ISSN: 2581 – 3633
PubMed - National Library of Medicine - ID: 101745081

International Journal of Medical Science and Advanced Clinical Research (IJMACR)

Available Online at: www.ijmacr.com

Volume – 5, Issue – 6, November – December - 2022, Page No. : 307 - 315

Effect of Negative Pressure Wound Therapy on Diabetic Foot Ulcers

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How to citation this article: Akshay Duppelly, "Effect of Negative Pressure Wound Therapy on Diabetic Foot Ulcers", IJMACR- November – December - 2022, Vol – 5, Issue - 6, P. No. 307 – 315.

Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

Background: In this study, we wanted to evaluate the effect of negative pressure wound therapy on diabetic foot ulcers.

Methods: This was a hospital based prospective comparative study, conducted among 40 patients who came for treatment of diabetic foot ulcers to the Department of General Surgery, Kamineni Academy of Medical Sciences and Research Centre, Hyderabad, Telangana, over a period of 2 years from September 2019 to September 2021, after obtaining clearance from Institutional Ethics Committee and written informed consent from the study participants.

Results: The increase negative pressure wound therapy (NPWT) and saline-soaked gauzed dressing (SSGD groups were found to be statistically significant. Mean change (increase) in NPWT & SSGD groups from day 0 to day 42 were 78.083 % and 66.103 % respectively. Whereas in NPWT and SSGD groups, the size of ulcer was decreased which was statistically significant. Mean decrease in NPWT & SSGD groups from day 0 to day 42 were 52 cm sq and 29.15 cm sq respectively. The mean duration of stay in hospital in NPWT & SSGD groups were 29.35 + 4.51 days and 32.75 + 4.75 days with p value of 0.02, which is statistically significant. Among patients with NPWT, response was present in 95 % (19) patients and among patients with SSGD, response was present in 85 % (17) patients. The association between the groups was found to be statistically not significant.

Conclusion: Length of stay was shorter in the NPWT group when compared with that of SSGD group.

Rate of granulation tissue formation was faster in NPWT group when compared to SSGD group. Reduction in ulcer size was significantly better in the NPWT group. Patient compliance and satisfaction was better in NPWT group.

Lesser number of changes of dressings were needed in the NPWT group. It could be concluded that negative pressure wound therapy helps in faster healing, better, safe, and convenient as compared to saline-soaked gauzed dressing in the treatment of diabetic foot ulcers.

Keywords: Negative Pressure Wound Therapy, Diabetic, Foot Ulcers

Introduction

Diabetes is attaining the status of a potential epidemic in India. 62 million individuals have been diagnosed with the disease at present. India (31.7 million) had the highest population of people with diabetes mellitus in the year 2000, followed by China (20.8 million) and the United States (17.7 million) in second and third place. According to Wild et al. the prevalence of diabetes is anticipated to double globally from 171 million in 2000 to 366 million in 2030 with a highest increase in India. It is prophesized that by 2030 diabetes mellitus may afflict up to 79.4 million individuals in India.[1]A wound is defined as an injury to living tissue caused by a cut, blow, or other impact, typically one in which the skin is cut or broken. The history of wound care courses from pre-history to modern medicine. The Egyptians were the first people to use adhesive bandages and were undoubtedly the first people to apply honey to the wounds. The Greeks implicated the importance of cleanliness and recommended washing the wound with clean water, often boiled first, vinegar (acetic acid), and wine. The Greeks also classified the wounds as “fresh,” or acute, and non-healing, or chronic wounds. Modern wound healing emerged in the 20th century. Currently, there are more than 5,000 wound care products. Modern dressings are composed of materials that are highly absorbent such as alginates, foam or carboxy methylcellulose. There are occlusive dressings and semi occlusive dressings. Growth factors, advanced honey-based dressings, and hypochlorous acid–based cleansers are other materials to name a few. Bioengineered tissue, negative pressure therapy, and hyperbaric oxygen therapy have paved the way for a better treatment of chronic wounds today.[2] Diabetic foot wounds present a great challenge to wound care practitioners and these ulcers have a multifactorial aetiology, with polyneuropathy, biomechanical stress, infection, lack of foot wear and ischemia as the major factors.[3,4] Conventional moist gauze dressings are the most commonly used dressing for DFUs but however are not a very effective method for the treatment of diabetic foot ulcers. The new technique of applying negative pressure dressings to DFU has found to be effective. In recent years, studies have shown that negative pressure dressing accelerated wound healing, improved rate of graft uptake, decreased the cost, hospital stay, reduced complications and morbidity in patients with diabetic foot ulcers. The vacuum dressing is more correctly known as negative pressure wound therapy involves applying an intermittent negative pressure of approximately-125 mmHg. It appears to hasten the debridement and the formation of granulation tissue in chronic wounds and ulcers. A foam is cut to size of the wound to fit the wound. A vacuum is then applied to the foam with a drain. Negative pressure may act by decreasing oedema, by removing interstitial fluid and increasing blood flow resulting in decreased bacterial counts and increased cell proliferation, thereby creating a suitable bed for graft or flap cover.[5]

Aims and Objectives

- The aim of this study was to evaluate the effectiveness of negative pressure wound therapy for the management of diabetic foot ulcers.
- To study the results of negative pressure wound therapy in the management of diabetic foot ulcers.
- To compare the effectiveness of negative pressure wound therapy with conventional moist gauze dressings.

Materials and methods

This was a hospital based prospective comparative study, conducted among 40 patients who came for

treatment of diabetic foot ulcers to the Department of General Surgery, Kamineni Academy of Medical Sciences and Research Centre, Hyderabad, Telangana, over a period of 2 years from September 2019 to September 2021, after obtaining clearance from Institutional Ethics Committee and written informed consent from the study participants.

Inclusion Criteria

- All patients with diabetic foot ulcers.
- Patients giving consent for VAC therapy.

Exclusion Criteria

- Malignant wounds
- Untreated underlying osteomyelitis
- Exposed vessels in wounds
- Dry gangrene

Equal number of patients were allotted to Group A involving the use of topical negative pressure therapy or to Group B involving conventional moist dressing using saline soaked gauze dressing.

Following investigations were done for all patients in both the study groups.

- Complete blood count.
- Complete urine examination
- Random blood sugar, HbA1c, blood urea, Serum creatinine, Serum albumin.
- Regular blood glucose monitoring
- Electrocardiogram.
- Culture and sensitivity of tissue from the wound.
- X-ray of the affected foot.
- Arterial Doppler of the affected limb.
- Chest x-ray and echocardiography (if patient's age is >50 years or when required).

All patients were explained in detail about the treatment protocols and written consent was obtained. Similar sizes of ulcer were included in both groups. All patients underwent initial wound debridement before undergoing NPWT or conventional saline dressings. All patients were treated with similar antibiotics initially and antibiotic coverage changed based on culture and sensitivity report. All patients received appropriate medical treatment to control diabetic status by diet restriction and insulin therapy and oral hypoglycaemic agents (OHAs).

Sample Size

A minimum of 40 patients were included in the study. 20 patients in the study group (NPWT), 20 patients in the control group (moist dressings).

Sample size has been calculated using single proportion formula

$n = Z^2P\ (1—P)/d^2$

n – Sample size Z–1.96

P – Expected prevalence of proportion (was assumed to be 5 %) d – Precision (5 %, d = 0.05)

Statistical Methods

Data entry was done using M.S. Excel and statistically analyzed using Statistical Package for Social Sciences (SPSS Version 16) for M.S Windows. Descriptive statistical analysis was carried out to explore the distribution of several categorical and quantitative variables. Categorical variables were summarized within (%), while quantitative variables were summarized by mean ± S.D. All results were presented in tabular form and are also shown graphically using bar diagram or pie diagram as appropriate.

The differences in the two groups were tested for statistical significance using parametric tests such as t-test and categorical variables tested by chi square test. P-value less than 0.05 considered to be statistically significant.

Results

The mean age in NPWT & SSGD groups were 66.55 + 12.79 years and 59.50 + 12.19 years. Minimum age being 29 and maximum age was 86 years. Among patients in group NPWT, males were 70 % (14 cases) and females were 30 % (6 cases). Among patients in group SSGD, males were 65 % (13 cases) and females were 35 % (7 cases).

Table 1: Demographic Distribution

	NPWT		SSGD	
	Mean	SD	Mean	SD
Age	66.55	12.796	59.50	12.194

Distribution of Patients Based on Age

			Group		Total
			NPWT	SSGD	
Gender	Male	n	14	13	27
		%	70.0 %	65.0 %	67.5 %
	Female	n	6	7	13
		%	30.0 %	35.0 %	32.5 %
Total		n	20	20	40
		%	100.0 %	100.0 %	100.0 %

Distribution of Patients Based on Gender among the Two Groups

Sex Distribution

Table 2

HbA1cLevels			Group		Total
			NPWT	SSGD	
	</= 8.1	n	9	7	16
		%	45.0 %	35.0 %	40.0 %
	> 8.1	n	11	13	24
		%	55.0 %	65.0 %	60.0 %
Total		n	20	20	40
		%	100.0 %	100.0 %	100.0 %
Mean + SD			8.49 + 1.53	9.02 + 1.88	

Distribution of Patients Based on HBA1C Levels

Among patients with NPWT, HbA1c levels were > 8.1 in 55 % (11) patients and among patients with SSGD, HbA1c levels were > 8.1 in 65 % (13) patients. The association between the groups was found to be statistically not significant. 8.1 was taken as cut off for poor control. Mean HbA1c levels in NPWT & SSGD groups were 8.49 + 1.53 and 9.02 + 1.88 years.

Table 3

Granulation Tissue AS % of Ulcer Floor	NPWT		SSGD		T Test	P Value
	Mean	SD	Mean	SD		
0 day	15.250	5.4952	11.250	3.1079	2.30	0.02
6 days	32.000	7.8472	19.737	6.1178	5.42	0.001
12 days	58.250	15.1549	35.000	11.2390	5.51	0.001
24 days	82.250	15.3447	60.789	17.5010	4.07	0.001
42 days	93.333	6.5134	77.353	13.8200	3.71	0.001
Distribution of Patients Based on Granulation Tissue as Percentage of Ulcer Floor						
Size of Ulcer (IN CM^2)	NPWT		SSGD		T Test	P Value
	Mean	SD	Mean	SD		
0 day	82.500	26.4426	70.150	36.0938	1.23	0.22
6 days	69.550	22.6076	70.400	37.8089	-0.08	0.93
12 days	52.750	23.4585	61.800	41.3262	-0.85	0.40
24 days	45.050	21.2714	57.850	48.5650	-1.08	0.28
42 days	30.500	8.3829	41.000	15.5563	-2.10	0.04
Distribution of Patients Based on Size of Ulcer among the Two Groups						
	NPWT		SSGD		T Test	P Value
	Mean	SD	Mean	SD		
DOS in Hospital (days)	29.350	4.5105	32.750	4.7559	-2.32	0.02
Distribution of Patients Based on Duration of Stay in Hospital.						

In the NPWT group, mean granulation tissue as percent of ulcer floor was increased from 15.20 % on day 0 to 93.33 % on day 42. In SSGD group, mean granulation tissue as percent of ulcer floor was increased from11.25 % on day 0 to 77.35 % on day 42. The increase in both the groups on different days (0, 6, 12, 24 & 42 days) was found to be statistically significant. Mean change (increase) in NPWT & SSGD groups from day 0 to day 42 were 78.083 % and 66.103 % respectively. In the NPWT group, size of ulcer was decreased from 82.50 cmsq on day 0 to 30.50cmsq on day 42. In SSGD group, size of ulcer was decreased from 70.15 cmsq on day 0 to 41 cmsq on day 42. The decrease showed statistical significance in both the groups only on 42nd day. Mean decrease in NPWT & SSGD groups from day 0 to day 42 were 52 cmsq and 29.15 cmsq respectively. The mean duration of stay in hospital in NPWT & SSGD groups were 29.35 + 4.51 days and 32.75 + 4.75 days with p value of 0.02, which is statistically significant.

Table 4

Procedure			Group		Total
			NPWT	SSGD	
	Nil	n	1	3	4
		%	5.0 %	15.0 %	10.0 %
	Spontaneous closure	n	3	4	7
		%	15.0 %	20.0 %	17.5 %
	Secondary suturing	n	2	2	4
		%	10.0 %	10.0 %	10.0 %
	Split skin graft	n	14	11	25
		%	70.0 %	55.0 %	62.5 %
Total		n	20	20	40
		%	100.0 %	100.0 %	100.0 %

Distribution of Patients Based on Procedure among the Two Groups

			Group		Total
			NPWT	SSGD	
End Result	Response	n	19	17	4
		%	95.0 %	85.0 %	10.0 %
	No response	n	1	3	36
		%	5.0 %	15.0 %	90.0 %
Total		n	20	20	40
		%	100.0 %	100.0 %	100.0 %

Distribution of Patients Based on End Result among the Two Groups

Among patients with NPWT, split skin graft was done in 70 % (14) patients, spontaneous closure was done in 15 % (3) patients and secondary suturing was done in 10 % (2) patients. Among patients with saline soaked gauze dressing, split skin graft was done in 55 % (11) patients, spontaneous closure was done in 20 % (4) patients and secondary suturing (2) was done in 10 % patients. The association between the groups was found to be statistically not significant. Among patients with NPWT, response was present in 95 % (19) patients and among patients with SSGD, response was present in 85 % (17) patients. The association between the groups was found to be statistically not significant.

Discussion

Age and Sex

In our present study, demographic profile of patients was studied and was comparable in both groups with no significant difference. Mean age in NPWT & SSGD groups were 66.55 + 12.79 years and 59.50 + 12.19 years. This is similar to the study done by Prabhdeep Singh Nain et al. where the mean age of patients in Group A (NPWT) was 61.33 ± 7.63 years and in Group B (SSGD) was 55.40 ± 11.54 years.

In this study, majority patients were males in both groups. In NPWT group, males were 70 % and females were 30 % in SSGD group, males were 65 % and females were 35 %. This was comparable to the study by

Atef Bayou mi et al. [6] where the predominant population were males. 19 out of 25 were males and 6 out of 25were females in their study.

Duration of Diabetes Mellitus

In the present study, duration of diabetes was compared in both groups and was found to be similar with no significant difference between both groups. Mean duration of DM in NPWT & SSGD groups were 7.96 + 4.04 years and 7.58 + 5.03 years and was found to statistically insignificant. In a study by Muhammad Tanveer Sajid, et al. [7] similar data was drawn. Mean duration of diabetes presentation was 15.65 ± 4.86 and 15.96 ± 5.79 years in group A and B, respectively (p = 0.74).

HbA1c Levels

Mean HbA1c levels in NPWT & SSGD groups were 8.49 + 1.53 years and 9.02 + 1.88 years. 8.1 was taken as cut off for poor control. Among patients with NPWT, HbA1c levels were > 8.1 in 55 % patients and among patients with SSGD, HbA1c levels were > 8.1 in 65 % patients. The association between the groups was found to be statistically not significant. This was comparable to a study done by Sangma M D James et al.[8] where the mean HbA1c levels were 8.74 and 8.54 in the VAC group and conventional dressing group respectively.

Granulation Tissue as Percentage of Ulcer Floor

In our study, the two parameters that were compared in terms of ulcer healing were rate of increase in granulation tissue as compared to ulcer floor and area reduction of ulcer. They were compared on day 0, 6, 12, 24 and 42.

In NPWT group, mean granulation tissue as percentage of ulcer floor was increased from 15.20 on day 0 to 93.33 on day 42. In SSGD group, mean granulation tissue as % of ulcer floor was increased from 11.25 on day 0 to 77.35 on day 42. The increase in both the groups on different days (0, 6, 12, 24 & 42 days) showed statistical significance. Mean change (increase) in NPWT & SSGD groups from day 0 to day 42 were 78.083 and 66.103 respectively.

These findings were comparable to the study done by Prabhdeep Singh Nain, Sanjeev K. Uppal et al. [9] In their study, there was a statistically significant difference in the rate of appearance of granulation tissue between the two groups; with granulation tissue appearing earlier in the study group. The study group promised a better outcome (80 % complete responders) as compared to the control group (60 % complete responders).

Our results are also comparable with that of Bagul A et al. [10]in 2014.The patients on VAC therapy had early appearance of granulation tissue as compared to patients treated by conventional dressing (90.9 % Vs 76 % at the end of one week. All patients developed granulation tissue by the end of 2 weeks.

Size of the Ulcer

In our study, the ulcer size was measured on day 0, 6, 12, 24, 42, and it was found that in the NPWT group, size of ulcer had decreased from 82.50 on day 0 to 30.50 on day 42. In SSGD group, size of ulcer had decreased from 70.15 on day 0 to 41 on day 42. The decrease in both the groups showed statistical significance only on 42nd day. Mean decrease in NPWT & SSGD groups from day 0 to day 42 were 52 and 29.15 respectively. Our results are similar to that of Muhammad Tanveer Sajid, et al. [7] the initial wound size in group A (NPWT) was 15.07 ± 2.92 cm2 and in group B (SSGD) 15.09 ± 2.81 cm2 (p = 0.95) (p < 0.001). Wound area reduction in both groups revealed statistically significant faster healing in group B as compared to group A (p < 0.001).

The results of the present study are comparable with the study of Ishtiaq Ahmed et al. [11]in which the initial average wound area was 50.6 ± 27.6 cm2. After VAC therapy, the wound area ranged from 3.4 to 92.35 cm2, the average area being 41.75 cm2. The actual reduction in wound area attained by VAC therapy varied from 3.4 to 38.6 cm2, with an average reduction of 11.4 ± 4.55 cm2. The percentage reduction in wound area ranged from 10.3 % to 62.11 %, with an average reduction of 27.9 ± 13.7 %. Wounds were healed after VAC therapy for an average of 21.75 ± 10.55 (range14 to 40) days.

Duration of Hospital Stay

Mean duration of stay in hospital in NPWT & SSGD groups were 29.35 + 4.51 and 32.75 + 4.75 days with p value of 0.02. which is statistically significant. This observation is comparable to the study done by Ali EnginUlusal, et al. [12] who had found that the average hospitalization period with VAC treatment was 32 days compared to 59 days with standard dressing treatment.

End Result

In our study, among 20 patients with NPWT, SSG was done in 14 patients, and among 20 patients with SSGD, SSG was done in 11 patients. At the end of day 42, among all patients with NPWT, response was present in 95 % patients and among patients with SSGD, response was present in 85 % patients. The results are comparable with that of Leo Francis Tauro et al. [13] who concluded that topical negative pressure dressings help in faster healing of chronic wounds and better graft take-up and reduce hospital stay of these patients.

Conclusion

Length of stay was shorter in the NPWT group when compared with that of SSGD group. Rate of granulation tissue formation was faster in NPWT group when compared to SSGD group. Reduction in ulcer size was significantly better in the NPWT group. Patient compliance and satisfaction was better in NPWT group. Lesser number of changes of dressing were needed in the NPWT group. It could be concluded that negative pressure wound therapy helps in faster healing, is better, safe, and convenient when compared to saline soaked gauze dressing in the treatment of diabetic foot ulcers

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