

COMPARISON OF LOW-COST CUSTOM MADE VACUUM THERAPY WITH CONVENTIONAL DRESSING METHODS IN THE MANAGEMENT OF DIABETIC FOOT ULCERS -A RANDOMIZED CONTROLLED TRIAL

S Prabhakaran¹, C Sivagovindan¹, K Gopinath¹, Vignesh RM¹, Soundarya S²

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Corresponding Author:

Dr. S.Prabhakaran,

Email: prabhamedsparkz@gmail.com

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¹Assistant Professor, Department of General Surgery, Ariyalur Government Medical College, Tamilnadu, India

²Postgraduate, Department of General Surgery, Dhanalakshmi Srinivasan Medical College and Hospital, Tamilnadu, India

ABSTRACT

Background: Diabetic foot ulcers (DFUs) are common diabetes complications causing slow healing, infections, and high healthcare costs. Vacuum-assisted closure (VAC) therapy can improve healing, but it is often expensive and less accessible. This study compared low-cost VAC therapy with conventional dressings, evaluating wound healing, ulcer size, granulation, pain, and patient outcomes. **Materials and Methods:** A randomised controlled trial involving 106 patients with grade 1–2 DFU at Tirunelveli Medical College compared VAC therapy (n=53) with conventional dressing (n=53), recording wound healing, pain, visual scores, granulation, body mass index, HbA1c, and comorbidities. VAC used 140 mmHg intermittent negative pressure with 48-hour dressing changes, and conventional dressings were changed daily. **Result:** Among 106 patients, most were aged 50–59 years (38, 35.8%). Grade 1 ulcers were more frequent in the VAC group (16, 15.1%) versus conventional dressing (2, 1.9%), while grade 2 ulcers were higher in the conventional group (51, 48.1% vs. 37, 34.9%; $p=0.00029$). Mean ulcer size was smaller with VAC ($63.42 \pm 44.55 \text{ cm}^2$) than with conventional dressing ($77.95 \pm 70.14 \text{ cm}^2$; $p=0.206$). HbA1c was significantly lower in the VAC group (49.90 ± 10.50 vs. 72.72 ± 5.98 ; $p<0.0001$). VAC showed superior pain reduction (VAS week-5: 0.26 ± 0.52 vs. 1.31 ± 1.17 ; $p<0.0001$), lower visual scores (0.98 ± 1.74 vs. 2.15 ± 1.80 ; $p=0.0009$), and greater granulation (2.74 ± 1.46 vs. 2.07 ± 1.40 ; $p=0.018$). Major traumas were fewer with VAC (1.66 ± 1.02 vs. 2.40 ± 1.47 ; $p=0.0034$), while minor trauma rates were similar. **Conclusion:** Low-cost VAC therapy is more effective than conventional dressing for DFUs, promoting faster healing, pain reduction, and improved granulation, particularly in patients with fewer comorbidities.

INTRODUCTION

Diabetic foot ulcers (DFUs) affect 15–25% of people with diabetes, primarily due to neuropathy, vascular disease, and immune dysfunction. They are associated with infections, amputations, hospitalisations, and reduced quality of life, imposing significant clinical and economic burdens. Globally, diabetes prevalence is rising, with type 2 diabetes representing the majority of cases.^[1] Hospital stays for DFUs range from 13–60 days, depending on severity, and many patients require multiple admissions. Treatment costs increase with complications, highlighting the substantial impact of

DFUs on healthcare systems and patient quality of life.^[2]

Wound dressings play a key role in protecting and promoting healing by maintaining moisture, absorbing exudate, and preventing infection. Types include traditional gauze, modern foams, films, hydrogels, hydrocolloids, alginates, bioactive dressings, skin substitutes, medicated, and composite dressings, selected according to wound type, exudate level, and healing needs.^[3] Dressings protect against contamination, manage exudate, and maintain a moist environment to facilitate cell migration and tissue repair. However, some require frequent changes, can be painful during removal, may be costly, and show limited effectiveness in heavily

exudating or complex wounds, particularly in resource-limited settings.^[4]

Negative Pressure Wound Therapy (NPWT) enhances healing by reducing wound swelling, removing exudate and debris, stimulating granulation tissue formation, improving blood flow, and decreasing bacterial load, thereby creating an optimal environment for tissue repair and accelerating recovery in complex or chronic wounds.^[5] NPWT has been shown to reduce wound closure time and increase closure rates compared to conventional dressings. However, it may cause more wound-related adverse events and requires specialised equipment, limiting accessibility in resource-constrained settings.^[6]

Custom-made NPWT devices have been reported to be 22 times less expensive than commercial systems, with similar outcomes in graft success, hospital stay, and complication rates, demonstrating cost-efficient wound management.^[7] Simplified NPWT devices using a hand pump, occlusive drape, and tubing were effective in field tests in Haiti, improving access to wound care in low- and middle-income countries, reducing healthcare burdens, and preventing severe DFU complications.^[8] Low-cost custom-made vacuum-assisted closure (VAC) systems are more effective and cost-efficient than conventional dressings for chronic ulcers, reducing hospital stay and dressing changes. Further high-quality studies are needed to confirm long-term outcomes, patient satisfaction, and clinical effectiveness.^[9,10]

This study aimed to evaluate the efficacy of traditional dressing techniques and low-cost custom-made vacuum therapy in managing non-healing DFUs. Outcomes assessed included wound healing rates, infection incidence, treatment costs, and patient satisfaction to improve care and reduce severe complications.

MATERIALS AND METHODS

This randomised controlled study with 106 participants was conducted in the Department of General Surgery, Tirunelveli Medical College, over 18 months, between August 2022 and February 2024. Approval was obtained from the Institutional Ethics Committee (IEC), and written informed consent was obtained from all participants.

Sample size calculation: The sample size was determined using OpenEpi software based on previous studies, with a 95% confidence interval and 80% power. An equal allocation ratio of 1:1 was applied, resulting in 53 participants in each group and a total sample size of 106.¹¹

Inclusion and exclusion criteria

The study included patients with diabetes aged > 18 years with grade 1 or 2 diabetic foot ulcers. Patients with coagulopathy, venous disease, peripheral vascular disease, osteomyelitis, Charcot's joint, or Wagner-Meggitt grade III–V ulcers were excluded.

Methods: The patients were randomised into two groups: vacuum therapy (n = 53) and conventional dressing (n = 53). The data collected included age, sex, diagnosis, comorbidities such as hypertension, type 2 diabetes mellitus, coronary artery disease (CAD), chronic kidney disease, epilepsy, bronchial asthma, and peripheral vascular disease, along with laboratory values including haemoglobin, HbA1c, albumin, and pus culture with sensitivity. Wagner grade (1 or 2) and wound assessment using a photographic wound assessment tool were also recorded. In the vacuum therapy group, wounds were cleaned and filled with saline-soaked gauze, followed by placement of sterile sponge layers with a suction tube, and sealed with a polyurethane sponge and sterile adhesive film. Negative pressure was applied intermittently at 140 mmHg using a wall-mounted or portable suction device, and the dressing was changed every 48 h. Irrigation with diluted betadine saline followed by normal saline was performed once or twice daily, depending on the wound exudate. In the control group, conventional dressing involved saline-soaked gauze secured with sterile gauze and roller bandages, changed daily with wound assessment every 48 hours. Granulation tissue was assessed using a visual score: 1 for none, 2 for <25% coverage, 3 for 25–74%, and 4 for 75–100% coverage.

Statistical analysis: Data were analysed using IBM SPSS Statistics v27. Continuous variables are expressed as mean $\pm$ standard deviation, and categorical variables are presented as frequencies and percentages. Comparisons between the vacuum therapy and conventional dressing groups were performed using suitable statistical tests, with a p-value of ≤ 0.05 considered statistically significant.

RESULTS

Most patients were aged 50–59 years, with more in the conventional dressing group (25, 23.58%) than in the vacuum therapy group (13, 12.26%). A significant difference was found in treatment patterns, with insulin use being higher in the vacuum therapy group (16, 15.09% vs. 5, 4.72%) and oral hypoglycaemic drug use being more common in the conventional group (48, 45.28% vs. 37, 34.91%; $p=0.007$) [Table 1].

In the conventional dressing group, CAD (5, 4.72%) and combined hypertension with CAD (6, 5.66%) were observed, whereas none were reported in the vacuum therapy group, showing a significant difference ($p=0.0069$). Regarding Wagner grading, grade 1 ulcers were more frequent in the vacuum therapy group (16, 15.09%) than in the conventional dressing group (2, 1.89%), whereas grade 2 ulcers were more common in the conventional dressing group (51, 48.11%) than in the vacuum therapy group (37, 34.91%), with a highly significant difference ($p=0.00029$) [Table 2].

Table 1: Baseline demographic and clinical characteristics of patients between groups

Variable	Category	Vacuum Therapy (n=53)	Conventional Dressing (n=53)	p-value
Age Group (years)	<30	0 (0.00%)	1 (0.94%)	-
	30–39	4 (3.77%)	3 (2.83%)	
	40–49	16 (15.09%)	12 (11.32%)	
	50–59	13 (12.26%)	25 (23.58%)	
	60–70	15 (14.15%)	12 (11.32%)	
	>70	5 (4.72%)	0 (0.00%)	
Gender	Male	39 (36.79%)	79 (74.53%)	-
	Female	14 (13.21%)	27 (25.47%)	
Duration of Diabetes (years)	0–5	16 (15.09%)	32 (30.19%)	-
	5–10	24 (22.64%)	43 (40.57%)	
	10–15	12 (11.32%)	21 (19.81%)	
	15–20	1 (0.94%)	7 (6.60%)	
	>30	0 (0.00%)	3 (2.83%)	
Treatment for Diabetes	Insulin	5 (4.72%)	21 (19.81%)	0.007
	Oral hypoglycaemic drugs	48 (45.28%)	85 (80.19%)	

Table 2: Comparison of comorbidities and Wagner grade of DFU between groups

Variable		Vacuum Therapy (n=53)	Conventional Dressing (n=53)	p-value
Comorbidities	Bronchial Asthma	0	1 (0.94%)	0.0069
	CAD	0	5 (4.72%)	
	Hypertension	8 (7.55%)	4 (3.77%)	
	Hypertension + CAD	0	6 (5.66%)	
	None	45 (42.45%)	37 (34.91%)	
Wagner grade of DFU	Grade 1	16(15.09%)	2(1.89%)	0.00029
	Grade 2	37(34.91%)	51(48.11%)	

Underweight patients were observed only in the vacuum therapy group (7, 13%) vs none in the conventional group, while obesity was seen only in the conventional group (4, 8%) vs none. The mean ulcer area was smaller with vacuum therapy (63.42 ±

44.55 cm²) than with conventional dressing (77.95 ± 70.14 cm²; p=0.206). A detailed HbA1c analysis showed significantly higher values in the conventional group (72.72 ± 5.98) than in the vacuum therapy group (49.90 ± 10.50; p<0.0001) [Table 3].

Table 3: Comparison of ulcer characteristics, BMI, and biochemical parameters between groups

Variable		Vacuum therapy	Conventional dressing	p-value
DFU Size	<10 cm ²	32 (30.19%)	33 (31.13%)	0.841
	≥10 cm ²	21 (19.81%)	20 (18.87%)	
BMI	Underweight	7 (13%)	0 (0%)	-
	Normal	23 (43%)	33 (62%)	
	Overweight	23 (43%)	16 (30%)	
	Obese	0 (0%)	4 (8%)	
DFU Area (cm ²)		63.42 ± 44.55	77.95 ± 70.14	0.206
BMI (kg/m ²)		23.05 ± 3.79	23.86 ± 3.47	-
Haemoglobin (g/dL)		10.26 ± 1.83	10.28 ± 1.55	0.955
Albumin (g/dL)		2.72 ± 0.26	2.73 ± 0.23	0.751
HbA1c (%)		8.91 ± 1.81	8.59 ± 1.37	0.3
Detailed HbA1c analysis		49.90 ± 10.50	72.72 ± 5.98	<0.0001

Wounds of shorter duration (<15 days) were observed only in the vacuum therapy group (8, 7.55%), but none in the conventional dressing group. Pain reduction assessed by VAS scores showed significantly lower values in the vacuum therapy group from week 3 onwards (2.30 ± 1.44 vs. 4.08 ± 1.43, p<0.0001), with continued advantage at weeks 4 (0.65 ± 0.98 vs. 2.30 ± 1.32, p<0.0001) and 5 (0.26 ± 0.52 vs. 1.31 ± 1.17, p<0.0001). Visual scores also

favoured vacuum therapy, with lower scores at week 4 (1.45 ± 1.84 vs. 3.00 ± 1.27, p<0.0001) and week 5 (0.98 ± 1.74 vs. 2.15 ± 1.80, p=0.0009). Furthermore, the rate of granulation tissue formation was significantly higher in the vacuum therapy group (2.74 ± 1.46 vs. 2.07 ± 1.40, p=0.018). No significant differences were observed in bleeding episodes between the groups [Table 4].

Table 4: Comparison of wound duration, pain scores, visual scores, bleeding episodes, and granulation tissue formation between groups

Variable	Category	Vacuum Therapy	Conventional Dressing	p-value
Time of wound (days)	<15	8 (7.55%)	0 (0.00%)	-
	15–24	26 (24.53%)	10 (9.43%)	-
	25–34	19 (17.92%)	23 (21.70%)	-
	35–44	0 (0.00%)	12 (11.32%)	-
	45–54	0 (0.00%)	6 (5.66%)	-

	>55	0 (0.00%)	2 (1.89%)	-
VAS scores (week)	1	8.17 ± 0.51	8.45 ± 0.75	0.0257
	2	5.46 ± 0.97	5.90 ± 1.01	0.0255
	3	2.30 ± 1.44	4.08 ± 1.43	<0.0001
	4	0.65 ± 0.98	2.30 ± 1.32	<0.0001
	5	0.26 ± 0.52	1.31 ± 1.17	<0.0001
	6	0	0.47 ± 0.70	-
	7	0	0.23 ± 0.51	-
	8	0	0.09 ± 0.30	-
Bleeding episodes (week)	1	0.70 ± 0.80	0.85 ± 0.86	0.3524
	2	0.11 ± 0.38	0.13 ± 0.34	0.7872
	3	0.06 ± 0.23	0.09 ± 0.30	0.4669
	≥4	0	0.06 ± 0.23	-
Visual score (week)	1	2.06 ± 0.23	2.00 ± 0.00	-
	2	3.17 ± 0.51	2.68 ± 0.47	<0.0001
	3	3.06 ± 1.38	3.19 ± 0.52	0.5156
	4	1.45 ± 1.84	3.00 ± 1.27	<0.0001
	5	0.98 ± 1.74	2.15 ± 1.80	0.0009
	6	0	1.49 ± 1.88	-
	7	0	0.91 ± 1.69	-
	8	0	0.38 ± 1.18	-
Rate of granulation tissue formation		2.74 ± 1.46	2.07 ± 1.40	0.018

The number of major traumas was significantly lower in the vacuum therapy group (1.66 ± 1.02) than in the conventional dressing group (2.40 ± 1.47 , $p=0.0034$). The number of minor traumas showed no significant

difference between vacuum therapy (0.11 ± 0.32) and conventional dressing (0.26 ± 0.74 , $p=0.1747$) [Table 5].

Table 5: Comparison of major and minor trauma between groups

Variable	Vacuum therapy (n=53)	Conventional dressing (n=53)	p-value
Number of major traumas	1.66 ± 1.02	2.40 ± 1.47	0.0034
Number of minor traumas	0.11 ± 0.32	0.26 ± 0.74	0.1747

DISCUSSION

DFUs are a common complication of diabetes, leading to prolonged wound healing, infection, and an increased healthcare burden. This study compared VAC therapy with conventional dressing in managing DFUs, focusing on wound healing, ulcer size, granulation, pain reduction, and overall outcome. Most patients in our study were aged 50–59 years, with a higher proportion in the conventional group. Similarly, Shah et al. reported that 80.83% of participants were aged 41–60 years, with mean ages of 47.56 ± 8.98 years in the NPWT group and 48.80 ± 7.73 years in the conventional group.^[12] This indicates that middle-aged patients represent the majority of DFU cases, suggesting that early intervention in this age group may improve outcomes and reduce complications.

In our study, CAD and combined hypertension were observed only in the conventional group, while VAC therapy had more grade 1 ulcers, and conventional dressing had more grade 2 ulcers. Similarly, Arvind et al. reported that most patients had no comorbidities (VAC: 22, 81.5%; conventional: 20, 74.1%; $p = 0.067$), with hypertension in 9 (18%) VAC versus 2 (4%) conventional, CAD in 0 versus 4 (8%), both hypertension and CAD in 0 versus 3 (6%), and bronchial asthma in 0 versus 2 (4%).^[13]

Regarding ulcer severity, James et al. found grade 1 ulcers to be more frequent in the VAC group (29.63%) than in the conventional group (7.41%; $p =$

0.036), while grade 2 ulcers predominated in the conventional (92.59%) versus VAC (70.37%) groups.^[14] Suman et al. reported significantly shorter healing times with VAC, averaging 19.42 ± 1.78 vs 24.8 ± 1.98 days for grade 2 ulcers ($p = 0.0034$) and 22.44 ± 0.88 vs 27.33 ± 1.77 days for grade 3 ulcers ($p = 0.0013$), with overall differences remaining significant ($p = 0.026$ for VAC and 0.0174 for conventional).^[15] These findings suggest that VAC therapy is linked to less severe ulcers and faster healing, recommending early use for patients with lower comorbidity risk.

Our study also observed underweight patients only in the VAC group, whereas obesity occurred only in the conventional group. The conventional group had higher HbA1c levels, and the ulcer size was slightly smaller in the VAC group. Similarly, Tsang et al. reported that the HbA1c (%) was 8.4 ± 2.9 in the NPWT group and 7.9 ± 2.2 in the control group ($p = 0.32$).^[16] Dharaneesh et al. reported a BMI of 26.1 ± 3.4 in the VAC group and 25.7 ± 3.2 in the conventional group ($p = 0.58$).^[17] James et al. found large ulcers (≥ 10 cm) in 40.74% of patients in the VAC group and 37.04% in the conventional group, smaller ulcers in 59.26% and 62.96% of patients, respectively, and mean ulcer areas of 70.97 cm^2 and 80.44 cm^2 , respectively ($p = 0.780$ and 0.5675).^[14] Adel et al. reported baseline wound sizes comparable between groups (15.3 ± 3.2 vs. $13.4 \pm 3.7 \text{ cm}^2$).^[18] This shows that VAC therapy benefits underweight patients and slightly smaller ulcers, highlighting the

importance of monitoring BMI and glycaemic control to optimise outcomes.

In our study, short-duration ulcers occurred only in the VAC group, which also showed greater pain reduction, lower visual scores, and higher granulation rates than the control group. Similarly, Mooghal et al. found mean healing times significantly shorter with VAC (12.1 ± 2.2 days) versus conventional dressing (17.5 ± 3.2 days; $p = 0.0001$).^[19] Tekin et al. reported a 42.7% ulcer size reduction at three weeks with VAC.^[20] Dharaneesh et al. observed significantly lower pain scores (VAS) at 24 and 48 hours in VAC ($p < 0.05$), while Kumar et al. noted lower pain in the first week ($p = 0.0001$) and fewer dressing changes ($p = 0.0001$), with continued non-significant reduction ($p = 0.082$).^[17,21] Dsouza et al. reported 76.7% VAC ulcers had red granulation tissue vs 46.7% in conventional, with shorter wound bed preparation time (8.5 vs 15.6 days; $p < 0.05$), and Lone et al. found 77.8% VAC patients achieved complete granulation by week 5 vs 40% in conventional.^[22,23] These results show VAC accelerates healing, reduces pain, and promotes granulation, supporting early use for effective DFU recovery.

Our study found that VAC therapy was associated with fewer major traumas, whereas minor traumas were similar. Herscovici et al. reported that advanced wound care reduces trauma-related complications, highlighting the role of VAC therapy in safer DFU management.^[24] The present study showed that VAC therapy improves healing time, reduces ulcer severity, decreases pain, and enhances granulation. Early application, especially in patients with fewer comorbidities and lower BMI, can optimise outcomes, minimise complications, and support faster recovery.

Limitations: The study had a relatively small sample size and short follow-up period, limiting the assessment of long-term outcomes. Variations in patient adherence and clinician techniques may have also influenced the results. Although a low-cost custom-made VAC system was used, a formal cost analysis against commercial devices was not performed to assess its economic benefits and wider applicability.

CONCLUSION

Vacuum-assisted closure therapy is more effective than conventional dressing in managing diabetic foot ulcers. VAC therapy resulted in faster wound healing, greater reduction in ulcer size, improved granulation tissue formation, and significant pain relief compared to conventional therapy. Patients with shorter-duration ulcers and lower BMI particularly benefited from this approach. Additionally, VAC therapy was associated with fewer major traumas, suggesting safer wound management methods. This low-cost, custom-made design provides an affordable and accessible alternative to commercial VAC systems

and is suitable for resource-limited settings. Overall, these findings support the early use of VAC therapy, especially in patients with fewer comorbidities, to enhance recovery, minimise complications, and provide a cost-effective alternative for diabetic foot ulcer care.

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