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Effect of Negative Pressure Wound Therapy (NPWT) /Vacuum Assisted Closure (VAC) versus Conventional Dressing in the Management of Diabetic Foot Ulcer in A Tertiary Care Centre in Kerala

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Abstract

Globally, the prevalence of diabetes is rising quickly, and more people are undergoing surgery to treat diabetic foot. Due to numerous surgical operations and extended hospital stays, foot issues account for a disproportionately high number of hospital days and hospital admissions Reason.

The most prevalent, intricate, and expensive aftereffects of diabetes mellitus are foot conditions such ulceration, infection, and gangrene. Treatment is sometimes challenging, with poor healing responses and high rates of complications, even for the most superficial wounds. In order to treat diabetic foot ulcers, this study compares the rate of ulcer healing using the negative pressure dressing approach to that of traditional moist dressings. This study was performed in a tertiary care centre in Thrissur district of Kerala, India. It was conducted as a cross sectional observational study comparing 30 patients who were treated for diabetic foot ulcers with saline dressing compared to 30 patients who were treated with negative pressure wound therapy. The primary goal of this study was to compare the reduction in surface area of wounds between the two dressing modalities. Along with the above parameters, time for appearance of granulation tissue and presence of infection were compared between the two wound care techniques.

Keywords: Diabetic Foot Ulcer, Negative Pressure Wound Therapy, Healing, Granulation Tissue, Infection.

Introduction

Diabetic foot, a significant consequence in people with advanced diabetes, is defined as foot infections, ulcers, and/or profound tissue degradation in the distal lower limb or limbs of these patients due to vascular lesions and nerve abnormalities[1]. An amputation for diabetic foot is done every 20 seconds for about 1 million people annually, which is a significant amount, according to the International Working Group on the diabetes Foot. By 2045, there will likely be 629 million diabetic patients worldwide, up from 425 million in 2017.

Multiple relevant factors function together to develop diabetic foot ulcers. Peripheral neuropathy and ischemia from peripheral vascular disease are identified as the main underlying causes of these[2]

The severity of diabetic foot depends on a number of factors. The primary causes are smoking, having a high body mass index, not controlling diabetes, the kind of diabetic medication, and advanced age. The severity of diabetic foot ulcers can also be influenced by other factors, including vascular problems, bacteria isolation, length of time, and patient referral delays. [3]

Half of diabetic foot ulcers become infected, leading to a substantial number of amputations. Consequently, diabetic foot ulcers contribute significantly to the overall cost of diabetes care, with ulcer-related complications being a primary reason for hospitalization among diabetic patients.[4] This has resulted in an increased risk of amputation among diabetic individuals, as 85% of those with a foot ulcer are at risk of requiring an amputation in the future.[5]

Apart from the serious consequences like amputation, diabetic foot ulcers have been linked to negative outcomes in terms of quality of life and significant financial burdens for both patients and the economy. The limitations in mobility, frequent and prolonged hospital stays, clinic visits, and the declining quality of life contribute to increased cardiovascular strain, resulting in a higher risk of mortality compared to the general population. Patients with diabetic foot ulcers face an annual mortality rate of nearly 10%, which escalates to 20% per year if amputation becomes necessary.

For diabetic patients who undergo amputation, the median mortality rate within 27 months post-operation is higher than that of nondiabetic patients with amputations, who have a median survival of 47 months post-operation.[6] Overall, the 5-year relative mortality rate for individuals with diabetes who experience a major limb loss is 70%.[7] The cost of treating diabetic foot ulcers also pose a financial burden on the patient and their family depending on the extent of the procedure and the duration of hospitalization.[8] Furthermore, limb amputations serve as indicators of further health deterioration, as up to 40% of patients who undergo a major lower extremity amputation may require amputation on the other limb within three years.[9]

Examination of the feet is an integral part of the physical examination of every patient, more so a in a patient with diabetes mellitus. One should look for neuropathic changes like dry skin, fissures, deformities, callus, abnormal shape of foot, ulceration, prominent veins, and nail lesions in these patients. Careful attention should be given to the interdigital spaces.

Negative pressure wound therapy is now a standard practice in majority of hospitals and wound care facilities and is an effective remedy for certain

challenging wound conditions. To prevent complications, the modality must be used cautiously and evaluated often. The NPWT system may not be able to adequately regulate increasing wound exudate as a result of bacterial colonization and biofilm formation. If this issue is not detected early and treated effectively, which usually involves systemic antibiotics, absorptive primary dressings changed often, and wound culture, a frantic infection may result. Significant pain, especially during dressing changes, and difficulty getting a good seal in wounds with unusual shapes are among the other concerns.

The cost of renting a device, purchasing wound dressings, and scheduling home nursing visits to change dressings are all additional expenses associated with incorporating NPWT into an outpatient wound treatment regimen. In order to maximize cost-efficacy, utilization should be carefully evaluated throughout time, especially for patients with larger, more complex wounds who are more likely to benefit from therapy. Numerous acute and chronic wounds now have an alternate therapeutic option thanks to NPWT.

Materials and Methods

The study took place in a tertiary care center in Thrissur, Kerala. It was a Cross-sectional observational study spanning over a period of 18 months. Study was initiated in November 2022 and completed in the month of May 2024.

The patients presenting to the Department of general surgery in Amala Medical College, Thrissur, Kerala, India in the above mentioned study period requiring management of diabetic foot ulcer were taken as the study samples.

A minimum sample size of 29 in each group was derived. Study was undertaken with 30 in each group. Sampling method used was convenient sampling.

The study was a hospital based Follow up study, carried out among patients with diabetic foot ulcers. 30 patients who will be treated with VAC and 30 patients who will be treated with conventional dressings will be followed up. Wounds of the subjects included in the study underwent initial sharp debridement to remove necrotic tissue and slough as far as possible. Ulcers were followed up for a period of 8 weeks or till the wound gets closed surgically or spontaneously (whichever was the earliest).

The subjects included in the study were those who gave complete willingness for the study - diabetic patients presenting to the general surgery outpatient department with diabetic foot ulcers and with ulcer of surface area ranging between 50cm^2 and 200cm^2. Diabetic foot ulcer patients with an obvious septicemia, wounds resulting from venous insufficiency, patients on corticosteroids, immunosuppressive drugs or chemotherapy were excluded from the study.

Institutional Research Committee and Ethical Committee clearance was obtained. Willingness to participate in the study was obtained in the form of written informed consent from the participants. Confidentiality was guaranteed, and involvement was voluntary.

1cm x 1cm graph paper was used for measuring the surface area of wound. A questionnaire for collecting patient information was developed which included age of the patient, gender of the patient, socioeconomic status, duration of diabetic foot ulcer, glycated hemoglobin levels, modality of treatment used (conventional dressing or negative pressure wound

therapy). Surface area of the wound during first visit and subsequent visits following therapy were measured. Signs of infection, presence of granulation tissue following treatment and overall duration of treatment were recorded.

Data was entered into Excel worksheet and analysis performed using SPSS 23. Results on continuous measurements were presented on mean ± SD and results on categorical measurements are presented in number (%). Significance was assessed at 5% level. Regression was done to assess predictability of variable. The difference of proportion analyzed using chi square test.

Results

In this study group consisting of 60 patients, 30 belonging to those in whom vacuum assisted closure has been applied and 30 belonging to the conventional dressing category. Out of the 60 patients, 20 patients belonged to 60-69 age group, 17 of them belonged to the 50-59 age group, 11 of them belonged to 70 – 79 age group, 7 of them belonged to less than 50 years age group and 5 of them belonged to more than 80 years age group.

Out of the 60 patients, 40 of them were males and 20 of them were females. 45 patients belonged to the lower middle class, 13 patients belonged to the upper middle class, 1 patient each belonging to the upper lower and upper class (Classification system used – Modified Kuppuswamy scale).

On assessing the duration of ulcer of the study population, 28 patients had an ulcer of 1-5 months duration. 13 patients had an ulcer of 5 – 10 months duration, 12 patients had an ulcer of 1 month or lesser duration and 7 of them has an ulcer of more than 10 months duration.

From the study it was assessed that overall duration of treatment was significantly lesser for patients treated with VAC (4.2 weeks) compared to those treated with conventional dressings (6 weeks). It was only found that the probability of appearance of granulation tissue after VAC therapy was higher (100%) compared to those treatment with conventional dressing (90%). The signs of infection post therapy were lower in the VAC treated group (10%) compared to those treated with conventional dressing (16.7%).The reduction in surface area was also higher in those treated with VAC compared to those treated with conventionally dressing.

Table 1: Comparison of effect of two types of diabetic foot ulcer care on early healing of diabetic wounds

	VAC			Conventional dressing			t	p
	Mean	SD	N	Mean	SD	N		
Surface area of wound	86.3	35.0	30	107.4	40.9	30	2.14*	0.037
Surface area of wound after therapy	60.7	29.1	30	87.6	39.1	30	3.03**	0.004

**: - Significant at 0.01 level, *: - Significant at 0.05 level

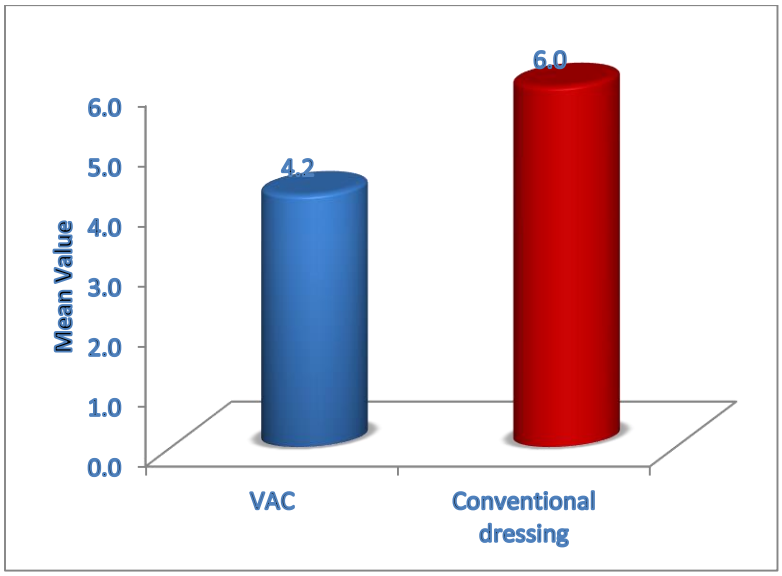
Table 2: Effectiveness of two types of diabetic foot ulcer care on early healing of diabetic wounds (ANCOVA)

Stage		Mean ± SD	df	F	p
Pre	VAC	86.3 ± 35	(1,58)	4.58*	0.037
	Conventional dressing	107.4 ± 40.9			
Post	VAC	60.7 ± 29.1	(1,58)	9.16**	0.004

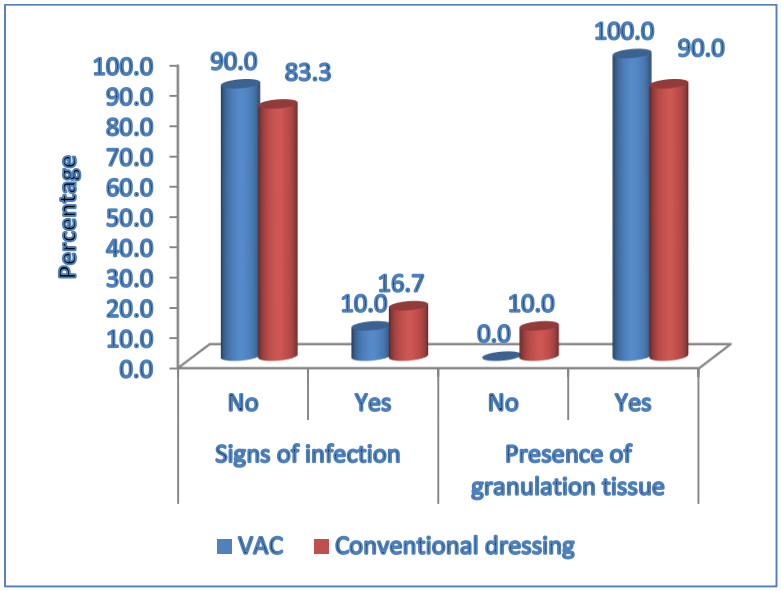
	Conventional dressing	87.6 ± 39.1			
Adjusted post	VAC	69.7 ± 2.1	(1,57)	8.43**	0.005
	Conventional dressing	78.7 ± 2.1			

**: - Significant at 0.01 level, *: - Significant at 0.05 level

Graph 1:



Graph 2:



Discussion

Vacuum assisted closure/ negative pressure wound therapy have been on the rise due to its effectiveness in the early healing of diabetic foot ulcers. In this study there was a significant difference in the VAC treated study population compared to those treated with conventional dressings not just in one parameter but many.

Most important difference noted was that the VAC treated study population had lesser overall duration of treatment compared to the conventional dressing study

population. This result was comparable to a randomized controlled trial undertaken in Pakistan in the year 2021[10]. Diabetes being a chronic disease, its complications can pose a financial burden to the patient as well as his/her family. Reducing the treatment duration can be a great relief to this crisis.

Appearance of granulation tissue is a marker for a healing wound. The appearance of granulation tissue was seen in all patients treated with VAC. Whereas not all those treated with conventional dressing had evidence of granulation tissue. The same interpretation was extrapolated in various other studies[11]. Those who underwent conventional dressing had prolonged hospital stay and the overall duration of treatment was high among them.

The signs of infection in a wound is a decelerating factor for wound healing. It was found to be higher in those treated with conventional dressing compared to those treated with conventional dressing. Though there is a reduction in infection rates following VAC therapy, the exact mechanism behind this phenomenon remains a puzzle. A similar result was obtained in a study conducted by an orthopedic team[12.] There is reduction in cost of treatment and number of days treated in a hospital setting in the VAC arm compared to the conventional dressing arm. This interpretation has also been derived in other studies[13].

The crus of this study lies on patient selection. Like any disease, diabetic foot ulcer needs independent care and a structured treatment modality. Diabetes being a systemic illness multiple patient factors are to be taken into consideration prior to treatment planning. Patient education and counselling of the family regarding the chronic nature of the disease, different treatment modalities and its cost are to be done beginning from a primary care centre itself. The right patient should be referred to a higher centre at the right time for receiving the right treatment modality that caters to the individual needs.

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