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Original Article

Role of Prophylactic Negative Pressure Dressings in Determining the Surgical Site Infection (SSI) on Closed Laparotomy Wounds in Abdominal Surgery: Randomized Controlled Open Label Trial: Vacuum Assisted Closure (Vac) Trial in a Tertiary Care Setup

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ABSTRACT

Background: Surgical site infections (SSIs) continue to pose a significant challenge in postoperative care, particularly in abdominal surgeries, due to their prevalence and the associated increase in morbidity, mortality, and healthcare costs. Despite advancements in surgical techniques and aseptic measures, the incidence of SSIs remains high, underscoring the need for innovative preventive strategies.

Objective: This study aims to evaluate the efficacy of vacuum-assisted closure (VAC) dressings compared to standard dressing methods in reducing the incidence of surgical site infections in patients undergoing closed laparotomy wounds in abdominal surgeries.

Methods: A randomized controlled trial was conducted over six months at Civil Hospital Karachi, involving 116 patients undergoing abdominal surgeries. Participants were randomly assigned to receive either the VAC dressing or standard dressing postoperatively. The primary outcome measured was the incidence of SSIs within 30 days post-surgery, evaluated using the CDC classification and Southampton wound grading system. Data were analyzed using SPSS version 25.0, employing descriptive statistics, independent t-tests, and Chi-square tests for continuous and categorical variables, respectively.

Results: The VAC group demonstrated a significantly lower incidence of SSIs (13.8%) compared to the non-VAC group (96.6%), with statistical significance ($p < 0.001$). Age and BMI showed significant differences between the groups; patients in the VAC group were younger (mean age 30.84 ± 10.71 years) and had a lower BMI (mean 19.69 ± 4.16 kg/m²) compared to the non-VAC group (mean age 37.31 ± 12.83 years, mean BMI 22.07 ± 4.41 kg/m²). The duration of surgery and length of incision did not significantly differ between the groups.

Conclusion: The use of vacuum-assisted closure dressings significantly reduces the incidence of surgical site infections in abdominal surgery patients, offering a superior alternative to standard dressings. This method not only enhances patient outcomes but could also lead to a reduction in healthcare costs by minimizing complications associated with SSIs.

Keywords: Surgical Site Infections, Vacuum-Assisted Closure, Negative Pressure Wound Therapy, Abdominal Surgery, Randomized Controlled Trial, Postoperative Complications, Wound Management.

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INTRODUCTION

Surgical site infections (SSIs) are a major concern in postoperative patient care, significantly contributing to increased morbidity and mortality despite advancements in aseptic techniques and sterile surgical environments. These infections exacerbate the public health burden, leading to higher healthcare costs associated with prolonged hospital stays, additional diagnostic tests, antibiotic treatments, and sometimes further surgical interventions (1). Given that SSIs can occur at rates of 20% to 30% following high-risk surgeries, there is a pressing need for innovative measures to reduce these infections. One promising approach that has emerged is Negative Pressure Wound Therapy (NPWT), also known as vacuum-assisted closure (VAC), which has shown effectiveness in both clean-contaminated and clean or contaminated surgical wounds (2). NPWT has demonstrated a substantial reduction in superficial incisional SSI rates, with a decrease from 32% to 8.3% in SSI incidence at 30 days post-operation in the treatment group compared to the control group (1-3).

The World Health Organization's SSI Guidelines endorse the prophylactic use of incisional NPWT for patients with high-risk surgical wounds, though without specific recommendations for different types of surgeries. The VAC system consists of a sponge or filler material, an adhesive drape, a connecting tube, and a fluid collection canister, and has been used effectively not only in abdominal surgeries but also in managing incisional wounds following lower extremity fractures and sternotomy wounds in obese patients, significantly lowering SSI rates (4-7). The development of controlled suction through open-cell foam in 1997 by Dr. Louis Argentina and Dr. Michael Morykwas marked a pivotal advancement in the evolution of NPWT, enhancing blood flow to the wound area and promoting angiogenesis and collagen fiber synthesis, which facilitate neovascularization and improve tensile strength during the healing process (8-10).

Despite these promising outcomes, the literature reveals a lack of consensus regarding the efficacy and best practices of NPWT. This divergence underscores the necessity for further research to determine the optimal use of NPWT, especially in the context of closed laparotomy wounds in abdominal surgery. This study aims to compare the incidence of SSIs in closed laparotomy wounds treated with prophylactic negative pressure dressing versus standard dressing, to provide definitive evidence on the efficacy of NPWT. By doing so, it seeks to rationalize wound management strategies in clinical practice, ensuring that future surgical interventions are guided by evidence-based methodologies that prioritize patient safety and outcome optimization.

MATERIAL AND METHODS

To address the prevalent issue of surgical site infections (SSIs) in abdominal surgeries, a rigorous randomized controlled trial was conducted over a six-month period, from June 19, 2020, to December 19, 2020, at Civil Hospital Karachi, within the Surgical Wards I-VI. This study aimed to compare the efficacy of prophylactic negative pressure dressings versus standard dressing methods in reducing the incidence of SSIs in patients with closed laparotomy wounds. Utilizing a non-probability consecutive sampling method, the sample size was determined using the WHO sample size calculator based on parameters from a critical reference, which reported SSI incidences of 8.3% and 32% for prophylactic negative pressure and standard dressings, respectively. Aiming for a power of 90% and a significance level of 5%, the required initial sample size was calculated to be 96 patients. Anticipating potential attrition, this number was increased by 20%, resulting in a total of 116 patients, divided into two groups of 58 each (11-13).

Participant inclusion criteria were selective, targeting a demographic of both genders aged 18 to 60 years, undergoing emergency midline laparotomy for clean-contaminated and contaminated wounds classified as ASA grades I and II. Exclusion criteria were stringent, disqualifying individuals with dirty wounds, a BMI of ≥40, an ASA grade of >3, more than two significant comorbidities, the presence of fistulae, or those undergoing treatment with corticosteroids, immunosuppressants, chemotherapy agents, and radiotherapy. Data collection commenced at the ER and OPD, where eligible patients were invited to participate following the attainment of informed consent, which was obtained after securing ethical clearance from the institutional ethical board in compliance with the Declaration of Helsinki principles (12-16).

The randomization process involved the use of sealed opaque envelopes, which assigned participants to either the negative pressure dressing group or the control group in a non-blinded manner. The intervention entailed the application of VAC dressings, ensuring an airtight seal around the wound with waterproof adhesive tape, whereas the control group received standard saline-soaked gauze dressings. All patients were administered a prophylactic antibiotic regimen of a third-generation cephalosporin, initiated 30 minutes before incision and continued for four days postoperatively, followed by an oral substitute for the next three days.

Wound assessments were meticulously performed on the 4th, 7th, 15th, and 30th days post-operation using the CDC classification and Southampton wound grading system. Follow-up was extended beyond the hospital through outpatient visits and digital interactions, enabling patients to submit wound images via social media platforms like WhatsApp. Data analysis was conducted using SPSS version 25.0, ensuring rigorous comparability of data between groups. Descriptive statistics summarized both categorical and

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continuous variables, with mean differences in continuous variables like age and BMI analyzed using independent t-tests. Categorical variables such as gender and wound type were compared using the Chi-square test, with a significance level set at $p<0.05$. Further analyses evaluated the impact of confounding variables, enhancing the robustness and breadth of the study's findings. This thorough investigation not only highlighted the relative effectiveness of prophylactic negative pressure dressings but also aimed to contribute significantly to the standardization of practices potentially revolutionizing the management of SSIs in abdominal surgeries.

RESULTS

In the randomized controlled trial conducted to evaluate the efficacy of prophylactic negative pressure dressings, significant differences in several quantitative variables were observed between the non-VAC and VAC groups (Table 1). The mean age of participants in the non-VAC group was higher at 37.31 years with a standard deviation of 12.83, compared to 30.84 years with a standard deviation of 10.71 in the VAC group, yielding a statistically significant p-value of 0.004. The confidence interval for this age difference ranged from 2.12 to 10.81, highlighting a younger demographic in the VAC group. Conversely, the mean heights of the two groups were almost identical, with the non-VAC group averaging 160.36 cm (SD = 14.29) and the VAC group 160.55 cm (SD = 9.93), resulting in a non-significant p-value of 0.934 and a confidence interval from -4.71 to 4.34.

Furthermore, the weight and BMI of participants also differed significantly. The non-VAC group had a mean weight of 55.81 kg (SD = 7.84) compared to the VAC group's mean of 50.53 kg (SD = 10.37), with a significant p-value of 0.003 and a confidence interval for the difference ranging from 1.89 to 8.66. Additionally, the BMI in the non-VAC group averaged 22.07 kg/m² (SD = 4.41) versus 19.69 kg/m² (SD = 4.16) in the VAC group, with a p-value of 0.004 and a confidence interval of 0.77 to 3.97, reinforcing the trend of a healthier weight status in the VAC group.

The duration of surgery and the length of the incision were comparable between the two groups, with no statistically significant differences noted. The mean duration of surgery was 2.37 hours (SD = 0.74) in the non-VAC group and 2.29 hours (SD = 0.73) in the VAC group, with a p-value of 0.565. The mean length of the incision was slightly greater in the VAC group at 16.81 cm (SD = 1.67) compared to 16.63 cm (SD = 1.81) in the non-VAC group, resulting in a p-value of 0.595.

Table 1: Mean Difference of Quantitative Variables with Respect to Group (n=116)

Variables	Non-VAC Group (n=58)	VAC Group (n=58)	p-value	95% CI
Age, years	37.31 ± 12.83	30.84 ± 10.71	0.004	2.12 to 10.81
Height, cm	160.36 ± 14.29	160.55 ± 9.93	0.934	-4.71 to 4.34
Weight, kg	55.81 ± 7.84	50.53 ± 10.37	0.003	1.89 to 8.66
BMI, kg/m²	22.07 ± 4.41	19.69 ± 4.16	0.004	0.77 to 3.97
Duration of Surgery, hours	2.37 ± 0.74	2.29 ± 0.73	0.565	-0.19 to 0.35
Length of Incision	16.63 ± 1.81	16.81 ± 1.67	0.595	-0.81 to 0.47

Table 2: Frequency Distribution of Categorical Variables (n=116)

Variables	Count	Percentage
Age ≤ 30 years	54	46.6%
Age > 30 years	62	53.4%
Male	97	83.6%
Female	19	16.4%
BMI ≤ 25 kg/m²	98	84.5%
BMI > 25 kg/m²	18	15.5%
Incision ≤ 18 cm	99	85.3%
Incision > 18 cm	17	14.7%
Diabetes	20	17.2%
Hypertension	45	38.8%
Tuberculosis	1	0.9%
Obesity	1	0.9%
Chronic Renal Failure	0	0%
Clean Contaminated Wound	54	46.6%
Contaminated Wound	62	53.4%

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Table 3: Regression Analysis of Variables Associated with Surgical Site Infection (n=116)

Variables	OR (95% CI)	p-value	aOR (Adjusted OR) (95% CI)	p-value
Group VAC	0.01 (0.01-0.03)	<0.001	0.01 (0.01-0.03)	<0.001
Age ≤ 30	0.44 (0.21-0.93)	0.031	0.31 (0.07-1.28)	0.106
Male	2.44 (0.88-6.74)	0.085	-	-
BMI ≤ 25 kg/m²	0.42 (0.14-1.26)	0.121	-	-
Duration of Surgery ≤ 2 hours	0.60 (0.28-1.26)	0.178	-	-
Diabetes	1.27 (0.47-3.38)	0.634	-	-
Hypertension	1.86 (0.87-4.01)	0.112	-	-
Clean Contaminated Wound	1.33 (0.63-2.79)	0.458	-	-

In terms of categorical variables, the distribution of age, gender, BMI, and the length of the incision showed varied trends (Table 2). Approximately 46.6% of participants were aged 30 years or younger, with a slightly higher prevalence of older participants. The majority of participants were male (83.6%), and most had a BMI of 25 kg/m² or less (84.5%). The length of the incision was less than 18 cm for 85.3% of participants, indicating a consistency in surgical practices across the cohort.

Regression analysis provided further insights into factors associated with surgical site infection (Table 3). The odds of developing an SSI were significantly reduced in the VAC group with an odds ratio (OR) of 0.01 and a confidence interval spanning 0.01 to 0.03, which was statistically significant ($p < 0.001$). Age was also a notable factor; participants aged 30 years or younger had a lower risk of SSI compared to those older than 30, although the adjusted odds ratio showed a broader confidence interval, reducing the significance ($p = 0.106$). Other variables such as gender, BMI, and the presence of comorbid conditions like diabetes and hypertension did not show a statistically significant association with SSI risk in the adjusted model.

These results collectively highlight the potential benefits of prophylactic negative pressure dressings in reducing the risk of SSIs among patients undergoing abdominal surgeries, particularly noting the importance of age and operative care standards in influencing outcomes.

DISCUSSION

The exploration of surgical site infections (SSIs) within abdominal surgeries has been a significant focus in studies of postoperative complications, largely due to their prevalence and considerable impact on patient outcomes. In this study, a pronounced reduction in SSIs was observed among patients treated with vacuum-assisted closure (VAC) compared to those using standard dressings. Specifically, the incidence of SSIs was markedly lower in the VAC group, with only 8 (13.8%) of patients affected, versus 56 (96.6%) in the non-VAC group, highlighting the effectiveness of prophylactic negative pressure dressings in mitigating infection risk.

The favorable outcomes associated with the immediate application of VAC following injury or surgical debridement are well documented in the literature. For example, Banwell et al. have noted significant benefits in acute and traumatic wounds when VAC is used, suggesting dressing changes every 4–5 days or more frequently if signs of infection are evident (11). Similarly, Mullner et al. reported an 80% reduction in the size of pressure sores and soft tissue injuries under VAC treatment, which facilitated early grafting (12). These findings are consistent with those of the current study, reinforcing the efficacy of VAC in promoting wound healing and reducing infection rates.

The practice of delayed primary suture in highly contaminated surgeries was revisited, highlighting its viability in reducing SSI rates. This approach aligns with experimental evidence suggesting significant reductions in infection and mortality rates (13-15). The utility of NPWT, particularly in deep sternal wound infections (DSWI), has demonstrated a decrease in early reinfections and a reduction in hospital stay length, further aligning with the observed outcomes in the current investigation (16,17).

Despite the compelling evidence supporting NPWT, it is important to acknowledge observed side effects, such as blisters at the foil to skin contact points, which are attributed to tension during OPSITE application rather than the NPWT itself, and typically resolve without further complications (18). The integration of NPWT in closing high-risk incisions has been praised for its low SSI rates, cost-effectiveness, and manageability, benefiting both patients and healthcare staff (19,20).

The current study's findings also elucidated the mechanics behind NPWT's success; by compressing the wound and eliminating dead space, NPWT acts as a splint to minimize shearing forces, thereby facilitating early vascularization from the wound bed to the skin flap. This mechanism was further validated by a reduction in hematoma/seroma levels in patients treated with closed incision management (CIM), a variant of NPWT, highlighting its efficiency in preventing fluid accumulation without necessitating canister fluid collection (21).

However, the study is not without its limitations. The restricted study period and the limited sample size may impact the generalizability of the findings. Moreover, certain significant variables that have been reported in previous studies were not examined, suggesting that the comprehensive benefits and drawbacks of NPWT could be more extensively explored in future research. This study contributes valuable insights to the growing body of evidence favoring NPWT and paves the way for future large-scale, multicenter studies. Such investigations are crucial to validate these findings and potentially revolutionize postoperative care through the widespread adoption of NPWT in managing surgical wounds, particularly in abdominal surgeries where the risk of SSIs remains a pressing concern. In conclusion, this research conclusively demonstrates that the application of vacuum-assisted closure significantly reduces the incidence of surgical site infections in abdominal surgery patients compared to standard dressing methods, thereby highlighting the superior efficacy of prophylactic negative pressure dressings in minimizing postoperative complications and enhancing patient recovery outcomes.

CONCLUSION

This study conclusively demonstrates that the use of vacuum-assisted closure (VAC) significantly reduces the incidence of surgical site infections in patients undergoing abdominal surgery, compared to standard dressing methods. By dramatically lowering infection rates, VAC not only enhances patient recovery outcomes but also holds the potential to decrease healthcare costs associated with prolonged hospital stays and additional treatments. These findings advocate for the broader adoption of prophylactic negative pressure dressings in surgical practices, suggesting a substantial improvement in postoperative care and patient safety across healthcare systems.

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