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Original Research Article

A comparative analysis of vacuum assisted closure therapy and conventional dressings: outcomes in chronic diabetic foot ulcers among Indian patients

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ABSTRACT

Background: India faces a growing diabetes epidemic, with approximately 77 million individuals affected. Chronic non-healing diabetic foot ulcers (DFUs) are a common complication of diabetes and a major healthcare challenge in Conventional wound care methods often result in prolonged healing times, increasing the risk of infection, hospitalization, and amputations. Vacuum-assisted closure (VAC) therapy, a modern treatment modality, offers a potentially more effective approach to managing these ulcers.
Methods: This prospective, observational study was conducted at a tertiary care hospital in India from March 2022 to March 2024. One hundred patients with chronic non-healing DFUs were randomized into VAC therapy or conventional dressing groups. The primary outcomes included wound size reduction and healing time, while secondary outcomes involved patient satisfaction and cost-effectiveness.
Results: VAC therapy significantly reduced wound size (65.2% vs. 40.5%) and shortened healing time (6.2 vs. 10.9 weeks) compared to conventional dressings. Additionally, VAC therapy led to higher patient satisfaction and proved more cost-effective due to fewer dressing changes and shorter hospital stays.
Conclusions: VAC therapy outperforms conventional dressings in managing DFUs, offering faster healing, better patient satisfaction, and cost-effectiveness. Expanding its use in India could greatly improve diabetic foot care outcomes.

Keywords: DFUs, VAS, Wound dressings

INTRODUCTION

India, with its burgeoning population and rapid urbanization, faces an escalating diabetes epidemic. As of 2020, approximately 77 million Indians are living with diabetes, a number projected to rise substantially in the coming decades.[1] Among the myriad complications associated with diabetes, chronic non-healing DFUs stand out as a particularly severe issue. Studies suggest that up to 25% of diabetic patients in India will develop DFUs at some point in their lives, which can lead to serious outcomes such as infections, lower-limb amputations, and increased mortality.[2] DFUs are complex, multifactorial wounds that are resistant to healing due to a combination of factors including poor circulation, neuropathy, and prolonged exposure to pressure and trauma.[3]

The use of saline-moistened gauze has long been the preferred method conventionally, but maintaining a consistently moist environment with these dressings has proven difficult. Subsequently, other treatments have been proposed, including hydrocolloid wound solutions, growth factors, enzymatic debridement agents, hyperbaric oxygen therapy, and cultured skin substitutes.

However, these options are often costly and are sometimes applied without sufficient scientific evidence to validate their effectiveness.[4] The traditional management of these ulcers in India primarily involves the use of saline-moistened gauze dressings. While these dressings are widely available and relatively inexpensive, they often fail to create an optimal healing environment. This can lead to prolonged wound healing times, increased risk of infection, and greater overall healthcare costs.

Negative pressure wound therapy (NPWT) is a newer non-invasive adjunctive therapy system that uses controlled negative pressure, using VAC device, to help promote wound healing. VAC therapy is also known as vacuum dressing, vacuum sealing, vacuum pack treatment, sub atmospheric pressure treatment, or topical negative pressure therapy, works through a complex mechanism involving multiple factors. These include removing bacteria and toxins, regulating moisture, enhancing blood circulation and vascularity, and promoting the formation of granulation tissue, all of which contribute to improved wound healing. Studies show that vacuum therapy increases blood flow to the skin, reduces fluid accumulation (edema), and helps preserve damaged tissue.[5]

VAC involves placing open-cell foam on the wound, covering it with an adhesive drape, and applying controlled sub-atmospheric pressure. The dressing used in VAC therapy is made of open-cell polyether foam, constructed from medical-grade polyurethane, and approved by the FDA for treating open wounds. The foam's pore size, typically between 400 and 600 μm, is considered ideal for promoting tissue growth. The foam is custom-fitted and securely placed on the wound. A drainage tube with side openings is embedded in the foam to ensure even distribution of negative pressure across the wound bed. A protective adhesive drape is then applied over the area, extending 3-5 cm beyond the intact skin to create a complete seal.[6] VAC has shown significant efficacy in accelerating wound healing and reducing complications in various settings globally. However, its adoption in India has been limited due to perceived high costs and limited accessibility.[7]

The disparity between the conventional and advanced wound management techniques underscores the need for a comprehensive evaluation of VAC therapy within the Indian healthcare system. To address this, our study aims to provide a detailed comparison of VAC therapy and conventional dressings in the management of chronic non-healing DFUs among Indian patients. This study not only assesses clinical outcomes such as wound size reduction and time to healing but also evaluates patient satisfaction and cost-effectiveness. By providing a comparative analysis, this research seeks to inform healthcare practitioners and policymakers about the potential benefits of VAC therapy in the Indian context. The goal is to enhance wound care strategies and improve patient outcomes, particularly in a country where the burden of diabetes and associated complications is profound. The findings from this study could have significant implications for the adoption of advanced wound care technologies and the improvement of overall diabetic foot care practices in India.

METHODS

Study design

This study employed a hospital based, prospective, observational design conducted at the department of general surgery, Rama medical college hospital and research centre, Hapur, Uttar Pradesh, India over a two year period from March 2022 to March 2024. The study was designed to evaluate and compare the effectiveness of VAC therapy versus conventional dressings in the treatment of chronic non-healing DFUs among Indian patients.

Sample size

The sample size of 100 patients was determined based on the anticipated effect size of VAC therapy compared to conventional dressings, with considerations for statistical power and potential dropouts. An estimated effect size of 20% difference in wound size reduction was used to achieve a power of 80% at a significance level of 0.05.

Patient recruitment

A total of 100 patients with chronic non-healing DFUs were recruited from the hospital's wards. Participants were randomly assigned to either the VAC therapy group or the conventional dressing group using a computer-generated randomization list.

Inclusion criteria

Diagnosis of diabetes mellitus for at least one year, presence of chronic non-healing DFUs that have persisted for more than three months despite standard care and ability and willingness to provide informed consent and comply with study protocols were included.

Exclusion criteria

Wounds smaller than 2 cm in diameter, which were considered too small for the study's focus on chronic non-healing ulcers. Ulcers of non-diabetic etiology or those associated with malignancy or other systemic diseases and poor compliance to diabetic management, severe comorbid conditions, or contraindications to VAC therapy were excluded.

Intervention

VAC therapy group: Patients in this group received VAC therapy using a portable VAC system. The VAC device

was applied to the wound using a polyurethane foam dressing, connected to a vacuum pump that applied negative pressure. Dressings were changed every 3-5 days, depending on the level of wound exudate and clinical judgment.

Conventional dressing group: Patients in this group received standard wound care with saline-moistened gauze dressings, which were changed daily or as needed based on the wound condition. This approach was designed to maintain a moist wound environment but did not involve the advanced techniques of VAC therapy.

Primary outcomes

Wound size reduction: The primary measure of efficacy was the reduction in wound size, assessed weekly. Wound size was calculated using the formula for area (length × width) and measured in square centimetre (cm^2).

Time to healing: This outcome was defined as the time required for the wound to achieve complete epithelialization or be ready for surgical closure, measured in weeks from the initiation of treatment to the final assessment.

Secondary outcomes

Patient satisfaction: Patient satisfaction was evaluated using a 5-point Likert scale (1=very dissatisfied, 5=very satisfied). This measure included aspects such as comfort during dressing changes, overall satisfaction with the treatment, and perceived improvement in wound condition.

Cost-effectiveness: The total cost of treatment, including the cost of materials, number of dressing changes, duration of treatment, and associated hospital stays, was calculated. Cost-effectiveness was analyzed by comparing the overall costs between the VAC therapy and conventional dressing groups.

Data collection

Data were collected through regular clinical assessments, patient interviews, and review of medical records. Measurements of wound size were taken using a standardized protocol to ensure accuracy. Patient satisfaction was assessed using a structured questionnaire administered at the end of the treatment period.

Statistical analysis

Data were analyzed using statistical software (e.g., SPSS, version 28). Descriptive statistics were used to summarize demographic characteristics and baseline variables. Comparative analyses between the VAC therapy and conventional dressing groups were conducted using independent t-tests for continuous variables and chi-square tests for categorical variables. Statistical significance was set at a $p<0.05$. Cost-effectiveness analysis involved comparing the total costs and benefits between the two groups.

By following this methodology, the study aimed to provide a comprehensive assessment of the relative efficacy and cost-effectiveness of VAC therapy versus conventional dressings in managing chronic non-healing DFUs, specifically within the Indian healthcare context.

RESULTS

Demographic and clinical characteristics

The mean age of patients was 58.4±10.7 years. Of the 100 patients, 60% were male and 40% were female (Table 1). Mean duration of diabetes was 10.2±4.5 years. Most patients (72%) hailed from rural areas, and 50% had comorbid hypertension, while 22% had ischemic heart disease and 18% hypothyroidism (Table 2).

Table 1: Demographic characteristics of patients.

Characteristic	Value
Mean age (in years)	58.4±10.7
Gender	
Male	60%
Female	40%
Residence	
Rural	72%
Urban	28%

Table 2: Clinical characteristics and comorbidities.

Clinical characteristics	Value
Mean duration of diabetes (years)	10.2±4.5
Comorbid conditions	
Hypertension	50%
Ischemic heart disease	22%

Wound size reduction

The VAC therapy group exhibited an average wound size reduction of 65.2%±8.4% (Table 3) at the end of the study, significantly higher than 40.5%±7.9% reduction observed in the conventional dressing group ($p<0.001$).

Table 3: Reduction of wound size.

Outcome	VAC therapy	Conventional dressing	P value
Wound size reduction	65.2%± 8.4%	40.5%± 7.9%	<0.001

Time of healing

Patients in the VAC therapy group experienced significantly faster wound healing, with a mean time to

epithelialization or surgical intervention readiness of 6.2±1.8 weeks (Table 4). In contrast, the conventional dressing group required 10.9±3.4 weeks (p<0.01).

Table 4: Time of healing.

Outcome	VAC therapy	Conventional dressing	P value
Time of healing	6.2±1.8	10.9±3.4	<0.01

Patient satisfaction

Patient satisfaction was markedly higher in the VAC therapy group, where 82% of patients reported being "very satisfied" or "satisfied," compared to 58% in the conventional dressing group. Complaints of pain and discomfort during dressing changes were more frequent in the conventional group, and unpleasant odors were more often reported in the conventional group as well (Table 5).

Table 5: Patient satisfaction.

Satisfaction level	VAC therapy	Conventional dressing	P value
Very satisfied	82%	58%	<0.05
Complaints of pain/ discomfort	27%	46%	<0.01
Unpleasant odors	12%	39%	<0.01

Cost effectiveness

Although the upfront costs of VAC therapy were higher, the total treatment cost for VAC therapy was ₹75,000 compared to ₹90,000 for conventional dressings. The higher cost-effectiveness in the VAC group resulted from fewer dressing changes, reduced hospital stays, and faster healing, which lowered the overall resource burden (Table 6).

Table 6: Cost effectiveness.

Variables	VAC therapy	Conventional dressing
Average number of dressing changes	10	32
Average hospital stay (days)	14	21

DISCUSSION

This study highlights the superior efficacy of VAC therapy compared to conventional dressings in the management of chronic non-healing DFUs among Indian patients. The significant differences in wound size reduction, healing time, and patient satisfaction between the two groups demonstrate the potential of VAC therapy as a game-changer in diabetic wound care in India.

Wound healing and reduction

One of the most striking findings of this study is the substantial difference in wound size reduction between the VAC therapy group and the conventional dressing group. The VAC therapy group demonstrated an average wound size reduction of 65.2%±8.4%, compared to 40.5%±7.9% in the conventional group. This can be attributed to the mechanism of action of VAC therapy, which applies controlled negative pressure to the wound, promoting faster granulation tissue formation, reducing edema, and enhancing local blood flow.

In the Indian context, where chronic DFUs are often complicated by delays in seeking care, poor glycemic control, and limited access to advanced treatment options, the accelerated healing seen with VAC therapy is of particular importance. Traditional methods, such as saline-moistened gauze dressings, may maintain a moist wound environment, but they lack the ability to actively stimulate wound contraction and promote tissue growth. This is particularly concerning in rural areas, where the majority of the diabetic population resides, and access to specialized wound care is often limited. The ability of VAC therapy to expedite healing not only improves patient outcomes but also reduces the likelihood of infections, sepsis, and the need for amputations, which are unfortunately common in India due to late-stage presentation of DFUs.[8]

Time to healing

The significantly faster healing times observed in VAC therapy group (6.2±1.8 weeks compared to 10.9±3.4 weeks in the conventional group) further underscores the advantages of this treatment modality. In a country like India, where prolonged hospital stays and recurrent clinic visits are burdensome for both the healthcare system and patients, the ability to reduce healing time has substantial benefits. Quicker healing translates to fewer hospital admissions, shorter duration of care, and ultimately a reduction in healthcare resource utilization, which is crucial in resource-limited environment.

Faster healing also has significant implications for preventing complications. In India, patients often present with advanced ulcers, some of which are infected or ischemic. Prolonged open wounds increase the risk of systemic infections, osteomyelitis, and gangrene. By reducing the healing time, VAC therapy not only improves the prognosis of individual patients but also decreases overall disease burden associated with DFUs.[9]

Patient satisfaction and quality of life

Patient satisfaction is an essential factor in wound care, especially in chronic conditions like DFUs, where long-

term management is critical. In our study, patient satisfaction was significantly higher in the VAC therapy group (82% satisfaction) compared to the conventional dressing group (58%). This difference can be explained by the less frequent dressing changes, better control of wound exudate, reduced pain, and a noticeable reduction in unpleasant wound odor. These are the factors that are crucial in the management of chronic ulcers.

The frequency of dressing changes is a particularly relevant issue in India, where many patients face difficulties accessing healthcare facilities for regular wound care. In the conventional dressing group, daily or frequent dressing changes were required, which often led to discomfort, disruption of wound healing, and increased costs. In contrast, VAC dressings could be changed every 3-5 days, offering patients a more convenient and less painful treatment experience. This is especially advantageous for patients from rural areas, where healthcare facilities are not always easily accessible, and frequent visits to hospitals can impose a financial burden.[10]

Improved patient satisfaction with VAC therapy also suggests better long-term compliance with wound care protocols. Given that diabetic foot care requires consistent follow-up and rigorous adherence to treatment plans, a therapy that is perceived as more comfortable and less invasive is likely to improve patient compliance, ultimately leading to better outcomes.

Cost-effectiveness

Cost is a critical factor in the Indian healthcare system, where many patients pay out-of-pocket for medical expenses, and the availability of advanced treatment options like VAC therapy is limited in government hospitals and rural clinics. Although VAC therapy has a higher upfront cost due to the need for specialized equipment and materials, our study showed that the overall treatment costs were lower in the VAC group compared to the conventional dressing group.

The cost savings in the VAC group can be attributed to the shorter duration of treatment and reduced frequency of dressing changes, which led to fewer hospital visits, decreased need for surgical interventions, and lower risk of complications such as infections and amputations[6]. While the initial setup cost of VAC therapy may be prohibitive for some patients, especially in rural areas, the long-term savings make it a cost-effective option for chronic DFU management. Additionally, the availability of portable VAC systems allows patients to receive treatment at home, reducing the need for prolonged hospital stays.

In the broader context of Indian healthcare, integrating VAC therapy into public health systems, particularly in tertiary care centers, could significantly improve the management of diabetic wounds and reduce the economic burden associated with long-term wound care. Government initiatives to subsidize or support the use of VAC therapy in government hospitals could further enhance access to this technology for economically disadvantaged patients.

Challenges and limitations

While VAC therapy offers clear advantages over conventional dressings, there are challenges to its widespread adoption in India. The high upfront cost of VAC systems remains a barrier, particularly in rural areas and smaller healthcare facilities.[11] Additionally, trained personnel are required to operate VAC systems and monitor patients, which can be a limitation in under-resourced settings. Ensuring access to VAC therapy in rural and underserved regions will require investment in training and infrastructure, as well as efforts to reduce the cost of VAC devices through government subsidies or partnerships with medical device manufacturers.

Moreover, the study's limitation includes the relatively small sample size of 100 patients, which may not be fully representative of the diverse Indian population. A larger multicentric study involving multiple healthcare settings across India would provide more robust data on the efficacy and cost-effectiveness of VAC therapy in different regions and among varied socioeconomic groups.

Future directions

Given the promising results of this study, further research is warranted to explore the long-term outcomes of VAC therapy in Indian patients with DFUs, including its impact on recurrence rates, long-term quality of life, and its potential role in reducing amputations. Moreover, future studies should focus on the development of cost-effective VAC systems tailored to the Indian market, as well as strategies to integrate VAC therapy into national diabetic foot care guidelines.

This study demonstrates that VAC therapy is not only more effective than conventional dressings in treating chronic non-healing DFUs in Indian patients, but it also offers significant advantages in terms of patient satisfaction and cost-effectiveness. As the prevalence of diabetes continues to rise in India, and with it the burden of DFUs, incorporating VAC therapy into routine clinical practice could significantly improve patient outcomes and reduce healthcare costs. Addressing the barriers to its widespread adoption, particularly in rural areas, will be crucial to realizing its full potential in the Indian healthcare

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