
Role of Negative Pressure Therapy in Healing of Diabetic Foot Ulcers

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Abstract: Thirty patients (17 female and 13 males) with chronic diabetic foot ulceration, age ranged from 50 to 65 years (53.4 ± 4.1 years), were selected from outpatient clinic of Benha teaching hospitals, Egypt from April 2013 to March 2014. *Aim:* Foot ulceration is one of the most common and severe complications of diabetes. The aim of the current was to clarify the effectiveness of topical negative pressure as a non invasive treatment approach for diabetic ulcers. *Methods:* Patients were divided into two equal groups; the first group was the control group and treated by traditional dressing while the second one was treated by negative pressure. The treatment course was extended up to six weeks; dressing was changed daily for the first group and day after day for the second group. Assessment was carried out before starting the course and after six weeks of treatment for both groups. The ulcer volume assessment was done by using a 10 cm syringe filled by terramycin ointment, and the wound surface area by using a graded plastic sheet. Student t-test was used to analyze the gained data of wound volume and surface area. *Results:* There was a significant improvement in the wound volume and surface area in the negative pressure group than that of the control group. *Conclusion:* It could be concluded that topical negative pressure is an effective non-invasive method in treating chronic diabetic foot ulceration.

Keywords: Diabetic Ulcer, Negative Pressure Therapy, Wound Measurement

1. Introduction

The global prevalence of diabetes, the estimated number of cases in Egypt is expected to reach 6.7 million in 2030, which places the country tenth in the list of countries with the most cases. The number of diabetic patients with foot ulceration is therefore expected to rise in Egypt. The use of new therapeutic methods may improve health-related quality of life, thereby significantly reducing overall costs and lower extremity amputations^(1,2).

Negative pressure wound therapy (NPWT) also known as treatment with topical negative pressure (TNP) is a vacuum assisted method for ulcer care using a negative pressure of 60-125 mm Hg on wound bed^(3,4). If excess fluid is not adequately removed from a wound after surgery, may act as both physical and chemical deterrents to healing process. TNP therapy removes excess interstitial fluid as well as transmitting a mechanical force to the surrounding tissues providing deformation of the extracellular matrix and decreasing in wound size^(5,6).

TNP therapy device is a non-invasive system, where one

unite delivers negative pressure to the wound bed through a drainage tube, which decompresses a sponge of polyurethane alternatively gauze in a continuous or intermittent manner^(7,8).

Negative pressure therapy decreases wound volume and depth significantly more than moist gauze dressings (59% versus 0% and 49% versus 8%, respectively)^(9,10). TNP can be used as a primary treatment for chronic wounds or as an adjunct to surgery⁽¹¹⁾.

2. Materials and Methods

Thirty patients (17 females and 13 males), with age ranged from 50-65 years suffering from chronic diabetic foot ulceration selected randomly from the outpatient clinic of Benha teaching hospitals, they were randomly divided into two equal groups. The first group (control group) was treated with traditional wound care methods while the second group (treatment group) was treated with topical negative pressure the treatment was carried out three times weekly, up to six weeks. All participants were informed about the nature and the effect of the treatment and measurement device. The patients were instructed to report any side effects during the

treatment sessions (e.g itching, pain).

This study has been carried out in accordance with the code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans, an informed consent form had been signed from each patient before participating in the study.

2.1. Inclusive Criteria

The patient had been chosen under the following criteria

- Both sexes shared in the study.
- Patient's age ranged from 50 to 65 years.
- Pressure ulcers; Grade III according to European Pressure Ulcer Advisory Panel Grading System
- Free from immune deficiency diseases as well as collagen diseases.
- Free from blood clotting disorders as hemophilia.
- All patients received the same medical care.

2.2. Exclusive Criteria

Patients with the following criteria were excluded from the study

1. Malignancies or receiving radiotherapy or chemotherapy.
2. Skin diseases.
3. Deep venous thrombosis.
4. Renal failure.
5. Recent therapy with immunosuppressant or anticonvulsants.
6. Acute inflammation & strangulated tissues.

Assessment of wound surface area was carried out by using graded plastic sheet, by equating the results by weighing the area deduced, while the wound volume was done by using a ten cubic centimeters syringe and terramycin ointment for filling the area and space of ulcer to

determine its volume⁽¹²⁾.

2.3. Negative Pressure Device

VAC system 125mmhg (KCI negative pressure equipment).

2.3.1. Wound Surface Area Tracing Tools

- Sterilized transparency film.
- Fine tipped transparency permanent marker.
- Carbon and a white A4 papers.
- Metric graph paper (1mm²).

2.3.2. Wound Volume Assessment procedure

- Using a syringe of ten cubic centimeters filled with the terramycin ointment.
- The wound is filled with the terramycin ointment
- The amount of terramycin injected into the wound was detected in cubic centimeters.

2.4. Treatment Procedures

- The NPWT device should be suited with pressure of 125 mmHg, with duration of 5 minutes on and 2 minutes off.
- Dressing should be away from the boundaries of wound about 2-3 mm. the dressing used was a spongy dressing.
- A sterilized catheter was inserted into the dressing and connected into the device.
- The dressing was applied day after day.

3. Results

The patient characteristics were considered and analyzed as shown in table (1) there was no significant difference between both groups in their age, weights, and heights (p >0.05).

Table (1). General characteristics of patients in both groups (A&B).

Items	Control group		Treatment group		Comparison		S
	Mean	±SD	Mean	±SD	t-value	P-value	
Age (yrs)	57.46	4.8	56.66	5.42	0.42	0.67	NS
Weight (Kg)	72.0	9.9	76.0	11.23	1.03	0.31	NS
Height (cm)	169.46	6.56	168.73	6.87	0.29	0.76	NS

*SD: standard deviation, P: probability, S: significance, NS: non-significant.

3.1. Results of Wound Surface Area

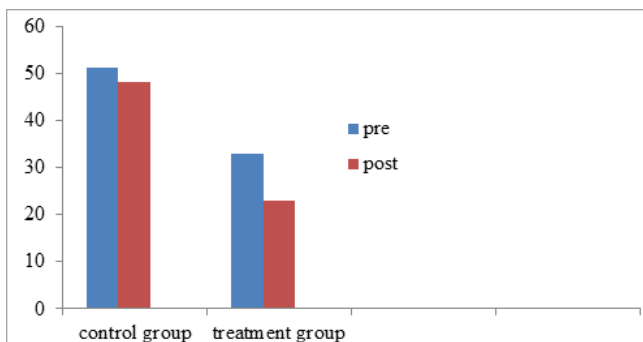


Figure (1). Mean values of pre and post-treatment measurements of wound surface area for each group.

There was a non significant improvement in wound surface area for the control group. On the other hand there was a significant improvement in the surface area of the treatment group as shown in table (2) and figure (1)

Table (2). Pre and post-treatment measurements of wound surface area for each group.

	Control group		Treatment group	
	pre	post	Pre	post
Mean	51.09	48.01	32.91	23.03
±SD	27.7	27.01	17.44	14.46
MD	6.56		9.88	
% of improvement	4.03%		30.05%	
t-value	7.05		5.74	
p-value	0.06		0.001	
Significance	Non significant		Significant	

There was a non significant improvement in wound surface area for both groups pre-treatment. While the post-treatment measurement revealed a significant improvement in the treatment group than in the control group as shown in table (3) and figure (2)

Table (3). Pre and post-treatment comparison of wound surface area for both groups.

	Pre-treatment		Post-treatment	
	control	treatment	control	treatment
Mean	51.09	32.91	48.01	23.03
±SD	27.7	17.44	27.01	14.46
MD	-18.18		-22.28	
t-value	-1.68		-2.19	
p-value	0.11		0.037	
significance	Not significant		significant	

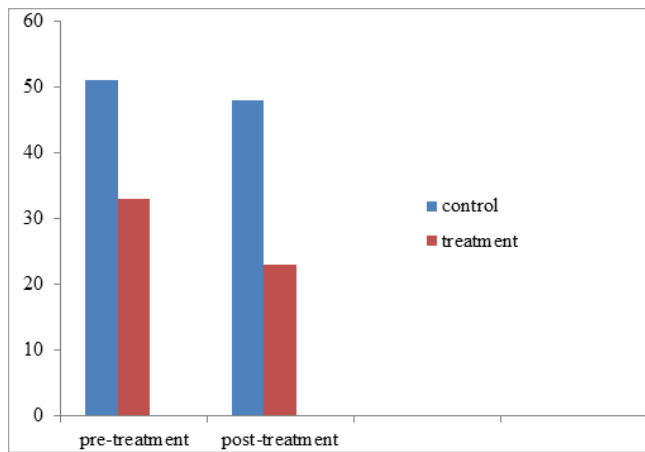


Figure (2). Mean values of pre and post-treatment comparison of wound surface area for both groups.

3.2. Results of Wound Volume

There was a non significant improvement in wound volume for the control group. On the other hand there was a significant improvement in wound volume of the treatment group as shown in table (4) and figure (3)

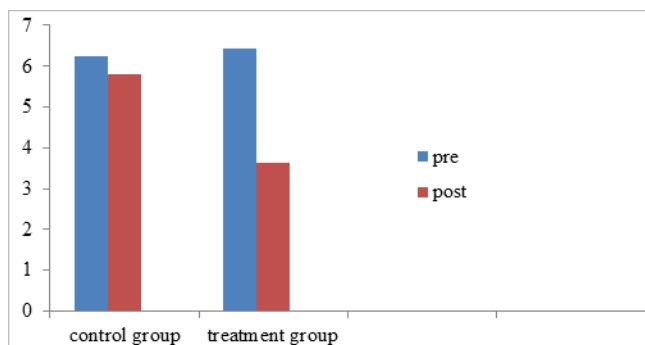


Figure (3). Mean values of pre and post-treatment measurements of wound volume for each group.

Table (4). Pre and post-treatment measurements of wound volume for each group.

	Control group		Treatment group	
	pre	post	pre	post
Mean	6.23	5.81	6.44	3.62
±SD	2.77	2.9	2.94	1.88
MD	0.6		2.82	
% of improvement	4.9%		43.78%	
t-value	9.3		8.39	
p-value	0.07		0.003	
significance	Not significant		Significant	

There was a non significant improvement in wound volume for both groups pre-treatment. While the post-treatment measurement revealed a significant improvement in the treatment group than in the control group as shown in table (5) and figure (4).

Table (5). Pre and post-treatment comparison of wound volume for both groups.

	Pre-treatment		Post-treatment	
	control	treatment	control	treatment
Mean	6.23	6.44	5.78	3.62
±SD	2.77	2.94	2.71	1.88
MD	0.207		-2.16	
t-value	0.201		-2.54	
p-value	0.84		0.02	
significance	Non significant		Significant	

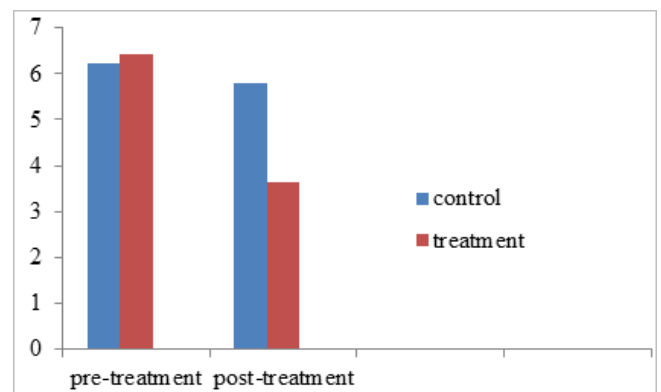


Figure (4). Mean values of pre and post-treatment comparison of wound volume for both groups.

4. Discussion

Foot ulceration is one of the most common and sever complications of diabetes, peripheral vascular disease, infection and the most frequent cause of hospitalization in patients with the disease. Fifteen per cent of people with diabetes will experience a chronic foot ulcer in their lifetime, and this can cause substantial emotional, physical, productivity and financial losses⁽¹³⁾.

Chronic lower limb ischemia becomes increasingly common with age and approximately 5% of people over 50 years have lower limb ischemia. It is more common in men with a ratio of males to females of 2:1. Approximately 10% of patients will progress to critical ischemia with ulceration on toes or foot and tissue loss or gangrene that requires

urgent action to salvage the affected limb. Between 2% and 4% patients will require amputation⁽¹⁴⁾.

Negative pressure wound therapy is a vacuum assisted method for ulcer care using negative pressure of 60-125 mmHg on the wound bed. The devices are non-invasive system, where one unite delivers negative pressure onto the wound bed through a drainage tube, which decompresses a sponge of polyurethane alternatively gauze in a continuous or intermittent manner. The wound fluid drain into a canister. Dressings are usually changed three times a week⁽¹⁵⁾.

Regarding to the wound surface area; the results of this study revealed that were significant decrease in surface area in the treatment group than in the control group .The significant difference between treatment and control groups could prove the efficacy of the NPWT in patients with diabetic foot ulcer.

In relation to wound volume, the results revealed a significant decrease in wound volume of treatment group than in the control group. This difference between the treatment and control groups could prove the efficacy of the NPWT in patients with diabetic foot ulcer.

The results of the current study are supported by a another one which approved that;results for patients treated with NPWT were superior to those for the patients treated with standard wound treatment, where NPWT improve the circulation in the wound and increase granulation tissue formation. These results appear to indicate that wound duration should not deter the clinician from using this modality to treat complex wounds^(16, 17).

Results of the current study concerning the effect of negative pressure wound therapy in patients with diabetic foot ulcers are supported by many studies that explained the biological effects of NPWT on ulcers; as it causes micromechanical deformation as well as promotes the process of angiogenesis^(18,19).

5. Conclusion

It could be concluded that; negative pressure therapy is an effective, inexpensive, and non invasive method for treating chronic diabetic foot ulceration.

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