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Original Research Article

Comparison of negative pressure wound therapy with moist wound therapy in the treatment of diabetic foot ulcers with non-revascularisable peripheral vascular disease

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ABSTRACT

Background: Diabetic foot problems are the commonest reason for hospitalization of diabetic patients (about 30% of admissions) and absorb some 20% of the total health-care costs of the disease more than all other diabetic complication. The numbers of patients with chronic wounds and wound complications continues to increase. Wound management is a challenge in diabetic wound. Chronic wounds require significant medical, nursing and financial input with poor long-term results. One-third of all diabetic patients have significant peripheral neuropathy and/or peripheral vascular disease (PVD). In India prevalence of foot ulcers in diabetic patients in clinic population is 3%. Over the past several years negative pressure wound therapy (NPWT) using vacuum- assisted closure has emerged as the treatment of complex wounds of the diabetic foot. Many reports on the use of Vacuum Assisted Closure (VAC) therapy after failed revascularization have found increased chances of success. Clinicians should consider negative pressure wound therapy as an adjunct to other modalities in an effort to avoid complications.
Methods: Total of 51 patients were included in this prospective study. They were randomly divided into two groups, negative pressure wound therapy (NPWT) group (25 patients) and control group (26 patients) who were treated with regular dressings. All the patients included had peripheral vascular disease which was declared non-revascularisable after vascular workup. Initial mean surface area was measured in each patient. Transcutaneous oxygen pressure was recorded in all the patients and each patient followed up based on their granulation tissue development and need for amputation in each group.
Results: After wound management, mean surface area of the diabetic wounds was 39.08cm^2 in the NPWT group (P=0.019), and 38.63cm^2 in the control group (P=0.327). The use of NPWT may be an effective initial wound therapy to achieve faster wound bed granulation showing signs of healing in 19 among 25 patients (76%) compared to control group 7 showed granulation among 26 patients (26%) (P=0.001). The incidence of secondary higher amputation in NPWT group is 6/25 (24%), the control group 17/26 (65%) (P=0.003), suggesting reduced incidence of secondary higher amputations in NPWT group. After treatment, the experimental group significantly improved in measures of foot ulcer surface area compared with the control group. Further studies are needed to clarify the effects and indications and to modify the technique of this alternative treatment for use on non healing wounds.
Conclusions: NPWT-treated patients reached a successful wound treatment endpoint more rapidly, and the benefit was apparent in all wound sizes. NPWT appears to be a safer and efficacious method, than moist wound therapy for the treatment of diabetic foot ulcers.

Keywords: Diabetic foot ulcer, Negative pressure wound therapy, Non-healing wounds, Peripheral vascular disease

INTRODUCTION

A multidisciplinary team, approach, particularly in specific diabetic foot clinics, is very successful in avoiding and treating foot complications. This strategy has been shown to reduce both the incidence of major leg amputation (by 40% or more), and the duration of in-patient admissions for the treatment of diabetic foot ulceration.[1,2]

Foot ulceration is common, affecting up to 25% of patients with diabetes during their lifetime. Over 85% of lower limb amputations are preceded by foot ulcers and diabetes remains a major cause of non-traumatic amputation across the world with rates being as much as 15 times higher than in the non-diabetic population.[3] Prevention is the first step towards solving diabetic foot problems. Although it was estimated that an ankle is lost to diabetes somewhere in the world every 30 seconds, a more important fact is that up to 85% of all amputations in diabetes should be preventable.[4] Strategies aimed at preventing foot ulcers are cost-effective and can even be cost-saving if increase education and effort are focused on those patients with recognized risk factors for the development of foot problem.[5]

Diabetic foot problems are the commonest reason for hospitalization of diabetic patients (about 30% of admissions) and absorb some 20% of the total health-care costs of the disease more than all other diabetic complication.[2,6]

One-third of all diabetic patients have significant peripheral neuropathy and/or peripheral vascular disease (PVD). In India prevalence of foot ulcers in diabetic patients in clinic population is 3% The prevalence of PVD increases with advancing age and is 3.2% below 50 years of age and rises to 55% in those above 80 years of age.[2, 7]. Similarly it also increases with increased duration of diabetes, 15% at 10 years and 45% after 20 years.[8]

Over the past several years negative pressure wound therapy (NPWT) using vacuum-assisted closure has emerged as the treatment of complex wounds of the diabetic foot.[9]

Mechanism by which it works appears to be decreasing local tissue edema and removing excessive fluid and pro-inflammatory exudates from the wound bed. There is now controlled trial evidence for the use of NPWT in both local postoperative wounds in the diabetic foot.[10] and, more recently, in the management of complex but non-surgical diabetic foot ulcers.[11] It is clear that this treatment helps promote the formation of granulation tissue.

METHODS

Total of 51 patients were included in this prospective study. All the patients had peripheral vascular disease which was non-revascularizable. They were randomly divided into two groups, negative pressure wound therapy (NPWT) group (25 patients) and control group (26 patients). Initial assessment of the wound was done in all the patients with Doppler and CT/ MR angiography apart from the routine clinical evaluation.

All the patients underwent thorough debridement of the foot ulcer initially. Control patients were treated with antibiotics, drugs to improve circulation and moist wound dressings. Test patients were given negative pressure wound therapy daily without any dressings.

Transcutaneous oxygen pressure was measured in all these patients before undergoing the therapies. Periodic follow up of these patients was done and the amount of granulation tissue noted in each case. Average duration of treatment was 7-28 days in both control and test patients. Surface area of the wound was measured in each case before starting the treatment and the same was followed up.

RESULTS

After wound management, mean surface area of the diabetic wounds was 39.08cm^2 in the NPWT group (P=0.019), and 38.63cm^2 in the control group (P=0.327).

Table 1: Age distribution of the patients in the control group.

Age	Male	Female
50-60	3	0
61-70	12	4
71-80	3	1
81-90	1	1

The use of NPWT may be an effective initial wound therapy to achieve faster wound bed granulation showing signs of healing in 19 among 25 patients (76%) compared to control group 7 showed granulation among 26 patients (26%) (P=0.001). The incidence of secondary higher amputation in NPWT group is 6/25 (24%), the control group 17/26 (65%) (P=0.003). There was a significant improvement in granulation with NPWT therapy.

Table 2: Age distribution of the patients in the test group.

Age	Male	Female
45-60	5	0
61-70	8	3
71-80	9	0
81-90	0	0

Transcutaneous oxygen pressure was poor in 17 patients among those who underwent VAC therapy, borderline in 5 patients and good in 3 patients whereas 23 had poor

$TcPO_2$ in the control group, 2 had borderline and 1 had good index.

Table 3: $TcPO_2$ in patients before any treatment.

TcPO2	Non-VAC group	VAC group
Poor	23	17
Borderline	2	5
Good	1	3

Table 4: Results showing improvement in granulation with or without VAC therapy.

% of granulation in the wounds	Without VAC (control)	With VAC (test)
No improvement	20	4
<25%	3	1
50%	2	5
75%	1	4
90%	-	3
Fully granulated	-	8

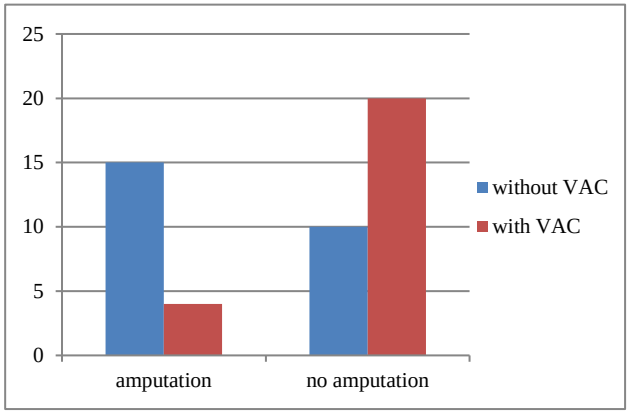

Figure 1: Amputation results in both groups.

Figure 2: A case of ischemic heel wound post debridement showing improvement with NPWT.

DISCUSSION

6 of 25 (24%) in the control group were females whereas 19 of 25 (76%) in the control group were males. 3 of 26 (11%) in the test group were females and 23 of 26 (89%) were males. 3 of 25 (12%) in the control group were below the age of 60 and 88% were above 60 years of age. 5 of 26 (19%) in the test group were below 60 years and 81% were above 60 years of age.

Initially, the mean surface area of wounds in the NPWT group was 45.44cm^2, the control group 38.52cm^2. The mean duration of open wound care was 17.96 days in the NPWT group and 21.88 days in the control group**.**

13/26 (50%) patients underwent BK in the control group and 4/25 (16%) patients underwent BK in the test group. The reason for BK among the test group was discontinuation of follow up due family problems in two of them, one had ankle joint exposure and one had osteomyelitis.

Granulation of the wounds was >50% in 20 of the 25 patients undergoing NPWT whereas only 3 of the 26 in the control group had shown >50% granulation.

NPWT is the controlled application of sub-atmospheric pressure to a wound using a therapy unit to intermittently or continuously convey negative pressure to a specialized wound dressing to help promote wound healing. The wound dressing is a resilient, open-cell foam surface dressing (such as GranuFoam® and V.A.C.® WhiteFoam) that assists tissue granulation and is sealed with an adhesive drape that contains the subatmospheric pressure at the wound site.[12,13]

General technique for NPWT is as follows: "protect the periwound by applying a skin barrier then it should be followed by a transparent film."[14] A dressing or filler material is fitted to the contours of a wound (which is covered with a non-adherent dressing film) and the overlying foam is then sealed with a transparent film. A drainage tube is connected to the dressing through an opening of the transparent film. A vacuum tube is connected through an opening in the film drape to a canister on the side of a vacuum pump or vacuum source, turning an open wound into a controlled, closed wound.[15] While removing excess fluid from the wound bed to enhance circulation and remove wound fluids. This creates a moist healing environment and reduces edema.

Therapy system helps direct drainage to a specially designed canister that reduces the risk of exposure to exudate fluids and infectious materials. NPWT assists granulation tissue, applies controlled, localized negative pressure to help uniformly draw wounds closed, helps remove interstitial fluid allowing tissue decompression, helps remove infectious materials, provides a closed, moist wound healing environment, helps promote flap and graft survival. Contraindications for NPWT are

malignancy in the wound, untreated osteomyelitis, non-enteric and unexplored fistula, or necrotic tissue with eschar and not to place NPWT dressing over exposed blood vessels or organs.

Negative pressure wound therapy is not a replacement to surgical procedures. It is vital to remove all necrotic tissue prior to NPWT. Dressings are changed every 48-72 hours at the bedside using clean technique.

Results of the study have a definite inclination towards negative pressure wound therapy in improving the wound healing among patients with non-healing wounds especially in cases with poor perfusion where patients are usually suggested amputation.

In future to decrease the number of amputations in diabetic foot, negative pressure wound therapy holds promising results.

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