Section: General Surgery

Original Research Article

COMPARATIVE STUDY OF NEGATIVE PRESSURE WOUND THERAPY (NPWT) USING HOMEMADE VACUUM ASSISTED CLOSURE (HVAC) WITH CONVENTIONAL DRESSING IN THE TREATMENT OF DIABETIC FOOT ULCERS

Virendra Limbaraj Gawli[1], Saurabh Gandhi[2], Basavraj Kadalage[3], Vatsal Patel[4]

[1]Medical Director¸ Department of General Surgery, Chirayu Hospital, Dharashiv, India.
[2]Associate Professor, Department of General Surgery, D. Y. Patil Medical College, Kolhapur, India.
[3]Assistant Professor, Department of General Surgery, D. Y. Patil Medical College, Kolhapur, India.
[4]Senior Resident and Fellow, Minimal Access Surgery, Department of General Surgery, D. Y. Patil Medical College, Kolhapur, India.

Received *: 29/04/2025*
Received in revised form *: 21/06/2025*
Accepted *: 03/07/2025*

Corresponding Author:
Dr. Vatsal Patel,
Senior Resident and Fellow. Minimal Access Surgery, Department of General Surgery, D. Y. Patil Medical College, Kolhapur. India.
Email: vatsalanderpa@gmail.com

DOI: 10.70034/ijmedph.2025.3.138

Source of Support: Nil,
Conflict of Interest: None declared

Int J Med Pub Health
2025; 15 (3); 743-749

ABSTRACT

Background: Diabetic foot ulcers (DFUs) are a common and serious complication of diabetes mellitus, often leading to hospitalization and lower limb amputations. Negative Pressure Wound Therapy (NPWT) has shown promise in improving wound healing. This study evaluates the efficacy of a cost-effective, Homemade Vacuum Assisted Closure (HVAC) system compared to conventional saline gauze dressing (SGD) in the management of DFUs.

Materials and Methods: A prospective, randomized controlled trial was conducted on 60 patients with diabetic foot ulcers admitted to Sir J.J. Group of Hospitals, Mumbai. Participants were divided into two groups: HVAC (n=30) and SGD (n=30). Key outcomes assessed included hospital stay, wound granulation, graft uptake, ulcer area reduction, rate of infection, and surgical intervention rates.

Results: The HVAC group showed a significantly shorter mean hospital stay (37 vs. 49.7 days, $p < 0.01$), higher granulation tissue coverage (97.5% vs. 93.4%, $p = 0.002$), and greater ulcer area reduction post-intervention (29.3 cm^2 vs. 20.4 cm^2). Although graft uptake was slightly higher in the HVAC group (96.7% vs. 94.3%), the difference was not statistically significant ($p = 0.06$). Infection rates were significantly lower in the HVAC group, with 53% showing negative wound cultures compared to none in the SGD group ($p < 0.01$). Rate of granulation formation was also higher with HVAC (0.76 vs. 0.50 cm^2/day, $p = 0.048$).

Conclusion: Homemade NPWT using HVAC significantly enhances wound healing, reduces infection rates, and shortens hospital stay compared to conventional saline gauze dressings in diabetic foot ulcers. Given its low cost and effectiveness, HVAC presents a viable alternative for wound management in resource-constrained settings. Further studies with larger sample sizes are warranted to validate these findings.

Keywords: Negative Pressure Wound Therapy (NPWT), Homemade Vacuum Assisted Closure (HVAC), Conventional Dressing, Diabetic Foot Ulcers.

INTRODUCTION

Diabetes Mellitus Type- II has become the most common metabolic disorder and diabetic foot ulcer is the commonest complication of diabetes and is leading cause of a hospitalization and prolonged in patient treatment. Diabetic foot ulcers are a significant health problem affecting more than 1 million patients at some point in their life time.[1]

India currently leads the world with an estimated 41 million people with diabetes; this figure is predicted

to increase to 66 million by 2025. The diabetes epidemic is more pronounced in urban areas in India, where prevalence rates of diabetes are roughly double than those in rural areas. [2] The prevalence of diabetes in adults is about 2.4%rural and 4.0-11.6% in urban dwellers. High frequencies of impaired glucose tolerance, shown by the above studies ranging from 3.6 – 9.1% indicate the potential for further rise in the prevalence of diabetes mellitus in the coming years.[3]

Diabetic foot is one of the most devastating chronic complications of diabetes. A diabetic foot ulcer is the single biggest risk factor for non-traumatic foot amputations in persons with diabetes and is the leading cause of lower limb amputation.[4] It is believed that every 30 seconds a lower limb is lost somewhere in the world as a consequence of diabetes. In India approximately 45,000 legs are amputated every year, and the numbers are increasing each year. Almost 75 % of these amputations are carried out in neuropathic feet with secondary infection, which are potentially preventable.

Certain factors like bare – foot walking, illiteracy, low socio-economic status, late presentation by patients, ignorance about diabetic foot care among primary care physicians and belief in alternative systems of medicine contribute to this high prevalence. Lack of trained professionals in diabetic foot care in India and profession of podiatry being non – existent compound the problem further.

Foot ulcers remain the leading cause of hospitalization in patients with diabetes. Treatment for complex and chronic wounds is still sub-optimal. Foot ulcers frequently develop complications and become chronic, representing a considerable challenge as these are typically very difficult to treat. The peculiar characteristic is the refusal of the diabetic foot ulcer to heal despite the best wound care management given.

Treatment of diabetic foot ulcers involves a number of sequential steps. First, prepare the ulcer for healing, ensuring that the blood supply is adequate, there is no infection, pressure is removed, and the ulcer is clean. The dressing can then facilitate the healing process.[7] The principles of good wound care includes use of proper footwear, non-weight bearing limb support, use of appropriate antibiotics, debridement, aggressive revascularization, control of serum glucose levels, and careful monitoring of the ulcer.[1] Many techniques have been tried over the centuries to heal chronic leg ulcers. Although there exists no ideal wound dressing the management of chronic wounds especially diabetic foot ulcers has seen many new developments. The traditional moist dressings were initially supplemented with hydrocolloid dressings, gels, foams, and other measures like hyperbaric oxygen, growth factors, and various offloading therapies. New therapies are needed to address these wounds and there is an increasing focus on negative pressure wound therapy (NPWT). NPWT has emerged as a non-pharmacological treatment for acute and chronic wounds, including pressure ulcers, diabetic wounds, abdominal wounds, and trauma wounds. It is primarily used for more complex chronic wounds. Chronic, non-healing open wounds remain an ongoing challenge.

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 above study was conducted to assess the efficacy of NPWT using HVAC with conventional saline-gauze dressings. So the study compares uptake of graft for both type of commercial VAC devices dressings and Homemade VAC dressing. And so to prove that the NPWT using Homemade VAC may have same outcome as that of commercial available VAC devices in management of diabetic foot ulcers and so chronic ulcers.

MATERIALS AND METHODS

The e study was conducted from September 2011 to December 2013 on patients admitted in the Sir J. J. Group of Hospital ‘s & Grant Government Medical College, Mumbai who have diabetic wounds / foot. In these study 30 randomly selected patients were assigned to the study group (Topical Negative Pressure / Homemade Vaccum Assisted Closure-TNP/HVAC) based on their willingness for undergoing topical negative pressure dressings and 30 patients to the control group (Moist Saline Gauze Dressings-SGD).

All patients were studied and clinical findings were recorded as per the Performa case sheet, necessary investigations ordered and appropriate treatment given. All cases were followed up to discharge and subsequently for a follow up on 2nd week &end of month.

Inclusion Criteria

Patients with age between 20 - 70 years, with chronic foot ulcers up to grade 2 with diabetes mellitus, diabetes mellitus with non- progressive gangrenous changes only after through debridement, Ulcer size <5% TBSA and willing to give consent for NPWT using homemade VAC therapy.

Exclusion Criteria

Chronic non-healing wounds of other etiology, Diabetes mellitus with progressive gangrenous changes, other co-morbid condition like renal failure, generalized debility and other factors, which adversely affect wound healing, patients not willing for NPWT using homemade VAC therapy.

On admission, patients were medically treated to control their diabetic status by a diet restriction, insulin (dose adjusted according to blood glucose levels). Wounds were debrided upon admission with an aim to achieve complete skin cover and save the limb. Regular dressings were done on a once in 2-day basis for the study group and twice in control groups respectively as per recommendations.

The study group was dressed using polypropylene dressing with a Vacuum assisted closure using

Sponge, Saline Gauge, Suction cannula covered with transparent semi permeable adhesive plastic membrane sheet (OPCITE) attached to wall mount central / electric suction to provide an air tight seal.

Figure 1: Diabetic foot ulcer before debridement

The dressing used in the study group was cut to the shape of the wound and kept on a thoroughly debrided wound over a tube drain. The surrounding area was made air tight by using a semi permeable, transparent membrane.

Figure 2: Wound site Homemade VAC dressing for creation of closed environment for NPWT

The distal end of the drain was connected to the central vacuum suction device that provides a negative suction of about – 20 to – 200 mmHg. the fluid through the foam. The wound site pressure was adjusted via pressure gauze valve. The pressure was maintained at 90 to 125 mm of Hg.

Wound size was calculated as height × width=cm2

OR length × Height = area (cm^2)

Figure 3: Diabetic ulcer just after debridement

Figure 4: Diabetic ulcer during dressing

Figure 5: Lt foot diabetic foot ulcer

Figure 6: Diabetic foot ulcer after skin grafting on follow up

HVAC intervention

The amount of granulation tissue as percent of the ulcer floor covered was assessed at the end of 1st week, 2nd week, 3rd week… and so on weekly as per need (up to 6th week). Once the ulcer showed adequate evidence of healing / good granulation tissue the wound were subjected to split thickness skin grafting (STSG) was done. Presence of necrotizing fasciitis, rapidly spreading infection, failure to conservative form of treatment, or if the Doppler showed evidence of complete arterial blocks, septicemia, and locally spreading cellulitis were indications for amputation.

Upon discharge patient was advised regarding diabetic diet to be followed, diabetic medication (insulin / OHA's), and foot care, followed for 2 weeks & 1-month immediate post discharge. The mean rate of granulation tissue formation, graft survival and hospital stay was calculated and compared for both groups.

Data was analyzed and entered into the Microsoft excel using SPSS version 28.0 in the form of graphs and tables.

RESULTS

Table 1: Comparison of sex distribution in both Type of dressing (p = 0.72)

Gender	Type of dressing		Total
	HVAC	SGD	
Female %	0.167	0.133	0.15
Male %	0.833	0.867	0.85
Total	30	30	60

Male patients had 0.833-HVAC and 0.867-SGD, while Female had 0.167- HVAC and 0.133-SGD. Indicating both groups does not have significant difference between type of dressing offered but demonstrates very significant gender difference (Males: Female is 85:15) between each type of dressing.

Table 2: Comparison of Age, Hospital stay and Duration of Diabetes mellitus

Variables	Type of dressing	N	Mean	Std. Deviation	P-value
Age (years)	HVAC	30	53.6	10.6	**0.11**
	SGD	30	49.4	8.7	
Hospital stay (days)	HVAC	30	37	8.7	**< 0.01**
	SGD	30	49.7	9.9	
Duration of DM (years)	HVAC	30	8.7	4	**0.076**
	SGD	30	7.2	2.5	

Hospital stay of 37 ± 8.7 days for HVAC and 49.7 ± 9.9 days for SGD having P < 0.05 suggest that the hospital stay was very less in HVAC group than SGD group of dressing. The difference of 'Age & Duration of diabetes' is insignificant.

Table 3: Comparison of Mode of presentation between two type of patient

Types			Type of dressing		Total
			HVAC	SGD	
Mode of presentation	Abscess		6	5	11
	Abscess, Gangrene		0	1	1
	Cellulitis		13	10	23
	Cellulitis, Abscess		3	5	8
	Cellulitis, Gangrene		2	3	5
	Ulcer		4	4	8
	Ulcer, Abscesss		1	1	2
	Ulcer, Cellulitis		1	1	2
Total		N	30	30	60
		%	100.00	100.00	100.00

P= 0.94; insignificant difference

Table 4: Comparison of Surgical intervention required during t/t

Surgical Intervention	Type	Type of	Total

		dressing		
		HVAC	SGD	
	Debridement (D)	46.70	43.30	45.00
	Debridement with Below knee amputation (D, BKA)	13.30	20.00	16.70
	Debridement with Toe/Trans metatarsal Amputation (D, TA)	26.70	26.70	26.70
	Toe/ trans metatarsal Amputation (TA)	13.30	6.70	10.00
	Toe/ trans metatarsal Amputation f/b below knee Amputation (D,BKA)	0.00	3.30	1.70
Total	N	30	30	60
	%	100.00	100.00	100.00

P = 0.71; insignificant difference

Suggesting the surgical intervention is independent factor, mostly depending on patients affected parts at time of presentation and other factors. But numbers of patient from SGD type are more progressing to Below knee amputation than HVAC- type.

Table 5: Comparison of ulcer area and Granulation % between two

Variables	Type of dressing	N	Mean	Std. Deviation	P-value
Ulcer Area Before Intervention	HVAC	30	117.1	71	0.005
	SGD	30	163.6	51.7	
Ulcer Area After Intervention / Skin grafting	HVAC	30	87.8	53.3	< 0.001
	SGD	29	143.2	46	
Graft uptake in %	HVAC	29	96.7	4.9	0.06
	SGD	29	94.3	5	
Granulation Area % on Floor	HVAC	30	97.5	3.9	0.002
	SGD	29	93.4	5.7	

The data analysis clearly indicates there is significant decrease in mean ulcer area for SGD group is from 163.6 cm2 to 143.2 cm2 (20.4cm2) as compared with HVAC group from 117.1 cm2 to 87.8 cm2 (29.3 cm2) after intervention in terms of dressing and at completion or before skin grafting. This was statistically significant as area after intervention as p is <0.05. But it also demonstrated the higher granulation area.

Table 6: Comparison between Wound swab & culture reports

Wound Swab Culture study		Type of dressing		Total
		HVAC	SGD	
Negative	N	16	0	16
Positive	N	14	30	44
Total	N	30	30	60
	%	100.00%	100.00%	100.00%

P-value: - <0.01

Significant difference exists between the HVAC group and SGD group for wound swab culture at time of grafting, with high negativity rate in HVAC group than SGD group. There is also higher prevalence of Pseudomonas sp. with p-value <0.01 indicating hospital transmission of micro-organisms.

Table 7: Comparison of Mean Rate of granulation between two dressing

Group Statistics					
Type of dressing		N	Mean	Std. Deviation	Std. Error Mean
Rate of Granulation	HVAC	30	0.76	0.51492	0.09401
	SGD	30	0.50	0.74153	0.13538

This clearly Indicated higher rate of granulation for HVAC (0.76±0.51) than SGD (0.50±0.74), so early wound granulation & early wound closure was found in HVAC than SGD.

Table 8: Comparison of reduction in ulcer area for both dressing

Group Statistics

Type of dressing		N	Mean	Std. Deviation	Std. Error Mean
Reduction in Ulcer Area	HVAC	30	29.3	25.01714	4.56748
	SGD	30	25.1	38.88243	7.09893

Though higher mean ulcer size reduction area in HVAC (29.3 ± 4.56) than SGD (25.1 ± 7.09) is statistically insignificant. But clearly indicated the HVAC also decreases mean ulcer area than SGD, requiring smaller donor grafts.

Table 9: Mann- Whitney Test

Ranks			
Group	N	Mean Rank	Sum of Ranks

Rate of Granulation	HVAC	30	34.55	1036.5
	SGD	30	26.45	793.5
	Total	60		
Reduction in Ulcer Area	HVAC	30	31.05	931.5
	SGD	30	29.95	898.5
	Total	60		

Test Statistics [a]

	Rate of Granulation	Reduction in Ulcer Area
Mann-Whitney U	328.5	433.5
Wilcoxon W	793.5	898.5
Z	-1.989	-0.244
Asymp. Sig. (2-tailed)	0.048	0.807

a. Grouping Variable: Group

Table 10: Comparison of follow up status of patients

FU after 1 Month		Type of dressing		Total
		HVAC	SGD	
Complete/ Healed	N	29	25	54
Expired	N	1	1	2
NAF	N	0	1	1
Non-Healed/ Ulcer	N	0	3	3
Total	N	30	30	60
	%	100	100	100

Follow up status was not statistically significant but number of non- healed or recurrence of ulcer cases is higher in control group.

DISCUSSION

The above study was conducted as a prospective randomized controlled comparative study to compare the efficacy of topical negative pressure moist dressing using Homemade Vacuum assisted closure (HVAC) to conventional saline moist wound dressing (SGD) in management of chronic wounds.

Sex distribution – The Blume et al,[5] study showed 79 % of Male population while 21% were females while Abdulla et al,[6] did not showed any gender data. Ravari et al,[7] had 65% were males and 35% females but Tauro et al,[8] showed 55% males and 45% of females. In above study, 85% were males and 15% female. So there was similarity in between Blume et al. and above study but the other studies showed significant difference.

Age, and Hospital stay –In the above study, Mean age of presentation was 51.5 years (study group of 53.6 years and control group of 49.4 years) which is of non-statistical significance. Blume et al,[5] showed mean age of 58 years, Abdullah et al,[6] shows mean age of 65.45 years (study group 66.2 & control group 64.7 years) and Tauro et al,[8] have mean age of 47.5 years (study group 47.59 & control group 47.42 years).

The hospital stay in above study was of 37.0 days for study group and 49.7 days in control group with significant P-value of < 0.01. Similarly, Blume et al,[5] have hospital stay of 63.60 days for study group and 78.10 days for control group, Abdullah et al,[56] have hospital stay of 11.50 for study and 15.75 for control group (p = 0.05).

Mode of presentation - The diabetic patients have presented in varied forms like abscess, gangrene, cellulitis, ulcer and different combination of all types. The above study does not show any statistically significant difference in two groups. The other studies under consideration have not mentioned any form of presentation.

Surgical intervention required –The above study shows the diabetic foot patient undergone surgical intervention in form of selective debridement of site and or with selective amputation like digital Ray's amputation (single/ multiple), forefoot amputation (trans metatarsal), Lisfrank (tarsometatarsal), below knee (i.e. standard transtibial) amputation and above knee (Transfemoral) amputation other form of amputation were done. The study does not show statistical significant difference, but have significantly lower major amputations (BKA/ AKA) in study group (13.3%) than control group (23.3%) while minor amputations (like toe / trans metatarsal) are slightly higher in study group (37%) than control group (33.4%). Also other studies like Blume et al,[5] showed fewer amputations in study group (4.1%) than control group (10.2%). While none of study have assessed interventions needed to different group except Tauri et al,[8] had comment of lower amputation rate in study group than control group.

Reduction in ulcer area and granulation percentage- The above study did not show any significant difference in ulcer area before dressing intervention but did show statistically significant improvement of (P < 0.001) after intervention with lesser ulcer area in study group than control group. This data also showed better reduction in mean ulcer of study group (8.9 cm^2) over control group. It also showed better granulation area percentage in study group (97.5%) than control group (93.4%). Abdullah et al. [6] shows similar comparable results with mean reduction of ulcer of 20.4 cm^2 in study group as

compared to 9.5 cm^2 in control group ($p < 0.05$). Raveri et al. [7] also have shown 10.7cm^2 reduction in ulcer area in study group over controls while for granulation formation 70% study group and 50% control group data was recorded. Tauro et al. [8] have 71.43 % ulcer granulation in study group and 52.85 % in control group. The graft uptake does not show any significant difference, but is better for study group than controls.

Wound swab and culture reports – The above study had significant difference (p-value – 0.01) in study (14%- positive) and controls (100% positive) culture. Deva Boone et al,[9] study could do not isolate any of positivity wound culture reports. None of other studies shows any comparison in terms of wound swab and culture reports.

Mean rate of granulation and Graft Uptake–The study showed higher rate of granulation in study group of 0.76 cm^2 /day while control group show lower rate of 0.50 cm^2/day. The Tauro et al. [8] showed rate of granulation in study group of 71.43% of ulcer area while 52.85% of ulcer area in control group over duration of 10 days. Peter blume et al,[5] showed 95% granulation in study group but the control group data is not available. Abdullah et al,[6] had 1.81 cm2/ day in study group while 0.60 cm2/ day in control group. Similarly, Joseph et al,[10] also showed better rate of granulation in study group than control group.

Still the rate of granulation tissue formation (though dependent on the size of the ulcer, nutrition of the patient, local limb factors) was significantly faster in the present vacuum study group than control group. There is also significant difference in graft uptake at tissue level. Above conducted study shows highest graft uptake than rest of the studies. As the dressings were continued till wound granulation was > 90 percent. This resulted in better graft uptake. Other studies showed graft uptake from 28.9 % to 85.3 % but none was > 90%.

CONCLUSION

From the above study it can be concluded that the application of Topical Negative Pressure using homemade vacuum assisted closure increased the rate of formation of granulation tissue and had better graft uptake than the patients who underwent a conventional dressing using moist gauze 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 using homemade vacuum assisted closure 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 for other benefits and limitations before topical negative pressure dressing can be added to the wide spectrum of treatment modalities available in the management of diabetic foot. Commercially available VAC devices do add cost to diabetic foot care so HVAC are better option at hospital settings.

REFERENCES

1. Seed, David L., 1998: ―Foundations of good ulcer carel. Am J of surg, (Suppl) 176: No.2A, 20S-25Spp.
2. Reducing Diabetic Foot Problems and Limb Amputation: An Experience from India, Sharad Pendsey, Global perspective of diabetic foot ulcerations.
3. WHO (1998), Prevention and control of diabetes mellitus, report of an intercountry workshop, Dhaka Bangladesh 27-30 April 1998, SEA/NCD/40.
4. Boulton, A. J., Vileikyte, L., Ragnarson- Tennvall, G., et al. The global burden of diabetic foot disease. Lancet 366: 1719, 2005.
5. Peter A. Blume, DPM1, Jodi Walters, DPM2, Wyatt Payne, MD3, Jose Ayala, DPM4, John Lantis, MD5 Comparison of Negative Pressure Wound Therapy Using Vacuum-assisted Closure with Advanced Moist Wound Therapy in the Treatment of Diabetic Foot Ulcers, A multicenter randomized controlled trial.
6. Abdullah Etoz, MD; Ramazan Kahveci, MD, Negative Pressure Wound Therapy on Diabetic Foot Ulcers Posted: 11/08/2007; Wounds. 2007;19(9):250-254.
7. Hassan Ravari, Mohammad-Hadi Saeed Modaghegh, Gholam Hosein Kazemzadeh, Hamed Ghoddusi Johari,1 Attieh Mohammadzadeh Vatanchi, Abolghasem Sangaki, and Mohammad Vahedian Shahrodi
8. Comparison of vacuum assisted closure and Moist wound dressing in the treatment of Diabetic foot ulcers, Journal of cutaneous Aesthetic Surgery, 2013 Jan- Mar; 17-20,
9. Leo francis Tauro, J Ravikrishnan, S satish rao, H Divakar shenoy, SR Shetty, Leo T Menezes, Indian Journal of Plastic surgery, A comparative study of the efficacy of topical negative pressure moist dressings and conventional moist dressing in chronic wounds., Year:2007, Vol-40, Issue-2, Page: 133-140.
10. Deva Boone, MD, Elissa Braitman, MD, Cynthia Genetics, RN, John Afthinos, D, Jawad Latif, MD, Emilia Sordillo, MD, PhD, George Todd, MD, John C. Lantis II, MD
11. 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.