

Original Research Article

Subcutaneous negative pressure versus simple closure of skin incision following an emergency laparotomy: a randomized control study

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ABSTRACT

Background: Surgical site infection (SSI) is a major problem associated with open abdominal surgery and is related to increased morbidity, mortality and healthcare costs. A subcutaneous negative pressure drain reduces dead space in subcutaneous tissue by preventing accumulation of fluid. The aim of present study was to establish the efficacy of a subcutaneous negative pressure for preventing SSI following exploratory laparotomy.

Methods: A total of eligible 76 patients who underwent emergency abdominal surgical procedure, between October 2016 to March 2018, were randomized into subcutaneous drainage (DG) and no drainage group (NDG). Antibiotic prophylaxis was applied to each patient. The diagnosis of superficial SSI was made and was graded according to Southampton Grading System.

Results: 5 patients in drain group (40) and 25 patients in no drain group (36) had incisional SSI with statistical difference ($p < 0.05$). No statistical difference between groups was observed for age, sex, hospital stay ($p > 0.05$).

Conclusions: Subcutaneous negative pressure prevents post-operative surgical site infection significantly. Subcutaneous negative pressure drainage reduces hospital stay in a patient undergone emergency laparotomy, compared to patients in whom negative pressure drain was not placed.

Keywords: Abdominal surgery, Subcutaneous negative pressure drain, Surgical site infection

INTRODUCTION

Peritonitis is one of the most common surgical emergencies which present to surgery department. Peritonitis is the inflammation of the serosal membrane that lines the abdominal cavity and the organs contained therein.¹

The first clinical description of perforated peptic ulcer was made by Crisp in 1843.

Smoking and use of non steroidal anti inflammatory drugs are important risk factors for perforation.²

Surgical infections are characterized by a breach of mechanical or anatomic defense mechanisms and are associated with greater morbidity, significant mortality, and increased health care cost.³

Prevalence of SSI may be partially explained by the emergence of antimicrobial-resistant pathogens and the increased numbers of surgical patients who are elderly and/or have a wide variety of chronic, debilitating, or immunocompromising underlying diseases.⁴

SSI can double the length of hospital stay and thereby increase the costs of health care. The main additional

costs are related to re-operation, extra nursing care and interventions, and drug treatment costs.

Surgical site infection, is one of the most common postoperative complications, occurring in at least 5% of all patients undergoing surgery and 30-40% of patients undergoing abdominal surgery, depending on the level of contamination.

Abdominal wall closure in the presence of sepsis presents a challenge to the surgeon.

After dealing with pathology and peritoneal cavity washing, if tight closure of abdominal wall is done, it may lead to compartment syndrome or wound dehiscence or burst abdomen in a significant number of patients.

Sometimes the surgeon has to resort to measures like vacuum closure system, which is very expensive and need secondary suturing of skin later. In other patients where the wound is closed primarily, wound infection and gapping of the wound can occur, sometimes progressing to burst abdomen.

Surgeons have used various suture materials for closure of the abdomen varying from delayed absorbable to non-absorbable sutures.⁵

The incidence of surgical-site infection increases with the degree of contamination; therefore, surgical-site infection occurs at much higher rates after operations for peritonitis (i.e. 5-15%, compared with <5% for elective abdominal operations for non-infectious etiologies).

If the abdomen cannot be closed primarily or there is danger of compartment syndrome, the vacuum pack system has been demonstrated to be effective, although the final selection for temporary abdominal closure will depend on the experience of the institution as well as the surgeon's preference. The vacuum pack system for temporary abdominal closure of the open abdomen is an effective alternative in patients with abdominal sepsis.⁶

Surgical-site infection may be expected if the wound is closed in the setting of gross abdominal contamination and lavage of the wound at the end of therapy does not reliably prevent this complication.⁷

Negative suction in the subcutaneous space with or without irrigation with antibiotic solution has been shown to reduce the incidence of infection by evacuation of infected contents.

This study is to compare the subcutaneous negative suction, conventional closure of skin and subcutaneous planes in cases of emergency laparotomy and to evaluate advantages and disadvantages of each of these two techniques with regard to surgical site infections, duration of hospital stay, subsequent surgeries, expenditure and morbidity.

Objective of the study

To find out the best method of managing laparotomy wounds among the two techniques (Subcutaneous negative pressure closure, conventional primary closure of skin and subcutaneous tissue).

To determine the advantages and disadvantages of each methods to individualise the technique based on patient profile with regard to surgical site infection (SSI), hospitalisation, cost and morbidity.

METHODS

Operated cases by exploratory laparotomy in the Department of General Surgery at SDM College Of Medical Sciences And Hospital between the period October 2016- March 2018, are included in the study.

The study was approved by institutional ethics committee.

Sample size estimation is performed based on the following method.

% of SSI in first group=15% (P1)

% of SSI in second group=45% (P2)

Estimated risk of difference= $d=P1-P2=30\%$

$N=35$ in each group to achieve 80% power and 5% alpha error.

$n=2 (Z \alpha + Z \beta)^2 (pq)/d^2=35$ in each group.

$P=P1+P2/2$, $q=1-P$ $Z \alpha=1.96$ at 5% alpha error.

$Z \beta=0.842$ at 80% power.

Based on the above formula, minimum number of patients to be taken (with negative pressure subcutaneous drain and without negative pressure subcutaneous drain) are 35 in each group.

Method of collecting data

Study design is randomized control study. Total of 76 patients who had given consent for the study are observed.

Patients are randomized and 40 patients out of 76 were taken as cases and negative pressure subcutaneous drain placement was performed.

36 patients out of 76 were taken as control group and subcutaneous and skin closure performed without any drain placement.

Patients to be taken under the study are decided on the inclusion and exclusion criteria.

Patients who fulfill the criteria of inclusion are included in the study and rest cases are excluded from the study.

Inclusion criteria

Inclusion criteria were all the adult patients who have undergone laparotomy in the Department of General Surgery at SDM College of Medical Sciences and Hospital and age group between 16 years to 75 years patients.

Exclusion criteria

Exclusion criteria were patients with Immunogenic diseases or immunosuppressive therapy; age <16 years and >75 years patients; accidental removal of drain.

After taking detailed history, all the patients are investigated and required laboratory investigations were done.

Plain X-ray of abdomen and chest to look for free air under the domes of the diaphragm or multiple air fluid levels is performed for all the patients in the study.

Nasogastric suction, correction of fluid and electrolytes is done and appropriate antibiotics started. All the patients are started on piperacillin tazobactam 4.5 gm intravenously and metrogyl 500 mg intravenously.

Demographic and clinical variables are recorded at the time of admission.

Variables for each patient included: age, gender, diagnosis, total leucocyte counts, intra operative contamination, surgical site infection (SSI), duration of subcutaneous drain and post operative stay.

Patients who have given consent for the study are randomized. Patients diagnosed to have acute abdomen clinically, radiologically are planned for emergency exploratory laparotomy.

Parts preparation performed just before the onset of surgery. One dose of antibiotic is given at the time of admission and intraoperatively and efforts taken so that cases are taken up for surgery within 24 hrs.

Rectus sheath is incised and preperitoneal pad of fat is noted. Peritoneum is demonstrated and using two artery forceps and sterile blade peritoneum entered.

Amount of contamination is noted and documented for each case in cases with perforation, site of perforation noted and documented. Perforation closure performed using 2-0 vicryl suture material and Grahams omental patch repair.

In cases with resection and anastomosis, 2 layered anastomosis performed using 2-0 Vicryl suture material

for first layer and Lembert sutures were placed for second layer using 2-0 Mersilk suture material.



Figure 1: Negative pressure suction drain.

Table 1: Southampton wound–grading system.⁸

Grade	Appearance
0	Normal healing
I	Normal healing with mild bruising or erythema
	I _a Some bruising
	I _b Considerable bruising
	I _c Mild erythema
II	Erythema plus other signs of inflammation
	II _a At one point
	II _b Around sutures
	II _c Along wound
	II _d Around wound
III	Clear or haemoserous discharge
	III _a At one point only (less than or equal to 2 cms)
	III _b Along wound (>2 cms)
	III _c Large volume
	III _d Prolonged (>3 days)
IV	Pus
	IV _a At one point only (less than or equal to 2 cms)
	IV _b Along wound (>2 cms)
V	Deep or severe wound infection with or without tissue breakdown; hematoma requiring aspiration

Thorough wash using normal saline performed during each case and abdominal drain placement performed as per requirement in each case. Rectus closure performed using Loop Ethilon suture material. In patients taken as

cases, 16F Romovac subcutaneous suction drain (Figure 1) placement performed and fixed in position using 2-0 Mersilk suture material. Subcutaneous closure performed using 2-0 vicryl (polyglactin) suture material and skin closure performed using 2-0 Ethilon (NYLON)suture material and skin staples.

Patients are followed up and surgical wound is examined daily postoperatively for any evidence of surgical site infection. Wounds are graded depending on Southampton grading system (Table 1). Pus was sent for culture and sensitivity and antibiotics given according to culture sensitivity report.

Patients are compared mainly in terms of incidence of surgical site infection with drain placement and without drain placement, post operative stay in patients with drain placement and without drain placement.

RESULTS

The gender wise distribution of patients is as shown in Table 2. The highest number of patients encountered in this series was in the age group 50 years and above followed by the age group of 21-29 years. The mean age group in this study was 43.72 years.

Table 2: Gender wise distribution of patients.

Gender	Number of patients	% of patients
Male	43	56.58
Female	33	43.42
Total	76	100.00

Table 2 showing gender wise distribution of patients. 43 out of 76 are male and 33 out of 76 are female 2 years.

Total number of male patients in the study- 43 (56.58%). Total number of female patients in the study- 33 (43.42%).

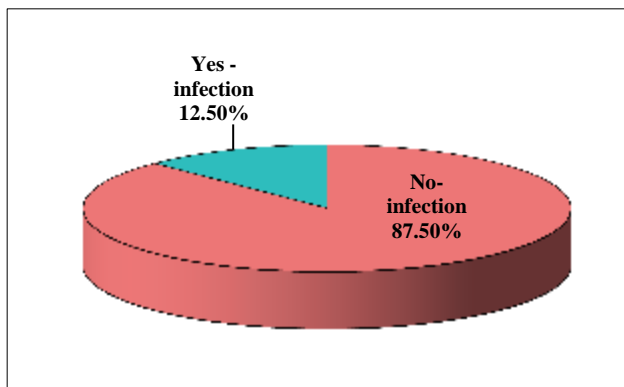


Figure 2: Surgical site infection with drain (n=40).

In total of 40 cases subcutaneous negative pressure drain was placed. No evidence of surgical site infection was found in 35 cases with drain and there was evidence of

surgical site infection in 5 cases with drain with a significant P value ($p < 0.05$ (significant)) (Figure 2).

87.50% of cases with drain have not developed SSI with significant $p = 12.5\%$ of cases with drain have developed SSI.

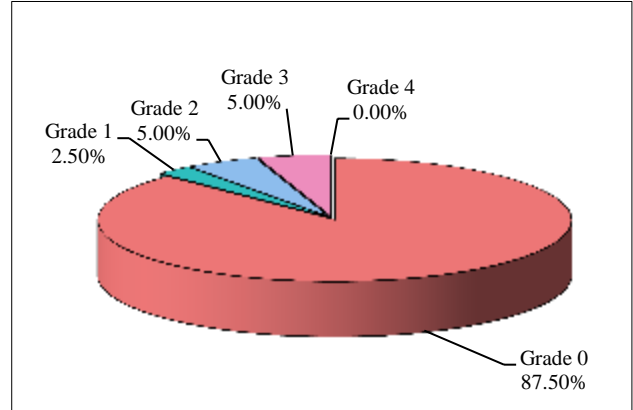


Figure 3: Grades wise distribution of patients with drain (n=40).

Total number of patients with drain-40. Total number of patients with no surgical site infection-35. Total number of patients with Grade 1 infection with drain-1. Total number of patients with Grade 2 infection with drain-2. Total number of patients with Grade 3 infection with drain-2. Total number of patients with Grade 4 infection with drain-0 (Figure 3).

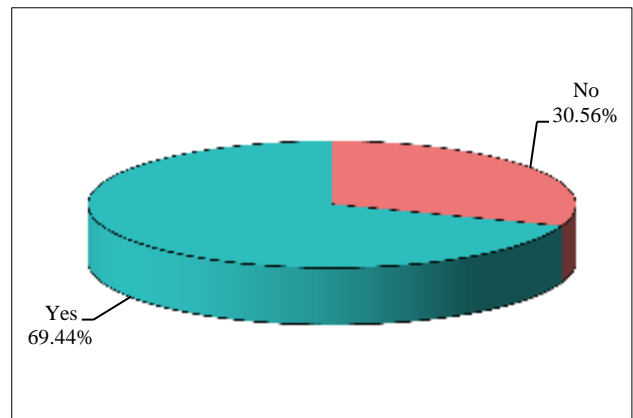


Figure 4: Surgical site infection without drain (n=36).

Figure 4 showing percentage of cases developed SSI without subcutaneous negative pressure drain. 69.44% cases developed surgical site infection without drain and 30.56% cases have not developed SSI without drain.

Total numbers of patients without subcutaneous negative pressure drain placement were 36. Total number of patients who developed surgical site infection without drain were 25. Total number of patients with no evidence of surgical site infection without drain were 11 (Figure 4).

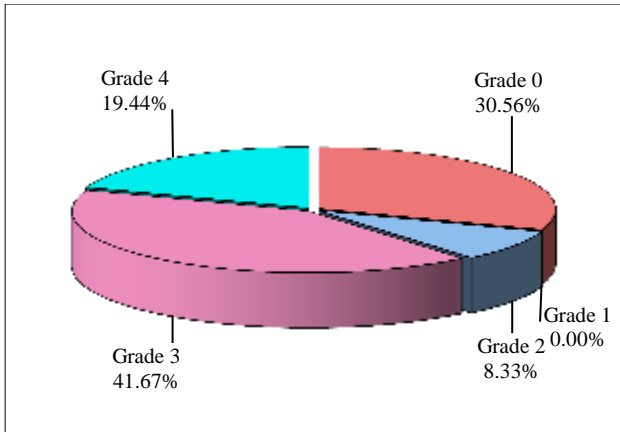


Figure 5: Grade wise distribution of patients without drain (n=36).

Total number of patients without drain-36. Total number of patients with no surgical site infection without drain-11. Total number of patients with Grade 1 infection without drain-0. Total number of patients with Grade 2 infection without drain-3. Total number of patients with Grade 3 infection without drain-15. Total number of patients with Grade 4 infection without drain-7 (Figure 5).

Table 3 represents association between status of drain (with and without) and surgical site infection. Chi-square value is 25.7163, with propability value $p=0.0001$. P value is less than 0.05 showing the statistical significance of the study. This implies that there is significant reduction in development of surgical site infection following exploratory laparotomy in cases with placement of subcutaneous negative pressure drain.

Table 3: Association between status of drain (with and without) and surgical site infection.

Surgical site infection	With drain	%	Without drain	%	Total	%
No	35	87.50	11	30.56	46	60.53
Yes	5	12.50	25	69.44	30	39.47
Total	40	100.00	36	100.00	76	100.00

Chi-square=25.7163; $p=0.0001$ ** $p<0.05$.

Table 4: Association between status of drain (with and without) and post operative stay.

Post operative stay (in days)	With drain	%	Without drain	%	Total	%
≤5	2	5.00	3	8.33	5	6.58
6-10	17	42.50	18	50.00	35	46.05
11-15	16	40.00	8	22.22	24	31.58
16-20	3	7.50	4	11.11	7	9.21
≥21	2	5.00	3	8.33	5	6.58
Total	40	100.00	36	100.00	76	100.00

Chi-square=4.4682; $p=0.3461$.

Table 4 represents association between status of drain (with and without) and post operative stay. P value is 0.3461 with no statistical significance. But there is reduction in the postoperative stay in cases with negative pressure drain compared to cases without drain in our study.

Average postoperative stay with drain-5 to 15 days. Average postoperative stay without drain-5 to 20 days (Table 4).

DISCUSSION

Operated cases by exploratory laparotomy in the Department of General Surgery at SDM College of Medical Sciences and Hospital between the period October 2016- March 2018 following ethical committee clearance, were included in the study.

Perforation of the colon or rectum is categorized as Class IV (dirty-infected) based on the CDC definitions and is considered to be an extremely high-risk condition.⁹

Several approaches to preventing SSI such as perioperative high inspired oxygen therapy, wound protectors, timing of antimicrobial prophylaxis, and subcutaneous drains have been reported.¹⁰⁻¹⁵ Some studies found that subcutaneous drains do not reduce the incidence of SSI, however, subjects of these studies were not limited to high-risk patients.¹⁶

The incisional SSI rate in patients with thick subcutaneous fat tissue was significantly reduced in high-risk cases, which is a result similar to that reported previously for obese women undergoing cesarean delivery.^{11,12}

Furthermore, in the case of dirty wounds, the only study of the utility of a subcutaneous drain has been that by Fujii et al.¹² This study assessed the efficacy of the J-VAC drainage system as a subcutaneous closed suction drain system in patients undergoing surgery for colorectal perforation. Using the J-VAC drainage system was shown to be significantly more effective than not using such a system in preventing incisional SSI in high-risk

patients undergoing emergency operations for colorectal perforation. Furthermore, in patients with factors such as history of laparotomy, history of diabetes, preoperative use of steroid, and a smoking habit, which were considered as risk factors of incisional SSI in previous reports, the use of the J-VAC Drainage System was more effective.¹⁶⁻¹⁹

In our present study, total of 76 cases and controls were included with particular criteria fixed during the study period and were selected randomly.

Our study results are comparable to study done by Fujii et al.¹²

Total number of patients in the study (Fujii et al) are 79.44 are taken as control group and drain was placed in 35 patients.¹² Among 44 patients without drain 17 developed SSI and in 27 patients, there is no evidence of SSI, with percentage infection of 38.6.

Among 35 patients with drain only 5 patients developed SSI and in rest 30 patients no evidence of SSI (p=0.017) (Table 5).

Table 5: Comparison between our study and similar studies.

Study	Year	Patients	Total control	SSI	NO SSI	% infection	Total drain	SSI	No SSI	% infection	CI 95% P value
Present study	2018	76	36	25	11	69.44	40	5	35	12.5	0.0001
Shaffer et al²⁰	1987	194	92	10	82	10.9	102	11	91	10.8	0.985
Fujii et al¹²	2011	79	44	17	27	38.6	35	5	30	14.3	0.017
Imada et al²¹	2013	282	131	8	123	6.1	151	8	143	5.3	0.770
Tochika et al²²	2011	100	70	12	58	17.1	30	0	30	0.0	0.016
Cardosi et al²³	2006	144	77	15	62	17.5	67	15	52	22.4	0.668
Baier et al²⁴	2010	200	100	9	91	9	100	10	90	10	0.809
Tsujita et al²⁵	2012	149	88	14	74	15.9	61	2	59	3.3	0.014
Kozol et al²⁶	1986	98	45	4	41	8.9	53	6	47	11.3	0.692
Farnell et al²⁷	1986	1618	803	41	762	5.1	815	45	770	5.5	0.709

Tsujita et al, conducted study on 149 patients.²⁶ 88 cases are taken as control group and no drain was placed. 14 cases developed SSI and in 74 patients there is no evidence of SSI. In 61 cases drain was placed and only 2 patients developed SSI and in rest 59 cases no evidence of SSI with percentage infection of 3.3%. P value of the study is 0.014 (Table 5).

In our study total number of patients who has given consent are 76. Total number of patients taken as control group is 36, among which no drain is placed. 25 patients developed surgical site infection, Southampton Grade 2 SSI in 3 cases, Grade 3 in 15 cases and Grade 4 in 7 cases.

1 patient out of 7 patients who developed grade 4 infection landed up with wound dehiscence and herniation of bowel. Patient was taken up for emergency surgery and was underwent reduction of bowel contents with repair of rectus sheath and closure of subcutaneous tissue and skin.

Total numbers of patients with drain are 40.35 patients with drain have no evidence of surgical site infection. 1 patient developed grade 1 infection, 2 patients developed grade 2 infection and 2 patients developed grade 3 infection.

Our study results are comparable with studies done by Fujii and Tsujita and the probability value is significant in our study.^{12,26}

Postoperative stay in patients with drain is less compared to patients without drain. But the probability is not significant in case of postoperative stay in our study. Overall mean postoperative stay in patients with drain is 5 to 15 days. Postoperative stay in patients without drain is 5 to 20 days.

Incisional SSI has some of the following causes: bacterial load, hematoma formation, subcutaneous fusion, subcutaneous dead space, and local ischemia of the skin or subcutaneous tissue.

In addition to suturing the dermiclayer and sufficient irrigation of the wound, the use of the subcutaneous negative pressure drain was effective in reducing the incidence of incisional SSI not only because of the continuous suction of the subcutaneous effusion, hematoma, and bacteria, but also because of reduction in the subcutaneous wound area dead space.

CONCLUSION

Subcutaneous negative pressure significantly reduces the post-operative surgical site infection.

Subcutaneous negative pressure drainage also reduces duration of postoperative stay following emergency laparotomy.

Aggressive wound management, often involving multidisciplinary approach, will reduce the incidence of wound sepsis and its associated morbidity and costs.

This study method having no impact on mortality, shows improved rate of recovery, less SSI and finally decreased morbidity in terms of hospital stay.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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