecum; A = ascending colon;
T = transverse colon; D = descending colon; S = sigmoid colon; R = rectum;
ASA score = American Society of Anesthesiologists physical status; CRP = C-reactive protein.
* Average of three measurement points.

two facilities who underwent elective laparotomy with median incision and colorectal resection between February 1, 2010 and March 31, 2014. Patients ranged in age from 20 to 80 years. No patient undergoing emergency surgery, with an inflamed peritoneum, or with a serious adverse event was included in the study. The study patients included cases with subcutaneous drainage (39 patients) or no subcutaneous drainage (42 patients). Patient characteristics, including age; height; weight; body mass index; location of the tumor; American Society of Anesthesiologists (ASA) physical status; depth of subcutaneous tissue; and pre-operative hemoglobin, total protein, albumin, blood glucose, and C-reactive protein (CRP) levels did not differ significantly between the groups (Table 1). Only the sex ratios differed significantly ($p = 0.024$). Approval for the study was obtained from the institutional review board, and each patient provided written informed consent for participation in the study.

2. Methods

Before the study, demonstration videos were used to standardize the closure technique of the surgical wound among the five surgeons who participated in the study. We placed a polyurethane wound protector (Alexis wound protector/retractor) immediately after making the abdominal incision. At the time of closure, synthetic absorptive filament (1-0 polyglactin Suture) was used for the fascia, and hemostasis was confirmed after pressure irrigation of the subcutaneous fatty tissue with 500 mL saline solution. A single subcutaneous closed suction drain (10 Fr Blake drain, Ethicon) was placed from top to bottom of the incision, then the skin was carefully closed with absorbable buried sutures (5-0 polydioxanon Suture). The wound was covered with a polyurethane film dressing and left in place for 48 hours. Patients were given 1 g flomoxef sodium by intravenous injection just before surgery and twice a day after the surgery on postoperative days (PODs) 1-3 for antimicrobial prophylaxis. The subcutaneous drain was removed 72 hours after surgery or if the discharge was 20 mL per day or less.

All patients' wounds were checked by their surgeon, and any seroma was evaluated ultrasonographically on POD 7. Any subcutaneous accumulation of exudate or blood without inflammation was diagnosed as seroma and taken as the primary outcome. The development of incisional SSI was noted and taken as the secondary outcome. The incidences of organ/space SSI, post-operative compli-

Table 2 Perioperative/operative variables per study group

	Non-drainage group (n = 42)	Drainage group (n = 39)	p value
Operation time (min)	179 ± 54	185 ± 56	0.110
Estimated blood loss (mL)	135 ± 170	125 ± 189	0.339
Stoma reversal (n)	5	5	0.900
Perioperative hypothermia (n)	15	14	0.986
Abdominal drain (n)	29	33	0.099
Procedure			
Ileo-cecal resection (%)	3 (7.1)	4 (10.2)	
Right hemi-colectomy (%)	6 (14.2)	7 (17.9)	
Transverse colectomy (%)	6 (14.2)	3 (7.6)	
Left colectomy (%)	4 (9.5)	9 (23.1)	
Anterior resection (%)	20 (47.6)	14 (35.9)	
Miles operation (%)	3 (7.1)	2 (5.1)	0.806
Hemoglobin level after surgery (g/dL)	11.5 ± 1.8	11.5 ± 1.8	0.475
Hemoglobin level on POD 3 (g/dL)	11.6 ± 1.4	11.5 ± 1.6	0.341
Hemoglobin level on POD 7 (g/dL)	11.8 ± 1.5	12.0 ± 1.7	0.719
Hemoglobin level on POD 14 (g/dL)	12.0 ± 1.3	12.2 ± 1.6	0.717
Total protein level after surgery (g/dL)	4.8 ± 0.68	5.0 ± 0.47	0.909
Total protein level on POD 3 (g/dL)	5.5 ± 0.76	5.6 ± 0.47	0.806
Total protein level on POD 7 (g/dL)	5.7 ± 0.93	6.2 ± 0.55	0.989
Total protein level on POD 14 (g/dL)	6.1 ± 0.77	6.6 ± 0.75	0.964
Albumin level after surgery (g/dL)	3.0 ± 0.54	3.0 ± 0.35	0.552
Albumin level on POD 3 (g/dL)	3.2 ± 0.58	3.1 ± 0.36	0.132
Albumin level on POD 7 (g/dL)	3.5 ± 0.56	3.5 ± 0.44	0.517
Albumin level on POD 14 (g/dL)	3.7 ± 0.67	3.8 ± 0.50	0.697
Glucose level after surgery (g/dL)	110.9 ± 23.8	107.4 ± 30.3	0.281
Glucose level on POD 3 (g/dL)	119.9 ± 40.6	112.2 ± 24.1	0.151
Glucose level on POD 7 (g/dL)	110.0 ± 24.2	111.3 ± 21.2	0.596
Glucose level on POD 14 (g/dL)	104.0 ± 23.0	105.3 ± 25.4	0.592
CRP level after surgery (mg/dL)	0.41 ± 0.72	0.74 ± 1.45	0.897
CRP level on POD 3 (mg/dL)	7.95 ± 3.78	7.85 ± 4.28	0.455
CRP level on POD 7 (mg/dL)	2.49 ± 3.20	2.10 ± 2.79	0.279
CRP level on POD 14 (mg/dL)	0.75 ± 1.08	0.67 ± 1.66	0.401

POD = post-operative day.

Table 3 Incidences of seroma and SSI per study group

	Non-drainage group (n = 42)	Drainage group (n = 39)	p value
Seroma (%)	19 (45.2)	8 (20.5)	0.017
SSI (%)	3 (7.1)	4 (10.2)	0.618
Incisional/organ, space	2/1	3/1	

cations, seroma at the subcutaneous level (Table 3) and bacteria cultivated from the drain tip were determined.

The following patient characteristics were recorded: age, sex, height, weight, and body mass index; TNM cancer stage, ASA score; diabetes; total parenteral nutrition; type of surgical procedure; operation time; estimated blood loss; type of anastomosis; stoma reversal; perioperative hypothermia; use of abdominal drain; and depth of subcutaneous tissue. Blood samples were taken before and after surgery and on POD 1, POD 3, POD 7, and POD 14 for comparison of hemoglobin, total protein, albumin, glucose, and CRP levels (Table 2). The depth of subcutaneous tissue was measured ultrasonographically by single viewer in millimeters at three points (2 cm above the umbilicus, 2 cm below the umbilicus, and at the mid-point between the umbilicus and pubis) to minimize the quantifiable risk from the epidermis to the anterior layer of the rectus abdominal sheath.

Relations between independent variables and subcutaneous seroma were evaluated by applying Akaike's information criterion (AIC). The top 15 AIC-determined variables determined were entered into a multivariate logistic regression model by means of backward stepwise selection based on the Wald statistic. Results of the logistic regression are reported as odds ratios (OR) with 95% confidence intervals (CIs).

Table 4 Results of AIC-based univariate analysis

Rank	Explanatory variable	AIC
1	Glucose level on POD 14 (g/dL)	−11.93
2	Total protein level on POD 7 (g/dL)	−9.42
3	Hemoglobin level on POD 7 (g/dL)	−8.52
4	Hemoglobin level on POD 3 (g/dL)	−8.37
5	Pre-operative hemoglobin level (g/dL)	−8.26
6	Pre-operative total protein level (g/dL)	−6.28
7	Glucose level on POD 3 (g/dL)	−5.13
8	Glucose level on POD 7 (g/dL)	−4.65
9	Total protein level on POD 14 (g/dL)	−3.92
10	Total protein level after surgery (g/dL)	−3.82
11	Absence of subcutaneous drainage	−3.69
12	Pre-operative glucose level (g/dL)	−3.65
13	Diabetes (n)	−3.55
14	Operation time (min)	−2.51
15	CRP level on POD 7 (mg/dL)	−2.25
16	Glucose level after surgery (g/dL)	−2.06
17	Depth of subcutaneous tissue (2 cm above umbilicus)	−1.99
18	Albumin level on POD 3 (g/dL)	−1.61
19	CRP level on POD 14 (mg/dL)	−1.43
20	Total protein level on POD 7 (g/dL)	−1.39
21	CRP level on POD 3 (mg/dL)	−1.05
22	Hemoglobin level on POD 14 (g/dL)	−0.91
23	Age (years)	−0.75
24	Albumin level on POD 14 (g/dL)	−0.37
25	Albumin level after surgery (g/dL)	−0.07
26	Pre-operative albumin level (g/dL)	−0.07
27	Depth of subcutaneous tissue (2 cm below umbilicus)	0.05
28	Estimated blood loss (mL)	0.17
29	Depth of subcutaneous tissue (between umbilicus and pubis)	0.37
30	Total protein level on POD 3 (g/dL)	0.42
31	Pre-operative CRP level (mg/dL)	1.14
32	Absence of intra-abdominal drainage (n)	1.16
33	Organ/space SSI (n)	1.23
34	Sex (M : F)	1.38
35	Perioperative hypothermia (n)	1.57
36	CRP level after surgery (mg/dL)	1.78
37	Hemoglobin level after surgery (g/dL)	1.86

Results

1. Primary and secondary outcomes (Table 3)

Seroma was diagnosed in 8 of the 39 (20.5%) patients in the subcutaneous drainage group and in 19 of the 42 (45.2%) patients in the non-drainage group. This difference in the incidence of seroma was statistically significant ($p = 0.017$).

The overall incidence of SSI was 8.6%. No statistical difference was observed between the incidence of SSI in the subcutaneous drainage group (10.2%) and that in the non-drainage group (7.1%) ($p = 0.618$). There was also no statistical difference between the incidence of incisional SSI between the drainage group (7.7%) and the non-drainage group (4.8%) ($p = 0.583$).

2. Risk factors for seroma

The patient characteristics and perioperative variables shown in Table 1, 2 were evaluated in relation to seroma formation (Table 4). Of the top 15 AIC-determined variables, we excluded the POD 14 glucose level and total protein level as potential predictive variables. The results of multivariate analysis are summarized in Table 5. The POD 3 glucose level and the use of subcutaneous closed suction drainage were shown to be independent factors influencing seroma formation.

Discussion

In our study, we found no statistical difference in the incidence of SSI between use and non-use of a subcutaneous drain, but the primary outcome, i.e., post-operative subcutaneous seroma formation did

Table 5 Factors predictive of seroma

	Odds ratio	Confidence interval (95%)	p value
Pre-operative total protein level (g/dL)	2.387	0.881-7.120	0.0879
Glucose level on POD 3 (g/dL)	1.040	1.002-1.089	0.0383
Glucose level on POD 7 (g/dL)	1.013	0.974-1.056	0.5152
Absence of subcutaneous drainage	3.201	1.088-10.66	0.0344

differ significantly. The overall incidence of SSI in patients treated for colon cancer is 13.2% and in those treated for rectal cancer is 15.5%, according to the 2013 infection control surveillance conducted and reported by the Ministry of Health, Labour and Welfare of Japan. Theoretically, approximately 2,000 cases are needed to determine the effect of subcutaneous drainage on the incidence of SSI. Therefore, we used the incidence of seroma as the primary outcome measure in our study. The incidence of seroma was significantly decreased in our subcutaneous drainage group. In recent 2 studies (Weldrick et al[10] and Berger et al[11]), meta-analysis concludes seroma was not associated with SSI in clean surgery. On the other hand, Ten et al[12] reported closing the dead space by quilting after breast cancer surgery prevents the incidence of seroma and SSI. Kuy et al[13] reported after lower extremity revascularization procedures seroma of hematoma was an independent predictor of SSI. These authors hypothesized that seroma formation or any factors which causes delay of resorption, in this case lack of oxygen, has potential risk of increasing the incidence of SSI. In clean-contaminated surgery, controversy remains, whether seroma is an independent factor for SSI.

Along with drainage of the surgical wound, the eradication of the dead space enhances wound healing. Various risk factors such as effusion, steatolysis, necrotic tissue, and wound infection can lead to the formation of seroma[14]. Prior to this study, prolonged operation time, increased estimated blood loss, and subcutaneous tissue more than 20 mm deep were thought to be the risk factors for seroma and SSI[15][16]. However, by using the Alexis wound protector/retractor, osmotic balance within the wound is maintained[17], and the fatty tissue is protected from compromise that could lead to seroma. All drains in our patients were inspected and cultured, but only 1 of the 39 drains, including the 3 in patients who developed SSI, tested positive for *Enterococcus faecalis*. Therefore, further study is needed to determine the suitable time for removal of the drain. A multi-center surveillance conducted in the field of gynecology and obstetrics indicated that subcutaneous tissue of more than 20 mm in depth increases the risk of SSI after cesarean section[18]. However, in our study, which included only elective open colorectal surgery patients with normal immunity, the depth of subcutaneous tissue had no influence on the development of SSI. AIC results were negative as well.

A further objective of this study was to identify factors independently predictive of the development of seroma. Of the top 15 AIC-determined variables, we excluded the POD 14 glucose and total protein levels. Of the remaining variables, multivariate analysis showed the total protein level before surgery, the POD 3 glucose level, the POD 7 glucose level, and the use of a subcutaneous closed suction drain to be significant. Although the preoperative total protein level was not shown to be significant, it tended to be elevated in patients in whom seroma developed. Severe protein-calorie malnutrition is roughly associated with postoperative nosocomial infections[19] and impaired wound healing. A high glucose level on POD 3 was shown to be predictive of seroma. Data suggest that glucose tolerance is abnormal during the first 24 hours after surgery (flow phase) but that it normalizes within 24 to 48 hours after surgery[20] (ebb phase). It is possible that wound infection or any inflammation related to abnormal glucose tolerance after surgery causes delayed effusion resorption, creating an environment that fosters seroma formation. We believe sufficient glucose control is needed especially in the early phase. Thus, ultrasonographic reevaluation for seroma formation and the possibility of postoperative SSI development is necessary. One of the cases of incisional SSI in our non-drainage group was such a case, and rapid improvement was achieved with early detection and drainage.

Conclusions

Minimal contamination of the surgical wound is important to prevent SSI in patients treated by elective open colorectal surgery. In our study, subcutaneous closed suction drainage lowers the incidence of seroma. However, there was no statistical difference in the incidence of SSI with our samples. In clean-contaminated surgery such as colorectal cancer surgery, further RCTs are required with larger sample sizes to clarify the efficacy of subcutaneous drainage on SSI.

The authors have no conflict of interest to declare.

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大腸癌手術における皮下閉鎖式吸引ドレーン留置はセローマの発生を減少させる

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〔目的〕手術部位感染（surgical site infection：SSI）に対して近年エビデンスレベルの高い対策が報告され，当施設でも実施してきた．しかしながら消化器外科手術後の皮下ドレーンに関する報告は少なく，今回我々は大腸癌手術における皮下閉鎖式吸引ドレーン留置のSSI予防の有効性を検討した．〔対象〕2012年2月から2016年3月までに施行した大腸癌手術例81例．〔方法〕各症例をドレナージ施行群39例，非ドレナージ群42例に分け比較を行った．皮下ドレーンとしては閉鎖吸引式皮下ドレーンを用い，ドレーン抜去の基準は術後24時間での排液が20 ml以下あるいは72時間で抜去とした．両群とも術前後の処置，抗生剤投与法，開腹，閉腹手技は統一し，SSIの診断はCDCガイドラインに基づき複数の医師で行った．なおSSI発生頻度以外に，セローマ発生頻度をprimary endpointとして評価を行った．〔結果〕SSI発生率はドレナージ群10.2%，非ドレナージ群7.1%と統計学的有意差は認めない（p＝0.618）ものの，術後1週間での皮下セローマ形成はドレナージ群20.5%，非ドレナージ群45.2%と有意差を認める結果となった．術前後の観察項目を赤池情報量基準（AIC）にて予測因子の検討を行った結果，皮下ドレーンの有無（p＝0.034）と術後第3病日の血糖値（p＝0.038）に有意差ありと抽出された．〔考察〕待機開腹大腸癌手術において皮下ドレーンを留置し，浸出液を吸引することにより一次治癒促進を認めた．感染の培地となりうるセローマを予防することが可能であった．セローマのSSIへの関与については今後さらなる大規模研究により明らかにする必要があると思われた．