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ROLE OF NEGATIVE PRESSURE WOUND THERAPY IN HEALING DIABETIC FOOT ULCERS A RANDOMIZED CONTROL STUDY

General Surgery

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ABSTRACT

The prevalence of Type 2 diabetes has increased significantly globally. Diabetes mellitus often results in complications, including lower extremity issues such as foot ulcers and infection. **MATERIALS AND METHODS:** This study investigates the effectiveness of Negative Pressure Wound Therapy (NPWT) compared to traditional saline dressings in treating diabetic foot ulcers. Conducted at ASRAM hospital in Eluru, the randomized controlled study included 30 patients divided into two groups: Group A (NPWT) and Group B (saline dressings). **RESULTS** indicated that Group A experienced faster reduction in wound discharge, earlier and more significant formation of granulation tissue, and a greater decrease in wound size compared to Group B. Additionally, bacterial load decreased more rapidly in Group A, with 40% of cultures showing no growth by the third week versus 20% in Group B. Though both groups received similar wound closure treatments, the study group demonstrated faster healing times, with 80% of Group A achieving complete response compared to 60% in Group B. In **CONCLUSION**, NPWT proved significantly more effective than saline dressings in treating diabetic foot ulcers. NPWT not only accelerates healing but also reduces the risk of complications, making it a superior, cost-effective, and patient-friendly treatment option. Patient education on proper foot care and timely medical consultation remains crucial in managing diabetic foot complications.

KEYWORDS

negative pressure, healing, diabetic foot ulcer, dressing

INTRODUCTION

Worldwide the rates of Type 2 diabetes are on the increasing trend. Diabetes mellitus is a consequence of increasing BMI and physical inactivity, according to the most recent data from the Global burden of Disease project, the prevalence of diabetes increased 129.7% for males and 120.9% for females between 1990 and 2017. Diabetes-related complications affect many organ systems and are responsible for the majority of morbidity and mortality associated with the disease.

Diabetes mellitus causes lower extremity complications like foot ulcers and infections. Various causes of these disorders involve several pathogenic factors and the interaction between them; neuropathy, abnormal foot mechanics, PAD, poor wound healing.Patients with diabetes are prone to infections because of: (1) Peripheral neuropathy, (2)Peripheral vascular disease and (3) Impaired resistance to infection

Despite efforts to prevent them, foot ulcers and infections frequently occur and pose a significant challenge. Managing these wounds involves a multidisciplinary approach due to the complex causes of lower extremity ulcers, requiring expertise in orthopedics, vascular surgery, endocrinology, podiatry, and infectious diseases. Ulcers most commonly develop on the bottom surface of the foot.

The causes of diabetic foot infections are similar to those of bone infections in non-diabetic individuals, such as S. aureus, β-haemolytic streptococci, and aerobic Gram-negative bacteria. Pseudomonas is more common than usual, so treatment for severe infections should include medication effective against this organism. Anaerobic bacteria might also be present, and adding metronidazole should be considered, especially for abscesses or tissue that has lost its blood supply.Surgical removal of dead tissue and collections is necessary for necrotic areas or when osteomyelitis is extensive. It is crucial to differentiate between superficial bone inflammation due to soft tissue loss, often linked with vascular issues, and more severe bone involvement. In cases of superficial osteitis, biopsy and antibiotic treatment may have limited benefits compared to optimizing blood sugar levels, enhancing vascular circulation, and reducing pressure with suitable footwear.This strategy could potentially prevent extensive tissue damage or the need for future amputation.

Many diabetic patients with foot infections experience significant vascular impairment and nerve damage, complicating post-surgical healing. A comprehensive vascular evaluation is essential for those with weak peripheral pulses. Proximal angioplasty or bypass surgery may enhance blood flow to the affected area, potentially improving the outcome of foot infection surgery. Amputation is a challenging decision in diabetic foot disease, as wound healing can be difficult. Generally, surgical excision should completely remove infected tissue, and excess bone may require removal to allow for wound closure without tension. In cases of extensive peripheral nerve damage, amputation below the knee in a region with better sensation may be more suitable.

Interventions with demonstrated efficacy in diabetic foot ulcers or wounds include:
(1) off-loading,
(2) debridement,
(3) wound dressings,
(4) appropriate use of antibiotics,
(5) revascularization, and
(6) limited amputation.

WOUND-HEALING

It occurs in three phases: inflammation, proliferation, and maturation Local and systemic factors influencing wound healing are as follows

LOCAL

Skin tension
Hypoxia and ischaemia
Vascular insufficiency
Lymphoedema
Contamination
Infection
Presence of foreign bodies
Radiotherapy

SYSTEMIC

Advancing age
Obesity
Malnutrition
Smoking
Diseases (e.g. diabetes mellitus, connective tissue diseases)
Immunocompromised (e.g. acquired immunodeficiency syndrome)
Medications (e.g. steroids, immunosuppressants, chemotherapy)

FACTORS THAT INHIBIT WOUND HEALING

Infection
Ischemia: Circulation, Respiration, Local tension
Diabetes mellitus

Ionizing radiation
Advanced age
Malnutrition
Vitamin deficiencies: Vitamin C, Vitamin A,
Mineral deficiencies: Zinc, Iron
Exogenous drugs: Doxorubicin(Adriamycin), Glucocorticosteroids

NEGATIVE-PRESSURE WOUND THERAPY (NPWT)

Since its introduction in the 1990s, negative-pressure wound therapy (NPWT) has become widely used. While it does not replace definitive wound closure, it serves as a valuable adjunct. Negative pressure aids in drawing the wound edges together, removing exudate, reducing oedema, and promoting granulation tissue formation. However, NPWT is not advised for use with exposed vessels, malignancy, untreated osteomyelitis, necrotic tissue, or non-enteric and unexplored fistulae.

Caution should be exercised to prevent fungal infections, particularly those caused by Candida species, in immunocompromised patients or those with extensive antibiotic exposure. These infections are common after prolonged use of negative-pressure wound therapy.

MECHANISM OF ACTION OF NPWT:

Acts by MECHANOTRANSDUCTION
Decreases interstitial fluid content of wound, reduces local oedema, tissue exudate and reduce bacterial load.
Promotes granulation tissue
Wound covered in open cell sponge, covered with a polyurethane adhesive film
Negative Pressure upto -120 mm of hg for acute, -50-70 mm of hg for chronic wounds Intermittent or continuous topical suction

TECHNIQUE APPLICATIONS:

As a dressing to secure a skin graft to its recipient bedtemporary coverage of a complex acute wound (e.g. an open abdomen) until definitive cover can beachieved or to manage chronic wounds such as pressureulcers.

CONTRAINDICATIONS TO NPWT

Malignancy
Untreated osteomyelitis
Fistulae
Necrotic tissue
Ischemic tissue

MATERIALS AND METHODS

This randomized control study was performed on 30 patients at Alluri Sitarama Raju Academy of medical sciences, ASRAM hospital, Eluru.
STUDY PERIOD: 1st December 2022 to 31st December 2023

PATIENTS WERE DIVIDED INTO TWO GROUPS:

Group A: Received Negative Pressure wound therapy
Group B: Received local wound care with Saline dressings twice a day

INCLUSION CRITERIA

Age above 18 years
Diabetic foot ulcers

EXCLUSION CRITERIA

Age less than 18 years or more than 75 years
Osteomyelitis
Venous ulcers
Malignant ulcer

Patients on corticosteroids, immunosuppressants, chemotherapy After taking informed consent, all the subjects with diabetic foot ulcers initially underwent debridement to create an ulcer bed devoid of slough and necrotic material and were then randomly divided into two groups.

Group A; A sterile sponge into which a suction tube connected to a fluid filled canister contained in a portable suction apparatus is inserted is placed on the ulcer bed and an adhesive drape is used to cover the ulcer and create an airtight seal. Group B; received Saline dressings twice daily.

A negative pressure ranging from -50 to -125 mm of Hg is applied intermittently 6th hourly daily.Wound swabs were taken from the floor and edges of the ulcer and sent for culture sensitivity, based on which antibiotics are initiated.

RESULTS

Fig.1: NPWT dressing on Right Diabetic Foot

In a total of30 patients, aged between 18 and 75 years and with either sex were taken and the age and sex distribution, wound discharge, granulation tissue, wound size, bacterial load and time to closure were compared.

AGE AND SEX:

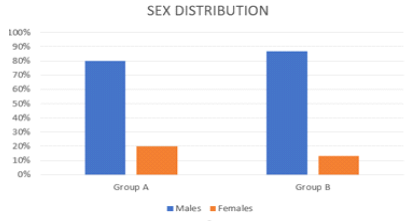

Fig. 2: Sex Distribution

WOUND DISCHARGE:

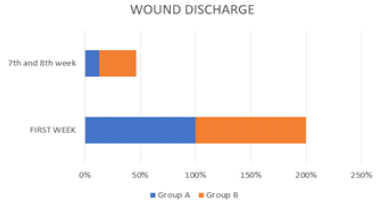

Fig 3: Wound discharge: Group A had a faster reduction in discharge.
Granulation Tissue

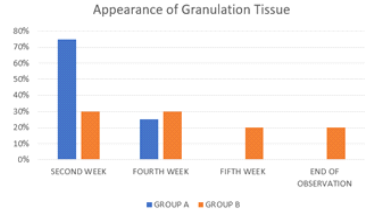

Fig 4. Appearance of Granulation Tissue: Early appearance in Group A, statistically significant.

WOUND SIZE:

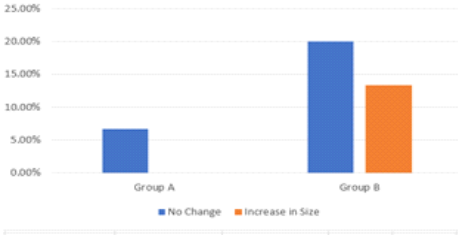

Fig. 5 Effect of NPWT on Wound size: Significant decrease in Group A.

BACTERIAL LOAD:

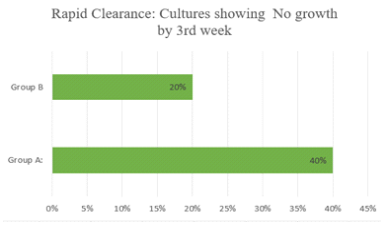

Fig. 6: Rapid Clearance

Common Bacteria
- Group A: Staphylococcus aureus.
- Group B: Mixed growth and Acinetobacter.

TIME TO WOUND CLOSURE:

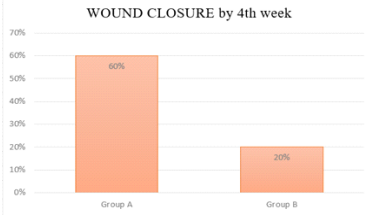

Fig. 7: Wound Healing Rate

Statistical Comparison:Comparable (P>0.10), but faster healing in Group A.

TREATMENT AND OUTCOME:
Treatment:Similar in both groups, common mode STSG.

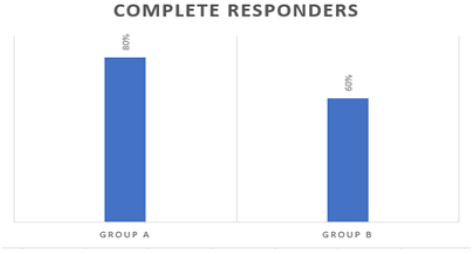

Fig. 8. Outcome: Complete Responders

DISCUSSION
Group A had diabetic foot ulcers treated with negative pressure wound therapy (NPWT), while Group B used saline dressings. NPWT reduces bacterial load and interstitial fluid, improves blood flow, and promotes cytokine production, enhancing wound healing with minimal complications. This study aimed to use NPWT for effective, rapid healing of diabetic foot ulcers.

A statistical analysis revealed no significant demographic differences between the groups. The average age in Group A was 61.33 ± 7.63 years, and in Group B, it was 55.40 ± 11.54 years, similar to Blume et al.'s multicenter randomized controlled trial findings. The gender distribution was also similar, with 79% male participants in the referenced study.

Both groups showed a decreasing trend in wound discharge. NPWT enhanced local circulation and angiogenesis, promoting granulation tissue formation. In Group A, 75% of patients with initially absent granulation tissue showed it by the end of the second week, compared to only 30% in Group B, a statistically significant difference ($P<0.05$). Shrestha et al. also noted consistent wound size reduction and healthy granulation tissue development in nine renal transplant patients with wound infections.

The percentage change in wound size was significantly different between the groups ($P<0.05$). Group A had an average wound size decrease of -16.14 ± 13.04 cm^2 compared to -5.98 ± 14.41 cm^2 in Group B. McCallon et al. reported a 28.4% average decrease in wound size for the VAC group, while the control group saw a 9.5% increase. Mark Eginton et al. also found significant reductions in wound volume and depth with VAC dressings compared to moist gauze dressings (59% vs. 0% and 49% vs. 8%, respectively).

Group A experienced a faster reduction in bacterial load compared to Group B. By the third week, 40% of cultures from Group A showed no growth, while only 20% from Group B had the same result. This decrease in bacterial load may have been influenced by antibiotic treatments, introducing potential bias. Staphylococcus aureus was the most prevalent organism in Group A, while Group B exhibited mixed growth, including Acinetobacter. Moues et al. reported a significant reduction of non-fermentative Gram-negative bacilli in wounds treated with vacuum-assisted closure, alongside an increase in S. aureus.

The primary endpoint was statistically comparable ($P>0.10$), but Group A showed better outcomes, with 80% complete responders compared to 60% in Group B. Our analysis suggests that NPWT significantly promotes granulation tissue proliferation, reduces wound size, and clears wound discharge and bacterial load more effectively than saline gauze dressings during the first four weeks of therapy. NPWT is proposed as a cost-effective, user-friendly method for treating diabetic foot ulcers, facilitating early wound closure, and preventing complications, promising better outcomes.

CONCLUSION
Patient education should emphasis:
1. Choosing the right footwear carefully,
2. Inspecting the feet daily for early signs of ill-fitting shoes or minor injuries,
3. Maintaining daily foot hygiene to keep the skin clean and moist,
4. Avoiding self-treatment of foot issues and walking barefoot,
5. Consulting a healthcare provider immediately if any abnormalities are noticed.

Risk factor modification interventions include orthotic shoes and devices, callus management, nail care, and preventive measures to reduce skin pressure due to abnormal foot structure. Managing other vascular disease risk factors (such as smoking, high cholesterol, and hypertension) and improving blood sugar control are also crucial.

The study reveals that the use of Negative Pressure Wound Therapy (NPWT) is significantly more effective in treating diabetic foot ulcers compared to traditional saline dressings. NPWT accelerates the reduction of wound discharge, enhances the formation of granulation tissue, decreases wound size more effectively, and reduces bacterial load more rapidly. The faster healing times and improved outcomes associated with NPWT highlight its potential as a superior treatment modality for diabetic foot ulcers. This method not only promotes early wound closure but also reduces the risk of complications, making it a cost-effective, user-friendly, and patient-friendly option for managing diabetic foot ulcers.

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