Negative pressure wound therapy for chronic venous ulcer: a randomized-controlled study

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Received 22 December 2017
Accepted 4 February 2018

The Egyptian Journal of Surgery
2018, 37:196–199

Objective
The purpose of this study was to evaluate the efficacy of negative pressure wound therapy (NPWT) in promoting wound healing of venous leg ulceration.
Patients and methods
This study was designed as a single-center randomized-controlled trial. Patients with venous leg ulcer of at least 3 months in duration were enrolled in this study. The first group (NPWT group) was treated by NPWT using standardized method. Intermittent negative pressure at –100 to –150 mmHg was applied, and the dressings were changed every 48–72 h. The second group (control group) was treated by conventional daily dressing using normal saline.
Results
After 15 days of treatment, significant differences in ulcer size and percent of ulcer healing were detected between the two treatment groups. The wound healing rate was 13.1 and 2.8 mm^2/day in NPWT group and control group, respectively. After 30 days of treatment, 17 (68%) ulcers revealed 90% healing in NPWT group, with mean duration of 24 days needed for healing. None of the ulcers in control group completed 90% healing after the 30 days of treatment.
Conclusion
NPWT improved wound healing and may be considered as treatment for venous leg ulcer.

Keywords:
chronic venous insufficiency, negative pressure wound therapy, venous ulcer

Egyptian J Surgery 37:196–199

1110-1121

Introduction

Venous leg ulcers (VLUs) represent the most severe manifestation of chronic venous insufficiency and account for most lower extremity ulcerations [1]. VLU has been estimated to affect 500 000–600 000 people annually in the USA and is the most common leg ulcer treated in wound care centers. Furthermore, it has been stated that ~1% of all adults will develop a VLU at some point in their lives [2]. These ulcerations are known to be difficult to heal leading to negative effect on the patient's quality of life, with a significant economic burden on the healthcare system [3].

Negative pressure wound therapy (NPWT) was developed as an alternative to standard wound management incorporating the use of intermittent negative pressure to optimize wound healing conditions with positive results [4]. NPWT consists of a wound filler material covered with an adherent airtight drape connected to a source of negative pressure such as a pump [5].

NPWT appears to act through multiple mechanisms including exudate management, removal of edema, promoting tissue perfusion, and stimulation of granulation tissue formation [6]. NPWT has been used for different types of wounds with promising results; however, only a few studies have evaluated its role in VLU. Therefore, the purpose of this study was to evaluate the efficacy of NPWT in promoting wound healing of VLU.

Patients and methods

This study was designed as a single-center randomized-controlled trial at the Department of General Surgery Menoufia University, with prior approval from our Institution's Ethics Review Board.

Inclusion criteria

Patients with VLU of at least 3 months in duration were enrolled in this study. The diagnosis of VLU was made by the associated clinical manifestation of primary or secondary venous disease and confirmed by duplex ultrasound.

 DOI: 10.4103/ejs.ejs_147_17

Exclusion criteria were patients with reflux at the saphenofemoral junction, long saphenous vein or saphenopopliteal junction, absent pedal pulse, age younger than 18, poorly controlled diabetes mellitus, recent history of chemotherapy, and patients with active cancer. Patients with severe anemia, those with hypoalbuminemia, or immunocompromised patients were also excluded.

After written informed consent, eligible patients were randomized using a computerized list into two groups. The first group (NPWT group) was treated by NPWT using standardized method. Sterile, open-cell foam dressing was gently placed into the wound cavity; a fenestrated evacuation tube was then embedded in the foam and connected to vacuum pump that contains a fluid collection canister; the site is then sealed with an airtight adhesive drape. Intermittent negative pressure at −100 to −150 mmHg was applied, and the dressings were changed every 48–72 h. The second group (control group) was treated by conventional daily dressing using normal saline. Patients with bilateral leg ulcers were randomized separately for each leg.

The wound size was evaluated before initiation of treatment and during follow-up. The elliptical method described by Shaw *et al.* [7] and the mathematical formulae described by Johnson [8] were used for wound measurement. Wound healing rate, defined as absolute area healed per day, was recorded in both groups. Ulcer healing was the outcome of interest in this study, and the endpoint was 30 days of treatment or 90% healing of the index ulcer.

Statistical analysis

Statistical analysis was performed using SPSS, version 24.0 (IBM Corp., Armonk, New York, USA). Discrete variables were presented as numbers (counts) and percentage. Continuous variables were presented as mean and SD. Student's *t*-test was used for intergroup comparisons to test the significance of difference between two different variables. *P* value less than 0.05 was considered statistically significant.

Results

From March 2016 to October 2017, 50 patients were eligible to participate in this study. They were randomly assigned into two groups, each containing 25 patients.

Baseline patient characteristics are shown in Table 1. The two groups were comparable regarding ulcer size, chronicity, history of diabetes, and deep venous thrombosis at randomization.

Ulcers size was evaluated after 15 days of treatment, and significant differences in ulcer size and percent of ulcer healing were detected between the two treatment groups, as shown in Table 2. The mean ulcer size was reduced from 3.58 to 1.63 cm^2 (56% healing) in NPWT group, whereas in the control group, the size was reduced from 3.12 to 2.71 cm^2 (14% healing), with significant statistical difference between the two groups.

The wound healing rate was 13.1 and 2.8 mm^2/day in NPWT group and control group, respectively. After 30 days of treatment, 17 (68%) ulcers revealed 90% healing in NPWT group (Figs 1 and 2), with mean duration of 24 days needed for healing. None of the ulcers in control group completed 90% healing after the 30 days of treatment. The remaining eight (32%) ulcers of NPWT group showed mean healing percentage of 70% of original ulcer size (Figs 3 and 4).

Table 1 Baseline patient characteristics

	Negative pressure wound therapy (*n*=25)	Control (*n*=25)	*P* value
Male/female (*n*)	15/10	18/7	0.54
Age (years)			0.15
Range	25–55	29–61	
Mean±SD	38.2±5.8	40.7±6.3	
Ulcer size (cm^2)			0.11
Range	2.24–8.7	2.51–7.33	
Mean±SD	3.58±1.2	3.12±0.9	
Ulcer chronicity (months)			0.28
Range	3–9	3–7	
Mean±SD	5.1±1.4	4.7±1.2	
Diabetes	7	4	0.49
History of deep venous thrombosis	16	11	0.26

Table 2 Ulcer healing in both groups

	Negative pressure wound therapy (*n*=25)	Control (*n*=25)	*P* value
Ulcer size after 15 days (mean±SD) (cm^2)	1.63±0.42	2.71 ±0.56	0.001
Ulcer healing after 15 days (%)	56	14	0.004
Healing rate at 15 days (mm^2/day)	13.1	2.8	0.001
No healed ulcer (90% healing) after 30 days [*n* (%)]	17 (68)	0 (0)	0.001
Days needed for 90% healing	24	0	0.001

Figure 1

Ulcer before treatment.

Figure 2

90% healing after 19 days of NPWT.

Discussion

Chronic VLUs represent a great challenge to vascular surgeons worldwide because of their notoriously slow healing and high recurrence rates. VLUs pose significant physical, emotional, and socioeconomic costs to patients, families, and the healthcare system [9].

NPWT has become a major component of wound care therapy and has been shown to be effective in the treatment of acute and chronic wounds. Whether used as an end therapy or a bridge to surgery, evidence shows NPWT to be effective in reducing wound exudates and increasing granulation tissue formation [10].

The application of NPWT in treatment of VLUs has been reported in few studies, and owing to a variety of chronic leg ulcers, no randomized-controlled study was conducted on venous ulcers only.

Figure 3

Large ulcer before treatment.

Figure 4

70% healing after 30 days of treatment by NPWT.

In this study, the effectiveness of NPWT on VLUs was evaluated. The NPWT group did show a significant reduction in wound size after 15 days of treatment when compared with the control group. Significant difference in the number of ulcers reached 90% healing also was detected with superiority of NPWT. Owing to different wound sizes between patients, the absolute area healed per day, wound healing rate, was evaluated in both groups, and NPWT showed a significantly higher healing rate.

Supporting our results, Yao *et al.* [11] reported that NPWT has been demonstrated to accelerate wound healing successfully in patients with low extremity ulcers including venous ulcer. In a study by Vuerstaek *et al.* [12], NPWT also had a better effect on healing of different types of leg ulcers when compared with moist wound treatment.

Conflicting with our results, Capobianco and Zgonis [13] summarized that NPWT has proved to be an effective modality for wound therapy in several areas, most notably diabetic foot ulcers, open fractures, and skin grafts. However, the use of NPWT on venous stasis ulcers and burns in particular has been less than satisfactory [13].

Clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum suggested against routine primary use of NPWT for VLUs (grade – 2; level of evidence – c); however, they had explained this recommendation by absence of enough information to support the primary use of NPWT for VLUs, although evidence supports positive effects with the use of negative pressure therapy for wound healing in general [14].

All these studies either supporting or opposing our results had not addressed the VLU as a separate problem in a randomized-comparative study which may be necessary before recommending or opposing NPWT as a treatment to VLUs.

A drawback of our study is that we compared the NPWT to conventional dressing and not to the compression therapy which represents the standard treatment of VLU now in clinical practice [15]. However, we had tried in this study to evaluate the NPWT in a randomized study, and we considered conventional dressing as a placebo treatment to VLU, and with these encouraging results of the NPWT, we are planning to conduct a randomized-comparative study between NPWT and compression therapy with a longer duration and a larger scale of patients.

Financial support and sponsorship
Nil.

Conflicts of interest
There are no conflicts of interest.

References

1 Abbade LP, Lastoria S. Venous ulcer: epidemiology, physiopathology, diagnosis and treatment. Int J Dermatol 2005; 44:449–456.

2 Lal BK. Venous ulcers of the lower extremity: definition, epidemiology, and economic and social burdens. Semin Vasc Surg 2015; 28:3–5.

3 Ma H, O'Donnell TF, Rosen NA, Iafrati MD. The real cost of treating venous ulcers in a contemporary vascular practice. J Vasc Surg Venous Lymphat Disord 2014; 2:355–361.

4 Gonzalez IG, Angel MAL, Baez MV, Flores BR, Ferretiz MM, Woolf SV, *et al.* Handcrafted vacuum-assisted device for skin ulcers treatment versus traditional therapy, randomized controlled trial. World J Surg 2017; 41: 386–393.

5 Argenta LC, Morykwas MJ. Vacuum-assisted closure: a new method for wound control and treatment: clinical experience. Ann Plast Surg 1997; 38:563–577.

6 Argenta LC, Morykwas MJ, Marks MW, deFranzo AJ, Molnar JA, David LR. Vacuum-assisted closure: state of clinic art. Plast Reconstr Surg 2006; 117:127s–142s.

7 Shaw J, Hughes CM, Lagan KM, Bell PM, Stevenson MR. An evaluation of three wound measurement techniques in diabetic foot wounds. Diabetes Care 2007; 30:2641–2642.

8 Johnson JD. Using ulcer surface area and volume to document wound size. J Am Podiatr Med Assoc 1995; 85:91–95.

9 Gould JL, Dosi G, Couch K, Gibbons GW, Howell RS, Brem H, Canic M. Modalities to treat venous ulcers: compression, surgery, and bioengineered tissue. Plast Reconstr Surg 2016; 138:199–208.

10 Desai KK, Hahn E, Pulikkotill B, Lee E. Negative pressure wound therapy: an algorithm. Clin Plast Surg 2012; 39:311–324.

11 Yao M, Fabbi M, Hayashi H, Park N, Attala K, Gu G, *et al.* A retrospective cohort study evaluating efficacy in high-risk patients with chronic lower extremity ulcers treated with negative pressure wound therapy. Int Wound J 2014; 11:483–488.

12 Vuerstaek JD, Vainas T, Wuite J, Nelemans P, Neumann MH, Veraart JC. State-of-the-art treatment of chronic leg ulcers: a randomized controlled trial comparing vacuum-assisted closure (V.A.C.) with modern wound dressings. J Vasc Surg 2006; 44:1029e37.

13 Capobianco CM, Zgonis T. An overview of negative pressure wound therapy for the lower extremity. Clin Podiatr Med Surg 2009; 26:619–631.

14 O'Donnell TF, Passman MA, Marston WA, Ennis WJ, Dalsing M, Kistner RL, *et al.* Management of venous leg ulcers: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. J Vasc Surg 2014; 60:3S–59S.

15 Gloviczki P, Comerota AJ, Dalsing MC, Eklof BG, Gillespie DL, Gloviczki ML, *et al.* The care of patients with varicose veins and associated chronic venous diseases: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. J Vasc Surg 2011; 53:2s–48s.