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Comparing Conventional Dressing to Vacuum Assisted Dressing – A Hospital based Prospective Comparative Observational Study

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KEYWORDS

Conventional Dressing, Vaccum Assisted Dressing, Diabetic Foot Ulcer, Chronic ulcer, Wound healing, Granulation

ABSTRACT:

Background: Diabetic foot ulcers (DFUs) are a major complication of diabetes, leading to significant morbidity, prolonged hospital stays, and increased healthcare costs. Traditional wound care methods often yield suboptimal outcomes, prompting the need for advanced therapies. Vacuum-assisted closure (VAC) therapy has emerged as a promising technique to enhance wound healing and reduce complications in DFUs.

Objectives: To assess the impact and efficacy of vacuum-assisted dressing in comparison to conventional saline dressing, and to evaluate its benefits in promoting wound healing in chronic diabetic ulcers.

Methods: This was a hospital based, prospective, comparative observational study conducted in the Department of General Surgery, Indira Gandhi Government General Hospital & Post Graduate Institute, Puducherry, India between January 2024 and December 2024.

Results: A total of 64 patients were enrolled, evenly divided into VAC and CD groups. Baseline characteristics, including age, gender, comorbidities, and BMI, were comparable between the groups. Over two weeks, significant improvements in wound healing parameters were observed in the VAC group. By Week 1, the mean ulcer size reduced significantly in the VAC group (4.8 cm^2 vs. 6.5 cm^2, $p = 0.001$), with further reductions by Week 2 (3.8 cm^2 vs. 4.9 cm^2, $p = 0.001$). Granulation tissue appeared earlier and more frequently in the VAC group, with 50% of patients developing granulation tissue by Week 2 compared to 21.9% in the CD group ($p = 0.019$). The Bates-Jensen Wound Assessment Tool (BWAT) scores also improved more significantly in the VAC group by Week 2 (26.6 vs. 33.5, $p < 0.001$). VAC therapy resulted in faster wound healing, with a 40.4% reduction in ulcer surface area compared to 11.2% in the CD group ($p = 0.002$).

Conclusion: These findings demonstrate that VAC therapy is a safe, effective, and superior alternative to conventional dressing for managing chronic DFUs, promoting faster wound healing and greater patient satisfaction.

Introduction

Diabetes mellitus (DM) is a chronic metabolic disorder characterized by persistent hyperglycaemia resulting from either insufficient insulin secretion or ineffective insulin action. This condition is associated with long-term complications affecting multiple organ systems, including vascular, neurological, and immune

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systems.(1) Among the various complications of diabetes, diabetic foot ulcers (DFUs) are among the most prevalent and severe. They significantly impair the quality of life of affected individuals, contributing to increased morbidity, reduced mobility, and diminished mental health.(2) DFUs represent a major clinical challenge, with lower extremity ulcers accounting for more than 60% of non-traumatic lower leg amputations in diabetic patients.(3) These ulcers result from a combination of factors such as neuropathy, poor circulation, and impaired wound healing, with diabetic neuropathy playing a pivotal role in increasing the risk of foot infections and subsequent amputations.(1)

The pathophysiology of DFUs involves a complex interplay of cellular and molecular factors that delay wound healing. Diabetic patients often experience prolonged inflammation, impaired collagen synthesis, and reduced angiogenesis, all of which hinder the normal wound healing process.(4) This delay in healing is exacerbated by metabolic disturbances associated with diabetes, such as hyperglycaemia and altered immune function, which predispose individuals to chronic infections and further complications.(5) As a result, management of DFUs becomes a multifaceted approach requiring not only wound care but also systemic management of diabetes and its associated complications.

One commonly used classification system for DFUs is the Wagner Classification, which categorizes ulcers based on their depth and the extent of associated tissue involvement. The system ranges from Grade 0 (no open lesion) to Grade 5 (whole foot gangrene).(6) Wounds in higher-grade categories typically require more intensive management, including surgical interventions, which further complicates treatment. Effective management of diabetic ulcers thus necessitates early detection, proper wound assessment, and timely intervention.

Traditional treatment options for DFUs include a combination of debridement, antibiotic therapy, appropriate dressings, and offloading of pressure from the affected area.(7, 8) However, despite these interventions, healing may be delayed, and recurrence of ulcers is common. In recent years, novel therapeutic modalities have emerged, such as vacuum-assisted closure (VAC) therapy, which aims to enhance wound healing by promoting the formation of granulation tissue and reducing oedema.(9, 10) VAC therapy involves the application of a non-adhesive film over the wound, followed by the placement of a medical-grade sponge and the application of an airtight occlusive dressing. This creates a negative pressure environment that facilitates wound healing by promoting blood flow, removing excess exudate, and enhancing cellular activity in the wound bed.(10) Studies have suggested that VAC therapy can lead to faster granulation, improved tissue perfusion, and shorter healing times compared to conventional treatments.(11) Given the challenges associated with the management of DFUs and the promising results from VAC therapy, the objectives of the present study were to compare the effectiveness of VAC with conventional dressings in the healing of diabetic ulcers, specifically in terms of healing rate (time required to prepare the wound for closure either spontaneously or through surgical intervention), safety, and patient satisfaction.

Materials and Methods

This was a hospital based, prospective, comparative observational study conducted in the Department of General Surgery, Indira Gandhi Government General Hospital & Post Graduate Institute, Puducherry, India over a period of 12 months between January 2024 and December 2024. The study was approved by the Institutional Human Ethics Committee (IHEC). The participants (and their attenders) were given the Participant Information Sheet (PIS) in their native language, and its contents were verbally explained to ensure their understanding and satisfaction. Enrolment into the study proceeded upon receipt of written informed consent. The study included patients (30-80 years of age), of both gender, with a diagnosis of DFUs (Wagner's classification grade 1 and 2), of >3 weeks duration. However, patients with peripheral vascular disease, human immunodeficiency virus (HIV), hepatitis, and critically ill; pregnant; chronic venous and/or arterial insufficiency ulcer; malignant ulcer; severe anaemia (haemoglobin <7gm/dl); with known or suspected osteomyelitis; and ulcers <2 cm in size were excluded.

The sample size was calculated using OpenEpi with 95% confidence and 80% power, assuming an odds ratio of

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2.0 based on proportions of 0.5 (exposed) and 0.25 (unexposed). Z-scores of 1.96 and 0.84 were applied using the standard formula for comparing proportions. The estimated sample size was 64, with no design effect adjustment. We used nonprobability sampling technique – purposive sampling/complete enumeration to enrol patients. A comprehensive medical history was obtained from all participants, including details of chronic medical illnesses, prior surgical interventions, and ulcer duration. Thorough general and local examinations were conducted before assigning participants into two groups: the VAC group (n = 32), treated with vacuum-assisted closure, and the conventional dressing (CD) group (n = 32), managed with saline dressings. Ulcer dimensions were recorded by tracing onto transparent sheets and transferring the outlines onto graph paper prior to dressing. Routine wound cultures and sensitivity tests were performed, and antibiotics were administered accordingly. To ensure consistency, no local antiseptics were applied in either group. Interventions were delivered over the first week. Ulcer status was reassessed at the end of the first and second weeks. Surface area measurements were repeated using the same graph paper method by a blinded observer. Granulation tissue development and graft readiness were assessed by the treating consultant. Adverse effects such as pain, rashes, or irritation were monitored; affected individuals were withdrawn and treated. The percentage reduction in ulcer surface area was calculated using the formula: [(Pre-treatment surface area − Final surface area) / Pre-treatment surface area] × 100.

Statistical analysis: The data obtained was manually entered into Microsoft Excel, coded, and recoded. The analysis was done using Statistical Package for Social Sciences (SPSS) v27. All the categorical variables were summarised using frequencies/numbers and percentages. Continuous variables were summarized using mean (standard deviation) and/or median (interquartile range) (based on the results of data normality, tested using Kolmogorov–Smirnov test and the Shapiro–Wilk test). To test for association and baseline comparison of study groups, Chi square test or Fisher exact test (for categorical variables) and independent 't' test or Mann Whitney U test (for continuous variables) was used. The before and after treatment comparison was done based on repeated measures analysis of variance (ANOVA) test. Statistical significance was considered at p value less than 0.05.

Results

A total of 76 patients with DFUs were assessed for eligibility. Of these, 12 were excluded (7 for not meeting inclusion criteria and 5 for declining participation), leaving 64 patients who were allocated equally into two groups: Group VAC (n = 32) received vacuum-assisted closure therapy, and Group CD (n = 32) received conventional dressings. All participants received the allocated interventions with no dropouts or losses to follow-up. Both groups were followed and analysed at baseline (day 0), week 1, and week 2. Baseline characteristics of the groups were comparable with no statistically significant differences. The mean age was 51.5 ± 11.6 years in Group VAC and 49.5 ± 11.1 years in Group CD ($p = 0.483$). Both groups had a similar distribution of gender, comorbidities (including hypertension, chronic kidney disease, and coronary artery disease), smoking status, haemoglobin levels (10.2 g/dL), BMI (~25 kg/m²), HbA1C levels (VAC: 9.7%, CD: 10.3%), and wound culture results.

At baseline (Day 0), the mean ulcer size was comparable between the VAC group (6.8 ± 1.9 cm²) and the CD group (6.7 ± 2.3 cm²; $p = 0.561$). However, by Week 1 and Week 2, the VAC group showed significantly greater ulcer size reduction (Week 1: 4.8 ± 1.5 cm² vs. 6.5 ± 2.4 cm²; Week 2: 3.8 ± 1.2 cm² vs. 4.9 ± 1.3 cm²; $p = 0.001$ for both), with significant improvement across time confirmed by RM-ANOVA ($p < 0.001$). Granulation tissue formation was significantly higher in the VAC group at both Week 1 (34.4% vs. 12.5%; $p = 0.039$) and Week 2 (50.0% vs. 21.9%; $p = 0.019$). The Bates-Jensen Wound Assessment scores, which reflect wound healing, were not significantly different at baseline (46.3 vs. 43.9; $p = 0.202$), but showed significantly greater improvement in the VAC group by Week 2 (26.6 ± 5.7 vs. 33.5 ± 8.8; $p < 0.001$), with within-group changes over time also significant (RM-ANOVA, $p < 0.001$ for both groups). These findings indicate superior healing outcomes with VAC therapy.

The mean percentage reduction in ulcer surface area was significantly greater in the VAC group compared to the CD group. Patients treated with vacuum-assisted closure showed a mean reduction of 40.4% ± 21.9%, whereas

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those in the conventional dressing group had a mean reduction of only 11.2% ± 47.5% ($p = 0.002$).

Discussion

The present study aimed to compare the effectiveness of VAC and CD in DFUs, focusing on demographics and baseline characteristics to ensure comparability between the two groups. The results indicate that there were no statistically significant differences between Group VAC and Group CD in terms of age, gender distribution, comorbidities, BMI, or smoking status, confirming that both groups were well-matched for baseline characteristics. The mean age of participants in both groups was approximately 50 years, with no significant difference. This aligns with previous research suggesting that diabetic foot ulcers commonly occur in middle-aged and older adults due to the cumulative burden of diabetes and associated microvascular and macrovascular complications.(12) The categorization of patients into age groups (<50 years and ≥50 years) showed a similar distribution in both groups, further validating the comparability of the study cohorts. This is important as age is a known factor influencing wound healing due to declining regenerative capacity and the presence of age-related comorbidities.(13) The gender distribution in both groups was also comparable, with no statistically significant difference. While males accounted for a slightly higher proportion in both groups, females were also well-represented. Similar distributions have been reported in other studies on DFUs, where males are often more affected due to higher rates of outdoor activity, trauma, and smoking.(14, 15) However, gender is not typically considered a primary determinant of DFU outcomes, suggesting that any differences in treatment response are unlikely to be influenced by gender distribution in this study.

Approximately half of the participants in each group had comorbidities, with no significant differences between the groups. The prevalence of hypertension, CKD, and CAD was similar in both groups. Comorbidities such as hypertension and CKD are well-established risk factors for delayed wound healing due to impaired microcirculation, tissue oxygenation, and immune function.(16, 17) The similarity in comorbidity profiles across groups ensures that these factors did not bias the outcomes in favour of one treatment modality over the other. The mean BMI was comparable between the two groups, with values within the overweight category according to WHO criteria. Obesity is a recognized risk factor for poor wound healing due to increased inflammation, impaired angiogenesis, and delayed re-epithelialization.(18) However, since both groups exhibited similar BMI profiles, the impact of body weight on healing outcomes is unlikely to differ significantly between VAC and CD treatments in this study. Smoking was more prevalent in Group VAC (56.3%) than in Group CD (37.5%), but the difference was not statistically significant. Smoking is a critical modifiable risk factor for impaired wound healing, as it reduces oxygen delivery to tissues, impairs angiogenesis, and disrupts fibroblast function.(19, 20) Despite the higher prevalence of smokers in Group VAC, the lack of statistical significance suggests that smoking status was unlikely to introduce a bias between the groups. The absence of significant differences in demographic and baseline characteristics between the two groups reinforces the internal validity of the study.

The mean haemoglobin levels were identical in both groups (10.2 g/dl), with no statistically significant difference. Anaemia is a well-documented factor that can impair wound healing, primarily due to reduced oxygen delivery to tissues.(21, 22) Maintaining comparable haemoglobin levels ensures that oxygenation-related factors did not influence differences in ulcer healing between the two groups. The mean HbA1C levels were slightly higher in Group CD (10.3%) than in Group VAC (9.7%), but this difference was not statistically significant. Elevated HbA1C levels reflect poor glycaemic control, which is associated with delayed wound healing, impaired immune function, and increased susceptibility to infections.(23) Baseline wound culture results showed no statistically significant differences between the groups, with approximately 56.3% of patients in Group VAC and 53.1% in Group CD exhibiting positive cultures. Bacterial colonization is a common complication in DFUs and can significantly delay wound healing by promoting chronic inflammation and tissue degradation.(24, 25) The similarity in culture results at baseline indicates that both groups started with comparable microbial burdens, suggesting that differences in ulcer size reduction and granulation tissue formation were not driven by initial infection status.

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The reduction in ulcer size was significantly greater in the VAC group compared to the CD group at both Week 1 and Week 2. At baseline, the mean ulcer size was comparable between the groups ($p = 0.561$), ensuring a fair starting point for assessing treatment efficacy. By Week 1, the mean ulcer size in Group VAC decreased significantly to 4.8 cm^2 compared to 6.5 cm^2 in Group CD ($p = 0.001$). This trend continued at Week 2, with mean ulcer sizes of 3.8 cm^2 in Group VAC and 4.9 cm^2 in Group CD ($p = 0.001$). The repeated measures analysis of variance further confirmed a significant reduction in ulcer size over time within both groups, with VAC therapy demonstrating superior efficacy. These findings align with existing literature, which consistently demonstrates the advantages of VAC therapy in accelerating wound contraction and reducing ulcer size.(26-28) VAC therapy promotes wound healing by creating a controlled subatmospheric pressure environment, which enhances angiogenesis, reduces interstitial oedema, and removes exudate, thereby stimulating granulation tissue formation.(10)

Granulation tissue, a key indicator of wound healing, was not observed in any patients at baseline in either group. However, by Week 1, 34.4% of patients in Group VAC exhibited granulation tissue formation compared to only 12.5% in Group CD, with a statistically significant difference. This improvement was even more pronounced by Week 2, with 50.0% of patients in Group VAC developing granulation tissue compared to 21.9% in Group CD. The enhanced granulation tissue formation in the VAC group is consistent with the mechanistic benefits of VAC therapy. The application of negative pressure not only promotes tissue perfusion but also stimulates the release of growth factors such as VEGF and TGF-β, which are critical for granulation and re-epithelialization.(29) In contrast, conventional dressings provide a less dynamic wound environment, which may explain the slower granulation response observed in Group CD. The findings of this study support the growing body of evidence advocating for the use of VAC therapy in managing DFUs. Accelerated ulcer size reduction and granulation tissue formation are critical determinants of successful wound healing, and VAC therapy appears to outperform conventional dressing in these aspects. The statistically significant differences observed as early as Week 1 and sustained through Week 2 highlight the potential of VAC therapy to shorten the healing timeline, reduce the risk of complications, and improve patient outcomes.

The BWAT is a validated tool widely used to assess wound status, encompassing dimensions such as size, depth, edges, necrotic tissue, granulation tissue, and exudate type and amount.(30) At baseline (Day 0), the mean BWAT scores in Group VAC (46.3) and Group CD (43.9) were comparable, with no statistically significant difference ($p = 0.202$), ensuring a uniform starting point for comparing the efficacy of the two treatments. By Week 1, both groups demonstrated improvement, but the reduction in mean BWAT score was greater in Group VAC (34.8) than in Group CD (38.5), although this difference did not reach statistical significance ($p = 0.089$). By Week 2, however, the difference became highly significant, with Group VAC achieving a mean BWAT score of 26.6 compared to 33.5 in Group CD ($p < 0.001$). The repeated measures analysis of variance also confirmed significant improvement in wound status over time in both groups, highlighting the effectiveness of both interventions in promoting wound healing. The superior performance of VAC therapy in reducing BWAT scores aligns with previous studies that have shown VAC therapy's ability to enhance wound healing parameters, such as tissue perfusion, reduction in exudate, and formation of granulation tissue.(10, 29)

The reduction in ulcer surface area was another critical parameter that demonstrated the superiority of VAC therapy. Group VAC showed a mean reduction of 40.4% (SD = 21.9) in ulcer surface area, which was significantly greater than the 11.2% (SD = 47.5) reduction observed in Group CD. This finding is consistent with prior evidence demonstrating that VAC therapy promotes faster and more pronounced wound contraction compared to conventional methods.(31) The substantial reduction in ulcer surface area in Group VAC can be attributed to several factors. VAC therapy applies controlled subatmospheric pressure to the wound bed, which promotes angiogenesis, enhances wound contraction, and stimulates cellular proliferation.(10) Additionally, the removal of exudate and pro-inflammatory cytokines creates a more favorable environment for tissue repair.(29) In contrast, CD relies primarily on passive absorption of exudate, which does not actively enhance wound contraction or granulation tissue formation. The significant improvement in BWAT scores and ulcer

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surface area reduction in Group VAC is consistent with the results of previous clinical studies. For instance, Armstrong and Lavery (2005) demonstrated that VAC therapy significantly reduced wound healing time and improved wound closure rates in patients with DFUs compared to traditional therapies.(32) Similarly, a systematic review by Dumville et al. (2014) highlighted the effectiveness of VAC therapy in promoting wound healing, although the authors noted variability in study designs and patient populations.(33)

The present study has several limitations. The relatively short follow-up period of two weeks may not capture the long-term benefits or outcomes of both VAC therapy and CD, such as time to complete wound closure, prevention of recurrence, or overall impact on patient quality of life. Additionally, the sample size, though adequate for detecting short-term differences, may limit the generalizability of the findings to broader populations. The study did not account for certain confounding factors, such as variations in patient adherence to wound care protocols, nutritional status, or differences in underlying comorbid conditions, which could influence wound healing. Furthermore, while the study provided detailed comparisons of clinical outcomes, it did not assess the cost-effectiveness of VAC therapy, which is a critical consideration, particularly in resource-limited healthcare settings. Future research addressing these limitations could provide a more comprehensive understanding of the comparative efficacy and value of VAC therapy.

Conclusion

The present study highlights the superior efficacy of VAC therapy compared to CD in promoting the healing of DFUs. While baseline characteristics such as age, gender, comorbidities, and initial wound parameters were comparable between the two groups, VAC therapy demonstrated significantly better outcomes in terms of reduction in ulcer size, granulation tissue formation, and improvement in BWAT scores over a two-week period. The findings underscore the ability of VAC therapy to accelerate wound healing, reduce ulcer surface area, and enhance wound bed preparation for closure compared to conventional methods.

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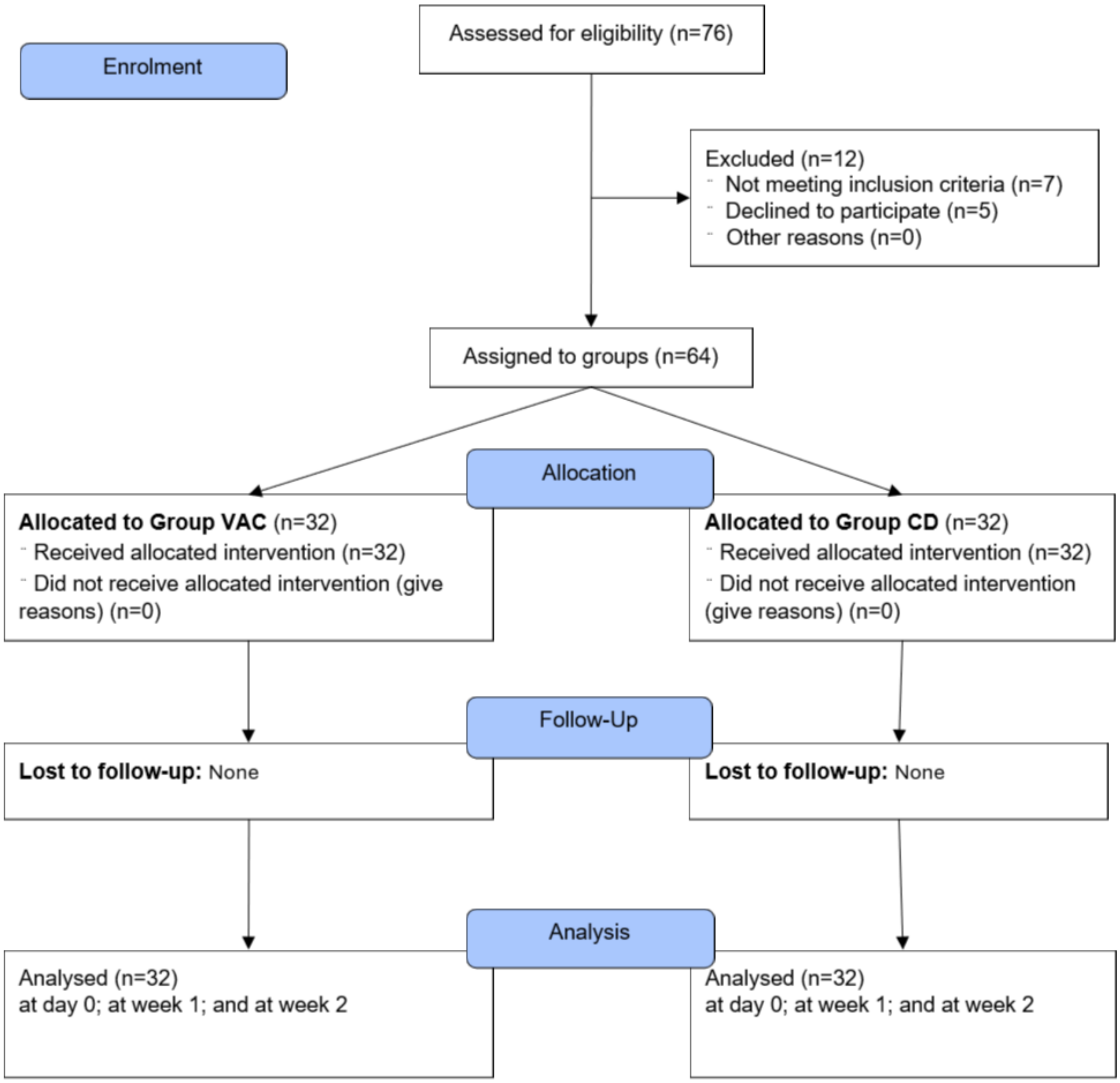

Figure 1: CONSORT flow diagram

Table 1: Baseline characteristics of the study groups

		Group VAC N = 32 n (%)	Group CD N = 32 n (%)	P value
Age (in years), Mean (SD)		51.5 (11.6)	49.5 (11.1)	0.483
Age (in years)	≤50	11 (34.4)	12 (37.5)	0.794
	>50	21 (65.6)	20 (62.5)	
Gender	Female	14 (43.8)	12 (37.5)	0.611
	Male	18 (56.3)	20 (62.5)	

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Comorbidities	Present	16 (50.0)	13 (40.6)	0.451
	Absent	16 (50.0)	19 (59.4)	
Hypertension	Present	7 (21.9)	5 (15.6)	0.522
	Absent	25 (78.1)	27 (84.4)	
Chronic kidney disease	Present	4 (12.5)	4 (12.5)	1.000
	Absent	28 (87.5)	28 (87.5)	
Coronary artery disease	Present	6 (18.8)	6 (18.8)	1.000
	Absent	26 (81.3)	26 (81.3)	
BMI (in kg/m2), Mean (SD)		24.7 (1.8)	25.0 (2.2)	0.587
Smoking	Present	18 (56.3)	12 (37.5)	0.133
	Absent	14 (43.8)	20 (62.5)	
Haemoglobin (in g/dl), Mean (SD)		10.2 (1.6)	10.2 (1.8)	0.999
HbA1C (in %), Mean (SD)		9.7 (1.5)	10.3 (1.4)	0.103
Culture	Positive	18 (56.3)	17 (53.1)	0.802
	Negative/no growth	14 (43.8)	15 (46.9)	

*Statistically significant at p<0.05
SD, Standard deviation; HbA1C, Glycated haemoglobin

Table 2: Comparison of study groups, by ulcer size (in cm2), granulation and Bates-Jensen Wound Assessment Tool

	Group VAC N = 32	**Group CD N = 32**	**P value**
	Mean (SD)	**Mean (SD)**	
Ulcer size (in cm2)			
Day 0	6.8 (1.9)	6.7 (2.3)	0.561
Week 1	4.8 (1.5)	6.5 (2.4)	0.001*
Week 2	3.8 (1.2)	4.9 (1.3)	0.001*
RM-ANOVA	<0.001*	<0.001*	
Granulation			
Day 0	0 (0.0)	0 (0.0)	1.000
Week 1	11 (34.4)	4 (12.5)	0.039*
Week 2	16 (50.0)	7 (21.9)	0.019*
Bates-Jensen Wound Assessment Tool			
Day 0	46.3 (7.6)	43.9 (6.8)	0.202
Week 1	34.8 (9.0)	38.5 (7.5)	0.089
Week 2	26.6 (5.7)	33.5 (8.8)	<0.001*
RM-ANOVA	<0.001*	<0.001*	

*Statistically significant at p<0.05
RM-ANOVA, Repeated measures analysis of variance

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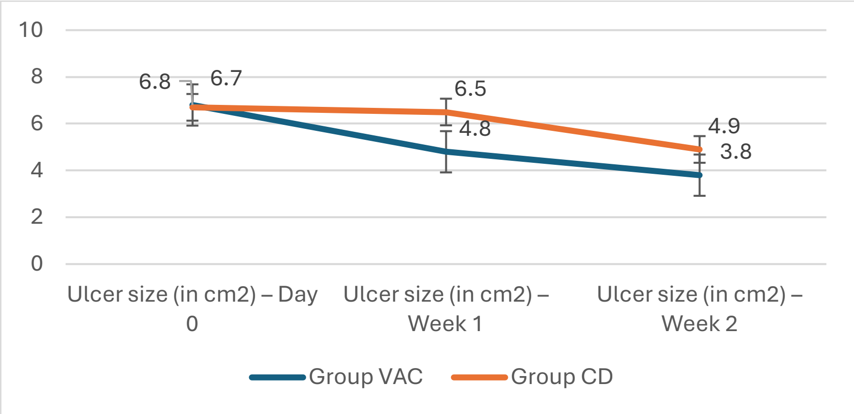
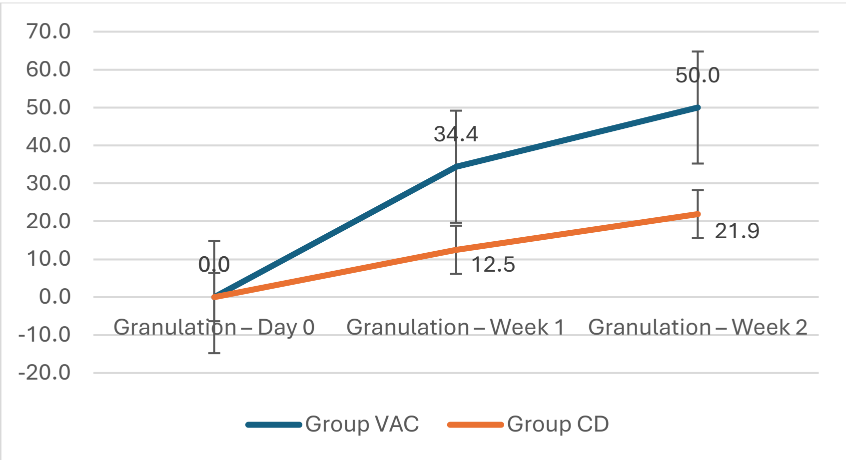
Ulcer size (in cm2)



Granulation



Bates-Jensen Wound Assessment Tool

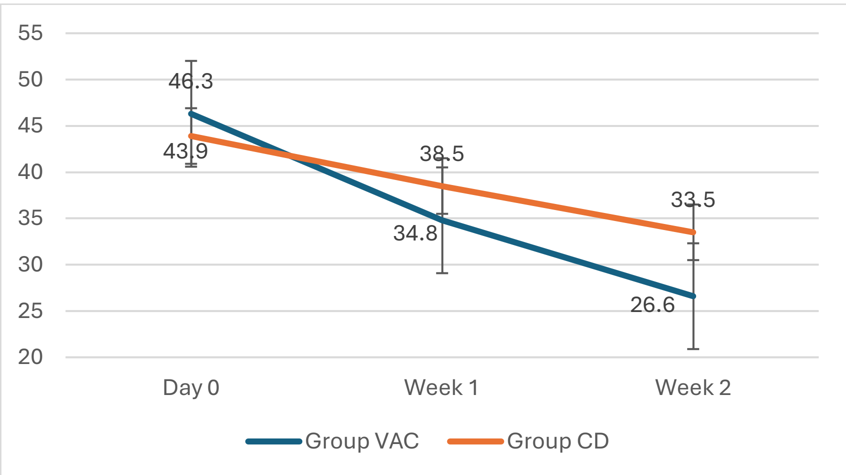


Figure 2: Comparison of study groups, by ulcer size (in cm2), granulation and Bates-Jensen Wound Assessment Tool

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Table 3: Comparison of study groups, by percentage change in ulcer surface area

	Group VAC N = 32	**Group CD N = 32**	**P value**
	Mean (SD)	**Mean (SD)**	
Change (reduction) in ulcer surface area (in %)	40.4 (21.9)	11.2 (47.5)	0.002*

*Statistically significant at $p<0.05$