



EFFICACY OF VACUUM SYSTEM THERAPY ON DIABETIC FOOT ULCERS

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ABSTRACT

Background: In clinical practice many wounds are slow to heal and difficult to manage. And so, this study was performed to evaluate the effect of Negative Pressure Wound Therapy on patient with lower limb ulcers. **Methodology:** thirty patients were included in this study. Their ages ranged from 50 to 70 years, divided into two groups: Group (A) received traditional medical treatment for 6 weeks. Group (B) received treatment with negative pressure wound therapy plus traditional medical treatment, 3 days/week for 6 weeks. The measurements were done before the study and after 6 weeks of treatment for both groups by using wound volume (saline injection) and wound surface area tools (Tracing method). **Results:** It showed reduction in the wound volume and wound surface area after treatment for group (A) and (B), with percentage of 7.79 %, 42.39 %, respectively for the wound volume and 10.51 %, 37.57 %, respectively for wound surface area. There was a highly significant difference between two groups after the treatment. **Conclusion:** Negative Pressure Wound Therapy was found to facilitate the rapid of granulation tissue and shorten healing time of the lower limb ulcers.

Key words: vacuum, lower limb, ulcers.

Introduction:

Chronic, non-healing open wounds remain an on-going challenge. The lifetime risk of a person with diabetes developing a foot ulcer is as high as 25% and foot ulcers are the leading cause of hospitalization of patients with diabetes. In the US approximately 16% of hospital admissions and 23% of total hospital days are attributed to diabetic foot complications. [1]

Ischemia, a major factor of which is tissue hypoxia, has been shown to decrease granulation tissue formation, impair epithelialization and diminish biomechanical strength parameters in wounds. Decreased tissue oxygen tension has been shown to diminish collagen production in wounds, increase matrix metalloproteinase activity and cause abnormal expression of a variety of growth factors and cytokines within the wound. [2]

Some specific physiotherapy modalities are used to enhance and control wound healing process such as LASER therapy, therapeutic ultrasound waves, electrical stimulation and ultraviolet rays. Other adjunct therapeutic modalities include the use of hyperbaric oxygen therapy and Ozone therapy. [3]

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. The method has been used since 1995 as one method for treating surgical wounds, acute wounds and more scarcely for hard-to- heal ulcers. [4]

So we designed this study to detect the effect of vacuum system on the diabetic foot ulcers.

Material and methods:

Thirty patients suffering from lower limb diabetic ulcer with age 50-70 years was selected from Vascular and General Surgeries Departments of south valley university. Patients suffered from amputations, osteomyelitis, malignancy, renal failure, skin diseases were excluded from this study. The patients in the study were randomly assigned into two equal groups: Group (A) (control group) Fifteen patients were assigned randomly. They were received medical treatment and traditional wound care, for period of 6 weeks, in addition to their medical treatment. Group (B) (Negative pressure group) Fifteen patients were treated with medical treatment and traditional wound care and negative

pressure three times per weeks for 6 weeks duration.

Assessment & treatment procedures:

a-assessment procedures

1. Saline injection tool:

By injection sterilized saline into the wound by using graded syringe and calculate the amount of saline needed to full the wound for assessment of wound volume because the granulation begins from the bed of wound toward the surface.(Figure:1)



Figure 1: Application of saline injection method.

2-Wound surface area tracing tools:

- Sterilized transparency film.
- Fine tipped transparency permanent marker.
- Carbon and a white A4 papers.
- Metric graph paper (1mm²). (Figure:2)



Figure (2): Application of wound surface area assessment tools.

(b)-Treatment Procedures:

Vacuum system therapy procedures:-

The procedures of the treatment were achieved under the following steps:-

- Firstly, the parameters of NPWT device should be suited with negative pressure of 125 mmHg, with duration of five minute on and two minute off.
- Then apply the dressing that should be away from the boundaries of wound about 2-3 mm. the dressing used should be spongy dressing to be suitable to the device.
- Then insert sterilized catheter into the dressing.
- Then connect the catheter into the negative pressure device and begin the treatment. (**Figure.3**).



Figure (3). Application Negative pressure device (V.A.C. system equipment).

Statistical procedures:

In this study, the mean, standard deviation and standard error were calculated for all patients. The mean and standard deviation were used as a kind of central tendency to describe a group of individuals with single measurement (descriptive statistics). The value we use to describe the group will be the single value that is the most common methods as statistical tools and the most important measure of variability. The standard deviations use the mean of the distribution as reference point and measures variability by considering the distance between each score and the mean. The mean, standard deviation and range will be used as a primary source of connecting facts about each parameter. On the other hand, the standard error measures the standard distance between a sample mean and population mean, therefore the standard error is the appropriate measure of variability.

Comparisons will be made by independent t-test to compare between control and NPWT groups. Paired t-test will be used to compare before and after treatment in the same group. A value of $P < 0.05$ will be considered statistically significant. All statistical analysis was applied through the statistical package for social studies (SPSS) version 25 for windows (IBM SPSS, Chicago, IL, USA).

- Results

- Subject characteristics:

Group (A): (control group)

Fifteen patients were included in this group. The data in table (1) and (Fig. 11, 12, 13) represented their mean age (57.46 ± 4.8)

years, mean weight (72.0±9.9) kilograms (Kg), and mean height (169.46±6.56) centimeters (cm).

Group (B): (Study Group)

Fifteen patients were included in this group. The data in table (1) and (Fig.11, 12, 13) represented their mean age (56.66±5.42) years, mean weight (76.0±11.23) kilograms (Kg), and mean height (168.73±6.87) centimeters (cm).

There was no significant difference between both groups in their ages, weights, and heights where their t and P-values were (0.42, 0.67), (1.03, 0.31), and (0.29, 0.76) respectively.

Table (1): Mean and ±SD, t and P values of (Wound Volume) pre and post treatment of group (A)

Group A (Control Group)	Wound Volume	
	Pre treatment	Post treatment
Mean	17.7	16.32
SD±	±3.17	±3.2
Mean difference	1.38	
Percentage of improvement	7.79 %	
DF	14	
t-value	7.54	
P-value	0.0001	
S	S	

*SD: standard deviation, P: probability, S: significance, S: significant, DF: degree of freedom

2-Results of group A (control group).

A-Wound Volume:

Group (A):

Table (2) demonstrated the Wound Volume pre and post -treatment for group (A). There was no significant difference in the paired t-test between pre and post treatment Wound Volume as the mean value of pre- treatment was (17.7± 3.17) and for post treatment was (16.32±3.2) where the t-value was (7.54) and P-value was (0.0001). The percentage of improvement was 7.79 %.

Table (2): Mean and ±SD, t and P values of (Wound Surface area) pre and post treatment (after 6 weeks) of group (A).

Group A (Control Group)	Wound Surface area	
	Pre treatment	Post treatment (after 6 weeks)
Mean	7.13	6.38
SD±	±4.26	±3.87
Mean difference	0.75	
Percentage of improvement	10.51 %	
DF	14	
t-value	4.65	
P-value	0.0001	
S	S	

*SD: standard deviation, P: probability, S: significance, S: significant, DF: degree of freedom.

b-Wound Surface area:

Group (A):

Table (3) demonstrated the Wound Surface area pre and post treatment (after 6 weeks) for group (A). There was no significant difference in the paired t-test between pre and post treatment Wound Surface area as the mean value of pre-treatment was (7.13± 4.26) and for post treatment was (6.38±3.87) where the t-value was (4.65) and P-value was (0.0001). The percentage of improvement was 10.51 %.

Table (3): Mean and ±SD, t and P values of (Wound Volume) pre and post treatment of group (B).

Group B (Study Group)	Wound Volume	
	Pre treatment	Post treatment
Mean	16.44	9.47
SD±	±1.95	±1.68
Mean difference	6.97	
Percentage of improvement	42.39 %	
DF	14	
t-value	17.75	
P-value	0.0001	
S	S	

*SD: standard deviation, P: probability, S: significance, S: significant, DF: degree of freedom.

2-Results of group B (Negative Pressure Wound Therapy group).

a-Wound Volume:

Group (B):

Table (4) demonstrated the Wound Volume pre and post treatment for group (B). There was a significant difference in the paired t-test between pre and post treatment

Wound Volume as the mean value of pre-treatment was (**16.44**± 1.95) and for post treatment was (9.47±1.68) where the t-value was (17.75) and P-value was (0.0001). The percentage of improvement was 42.39 %.

Table (4): Mean and ±SD, t and P values of (Wound Surface area) pre and post treatment (after 6 weeks) of group (B).

Group B (Study Group)	Wound Surface area	
	Pre treatment	Post treatment (after 6 weeks)
Mean	6.44	4.02
SD±	±2.15	±1.28
Mean difference	2.42	
Percentage of improvement	37.57 %	
DF	14	
t-value	9.49	
P-value	0.0001	
S	S	

*SD: standard deviation, P: probability, S: significance, S: significant, DF: degree of freedom.

b-Wound Surface area:

Group (B):

Table (4) demonstrated the Wound Surface area pre and post treatment (after 6 weeks) for group (B). There was a significant difference in the paired value of pre treatment was (**6.44**± 2.15) and for post treatment was (4.02±1.28) where the t-value was (9.49) and P-value was (0.0001). The percentage of improvement was 37.57 %.

4-Comparison between both A and B groups.

a-Wound Volume:

Table (5) revealed the independent t-test results for the Wound Volume pre and post treatment between groups A and B. There was no significant difference in pre treatment values where the t-value was (1.3) and p-value was (0.2). But there was a significant difference in the post treatment (after 6 weeks) values (P<0.05) where the t-value was (7.34) and p-value was (0.0001).

Table (5): Independent t-test between groups A and B for (Wound Volume) pre and post treatment (after 6 weeks).

Independent t-test	Wound Volume	
	Pre-treatment	Post-treatment (after 6 weeks)
Mean difference	1.26	6.85
t-value	1.3	7.34
P-value	0.2	0.0001
S	NS	S

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

b-Wound Surface area:

Table (6) revealed the independent t-test results for the Wound Surface area pre and post treatment between groups A and B. There was no significant difference in pre-treatment values where the t-value was (0.55) and p-value was (0.58). But there was a significant difference in the post treatment values (P<0.05) where the t-value was (2.24) and p-value was (0.03).

Table (6): Independent t-test between groups A and B for (Wound Surface area) pre and post treatment.

Independent t-test	Wound Surface area	
	Pre	Post
Mean difference	0.69	2.36
t-value	0.55	2.24
P-value	0.58	0.03
S	NS	S

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

Discussion:

The finding of this study indicated statistical differences in surface area and wound volume measurements between both groups after application of VAC therapy in Group Where there was significant differences between both groups in in wound volume and wound surface area.

Rut F., (2010) found that treatment with NPWT for wound management in primary

care in half of the cases lead to complete ulcer healing and in all cases accelerated the growth of granulation tissue. [5]

Vuerstaek et al, (2006) suggested that NPWT (topical negative pressure) technology should be considered the treatment choice for chronic (hard-to-heal) ulcers due to its significant advantages concerning time for wound healing and wound bed preparation compared with conventional therapy. [6]

Peter et al, (2008) suggested that NPWT is as safe as and more efficacious than traditional medical wound treatment in the treatment of diabetic foot ulcers. Where a significantly greater number of NPWT patients achieve complete ulcer closure and granulation tissue formation than traditional medical treatment. [7]

Armstrong and Lavery, (2005) reported that NPWT may be an alternative therapy to achieve an improved granulating wound bed in diabetic foot wounds to prepare the wound bed for other closure techniques by increasing blood supply into the wound. [4]

Gupta et al., (2004) Reported that the main mechanisms of action for NPWT are the provision of a moist wound healing environment, removal of fluids and infectious materials, assisted perfusion, decreased bacterial colonization and enhanced formation of granulation tissue. [8]

Gray et al., (2004) reported that Negative pressure wound therapy is indicated for remove the exudates and reduce pre wound edema, increase local micro vascular blood flow, promote formation of granulation tissue, reduce size and complexity of the

wound, optimize the wound bed prior to and following surgery, and act as barrier to bacteria. [9]

Mark et al., (2003) reported that over the first several weeks of therapy, VAC dressings decreased wound depth and volume more effectively than moist gauze dressings. Negative-pressure wound treatment may accelerate closure of large foot wounds in the diabetic patient. [10]

Borgquist et al., (2010) reported that Blood flow changed gradually with increasing negative pressure until reaching a steady state. And this increasing in blood flow improved the wound healing especially in chronic wounds and ulcers. [11]

Conclusions:-

From gained results of this stud the negative pressure wound therapy can be considered as an effective and safe method to treat the chronic diabetic foot ulcers.

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