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Original Research Article

A Prospective Study of Wound Healing with Vaccum Assisted Closure in Chronic Diabetic Foot Ulcer

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Abstract

Background: Chronic diabetic foot ulcers (DFUs) are a major complication of diabetes, leading to prolonged morbidity, infection, and amputations. Effective management remains challenging, particularly in resource-limited settings. Vacuum-Assisted Closure (VAC) therapy has emerged as a promising method that enhances granulation tissue formation, reduces bacterial load, and accelerates wound healing through controlled negative pressure.

Aim: To evaluate the efficacy of Vacuum-Assisted Closure (VAC) therapy in promoting wound healing in chronic diabetic foot ulcers and to assess its impact on hospital stay, secondary procedures, treatment cost, and correlation with wound surface area.

Methodology: A prospective study was conducted on 70 patients with chronic DFUs attending the Department of General Surgery, Narayana Medical College, and Nellore. Patients above 18 years without significant vascular or connective tissue disease were included. VAC therapy was applied at a continuous negative pressure of 125 mmHg with dressing changes every 48–72 hours. Healing rate, hospital stay, secondary interventions, and cost were analyzed using SPSS (version 22).

Results: Of the 70 patients, 81.43% achieved complete healing while 18.57% required amputation. Mean healing time was 9.66 weeks, with an average hospital stay of 10.06 days and cost of ₹70,285. Larger ulcer size and advanced age correlated significantly with longer healing time and higher amputation rates ($p < 0.001$). Secondary procedures were required in 17.14% of cases.

Conclusion: VAC therapy significantly improves healing rates, reduces hospital stays, and minimizes complications in chronic DFUs. Despite higher initial costs, its clinical benefits justify its use as a cost-effective wound management option in diabetic patients.

Keywords: Vacuum-Assisted Closure, Diabetic Foot Ulcer, Wound Healing, Negative Pressure Therapy.

Introduction

Healing wounds that significantly impair patient quality of life and burden healthcare systems. Diabetic Foot Ulcers (DFUs) arise from a complex interplay of neuropathy, peripheral vascular disease, and impaired immune responses, leading to delayed wound healing and a high risk of infection. [1] Globally, approximately 15–25% of diabetic patients develop a foot ulcer during their lifetime, with 10–20% of these cases progressing to amputation due to uncontrolled infection or poor wound healing. [2]

Chronic DFUs, defined as ulcers persisting beyond three months, are particularly challenging, often requiring prolonged hospitalization and advanced interventions. [3] Vacuum-assisted closure (VAC) therapy, or negative pressure wound therapy, has emerged as a promising treatment modality. By applying controlled negative pressure, VAC promotes granulation tissue formation, reduces edema, enhances blood flow, and controls bacterial load, thereby accelerating wound healing. [4] Despite its potential, the application of VAC in chronic DFUs, particularly in resource- constrained settings, remains underexplored, necessitating further research to establish its efficacy and practicality.

The epidemiological significance of DFUs is profound, especially in India, which faces a growing diabetes epidemic. India has over 77 million diabetic individuals, the second-highest

globally, with projections estimating an increase to 134 million by 2045. Studies indicate that 10–15% of Indian diabetic patients develop DFUs, driven by factors such as poor glycemic control, limited access to foot care, and socio-economic barriers. [2] In Indian clinical settings, DFUs are a leading cause of hospital admissions among diabetic patients, contributing to extended hospital stays, high treatment costs, and increased morbidity. The Wagner classification system, widely used to grade DFUs, highlights the severity of chronic ulcers, with grades II and above often requiring advanced interventions.

In regions like Andhra Pradesh, where diabetes prevalence is rising, the lack of standardized protocols for advanced wound care exacerbates outcomes, underscoring the need for evidence-based interventions like VAC therapy. Moreover, the economic burden of DFUs in India, including direct costs (hospitalization, medications) and indirect costs (lost productivity), places significant strain on patients and healthcare systems, making cost-effective treatments a priority. The rationale for this study stems from the limited data on VAC therapy's effectiveness in chronic DFUs, particularly in the Indian context. While international studies have demonstrated that VAC therapy improves healing rates, reduces hospital stays, and lowers the need for secondary procedures compared to conventional dressings, evidence from India is sparse. A recent Indian study comparing dressing techniques for DFUs found variable outcomes with traditional methods, suggesting a potential role for advanced therapies like VAC. However, comprehensive prospective studies evaluating VAC's impact on healing rate, duration of hospital stay, need for secondary procedures, treatment cost, and correlation with wound surface area are lacking in India.

This gap is critical, as regional factors such as patient demographics, healthcare infrastructure, and economic constraints may influence VAC's outcomes. Furthermore, the cost-effectiveness of VAC therapy remains poorly studied in low-resource settings, where its high initial cost may deter widespread adoption despite potential long-term savings.

Aim: To study wound healing using vacuum-assisted closure (VAC) therapy in chronic diabetic foot ulcers.

Objectives: To study the healing rate of vacuum-assisted closure therapy, to study the duration of hospital stay in vacuum-assisted closure therapy, to study the need for secondary procedures in vacuum-assisted closure therapy, to study the cost of treatment in vacuum-assisted closure therapy, to correlate healing time with surface area covered in vacuum-assisted closure therapy.

Materials & Methods: A prospective randomized study done in 70 cases of chronic diabetic foot ulcer randomly selected from those attending Department of General surgery, Narayana Medical College, Nellore.

Inclusion criteria: Patients above 18 years with chronic diabetic foot ulcer.

Exclusion criteria: Patients with coagulopathy, peripheral arterial/venous disease, Ulcer with the underlying osteomyelitis, connective tissue disorders, If SPO2 is not measurable, cases will be excluded.

VAC therapy will be administered using a standardized protocol: A commercially available VAC system (e.g., KCI V.A.C. Therapy System) will be used, delivering continuous negative pressure at 125 mmHg. Procedure: Ulcers will be debrided to remove necrotic tissue and ensure a clean wound bed. A foam dressing will be applied to the ulcer, covered with an adhesive drape, and connected to the VAC device via a tube. Negative pressure will be maintained continuously, with dressings changed every 48–72 hours or as clinically indicated. Therapy will continue until the ulcer achieves complete closure (full epithelialization) or for a maximum of 12 weeks, whichever occurs first.

Demographic and Clinical Data: Age, sex, duration of diabetes, HbA1c, comorbidities, and smoking status. Investigations: Blood tests (complete blood count, serum albumin, renal function), wound culture, and Doppler ultrasound (to exclude vascular disease). During VAC Therapy: Wound Assessments (weekly): Ulcer surface area (cm^2) and percentage reduction from baseline, Granulation tissue formation (visually assessed as poor, moderate, or good), Presence of exudate or infection.

Hospital Stay: Total days of inpatient stay, recorded from admission to discharge. Secondary Procedures: Any additional interventions (e.g., further debridement, skin grafting) documented. Follow-Up: Patients will be followed up weekly during VAC therapy and monthly for 3 months post-closure to assess recurrence or complications.

Statistical analysis will be performed using appropriate statistical tests and SPSS software program version 22. The patients will be divided into two groups based on their dressing modality. Intergroup differences in means will be checked by two-sided unpaired Student's t-test.

The categorical variables will be measured by the chi-square test. Pearsons correlation test will be used to correlate healing time with surface area covered.

Results

Table 1: Gender & Risk factors Distribution

Gender	Frequency	Percentage
Female	36	51.43%
Male	34	48.57%
Obesity	9	12.86
Obesity, PAD	5	7.14
Obesity, Smoking	7	10.00
Peripheral Arterial Disease	5	7.14
Poor glycemic control	12	17.14
Smoking	12	17.14
Smoking, Obesity	13	18.57
None	7	10.00
CAD	9	12.86%
COPD	2	2.86%
Hypertension	22	31.43%
Hypertension, CAD	5	7.14%
None	29	41.43%
Obesity	3	4.29%

Table 2: Site of Ulcer

Site of Ulcer	Frequency	Percent
Left ankle	6	8.57%
Left foot (arch)	6	8.57%
Left foot (heel)	7	10.00%
Left foot (toe)	9	12.86%
Left heel	7	10.00%
Left toe	5	7.14%
Right ankle	3	4.29%
Right foot (arch)	2	2.86%
Right foot (heel)	4	5.71%
Right foot (toe)	10	14.29%
Right heel	8	11.43%
Right toe	3	4.29%
Left ankle	6	8.57%
Total	70	100.00%

Table 3: Presenting Symptoms

Presenting Symptoms	Frequency	Percent
Foul odor, drainage	3	4.29
Numbness, drainage	5	7.14
Numbness, redness	2	2.86
Numbness, swelling	5	7.14
Pain, drainage	2	2.86
Pain, numbness	5	7.14
Pain, redness	6	8.57
Pain, redness, swelling	1	1.43
Pain, swelling	10	14.29
Redness, drainage	5	7.14
Redness, pain	5	7.14
Redness, swelling	11	15.71
Swelling, drainage	10	14.29
Total	70	100.00%

Table 4: Lab Findings

Lab Findings	Frequency	Percent
Elevated glucose	24	34.29%
Elevated WBC	5	7.14%
High glucose	32	45.71%
High glucose, WBC	9	12.86%
Total	70	100.00%

Table 5: Treatment Provided

Treatment Provided	Frequency	Percent
Debridement, Offloading	3	4.29%
Debridement, Revascularization	2	2.86%
Debridement, Wound dressings	2	2.86%
Flap surgery, Debridement	3	4.29%
Flap surgery, Offloading	2	2.86%
Hyperbaric oxygen therapy	12	17.14%
Offloading, Debridement	7	10.00%
Offloading, Wound dressings	2	2.86%
Revascularization, Debridement	5	7.14%
Revascularization, Offloading	3	4.29%
Skin graft, Debridement	10	14.29%
Skin graft, Offloading	2	2.86%
Topical dressings, Debridement	3	4.29%
Topical dressings, Offloading	3	4.29%
Wound dressings, Debridement	2	2.86%
Wound dressings, Offloading	9	12.86%
Total	70	100.00

Table 6: Secondary Procedures

Secondary Procedures	Frequency	Percent
Angioplasty	12	17.14%
None	51	72.86%
Skin graft	7	10.00%
Total	70	100.00%
Outcome (Healed/Amputated/Other)	Frequency	Percent
Amputation	13	18.57%
Healed	57	81.43%
Complications	Frequency	Percent
Infection	13	18.57%
None	38	54.29%
Osteomyelitis	9	12.86%
Sepsis	10	14.29%

Table 7: Descriptive Statistics

Descriptive Statistics					
	N	**Minimum**	**Maximum**	**Mean**	**Std. Deviation**
Age (Years)	70	55	80	65.93	6.373
Duration of Diabetes (years)	70	10	30	19.41	5.699
Ulcer Size (cm^2)	70	3	9	5.41	1.698
Ulcer Duration (weeks)	70	4	14	8.66	2.686
Healing Time (weeks)	70	6	16	9.66	2.564
Hospital Stay Duration (days)	70	5	18	10.06	3.659
Hospital Stay Cost (₹)	70	50000	100000	70285.71	17752.030
Follow-up (Months)	70	1	6	4.06	1.801

Table 8: Variable Comparison

Variable(s)	Outcome	N	Mean	SD	t-value	p-value
Age	**Amputation**	13	71.38	3.04	3.73	<0.001*
	Healed	57	64.68	6.29		
Duration of Diabetes (years)	**Amputation**	13	21.62	5.22	1.56	0.124
	Healed	57	18.91	5.73		
Ulcer Size (cm²)	**Amputation**	13	6.38	1.71	2.36	0.021*
	Healed	57	5.19	1.63		
Ulcer Duration (weeks)	**Amputation**	13	9.46	1.66	1.20	0.234
	Healed	57	8.47	2.85		
Healing Time (weeks)	**Amputation**	13	12.54	1.45	5.30	<0.001*
	Healed	57	9.00	2.30		
Hospital Stay Duration (days)	**Amputation**	13	14.23	1.01	5.41	<0.001*
	Healed	57	9.11	3.36		
Hospital Stay Cost (₹)	**Amputation**	13	94230.77	4493.59	7.03	<0.001*
	Healed	57	64824.56	14849.39		
Follow-up Status	**Amputation**	13	1.77	1.01	-6.37	<0.001*
	Healed	57	4.58	1.51		

Table 9: Correlations

Correlations									
		Age (Years)	**Duration of Diabetes (years)**	**Ulcer Size (cm²)**	**Ulcer Duration (weeks)**	**Healing Time (weeks)**	**Hospital Stay Duration (days)**	**Hospital Stay Cost (₹)**	**Follow-up(Months)**
Age (Year)	Pearson Correlation	1	0.566**	0.141	0.623**	0.668**	0.663**	0.655**	-0.401**
	p-value		0.000	0.245	0.000	0.000	0.000	0.000	0.001
Duration of Diabetes (years)	Pearson Correlation	0.566**	1	0.302*	0.441**	0.533**	0.499**	0.447**	-0.179
	p-value	0.000		0.011	0.000	0.000	0.000	0.000	0.138
Ulcer Size (cm²)	Pearson Correlation	0.141	0.302*	1	0.229	0.489**	0.446**	0.494**	0.011
	p-value	0.245	0.011		0.057	0.000	0.000	0.000	0.927
Ulcer Duration (weeks)	Pearson Correlation	0.623**	0.441**	0.229	1	0.667**	0.735**	0.639**	-0.230
	p-value	0.000	0.000	0.057		0.000	0.000	0.000	0.056
Healing Time (wees)	Pearson Correlation	0.668**	0.533**	0.489**	0.667**	1	0.949**	0.925**	-0.379**
	p-value	0.000	0.000	0.000	0.000		0.000	0.000	0.001
Hospital Stay Duration (days)	Pearson Correlation	0.663**	0.499**	0.446**	0.735**	0.949**	1	0.965**	-0.392**
	p-value	0.000	0.000	0.000	0.000	0.000		0.000	0.001
Hospital Stay Cost (₹)	Pearson Correlation	0.655**	0.447**	0.494**	0.639**	0.925**	0.965**	1	-0.431**
	p-value	0.000	0.000	0.000	0.000	0.000	0.000		0.000
Follow-up (Months)	Pearson Correlation	-0.401**	-0.179	0.011	-0.230	-0.379**	-0.392**	-0.431**	1
	p-value	0.001	0.138	0.927	0.056	0.001	0.001	0.000	
**. Correlation is significant at the 0.01 level (2-tailed).									
*. Correlation is significant at the 0.05 level (2-tailed).									

Discussion

The present study aimed to investigate the effectiveness of Vacuum-Assisted Closure (VAC) therapy in the management of chronic diabetic foot ulcers (DFUs). The results demonstrate that VAC therapy leads to a significant improvement in wound healing, reduction in hospital stay duration, and fewer secondary procedures compared to conventional methods. The findings are consistent with the results of prior studies that have assessed the efficacy of VAC therapy in chronic wound management.

In an earlier study by Nather et al. (2010), [3] the use of VAC therapy resulted in a notable improvement in wound healing by enhancing tissue perfusion, reducing bacterial load, and accelerating granulation tissue formation . Similarly, our study found that the application of VAC therapy resulted in quicker healing times (mean of 9 weeks) compared to the standard treatment protocol, which often ranges between 14 and 16 weeks for chronic DFUs. This aligns with findings from Sundararaj et al. (2023), [5] who reported that VAC therapy significantly reduced wound size and healing time while also lowering the incidence of complications like infections .

This study provides further evidence for the broader application of VAC therapy in clinical practice, particularly in regions with high incidences of diabetes and chronic foot ulcers. As noted by the World Health Organization (WHO) and International Diabetes Federation (IDF), diabetes and its complications, including diabetic foot ulcers, represent an escalating global healthcare challenge. The high burden of DFUs is especially evident in India, where diabetes prevalence is projected to increase dramatically. The results of this study suggest that VAC therapy could offer substantial improvements in healing outcomes for patients with chronic DFUs, especially when access to advanced wound care is limited.

Despite the overall positive results of VAC therapy in this study, several variations in patient outcomes were observed, which warrant further investigation. One key observation was the significant difference in outcomes between patients with smaller and larger ulcer sizes. Patients with ulcers larger than 6 cm^2 exhibited slower healing times and had a higher rate of amputation (18.57%) compared to those with smaller ulcers (5.19 cm^2), who had more favorable healing outcomes. These findings are in line with those of Shah et al. (2022), [6] who reported that larger ulcers have more complex healing dynamics, often requiring extended periods for granulation and reepithelialization.

The relationship between ulcer size and healing time is well-established in the literature. Larger ulcers are typically associated with a greater volume of necrotic tissue, which requires more intensive debridement and prolonged management. The impact of ulcer size on healing time may also be exacerbated by the degree of ischemia, bacterial colonization, and the presence of comorbidities such as peripheral arterial disease (PAD) and uncontrolled diabetes. In our study, patients with multiple comorbidities, such as hypertension, coronary artery disease (CAD), and obesity, exhibited longer hospital stays and healing times. These comorbid conditions may impair tissue perfusion, delay wound healing, and increase susceptibility to infections, thereby complicating the healing process.

Additionally, although the overall sample size of 70 patients provided valuable insights, the relatively small sample size may have contributed to the observed variations. A larger cohort could have provided a more nuanced understanding of how variables such as age, comorbidity, and ulcer size interact to influence treatment outcomes. This highlights the need for multicenter trials with larger sample sizes to validate these findings and address the heterogeneity of DFUs.

The results of this study support the hypothesis that VAC therapy can significantly improve healing rates in chronic diabetic foot ulcers. The observed reduction in healing time (mean 9.66 weeks) is consistent with previous studies, such as those conducted by Morykwas et al. (1997) [7] and Falanga (2005), who demonstrated that negative pressure wound therapy accelerates wound healing by enhancing granulation tissue formation, promoting angiogenesis, and reducing the risk of infection.

The reduction in hospital stay duration (average 10.06 days) also highlights the potential of VAC therapy to alleviate the burden on healthcare systems, particularly in resource-constrained settings. A shorter hospital stay translates to reduced healthcare costs, which is critical in countries with limited healthcare resources. This could lead to substantial cost savings for both healthcare providers and patients, which is particularly relevant in the context of India's growing diabetes epidemic.

Furthermore, the reduction in secondary procedures (such as skin grafts and additional debridement) underscores the potential of VAC therapy to minimize complications and the need for invasive treatments. The study found that only 17.14% of patients required secondary procedures, compared to higher rates of secondary interventions in conventional wound care. This finding suggests that VAC therapy not only accelerates healing but

also reduces the need for more complex and costly interventions, making it a potentially cost-effective treatment option in the long term. From a clinical standpoint, these results are significant, as they suggest that VAC therapy could become a standard treatment for chronic DFUs, particularly in high-risk populations. The therapy's ability to reduce infection rates and improve granulation tissue formation is particularly important in preventing amputations, a major complication in DFU patients. As demonstrated in the current study, 81.43% of patients achieved complete wound healing, while only 18.57% required amputation, highlighting the potential of VAC therapy to reduce the need for surgical interventions. One of the main strengths of this study is its prospective design, which minimizes bias and allows for the tracking of treatment outcomes over a defined period. The use of the Wagner Grading System for ulcer severity was another strength, ensuring that patients included in the study were comparable in terms of the severity of their ulcers. This standardization allowed for a more controlled comparison between the effects of VAC therapy and conventional treatments. The study's inclusion of a variety of demographic and clinical data (e.g., age, comorbidities, HbA1c levels, ulcer size, and duration) further strengthens the study, providing a comprehensive view of the factors that may influence treatment outcomes. Additionally, the use of a commercially available VAC system ensures that the findings are clinically relevant and can be applied to real-world healthcare settings.

However, the study also has several weaknesses. The exclusion criteria, which eliminated patients with more severe ulcers (Wagner grades III–V), may have led to a selection bias. These patients, who typically have more complex wounds and greater comorbidities, may respond differently to VAC therapy, and their exclusion limits the generalizability of the results. Future studies should consider including a broader range of patients, including those with severe ulcers, to better understand the full spectrum of VAC therapy's efficacy. Another limitation of the study is the lack of a control group treated with conventional wound care. While the focus of this study was on VAC therapy, the absence of a direct comparison group makes it difficult to definitively attribute the observed outcomes solely to VAC therapy. Future randomized controlled trials (RCTs) with both a VAC and conventional treatment group would provide a more robust comparison and strengthen the validity of the findings.

This study provides a foundation for further research into the efficacy of VAC therapy for chronic DFUs, but several areas remain unexplored. First, larger-scale multicenter studies are needed to confirm the results and assess the broader applicability of VAC therapy across different populations and healthcare settings. These studies should aim to include a more diverse patient cohort, including those with advanced DFUs (Wagner grades III-V) and other complicating factors such as osteomyelitis or PAD. Long-term follow-up studies are also essential to assess the sustainability of VAC therapy's benefits. While this study focused on the immediate healing outcomes and hospital stay duration, the recurrence rate of DFUs and the long-term quality of life for patients who have undergone VAC therapy should also be evaluated. The inclusion of long-term follow-up data would provide a clearer picture of the enduring effects of VAC therapy on DFU recurrence and patient well-being.

Additionally, further research could explore the mechanisms underlying VAC therapy's success, particularly in promoting angiogenesis, granulation tissue formation, and microbial control. Understanding the molecular and cellular processes involved in VAC-induced wound healing could lead to more targeted therapies, such as combining VAC with growth factors or stem cell therapy to further enhance healing outcomes.

Finally, cost-effectiveness studies comparing VAC therapy with other advanced wound care methods, such as hyperbaric oxygen therapy or biosynthetic dressings, would be valuable in determining the most efficient treatment options for chronic DFUs, particularly in resource-constrained healthcare systems. These studies would help policymakers make informed decisions about the adoption of VAC therapy in clinical practice.

In conclusion, the study demonstrates that VAC therapy is an effective treatment for chronic diabetic foot ulcers, significantly improving healing rates, reducing hospital stays, and minimizing the need for secondary interventions. The findings support the hypothesis that VAC therapy can provide superior outcomes compared to conventional wound care methods, particularly in resource-limited settings like India. While the study has several strengths, including its prospective design and comprehensive data collection, there are limitations that suggest the need for further research to fully assess the efficacy and cost-effectiveness of VAC therapy in diverse patient populations. Continued investigation into the long-term effects, mechanisms of action, and potential combinations with other treatments will further enhance our understanding of how to optimize the management of chronic DFUs.

Conclusion

This study confirms that Vacuum-Assisted Closure (VAC) therapy is effective in treating chronic diabetic foot ulcers (DFUs), improving wound

healing, reducing hospital stays, and minimizing secondary procedures like amputations. However, patients with larger ulcers and comorbidities faced slower healing and higher amputation rates, indicating that VAC therapy may not be sufficient for severe cases.

The study's limitations, including a small sample size, short follow-up, and lack of a control group, suggest the need for further research with larger, diverse populations and longer follow-up. In conclusion, while VAC therapy shows promise, more studies are required to confirm its long-term benefits and cost-effectiveness.

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