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General Surgery

NEGATIVE PRESSURE WOUND DRESSING VERSUS SALINE DRESSINGS IN DIABETIC FOOT ULCERS

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ABSTRACT **Introduction:** Diabetic foot ulcers not only negatively affect patient mortality, morbidity, and quality of life, but also use a lot of resources to heal completely. Managing massive skin defects and complicated diabetic foot wounds poses challenge to surgeons. Here, negative pressure wound care is utilized to treat complicated diabetic foot wounds in order to evaluate its efficacy and safety to those of traditional moist dressing.**Resources and methods:** Thirty patients, who were split into two groups, participated in the study. One group received traditional saline-moistened gauze dressing, one group received a negative pressure dressing. Rates of wound healing were compared. **Results:** There was a statistical significant difference between the two groups in the timing of the formation of granulation tissue, in study group this difference appeared sooner. In comparison to the control group's results (60% complete responders), the study group claimed a superior result (80% full responders). **Conclusion:** The treatment of diabetic foot ulcers with negative pressure wound therapy is unquestionably effective.

KEYWORDS : Diabetic foot, negative pressure wound dressing, conservative dressing, wound healing, graft.

INTRODUCTION

The term "diabetes mellitus" (DM) refers to metabolic illness, and common chronic disease. Chronic hyperglycemia and abnormalities in protein, fat and carbohydrate metabolism are its hallmarks. The expense and resource demand of managing diabetes are significant for both the patient and the healthcare system. Diabetes and its complications have a huge financial impact on people, families, health systems, and nations.

A common secondary condition that frequently results in amputation is the diabetic foot. Infection or foot gangrene may occur as a result of vascular anomalies, diabetic neuropathy, and impaired wound healing. A frequent issue in healthcare is acute and chronic wounds with impaired healing [4]. Non-healing wound complications can be more prevalent and significant than those caused by the underlying disease, and they can range from bothersome to life-threatening. Whether due to viral or noninfectious causes, the incidence of poor wound-healing constitutes a multi-disciplinary therapy and expensive clinical problem.

Negative pressure wound therapy: Diabetic foot ulcers still need a clear-cut treatment plan. Several forms of moist dressings and topical medicines are part of contemporary wound therapy, but only a small number of these approaches have been conclusively demonstrated to result in greater wound closure rates than conventional wet gauze dressings [5,6]. An adhesive drape is placed over an open-cell foam dressing in NPWT. A vacuum pump attached to the dressing develops and sustains a sub-atmospheric pressure (intermittent or continuous). By draining fluid from open wounds through a sealed dressing and tubing that is attached to a vacuum-assist closure device (VAC), Negative Pressure Wound Treatment (NPWT), a more recent non-invasive adjunctive therapy approach, helps promote wound healing.in close proximity to a collecting container. It has been demonstrated that using sub-atmospheric pressure dressings, sold commercially as a VAC device, is an efficient technique to accelerate the healing of a variety of wounds. [7–10]

MATERIALS AND METHODS:

The current study involved 30 patients who were treated at the NRI Medical College and Hospital in Chinnakakani. Patients were split into the study group and the control group at random. The informed consent taken from the patients.

Study group: Negative pressure dressing treatment was administered. Control group: Gauze dressings were changed twice day with saline solution.

Inclusion criteria:

- Age range of 20 to 75 years.
- An ulcer with a 50 cm2 to 200 cm2 surface area.

Exclusion criteria:

- Age <20 to >75 years.
- An obvious septicemia.
- Osteomyelitis.
- Wounds resulting from venous insufficiency.
- Malignant disease in a wound.
- Patients being treated with corticosteroids, immunosuppressive drugs or chemotherapy.
- Any other serious pre-existing cardiovascular, pulmonary and immunological disease.

First debridement was performed on the study participants' wounds to get rid of slough and necrotic tissue. After that, they were randomly assigned to one of the groups.

Following the debridement, the study group's wounds received a foam-based dressing under strict aseptic guidelines. An adhesive drape was placed over the dressing to provide an airtight closure. A fluid collecting canister was housed within a portable vacuum/suction machine, and an evacuation tube implanted in the foam was attached to it. Three times a day, subatmospheric (negative) pressure in the range of -50 to -125 mmHg was administered on an irregular basis. If necessary, NPWT dressings were replaced. The control group got twice-daily gauze dressings soaked in saline. To evaluate the bacterial flora, weekly cultures from the ulcer floors were obtained. All of the patients received standard antibiotic regimens, initially consisting of wide spectrum antibiotics, and then in accordance with the cultural sensitivity assessment. The treatment of ulcers lasted until the wound healed surgically or naturally.

A wound must be completely healed in order for re-epithelialization or a scab to form, there must be no wound drainage, and no dressing is necessary.

Patients were divided into the following groups, at the conclusion of the study:

1. Complete responders: Ulcers that have fully healed.

2.Partial responders: there must be 50% or greater decrease from baseline in the product of the two longest perpendicular diameters.

3. Incomplete respondents: The product of the two longest perpendicular diameters was reduced from the baseline by < 50%.

4. Nonresponders: Neither an ulcer's size nor its area has changed from the beginning.

The observations were recorded, and all of the results—including age, fasting blood sugar, and the % change in wound size from the first to the eighth week—were evaluated using the Student t-test. The 2 test was used to determine if the appearance of granulation tissue and the main research end goal were significant. By using the Z-test, a study of the temporal state of the wound was created.

RESULTS:

Age and sex

Patients in Group A had a mean age of 61.33±7.63 years, whereas those in Group B had a mean age of 55.40±11.54 years. In both groups, the age distribution was comparable and statistically insignificant (P>0.10). Whereas 20% of the patients in Group A were female and 80% were male, 86.67% of the patients in Group B were male and 13.33% were female.

Wound discharge

Initially all of the patients in Groups A and B had discharge from wounds. Throughout the course of the observation period, both groups' discharge levels decreased; however, Group A patients saw a quicker rate of discharge disappearance. Just 13.33% of patients in Group A had wound discharge in the seventh and eighth weeks, compared to 33.33% and 26.67% in Group B.

Granulation tissue

According to the study, granulation tissue was absent during the first week in 4 patients in Group A and 10 patients in Group B. Granulation tissue was seen to form at the second week in three out of four patients (75%) and at the fourth week in the remaining patient (25%) in Group A. (Plate 4). Granulation tissue first showed up in three (30%), three (30%), and two (20%) patients in Group B patients at the second, fourth, and fifth weeks, respectively. Also, it was observed that in two (20%) of the patients, the granulation tissue was still missing at the end of the observation period. This showed granulation tissue appeared early in patients in Group A, and this finding was also determined to be statistically significant.

Wound size

One (6.67%) patient in Group A and three (20%) patients in Group B both had unchanged wound sizes. Also, 2 (13.33%) patients in Group B had wounds that had become larger. Patients in Group A saw a greater percentage reduction in wound size than those in Group B. Among patients in Group A, the mean reduction in wound size was -16.14 ±13.04 cm2, but in patients in Group B, it was -5.98 ±14.41 cm2. It was statistically significant (P 0.05).

Bacterial load

In contrast to Group B, patients in Group A displayed a quick clearance of the bacterial load. This was shown by the fact that 40% of the cultures in Group A, as opposed to 20% in Group B, had no development by the third week. Patients in Group A were found to have higher concentrations of Staphylococcus aureus than in Group B, where Acinetobacter and mixed growth were more common.

Time to wound closure

The patients in Group A appeared to recover more quickly than the patients in Group B, despite the fact that statistically the time status of wound closure was equivalent in both groups (P>0.10). In contrast to just 3 (0+2+1) (20%) patients in Group B, 9 (5+1+3) (60%) patients in Group A had wounds that were healed by the end of the fourth week. Patients who had amputations were not included in this study.

Similar wound closure methods were administered to both groups, with STSG being the most popular method. Although the primary trial endpoint was statistically similar in both groups (P>0.10), Group A promised a better result (80% complete responders) than Group B.

DISCUSSION:

The role of negative pressure dressing in the healing of diabetic foot ulcers is a novel way of influencing the chronic wound environment in a way that decreases bacterial burden and chronic interstitial wound fluid, increases vascularity and cytokine expression, and to some extent mechanically exploits the viscoelasticity of peri wound tissues. [12] With minimal contraindications or problems, VAC is typically well-tolerated and is emerging as cornerstone of contemporary wound treatment.

The statistical analysis of the demographic profile revealed no appreciable differences between the groups that were comparable to one another. The mean age of the patients in the study group was 61.33 ±7.63 years, and the mean age of the patients in the control group was 55.40±11.54 years, which was equivalent to the mean age of 58 years in the multicenter randomized controlled trial that Blume et al.[13] conducted with 342 patients. The gender breakdown was likewise comparable to the research mentioned above, which had 79% males.

In both groups, there was decreasing trend in the prevalence of wound discharge. Nonetheless, it was observed that the research group's rate of decrease in wound discharge eradication was faster. By the conclusion of the seventh and eighth weeks, only 13.33% of patients in the study group had discharge, compared to 33.33% and 26.67% of patients in the control group, respectively. This could be explained by the research group's higher rate of wound healing.

In a comparable research by Tamhankar et al.,[14] it was shown that NPWD treatment permits salvage of infected exposed mesh by clearing up the infection in four patients with mesh-associated infection following hernia repair. Applying NPWD to the wound bed improves local circulation and encourages angiogenesis, which aids in growth of granulation tissue. [15] Also, individuals receiving NPWD treatment had granulation tissue emerge earlier. The proportion of patients in the study group who originally lacked granulation tissue was 75%, compared to 30% in the control group by the end of the second week, and this was also shown to be statistically significant (P 0.05).

In their prospective analysis of nine renal transplant patients who experienced wound infections after RT, Shrestha et al.[16] saw a gradual reduction in the size of the wound and the growth of healthy granulation tissue.

The percentage change in wound size between two groups showe statistically significant difference (P 0.05). Comparing study group to the control group, the study group's mean reduction in wound size was greater (-16.14±13.04 cm2) than control group's (-5.98±14.41 cm2).

Our research is in line with that of McCallon et al. [17], who reported an average wound size decrease of 28.4% in the VAC group compared to an average rise of 9.5% in the control group.

As opposed to wet gauze dressings, the wound volume and depth considerably decreased with VAC dressings, according to Mark Eginton et al. [18] (59% vs. 0% and 49% vs. 8%, respectively).

Patients in the research group cleared their bacterial burden more quickly than those in control group. This was shown by the fact that 40% of the cultures in the experimental group, as opposed to 20% in the control group, had no development by the third week. The antibiotic regimens used throughout the trial may have contributed to the decrease in bacterial burden. S. aureus was found to be more prevalent in the study group, while Acinetobacter and mixed growth were more common in the control group's cultures.

Although both groups wound closure times were statistically equivalent (P>0.10), it was observed that the study group had a quicker rate of wound closure than the control group.

The endpoint was either a granulated wound, wound suitable for skin grafting, or wound that is healing spontaneously or by secondary intention. Both groups had received similar care for the wound closure, with STSG being the most popular method. Also, it was shown that patients in the control group failed at a greater rate than those in the research group. Robert Frykberg et al. [19] have also noted an overall rising wound debridement depth and amputation rates in control groups; however the same didnot occur in the NPWT group.

At the end of the study, although the primary endpoint was statistically comparable in both the groups (*P*>0.10), the study group promised a better outcome (80% complete responders) as compared to the control group (60% complete responders).

CONCLUSION:

According to our study, NPWT has a definitive role in promotion of proliferation of granulation tissue, reduction in wound size, rapid decrease in wound discharge and bacterial load. NPWD decrease the wound size more effectively than saline dressings over first 4 weeks of therapy. Therefore, NPWT is a cost-effective, easy to use and patient-friendly method of treating diabetic foot ulcers which helps in early closure of wounds, preventing complications and hence promising a better outcome.

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