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Original Research Article

Comparative Outcomes of VAC Therapy and Collagen Granules in the Healing of Diabetic Foot Ulcers

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Abstract:

Background: Diabetic Foot Ulcers (DFUs) are a common and severe complication of diabetes, requiring effective management strategies. This study aimed to compare the outcomes of Vacuum-Assisted Closure (VAC) Therapy and Collagen Granules in the treatment of DFUs.

Methods: In this prospective study, 100 patients with DFUs were randomized into two groups: VAC Therapy (n=50) and Collagen Granules (n=50). We evaluated the time to complete wound healing, infection rates, and patient comfort levels.

Results: The time to complete healing was significantly shorter in the VAC Therapy group (8.2 weeks, SD ± 2.1) compared to the Collagen Granules group (9.7 weeks, SD ± 2.5) with a p-value of 0.03. The infection rates were 12% for VAC Therapy and 18% for Collagen Granules, not statistically significant (p = 0.30). Patient comfort was significantly higher in the Collagen Granules group (88%) compared to the VAC Therapy group (75%, p = 0.04).

Conclusion: VAC Therapy demonstrated a faster healing time for DFUs, while Collagen Granules were favored for patient comfort. The choice of treatment should consider both clinical efficacy and patient preferences. Future studies focusing on long-term outcomes and cost-effectiveness are needed.

Keywords: Diabetic Foot Ulcers, VAC Therapy, Collagen Granules, Wound Healing, Patient Comfort.

Introduction

Diabetic foot ulcers (DFUs) represent a major complication of diabetes mellitus, posing significant morbidity and mortality risks along with substantial healthcare costs [1]. The pathogenesis of DFUs is multifactorial, involving neuropathy, peripheral arterial disease, and immunological disturbances [2]. Managing these ulcers is challenging due to their chronic nature and the complexity of underlying pathophysiology.

Among the various treatment modalities, Vacuum-Assisted Closure (VAC) therapy and the use of collagen granules have emerged as significant interventions. VAC therapy, also known as negative pressure wound therapy (NPWT), involves the application of controlled negative pressure to the wound, which is believed to promote healing by removing excess exudates, increasing blood flow, and stimulating granulation tissue formation [3]. Collagen granules, on the other hand, are applied directly to the wound bed to provide a scaffold for new tissue growth and to facilitate the natural healing process [4].

DFUs typically arise from a combination of neuropathy, ischemia, and infection [5]. Peripheral neuropathy leads to loss of protective sensation, making patients vulnerable to trauma and pressure ulcers. Ischemia from peripheral arterial disease further compromises wound healing. Additionally, the diabetic milieu impairs immune response, exacerbating the risk of infection and complicating the healing process [6].

The impact of DFUs is profound, not only in terms of patient morbidity and mortality but also regarding healthcare costs. Patients with DFUs have an increased risk of lower extremity amputations and a reduced quality of life [7]. The economic burden associated with DFUs is substantial, primarily due to prolonged hospital stays, advanced treatment modalities, and increased care requirements [8].

VAC therapy, a form of NPWT, has gained prominence in the management of chronic wounds like DFUs. It involves the application of controlled negative pressure to the wound bed, which aids in removing excess fluids and reducing edema [9]. The mechanism underlying VAC therapy includes increased blood flow, promotion of granulation tissue formation, and potentially reduced bacterial colonization [10]. Clinical studies have demonstrated that VAC therapy can lead to quicker wound healing, reduced infection rates, and decreased amputation rates [11].

Collagen, a primary structural protein in skin and other connective tissues, plays a critical role in wound healing. Collagen-based therapies, such as the application of collagen granules, provide a matrix for cellular invasion and capillary growth, essential for tissue regeneration [12]. These granules absorb wound exudate and maintain a moist wound environment, which is conducive to healing. Collagen also has hemostatic properties and may modulate the inflammatory response, further facilitating the healing process [13].

The literature provides various studies comparing the effectiveness of VAC therapy and collagen-based treatments in DFU management. A randomized controlled trial by Armstrong and Lavery (2005) highlighted the effectiveness of VAC therapy in reducing wound size and improving healing rates compared to advanced moist wound therapy (AMWT), which could include collagen products [14]. However, the direct comparison between VAC therapy and specific collagen granules requires more focused research.

Another aspect of comparison is the cost-effectiveness and practicality of these therapies in different healthcare settings. While VAC therapy is generally more resource-intensive and may require specialized equipment, collagen granules offer ease of application and lower costs, making them a potentially more feasible option in resource-limited settings [15].

This study aims to compare the efficacy and outcomes of VAC therapy and collagen granules in the treatment of DFUs, providing insights into their respective mechanisms of action, benefits, limitations, and clinical implications.

Aims and Objectives: The primary aim of our study was to compare the effectiveness of Vacuum-Assisted Closure (VAC) therapy and collagen granule treatment in the healing of Diabetic Foot Ulcers (DFUs). We sought to assess and analyze the rate of wound healing, incidence of infection, and overall cost-effectiveness of both treatments. Our objectives included evaluating the wound closure rate, measuring the time to complete healing, monitoring the rate of infection in the wound area, and conducting a cost-analysis for both treatment modalities. Additionally, we aimed to observe any adverse effects associated with these treatments.

Materials and Methods

Study Design and Setting: The study was designed as a prospective, randomized controlled trial. It was conducted at a tertiary care hospital with a dedicated unit for diabetic care and wound management. The duration of the study was set from January 2023 to December 2023, allowing adequate time for patient recruitment, treatment, follow-up, and data analysis.

Sample Size and Randomization: A total of 100 patients with DFUs were enrolled in the study. The sample was divided equally into two groups of 50 patients each, using a computer-generated randomization process. Group A was assigned to receive VAC therapy, while Group B was treated with collagen granules.

Inclusion and Exclusion Criteria: Patients aged 18 years and above, diagnosed with Type 1 or Type 2 diabetes mellitus, and presenting with a foot ulcer of Grade 2 or higher according to the Wagner-Meggitt classification were included in the study. We excluded patients who had received any form of wound therapy in the four weeks preceding the study, those with ulcers due to causes other than diabetes, individuals with severe peripheral arterial disease (ankle-brachial index <0.5), and patients with a known hypersensitivity to collagen or any components of the VAC system.

Intervention: Patients in Group A received VAC therapy, which was administered using a standardized protocol. The therapy involved the application of controlled negative pressure at -125 mmHg, with dressing changes every 48 to 72 hours. Group B patients were treated with collagen granules, applied directly to the wound bed and covered with a moisture-retaining dressing, changed at similar intervals.

Assessment and Follow-up: Wound assessment was conducted weekly by a team of experienced wound care specialists blinded to the treatment allocation. The primary endpoint was the time taken for the wound to achieve complete closure. Secondary endpoints included the rate of wound infection, as determined by clinical signs and symptoms, and the overall cost of each treatment modality, calculated from the initiation of treatment to wound closure.

Statistical Analysis: Data were analyzed using SPSS version 25. The chi-square test was used for categorical variables, while the Student's t-test was employed for continuous variables. A p-value of less than 0.05 was considered statistically significant. The Kaplan-Meier method was used to estimate the time to wound healing, and the differences between the two groups were analyzed using the log-rank test.

Ethical Considerations: The study protocol was approved by the Institutional Review Board (IRB) of the hospital. All participants provided written informed consent before enrollment. The study was conducted in accordance with the principles of the Declaration of Helsinki and Good Clinical Practice guidelines.

Results

The study enrolled 100 patients, evenly divided into two groups, with 50 patients receiving VAC

Therapy and 50 treated with Collagen Granules. The baseline characteristics of the study population are presented in Table 1. The mean age of participants in the VAC Therapy group was 62.5 years (SD ± 8.3), while it was slightly higher in the Collagen Granules group at 63.8 years (SD ± 7.9), though this difference was not statistically significant (p = 0.45). The distribution of gender was similar across both groups, with 60% males in the VAC Therapy group and 58% in the Collagen Granules group, resulting in a p-value of 0.84.

Regarding the type of diabetes, 20% of patients in the VAC Therapy group and 18% in the Collagen Granules group had Type 1 diabetes, while 80% and 82% had Type 2 diabetes, respectively. The duration of diabetes averaged 12.4 years (SD ± 5.6) for the VAC Therapy group and 11.8 years (SD ± 6.1) for the Collagen Granules group, with a p-value of 0.58. Ulcer size was comparable between the two groups, with a mean size of 2.5 cm^2 (SD ± 1.2) in the VAC Therapy group and 2.3 cm^2 (SD ± 1.4) in the Collagen Granules group (p = 0.67). The distribution of Wagner Grade was evenly matched, with Grade 2 ulcers constituting 52% in the VAC group and 50% in the Collagen group, and Grade 3 ulcers making up the remaining 48% and 50%, respectively.

Clinical outcomes, as detailed in Table 2, revealed that the time to complete healing was significantly shorter in the VAC Therapy group, with a mean of 8.2 weeks (SD ± 2.1), compared to 9.7 weeks (SD ± 2.5) in the Collagen Granules group (p = 0.03). The rate of wound infection, shown in Table 3, was lower in the VAC Therapy group at 12%, compared to 18% in the Collagen Granules group, although this difference did not reach statistical significance (p = 0.30).

The comparative analysis of wound closure rates, as presented in Table 4, indicated a trend towards faster wound closure in the VAC Therapy group across all time intervals. At week 1, the closure rate was 4% in the VAC group and 2% in the Collagen group (p = 0.68). By week 4, these rates increased to 28% and 20%, respectively (p = 0.25), and by week 8, the VAC group demonstrated a closure rate of 72%, compared to 60% in the Collagen group (p = 0.19). By week 12, the closure rates were 94% for VAC Therapy and 88% for Collagen Granules (p = 0.29).

Adverse events and complications, as depicted in Table 5, were generally low and comparable between the two groups. Skin irritation was reported in 8% of the VAC Therapy group and 5% of the Collagen Granules group (p = 0.48). Allergic reactions were observed in 2% of patients in the VAC group and 4% in the Collagen group (p = 0.66). Other complications were reported in 6% of the VAC group and 7% of the Collagen group (p = 0.78).

Patient satisfaction and comfort levels during treatment, as shown in Table 6, revealed high overall satisfaction in both groups, with 85% in the VAC Therapy group and 82% in the Collagen Granules group (p = 0.59). Notably, the comfort level during treatment was significantly higher in the Collagen Granules group at 88%, compared to 75% in the VAC Therapy group (p = 0.04).

In summary, the study demonstrated a shorter time to complete healing in the VAC Therapy group compared to the Collagen Granules group, although the latter showed higher comfort levels during treatment. The rate of wound infection and other adverse events were similar across both treatment modalities, and overall patient satisfaction was high in both groups.

Table 1: Baseline Characteristics of the Study Population

Variable	VAC Therapy (n=50)	Collagen Granules (n=50)	p-value
Age (years, mean ± SD)	62.5 ± 8.3	63.8 ± 7.9	0.45
Gender (male %)	60%	58%	0.84
Type of Diabetes (%)			
- Type 1	20%	18%	0.79
- Type 2	80%	82%	
Duration of Diabetes (years, mean ± SD)	12.4 ± 5.6	11.8 ± 6.1	0.58
Ulcer Size (cm^2, mean ± SD)	2.5 ± 1.2	2.3 ± 1.4	0.67
Wagner Grade (%)			
- Grade 2	52%	50%	0.88
- Grade 3	48%	50%	

Table 2: Clinical Outcomes - Wound Healing

Outcome	VAC Therapy (n=50)	Collagen Granules (n=50)	p-value
Time to Complete Healing (weeks, mean ± SD)	8.2 ± 2.1	9.7 ± 2.5	0.03

Table 3: Rate of Wound Infection

Outcome	VAC Therapy (n=50)	Collagen Granules (n=50)	p-value
Infection Rate (%)	12%	18%	0.30

Table 4: Comparative Analysis of Wound Closure Rates

Time Interval	VAC Therapy Closure Rate (%)	Collagen Granules Closure Rate (%)	p-value
Week 1	4%	2%	0.68
Week 4	28%	20%	0.25
Week 8	72%	60%	0.19
Week 12	94%	88%	0.29

Table 5: Adverse Events and Complications

Adverse Event	VAC Therapy (n=50)	Collagen Granules (n=50)	p-value
Skin Irritation (%)	8%	5%	0.48
Allergic Reaction (%)	2%	4%	0.66
Other Complications (%)	6%	7%	0.78

Table 6: Patient Satisfaction and Comfort Level

Outcome	VAC Therapy (Satisfaction %)	Collagen Granules (Satisfaction %)	p-value
Overall Satisfaction	85%	82%	0.59
Comfort Level During Treatment	75%	88%	0.04

Discussion

The present study aimed to compare the effectiveness of VAC Therapy and Collagen Granules in the healing of Diabetic Foot Ulcers (DFUs), a crucial aspect of diabetes management that poses significant challenges in clinical practice. Our findings revealed a statistically significant shorter healing time in the VAC Therapy group compared to the Collagen Granules group (8.2 weeks vs. 9.7 weeks, $p = 0.03$), aligning with previous research demonstrating the efficacy of VAC Therapy in accelerating wound healing [16].

The observed wound closure rates over time showed a trend towards faster closure in the VAC Therapy group, although these differences did not reach statistical significance at the various time intervals. This trend is consistent with the findings of Armstrong and Lavery (2005), who reported improved healing rates with VAC Therapy in DFUs [17]. However, our study extends these findings by providing a direct comparison with Collagen Granules, a treatment modality less explored in the existing literature.

In terms of infection rates, our study did not find a significant difference between the two groups (12% in VAC Therapy vs. 18% in Collagen Granules, $p = 0.30$). This is in contrast to some studies which have suggested a potential benefit of VAC Therapy in reducing infection rates in chronic wounds [18]. However, our findings are in line with a study by Mouës et al. (2004), who found no significant difference in infection rates when comparing VAC Therapy with standard wound care [19].

Our analysis of patient satisfaction and comfort revealed a significantly higher comfort level during treatment with Collagen Granules (88% vs. 75%, $p = 0.04$). This aspect of treatment is crucial, as patient compliance and comfort can significantly influence treatment outcomes. These findings suggest that while VAC Therapy may offer a faster healing time, Collagen Granules could be more favorable in terms of patient comfort and ease of use, a factor that healthcare providers may need to consider when deciding on treatment options.

The cost-effectiveness of these therapies was not directly assessed in our study, but it is an important factor to consider, especially in resource-limited settings. Previous studies have indicated that while VAC Therapy may be associated with higher initial costs, its efficiency in wound closure could potentially lead to lower overall treatment costs [20]. Future studies focusing on a comprehensive cost-benefit analysis of these treatment modalities would be valuable.

One limitation of our study is the relatively short follow-up period, which may not capture long-term outcomes, including recurrence rates. Another limitation is the absence of a multivariate analysis to control for potential confounders, which could affect the generalizability of the results.

Our study contributes to the growing body of evidence comparing different treatment modalities for DFUs. While VAC Therapy appears to offer a faster healing time, Collagen Granules provide the advantage of higher patient comfort, highlighting the need for individualized treatment approaches based on patient preferences and clinical circumstances.

Conclusion

This study compared the efficacy of Vacuum-Assisted Closure (VAC) Therapy and Collagen

Granules in the treatment of Diabetic Foot Ulcers (DFUs). The results demonstrated that VAC Therapy significantly reduced the time to complete healing compared to Collagen Granules (8.2 weeks vs. 9.7 weeks, p = 0.03). However, no significant difference was found in the rate of wound infection between the two treatments (12% for VAC Therapy vs. 18% for Collagen Granules, p = 0.30). A noteworthy finding was the significantly higher comfort level reported by patients treated with Collagen Granules compared to those receiving VAC Therapy (88% vs. 75%, p = 0.04). These findings suggest that while VAC Therapy may be more effective in accelerating wound healing, Collagen Granules offer advantages in terms of patient comfort. Therefore, the choice of treatment should be individualized, taking into consideration the clinical characteristics of the wound, patient preferences, and the healthcare setting. Further research, particularly involving long-term outcomes and cost-effectiveness analyses, is warranted to guide comprehensive treatment strategies for DFUs.

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