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Research Article

The Effect of Polyvinyl Alcohol Antimicrobial Foam Dressing with Two Organic Pigments vs. Silver Antimicrobial Foam on Exuding Venous Ulcerations: A Comparative Pilot Study

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Abstract

Background: Treatment of venous ulcers often includes incorporation of dressings, for reduction of bio-load. Evidence is lacking with regards to which dressing is ideal for healing chronic venous wounds. This study aimed to compare the healing effect of polyvinyl alcohol (PVA) antimicrobial foam dressing impregnated with two organic pigments (gentian violet and methylene blue) vs. silver antimicrobial foam dressing.

Research Design and Method: A quasi-experimental study was conducted. 28 participants were divided into two groups and treated with one of the antimicrobial foams. Patients reviewed weekly for 3 weeks. Wound healing was assessed using the Bates-Jensen Wound Assessment Tool.

Results: Over a period of 3weeks, both the PVA antimicrobial foam with two organic pigments and the silver antimicrobial foam dressings were effective in reducing mean BJWAT scores and wound healing ($p < 0.001$). The former was significantly better at week 1 ($p = 0.001$) and 2 ($p = 0.014$) but not at week 3 ($p = 0.881$).

Conclusion: PVA antimicrobial foam with two organic pigments showed some superiority over silver antimicrobial foam dressings in chronic venous ulcers. This should be considered when treating chronic venous ulcerations since the rate of healing was greater despite the extreme severity of ulcers at the start of the study.

Keywords: Venous Ulcerations; Wound Dressings; Wound Healing; Chronic Venous Insufficiency

Introduction

Chronic venous disease (CVD) is a great cause of morbidity, with a substantial portion of in-patient cases presenting with active venous ulceration. The prevalence of CVD is ten times that of peripheral arterial disease (PAD), [1]. Venous ulcerations are known to be the reason for hospital admissions related to wounds, with the risk of life-threatening episodes like cellulitis and deep vein thrombosis (DVT) being ever higher. This has also been reported globally in several developed world countries [2]. In Western Europe, 2% of the healthcare budget is spent on complications of venous insufficiency.

Dressings used during the inflammatory, proliferative and remodelling phases of venous ulcers are crucial, particularly, in reducing certain wound characteristic such as excessive exudate. General wound care supports the choice of dressing according to the: ease of application, comfort, wound drainage absorption, presenting active ingredients and cost [3].

No single wound product can be described as optimal or ideal for all types of ulcerations since the choice of dressing is dependent on a plethora of wound factors. Little consensus exists on which dressing would be ideal to treat venous ulcerations. This lack of evidence is due to the lack of research-based evidence to sustain the use of one particular treatment over another [4]. Bearing in mind that wound repair and management is a highly complex combination of matrix destruction and reorganization,[5] it is of utmost importance that research about the different wound products and treatment modalities currently available on the market is ongoing. No single wound product can be described as optimal or ideal for all types of ulcerations since the choice of dressing is dependent on a plethora of wound factors including the amount and type of drainage, size, depth, and type of ulceration, as well as the appearance of the surrounding skin [6].

While no ideal wound dressing exists [7], there is evidence that certain type of dressings are more indicated than others for the use in venous ulcerations. Antimicrobial foam dressings are being preferred over hydrocolloids, alginates and low adherent dressings when it comes to absorption of exudate since they contain active ingredients with certain crucial characteristics such as bacteriostatic and bacteriocidal properties, effective antimicrobial properties with minimal to no cytotoxic effects when dealing with highly exuding venous wounds however, randomized control trials available in this area have shown no significant difference in ulcer healing when comparing different dressing materials [8].

Nevertheless, some new foam dressings combined with certain active ingredients are showing better venous ulcer healing rates than others. Conwell, Mikulski and Tramontozzi [9], conducted a case series of lower extremity wounds managed with two new active ingredients on the market: gentian violet with methylene blue (MB/GV). The resulting conclusion was that MB/GV provided a healing trajectory when compared with conventional foams. Within the class of antibacterial dressings, GV/MB foam dressings are of lower cost alternative to silver- or iodine-based antibacterial dressings with no risk of absorption of any of the foam components into the tissues which are contraindicated in certain highrisk patients. Use of GV/MB dressings may improve wound healing outcomes and decrease overall costs through super absorption, promotion of autolytic debridement, bioburden reduction, ease of use, and decreased dressing change frequency [10].

With the increase and growing concern of antibiotic resistant microbes, the need for innovative topical treatments that reduce the colonization of bacteria in wounds is paramount. Antibacterial dressings play an increasingly important role in bioburden control and wound healing. A foam dressing incorporated with gentian violet and methylene blue (GV/MB) antibacterial agents has been shown to be effective against a wide spectrum of microorganisms found in wounds, including methicillin-resistant *staphylococcus aureus* (MRSA), vancomycin-resistant *enterococcus* VRE and Candida [10]. An advantage of MB/GV dressings is that no secondary dressings need to be used conjunct with them.

Thus, the main purpose of this research was to compare and evaluate the effectiveness of 2 treatment foam modalities for highly exuding venous ulcerations over a period of 3 weeks: PVA Antimicrobial Foam dressing with two organic pigments [MB/GV] versus Silver Antimicrobial Foam.

Material and Methods

This is a single-center clinical trial including 28 subjects with chronic venous insufficiency (CVI), previously diagnosed by venous duplex scanning and presenting as outpatients with a newly diagnosed venous ulceration in the foot, ankle and/or one third of the leg (gaiter area) to the Tissue Viability Unit at a general hospital. This study was approved by the University Research Ethics Committee and carried out in accordance with the principles of the Declaration of Helsinki, as revised in 2000. Patients provided their written informed consent.

Inclusion criteria were: > 18 years of age, CVI, new venous ulcer in the foot, ankle and/or one third of the leg (gaiter area). Exclusion criteria were arterial or traumatic ulcers, diabetes mellitus, rheumatoid arthritis, use of antibiotics, co-morbidities potentially affecting wound healing and unwillingness to participate in the study.

Treatment procedure

Using convenience sampling, participants were either assigned to Group A (Silver dressing) or to Group B (PVA antimicrobial foam). This was repeated until a total of 28 subjects were recruited.

Participants had to visit the hospital's outpatient clinic every week for assessment by a tissue viability nurse for 3 consecutive weeks (Time 0, time 1, time 2). They were reviewed clinically by the same independent researcher. During each visit, the wound was cleansed with normal saline, while wound debridement using a sterile scalpel was carried out when required. Any excess hyperkeratosis was also debrided from the borders of the ulcer to permit regularity in growth and to prevent scarring.

In group A, the silver dressing using an aseptic non-touch technique was applied, while in group B the PVA antimicrobial foam dressing with two organic pigments (MB/GV) was applied. The latter required prior soaking in sterile saline before application using the same technique. Both dressings were cut to fit the ulcer. A non-adherent padding was used to cover the dressing and the affected limb was entirely covered with compression bandaging. Compression bandaging was applied starting from just below the digits up to just below the knee. Care was taken to avoid creasing or overlapping when applying compression.

Measurement tools

Measurement tools in this study included a data collection sheet to record demographic data, sterile probes, sterile rulers, acetate paper with printed grids and a doppler ultrasound to exclude arterial insufficiency and to ensure that ulcerations were purely of venous nature. To ensure this spectral doppler waveform analysis of the posterior tibial and dorsalis pedis arteries was conducted as follows: A handheld continuous wave Doppler with an 8MHz probe was used to measure the waveforms of the dorsalis pedis and the posterior tibial. The probe was held steadily on the anatomical artery location at angle between 45-60 degrees against the flow of arterial blood. Interpretation of arterial pressure waveform results was based on standards from the literature. Waveforms were classified as triphasic, biphasic, monophasic discontinuous, and monophasic continuous. The triphasic waveforms were considered as normal, whereas the biphasic, monophasic discontinuous, and monophasic continuous waveforms were interpreted as abnormal. Measurements were carried out after patients rested for 5 minutes in the supine position with the upper body as flat as possible, since measurements in the sitting or semi-sitting position can result in a substantial blood increase in the tibial arteries. Patients were also asked to undo all tight clothing around the waist and arms. Handheld portable assessment systems (Dopplex Assist Series, Huntleigh, Cardiff, UK) were used to measure resting ABPI. According to the company specifications, ABPI measurement is one of the instrument's principal applications apart from waveform analysis. The series used for this study included an electric pump that deflates the pressure cuffs, requiring the investigator to simply press a button. An optimum Doppler signal is achieved at an angle of 45-60 degrees. When measured, the systolic blood pressures are automatically saved onto the system's software with the saved results then used to calculate the ABPI ratios by the system. A blood pressure cuff was applied to the arm to measure the brachial systolic pressure and to the ankle to measure the dorsalis pedis and posterior tibial pressures to determine the ankle pressure. The cuff was inflated to occlude the arterial pressure. A researcher obtained the systolic pressure by listening and noting the pressure on the manometer. The systolic pressure was noted and the higher values of the brachial and the ankle pressures were used to calculate the ABPI. Values were interpreted according to the criteria proposed by the American Heart Association and the American Diabetes Association [11]. In this research, ABPI calculations were interpreted as normal when within 0.9-1.29; lower-extremity vascular disease was defined an ABPI < 0.90 in either foot; and an ABPI > 1.3 was considered significantly elevated and indicative of vascular calcification.

Wound measurement procedure

An integral part of chronic wound management includes calculating the wound surface area and depth change over time. Although more complex methods of wound measurement exist (planimetry, digitizing techniques, and stereophotogrammetry), current practice focuses on wound measurement using simple ruler-based methods or by wound tracing, being relatively simple to conduct, these methods can prove just as effective provided that the clinician is well oriented with wound measurement [12].

During this study, the wound shape and location were noted. The acetate method was adopted for calculation of wound surface area. Firstly, the patient's limb was adjusted so as to ensure maximal wound exposure and easy measurement. For the purpose of this study, acetate tracing paper with a printed grid was used to calculate the area of the wound and sterile probes were used to calculate the depth of the wound. A fine-tipped permanent marker was used to trace the wound outline. Minimal pressure was applied whilst tracing to prevent distorting the shape and border of the ulceration. A 0.2 cm^2 grid was used to calculate the area of the ulcer to increase precision. Acetates offer a good indicator of wound size as confirmed by various studies which have compared this method to various other de vices such as planimetry [13]. When recording the depth of the ulcer, the deepest part was identified and the probe used had a millimeter scale to ensure precision.

This area was then rated, depending on the range of the BJWAT. Apart from depth being assessed descriptively on the BJWAT, sterile probes were used to assess undermining wound edges which are another dimension which influence wound depth [14]. The area of the applicator in touch with the wound surface is marked and the length between this mark and the tip of the applicator is measured. Plassman, Melhuish and Harding [15] make reference to circumferential measurements, made possible by use of transparent metric guides divided into pie shaped quadrants are also placed on the wounds to estimate: necrotic and granulation tissue amount and epithelialization. Diffusion of oedema and tissue induration on intact skin (peri-wound area) was made possible by sterile rulers; by first palpating the skin and then measuring away from the wound borders.

Bates-Jensen wound assessment tool

Accurate assessment of a chronic wound is crucial in order to identify the proper decisions which need to be made regarding intervention and treatment [16]. The Bates-Jensen Wound Assessment Tool (BJWAT) is a validated wound assessment tool found in the public domain which is used to assess wound healing. One can use this tool to measure/grade a wound initially and use it at regular intervals to track and evaluate the effectiveness of therapy. The BJWAT consists of 15 items, two of which are not scored (location and shape). The sum of the remaining 13 items is the total BJWAT score [17].

One can score each item from 1 to 5 to provide an assessment. A score of 1 indicates the healthiest and 5 indicates the unhealthiest attribute for each characteristic. After assessing and scoring each item, the sum of the 13 sub-scores arrive to a total score. One can plot the total BWAT as a continuum and provide a visual picture of wound progression of healing or non-healing of a wound. The 13 items the BWAT assesses

- Size (use a sterile ruler to measure the longest and widest aspect of the wound surface in centimeters; multiply length x width)
- Depth (depth, thickness, most appropriate to the wound, rated on a scale of 1 to 5, the larger the number denotes more tissue involvement including tendons or ligaments)
- Edges (indistinct, attached, not attached, rolled under, hyperkeratosis, fibrotic)
- Undermining (conducted by probing to full depth of the undermining edges)
- Necrotic tissue type (predominant type of necrotic issue such as colour, consistency and adherence to wound bed with a hard black eschar denoting worse stage)
- Necrotic tissue amount (A transparent metric divided into 4 quadrants was used to determine the wound area affected by necrosis)
- Exudate type (this ranged from bloody to foul odour and purulent and rated depending on clinical observations)
- Exudate amount (use of transparent metric. Reduction indicated healing)
- Skin color surrounding wound (assess tissues within 4 cm of wound edge. Any hyperpigmentation was observed and taken as a sign of regression)
- Peripheral tissue edema (classified as pitting or non-pitting. Common in venous ulcerations)
- Peripheral tissue induration (through manual palpation, highly indicated by a firmness around the wound margins)
- Granulation tissue (Any blood vessel proliferation and connective tissue fill in the wound was observed and recorded. Good granulation denoted healing.)
- Epithelialization (Pie-shape quadrants were used to estimate the area of coverage).

An additional asset of BJWAT is using the score to measure wound severity. This is important since the goal of wound care is to reduce wound severity. The total BWA scores are divided into four severity categories: 13-20 = minimal severity, 21-30 = mild severity, 31-40 = moderate severity, 41-65 = extreme severity. Grading is made possible by Likert scales, whereby, higher values indicate poorer healing stages. The BJWAT was found to have a high inter and intra-rater reliability even amongst health care professionals with limited experience in wound care [18]. Wound size (and area), depth, edges and undermining are all wound dimensions which reflect and predict robust healing, provided they reduce in numerical value. This reduction indicates closure and epithelialization with the unaffected surrounding skin [19].

Statistical analysis

Analysis was carried out with Statistical Package for Social Sciences version 25 (SPSS; SPSS Inc, Chicago, IL). Data were normally distributed, as shown by the Shapiro Wilks test. The independent sample t-test was employed to compare differences between the 2 groups and the One-Way ANOVA was used to compare the mean BJWAT scores for each individual foam dressing over a period of 3 weeks. Significance was defined at the 5% level (two-tailed $p < 0.05$). In order to identify which of the 13 items of the BJWAT were better predictors of wound healing throughout the study, regression analysis was performed.

Results

Demographics

A total of 28 participants presenting with CVI and with active venous ulceration were included in this study. A study population comprised of 46.4% females and 53.6% males with a mean age of 64 years. Non-smokers in this study amounted for 64.3% of the study population. Commonest locations of venous ulcerations of the study group were the medial malleolus followed by the lateral malleolus, anterior shin and medial leg.

Different type of compression bandaging was as follows: four-layer bandages n = 17, tubigrip of various layers n = 4, Jobst Ulcer Care n = 3, Putterflex/short-stretch n = 3, two-layer bandages n = 1. Half of the population were on no medication. Six participants were on anticoagulation therapy only, three participants were on antihypertensives only and two participants were on antiplatelet treatment only. Only two patients in this study were taking a combination of the fore-mentioned medications. Only one patient was on diuretics. Twenty patients had no other comorbidities, three patients presented with cardiac disease, two patients with hypertension and one patient with lymphoedema. There was one patient with a combination of hypertension and hyperlipidaemia.

Comparison of the BJWAT mean scores for each individual dressings at the start and end of the study

The One-Way ANOVA test was used to compare the mean BJWAT scores over a period of three weeks for each individual dressing. The reductions in mean BJWAT was significant for both types of dressing (p = 0.000). However, as seen in table 1 reduction in the mean improvement in BJWAT scores was greater in polyvinyl alcohol (PVA) antimicrobial foam dressing impregnated with two organic pigments (gentian violet and methylene blue) (baseline week 1 - 43.14 - extreme severity, SD 4.055 vs week 3 - 25.57 - mild severity, SD 4.398) than silver antimicrobial foam dressing (baseline week 1 - 35.71 - moderate severity, SD 6.533 vs week 3 - 25.29 - mild severity, SD 5.539), during the 3week period of the study.

Dressing	Week	Mean	Std. Deviation	P-value
	1	35.71	6.533	
silver antimicrobial foam dressing [Group A]	2	31.43	5.906	0.000
	3	25.29	5.539	
	1	43.14	4.055	
polyvinyl alcohol (PVA) antimicrobial foam dressing impregnated with two organic pigments (gentian violet and methylene blue) [Group B]	2	32.79	4.902	0.000
	3	25.57	4.398	

Table 1: Comparison of the BJWAT mean scores for each individual dressing at the start and end of the study.

Comparison of the BJWAT mean scores between groups over the 3-week study trial

The independent sample T-test was used to compare the mean BJWAT scores between the two different types of dressings over a period of 3 weeks as shown in table 2 and figure 1. At baseline, week 1, the mean BJWAT scores for silver antimicrobial foam dressing group was 34.71 - moderate severity- SD 6.533 versus the PVA group 43.14 - extreme severity - SD 4.055 p = 0.001, implying a significant difference in wound severity between groups. In week 2 the mean BJWAT scores reduced to 31.43 - moderate severity - SD 5.906 for Group A versus 32.79 - moderate severity - SD 4.902 Group B, p = 01014 implying a significant difference in wound severity between groups. However, at the end of the 3rd week the mean BJWAT mean scores reduced to 25.29 [SD5.539] for Group A Vs a mean of 25.57 [SD 4.398] for Group B p = 0.881, implying that at the end of the 3 week study period there was no significant difference in wound severity between groups and with both groups demonstrating mild severity of ulcerations as opposed to the start of the study when moderate severity of ulcerations was reported for Group A and extreme severity of ulceration was reported for group B.

Week	Dressing	Mean BJWAT Scores and Interpretation of Scores	Std. Deviation	P-value
1	Group A	35.71 (moderate severity)	6.533	0.001
	Group B	43.14 (extreme severity)	4.055	
2	Group A	31.43 (moderate severity)	5.906	0.014
	Group B	32.79 (moderate severity)	4.902	
3	Group A	25.29 (mild severity)	5.539	0.881
	Group B	25.57 (mild severity)	4.398	

Table 2: Comparison of the mean BJWAT scores between groups for each week separately.

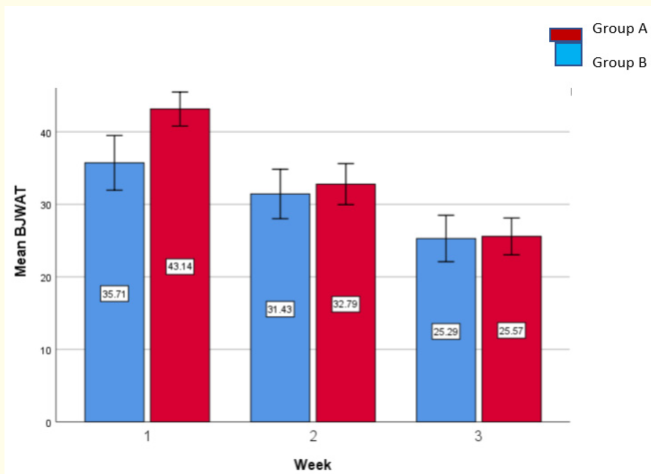

Figure 1: Differences in mean BJWAT scores between groups during the 3-week study period.

Comparison of each of the 13 items of the BJWAT mean scores between the study group at end of week 3

Regression Analysis at the 3rd week of study

In order to identify which of the 13 items of the BJWAT tool were the best predictors of wound healing regression analyses was

Dressing	BJWAT characteristics	Mean	Standard Deviation	p-value
Group A	Wound size	1.71	0.611	0.364
Group B		1.93	0.616	
Group A	Depth	2.07	0.475	0.035*
Group B		1.93	0.267	
Group A	Wound Edges	1.79	0.893	0.626
Group B		1.93	0.616	
Group A	Undermining	1.21	0.426	0.637
Group B		1.14	0.363	
Group A	Necrotic Tissue [Type]	1.64	0.633	0.196
Group B		1.36	0.497	

Group A Group B	Necrotic Tissue [Amount]	1.43 1.29	0.514 0.469	0.449
Group A Group B	Exudate Type	2.00 1.57	0.961 0.514	0.153
Group A Group B	Exudate Amount	2.50 2.14	0.855 0.770	0.256
Group A Group B	Skin Colour	2.86 3.36	1.167 0.745	0.190
Group A Group B	Peripheral Tissue Oedema	1.93 2.29	0.829 0.726	0.236
Group A Group B	Peripheral Tissue Induration	2.00 2.21	0.784 0.699	0.452
Group A Group B	Granulation	1.93 1.71	0.829 0.469	0.407
Group A Group B	Epithelialization	2.36 2.93	0.633 0.829	0.051

Table 3: Comparison of each of the 13 items of the BJWAT mean scores between the study group at end of week 3.

Model	R	R Square	Adjusted R Square	Std. Error
11 predictors	0.997	0.994	0.990	0.479

Unstandardized Coefficients				t P-value	
Coefficients		Std. Error Beta			
Granulation	1.057	0.243	0.144	4.349	0.000
Skin Colour	1.047	0.174	0.212	6.002	0.000
Wound Size	1.071	0.214	0.133	5.007	0.000
Peripheral Tissue Oedema	1.278	0.184	0.205	6.943	0.000
Exudate Amount	0.560	0.197	0.093	2.837	0.012
Necrotic Tissue Type	1.869	0.213	0.220	8.758	0.000
Edges	1.023	0.186	0.157	5.496	0.000
Epithelialization	1.003	0.183	0.159	5.479	0.000
Exudate Type	1.367	0.247	0.219	5.541	0.000
Peripheral Tissue Induration	0.918	0.210	0.138	4.376	0.000
Undermining	0.965	0.292	0.077	3.303	0.004

Table 4: Regression model for wound healing at the third week of the study.

performed at the end of the trial [week 3] as illustrated in table 4.

Granulation was seen to be the best predictor of wound healing at the end of the third week of the study followed by skin colour, wound size, Peripheral Tissue Oedema, exudate amount, necrotic tissue type, edges, epithelialization, exudate type, Peripheral Tissue Induration and undermining. All regression coefficients were positive, therefore, an increase in any of the 11 predictors would result in an increase in the BJWAT scores. For example, the regression coefficient for granulation (1.057) indicates that, for every one-unit increase in granulation, the BJWAT score is expected to increase by a value of 1.057, provided that, all other effects are kept constant.

Discussion

The aim of the study was to compare the healing effect of PVA antimicrobial foam dressing impregnated with two organic pigments (gentian violet and methylene blue) versus silver antimicrobial foam dressing in exuding venous ulcers over a period of 3 weeks. This study has shown that both dressings significantly decreased the mean BJWAT scores, effecting improvement in wound size, depth, edges, undermining, edema, exudate, skin color, necrotic tissue and epithelialization. Importantly, however, initial ulcer severity was significantly worse in group B (PVA dressing), and so participants in this group experienced a greater improvement.

This study is novel in nature, since up to the authors' knowledge only 1 similar study was conducted were the authors compared these specific two types of dressings for effectiveness in treating lower limb ulcerations. The study conducted by Conwell., *et al*. [9], recruited 40 participants with the authors also concluding that both dressings are effective in wound healing with the PVA foam having average days to healing of 67 days whilst the Silver dressing having average days to healing of 75 days, thus also confirming greater rates of improvement like in this present study.

The healing cascade is a complex process of orchestrated reactions and interactions with the goal of restoring structure and physical properties to damaged tissues. Through major advances in the field of medical sciences and greater understanding of treatment strategies, wound healing has gone through a great revolution in the past decade, however, none of the available dressings for venous ulcerations have yet gained universal acceptance and wounds are sometimes resistant to heal despite proper care. This study has shown that PVA antimicrobial foam dressing impregnated with two organic pigments (gentian violet and methylene blue) which has been FDA approved in 2014, provides a faster healing trajectory when compared to standard wound care.

This study has also looked into the predictors of venous wound healing using regression analysis from the BJWAT scores over a period of 3 weeks when using this particular dressing. In this study, the best predictor for chronic venous wound healing was found to be granulation tissue followed by skin colour, wound size, peripheral tissue oedema, exudate amount, necrotic tissue type, wound edges, epithelization, exudate type, peripheral tissue induration and undermining respectively. These findings have important implications for clinical practice, especially in an outpatient setting. Prediction of wound healing/outcome from any given wound dressing may be helpful for health-care professional in individualizing and optimizing clinical management of patients. Identification of determinants of good healing outcomes could result in improved health outcomes improved quality of life, and fewer diabetes-related foot complications.

One of the possible limitations of this study was the sample size. Although the sample size is small (n = 28) results of this study are consistent with findings reported in the literature [9]. Further prospective studies with the inclusion of a larger population sample should be conducted for generalizability of study results. One might argue that another possible limitation of this study was the short follow up after intervention; the duration of 3 weeks, however it was not the intention of this study to follow up the ulcerations to complete closure but rather to assess the short-term healing capabilities of these dressings bearing in mind the possible long- term complications such as infections amongst others that could arise with prolonged healing times. Thus the follow-up was rather short, but longer prospective data were beyond our scope.

In conclusion, while both dressings have shown to be efficacious in healing venous wounds, PVA antimicrobial foam with two organic pigments showed some superiority. These results encourage its further study and use in such patients.

Conclusion

While both treatments have shown to be effective at healing venous wounds, PVA antimicrobial foam with two organic pigments should be considered when treating chronic venous ulcerations since this study has shown that the rate of healing was better despite the extreme severity of the venous ulcerations at the start of the study. An antimicrobial foam dressing consisting of PVA foam bound with gentian violet and methylene blue showed encouraging results in this study population. This dressing may be a suitable option for lower-extremity venous chronic wounds as a standalone treatment or adjunct with other treatments.

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Conflict of Interest

The authors declare no conflict of interest.

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