

An Experience With and Without Insertion of Subcutaneous Wound Drain in Stomal Reversal

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ABSTRACT

Objectives: To evaluate the outcomes of SSI with or without Subcutaneous suction drain in ileostomy closure.

Study Design: Interventional randomized control trial study.

Place and Duration of Study: This study was conducted at two Units of Surgery at tertiary care academic hospitals of Liaquat University of Medical & Health Sciences Jamshoro (LUMHS) and People's University of Medical & Health Sciences, Nawabshah (PUMHS) from February 2013 to March 2016.

Materials and Methods: 140 patients of both genders from 16-60 years in age, who underwent for elective open reversal of protective Ileostomy were enrolled in this prospective interventional randomized control trial (RCT) study after having informed consent to participate as per described policy. Patient having ASA of group III or malignancy were not enrolled in this study. Study population was divided into two A and B groups based on having or not having insertion of SD respectively. The simple randomization for probability of sampling was achieved. While samples were of equal size of 70 each to maintain the balance. Follow up at 10th day after discharge then fort-nightly for 3 months.

Results: In this plot of 140 patients, 12 (8.57%) males and 5 (3.57%) female developed wound infection in general. While, the incidence of SSI in group B (without SD) was 20% (14/70) and 4% (03/70) in group A (with SD). Anastomosis leak was observed only in B group. The median post-operative hospital stay was 14 (range, 9-42 days) in B group and 12 days (range, 8-27 days) in group A. There were hospital re-admission in 03 patients of B group, with no mortality in any group. However, the incidence of SSIs when comparing both groups (group B versus group A), did reach statistical significance of $P < 0.38$.

Conclusion: We believe that SD has potential benefit in high risk patients and patients with deeper subcutaneous fat in closure of ostomy wounds.

Key Words: Subcutaneous wound drains, Ileostomy reversal, Post-operative wound infections

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INTRODUCTION

An ever-changing wound care evolves from pre-history to modern science, in ancient times the necessity of hygiene was realized with development of new concept of surgery, and in the 19th century the germ theory (microbiology) and cellular pathology assisted in improvement of wounds¹.

Surgical fecal diversion of any loop of intestine brought to anterior abdominal wall is called ostomy in field of surgery². There are many surgical and traumatic entities where temporary ileostomy is used to save unwanted complications and retain the optimal fitness of³.

Surgical site infections (SSIs) are defined as wound infection after surgical procedure, and are associated with ill-defined situation of surgical site.⁵ The medical literature is replete with postoperative complications of reversal of ileostomy standing upto 40%.⁶ The incidence of wound infection following ileostomy closure ranges between 2 and 41% as has reported by different studies.⁷

Wound infections utilizes health care system with unwanted morbidity with more hospital stay in patients who developed SSI.⁸

An adequate treatment of SSI can be achieved by local drainage, wound cleaning, and antibiotics, but cosmetic results remains unsatisfactory, and is associated with an increased risk of incisional hernias and a prolonged hospital stay.⁹

The antiseptic lines reducing the number of microbes on surgeon and patient been proposed with a view to reduce SSIs and routine became a standard in every surgery²⁵. So drains after surgery are not much rewarding.¹⁰

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The presence of devitalized tissue results in high rates of infections.¹¹ Hence the blood and serous fluids from the wound should be removed by drains before fluids can get infected. This concept is frequently implemented in clinics. Based on this theory, many techniques have attempted to improve SSI rates following ostomy closure. Medical literature identify the reduced rates of SSI after SD placement.^{12,13}

So the aim of this study was to evaluate the outcomes of SSI with or without Subcutaneous suction drain in ileostomy closure.

MATERIALS AND METHODS

140 patients of both genders from 16-60 years in age, who underwent for Elective Open reversal of Protective Ileostomy by two Units of Surgery at tertiary care academic hospitals of Liaquat University of Medical & Health Sciences Jamshoro (LUMHS) and People's University of Medical & health Sciences, Nawabshah (PUMHS) from February 2013 to March 2016 were enrolled in this prospective interventional randomized control trial (RCT) study after having informed consent to participate as per described policy. Patient having ASA of group III or malignancy were not enrolled.

Patient were divided into two cohorts for having SD insertion (A) and no SD insertion (B). While the eligible participants, who came for admission in wards and stood on odd number of study enrollment were assigned in study group A with insertion of SD and other who stood on even number were assigned in group B without insertion of SD. This was maintained through telephone & e-mails between two units and hence, the simple randomization for probability of sampling was achieved. While samples were of equal size of 70 each to maintain the balance.

Interventions

In Both Groups A & B: Prophylactic antibiotic (cefotaxime) 1gm half hour before surgery and afterward according to need. Post-operatively patients received intravenous fluids only and nothing else for 2-4 days. Vital were recorded twice a day. They were also observed for signs of infection or complication on daily basis.

Procedure:

Study Group A: As per SSI protocols, all patients received skin and stomal preparation pre-operatively in wards and intra operative skin antisepsis scrubbing with alcoholic chlorohexidine. After liberation of ileal loops and completion of hand – sewn end to end anastomosis and closure of abdominal muscles, subcutaneous space was irrigated with normal saline and an active negative pressure (Rodevac) continuous suction drain was placed along the entire length of the subcutaneous tissue under raised skin flaps. The exit of the drain was separated from the incision and then skin was re-approximated without tension with interrupted sutures of non-

absorbable polypropylene (Proline-1). Stiches were spaced by every 1cm across the wound. Sterile dressing was applied. While dressing was removed on 2nd post-operative day. While SD was removed on 4-5 days.

Control Group B: Above all the same procedure except subcutaneous drain.

Discharge: When condition was satisfactory

Outcomes observation duration: 3 Months.

Follow up: At 10th day after discharge then fort-nightly for 3 months.

Measurable Outcomes Indices:

1. SSI
 - a. Inflammation (Pain, swelling, tenderness).
 - b. Exudate.
2. Fever.
3. Length of hospital stay (days).
4. Incisional hernia.
5. Disruption of anastomosis.

Statistical Analysis: was performed using SPSS software version 18.0 (SPSS Inc. Chicago Illinois) for windows ordinal variable were analyzed using X² test, nominal variable were analyzed with fisher exact test, and P < 0.05 was set for statically significance.

RESULTS

A total of 146 patients met the inclusion criteria, 06 patients were drop out in follow up, hence, remaining 140 patients included from both hospitals in this study analysis.

Table No. 1: Basic characteristics of demographics, age, gender, body mass index

Characteristics/Patient Factors	Group B	Group A
Sex n (%)		
Male	42	46
Female	28	24
Age Years Median	43	44
Range	(20-57)	(24-58)
ASA (n %) I	46	48
ASA (n %) II	24	22
BMI, Kg/m ² Median	23.1 (15.3-28.5)	24.1 (17.4-30.2)
Diabetes Mellitus No	66	63
Diabetes Mellitus Yes	04	07
Reasons of Ileostomy	40	43
Typhoid Perforation		
Trauma	14	12
Others / (volvulus, TB, Adhesions)	16	15
Surgical approach		
• Closure of ileostomy site	68 02	67 03
• Re-Laparotomy		

Table No. 2: Objective outcomes in two groups.

Outcomes	Group B	Group A
Fever	16	10
SSI	14 (20%)	03 (4%)
Length of hospital stay	14 (9-42)	12 (8-27)
Disruption of anastomosis	03	00
Incisional hernia	03	00

Table No. 1 displays the basic characteristics of demographics, age, gender, body mass index, pre-operative comorbidities, ASA scores, reasons of protective ileostomies and types of surgical approaches. In both groups the experience of operating surgeons were more than 15 years.

In Group A, the mean age was 44 years (ranges, 24-58) in 46 (66%) of males and 24 (34%) of females.

In Group B, the mean age was 43 years (ranges, 20-57) in 42 (60%) of males and 28 (40%) of females.

In General, (Both groups) regarding co-morbidities 11 (7.85%) patients were Diabetic. According to American society of Anesthesiologists score 94 (67%) patients were in physical status II, while rest (46 / 33%) patients were in score III. Among these 140 patients the most common (83 / 59%) of protective ileostomy was typhoid ileal perforation.

After reversal of ileostomy, closure of wound was through ileostomy site in 135 and re-laparotomy in 05 patients respectively. There were hospital re-admission in 03 patients of group B and

While the Table No. 2 compares the objective outcomes (aims of study) in two groups.

In this plot of 140 patients, 12 (8.57%) males and 5 (3.57%) female developed wound infection in general. Out of these 17 patients six were diabetic. Among these six Diabetics, all 04 were from group B and two were from group A.

While, the incidence of SSI in group B (without SD) was 20% (14/70) and 4% (03/70) in group A (with SD). Anastomosis leak was observed only in B group.

The median post-operative hospital stay was 14 (range, 9-42 days) in B group and 12 days (range, 8-27 days) in group A.

There were hospital re-admission in 03 patients of B group, with no mortality in any group.

DISCUSSION

This study is attempted to report on the clinical experience between two groups having SD (B) and NO SD (A) in wound after reversal of protective ileostomy and describe the comparison of outcomes as mentioned in table No. 2. The number of studies investigating the effectiveness of SD currently limited.¹⁴⁻⁶

In spite of growing emphasis on patients outcomes still there are many unwanted complications resulting in unfavorable results.¹⁷ Among these complications, SSI is the most serious infections complication associated with rates of re-operation, prolonged hospital stay with

increased costs and discomfort to patient.¹⁸ While the current practice in surgery does not commonly approve the use of SD in wounds post operative. It is general thought that SSIs are related to number of bacteria, pool of effusion and hematoma in wound, subcutaneous dead space and altered local circulation. So the SD drains are still common in practice to remove the exudates and reduce the accumulation of inflammatory mediators at resource limited hospitals. The incidence of SSI in our study was 4% in patients with SD drains and 20% in patients having No drains. Several studies¹⁹⁻²¹ have reported SSI rates similar to what is demonstrated by our study.

Different studies have placed different rates of SSI with different procedures of ileostomy closure.²²⁻²⁴ While Higson and his colleagues found increased rates of SSI in SD group in comparison to no SD controlled cohort. Perhaps, all above mentioned studies²⁵⁻²⁷ are disapproved but others as having small samples in their studies, so we cannot rely on these non randomized quasi trials.

Medical literature again reflects reduction of SSI, when SD are used in emergency contaminated laparotomies.²⁸ While other studies show no remarkable difference with SD versus no SD, however SD helps to reduce SSI in high risk. The other meta-analysis is not supporting the obesity as a major reason for wound. However, despite the pros of SD, there have been conflicting reports in the literature about use of SD.

The length of hospital stay was not much significantly higher in SD group in comparison to other studies. Incisional hernia was observed in patients having no drains, and these findings somehow co-relate with study of Kashimura, et al.¹⁴

CONCLUSION

To aid clearance of SSIs from potentially contaminated cases and reduce high rate of morbidity, we believe that SD has potential benefit in high risk patients and patients with deeper subcutaneous fat in closure of ostomy wounds.

Conflict of Interest: The study has no conflict of interest to declare by any author.

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