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Comparison of Negative Pressure Wound Therapy Using Vacuum-Assisted Closure with Conventional Wound Dressing in the Treatment of Diabetic Foot Ulcers: Our Experience

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Abstract

Background: Diabetic foot ulcers (DFUs) are considered one of the most common and devastating chronic complications of diabetes. As a consequence of DFUs, a lower limb is lost every 30 seconds some where in the world, and the probability of losing the other leg is 50% after 3 years. DFUs contribute to 85% of non traumatic lower Lind amputations and lead to 13 to 17% of mortality rate in patients with diabetics mellitus. Negative pressure wound therapy (NPWT) is a newer non-invasive adjunctive therapy system that uses controlled negative. pressure, using vacuum assisted closure (VAC) device, to. help promote faster wound healing by removing fluid. from open wounds, preparing the wound bed for closure, reducing oedema, and promoting formation of granulation tissue. *Methodology:* We have conducted a study in Bangalore Medical College and Research Institute Bangalore for a period of one year comparing the conventional dressing versus VAC dressing in faster healing of the wound. Induced about 40 patients in the study. *Conclusion:* Patients treated with VAC therapy has faster appearance of granulation tissue than that with Conventional dressings. From our study VAC therapy has proved to be more effective than conventional dressing in healing of Diabetic Foot Ulcers.

Keywords: Diabetic foot ulcers (DFUs); Negative pressure wound therapy (NPWT). Diabetes mellitus (DM).

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Introduction

Diabetes mellitus (DM) is a syndrome characterized by hyperglycemia that results from absolute or relative impairment in insulin secretion and/or insulin action [1]. With the development of people's living standards and lifestyle changes, the incidence of diabetes has been rising. An estimated 382 million people had DM in 2013; this number will increase to 592 million by 2035 [2]. Hazards of DM usually present as complications; diabetic foot ulcers (DFUs) are considered one of the most common and devastating chronic complications of diabetes. The expected lifetime risk of a DM patient developing a foot ulcer is 12%–25%[3]. As a consequence of DFUs, a lower limb is lost every 30 seconds somewhere in theworld, and the probability of losing the other leg is 50% after 3 years. DFUs contribute to 85% of non traumatic lower Lind amputations and lead to 13 to 17% of mortality rate in patients with diabetics mellitus [4].

The management of the DFU is largely determined by its severity (grade), vascularity of the limb, and the presence of infection [5].

Conventional dressing is the standard method; however, maintaining a moist wound environment is difficult. Subsequently, various hydrocolloid wound gels, growth factors, enzymatic debridement compounds, hyperbaric oxygen therapy, cultured skin substitutes.

Negative pressure wound therapy (NPWT) is a newer non-invasive adjunctive therapy system that uses controlled negative. pressure, using vacuum

assisted closure (VAC) device, to. help promote faster wound healing by removing fluid. from open wounds, preparing the wound bed for closure, reducing oedema, and promoting formation of granulation tissue [6,7] The data available on the role of NPWT for the management of DFU (Diabetic Foot Ulcer) is limited. Therefore, we conducted a study to compare the effectiveness of VAC with conventional dressings in the healing of DFU.

Classification

Comparative study done by using university of Texas (UT) wound Classification as shown in Table 1.

Methods

Study design and area

A randomized controlled study was done in department of surgery in a tertiary care hospital in Bengaluru.

Study period: One year

Study population:

Patients admitted in department of general surgery in Bangalore Medical College and Research Institute. Bangalore.

Inclusion criteria

Patients with non healing ulcer in diabetic patients.

Exclusion Criteria

Ulcer associated with malignancy, collagen vascular disease, extensive osteomyelitis, charcots arthropathy, pregnancy and medications like corticosteroids, immunosuppressive drugs and chemotherapy.

Methodology

The study was a prospective time bound study conducted in Bangalore Medical College and Research Institute, Bengaluru.

History relevant investigations, local examination was done for all patients followed by thorough wound debridement and irrigation of Diabetic Wound for all diabetic wound patients. NPWT dressing was then applied. And NPWT dressing changed every week. And repeated debridement done when needed. NPWT dressing involves the pressure between - 125 mmhg to – 150 mmhg was maintained in all patients. Wound characteristics were recorded at every dressing with respect to size, shape, discharge, granulation tissue, etc.

Sample Size

A total of 40 patients were included in our study.

Efficacy assessment

The primary Efficacy end point was complete wound closure rate. Wound closure is defined as skin closure without drainage or dressing requirements. Secondary end point is defined as time for appearance of granulation tissue, reduction of size of ulcer.

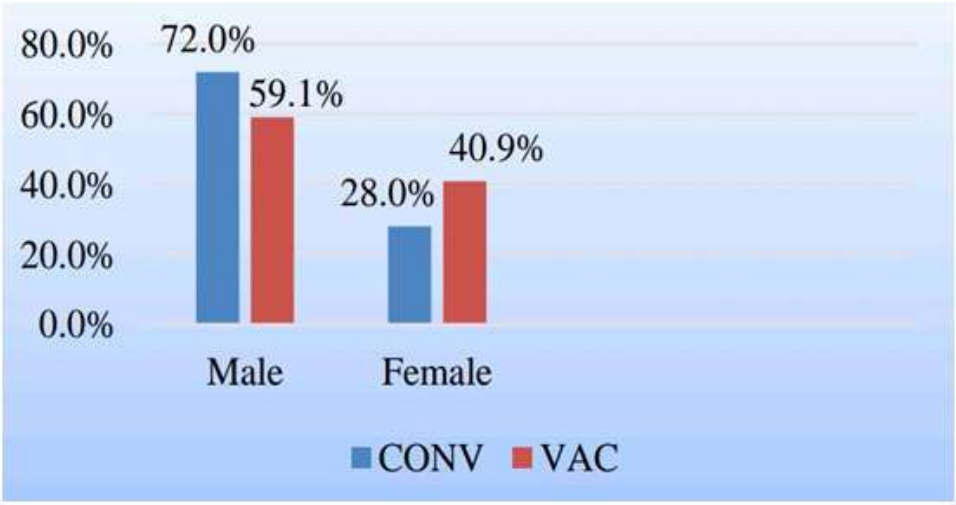
Results

Statistics

All the data entered in Microsoft excel sheet. All the quantitative data entered as mean standard deviation, and compared using student t test. P value less that 0.5 is considered significant.

Table 1: University of Texas Diabetic Wound Classification System.

Stage	Grade			
	0	1	2	3
A (No infection or ischemia)	Pre or post ulcerative lesion completely epithelialized)	Superficial wound not involving tendon capsule or bone.	Wound penetrating to tendon or capsule.	Wound penetrating bone or joint.
B	Infection	Infection	Infection	Infection
C	Ischemia	Ischemia	Ischemia	Ischemia
D	Infection and Ischemia	Infection and Ischemia	Infection and Ischemia	Infection and Ischemia



Graph 1: Distribution graph of patients based on age

Mean age of subjects was 53.6 and 53.1 years for conventional and VAC dressings respectively. (Graph 1).

Table 2: Destribution of patients based on gender

	Male	Female
Conventional	80%	20%
VAC	86%	14%

Male patient proportion is found to be greater in both conventional and NPWT groups. (Table 2).

Table 3: Distribution of patients based on Co morbidities

Comorbidity	VAC	Conventional
Hypertension	45%	38%
Chronic kidney disease	4.4%	12%
Bronchial asthma	5%	9%
Iscemic heart disease	16.8%	28%
None	35.6%	38.2%

Table 4: Distribution of patients based on UT Classification.

University of Texas classification	Conventional	VAC	Total
Stage A	4	1	5
Grade 1	16.6%	6.25	12.5
Stage A	5	2	7
Grade 2	20.8%	18.75	17.5%
Stage B	4	4	8
Grade 1	16.6	25%	20%
Stage B	11	9	20
Grade 2	45.8%	56.2	50%
Total	24	16	40
	100%	100%	100%

Most of the patients belong to stage B grade 2 according to UT Classification. (Table 4).

Table 5: Distribution of patients based on granulation tissue

Granulation tissue	Conventional	VAC	Total	P value
Week 1	16	13	29	0.3
	66.6%	81.2%	72.5%	
Week 2	24	16	40	1
	100%	100%	100%	

So from above table, patients treated with VAC therapy developed granulation tissue earlier than that treated with conventional dressings. (81.2% in VAC patients compared to 66.6% in conventional dressings). (Table 5).

Eginton et al compared the rate of wound healing with vacuum assisted close device with the conventional moist dressings for large diabetic wounds over 4 weeks and found that over first several weeks VAC dressings were decreased the wound depth and volume more effectively than the conventional moist dressings. They conclude that negative pressure wound therapy may accelerate the wound healing in diabetic Ulcers [13].

Table 6: Distribution in terms of reduction of granulation tissue

% decrease in the size of the wound	Conventional	VAC
Week 1	20%	40%
Week 2	30%	54%
Week 3	52%	75%

Distribution in terms of hospital stay.

Patients treated with VAC therapy went home after 4 weeks when compared to 6 weeks of stay in hospital in conventional dressings, in diabetic ulcer patients.

Discussion

The study measures time need for the complete wound closure in chronic diabetic patients using negative pressure wound therapy.

Time needed for complete healing and formation of granulation tissue by conventional dressings according to multiple studies were shown to be 60 to 130 days [15,16,17]

Mechanism of action negative pressure wound therapy.

Macrodeformation

Refers to induced wound shrinkage caused by collapse of the pores and centripetal forces exerted onto the wound surface by the foam [8,9]. Polyurethane ether foams exposed to 125 mmHg suction can decrease the foam volume by approximately 80% and result in a substantial decrease in wound surface area.

Microdeformation

In NPWT, cells are subjected to shear and hydrostatic pressure from extracellular fluid, stretch and compression from their surrounding matrix, and the ubiquitous pull of gravity. Microdeformation, in essence, is the morphologic result of these integrated mechanics. Cell shape has been demonstrated to be a determinant of cellular function [9].

Alteration of the wound environment

The PU drape is semiocclusive there by restricting evaporative water losses while remaining impermeable to proteins and microorganisms thereby maintaining a favourable and moist wound. In comparison with conventional therapies, the reduced number of required dressing changes in NPWT also can add to comfort of patient.

Fluid Removal

Excess fluid buildup is commonly accepted as a contravening factor in healing, partly owing to the compressive effect it can exert on local cells and tissues. The evacuation of fluid reduces micro vascular compression, increasing perfusion and allowing faster wound healing. Toxins from the wound, bacteria, and exudate can also be removed with the fluids. NPWT also induces a gradual increase in lymphatic density at wound edges, thereby improving drainage.

Angiogenesis

Negative Pressure Wound Therapy induces wound sitelocal hypoxia and stimulation of Vascular Endothelial Growth Factor with subsequent angiogenesis [10]. It is not surprising that NPWT demonstrates increased microvessel density during chronic wound treatment. NPWT stimulates wound-site angiogenesis through anumber of mechanisms: mechanical stimulation (microdeformation), removal of factors inhibiting angiogenesis.

Granulations tissue formation

NPWT helpsin increasing the proliferation of fibroblasts, migration of macrophage, and formation of early granulation tissue. In proliferation phase effect of NPWT include robust granulation tissue formation including the blood vessel sprouting [11].

During the inflammation phase, NPWT removes the infiltrating leukocytes and simultaneously induces the inflammation [14].

Outcome

The primary end point in the study the granulated wound is ready for Skin grafting of split skin grafting or healing by secondary intention. Lone et al observed that in 86.4% of the patients wounds were closed by split thickness skin grafting in VAC group as compared to 90.9% in conventional dressing patients. In rest of the patients wounds were closed spontaneously [12].

Conclusion

A total of 40 patients between 35 to 60 years with stage A or B with grade 2 according to UT Classification were divided in to two groups.

Group A: vacuum assisted closure.

Group B: convention wound dressing. And following observations made in the study.

- Hypertension and iscemic heart disease were the most common comorbidity associated in diabetic ulcer patients.
- Patients treated with VAC therapy had early appearance of granulation tissue that that treated with the conventional wound dressings. (81.2% when compared with the 66% the conventional wound dressings)

- Patients treated with VAC therapy have more decrease in the size of the ulcer wound when compared to that treated with conventional dressings.

So we can conclude that VAC (NPWT) is superior to conventional wound dressing in treating the diabetic ulcer patients in terms of early appearance of granulation tissue and duration of hospital stay.

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