

Original research article

Comparative Study of Negative Pressure Wound Therapy with Moist Gauze Dressing in the Treatment of Diabetic Wounds

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Abstract

Background: The purpose of this study was to evaluate speed, safety and efficacy of negative pressure wound therapy (NPWT) compared with moist gauze dressings (MGD) to treat foot ulcers in diabetic patients.

Materials and methods : The cases presented in this study are those patients admitted on inpatient basis from general surgical wards, plastic surgery and patients with surgery reference for diabetic foot care from all other departments like medicine, orthopaedics in PMCH Patna. Study duration of Two Years. This is a prospective interventional study. In this study 30 randomly selected patients were assigned to the study group (topical negative pressure) based on their willingness for undergoing topical negative pressure dressings and 30 patients to the control group (moist gauze dressings).

Results: The 60 patients admitted for the study were divided into two equal and comparable groups of 30 patients each. All the patients in the study were suffering from diabetes of varying duration, with some on regular treatment and the others on irregular treatment. In Vacuum assisted closure/Topical negative pressure therapy maximum patients of 11 were found in the age group 41-50yrs with 36.7% and in Moist gauze dressing group also same result but the age group being 61-70. Female patients were more in VAC group, compared to male in MGD.

Conclusion: Application of Topical Negative Pressure increased the rate of formation of granulation tissue and had better graft uptake, faster wound healing. It also lessens the length of hospital stay thereby improving final clinical outcome than the patients who underwent a conventional dressing for diabetic foot wounds.

Keywords: Topical Negative Pressure; Moist Gauze Dressing; Diabetes Mellitus; Granulation tissue; Split Skin Graft.

Introduction

DIABETIC FOOT ULCERS is the most common cause of chronic wounds throughout the world. The lifetime risk of a person with diabetes developing a foot ulcer could be as high as 25 percent, and it is believed that every 30 seconds a lower limb is lost somewhere in the world as a consequence of diabetes. Diabetic foot ulcers are the single biggest risk factor for non

traumatic foot amputations in persons with diabetes¹. The peculiar characteristic is the refusal of the diabetic foot ulcer to heal despite the best wound care management. By the year 2030, it is estimated that 366 million persons in the world will have diabetes. The worldwide prevalence of diabetes estimated to be 2.8 percent in 2000 and is expected to grow to 4.4 percent in 2030. Chronic wounds are a tremendous burden to the healthcare system, accounting for about \$20 billion in healthcare costs per year world wide. Many techniques have been tried over the centuries to heal chronic leg ulcers. Although there exists no ideal wound dressing in the management of chronic wounds, especially diabetic foot ulcers has seen many new developments. Recent studies have shown that application of a sub atmospheric pressure in a controlled manner to the wound site has got an important role in assisting wound healing. The treatment of diabetic foot wounds requires a multidisciplinary approach². Treatment of peripheral vascular disease (PVD), infection and pathological plantar pressure play a significant role in the overall management of these lesions. Topical treatment of wounds using advanced wound dressings has, unfortunately⁴, not yet produced entirely consistent results. Recently, more promising outcomes have been obtained in the treatment of neuropathic wounds due to the introduction of bioengineered tissue in clinical practice and to the availability of Vacuum-Assisted Closure Therapy.

The Vacuum-assisted closure (VAC®) device (KCI, San Antonio, TX) was pioneered by Dr. Louis Argenta and Dr Michael Moryk was in 1993 (Rosser *et al.* 2000). It is a development from the standard surgical procedure, which uses vacuum- assisted drainage to remove blood or serous fluid from an operation site to provide a drier surgical field and control blood flow (Thomas 2001). In VAC therapy, the application of topical negative pressure (vacuum) removes blood and serous fluid, reduces infection rates (closed/sealed system creates a hypoxic environment) and increases localised blood flow, thereby supplying the wound with oxygen and nutrition to promote accelerated healing (Vacuum therapy in wound management 2001, Genecov 1998)⁵. Alternative names for VAC wound suction are vacuum sealing and foam suction dressing (Vacuum therapy in wound management 2001)³.

Objectives

To compare the use of moist gauze dressings to negative pressure therapy in the treatment of diabetic wounds. The primary efficacy end point is the incidence of complete ulcer closure. Complete ulcer closure was defined as skin closure (100% re-epithelization). Secondary end points included reduction in the ulcer surface area over time, time to achieve complete ulcer closure either by surgery or secondary intention, and reduction in complications, including amputations.

Material and methods

The cases presented in this study are those patients admitted on in patient basis from general surgical wards, plastic surgery and patients with surgery reference for diabetic foot care from all other departments like medicine, orthopaedics in Patna medical college and Hospital Patna, Bihar. Study duration of Two years.

Inclusion criteria

All cases of diabetic wounds / foot presented to the hospital during the study period.

Exclusion criteria

Cases of diabetic wound / foot with cancerous surrounding tissue, fistulas to the other organs or body cavities and or osteomyelitis. Patients with recognized active Charcot disease or ulcers resulting from electrical, chemical, or radiation burns and those with collagen vascular disease, ulcer malignancy and untreated osteomyelitis were excluded from the study.

Exclusion criteria also included ulcer treatment with normothermic or hyperbaric oxygen therapy; concomitant medications such as corticosteroids, immunosuppressive medications, or chemotherapy; recombinant or autologous growth factor products; skin and dermal substitutes within 30 days of study start; or use of any enzymatic debridement treatments. Pregnant and nursing mothers were excluded from study participation. All the selected patients history, clinical presentations and physical findings were recorded according to the proforma.



Bed sore of ICU patient(post road traffic accident ,intracranial haemorrhage),wound debrided, surrounding area is shaved and Ryles tube placed in wound bed.



Different methods of vacuum dressing were also tried but this method was found very effective but one of its limitation was maceration of surrounding skin and impression of Ryles tube due to air tight dressing, this we tried to overcome by letting it dry to air for half an hour just before dressing.

Results

The 60 patients admitted for the study group were divided into two equal and comparable groups of 30 patients each. Patients subjected to the Topical Negative Pressure/Vacuum assisted closure(VAC) dressing were classified as Group I and those who underwent conventional Moist Gauze dressings (MGD) were classified as Group II.

Table 1: BASIC PATIENT DATA

		Group-I	Group-II			
Number of patients		30	30			
Mean age in years		55.23	57.60			
Male: Female ratio		1: 1.43	1: 0.43			
			Group		Total	
			VAC	MGD		
Ages	31-40	Count	3	8	11	
		% withingroup	10.0%	26.7%	18.3%	
	41-50	Count	11	3	14	
		% withingroup	36.7%	10.0%	23.3%	
	51-60	Count	7	3	10	
		% withingroup	23.3%	10.0%	16.7%	
	61-70	Count	4	11	15	
		% withingroup	13.3%	36.7%	25.0%	
	71+	Count	5	5	10	
		% withingroup	16.7%	16.7%	16.7%	
	Total		Count	30	30	60
			% within group	100.0%	100.0%	100.0%

Table 2: SEX DISTRIBUTION

Sex		Group	Total	
		VAC	MGD	
M	Count	14	21	35
	% within group	46.7%	70.0%	58.3%
F	Count	16	9	25
	% within group	53.3%	30.0%	41.7%
Total	Count	30	30	60
	% within group	100.0%	100.0%	100.0%

Table 3: Group Statistics

	group	N	Mean	Std. Deviation	Std. Error Mean
diab_durn	VAC	30	8.2000	6.11612	1.11665
	MGD	30	7.8667	5.58158	1.01905

Table 4: Independent Samples Test

t-test for Equality of Means				
	T	Df	Sig. (2-tailed) P value	Mean Difference
diab_durn	0.220	58	0.826	0.33333

In VAC Group split skin grafting was done for 10 patients, 8 patients showed 90% graft uptake one patient had graft failure Re grafting was done, another patient wound healed by secondary intention due to graft failure. In MGD dressing group split skin grafting was done only in 6 patients among them graft uptake rate was 84%. Except the two cases all of them were well cured. In other cases where doubtful arterial supply, aetiology mainly being atherosclerosis few Necrotising fasciitis cases proceeded with amputation depending upon the level of obstruction. Datas of amputation being above knee amputation (AKA) in 1 patient accounting for 3.3% only in MGD group, below knee amputation (BKA) in 1 patient (3.3%) in VAC group and 2 (6.7%) in MGD group and Symes (SY) and transmetatarsal (TMA) amputation in 2 patients with 6.7% only in MGD group. Patients in our study were mainly from rural background with low level of education and low socioeconomic background which posed problem in follow up. This was circumvented by collecting their phone numbers and proper counselling for regular follow up with free treatment facilities available in the hospital.

Crosstab					
			Group		Total
			VAC	MGD	
fu_1week	Nil	Count	1	0	1
		% within group	3.3%	0.0%	1.7%
	D	Count	0	5	5
		% within group	0.0%	16.7%	8.3%
	G0	Count	1	0	1
		% within group	3.3%	0.0%	1.7%
	GO	Count	18	5	23
		% within group	60.0%	16.7%	38.3%
	S	Count	10	20	30
		% within group	33.3%	66.7%	50.0%
Total		Count	30	30	60
		% within group	100.0%	100.0%	100.0%

Discussion

The concept of moist wound dressings which came into vogue in the 1960's which made revolution in wound care.^[11] In the early 1990's, the concept of topical negative pressure moist wound dressing was introduced into the field of chronic wound care. This type of dressing involved a combination of hydrocolloid dressings with topical negative pressure dressings.^[16] The high cost of the V.A.C. system led to the need to develop a less expensive comparably effective dressing, based on the same principles. Sterile sponge, wrapped in a layer of Jelonet is placed over the open wound. Evacuation tube is placed over the sponge, and covered with a second sponge layer. The whole area is covered with adhesive drape, creating an airtight seal.^[12,13] This study was done as a prospective randomized controlled comparative study to compare the efficacy of topical negative pressure moist dressing to conventional moist wound dressing in management of chronic wounds. The 60 patients admitted for the study group were divided into two equal and comparable groups of 30 patients each. Patients subjected to the Topical Negative Pressure/Vacuum assisted closure (VAC) dressing were classified as Group I and those who underwent conventional Moist Gauze dressings (MGD) were classified as Group II⁶. Mean age in years is 55.23 and 57.60 and Male:Female ratio of 1:1.43 and 1:0.43. Mean duration of diabetes was 7-8 years. Ulcer being most common mode of Presentation. On day 7 there was around 40% granulation tissue formation in 29 patients out of 30 in VAC Group, and only around 30% in 28 patients out of 30 in MGD Group. On 14 day it was 54% for 26 in VAC patients and 46% for 24 patients in MGD Group. Later formation of granulation

tissue was almost equal in both the groups⁷.

In VAC Group split skin grafting was done for 10 patients, 8 patients showed 90% graft uptake. In MGD dressing group split skin grafting was done only in 6 patients among them graft uptake rate was 84%. In other cases where doubtful arterial supply, aetiology mainly being atherosclerosis few Necrotising fasciitis cases proceeded with amputation depending upon the level of obstruction total of about 8 patients from both the groups more in MGD Group⁸. Among 30 patients (100%) in VAC group 19 (63.3%) showed **good(GO)** response with Complete cure rate, where as it was just 5 (16.7%) with good response in MGD group. **Satisfactory(S)** result was more in MGD group of 20 patients around 66% after proper counselling of patients for follow up and it was 33.3% for 10 patients in VAC group. **Death(D)** was seen in 5 patients accounting 16.7% only in MGD group in elderly age group with other coexistent morbidities and post operative patients mainly amputated cases⁹.

	Peter.A,Blume et al ^[14]		Joseph et al ^[15]		Present study	
	VAC (study Group)	MGD (control group)	VAC	MGD	VAC	MGD
Sample size	169	166	18	18	30	30
Mean age (years)	58	58	52.41	53.20	55.23	57.60
Rate of granulation formation	95%	-	81.56%	54.30%	Day7-40% Day14- 54%	30% 46%
Graft uptake	43.2%	28.9%	85.3%	56.43%	90%	84%
Hospital stay	63.6+/- 36.57	78.1+/- 39.29	36.24	70.4	20 days	20 days

Comparison of the present study with Joseph et al., and Peter A Blume et al.

The above table shows a comparison of the present study to a similar study conducted by Joseph et al¹⁵., and Peter A Blume et al with varied sample size in all three studies. Mean age group of our study patients was 55-57 years almost same as other two study group. Rate of granulation tissue in our VAC group was 40% at day 7, 54% at day 14 and 30% at day 7, 46% at day 14 in (MGD) group. Last two weeks those patients who were undergoing only conservative treatment by means of dressing without any surgical intervention due to proper debridement and repeated dressings percentage of granulation tissue formation was almost same in both the groups with slight difference, VAC group being on higher end, whereas it is 95% in Peter, Blume et al study group and 81.56% (VAC), 54.30% (MGD) in Joseph et al study group. Graft uptake was very good in our study that too VAC group compared to other two studies. Duration of hospital stay was very less in our study compared to other two. This might also be attributed to early discharge of patients in MGD group due to varied reasons and relatively longer stay of the patients in VAC group for treatment of their other co morbidities. Associated comorbidities include along with Diabetes Mellitus, Hypertension, Asthma, COPD (due to smoker patient in our trial), chronic liver diseases (due to more alcoholic patients from rural background), chronic cardiac disease and chronic CNS- post stroke (CVA), chronic epileptics, post Road traffic accident patients for observation after neurosurgical opinion and on treatment. Few patients had Haemorrhoids, Hernia and Urolithiasis also. Next to Diabetes, Hypertension was the commonest comorbidity in our patients. All medical comorbidities were treated by proper referral to physician and appropriate drugs¹⁰. Most of the surgical co-morbidities were treated by operative intervention. Glycosylated hemoglobin was used as a marker to assess the severity

of diabetes in patients with bad glycemic control and poor wound healing despite of treatment. so a high level of HbA1c >8 was taken as index of severity and seen in patients who presented with gangrene and Necrotising fasciitis. Compared to the control group almost 1/3rd study group were completely cured by the end of Second week and another 1/3rd by the end of third week either by conservative wound healing or by skin grafting.

Conclusion

study it was found that the application of Topical Negative Pressure increased the rate of formation of granulation tissue, less infection rate and had better graft uptake than the patients who underwent a conventional dressing for their ulcers. The patients in the study group had better patient compliance and had a shorter duration of hospital stay when compared to the control group. Thus, topical negative pressure moist wound dressing can be considered as a superior option in the management of diabetic foot ulcers. But further studies with larger population will be needed in the future before topical negative pressure dressing can be added to the wide spectrum of treatment modalities available in the management of diabetic foot.

References

1. Yorke Joseph, Akpaloo Joseph, Agbenorku pius. Management of Diabetic Foot Ulcers Using Negative Pressure with Locally Available Materials. *Modern Plastic Surgery* 2013;3: 84-88.
2. Singh, N., Armstrong, D. G., and Lipsky, B. A. Preventing foot ulcers in patients with diabetes. *J.A.M.A.* 2005; 293: 217.
3. WHO (1998), Prevention and control of diabetes mellitus, report of an intercountry workshop, Dhaka Bangladesh 27-30 April 1998, SEA/NCD/40.
4. International Diabetes Federation. Time to Act: Diabetes and Foot Care. Brussels: International Diabetes Federation, 2005.
5. Boulton, A. J., Vileikyte, L., Ragnarson-Tennvall, G., et al. The global burden of diabetic foot disease. 2005; *Lancet* 366: 1719.
6. Laing, Patric. The development and complications of diabetic foot ulcers. *Am J of surg* 1998;(Suppl 2A)11S-19S.
7. Robson MC. Wound infection. A failure of wound healing caused by an imbalance of bacteria. *Surg Clinics of North America* 1997; 77(3):637-50.
8. Van Gils, Carl C. et al. Amputation prevention by vascular surgery and podiatry collaboration in high risk diabetic and non diabetic patients. *Diabetes care.* 1999; 22(5): 678-683.
9. Venturi, Mark L; Attinger, Christopher E; Mesbahi, Ali N; Hess, Christopher L; Graw, Katherine S . Et al.; Mechanisms and Clinical Applications of the Vacuum-Assisted Closure (VAC) Device: A Review 2005;6(3):185-194.
10. David G Armstrong, Lawrence A Lavery. Negative pressure wound therapy after partial diabetic foot amputation : a multicentre , randomized controlled trial. *Lancet* 2005; 366 : 1704 – 10.
11. Atiyeh BS, El-Musa KA, Dham R. Scar quality and physiologic barrier function after moist and moist exposed dressings of partial thickness wounds. *Dermatol Surg* 2003 Jan; 29(1): 14-20.
12. Avshalom Shalom, Hadad Eran, Melvyn Westreich and Tal Friedman. Our Experience with a "Homemade" Vacuum-Assisted Closure System. *IMAJ* 2008;10:613–616.
13. DeFranzo AJ, Marks MW, Argenta LC, Genecov DG. Vacuum assisted closure for the treatment of degloving injuries. *Plast Reconstr Surg* 1999;104:2145–8.
14. Comparison of Negative Pressure Wound Therapy Using Vacuum-Assisted Closure With

Advanced Moist Wound Therapy in the Treatment of Diabetic FootUlcers : A multicenter randomized controlled trial. *Diabetes Care*.2008;31:631- 636.

15. Joseph et al. A prospective randomized trial of vacuum assisted closure versus standard therapy of chronic non-healing wounds. *Wounds* 2000; 12(3): 60-76.
16. Fleischmann W, Strecker W, Bombelli M, Kinzl L. Vacuum sealing as treatment of soft tissue damage in open fractures. *Unfallchirurg* 1993; 96(9):488-92.