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## COMPARISON OF NEGATIVE PRESSURE WOUND THERAPY USING VACUUM-ASSISTED CLOSURE WITH ADVANCED MOIST WOUND THERAPY IN THE TREATMENT OF DIABETIC FOOT ULCERS

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### Abstract

Managing comorbidities are very essential in treating diabetic foot ulcer. The prevalence of DM in US has been reported as most common reason for hospitalisation in western countries. There is a steady increase in incidence of type 2DM in obese and young population.<sup>1</sup>

### Diabetic foot

It is associated with morbidity, disability and thereby affecting quality of life. Foot ulcers occurs due to neuropathy, ischaemia or both. Injury can occur from mechanical or thermal trauma or from continuous mechanical stress. This results in amputation in severe conditions. Type II DM accounts for about 90% – 95% of total DM in accordance to American diabetic Association. Diabetic foot ulcer a painful and costly. Foot ulcers are most common condition which results to lower extremity amputation. Risk factors for diabetic foot ulcer are peripheral neuropathy and peripheral arterial disease.

Even after healing of the ulcerated foot care must be consider as a lifelong condition that requires monitoring and prevent recurrence.

### 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.<sup>1,2</sup>

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.<sup>3</sup> 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.<sup>4</sup> 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.<sup>5</sup>

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.<sup>2,6</sup>

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.<sup>2, 7</sup>. Similarly it also increases with increased duration of diabetes, 15% at 10 years and 45% after 20 years. <sup>8</sup>

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.<sup>9</sup>

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.<sup>10</sup> and, more recently, in the management of complex but non-surgical diabetic foot ulcers.<sup>11</sup> It is clear that this treatment helps promote the formation of granulation tissue.

Foot ulcers and amputations are major causes of morbidity, disability, and economic burden for people with diabetes<sup>2</sup>. While there is little information available, it seems reasonable to suggest that the clinical problems leading to foot disease and subsequent amputation have a major impact on the quality of life of individual patients.

Diabetes continues to be the leading cause of lower extremity amputations (LEAs) worldwide. Every year, more than 1 million people with diabetes lose a leg as a consequence of their disease. In other words, every 30 seconds a lower limb is lost to diabetes somewhere in the world<sup>2</sup>. Approximately 40-60% of all LEAs is related to diabetes and, in some areas of the world, proportions as high as 70-90% has been described<sup>3,4</sup>. It is difficult to estimate the incidence of LEA across countries because of the heterogeneity of study populations.

In the USA, more than 90,000 diabetes-related LEAs are performed annually<sup>5</sup>, and there are approximately 300,000 hospitalizations annually for foot cellulitis, ulcers, and deep infections among individuals with diabetes. In Europe, about 250,000 LEAs are performed annually, two-thirds of which are performed in Eastern European countries. In diabetics, LEA incidence represents 50% of all nontraumatic amputations<sup>6</sup>, and the age-adjusted risk for LEA is reportedly 15-60 times greater than that of the nondiabetic population<sup>7,9</sup>. Furthermore, foot complications are the most common reason for hospitalization in patients with diabetes. Diabetic foot ulcers and LEAs occur in more than 15% of people with diabetes during their lifetime<sup>10,11</sup>. More than half of diabetic amputees require amputation in the contralateral limb within 4 years of losing the first leg<sup>9,12</sup>.

Patients show an elevated mortality rate in the first 3-5 years after an amputation<sup>13</sup>, which is often attributed to cardiac or renal complications. A recent study in Denmark found a 30-day mortality rate of 30% in a consecutive series of 93 LEAs; more than half of the patients were dead by 1-year postamputation. The mortality rate was significantly related to age and the number of comorbidities<sup>16</sup>. Higher overall mortality rates have been reported in diabetic amputees compared to nondiabetic or other diabetic individuals in studies of Pima Indians in Arizona, USA. This population is notable for having the highest amputation rate among diabetic subjects (95% of all amputations were in diabetic subjects).

#### Economic costs of diabetic foot disease

In most countries, 25% to 50% of the cost for the inpatient care of diabetes is attributable to the diabetic foot. Two Swedish studies found the costs of topical treatment and outpatient stays to be the most substantial. Healing of a single ulcer costs approximately \$17,500. The time needed for complete wound healing after an amputation in patients with diabetes is variable and depends on the level of amputation. The

mean healing time for patients with minor or major amputation was shown to be as long as 52 or 38 weeks, respectively.

In the USA, Reiber estimated the total direct costs for amputation to be \$20,000 to \$25,000 (1992). At approximately the same time, Apelqvist et al. estimated that the cost varied between \$43,000 and \$65,000 in Sweden, depending on the level of amputation (1994). More recently, this cost was found to vary from about \$30,000 to \$33,500 in Sweden (2004). In the USA, the average inpatient cost for toe/transmetatarsal amputations was \$25,241, transtibial amputations was \$31,436, and transfemoral amputations was \$32,214 (2002). Long-term costs, including prostheses, special footwear, rehabilitation costs, costs for home care and social services, and costs related to any residual disability and productivity losses, must also be considered.

Given the high costs of diabetic foot disease, however calculated, to individuals and society, preventive foot care and low-cost interventions will almost certainly be effective. Interestingly, the cost of a minor amputation (e.g., of an infected phalanx or metatarsal head), including a short 3-day hospitalization, is less than the cost of the purely conservative approach of medical treatment encompassing 6 weeks of at-home intravenous antibiotic therapy. This kind of economic consideration is fully accepted by some health insurance companies, and is very nicely reflected by George Bernard Shaw (1856-1950, Nobel Prize award for literature in 1925), who said: “I marvel that society would pay a surgeon a large sum of money to remove a person’s leg – but nothing to save it.”

The reimbursement system may be one of the most dangerous enemies of the diabetic foot<sup>50,51</sup>. If the cost of a surgical amputation procedure is reimbursed but those of outpatient care and preventive strategies (e.g., foot care, protective shoes) are not, then the incidence rate of LEAs may continue to increase. In many European countries, most people are assured affordable governmental health care. In the USA, costs are more often paid by the patient or insurance company.

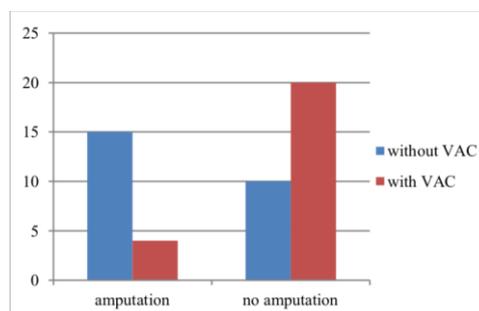
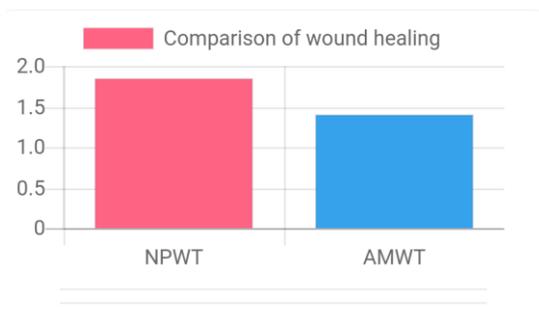
## **Methods**

Total of 59 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 (29 patients) and control group (30 patients).

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.

**Results**

After wound management, mean surface area of the diabetic wounds was 39.08cm<sup>2</sup> in the NPWT group (P=0.019), and 38.63cm<sup>2</sup> 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 29 patients (76%) compared to control group 7 showed granulation among 30 patients (26%) (P=0.001).



The incidence of secondary higher amputation in NPWT group is 6/29(24%), the control group 17/30 (65%) (P=0.003), suggesting reduced incidence of secondary higher amputations in NPWT group. After treatment, the NPWT group significantly improved in measures of foot ulcer surface area compared with the AMWT group.

AGE	MALE	FEMALE
40-50	6	3
51-60	5	8
61-70	1	6

AGE	MALE	FEMALE
40-50	2	8
51-60	12	2
61-70	5	1

**a: Age distribution in NPWT group.**

**b:Age distribution in AMWT group.**

**Discussion**

Granulation of the wounds was >50% in patients undergoing NPWT whereas only 3 of the 30 in the AMWT 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 (V.A.C.) that assists tissue granulation and is sealed with an adhesive drape that contains the sub atmospheric pressure at the wound site

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.

**Conclusion:**

The incidents of diabetic foot ulcers will increase in the future and require a high cost of care. DFU healing also takes a long time and can lead to amputation in the lower extremities, thus exacerbating quality of life and increasing mortality.

Wound healing requires infection control, inflammatory repair, regeneration of connective tissue matrix, angiogenesis/vasculogenesis, wound constriction and reepithelization.

Management of DFU management focused on prevention of amputation in lower limb with 3 strategies, namely: identification of risk factor of DFU, acute treatment and prevent complication.

Therapy performed on the wound of the DFU is carried out constantly with the type of action that depends on the severity of the ulcer and the presence or absence of ischemia.

The basis of DFU therapy are necrotomy/debridement, reducing offloading, managing the infection by diagnosing the type of bacteria and providing an adequate antibiotic, ulcer treatment using wound dressing clean and moist.

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