The effect of subcutaneous suction drains on surgical site infection in open abdominal surgery
A prospective randomized study

Ann. Ital. Chir., 2016 87: 49-55
pii: S0003469X16024490

Ilker Murat Arer, Hakan Yabanoglu, Huseyin Ozgur Aytac, Ali Ezer

**Baskent University, School of Medicine, Adana Teaching and Research Center, Department of General Surgery, Ankara, Turkey*

The effect of subcurtaneous suction drains on surgical site infection in open abdominal surgery. A prospective randomized study

AIM: *Surgical site infection (SSI) is a major problem associated with open abdominal surgery and related to increased morbidity and mortality rates, healthcare costs and also incisional hernia. A negative pressure subcutaneous drain reduces dead space in subcutaneous tissue by preventing accumulation of fluid. The aim of current study was to establish the efficacy of a subcutaneous drainage system for preventing SSI after open abdominal clean-contaminated surgery.*
MATERIAL AND METHODS: *A total of 62 patients underwent abdominal surgery, between November 2014 and March 2015, were enrolled. 48 eligible patients, were randomized into subcutaneous drainage (DG) and no drainage group (NDG). Antibiotic prophylaxis was appiled to each patient. The diagnosis of superficial SSI was made according to the Centers for Disease Control and Prevention's (CDC) definition.*
RESULTS: *The mean age of patients was 48.77 ± 12.62 years with a male-female ratio of 21:27. No statistical difference between groups was observed for age, sex, comorbidity, incision type, hemoglobin level, blood loss, hospital stay and operation time (P>0.05). 2 (8.7%) patients in DG and 8 (32%) patients in NDG had incisional SSI but no statistical difference was observed (P>0.05).*
CONCLUSION: *SSI appear to be reduced with subcutaneous suction drains in open abdominal surgery however prospective randomized larger scaled studies should be performed on this topic.*

KEY WORDS: Abdominal surgery, Subcutaneous drain, Surgical site infection

Introduction

Surgical site infection (SSI) is a major problem associated with open abdominal surgery. The incidence of SSI has been reported to be 20% after colorectal surgery, 21 % after liver resection and 2 % after all surgical procedures [1-3]. Seromas, hematomas and infections are the commonest complications of the wound and obese patients are at more risk of these complications [4]. SSI are related to increased morbidity and mortality rates, healthcare costs and also incisional hernia [5].
Mechanical bowel preparation with oral antibiotics, abdominal skin preparation, prophylactic intravenous antibiotics, laparoscopy and postoperative glycemic control in diabetics have been shown to reduce the risk of developing SSI. Besides these preoperative precautions, subcutaneous closure techniques such as intraoperative placement of subcutaneous drainage is one of the most

Pervenuto in Redazione Luglio 2015. Accettato per la pubblicazione Settembre 2015
Correspondence to: Murat Arer, Baskent University School of Medicine, Adana Teaching and Research Center, Department of General Surgery Dadaloglu District 2591 Street No:4/A 01250 Yuregir, Adana, Turkey (e-mail: igy1981@yahoo.com)

Abbreviations

CDC: Centers for Disease Control and Prevention's;
DG: Drainage group;
NDG: No drainage group;
SSI: Surgical site infection.

investigated interventions. A negative pressure subcutaneous drain reduces dead space in subcutaneous tissue by preventing accumulation of fluid 6. Especially for clean-contaminated wounds, fluid accumulation in dead space may lead to bacterial colonization resulting in superficial SSI.
Several drainage systems can be used as subcutaneous drain, e.g: Jackson-Pratt, Blake and Redon drain. Several studies have revealed that multi-channel drains with side slits prevent wound infection in colorectal and liver surgery [7,8]. However efficacy or advantage of subcutaneous drains has not been clearly shown yet.
The aim of current study was to establish the efficacy of a subcutaneous drainage system for preventing SSI after open abdominal clean-contaminated surgery.

Materials and Methods

Patients

Following the approval of the study protocol by the local ethics board, a total of 62 patients underwent abdominal surgery classified as clean-contaminated wound at Department of General Surgery in Baskent University Adana Teaching and Research Center, between November 2014 and March 2015. 14 patients were excluded and reasons were; the drain was removed earlier than postopertive day 5, the drain was placed improperly, comorbidity was diagnosed after hospitalization and giving up treatment. 48 eligible patients were enrolled, provided written informed consent, were randomized into either a group that would receive subcutaneous negative pressure drainage (Group 1) or a group with no drainage (Group 2). Study cluster distribution was done by random number table, a simple randomization technique. Randomization was done according to directories of website link; http://stattrek.com/statistics/random-number-generator.aspx. Data of the patients are collected prospectively. Clean-contaminated abdominal surgeries more than 2 hours were recruited for this study. The exclusion criteria were; neoadjuvant therapy, age below 18 and above 65 years, diabetes mellitus (DM), chronic renal failure, wound length less than 3 cm., immunosuppression and laparoscopic surgery.
This study was approved by Baskent University Institutional Review Board (Project No: KA14/208) and supported by Baskent University Research Fund.

Surgical Procedure

A skin incision was performed with a scalpel and subcutaneous fat was dissected by monopolar electrocautery. Wound closure was done using PDS® or Prolene® for the fascial layer and silk or stapler for the skin. No subcutaneous suture was applied. The subcutaneous negative pressure drainage system comprised of a 400 ml 12 CH Redon drain (B-VAK 400®, Bicakcilar Medical, Turkey) and was applied if the patient was randomized to the drainage group (DG). The exit of the drain was 3-5 cm. to the lower end of the incision. A gauze dressing was applied around the external end of the drain to absorb the drainage fluid. The subcutaneous drain was removed on postoperative fifth day (day 5) even if no drainge was observed. The drain was not removed untill drainage for 24 hours was less than 50 ml. Elective colorectal surgery was performed to all patients and mechanical bowel preparation (oral fleet phospho-soda) was done preoperatively. Prophylactic ceftriaxone and metronidazole was administrated for elective colorectal surgery and extended 24 hours after the operation and cefazoline sodium for other abdominal surgical procedures 30 minutes before the incision was made. The thickness of the subcutaneous tissue and length of the wound was evaluated by the surgeon with a sterile ruler. Every 10 cm wound was washed with 1 liter of normal saline (0.9 % sodium chloride). Then wound culture was collected for detection of bacterial contamination.

Diagnosis of SSI

The surgeon performed a physical examination everyday from the operating day until discharge and checked for signs of SSI in outpatient clinic on postoperative days 7 and 30. The diagnosis of superficial SSI was made according to the Centers for Disease Control and Prevention's (CDC) definition [9], which included the following criteria: (a) purulent drainage, with or without laboratory confirmation, from the superficial incision; (b) organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision; (c) at least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness or heat, which require the superficial incision to be deliberately opened by a surgeon, unless the incision is culture negative; and (d) diagnosis of superficial SSIs made by a surgeon or attending physician. Further, according to this definition, superficial SSI were defined as such findings occurring within 30 days after surgery.

Statistical Analysis

Statistical analysis was performed using *SPSS software* (Version 17.0, SPSS Inc., Chicago, IL, USA). If continuous variables were normal, they were describle as the

mean±standard deviation (p>0.05 in Kolmogorov-Smirnov test or Shapira-Wilk (n<30)), and if the continuous variables were not normal, they were described as the median. The continuous variables were compared by the use of *Mann-Whitney U* test depending on non-parametric values. The catagorical variables between the groups were analyzed by using the chi square test or Fisher's exact test. the level for statistical significance was predetermined AT P < 0.05.

Power Analysis

The sample size for this prospective randomized study was determined according to previous reports. One prospective study documented that SSI ratio can be decreased from 47% to 11% [6]. To detect this degree of difference in a single-sided design with the power of 0.90 and significance level 0.05, the required sample size is a total of 46 patients. Allowing for a dropout rate of approximately 13.5%, we decided that a total of 46 patients (23 for each group) would be sufficient for this study.

Results

Among 62 patients enrolled, 48 were eligible for our study. The mean age of patients was 48.77 ± 12.62 years (range between 24-64 years). Of 48 patients 21 (43.8%) were male and 27 (56.2%) were female. 7 (30.4%) patients in drainage group (DG) and 7 (28%) patients in no drainage group (NDG) have prior abdominal surgery. Characteristics of patients are described on Table I. The mean body mass index (BMI) was 25.92 ± 3.97 and 27.35 ± 5.74 kg/cm² for DG and NDG respectively with no significant difference (p>0.05). Though patients that have comorbidities affecting wound healing were excluded, only 6 (26.1%) patients in DG have hypertension and this was found to be strongly significant (p<0.05). Colorectal surgery was performed in 21 (43.8%) patients, hepatobiliary surgery in 11 (22.8%), pancreatic surgery in 8 (16.7%), other abdominal procedures in 5 (10.4%) and gastric surgery in 3 (6.3%) patients. Surgical procedure performed for patients are listed in Table II. The abdominal skin incision was midline in 33 (68.8%) and subcostal in 15 (31.2%) patients. Only 4 (8.3%) patients in NDG received preoperative blood transfusion. Of 5 (10.4%) patients received peroperative blood transfusion 3 (6.24%) were in DG and 2 (4.16%) were in NDG. The mean serum hemoglobin level was 12.8 ± 2.1 and 12.3 ± 2.2 g/dl for DG and NDG respectively and no statistical difference was observed (p>0.05). Mean intraoperative blood loss was 285.4 ml (range between 30-2000 ml) for DG and 222 ml (range between 50-2000 ml) for NDG (p>0.05). The mean length of incision for DG was 19.2 ± 3.9 cm and for NDG 21 ± 6.5 cm. Mean depth of subcutaneous

Table I - *Comparison of patient characteristics between drainage group (DG) and no drainage group (NDG)*

Characteristics	DG (n = 23)	NDG (n = 5)	P value
Gender (n)			1.000
Male	10	11	
Female	13	14	
Age (years) (mean)	51.1 ± 11.7	46.5 ± 132	0.204
Prior abdominal surgery (n)	7 (30.4%)	7 (28%)	1.000
BMI (kg/cm^2) (mean)	25.92 ± 3.97	27.35 ± 5.74	0.183
Comorbidity (n)			0.008
Hypertension	6 (26.1%)	0	
None	17 (73.9%)	25 (100%)	
Surgery (n)			0.769
Colorectal	10	11	
Hepatobiliary	4	7	
Pancreatic	5	3	
Gastric	2	1	
Other	2	3	
Skin incision (n)			0542
Midline	17	16	
Subcostal	6	9	
Hemoglobin (g/dl)	12.8 ± 2.1	12.3 ± 2.2	0.495
Blood loss (ml) (mean)	285.4 ± 426.6	222 ± 386.2	0.866
Operation time (minutes)	166.1 ±2.4	165.8 ± 82.6	0.909
Hospital stay (days)	59 ± 2.4	7.9 ±3.8	0.084
Incisional SSI (n)	2 (8.7%)	8 (32%)	0.075

Abbreviations: SSI; surgical site infection

Table III - *The size of skin incision*

	DG (n = 23)	SEG (n = 25)	P value
Length of incision (cm)	19.2 ± 3.9	21 ± 6.5	0.428
Depth of subcutaneous tissue (cm)	4.5 ± 1.7	3.8 ± 0.7	0.321

*cm: centimeter

TABLE II - *Surgical procedure performed for patients*

Surgical procedure	Number of patients (n = 43)
Hemicolectomy	9
Low anterior resection (Rectum)	7
Whipple procedure	6
Surgery for hydatid disease of liver	4
Cholecystectorny	3
Excision of intraabdominal legion	3
Colon resection	2
Transabdominal repair of rectal prolapsus	2
Liver resection	2
Distal pancreatectomy	2
Splenectomy + Primary repair of small bowel	2
Gastrectomy	9
Choledochoenterostomy	9
Abdominoperineal resection (Rectum)	1
Duodenoenterostomy	1

Table IV - Microorganisms encountered from tissue culture

	Number of patienis
Coagulase negative staphylococcus	13 (27.1%)
Coagulase negative staphylococcus and Streptococcus	2 (42%)
Coagulase negative staphylococcus and Enterococcus	2 (42%)
Coagulase negative staphylococcus and other staph.	2 (42%)
Enterococcus	2 (42%)
Eschericia coli	2 (42%)
Other	4 (8.4%)

Abbreviations: staph; staphylococcus

tissue was 4.5 ± 1.7 and 3.8 ± 0.7 cm for DG and NDG respectively. According to operation time and hospital stay no statistical difference was observed between groups (p>0.05).

2 (8.7%) patients in DG and 8 (32%) patients in NDG had incisional SSI but no statistical difference was observed (Table III) (p>0.05). 1 (4.3%) patient in DG and 2 (8%) patients in NDG had postoperative complications such as abdomianl hernia, intraabdominal abscess and biliary leakage.

Tissue culture of 21 (43.8%) patients were sterile. The most commonly encountered microorganism from tissue culture (41.8%) was coagulase negative staphylococcus species (Table IV). Of 8 patients in NDG have incisional SSI, tissue culture of 1 patient was sterile. Microorganism proliferation was observed in tissue culture of 12 (52.1%) patients in DG, however none of them can be able to produce SSI. Of these microorganisms encountered one was Candida species without progressing to SSI.

Discussion

SSI remains an important problem as a postoperative complication after abdominal operations and once it develops may lead to increased hospital stay, prolonged intravenous antibiotic treatment and increased healthcare costs [10,11]. Especially for contaminated wounds, SSI is almost inevitable. Obesity, increased age, smoking, prior abdominal surgery, excessive blood loss during surgery, elongated operation time, and performance of adhesiolysis as risk factors for wound complications [12,13]. Among these risk factors, obesity is a well-known and investigated one [14,15]. Thickness of subcutaneous tissue also found to be another risk factor for SSI that is also associated with obesity [16]. Due to multiple risk factors related to the patient, a systematic approach is needed for the prevention of SSI. Beside skin preparation methods or prophylactic use of antibiotics or subcutaneous closure techniques, use of subcutaneous drain is one of the most investigated interventions. However, the efficacy of a subcutaneous drain in preventing wound complications still remains controversial [12].

The mechanism due to subcutaneous drain for prevention of SSI is thought to be reduction of potential dead space and removal of residual fluid and blood from the wound that can serve as a medium for bacterial growth [17].

Bacterial contamination of the wound does not always yield SSI but in case of fluid accumulation it becomes almost inevitable. In our study we observed SSI in 1 patient in NDG that has sterile tissue culture. This finding also points out potential dead space or fluid accumulation in subcutaneous tissue is a significant risk factor for development of SSI.

There are numerous studies investigating use of subcutaneous drains in colorectal and obstetric surgery. Multiple drains are used in these studies. There is no consensus on type of drain should be used. Penrose drain (PD) that makes passive drainage has some disadvantages like inability to measure drainage amount and necessity to be removed on postoperative 3rd day. Imada et al. although did not find to reduce SSI significantly, encourage the use of PD in high risk patients [18]. PD has to be removed on postoperative 3rd day in order not to cause retrograde infection [19]. This makes limitation of this drain to inhibit accumulation of subcuta-

neous fluid after postoperative 3rd day. Numata et al. reported PD is useful for prevention of SSI for colorectal surgeries and found SSI of PD and no drainage groups 3.2 % and 9.8 % respectively, significantly different with a P value of 0.041 [20]. This difference was comes from open procedures since percent of SSI in laparoscopic surgery between groups are similar.

Negative pressure drains seem to be superior to passive drains however they have disadvantages like causing tissue damage because of high suction power. The Jackson-Pratt drain (JPD) has multiple holes to discharge fluid (2). Thus negative pressure of the drain is dependent on suction area, as a result of the higher power on the small suction holes, fatty tissue might be damaged while the JPD is in place [21]. However its silicone structure allows better flexibility.

Because the leakage from the site of insertion is prevented and retrograde infection is reduced, flexibility allows for precise indwelling in the tissue, there are no holes in its sides and is easily removed with less silicon-related removal pain and drain insertion-related pain, Kajiwara et al. found J-VAC drains (JVD) to be superior to JPD [22]. Several studies have reported that an SVD is effective for reducing SSI [4,7,17]. Pan et al. encourages use of JPD even for primary closure of ileostomy although higher risk of SSI for contamination of the surgical field compared with other abdominal surgeries [23]. Blake drains (BD) that have similar fashion to JVD, are also used as subcutaneous drainage. Inotsume-Kojima et al. reported subcuticular sutures and BD reduces SSI in obese women [24]. Fuji et al. found subcutaneous drains to be effective for preventing incisional SSI in patients with thick subcutaneous fat in colorectal surgery [7]. Fuji et al. measured the thickness of subcutaneous fat by computerized tomography that is also collected data together with length of the incision in our study. However in both studies no significant difference was observed. But for accurate measurement of subcutaneous tissue, as performed in our study, we recommend intraoperative measurement with a sterile ruler.

Another significant issue is exit of the drain. We placed the exit of drain 5 cm below the incision. The reason is to prevent potential subcutaneous space under the incision. When the exit of the drain is placed lateral to the incision, fluid accumulation is observed in the lower end of incision with the lack of suction function of that region.

Imada et al. also encourages irrigation of subcutaneous tissue with normal saline after fascial layer closed that is done routinely for all patients in our study [18]. Mechanical irrigation of subcutaneous tissue with normal saline results in removal and dilution of bacteria from contaminated wound. However this may also cause migration of bacteria from contaminated to non-contaminated part of the wound and leads to bacterial overgrowth alongside the whole incision. Mechanical irrigation can also result bleeding from subcutaneous vessels and inappropriate hemostasis yield subcutaneous hematoma or SSI.

Subcutaneous redon drain for laparotomy was first applied by Baier et al. in order to reduce SSI [25]. However reported that subcutaneous drains do not reduce SSI after laparotomy. Laparoscopic procedures are included and patients with a history of prior abdominal operations are excluded in their study. On the contrary we did not include laparoscopic operations and did not exclude patients with prior abdominal operations even known as a risk factor for SSI. Only 1 (4.3%) patient in DG and 4 (16%) patients in NDG with prior abdominal operation history had SSI in our study. 6(26%) patients in DG even had a prior abdominal surgery did not produce SSI. Thus redon drain reduces SSI even in patients with a history of prior abdominal surgery.

Microbiological studies have shown that most of SSI are caused by skin-derived bacteria such as Staphylococcus aureus and coagulase negative staphylococci (26,27). We observed coagulase negative staphylococcus most frequently (27.1%) in tissue culture of patients. Bacteria causing SSI in our study is a member of normal skin flora. This means mechanical irrigation with normal saline removes bacterial contamination of intestinal flora. At this point we want to take attention to the importance of preoperative skin preparation and appropriate antibiotic prophylaxis. Candida spp. was observed from tissue culture of 1 patient in DG therefore we also state that subcutaneous drain not only interrupts bacterial growth, it also prevents fungal infection. As limitation of our study is small population it is not found statistically significant.

The cost of subcutaneous saline irrigation and drainage is only 2.65 $ for each patinent however they prevent SSI thereby cost of antibiotic use, long hospital stay and complications of SSI.

Conclusion

Surgical site infection appear to be reduced with subcutaneous suction drains in (clean-contaminated) open abdominal surgery. Prospective randomized larger scaled studies should be performed on this topic.

Riassunto

L'infezione superficiale dell'incisione chirurgica (SSI) rappresenta un problema importante della chirurgia ad addome aperto, in rapporto con aumento di morbilità e mortalità, costi di gestione sanitaria oltre che responsabile di laparocele. Il drenaggio aspirativo del sottocutaneo ne riduce gli spazi morti e previene la raccolta di fluidi.

Lo scopo di questo studio è stato quello di definire l'efficacia di un sistema di drenaggio del sottocutaneo per prevenire queste infezioni nella chirurgia pulita-contaminata ad addome aperto.

Lo studio si è svolto su 48 pazienti utilizzabili da un totale di 62 pazienti sottoposti ad interventi addominali tra Novembre 2014 e Marzo 2015, randomizzati in gruppo a drenaggio aspirativo (DG) e senza (NDG).
Tutti i paziente sono stati sottoposti a profilassi antibiotica. La diagnosi di infezione superficiale dell'incisione (SSI) è stata fatta secondo la definizione dei Cenrti per Controllo e Prevenzione delle Malattie (CDC).
L'età media dei pazienti era di 48.77 ± 12.62 anni, con un rapporto umomo-donna di 21 a 27. Non vi era evidenza di differenze statistiche tra i gruppi per età, sesso, comorbilità, tipo di incisione, livello emoglobinico, perdite ematiche, durata dell'intervento chirurgico e della degenza ospedaliera (P>0.05).
2 pazienti (8.7%) del gruppo tientsDG e 8 (32%) del gruppo NDG hanno sviluppato SSI senza osservazioni di differenze statistiche (P>0.05).
In conclusione la SSI appare ridotta nel caso di adozione del drenaggio sottocutaneo in aspirazione in chirurgia ad addome aperto, anche se sono necessari più ampi studi prospettici randomizzati su questo tema.

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