

Original Article



Effectiveness of Prophylactic Negative Pressure Wound Therapy in Preventing Post-surgical Wound Infection of Abdominal Wounds Compared to Conventional Dressing; A Randomized Controlled Trial

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ABSTRACT

Objective: To compare the effectiveness of prophylactic negative pressure wound therapy in preventing post-surgical wound infection of abdominal wounds compared to conventional dressings.

Methodology: This randomized controlled trial was conducted in the Department of General Surgery, Unit-1, Pakistan Institute of Medical Sciences Hospital, Islamabad, from September 2020 to February 2021, using consecutive sampling technique. 120 patients who were planned for elective and emergency abdominal surgeries, were randomly divided into two groups by lottery method. In Group A, the negative suction dressing was applied while in Group B, the post-operatively closed incisional wound site was covered with pyodine dressing. Chi-square test was applied for comparison between both groups on the basis of surgical site infection (SSI) occurrence, abscess, wound dehiscence, and seroma formation. Two sample t-test was applied to compare the length of stay across both groups. A p-value of ≤ 0.05 was considered significant.

Results: SSI developed in 13 out of 120 patients during the follow-up period. SSI developed in 5% of patients in group A and 16.7% of patients in group B (p-value=0.04). The mean length of hospital stay was 9.1 ± 2.9 days in group A compared to 11.2 ± 5.9 days in group B (p-value=0.02). Both groups had no significant difference in abscess formation, seroma formation and wound dehiscence.

Conclusion: The rate of SSI was significantly lower, and the mean length of hospital stay was significantly shorter in patients who were administered negative pressure wound therapy (NPWT) compared to those who were applied with conventional dressing with pyodine.

Keywords: Laparotomy, Negative-Pressure Wound Therapy, Surgical Wound Infection, Surgical Wound Dehiscence, Seroma,

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Introduction

Surgical site infections (SSI) occur within thirty days of surgery or one year after implant placement.¹ They have become a matter of global concern after emerging as the most common healthcare-associated infection, and they tend to increase a patient's stay in the hospital or can lead

to morbidity.² SSIs are also known to increase the risk of mortality among patients who suffer hospital-acquired infections by eleven times.³ In lower-middle-income countries like Pakistan, the additional cost associated with SSI can reach up to thirty thousand dollars per patient.⁴

The most common organisms isolated from the infection sites include E-Coli, Bacteroides, Streptococcus

pneumoniae and *Pseudomonas*.⁵ Surgical site infection produces many early complications for patients as it may cause sepsis, wound dehiscence, cellulitis and delayed complications like wound contractures and incisional hernia.⁶ As compared to other forms of surgery, abdominal surgery has substantially higher rates of post-operative infections at surgical sites with an incidence ranging from 15% to 25%.⁷

SSIs can be prevented if appropriate techniques are used.⁸ Various wound closure methods have been developed to decrease the risk of SSIs like delayed primary closure, subcutaneous drain placement with or without irrigation, and loose dermal approximation with staples and wicks.⁹ As a standard, after primary closure of the wound, conventional dressings are applied to the wound consisting of pyodine-soaked gauze pieces however a newer dressing technique is now being applied at the wound site which is known as negative suction dressing (NSD). In the previous literature, a forty percent reduction in the incidence of SSIs was reported after using this newer technique.¹⁰

NSD is applied for 3 to 5 days. A drain is placed between folds of sterilized foam, and the wound is air-sealed with a fine transparent dressing (opsite). This design helps to remove serous fluid from the wound continuously and thus promotes neo-vascularization and decreases bacterial stasis at the wound site which leads to rapid wound healing hence reducing the incidence of SSIs.¹¹

It has been claimed in the literature that Negative-pressure wound therapy (NPWT) reduces the incidence of surgical site infection in different types of surgeries, but there are very few prospective randomized trials to assess its role in abdominal surgeries.¹² At the international level, recently a meta-analysis based on eleven randomized control trials was conducted in Switzerland which reported that prophylactic use of negative pressure wound therapy was effective in reducing the incidence of post-op infection of the surgical site in abdominal operations.¹³ At the national level, a randomized trial to assess the role of NPWT in soft tissue injury of the foot and a quasi-experimental study that evaluated the effectiveness of vacuum-assisted closure for open wounds, were found..^{14,15}

It has been found that the occurrence of surgical wound infections is affected by the types and modes of surgery, patient profiles, and different hospital-related factors.¹⁶ The current study was carried out to compare the effectiveness of NPWT in preventing post-surgical wound infection of abdominal wounds compared to conventional

dressings using a randomized control design in order to bridge the gap in the literature in the national context.

Methodology

This Randomized Controlled Trial was conducted in the Department of General Surgery, Unit-1, Pakistan Institute of Medical Sciences Hospital, Islamabad, for a duration of six months i.e. from September 2020 to February 2021. Sample size calculated by using WHO sample size calculator considering the level of significance to 5%, power of test to be 80%, anticipated population proportion (Rate of SSI in NPWT group) P1 as 38% and anticipated population proportion (Rate of SSI in control group) P2 as 56%.¹⁷ Sample size was calculated to be 60 for each group and so a total of 120 patients were included in the study. Non-probability consecutive sampling technique was used for enrollment of subjects in the study. The patients included in our study were either male or female of age between 13 and 60 years who were about to have any kind of emergency or elective abdominal surgery while the patients who were pregnant or were on ventilatory support or had history of poly-trauma, diabetes or any severe systemic disease, were excluded from the study.

Ethical permission to conduct this study was granted by Ethical Review Board and Advanced Studies and Research Board of Shaheed Zulfiqar Ali Bhutto Medical University vide letter No. F.1-1/2015/ERB/SZABMU/446, dated 23-7-2019, data collection was initiated. All patients presenting to out-door or emergency departments of the surgical unit-1, fulfilling the inclusion criteria were recruited in this study. Data was collected about patient's age, gender, mode of disease and type of intervention done. Informed consent was taken from each patient and they were divided into two groups by lottery method i.e. Group A (with negative suction dressing) and Group B (with conventional dressing). After admission, all baseline investigations and work up according to elective or emergency surgery protocol was done including CBC, PT/APTT, Urea and Electrolytes, Ultrasound of abdomen and pelvis with x-ray or CT scan was done. After abdominal surgery, incisional site was closed primarily in both groups.

In Group A, negative suction dressing was applied over closed incisional wound. redivac drain of 16 FR size was placed between two layers of sterilized foam and was placed over the incisional wound which was already closed by non-absorbable sutures or skin staples. Drain was connected to centrally mounted suction apparatus from "NISSHIN, MEDICOP or HEYER", in surgical wards.

Foam was made air tight by applying "OPSITE" dressing over it. Depending upon patient's tolerance, suction apparatus was set to give intermittent pressure between 0 to -30 kPa. It was applied for 3-5 days and later on wound infection will be assessed. In Group B, post operatively closed incisional wound site was covered with pyodine dressing and left in place for 3 days. Wound was assessed for infection after 3 days. Pyodine dressing was applied daily later on after 3 days.

All patients were treated post operatively with intra venous antibiotics for 5-7 days and patients in both groups were followed at 2nd, 3rd and 4th week post operatively on OPD basis after being discharged. At each visit wound was assessed and patients who failed to follow-up were contacted on Telephone. Primary outcome measure was surgical site infection (SSI) and secondary outcome measures were length of hospital stay and other complications like seroma formation, abscess formation and wound dehiscence.

Data was entered and analyzed using SPSS version 21. Qualitative variables included gender, SSI occurrence, abscess, wound dehiscence, seroma formation which were presented in the form of frequency and percentage. Quantitative variable of age was expressed in terms of mean and standard deviation. Chi-square test was applied to compare efficacy between both groups. Two sample t-test was applied to compare length of stay across both groups. A p-value of ≤ 0.05 was considered significant.

Results

There were 39 (65%) males and 21 (35%) females out of 60 participants in group A and 25 (41.7%) males and 35 (58.3%) females out of 60 patients in group B. Mean age of group A patients was 36.1 ± 13.7 years while for group B patients was 40.8 ± 10.8 years. Most frequent surgeries carried out were of stomach and small gut (53.3%) and more than sixty percent of the surgeries were emergency procedures.

During the follow up period SSI developed in a total of 13/120 (10.8%) patients. Across both groups, SSI developed in 5% (3/60) patients in group A and in 16.7% (10/60) patients in group B (p-value=0.04) as shown in Table I. Patients who underwent large gut surgeries were the most affected as 33.3% of them developed post-op SSI. The most frequent organism isolated from the infected wounds was E. coli (53.8%) as shown in Table II.

Table 1: SSI in both groups.

SSI	GROUPS		Total	p-value*
	NPWT	Conventional Dressing		
Present	3(5.0%)	10 (16.7%)	13	10.8%
Absent	57(95.0%)	50(83.3%)	107	89.2%
Total	60(100.0%)	60(100.0%)	120	100.0%

*Chi-square

Table II: Pathogens isolated from cultures of SSI positive patients.

TYPE OF PATHOGEN	N	%
E. COLI	7	53.8
S. AUREUS	3	23.1
PSEUDOMONAS	1	7.7
NO GROWTH	2	15.4
TOTAL	13	100.0

Table III: Comparison of Length of stay across both groups.

GROUPS	MEAN \pm SD LOS (DAYS)	p-value*
NPWT	9.1 \pm 2.9	
Conventional Dressing	11.2 \pm 5.9	0.02

* t-test

As shown in Table III, the mean length of hospital stay was greater in the group with conventional dressing i.e. 11.2 ± 5.9 days (p-value=0.02). No significant difference was observed in abscess formation, seroma formation and wound dehiscence in both groups at week 2 and 3 after the surgery ($p>0.05$). At week 4, no new complication was observed in both the groups as shown in Table IV.

Discussion

Our study aimed to assess the effectiveness of prophylactic negative pressure wound therapy in preventing surgical site infections in abdominal surgeries in terms of prevention of occurrence of SSI, reduced length of hospital stays and occurrence of other complications as compared to conventional dressings. Our results showed that rate of SSI was significantly lower (5% vs 16.7%, p-value=0.04) and the mean length of hospital stay was significantly shorter in patients who were administered with NPWT as compared to those who were applied with conventional dressing (9.1 days vs 11.2 days, p-value=0.02) and there was no significant difference in rate of complications

Table IV: Abscess, wound dehiscence and seroma at week 2 and 3.

			Group		p-value*
			NPWT	Conventional Dressing	
				total	
WEEK 2	ABSCESS	Present	8 13.3%	14 23.3%	22 18.3%
		Absent	52 86.7%	46 76.7%	98 81.7%
	WOUND DEHISCENCE	Present	3 5.0%	0 .0%	3 2.5%
		Absent	57 95.0%	60 100.0%	117 97.5%
WEEK 3	SEROMA	Present	0 .0%	1 1.7%	1 .8%
		Absent	60 100.0%	59 98.3%	119 99.2%
	ABSCESS	Present	0 0%	3 5.0%	3 2.5%
		Absent	60 100.0%	57 95.0%	117 97.5%
	WOUND DEHISCENCE	Present	2 3.3%	3 5.0%	5 4.2%
		Absent	58 96.7%	57 95.0%	115 95.8%
	SEROMA	Present	0 .0%	1 1.7%	1 .8%
		Absent	60 100	59 98.3%	119 99.2%

across both groups ($p>0.05$). The most frequent organism isolated was *E. coli*.

Several studies have reported incidence of SSI in patients undergoing abdominal surgeries. Alkaaki A et al described the incidence, pathogens involved and associated risk factors for SSI in patients undergoing abdominal surgery. Their follow up period (30 days) was similar to our study. They reported that the overall incidence of SSI was 16.3% (55/337). The most common bacteria isolated were extended-spectrum β -lactamase-producing *Escherichia coli*. They further demonstrated that open surgical approach, prolonged duration of surgery and emergency surgeries were the predictors of SSI.⁷

In a recent systematic review, Danwang C et al estimated the incidence of SSI after appendectomy at global and regional levels. They included a total of 226 studies from 49 countries comprising of 729 434 participants in their meta-analysis. They found an overall incidence of SSI of 7.0 per 100 appendectomies. They further highlighted a high burden of SSI after appendectomy in low-income countries.⁹

Tovar JR et al in another recent study on abdominal surgeries reported that incisional SSI was observed in 12.9% of patients.¹⁸ Chowdhury S et al also determined the incidence of SSIs after trauma laparotomy in Saudi population. They reported that a total of 9 out of 70 (12.9%; 95% confidence interval (CI): 6.9-22.7%) patients developed SSI and most cases were diagnosed within one week during the hospital stay.¹⁹

Several studies have reported efficacy of NPWT in terms of reduction of SSI rate after open abdominal surgeries. Using prophylactic negative pressure dressing for closed abdominal wounds after repair of ventral hernia can considerably lower the frequency of post-op infection at surgical site according to a meta-analysis done in China involving 1355 patients.²⁰ In Switzerland, a meta-analysis based on eleven randomized control studies found that using negative pressure wound care as a preventative measure also decreased the likelihood of surgical site infection after abdominal surgeries.¹³

The prophylactic use of negative pressure wound dressing has been assessed in different types of surgeries. A study conducted in Ireland based on 1500 breast incisions reported that prophylactic use of NPWT was related

to significantly fewer surgical site sequelae, such as SSI, seroma, wound dehiscence, and wound necrosis for closed breast incisions, as compared to traditional dressings.²¹ Another meta-analysis conducted in Ireland related to incidence of infections of groin wound site after vascular surgeries reported a protective effect of negative pressure dressings.²² The prophylactic use of negative pressure dressing after cesarean section among 5586 obese Chinese women has also been assessed in a meta-analysis and it was found to be associated with a significant decrease in frequency of post-op surgical site infections.²³

Some studies in the literature showed contrasting results. Murphy PB et al in a randomized controlled trial determined if NPWT reduces SSI in primarily closed incision after open and laparoscopic-converted colorectal surgery. They demonstrated that prophylactic use of NPWT was not associated with a decrease in SSI rate when compared with standard gauze dressing.²⁴ Another RCT conducted in Korea reported that there was no effect of use of negative pressure dressing as compared to traditional dressings in terms of reduction of SSI and number of days required for a patient to be hospitalized after stoma reversal surgery.²⁵ These contrasting results may be attributed to the fact that there is significant heterogeneity across the studies primarily in terms of patient selection criteria and infection control practices.

The results of our study have established NPWT as an effective wound management strategy as it reduces the incidence of SSIs with minimal complications and hence leads to shorter hospital stays. Pakistan is a lower-middle income country so cost-effective interventions are a need of our healthcare system so that it can serve more patients within the limited available resources. Our study attempts to explore the use of such an intervention in patients requiring surgeries, as surgeries are costly affairs.

While advising wound management strategies, surgeons should consider patient-specific factors such as wound type and patient co-morbidities as it is better to use NPWT at an early stay as this prevents the occurrence of further complications and improves patient outcomes. This leads to reduction in financial burden on both the patients and the country's healthcare system. A Shorter hospital stay also improves patient satisfaction with treatment and reduces exposure to other hospital-acquired infections.

Our study has some salient features. Firstly, it was designed as a prospective randomized controlled trial with stringent inclusion/exclusion criteria. Secondly, we assessed the patients at multiple follow-ups (1 week

interval over the period of one month) that enabled us to monitor effects of therapy and overall wellness of enrolled subjects at different time intervals. The present study also has some limitations. We feel the sample size was relatively smaller, yet sufficient to draw the inference and secondly, we did not stratify high-risk patients for developing postoperative SSI for enrollment purposes. Finally, we did not take into account the cosmetic outcomes and overall patient satisfaction with NPWT. We suggest future studies with larger sample size and taking into account appropriate risk stratification of enrolled patients. We also suggest to explore further into cosmetic outcomes and overall patients' satisfaction for NPWT.

Conclusion

Rate of SSI was significantly lower and the mean length of hospital stay was significantly shorter in patients who were administered with NPWT compared to those who were applied with conventional dressing. There was no significant difference in abscess formation, seroma formation and wound dehiscence during the follow up period in both the groups.

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