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Original Research Article

A Comparative Study of Efficacy of Negative Pressure Wound Therapy and Conventional Gauze Dressing in Healing of Diabetic Foot Ulcer

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Abstract:

Background: Globally, there are an approximate 171 million diabetics, and by 2030, that number is projected to reach 366 million. Without accounting for its role in cardiovascular death, the major cause of death among early diabetics, diabetes mellitus ranks as the seventh major cause of mortality as a direct cause. The traditional approach has been saline-moistened gauze, but it has been challenging to consistently maintain a wound that is moist with these dressings. The primary Negative Pressure on the wound's surface can be changed thanks to a connection between the wound dressing and a control unit via a set of suction tubes. Negative pressure between 80 and 125mmHg is most frequently applied, either constantly or in cycles. The control unit's container holds the wound fluid that has been suctioned into it.

Aim: Aim of the study is to compare negative pressure wound therapies with conventional dressing in the treatment of diabetic foot ulcer in terms of Rate of growth of granulation tissue; Change in size and depth of the ulcer; Duration to achieve complete healing by surgery or grafting; Duration of hospital stay of patients.

Materials and Methods: After taking the written informed consent, subjects were divided into two groups based on computer generated random numbers. Group NPT (negative pressure therapy) included 50 subjects and group CGD (conventional gauze dressing) included 50 cases. All participants were assessed for the demographic and clinical presentation by the principal investigator using a pre structured proforma. Following which the principal investigator assessed the detailed history of the participants and clinically examined the patients.

Results and Conclusion: We infer that negative pressure wound dressing is superior to conventional gauze dressing in terms of rate of growth of granulation tissue formation as percentage of ulcer surface area, reduction in size and depth of the ulcer during treatment, duration to achieve complete healing and duration of hospital stay of the patients.

Keywords: Wound Healing, Negative Pressure Dressing, Conventional Gauze Dressing.

Introduction

The most common metabolic non-communicable disease with a very high prevalence and a comparable number of undiagnosed individuals is Diabetes mellitus. Globally, there are an approximate 171 million diabetics, and by 2030, that number is projected to reach 366 million. Without accounting for its role in cardiovascular death, the major cause of death among early diabetics, diabetes mellitus ranks as the seventh major cause of mortality as a directcause [2].

People with Indian ancestry have one of the highest rates of T2DM worldwide [3]. Among the most prevalent, dangerous, expensive, and disabling effects of diabetes is foot ulceration. A diabetic's lifetime risk of acquiring a foot ulcer ranges from 15 to 25%, with diabetics with neuropathy having a higher life time risk [4]. Diabetic foot ulcer is a major reason for hospitalisation, and in industrialized nations as well, it accounts for 23% of all hospital days and 16% of all hospitalisations. In developed countries, DFUs account for more over 85% of non-traumatic lower-limb amputations [5]. At 2 to 5 years after a lower limb amputation, 50% of patients will develop a new ulcer or require a contralateral amputation2.

Alarmingly, the prognosis gets worse as the extent of amputation increases and only 40 to 50% of amputees live 5 years. Also, diabetic foot infection (DFI), affects more than 50% of DFUs and is associated with a high mortality and morbidity rate. DFIs have are admission rate of about 40%, while 1 in 6 patients pass away within a year after infection, with severe social, psychological, and financial repercussions [6].

The ideal course of treatment for DFU is yet unknown. The traditional approach has been saline-moistened gauze, but it has been challenging to consistently maintain a wound that is moist with these dressings. Different hydrocolloid wound gels were created as a result, which offered more reliable moisture retention. The addition of other pharmacological substances, including as tissue factor and enzymatic exfoliation chemicals, has been made possible by improvements in topical ointments. Other wound treatments that have been promoted include hyperbaric O2 therapy and cultured skin substitutes. All of these treatments come with a hefty price tag and are sometimes used despite a lack of solid scientific proof of their effectiveness. As a result, the hunt for an effective, practical, and economical therapy continues [7,8].

Since the 1940s, several drains that use negative pressure to treat wounds have been in use [9,10]. In the 1990s, Germany and US developed a negative pressure based method of treating open wounds [11-13]. The process is patented under the term Vacuum Assisted Closure by Kinetic Concepts Inc. The general term Negative pressure wound therapy is frequently used in the English language. The method of treatment is local negative pressure that is administered to the wound surface uniformly. An airtight film and separate dressings are used to cover the open wound [11].

The primary Negative pressure on the wound's surface can be changed thanks to a connection between the wound dressing and a control unit via a set of suction tubes. Negative pressure between 80 and 125 mmHg is most frequently applied, either constantly or in cycles. The control unit's container holds the wound fluid that has been suctioned into it.

Nearly all acute and chronic wounds, including pressure injuries, diabetic skin ulcers, lower leg lacerations, surgical incisions, traumatic lacerations, burns, decubitus ulcers, necrotizing fasciitis, infected sternal wounds, and wounds following skin grafting, have been advised for NPWT to speed recovery. Depending upon the treatment goal and the type of wound, the therapy can last anywhere from just few days to months [13]. Hydrogel dressings absorb wound exudate, rehydrate necrotic tissue to enable simple debridement, and maintain a humid environment for wound healing. Dressings made of hydrocolloid for dry wounds like venous stasis ulcers [14]. Alginate bandages are complex carbohydrates that are made of the seaweed-derived glucuronic and mannuronic acids. They are slightly sticky and can be used on wounds that exude a lot of fluid. Hydrofibers for thick excretions films with adhesive for superficial wounds. Other treatments for treating persistent wounds include growth hormones, skin substitutes, and hyperbaric O2 therapy [15].

Elevating the affected limb and applying a compressive dressing are helpful treatments for edoema. Unna boots and pneumatic compression devices can also be utilised when there is venous stasis [16]. However, the conventional moist gauge dressing and Negative pressure wound dressing are widely used these days. But the outcome of these two treatment modalities remains an unsolved question. Hence this study was conducted to assess the efficacy of these two modalities in healing of DFU.

Aims and Objectives

1. To compare negative pressure wound therapy with conventional dressing in the treatment of diabetic foot ulcer in terms of.
2. Rate of growth of granulation tissue formation as percentage of ulcer surface area. Change in size and depth of the ulcer during treatment Duration to achieve complete healing by surgery or grafting.
3. Duration of hospital stay of the patients.

Materials and Methods

Study Design: Prospective Cross Sectional Analytical Study.

Study Area: This study was conducted in the department of General Surgery in a Tertiary Care Hospital.

Study population: Patients attending outpatient and inpatient department of General surgery with DFU.

Study period: January 2021 to August 2022.

Sample size: A total of hundred patients with DFU were included and among them 50 were treated with NPWD and the rest 50 cases were treated with conventional gauze dressing. Ethical committee approval was obtained for this study from the Institutional Human Ethics Committee.

Inclusion criteria: Cases with DFU; cases aged above 18 years.

Exclusion criteria: Cases with Traumatic ulcer, Arterial ulcer, Malignant ulcer, Venous ulcer.

Data Collection: After taking the written informed consent, subjects were divided in to two groups based on computer generated random numbers. Group NPT (negative pressure therapy) included 50 subjects and group CGD (conventional gauze dressing) included 50 cases. All participants were assessed for the demographic and clinical presentation by the principal investigator using apre structured proforma. Following which the principal investigator assessed the detailed history of the participants and clinically examined the patients. Outcome includes comparison between two groups in terms of Rate of growth of granulation tissue formation as percentage of ulcer surface area; Change in size and depth of the ulcer during treatment; Duration to achieve complete healing by surgery or grafting; Duration of hospital stay of the patients.

Data analysis: The data was entered in excel sheet and analyzed using SPSS (Version 19). Descriptive statistics with mean, standard deviation and proportions (%) were calculated for quantitative variables. To test the hypothesis Chi Square test and Independent sample t test were assessed. Pvalue <0.05 was considered as statistically significant.

Results

Table1: Age wise distribution of patients

Age group	Group NPT	Group CGD	Total	P value
≤40 years	7	6	13	0.8863
41-50years	13	15	28	
51-60years	19	16	35	
>60years	11	13	24	
Total	50	50	100	
Mean	48.5 ± 13.7	46.6 ± 14.2		0.4975

Table 2: Gender distribution of cases

Gender	Group NPT	Group CGD	Total	P value
Male	37	35	72	0.6560
Female	13	15	28	
Total	50	50	100	

Table 3: BMI vs group NPT and CGD

BMI	Group NPT	Group CGD	Total	P value
Normal	27	29	56	0.9173
Overweight	15	14	29	
Obese	8	7	15	
Total	50	50	100	
Mean	24.7±4.7	23.7±5.6		0.3358

Table 4: Duration of DM vs NPT and CGD group

Duration of DM	Group NPT	Group CGD	Total	P value
<5years	17	15	32	0.9101
5-10years	21	22	43	
>10years	12	13	25	
Total	50	50	100	
Mean	7.4 ± 6.8	8.1 ± 6.2		0.5919

Table 5: Medications for DM vs NPT and CGD group

Medications for DM	Group NPT	Group CGD	Total	Pvalue
OHA	35	32	67	0.7914
Insulin	3	3	6	
Both	12	15	27	
Total	50	50	100	

Table 6: Blood glucose levels

RBS	Group NPT	Group CGD	P value
Mean FBS (mg/dl)	202.5 ± 31.5	195.7 ± 38.6	0.3369
Mean PPBS (mg/dl)	268.8 ± 68.1	273. ± 72.5	0.7659
Mean HbA1c (%)	8.3 ± 1.7	8.5 ± 1.4	0.5223

Table 7: Hypertension among study group participants

Hypertension	Group NPT	Group CGD	Total	Pvalue
Present	21	18	39	0.5385
Absent	29	32	61	
Total	50	50	100	

Table 8: Dyslipidemia among study group participants

Dyslipidemia	Group NPT	Group CGD	Total	P value
Present	14	17	31	0.5165
Absent	36	33	69	
Total	50	50	100	

Table 9: Smoking Habit vs group NPT and CGD

Smoking	Group NPT	Group CGD	Total	P value
Present	21	20	41	
Absent	29	30	59	
Total	50	50	100	0.8388

Table 10: Alcohol consumption vs group NPT and CGD

Alcohol	Group NPT	Group CGD	Total	P value
Present	16	19	35	0.5293
Absent	34	31	65	
Total	50	50	100	

Table 11: Extremity involved for diabetic ulcer

Extremity Involved	Group NPT	Group CGD	Total	Pvalue
Right	27	22	49	0.3172
Left	23	28	51	
Total	50	50	100	

Table 12: Pre- Tx Wagner's Classification vs NPT and CGD group cases

Wagner's Classification	Group NPT	Group CGD	Total	Pvalue
Grade1	13	18	31	0.2796
Grade2	37	32	69	
Total	50	50	100	

Table 13: Granulation tissue formation

Granulation tissue	Group NPT	Group CGD	P value
Week0	0.2±0.2	0.2±0.1	**1.0000**
Week1	0.8±0.5	0.6±0.4	0.0295*
Week2	1.3±0.9	0.9±0.5	0.0072*
Week3	4.5±1.8	1.5±1.0	<0.0001*
Week4	7.7±2.4	3.6±1.7	<0.0001*
Week5	8.6±2.1	5.7±1.5	<0.0001*
Week6	9.4±1.7	6.8±1.8	<0.0001*

*Significant

Table 14: Mean ulcer size among the study groups

Ulcer Size (in cms)	Group NPT	Group CGD	Pvalue
Week0	10.4±5.7	9.4±6.1	0.3991
Week1	9.1±4.9	9.3±5.8	0.8526
Week2	7.5±2.8	8.6±4.2	0.1266
Week3	5.8±2.4	7.8±4.1	0.0037*
Week4	4.4±1.5	6.9±2.6	<0.0001*
Week5	3.6±1.3	5.5±1.5	<0.0001*
Week6	2.0±0.5	4.3±2.1	<0.0001*

*Significant

Table 15: Ulcer Depth vs group NPT and CGD

Ulcer Depth (in cms)	Group NPT	Group CGD	P value
Week0	1.2±0.6	1.1±0.5	0.3675
Week1	1.0±0.5	1.1±0.4	0.2722
Week2	0.9±0.4	1.1±0.4	0.0141*
Week3	0.6±0.5	1.0±0.3	<0.0001*
Week4	0.5±0.3	0.9±0.5	<0.0001*
Week5	0.3±0.3	0.7±0.5	<0.0001*
Week6	0.2±0.2	0.6±0.4	<0.0001*

*Significant

Table 16: Rate of Growth of granulation tissue before and after treatment

Rate of Growth of granulation tissue (%)	Group NPT	Group CGD	Pvalue
Before TX	2.5±1.2	2.5±1.0	1.0000
After TX	93.4±4.2	72.2±15.7	<0.0001*
P value	<0.0001*	<0.0001*	-

*Significant

Table 17: Ulcer size before and after treatment

Ulcer Size (in cms)	Group NPT	Group CGD	P value
Before TX	10.4±5.7	9.4±6.1	0.3991
After TX	2.0±0.5	4.3±2.1	<0.0001*
P value	<0.0001*	<0.0001*	-

*Significant

Table 18: Ulcer depth before and after treatment

Ulcer Depth (in cms)	Group NPT	Group CGD	P value
Before TX	1.2±0.6	1.1±0.5	0.3675
After TX	0.2±0.2	0.6±0.4	<0.0001*
P value	<0.0001*	<0.0001*	

*Significant

Table 19: No of debridements

No of debridement	Group NPT	Group CGD	Total	P value
≤5 times	45	36	81	0.0217*
> 5times	5	14	19	
Total	50	50	100	

*Significant

Table 20: Skin Grafting among the group participants

Skin Grafting	Group NPT	Group CGD	Total	P value
Done	4	11	15	0.0499*
Not done	46	39	85	
Total	50	50	100	

*Significant

Table 21: Post TX Wagner's Classification

Post TX Wagner's Classification	Group NPT	Group CGD	Total	P value
Grade0	48	35	83	0.0023*
Grade1	1	10	11	
Grade2	1	5	6	
Total	50	50	100	

*Significant

Table 22: Complete healing among the study groups

Complete Healing	Group NPT	Group CGD	Total	P value
Achieved	48	35	83	0.0005*
Not achieved	2	15	17	
Total	50	50	100	

*Significant

Table 23: Mean Duration to achieve complete Healing

Parameter	Group NPT	Group CGD	Pvalue
Duration to achieve complete Healing (in weeks)	2.6±1.4	3.7±2.1	0.0027*

*Significant

Table 24: Mean duration of hospital stay

Parameter	Group NPT	Group CGD	P value
Duration to hospital stay (in days)	9.3±4.2	16.5±6.8	<0.0001*

*Significant

Discussion

Findings of the present study were comparable with the following studies. Vikatmaa P et al [16] stated that in every experiment, NPWD has been at least as efficient as the control treatment, and in other instances, it was even more effective. The majority of research demonstrates that NPWD is beneficial in treating posttraumatic and chronic leg ulcers. Serious side effects have been documented seldom, and NPWD seems to be a safe and effective treatment. Only 2 studies were deemed to be "high quality" studies, and the others were deemed to have poor validity. They came to the conclusion that NPWD is at least as successful as if not more effective as current local wound care.

Gregor S et al [17] systematically compared the clinical efficacy and safety of NPWD with that of traditional wound therapy. In two of the five RCTs and two of the four non-RCTs, they reported that there were significant differences infavour of NPWD for the duration of the wound or the frequency of wound closure. NPWD was preferred in an MA of changes in wound contraction that also included 4 RCTs and 2 non-RCTs.

Similarly, Xie X et al [18] in their review evaluated the effectiveness of NPWD, there is enough data to support its application in the treatment of long-term leg wounds caused by diabetes and to demonstrate that it is safe and will speed healing.

Nain P S et al [19] performed a study to contrast the rate of wound repair between the MGD in DFU and the NPWD. According to their findings, there was an earlier granulation tissue emergence in the study group than in the control group, which was statistically significant. In comparison to the control group, the study group was expected to produce greater results. They came to the conclusion that NPWD plays a clear part in the recovery of DFU. Peinemann F et al [20] in their SR research, only 5 of the 9 new papers mention the incidence of complete wound closure, and only 2 of the trials indicated a remarkable effect in favor of NPWD. Due to bias that appears to exist as well as the fact that different types of injuries were treated, the findings of 8 out of the 9 new studies are difficult to interpret. They came to the conclusion that, despite the possibility of NPWD having a beneficial effect, there was no conclusive evidence that wounds would heal better or worse following NPWD than with standard therapy.

However, Ross L Y et al [21] compared how NPWD and traditional wound dressings are used to treat DFU. In comparison to traditional wound dressings, they discovered that NPWD was more successful at treating diabetic foot wounds. The formation of granulation tissue, wound healing, the elimination of infection from the foot ulcer beds, and the reduction of wound size were all accelerated by NPWD. Additionally, data revealed a higher frequency of amputations in patients who received moist wound dressings. They came to the conclusion that diabetic foot wounds could benefit from NPWD as a main treatment. In order to put NPWD into practise, factors like patient acceptability and cost effectiveness will need to be looked in to as they may have an effect on this treatment.

Dumville J C et al [22] stated that studies involving patients with DM and post amputation wounds were considered, and they found that considerably more patients in NPWD group than in the wet dressing group recovered. A statistically significant rise in the percentage of healed ulcers was seen in the NPWD group compared to the MGD in different research that involved individuals with debrided foot ulcers. They came to the conclusion that NPWD is superior to moist wound dressings in treating post-operative foot wounds and foot ulcers in individuals with DM. Due to the potential for bias in the first investigations, these conclusions are, none the less, unclear.

In another study, ZhangJ et al claimed that negative pressure caused a considerably larger percentage of cured ulcers, more ulcer area reduction, and a lesser duration to wound healing as compared to diabetic foot ulcers that weren't treated with NPWD. Patients with NPWD also had significantly fewer major amputations; however, there was no difference in the frequency of minor amputations. There was no discernible difference between non-NPWD and negative-pressure wound therapy. There was no evidence of study heterogeneity. They came to the conclusion that NPWD looks to be safer than non-NPWD and appears to be more beneficial for diabetic foot ulcers.

Wang R et al [24] reported that NPWD with VAC improved healed ulcers as effectively as ultrasound debridement. NPWD with ultrasound debridement (UD) considerably outperformed routine wound care in terms of time to wound closure and reduction in wound area while treating diabetic foot ulcers. Between the NPWD and UD groups, neither indicator showed any differences that were significant. In comparison to the group receiving normal wound care, fewer patients in the NPWD and UD groups likely to need an amputation. They came to the conclusion that NPWD for diabetic foot ulcers was comparable to ultrasound debridement but superior to normal wound care in terms of efficacy and safety.

In addition, Liu X et al [25] stated that NPWD led to significantly lower rates of infection, shorter periods of time needed to cover and heal wounds, shorter periods of hospitalisation, and a decreased rate of amputation. However, there was no discernible change in the percentage of free flaps, the rate of flap failure, or the incidence of fracture non-union.

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