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Original Research Article

To Study the Use of NPWT in Treatment of Diabetic Foot Ulcer

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Abstract

Background & Methods: The aim of the study is to study the Use of NPWT in treatment of Diabetic Foot Ulcer. Chronic leg and foot ulcers occur in many adults with diabetes and are attributed to chronic venous insufficiency, arterial disease, prolonged pressure. The assignment to NWPT was non-random and based on the common and routine clinical practice considering wound characteristics.

Results: Treatment-related rates for secondary amputations, edema, wound infection, cellulitis, osteomyelitis, staphylococcal infection, and infected skin ulcers at 6 months. Significantly (P =0.046) fewer amputations were observed in NPWT patients (7 of 100). In all other categories, no significant differences were observed.

Conclusion: NPWT has been a major breakthrough in wound care over the last decade. In diabetic foot management, NPWT has had a significant impact on limb salvage. The science of NPWT is still evolving and new additions such as instillation and nanocrystalline antimicrobials may further improve outcomes in infected wounds. Portable devices and home-care protocols are also expanding NPWT's usage beyond the hospital setting. However, it is important to emphasize that diabetic foot management is a multidisciplinary effort, and NPWT is only one of the essential tools in the overall management. Successful outcome is heavily dependent on all treatment modalities including adequate wound debridement, appropriate antibiotic therapy, optimization of healing markers, and meticulous wound monitoring.

Keywords: NPWT, diabetic, foot & ulcer.
Study Design: Observational Study.

1. INTRODUCTION

Negative-pressure wound therapy (NPWT) is an innovative technique in managing complex wounds. It was first described by Charikar as an experimental technique for treating subcutaneous fistulas[1]. However, it was the clinical work by Argenta and Moryk was a decade later that allowed NPWT to gain recognition as a useful clinical tool for managing complex and difficult wounds.

Today, NPWT is well established for treating trauma wounds, general surgical wounds, and diabetic foot wounds. Supporting evidence for NPWT in the treatment of diabetic foot wounds includes numerous prospective and multi-centered randomized controlled trials[2]. This review article summarizes current knowledge about NPWT's role in diabetic foot

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management, focusing on its mode of action, clinical applications, and recent developments [3].

The risk of lower limb amputation is much greater for people with DM than for those without. The major underlying pathophysiological conditions associated with amputation are neuropathy and ischaemia[4]. Lower limb amputation can have devastating consequences for people's health status and health related quality of life, as well as having a large financial impact on healthcare providers and users. The cost of diabetic foot care in 2010 to 2011 was estimated at GBP 580 million, almost 0.6% of NHS expenditure in England. Of hospital admissions with recorded diabetes, 8.8% included ulcer care or amputation. In the US, the 2008 prevalence of lower extremity amputation in Medicare recipients was 1.8%, with a total mean annual Medicare reimbursement cost for each person with DM and a lower extremity amputation estimated at USD 54,000. Ulcers are often considered to be chronic wounds, while postsurgical amputation sites are considered to be acute wounds, unless they do not heal [5].

Diabetic foot is a serious complication in patients who have advanced diabetes and refers to foot infections, ulcers and/or deep tissue destruction caused by nerve abnormalities and vascular lesions in the distal lower limb(s) of these patients. According to the International Working Group on the Diabetic Foot [6], an amputation for diabetic foot is performed every 20 seconds and for more than 1 million people every year. In 2017, there were 425 million diabetic patients globally and this is expected to increase to 629 million by 2045.

2. MATERIAL AND METHODS

NPWT gives optimal results when used by a multidisciplinary team in the management of diabetic foot wounds. Indications of usage include post-debridement wounds following surgery for necrotizing fasciitis, foot abscesses, infective heel ulcers and exposed bone, capsule and tendon.

Briefly, we included patients who had a clinical diagnosis of T2DM, clinically non-infected, non-ischaemic ipsilateral foot wounds. The assignment to NWPT was non-random and based on the common and routine clinical practice considering wound characteristics, mainly its area. We allocated to the NPWT treatment T2DM individuals with a wound area >1.0 cm2. Patients with ulcerations ≤1.0 cm2.

Exclusion Criteria:

(a) clinically significant ischemia defined by the lack of pulses of both main pedal arteries and/or an ankle-brachial index less than 0.9;
(b) clinical symptoms of infection;
(c) bilateral ulcerations;

Inclusion Criteria:

Patients selected for NPWT must be meticulously examined for conditions that may lead to suboptimal treatment outcomes.

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3. RESULT

Table No. 1: Gender Distribution

S. No.	Gender	No.	Percentage
1	Male	63	63
2	Female	37	37

Age in years, Mean (SD): 63.7 (2.9)

Table No. 2: Mean Stats

S. No.		Mean	SD
1	Length of care (days)	86.2	31.1
2	Length of hospital stay (days)	14.7	17.4
3	Length of NPWT (days)	30.3	32.3

Table No. 3: Characteristics of the patients

S. No.		Mean	SD
1	Wound area, cm2	12.6	5.1
2	Diabetes duration, years	14.2	6.4
3	HbA1c	7.3	1.6

Table No. 4: Insulin Dose

S. No.		Mean	SD
1	Insulin therapy, n Y/N, Y%	87/13, 87.5%	5.3
2	Total daily insulin dose, units	46.3	2.7
3	Total daily insulin dose, units/kg body weight	0.57	0.4

Table No. 5: Results of safety analysis

S. No.		No.	Percentage	P Value
1	Secondary amputations	07	07	0.046
2	Edema	05	05	
3	Wound infection	04	04	
4	Cellulitis	04	04	
5	Osteomyelitis	01	01	
6	Staphylococcus infection	01	01	
7	Infected skin ulcer	01	01	

Treatment-related rates for secondary amputations, edema, wound infection, cellulitis, osteomyelitis, staphylococcal infection, and infected skin ulcers at 6 months. Significantly (P =0.046) fewer amputations were observed in NPWT patients (7 of 100). In all other categories, no significant differences were observed.

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4. DISCUSSION

Evaluation and management of the effect of NPWT in treating diabetic foot wounds For surgical debridement of diabetic foot wounds, the 'nibbling' principle, with limited batched debridement, is usually adopted. There are an abundance of soft tissue and fascial spaces in the feet. In clinical practice, a small amount of necrotic tissue may remain within the wound and, even after several rounds of debridement, it is unlikely that hidden foci of infection would have been removed. Therefore, there is a risk that infection may spread after NPWT [7]. In addition, even after revascularization of the ischemic wound, there is a short-term risk of reclosure of blood vessels and wound ischemia. At the same time, for patients who need to take anticoagulants for a long duration, there may be a risk of wound bleeding after NPWT.

In the DiaFu study, treatment length within 16 weeks was significantly shorter with NPWT than with SMWC, which corresponds to the previously reported finding that time to complete, verified and sustained wound closure was significantly shorter with NPWT in the PP population [8]. Furthermore, in the additional analysis on wound closure without evidence on reopening within 14 days after initial closure within 16 weeks, we demonstrated that NPWT was superior to SMWC in both wound closure rate and time to wound closure. The results of studies with diabetic foot wounds and with wounds of other origins showing that NPWT shortens treatment time were confirmed in our study[9].

In order to detect potential risks like infection, bleeding, ischemia, it is recommended that daily evaluation is done to carefully inspect for wound pain, redness and swelling; changes in skin color and temperature around the wound; and color, odour and volume of wound drainage fluid; along with blood tests and imaging to comprehensively evaluate for wound infection, ischemia, bleeding, and the overall condition of the patient [10-13]. If wound infection is not under control, avascular necrosis is aggravated or the wound continues to bleed, the negative pressure dressings should be removed and the wound should be re-evaluated. NPWT may be applied again only after infection is controlled, tissue ischemia has improved and the risk of bleeding has reduced [14]. If pain and swelling are aggravated, but without wound infection, tissue ischemia, or other systemic conditions, it is recommended to reduce or suspend the negative pressure, change the mode of negative pressure treatment for observation and remove the negative pressure if necessary.

After 1–2 rounds of NPWT application, a comprehensive evaluation of its effects should be conducted. The effectiveness evaluation and recommended treatment measures are as follows:

(1) **Significantly effective**: there is growth of new granulation tissue on the wound surface or a reduction of the wound surface with surrounding epithelialization; it is recommended to continue NPWT.

(2) **Effective:** wound infection or tissue ischemia improves, the wound is ruddy and blood perfusion is good; it is recommended to apply NPWT 1–2 times and re-evaluate.

(3) **Ineffective:** wound infection or tissue ischemia does not improve, the infection is aggravated or the tissue is more necrotic; it is recommended to stop the NPWT, recanalize the blood

5. CONCLUSION

NPWT has been a major breakthrough in wound care over the last decade. In diabetic foot management, NPWT has had a significant impact on limb salvage. The science of NPWT is still evolving and new additions such as instillation and nanocrystalline antimicrobials may

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further improve outcomes in infected wounds. Portable devices and home-care protocols are also expanding NPWT's usage beyond the hospital setting. However, it is important to emphasize that diabetic foot management is a multidisciplinary effort, and NPWT is only one of the essential tools in the overall management. Successful outcome is heavily dependent on all treatment modalities including adequate wound debridement, appropriate antibiotic therapy, optimization of healing markers, and meticulous wound monitoring.

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