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ROLE OF NEGATIVE PRESSURE WOUND THERAPY IN DIABETIC FOOT ULCER: A PROSPECTIVE INTERVENTIONAL STUDY

Dr. Amaloju Sagar[1], Dr. Subimal Gupta[2], Dr. A.K. Malhotra[3], Dr. Gopal V.K.[4], Dr. Pankaj Mudgil[5], Dr. Y.S. Sunil Kumar[6]

[1] DNB General Surgery Resident, Central Hospital, South Eastern Railway
[2] Senior Consultant, General Surgery, Central Hospital, South Eastern Railway
[3] Senior Consultant, General Surgery, Central Hospital, South Eastern Railway
[4] ADMO General Surgery, Central Hospital, South Eastern Railway
[5] Resident Urology General Surgeon, RGKAR Medical College and Hospital
[6] DNB General Surgery Resident, Central Hospital, South Eastern Railway

Corresponding author: Dr. Pankaj Mudgil*

ABSTRACT

Background: Diabetic foot ulcer (DFU) is a major complication of diabetes mellitus and may result in prolonged hospitalization, repeated surgical procedures and limb amputation. Management requires assessment of the ulcer, debridement where indicated, infection control, adequate perfusion, glycaemic control, off-loading and appropriate wound care. Negative pressure wound therapy (NPWT) is an adjunctive wound-management modality that may facilitate wound-bed preparation, granulation tissue formation and reduction of wound dimensions. The present study evaluated the clinical efficacy and safety of NPWT in patients with diabetic foot ulcers.

Methods: This prospective interventional study was conducted in the Department of General Surgery, Central Hospital, South Eastern Railway, Kolkata, from 1 April 2019 to 30 September 2020. Seventy adult patients with diabetic foot ulcers fulfilling predefined inclusion and exclusion criteria were enrolled. Patients underwent assessment, appropriate debridement, glycaemic control, culture-directed antibiotic therapy and off-loading, followed by NPWT. Outcomes included time to healthy granulation tissue formation, change in ulcer size, healing rate, requirement for surgery, amputation, bacterial load and duration of hospital stay.

Results: Seventy patients were included. Mean age was 53.57 ± 10.45 years; 55 (79%) were male and 15 (21%) were female. Mean duration of diabetes was 7.93 ± 3.41 years and mean duration of DFU was 6.19 ± 2.02 months. Wagner grade 1 ulcers constituted 44%, grade 2 34%, grade 3 19% and grade 4 3%. Mean time to healthy granulation tissue was 8.50 ± 2.20 days. Mean ulcer size decreased from 10.60 ± 3.00 cm^2 at admission to 5.10 ± 2.61 cm^2 following NPWT ($p < 0.001$). Mean reduction was 5.50 ± 1.82 cm^2 and mean healing rate was 0.31 ± 0.11 cm^2/day. Surgery was required in 24 (34%) patients and amputation in 7 (10%). Bacterial load decreased in 64 (91%) patients. Mean hospital stay was 17.93 ± 2.74 days.

Conclusion: In this prospective single-arm study, NPWT was associated with reduction in diabetic foot-ulcer dimensions, early formation of healthy granulation tissue and a low observed rate of amputation. NPWT appears to be a useful adjunct in the multidisciplinary management of appropriately selected diabetic foot ulcers. The absence of a concurrent control group limits causal inference.

Keywords: Diabetic foot ulcer; negative pressure wound therapy; NPWT; vacuum-assisted closure; wound healing; granulation tissue; amputation.

INTRODUCTION

Diabetic foot ulcer is an important complication of diabetes mellitus and may progress to deep infection, tissue loss and amputation. The clinical management of a diabetic foot ulcer is multifactorial. Assessment of the ulcer is followed, where indicated, by debridement, infection control, attention to perfusion, glycaemic control, off-loading and appropriate wound care. The prolonged course of an ulcer may require repeated clinical assessment and surgical intervention, making wound-bed preparation and progression toward healthy granulation clinically important.

Negative pressure wound therapy is an adjunctive wound-care technique in which controlled subatmospheric pressure is applied to a wound through a sealed dressing system. Within the context of this study, NPWT was used after appropriate debridement and other basic measures including glycaemic control, culture-directed antibiotics and off-loading. The study therefore evaluated NPWT as an adjunct rather than as an isolated treatment for diabetic foot ulcer.

The present study was undertaken in the Department of General Surgery, Central Hospital, South Eastern Railway, Kolkata, over the period from 1 April 2019 to 30 September 2020. The study included 70 adult patients with Wagner grade 1–4 diabetic foot ulcers. The principal clinical outcomes assessed were time to healthy granulation tissue, change in ulcer size, healing rate, requirement for surgery and amputation, time to surgery, change in bacterial load and duration of hospital stay.

The purpose of presenting these outcomes together is to provide a clinical description of the observed course of diabetic foot ulcers managed with NPWT in this prospective cohort. Because the study was single-arm and did not include a concurrent control group, the results are interpreted as associations observed during treatment rather than proof that NPWT alone caused the improvements.

AIM AND OBJECTIVES

Aim

To determine the efficacy of negative pressure wound therapy in the management of diabetic foot ulcers.

Objectives

- To evaluate the time to development of healthy granulation tissue.
- To assess the change in ulcer size following NPWT.
- To determine the observed healing rate.
- To assess the requirement for surgery and amputation.
- To evaluate the time to surgery.
- To assess change in bacterial load during treatment.
- To assess the duration of hospital stay.

MATERIALS AND METHODS

Study design and setting

The study was designed as a prospective interventional study and was conducted in the Department of General Surgery, Central Hospital, South Eastern Railway, Kolkata. The study period extended from 1 April 2019 to 30 September 2020. Seventy patients fulfilling the stated eligibility criteria were included.

Sample size

Seventy patients were included in the study. The calculated minimum sample size was 44. The final cohort therefore exceeded the calculated minimum sample size reported in the manuscript.

Eligibility criteria

Adults aged 20–75 years with diabetes mellitus and Wagner grade 1–4 diabetic foot ulcer were eligible for inclusion.

The exclusion criteria were pregnancy; non-diabetic foot ulcer; age below 20 years or above 75 years; septicaemia; osteomyelitis; malignancy; radiotherapy; steroid therapy; and chemotherapy.

Treatment protocol

Patients received glycaemic control, culture-directed antibiotic therapy, off-loading and appropriate debridement followed by NPWT. Wound dimensions and clinical outcomes were assessed during treatment. The treatment strategy was therefore based on the overall management of the diabetic foot ulcer, with NPWT functioning as an adjunctive component.

Outcome assessment

The principal outcomes recorded were time to healthy granulation tissue formation, change in ulcer area, healing rate, requirement for surgery, amputation, time to surgery, change in bacterial load and duration of hospital stay. The manuscript reports the principal numerical outcomes for wound-area reduction, granulation, surgery, amputation, bacterial load and hospital stay.

Ethical considerations

Institutional scientific and ethical committee approval was obtained before initiation of the study. Written informed consent was obtained from participating patients.

RESULTS

Patient profile

A total of 70 patients were included. The mean age was 53.57 ± 10.45 years. There were 55 male patients (79%) and 15 female patients (21%). The mean duration of diabetes was 7.93 ± 3.41 years, while the mean duration of diabetic foot ulcer was 6.19 ± 2.02 months.

Wagner classification

Wagner grade 1 ulcers accounted for 44% of the cohort, grade 2 for 34%, grade 3 for 19% and grade 4 for 3%. In absolute numbers, the distribution was 31 patients with grade 1, 24 with grade 2, 13 with grade 3 and 2 with grade 4 ulcers.

Granulation tissue formation

The mean time to healthy granulation tissue formation was 8.50 ± 2.20 days. This outcome was one of the principal measures used to assess wound-bed progression during treatment.

Ulcer area

The mean ulcer area at admission was 10.60 ± 3.00 cm². Following NPWT, the mean ulcer area was 5.10 ± 2.61 cm². The reported p value for the reduction was less than 0.001. The mean reduction in ulcer area was 5.50 ± 1.82 cm², and the mean healing rate was 0.31 ± 0.11 cm²/day.

Requirement for surgery and amputation

Surgery was required in 24 patients (34%). Amputation was reported in 7 patients (10%). These figures represent the observed requirement for additional surgical management within the study cohort.

Bacterial load and hospital stay

A decrease in bacterial load was reported in 64 patients (91%). The mean duration of hospital stay was 17.93 ± 2.74 days.

Table 1. Baseline characteristics

Variable	Result
Number of patients	70
Mean age, years	53.57 ± 10.45
Male	55 (79%)
Female	15 (21%)
Mean duration of diabetes, years	7.93 ± 3.41
Mean duration of DFU, months	6.19 ± 2.02

RESULTS – DETAILED OUTCOME PRESENTATION

Table 2. Wagner classification

Wagner grade	n (%)
Grade 1	31 (44%)
Grade 2	24 (34%)
Grade 3	13 (19%)
Grade 4	2 (3%)

Table 3. Main clinical outcomes

Outcome	Result
Time to healthy granulation	8.50 ± 2.20 days
Ulcer area at admission	10.60 ± 3.00 cm²
Ulcer area after NPWT	5.10 ± 2.61 cm²
Mean reduction	5.50 ± 1.82 cm²
Healing rate	0.31 ± 0.11 cm²/day
p value	<0.001
Surgery required	24 (34%)
Amputation	7 (10%)
Bacterial load decreased	64 (91%)
Mean hospital stay	17.93 ± 2.74 days

Interpretation of the observed outcomes

The numerical results demonstrate a reduction in mean ulcer area from 10.60 ± 3.00 cm² at admission to 5.10 ± 2.61 cm² after NPWT. The reported statistical result was $p < 0.001$. In addition, healthy granulation tissue was reported after a mean of 8.50 ± 2.20 days, with a mean healing rate of 0.31 ± 0.11 cm²/day.

The study also documented clinical events that remained relevant to overall wound management. Surgery was required in 34% of patients and amputation in 10%. Bacterial load decreased in 91% of patients. The mean hospital stay was 17.93 ± 2.74 days. These findings describe the course of the treated cohort and should be considered alongside the single-arm design.

The reported distribution of Wagner grades indicates that the study included ulcers across grades 1 through 4, with grade 1 representing the largest subgroup. The inclusion of different ulcer grades provides a clinical spectrum within the defined eligibility range, although the manuscript does not provide separate outcome analyses for each Wagner grade.

DISCUSSION

The present prospective interventional study evaluated NPWT as an adjunctive wound-management modality in 70 patients with diabetic foot ulcers. The central finding was a reduction in mean ulcer area from 10.60 ± 3.00 cm² at admission to 5.10 ± 2.61 cm² following treatment, with a reported p value of less than 0.001. The study also recorded a mean time to healthy granulation tissue of 8.50 ± 2.20 days and a mean healing rate of 0.31 ± 0.11 cm²/day.

The findings demonstrate reduction in wound area and relatively early formation of healthy granulation tissue following NPWT in this cohort. These outcomes are clinically relevant because wound-bed preparation and progression toward healthy granulation are important components of management in patients with diabetic foot ulcers.

The treatment approach in this study incorporated several components of diabetic foot care. Patients received glycaemic control, culture-directed antibiotics, off-loading and appropriate debridement before NPWT. Therefore, the observed wound response reflects management in which NPWT was used as an adjunct to these measures. It would not be appropriate to attribute every observed outcome to NPWT alone.

The decrease in bacterial load reported in 64 patients (91%) is another notable observation. However, the study description does not provide a control group or a separate analysis linking bacterial-load changes independently to NPWT. The result is therefore best presented as an observed change during the treatment period.

Surgery was required in 24 patients (34%) and amputation in 7 patients (10%). These outcomes demonstrate that a proportion of patients continued to require operative management despite adjunctive NPWT. The study consequently does not support the interpretation that NPWT eliminates the need for surgery; rather, it describes NPWT within a broader treatment pathway.

The mean hospital stay was 17.93 ± 2.74 days. Hospital duration can be influenced by multiple aspects of diabetic foot management, and the present manuscript does not provide a comparative analysis separating the effect of NPWT from other clinical factors.
The study findings are broadly consistent with the clinical literature cited in the source thesis. The references include published work addressing diabetic foot-ulcer prevention and management and studies evaluating negative pressure wound therapy in diabetic foot ulcers. The current study adds a prospective single-arm clinical description from the stated hospital setting.

An important consideration in interpreting these findings is the absence of a concurrent control group. Without a comparator, it is not possible to establish whether the observed reduction in ulcer area, formation of granulation tissue or other outcomes would have differed from those achieved with standard wound care alone. The findings therefore support an association between the treatment period involving NPWT and the observed clinical outcomes, rather than a definitive causal effect.
The study was also described as exploratory, and the source manuscript identifies sample size and study duration as limitations. Larger comparative studies would be required to confirm the magnitude of benefit and to determine which patients are most likely to benefit from NPWT.

LIMITATIONS

The principal limitation of the study was the absence of a concurrent comparator group. Because this was a prospective single-arm study, changes observed during treatment cannot establish that NPWT alone caused the improvement in wound dimensions or other clinical outcomes.
The original study also identified the sample size and study duration as limitations and described the study as exploratory. The cohort consisted of 70 patients and was drawn from a single hospital setting.
The manuscript does not provide separate outcome analyses according to Wagner grade, nor does it provide a controlled comparison of NPWT with another wound-management strategy.
The treatment pathway included glycaemic control, culture-directed antibiotics, off-loading and debridement in addition to NPWT. Consequently, the contribution of each component to the final outcome cannot be independently determined from the available study design.
The reported outcomes should therefore be interpreted within the context of the study design. The findings are useful for describing the clinical course observed in the cohort, but they should not be interpreted as definitive evidence of superiority of NPWT over standard wound care.

CONCLUSION

NPWT was associated with significant reduction in diabetic foot-ulcer area, early granulation tissue formation and a mean healing rate of 0.31 ± 0.11 cm^2/day in this prospective single-arm study. The mean ulcer area decreased from 10.60 ± 3.00 cm^2 at admission to 5.10 ± 2.61 cm^2 following NPWT, with a reported p value of less than 0.001.
The study also documented a 34% requirement for surgery, 10% amputation rate and decrease in bacterial load in 91% of patients. Mean hospital stay was 17.93 ± 2.74 days. Taken together, the findings support NPWT as a useful adjunctive modality in appropriately selected diabetic foot ulcers within a multidisciplinary management approach.
Because the study lacked a concurrent control group, causal inference is limited. Larger comparative studies are warranted to establish the effectiveness of NPWT more conclusively and to clarify its role across different clinical grades of diabetic foot ulcer.

DECLARATIONS

Ethics approval

Institutional scientific and ethical committee approval was obtained before initiation of the study.

Consent

Written informed consent was obtained from participating patients.

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