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Comparison of Negative Pressure Wound Therapy with Conventional dressing in the Treatment of Diabetic Foot Ulcers with Non-Revascularisable Peripheral Vascular Disease

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Abstract: ***Introduction: 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. Aims and Objectives: This study has been taken upto identify the efficacy of newer technique in diabetic wounds with non-revascularisable PVD management in comparison to advanced conventional dressing. Material and Methods: Total of 30 patients were included in this prospective study, who have a non revascularisable peripheral vascular disease for whom on performing peripheral angiography, the distal runoff vessel is less than 10cm, not suitable for intervention. They were randomly divided into two groups, negative pressure wound therapy (NPWT) group (15 patients) and control group (15 patients) who were treated with regular dressings. 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 11 among 15 patients (76%) compared to control group 4 showed granulation among 15 patients (26%) (P=0.001). The incidence of secondary higher amputation in NPWT group is 4/15 (24%), the control group 10/15 (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. Conclusion: 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 conventional dressing for the treatment of diabetic foot ulcers with non-revascularisable PVD.***

Keywords: Negative pressure wound therapy, Peripheral Vascular Disease, Non Revascularisable PVD, Conventional wound dressing, Diabetic foot

1. Introduction

Over the past decades there has been an alarming rise in the prevalence of diabetes. Diabetes is beginning to appear much earlier in life in India which implies, the chronic long term complications are becoming more common. Foot problems such as ulceration, infection, gangrene are common in diabetes. These account for frequent and prolonged hospitalisation with significant morbidity and mortality. One-third of all diabetic pts have significant peripheral neuropathy (or) peripheral vascular disease (PVD).

Hence this study has been taken up to identify the efficacy of newer technique in diabetic wounds with non-revascularisable PVD management in comparison to advanced conventional dressing. 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 therapy after failed revascularisation 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.

2. Materials and Methods

- Total of 30 patients were included in this prospective study, who have a non revascularisable peripheral vascular disease for whom on performing peripheral angiography, the distal runoff vessel is less than 10cm, not suitable for intervention.
- They were randomly divided into two groups; negative pressure wound therapy (NPWT) group (15 patients) and control group (15 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 conventional dressings.
- Test patients were given negative pressure wound therapy daily without any dressings.
- 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.

3. Results

- After wound management, mean surface area of the diabetic wounds was 39.08cm^2 in the NPWT group (P=0.019), and 38.63cm2 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 12 among 15 patients (76%) compared to control group 4 showed granulation among 15 patients (26%) (P=0.001).
- The incidence of secondary higher amputation in NPWT group is 4/15 (24%), the control group 10/15 (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.

Age distribution of the patients

Table 1: Control Group

Age	*Male*	*Female*
50-60	3	0
61-70	4	2
71-80	3	1
81-90	1	1

Table 2: Test Group

Age	*Male*	*Female*
50-60	3	0
61-70	3	3
71-80	3	1
81-90	2	0

Results showing improvement in granulation with (or) without VAC therapy

Table 3

% of granulation in the wounds	*Without VAC (control)*	*With VAC (test)*
No improvement	11	2
<25%	2	1
50%	1	3
75%	1	2
90%	-	2
Fully granulated	-	5

4. Discussion

- 4 of 15 (24%) in the control group were females whereas 11 of 15 (76%) in the control group were males.
- 4 of 15 (24%) in the test group were females and 11 of 15 (76%) were males. 3 of 15 (20%) in the control group were below the age of 60 and 80% were above 60 years of age.
- 3 of 15 (20%) in the test group were below 60 years and 80% were above 60 years of age.
- Initially, the mean surface area of wounds in the NPWT group was 45.44cm2, the control group 38.52cm2.
- The mean duration of open wound care was 17.96 days in the NPWT group and 21.88 days in the control group.
- 10/15 (65%) patients underwent BK in the control group and 4/15 (24%) 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 12 of the 15 patients undergoing NPWT whereas only 2 of the 15 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.
- General technique for NPWT is as follows: "protect the periwound by applying a skin barrier then it should be followed by a transparent film.“
- 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.
- 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, conventional 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.

5. Conclusion

- 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 safe and efficacious method, than conventional dressing for the treatment of diabetic foot ulcers with non-revascularisable PVD.

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