International Journal Dental and Medical Sciences Research
Volume 5, Issue 5, Sep-Oct 2023 pp 432-439 www.ijdmsrjournal.com ISSN: 2582-6018

Comparing the Efficacy of Vacuum Assisted Closure Therapy with Conventional Dressing on Wound Healing in Patients with Diabetic Foot Ulcer.

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Date of Submission: 15-10-2023 Date of Acceptance: 25-10-2023

ABSTRACT

Introduction: Hyperglycemia in blood damages blood vessels & the nervous system. High blood sugar levels affect the nerves and its ability in the signal transmission. The NPWT system is comprised of a fluid collection system, an open-pore foam sponge, a semi occlusive adhesive and a suction pump[7]. This study was done to corelate the efficacy and other effects of the use of vacuum therapy on diabetic ulcers among the Indians.

Aim: To do a comparative analysis on the incidence and the time taken for the wound to heal following vacuum therapy over conventional dressing among the patients with diabetic foot ulcers.

Materials and methods:This is a prospective study sampled via randomized case-controlled method done at the Dept of General Surgery, TSRMMCH & RC during Dec 2021- Nov 2022. A total of 100 patients with diabetic foot ulcers with 50 in each group (Group A- NPWT; Group B- conventional dressing) was taken up for the study.

All the patients with T2DM 20-70 years of age with ulcer were included and cases with vascular diseases, coagulopathies, venous diseases, underlying osteomyelitis, charcot's joints, ulcers of the grades (3,4,5), peripheral arterial/ venous diseases, ulcers involving both the feet were excluded from the study.

Results: Out of the 100 patients, 28 - male ; 22 - female. It was reported from 28 males and 24 females - VAC therapy; 27 males and 23 female - conventional dressing. From the gender wise distribution it was uniform in both groups with the Pearson Chi test p value - 0.789. 2 cases - T2DM were not on any drugs. 37 patients were on OHA, 11 on insulin; 2 - oral drugs and insulin. Study group - one 1 with T2DM, 25 on orals, 20 on insulin and 3 on both; control batch – 37 on oral drugs, 11 on insulin and 2 on both. Pearson Chi 2 test - p-value of 0.789. 42% had no other illnesses, 11 - increased BP, 3.7% - heart diseases, (3%) had both, (2 %) - asthmatics. The co-morbidities among groups had p-value 0.0670. Time for granulation cover within >75% (Visual Score - 4) were found to be significantly better among patients that received VAC. ROG for ulcers <100 mm and >100 mm between both groups (p-value- 0.03510) for those with ulcers <100 mm (p value- 0.3598) for those with >100 mm.

Conclusion: This RCT comparing vacuum to saline dressing in diabetic ulcers found that vacuum dressing to be successful in decreasing the time required to wound closure. Further studies with a larger sample of patients are recommended to deduce the findings of this investigation.

Keywords: 1 Negative Pressure Wound Therapy,2 Diabetic Foot Ulcers,3 Saline Dressing

I. INTRODUCTION:

Hyperglycemia in blood damages blood vessels & the nervous system. High blood sugar levels affect the nerves and its ability in the signal transmission. It also causes certain chemical damages within the systemic regulation. As a result of the imbalance in the sugar levels in blood deteriorates the blood vessel that carries the nutrients and oxygen to the nerves. Consequently, the high blood sugar increases the risk of peripheral neuropathy, in which the nerve in the legs, foot, arms and hands are damaged. It affects about one-third to the diabetic population [1].Diabetic peripheral neuropathy in general greatly affects the foot complications risk by deteriorating the blood vessels and nerves in the body.

General symptoms are burning and tingling sensation in the extremities during the initial stages damaging the small nerves in the body. Likewise, when a large nerve fiber is damaged it causes the loss of protective sensation (LOPS). This leads to the increase in the risk of foot ulcers [2].

The most common symptoms of peripheral neuropathy include numbness,tingling, pain, burning/stinging, foot weakness, loss of feeling, inability to feel hot and cold sensations,

changes to the shape of feet or toes [2].Population affected by neuropathy are mostly asymptomatic, who don't have any of the indications. The American Diabetes Association recommends that all the patients get assessed when they are diagnosed with type 2 diabetes immediately and five years after diagnosing with type 1 diabetes, subsequently every year [3].

DFU is one of the most crucial side effects of T2DM with 25 percent risk of developing it [4]. Foot ulcers greatly affect the quality of life due to larger hospital stay and morbidity. The importance even more noteworthy in a country like India that has the largest number of diabetics [3]. If not treated immediately, the progress of the disease may demand a limb amputation [4].The effect of diabetic foot ulcers presents difficult in terms of quantifying from the historical perspective. Until now, it is observed that among 50 percent of the individuals with foot wounds were likely to die and three times more likely to be hospitalized. The details in the Medicare Limited Data Set taken between 2013 and 2019 among 78,716 recipients (average age of 70.9 years) were identified with at least one diabetic food ulcer case as assessed by researchers. The rate of incidence were 4.6 diabetic foot ulcers per 100 beneficiaries. Additionally, the diabetic foot ulcer (DFU) was in relation with renal failure, heart failure and lower limb amputation in endocrine, nutritional and metabolic disorders with the major complications and cellulitis [5].

Treating of the diabetic foot is a challenging task since it requires a multimodal approach including the control of the disease by the use of drugs, debridement, glycemic control and also negative pressure dressing. Closure of the ulcers takes pointedly larger time even along with strict sugars control. Larger diabetic ulcers needs a longer time duration for wound closure. Many studies have shown that vacuum therapy to be a more reliable method to form granulation and heal different types of wounds [5,6].

Negative pressure wound therapy (NPWT), is a dressing technique in which a periodical or a continuous sub atmospheric pressure is being applied to the system that creates a positive pressure in the surface of the wound. In the animal models, the sub atmospheric pressure applied, has numerous benefits on wound healing.

For negative pressure wound therapy (NPWT), the commercially available systems are the Chariker-Jeter wound sealing kit and the vacuum-assisted closure device. The NPWT system is comprised of a fluid collection system, an open-pore polyurethane ether foam sponge, a semi occlusive adhesive cover and a suction pump [7].

II. MATERIALS AND METHODS:

Type of Study- The present investigation is a prospective evaluation with sample population determined via randomized case-controlled study.

Place of study: Department of General Surgery, Trichy SRM Medical College Hospital and Research Centre.

Duration of the study: The research work was performed between December 2021 to November 2022.

Sample Size: The sample size taken for the current study comprised a total of 100 patients with diabetic foot ulcers with 50 participants in each group (Group A- NPWT; Group B- conventional dressing). The expected dropout rate was observed to be 10%, and the sample size comprising of 50 in each group was planned and taken up for the study.

Inclusion Criteria: All the patients with diabetes mellitus belonging to 20-70 years of age who were admitted at SRM Medical College Hospital and Research Centre inpatient wards with a diabetic foot ulcer (DFU).

Exclusion Criteria: Patients presenting with vascular diseases over the age of 70 years, coagulopathic conditions, venous disease conditions, diabetic ulcer patients present with underlying osteomyelitis, diabetic ulcer patients presenting with Charcot's joints, diabetic ulcers that fall under the grades (3,4,5), peripheral arterial and venous disease conditions, diabetic ulcers involving both the feet.

III. RESULTS:

A total of 132 patients were later then assessed in terms of eligibility from the inclusion criteria in study. Of which around 18 patients were excluded for having their Wagner's grade that is greater than III and more and thereby being excluded from the research study.

Likewise, when considering 11 patients were investigated with the association of peripheral vascular disease and three of them reported with osteomyelitis of foot region and bilateral diabetic foot infections and the patients were found to be declined with the study participation. Following their assessment that was concerning with eligibility criteria, 100 of the patients who were satisfying both the inclusion and exclusion criteria were then enrolled for the study and were randomized under two groups with 50 patients falling under each of the group.

None of the patients from the control group, the vacuum therapy needed to be stopped.

Three of the patients from the conventional saline dressing group and patients from the vacuum dressing group withdrew the consent from taking part in the study within the initial first week of the treatment.

Also, in VAC group one of the patient absconded during the 2nd week of their DFU treatment and thus a total of 50 patients were taking part after the exclusion of patients from the study, thereby the patients from each of the from our investigation involving the demographics alongside with the factors that are impacting on wound healing were comparable between two of the groups from the study population.

From the table it could be inferred that the age-wise distribution was noted as normal across both study as well as the control with One Sample Kolmogorov-Smimov (KS) test presenting with p-value of 0.115 and 0.145 respectively. Considering the mean age observed among patients were subjected with VAC therapy were estimated with an overall range of 52.85 years (between the inclusion criteria of the age between 20- 70 years age group) whilst when considering among the patients were treatment via the conventional dressing and were reported with mean age of 51.3 years. The age (in years) presented between two of the groups were compared via utilizing unpaired t-test were indicated with nil difference that lies between two of the groups with the reported p value presenting as 0.3345. Most patients were noted between the ages that lies between 40-65 years of age (55.6% & 77.8% in the study trial and control group separately).

Out of the 100 patients, 28 were male followed with 22 being female. It was reported from 28 males and 24 females received VAC therapy, while 27 were males and 23 female received conventional dressing. From the gender wise distribution were found to be uniform between both the groups with Pearson Chi test providing that the p value presenting with 0.789.

The total of 100 cases that were included into the study, 2 of the cases had newer onset of T2DM were not on any regimen for the control of the disease before the patient's hospitalization. 37 patients (74%) were on OHA, 11 were administered with insulin treatment (22%) and 2 were on both oral medications and insulin. In the study group, one of them were newly diagnosed case with T2DM, 25 patients were on orals, 20 taking insulin and 3 were by both orals and insulin; from the control batch 37 were on oral drugs, 11 on insulin and 2 of them were on both oral drugs and insulin. This was weighable among the two groups by the Pearson Chi 2 test revealing a p-value of 0.789.

Assessing by the co-morbidities of the cases, 42% of the cases had no other illnesses, 11 were having increased BP, 3.7% had heart diseases alone, 3 (3%) had both BP elevation and heart diseases whereas 2 (2 %) were asthmatics. The co-morbidities were weighable within the two groups with a p-value ranging around 0.0670. The mean BMI, Hb, protein and glycated hb among the study group were 22.99, 10.280, 2.77 and 8.740 respectively while in among control group it was 23.26, 10.180, 2.72 and 8.540 respectively. These parameters were uniform within the two groups with the p-values ranges of 0.7780, 0.8163, 0.52870 and 0.6525 respectively.

The distribution of the wagner grades one and 2 ulcers were reported as unequal from two of the sets; eight grade 1 ulcer were on the conventional saline dressing group while as only two grade 1 ulcers were on the vacuum therapy group. However, the possibility that this distribution inclines results in the vacuum dressing group was not likely, as both these grades of wagner were superficial. Also, when the 1st degree objective in the two groups was weighed by stratifying based on the wagner's grades, results were in favor for negative pressure dressing for both the Wagner grades 1 and 2 diabetic ulcers.

Taking into account that size of the ulcer could affect the duration for wound healing, the patients among the groups were split as those having ulcers lesser and greater than 100mm. A sum of 21 among 100 patients had ulcers >100mm. In these 11 were in the study set and 10 in the control team. Of the 21 of them with ulcer size <100mm; 11 belonged to study group and 10 were on side with the control group. These numbers were comparable among the two groups with a p-value of 0.7840 as exposed by the Pearson Chi 2 testing method.

Ulcer surface area determined at the beginning of the study was normally distributed in two sets in the patients receiving vacuum pressure therapy and conventional saline guaze dressing. The mean surface areas were 71.1 cm^2 and 81.230 cm^2 in the study and control teams respectively; and weighable between the two groups with a p-value of 0.56850.

The key objective with regards to the research investigation i.e., time involved for diabetic foot healing, were found to be associated with significant association which appeared better from the study group with the estimated p-value <0.0001. Considering mean as well as the median time involved with DFU healing reported as 22 and

International Journal Dental and Medical Sciences Research
Volume 5, Issue 5, Sep-Oct 2023 pp 432-439 www.ijdmsrjournal.com ISSN: 2582-6018

33 full days respectively in study groups whilst these were 32.850 days and 33.0 days respectively among the control sets. The biggest time for DFU heal were reported 35.0 days and 54 days in the trial and control teams respectively.

The observed time taken considering the development of the granulation that is cover within >75% (Visual Score - 4) were found to be significantly better among patients that received VAC therapy as the p value <0.0001. However, this is not for in case of the visual score achieving 3 whereas p value was observed as 0.5611. From the observed mean time that is achieved with scoring range of III was 13.52 days and 14.04 days among the study as well as the ctrl group respectively, whilst in the case for instances wherein the scoring is of 4 it was estimated as 22.33 days and 31.15 days respectively.

The velocity of granulation tissue forming which was achieved by dividing the ulcer surface area by the sum of days to heal. The mean and median values were found to be 2.910 cm^2/day & 2.40 cm^2/day and 2.161 cm^2 /day & 1.70 cm^2 /day in the study and control teams respectively with a p-value of 0.03060. The speed of granulation tissue was also weighed separately for ulcers <100 mm and >100 mm between the study and control sets, during which this was found to be noteworthy (p-value- 0.03510) for those with ulcer wounds <100 mm while it was not significant (p value- 0.3598) for those with ulcers >100 mm.

Group A- NPWT group; Group B- Conventional Dressing group; DM- Diabetes Mellitus; DFU-Diabetic Foot Ulcer; OHA-Oral Hypoglycemic Agents; HTN- Hypertension; CAD-coronary artery disease; BA-Bronchial Asthma; BMI- Body Mass Index; Unpaired t-test[a]; Pearson Chi^2 test[b].

BaselineCharacteristics		**Group A**	**GroupB**	**P-value**
Age(Mean)(years)		52.85(20-70)	51.3(20-70)	0.3345[3]
Gender	Male	28(56%)	27(54%)	0.673[b]
	Female	22(44%)	23(46%)	
Diagnosis	R.DFU	32(64%)	24(48%)	0.423[b]
	L.DFU	18(40.74%)	26(52%)	
DurationofDM		7.4years	6.34years	0.442[3]
Treatment ofDM beforestudy	Newonset	2(4%)	1(2%)	0.789[b]
	OnOHA	25(50%)	37(74%)	
	Oninsulin	20(40%)	11(22%)	
	On insulin&OHA	3(6%)	2(4%)	
Co-morbidities	None	22(81.48%)	20(74.07%)	0.067[b]
	CAD complication	0(0%)	4(8%)	
	Hypertension	9(18%)	2(4%)	
	HypertensionandCAD	0(0%)	3(6%)	
	BA	0(0%)	2(4%)	

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BMI(kg/m^2)	23.2	24.1	0.7780[3]
Haemoglobin(g/dL)	10.2	10.14	0.8163[a]
Albumin(g/dL)	2.75	2.77	0.5287[3]
HbAlC	8.72	8.64	0.6525[3]
Wagner-MeggitGrade GradeI	15(30%)	4(8%)	0.036[b]
GradeII	35(70%)	46(92%)	
Number ofpatientswithulcersize >10 centimeter	11(40.74%)	10(37.04%)	0.784[b]
<10 centimeter	30(60%)	31(62%)	
areaincmcoveredwithulceration	71.1	81.23	0.5685[3]

Table 1. Baseline demographic profiles of the sample population

Timetowoundhealing			**Group A**	**GroupB**	**P-value**
Timeto wound Healing in days	Mean		21.52	32.85	<0.0001[c]
	Median		22	33	
	Min		14	17	
	Max		35	54	
	Ulcersizeestimated	Mean	28.36	37.5	0.0042[c]
	>10cm	Med.	30	39.5	
		Min	18	28	
		Max	35	51	
	<10 cmsizeulcers	Mean	17.82	31.13	<0.0001[c]
		Median	17.6	32	

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		Min	15	16	
		Max	25	55	

Table 2: Time to wound healing

Mann Whitney test; Group A- NPWT group; Group B- Saline Dressing group

Visual Score	**Gr A**	**Gr B**	**P-value**
III	13.52 days	14.04 days	0.551 1[a]
IV	22.33 days	31.15 days	<0.0001[a]

Table 3: Mean days taken for the granulation of the tissue cover considering the Visual score in ranges of III and IV.

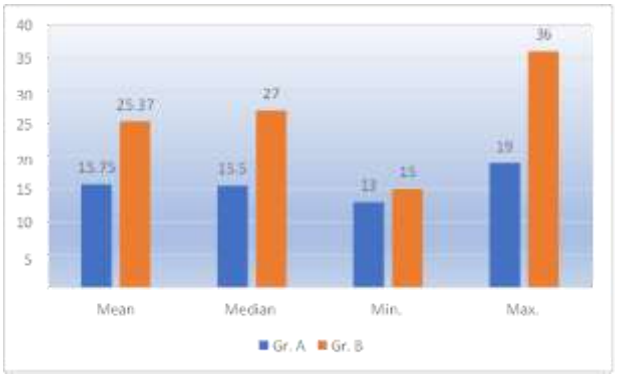

Figure:1

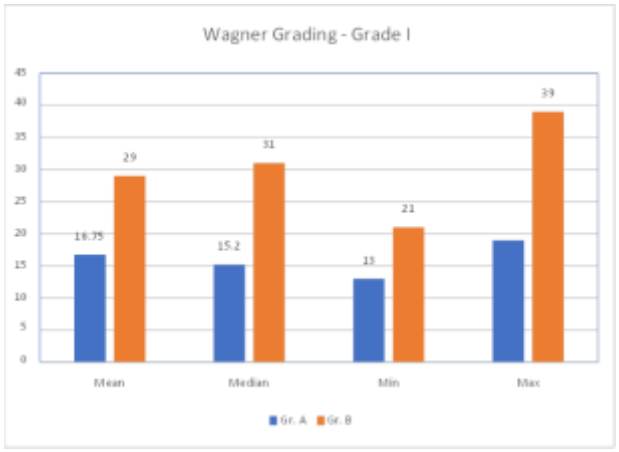

Figure:2

Graphical representation illustrating the overall time taken for wound healing among the study groups A and B

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Figure:3

IV. DISCUSSION:

Diabetic foot ulcers occur in a sizable percentage of diabetes patients (DFU). DFU prevalence varies from 1% in Western populations to up to 11% in African populations 17. In as many as 85% of cases, Diabetes is a chronic disease is the leading cause of non-traumatic amputation 92. Patients with DFU have a mortality rate that is approximately twice as high as those without DFU. Between 43percent of the total and 55% of DFU patients died five years following their diagnosis, while 74% of DFU patients who underwent significant amputations perished.

The price of treating DFUs is a significant additional worry. DFUs were responsible for 33% of the overall cost of treating diabetes and its accompanying complications in 2007.

In comparison to diabetics lacking foot ulcers, individuals with DFUs had care costs that were nearly five times greater in the first year 94. This is primarily caused by the lengthy hospital stays required for DFU patients. Due to low levels of education programs and a deficient health service in India, as well as the fact that the majority of DFU patients come from poorer communities, the severity of the problems is more significant. One of the best ways to treat DFU wounds, NPWT has proven to improve and hasten the healing process.

This study evaluated the time to recovery (refers to the period required to make the lesion suitable for grafting), granulated cover, and issues associated with NPWT to traditional saline dressings in order to show the effectiveness and security of NPWT inside the management of DFU. A total of 54 patients were analysed, 27 of whom were in the study group receiving NPWT therapy and 27 of whom were in the comparator group receiving traditional dressing.

V. CONCLUSION:

According to the findings of the current study, VAC treatment significantly reduced the overall time required for wound healing when compared to standard dressing.

Furthermore, VAC service was reported to have dramatically increased the overall granulation coverage over its wound, and the investigation revealed a very high regeneration rate for tissue creation with the treatment impact of the VAC therapy patients. Second, it was discovered that the pain scores were significantly associated with a better outcome at the third week with the VAC group when compared to the standard dressing groups, and the study also discovered that there were no significant complications in the outgrowth of the infection and bleeding in the VAC therapy inhabitants.

This examination demonstrated a significant reduction in the size of the ulcer in the vacuum group as compared to the standard saline dressing group. Furthermore, the reduction in size appeared to be significantly more pronounced in diabetic ulcers larger than 10 cm in size. We were unable to identify any significant differences in the number of amputations/debridement between the two comparison groups.

This randomised controlled trial comparing suction dressing therapy to standard treatments in diabetic foot ulcerations found that vacuum dressing therapy was more successful in decreasing the time required to achieve finished

wound closure and enhanced formation with no increase in complications such as bleeds and wound infections. Further studies with a larger sample of patients are recommended to deduce the findings of this investigation.

Funding: None
Conflict of Interest: None
Ethical Approval: Obtained

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