Section: General Surgery

Original Research Article

A RANDOMIZED CONTROLLED TRIAL ON COMPARISON OF INNOVATIVE VACUUM-ASSISTED WOUND DRESSING AND CONVENTIONAL DRESSING ON WOUND HEALING IN PATIENTS WITH LOWER LIMB ULCERS

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Abstract

Background: Leg ulcers (LUs), which have a poor prognosis for healing, are a serious healthcare issue. The vacuum-aided closure (VAC) concept offers a fresh approach to treating wounds. The study compares the mean wound healing times and treatment outcomes following VAC and conventional dressing (CD) in patients with lower extremity ulcers. **Materials and Methods:** The surgical department of the government hospital in Thoothukudi was the site of this randomised controlled study, including 50 patients with ulcers in Wagner's Grades 1 and 2 divided equally among two treatment groups. The wound surface area, granulation tissue score, haemorrhage and wound culture sensitivity, and healing time were compared within each group. **Result:** Compared to the standard dressing group, the VAC treatment group's time to wound healing was noticeably faster. Compared to the control group (8.9%), the mean percentage of ulcer shrinking in the study group is higher (24.5%). Compared to the control group (40.28 days), the study group's average hospital stay is shorter (20.6 days). The study group has a higher mean number of bleeding episodes (0.36 days). Only 24 percent of the research group exhibited culture growth, while 76% were without it. The study group showed a lower percentage of culture growth than the control group. In the study group, Staphylococcus aureus and E. coli were the most frequently seen microorganisms. **Conclusion:** VAC treatment helps accelerate wound healing and enhance granulation cover while significantly shortening hospital stays.

INTRODUCTION

Extremity wounds are a frequent source of concern for surgeons. Leg ulcers (LUs) are more prevalent among older people, and as the population's average age rises, so is the likelihood that this trend will continue.[1] The most common causes of LUs are diabetes, neuropathy, venous insufficiency, arterial insufficiency, or a combination of these conditions. Managing delayed wound healing is crucial because it leads to higher morbidity, longer hospital stays, missed workdays, and greater financial burden.[2] Local wound management techniques such as ultrasound, infrared, platelet-rich plasma, Negative pressure wound therapy (NPWT), and vacuum-assisted closure (VAC) can enhance wound healing, especially for reconstructive procedures, acute wounds, and non-healing ulcers.[3] Vacuum-assisted closure dressing is a non-invasive technique for dressing wounds by applying controlled negative pressure. It removes excess fluid, reduces edema, and promotes the formation of granulation tissue to speed up wound healing and prepare the wound bed for transplant.[4]

Diabetes ulcers must be treated using a multimodal strategy that includes effective pressure off-loading, serial debridement, tight glycemic control, and infection management with sensitive antibiotics.[5] Due to the bigger raw area that takes a long time to cover with granulation tissue, healing of diabetic foot ulcers takes longer, even with adequate therapy. Numerous studies have demonstrated the effectiveness of NPWT in treating various wounds, including sternal wounds, open abdominal wounds, burn wounds, diabetic foot ulcers, and venous ulcers. According to this research, granulation tissue forms at higher rates and wounds heal more quickly, reducing the need for additional amputations.[3]

Additionally, NPWT improves patient satisfaction, reduces bacterial burden, and increases safety. Even though NPWT is considered "revolutionary" in the care of DFU, it is described as an "adjunctive" therapy. It is advised to be used if regular wound therapy for four weeks does not improve.[6] Despite the majority of research conducted on Western populations and producing substantial results, the Indian population differs from the Western population in several ways.[7] Due to the early development of complications, such as DFU, in Indian diabetic patients as a result of variations in genetics, lifestyle, culture, socioeconomic status, and health education, research is needed to determine the effectiveness and safety of VAC therapy in the treatment of DFUs in the Indian population.[8,9]

Additionally, in the Indian population, healing-related patient parameters like BMI and albumin and wound features like size and bacteriology are substantially different. The study aimed to compare VAC therapy's effectiveness in treating lower leg ulcers caused by trauma or diabetes to standard dressings at our hospital.

MATERIALS AND METHODS

All patients with lower leg ulcers admitted to the General Surgery wards of the Thoothukudi government hospital were included in the trial after fulfilling the exclusion criteria and providing written informed permission. After initial debridement and after the lesion is declared clean, patients with lower limb ulcers are split into two groups. Fifty patients were divided equally into two groups that received VAC and CD therapies.

Inclusion Criteria

The research comprised diabetic patients (>18 and <70 years of age) admitted to the general surgery ward with lower limb ulcers of Wagner's grades I and II and individuals with all cases of traumatic lower limb ulcers.

Exclusion Criteria

Patients outside the age criteria, Wagner grade 3 and 4 ulcers, and those with peripheral vascular disease, Osteomyelitis, Coagulopathy and Immunocompromised were excluded.

The wound size of both groups is depicted on graph sheets before and after the corresponding dressings. This study complied with the Helsinki Declaration. VAC treatment was administered to patients in the experimental group but not those in the control group. The control group received the normal dressing. Wagner's DFU grade, the patient's history of diabetes (measured in years), the patient's use of insulin, oral hypoglycemic agents, or both before the study, HbAlc, baseline albumin, haemoglobin, BMI, and comorbidities were all taken into account. Albumin and haemoglobin levels were checked daily.

VAC therapy: The suction device positioned on the wall created the Hoover. A 16Fr Ryle's tube is placed inside a sterile sponge. A sterile transparent polyurethane coating sheet was then used to seal the wound. The pressure in the tube was adjusted to 125mm of HG and connected to a suction device mounted on the wall (Figure 1). The dressing was changed every 72 hours. VAC treatment was immediately postponed if the treating surgeon saw anything unexpected throughout the trial or in the case of any unfavourable wound parameters.

CAD therapy: The control group received a typical dressing. After cleaning, a piece of gauze soaked in saline is put over the wound bed. There were two layers of sterile gauze over the dressing. The wound was bandaged using rolling bandages. The dressing was changed daily, and the treating surgeon evaluated the wound every 72 hours to see whether any wound characteristics needed to be modified.

Figure 1: A device used for creating a vacuum in this study – wall-mounted suction apparatus

Patients were monitored until the incision had fully healed. The main outcome parameter was the time it took to finish wound healing. Secondary outcome criteria included bleeding, pain, infection complications, and the creation of granulation tissue. The sensitivity of the wound culture and bleeding between the two groups were compared. An evaluation was conducted every 72 hours, generating a weekly mean value.

The number of times the wound dressing had to be changed was a good indicator of how much blood had seeped into it. Wound culture sensitivity was sent out weekly, and the grown organisms were noted for analysis. Using the ruler, wound surface area was calculated at the start and conclusion of the research, and the difference between the two was used to calculate the decrease in wound surface area. The granulation tissue development rate was calculated by dividing the wound surface area into four quadrants and then using a visual score at the research's start and conclusion. We evaluated the pace of granulation tissue development with the shrinkage of the wound's surface area. To eliminate confounding variables, age, gender, BMI, glycemic control, and other wound characteristics are matched

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across patients in both groups. Statistical analytical tools were used for data gathering and processing.

Statistical Analysis

Microsoft Excel (Windows 10, version 2007) was used to enter the data, and SPSS for Windows (trial version 20; SPSS Inc., Chicago) was used to conduct the analysis. Frequencies and percentages were utilised for categorical variables, and mean and standard deviation were used for continuous variables. For the visual depiction of data, bar charts and pie charts were employed. The chi-square test was employed to determine any associations between two categorical variables. An Independent t-test was used to determine the relationship between the means of the two groups. The significance threshold was set at 0.05.

RESULTS

Among the patients included in the study, 46 percent were in the 45–59 age range. Age greater than or equal to 60 comes next (30%). Only 8% of participants were between 31 and 45, while 16% were under 30. The participants' average age is 50.5 years. The age varied from 18 to 69 years old. Most participants were males (68%), and females comprised only 32% of participants.

Table 1: Etiological parameters

Etiology		Number	Percentage
Cause of Ulcer	Diabetes Mellitus	37	74
	Traumatic	13	26
Affected limb side	Right	25	50
	Left	25	50
Wagner's Grading	I	23	46
	II	27	54

Most individuals in the research and control groups were between 45 and 59. In both groups, this was followed by ≥ 60 years, with 32% in the control group and 28% in the study group. Participants aged < 30 comprised 20% of the study group and 12% of the control group. Only 4% of the control and 12% of the experimental groups were aged 31 to 45.

This age distribution was not significantly different between the two groups. Age-wise, both groups were comparable ($P>0.05$). Male participants comprised the majority in both the research and the control group. Women comprised 36% of the control group and 28% of the study group (Figure 4). This gender distribution was not statistically significant between the two groups, and both groups were comparable ($P>0.05$).

In both the research and the control groups, diabetes was the most common cause of ulcers. Traumatic developed 20% in the control group and 32% in the experimental group. This distribution of ulcer aetiology was not statistically significant for either group. Regarding ulcer causation, both groups were comparable ($P>0.05$). Wagner grade distribution is the same between the two groups. Most (52% and 56%) of the research and control group members were in grade II. Grade I students comprised 44% of the control group and 48% of the research group. This Wagner grade distribution was not statistically significant for either group. The grades Wagner assigned to the two groups were comparable ($P<0.05$).

Comparison of outcome among two groups

After an intervention, the Pus culture has grown differently in both groups. Only 24% of the research group's members had culture growth, whereas the rest (76%) did not. Only 16% of the control group had no culture development, compared to 84% who did. Both groups' distributions of cultural progress were statistically significant. The percentage of culture growth in the study group was lower than in the control group, and this difference was statistically significant ($P<0.001$). Staphylococcus aureus, Streptococcus, and E. coli were among the 76 prevalent organisms discovered in the control group. Klebsiella pneumonia was observed in 3 individuals, while Acinetobacter, Citrobacter, and Pseudomonas aeruginosa were present in 2 individuals. Staphylococcus aureus and E. coli were the most prevalent organisms in the research group [Figure 2].

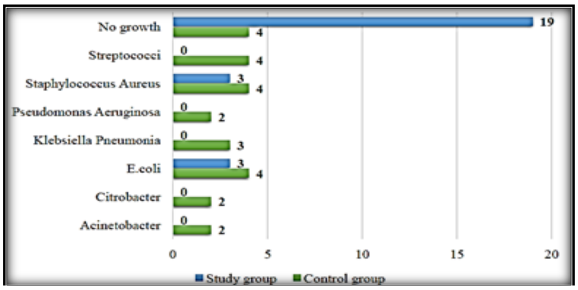

Figure 2: Culture growth of various organisms in both groups

The Granulation tissue formation score varies between the two groups. Only 12% of the study group scored 2, while the majority (48%) scored 4. In the study group, none had a granulation tissue score of 1. Only 8% of the participants in the control group received a score of 1, while the majority (76%) received a score of 2. In the control group, none had a granulation tissue score of 4. The granulation tissue score was greater in the study group than the control group, and this difference was statistically significant ($P < 0.001$).

The average ulcer size in square millimetres when patients were ready for split skin grafts was 1977.7

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sum in the trial group and 3100 sq mm in the control group. The study group's mean ulcer size is smaller than the control group. With a P value of 0.001, this difference was statistically significant. The mean percentage of ulcer shrinking in the experimental group was 24.5%, whereas, in the control group, it was 8.9%. Compared to the control group, the mean percentage of ulcer shrinking in the study group is higher. P 0.001 indicates that this difference was statistically significant.

The mean percentage of ulcer shrinkage in the experimental group was 24.5%, compared to 8.9% in the control group. The study group's mean ulcer shrinkage percentage is larger than the control group's. This difference was statistically significant, as shown by the value of P< 0.001. The mean bleeding episodes in the study group were 0.36 days, compared to 0.08 days in the control group. The study group has a higher mean number of bleeding events than the control group. With a P value of 0.05, this difference was statistically significant. The mean hospital stay in days for the study group was 20.6 days, compared to 40.28 days for the control group. The study group's mean hospital stay is shorter than the control group. With a P value of.001, this difference was statistically significant.

DISCUSSION

Diabetic foot ulcers (DFUs) happen in some diabetes mellitus patients. DFUs are the most frequent reason for non-traumatic amputation, accounting for up to 85% of cases.10 Patients with DFU have a mortality risk of approximately twice as high as those without DFU. The cost of care for patients with DFUs was nearly five times greater in the first year than for people with diabetes without foot ulcers. This is mostly caused by the lengthy hospital stays required for DFU patients.[11] Due to low levels of health education and a deficient healthcare system in India, as well as the fact that most patients with lower leg ulcers come from lower socioeconomic groups, the severity of the issues is more significant. NPWT has proven to be one of the most effective wound care techniques for lower leg ulcers and has been found to facilitate and hasten healing.[12] Analysis was performed on 50 patients, 25 in the study group receiving NPWT treatment and 25 in the control group receiving traditional dressing.

The age distribution was not significantly different between the two groups. In past research done in India, patients with LUs were shown to have a similar mean age range. Only 32% of the participants were women, with men making up the majority (68%) of the group. This gender distribution was not statistically significant between the two groups. A likely dominance in male patients with LUs was reported in several studies. This suggests that males are more likely than women to acquire lower leg ulcers, regardless of whether the cause is trauma or diabetes. According to research, women have higher joint mobility, mild neuropathy, and lower foot pressure than males. Men are more likely to get lower limb ulcers than women because of lifestyle, behaviour, and employment differences.[13]

The well-known processes of inflammation, granulation tissue production and epithelialization, and scar tissue maturation are all required to heal a diabetic foot ulcer to ensure the durable restoration of skin and tissue integrity.[14] Compared to the standard dressing group, the VAC treatment group's time to wound healing was noticeably faster. Similar findings were seen in subsequent studies that compared the two groups, and the study group's time to full healing was much faster than the standard dressing group in diabetic and traumatic instances of lower limb ulcers. In the conventional therapy group, the wound closed after 58.9 days, compared to 41.2 days for the VAC group. According to Guffanti, more patients who had NPWT management saw an improvement in their wounds or full healing of the wound. Faster healing in NPWT is caused by the macro-deformation, which includes stabilising the wound environment, reducing oedema, contracting the wound during healing and micro-deforming the wound.[15] It also includes a decrease in bacterial burden with a therapeutic environment conducive to recovery, an increase in cellular proliferation, and angiogenesis. This also results in enhanced granulation cover.[16] The number of healing days decreased less in our study than in James et al.'s report.[17] However, the days were comparatively longer compared to the outcomes reported by Armstrong DG and Singh et al.[18,19] This is because spontaneous, full closure, or 100% reepithelization, was used to define the endpoints in the latter investigations.

The study group's mean ulcer shrinkage percentage is larger than the control group's. Through macro deformation caused by centripetal pressures operating at the wound-foam interface, NPWT accelerates wound shrinkage. The deformability of the wound tissue determines the magnitude of the macro deformation.[3] Similar outcomes to the current study were found in Indian research by Nain et al., with mean ulcer area reductions of 16.14 cm2 and 5.98 cm2 in DFUs treated with NPWT and traditional dressing, respectively.[20]

The average hospital stay in the study group was shorter than in the control group. James et al. also reported that a long time for healing and wound closure would enhance hospital stay, especially in cases of DFUs. Since bleeding is one of the most significant NPWT side effects, bleeding was also compared between the two groups as a frequent NPWT-related result.[17] The study group has a greater mean number of bleeding episodes (0.36 days) than the control group (0.08 days). This was following the results published earlier in a similar study conducted in patients with DFUs.[17,19]

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Following the intervention, the two groups Pus cultures developed differently. Only 24 percent of the research group exhibited culture growth, while 76% were without it. The study group showed a lower percentage of culture growth than the control group. In the study group, Staphylococcus aureus and E. coli were the most frequently seen microorganisms. In a randomised control study, Pseudomonas aeruginosa and Acinetobacter were the most often cultured organisms in the NPWT group. In contrast, P aeruginosa and Klebsiella were discovered in the control group, compared to our study, where S. aureus was the most prevalent bacterium.[21] S. aureus was also noted as being prevalent by James et al. Our study also reported the presence of Klebsiella pneumoniae, Acinetobacter, Citrobacter, and Pseudomonas aeruginosa.[17] Studies have shown that NPWT reduces bacterial load and infection, yet Armstrong listed infection as a side effect. The infection in NPWT is linked to inadequate debridement, foam retention, air leak, closure of any underlying infection, and bleeding brought on by NPWT, which serves as a culture media.[18] Although studies, such as the current study, have shown that NPWT positively impacts wound microbiology, NPWT should not be viewed as a substitute for other infection management measures.

Limitations

The uneven distribution of Wagner's grade between the two groups may have been averted with a bigger sample. Although a substantial beneficial result was shown by a stratified analysis of the major outcome variable based on grade, this analysis might have been avoided if Grade 1 and Grade 2 DFUs had been evenly distributed by stratification in the research groups. Although bleeding was evaluated, logistical issues prevented the process from being objective. Comparisons of costs, quality of life, and patient satisfaction are other crucial factors that may have improved the study's relevance.

CONCLUSION

According to the current randomised controlled trial, VAC treatment for LUs is efficient and secure. Accelerating the production of granulation tissue shortens the time needed for wound healing to be completed while posing no increased risk for complications like bleeding and infection. This study demonstrates that VAC treatment helps accelerate wound healing and enhance granulation cover while significantly shortening hospital stays. Conducting more RCTs with a bigger sample size is advised to extend the current study's findings.

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