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ORIGINAL ARTICLE

Four Layer Bandage Versus Two Layer Bandage in Management of Venous Leg Ulcers

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[*] Corresponding author:		ABSTRACT		
Mostafa Kamal Ibrahem		Background: Venous leg ulcers are the most prevalent kind of leg ulcers.		
Email:		The key to managing venous ulcers is lowering ambulatory venous		
Safokamal555@gmail.com		hypertension (AVH), which lowers edema and inflammation in the leg and, if kept at optimal venous pressure, promotes ulcer healing and		
Submit Date Accept Date	09-03-2025 22-03-2025	prevents recurrence. Comparing the healing of ulcers treated with compression using two-layer and four-layer techniques was the goal of this study.		
L		Methods: This Randomized Control Trial study was conducted at the vascular surgery department Zagazig university hospitals, included 42 patients with venous leg ulcers, 21 were given four-layer (group A) compression therapy, and the other 21 were given two-layer (group B) compression therapy. Outcomes after both therapies were analyzed. Results: We discovered that most patients who received a four-layer bandage for VLU needed more than four weeks of follow-up. Nevertheless, it took more than four weeks of follow-up for all patients using a two-layer bandage for the ulcer to fully heal, the period was statistically significant between the two groups (8.52 ± 2.89 for four-layer group vs.12.92 ± 4.39 for the two-layer group, p <0.001HS). We found that Most of the studied patients within both groups had complete healing by the end of follow-up time 81% of four layers compression group versus 61.9% of other group p = 0.389 NS with no significant difference between them. Conclusion: Compared to a two-layer bandage, a four-layer bandage is more successful at improving the healing status and reducing the size of		
		Keywords: Venous leg ulcers; ambulatory venous hypertension; Four Layer Bandage Versus; Two Layer Bandage		

INTRODUCTION

In its later phases, chronic venous disease (CVD), also referred to as chronic venous insufficiency (CVI), is characterized by venous leg ulcers. This is defined as venous dysfunction resulting valvular in an improperly functioning venous system. The deep veins, superficial veins, or both may be impacted by the aberrant function. There may or may not be obstructions to venous outflow. The development of this syndrome can be influenced by a wide range of circumstances, including heredity, female sex, pregnancy, age, prolonged standing, trauma, and obesity. Many people will eventually develop CVD

because some of these risk factors can be decreased by changing their lifestyle (e.g., increasing activity, maintaining a healthy weight, and stopping smoking). The gold standard for diagnosing this illness is duplex ultrasonography, which is determined by a combination of clinical presentation, history, and diagnostic testing. In order to manage this disease, it is essential to comprehend how it develops and how it might be stopped or slowed down [1].

An explanation of vascular ulcers according to the 2004 publication of the new CEAP classification of chronic venous illness, this condition is characterized as a full-thickness skin defect that is most commonly found in the ankle area. The presence or prior history of venous disease, such as axial venous reflux, deep vein blockage, or a history of DVT, is the working diagnostic for a venous leg ulceration. A full thickness skin defect in the lower leg, usually accompanied by skin alterations and/or pigmentation, is the second. (3) Absence of another ailment that could be the main cause of ulcer formation [2].

Of all leg ulcerations that develop in the presence of venous disease, 60-80% are venous leg ulcers (VLUs), which are open lesions of the lower limb. 75% of patients return within 3 weeks after they are healed, and only 60% of patients are usually healed by 12 weeks on average. The outcome of at least 60% of VLUs is a chronic wound. Older people with concurrent chronic venous insufficiency are more likely to have VLUs. They are more prevalent in women than in men, and they place a significant financial strain on patients and healthcare systems. They impact those who are obese, sedentary, have a history of deep vein thrombosis (DVT), have phlebitis, or have a congenital vein deficiency [3].

Venous ulcers can be distinguished from other lower extremity ulcers based on their clinical history, appearance, and physical examination findings. Obtaining a history of deep vein thrombosis or superficial vein thrombosis is crucial, ulcer recurrence, or pulmonary embolism in addition to other concomitant diseases. Venous ulcers are usually irregularly shaped and have distinct edges. Commonly reported symptoms include edema. discomfort, pruritus, and leg Elevation heaviness. alleviates these sensations, which worsen over the day. Symptoms of venous illness such as varicose veins, edema, or venous dermatitis may be discovered during physical examinations. Other indications of the disorder include the occurrence of venous ulcers over bony prominences, like the area over the medial malleolus in the gaiter region [4].

All patients with suspected venous ulcers should have first noninvasive imaging, including complete venous duplex ultrasonography, arterial pulse assessment, and ankle-brachial index measurement. Because standard treatment for venous ulcers can be harmful in patients with ischemia, additional ultrasound evaluation to assess arterial blood flow is indicated when the ankle-brachial index is abnormal and there are certain comorbid conditions like diabetes mellitus, chronic kidney disease, or other conditions that cause vascular calcification. Color duplex ultrasonography is advised in order to search for obstruction and both superficial and deep venous reflux. Further evaluation with a biopsy or referral to a subspecialist is required if ulcer healing ceases or the ulcer seems abnormal [4].

The cornerstone of care for venous leg ulcers (VLU) is compression therapy. Most mild, transient venous ulcers will heal with proper wound care and compression therapy. The goals of compression therapy are to lessen discomfort and edema, encourage ulcer healing, and stop recurrence. Due to its ability to constrict veins, improve valve function, lower ambulatory venous pressure, and lessen venous reflux (VR), compression is utilized to treat VLU. It also reduces capillary fluid leakage and increases capillary flow to treat leg edema and lower inflammatory cytokines. It also improves lymphatic function, boosts fibrinolysis, and decreases the severity of lipodermatosclerosis [5].

The purpose of this study was to examine the healing of ulcers treated with compression bandages made of two layers versus four layers.

METHODS

This Randomized Control Trial study was conducted at the vascular surgery department Zagazig university hospitals, period from December 2023 to May 2024. The follow up period of the series was 6 months. An informed consent was taken from all patients, and the study was authorized by the research ethical council (IRB# 11331) at Zagazig University's Faculty of Medicine. The World Medical Association's Code of Ethics for Human Studies, known as the Declaration of Helsinki, was followed when conducting the inquiry.

Inclusion Criteria were patients aged over 18 years old, post phelibitic venous ulcers, venous ulcers with primary varicose vein with incompetent perforators, venous ulcers with

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incompetent perforators, mobile and able to return for required treatment and follow ship. Patients who were excluded had chronic illness like severe liver disease, cardiac disease, ABPI< 0.8, concurrent arterial disease, recent deep vein thrombosis, pregnancy, known allergy to sclerosant material, DM or chronic pulmonary disease, a medical condition that was likely to require systemic corticosteroids during the study period, or ulcers that were found to have an etiology such alternative as vasculitis. squamous cell carcinoma, or basal cell carcinoma. people with infected ulcers as well.

They were randomization was done through give number for patients who complain of venous leg ulcers. Patient classified into two groups (group A, group B). Group A: included 21 patients started four-layer compression bandage and group B: included 21 patients become under two-layer compression bandage.

Preoperative

Every patient had demographic information collected, such as age, sex, and any unique medically significant habits, as well as information about their ulcer history and past ulcer treatments. Both groups underwent a general physical examination on their first visit, with a focus on measuring vital signs, vascular assessment for signs of lower limb ischemia, chronic venous insufficiency, and ankle joint mobility, infection, ankle brachial index, and physical examination for blood diseases or anemia. Measurements of the ulcer's greatest length and width were made at the initial visit and every three weeks, and the ulcer's size was then calculated using an elliptical formula: Length \times width \times 0.7854, Digital images of the ulcer were taken, and the surrounding skin was examined for indications of infection or inflammation. Every patient underwent a duplex scan to evaluate the venous systems of both lower limbs in order to determine the kind of CVI and whether surgery was necessary.

Ulcer management protocol for group A patients

During the initial visit, the ulcer was severely mocked and cleaned by rinsing it with a saline solution to get rid of any discharge. The lesion was covered with sterile gauze and secured with a sterile roller bandage. At subsequent visits every two weeks, saline cleaning is used instead of debridement. After three weeks, the four-layer bandaging technique used for compression therapy was switched.

Ulcer management protocol for group B patients

During the initial visit, the ulcer was severely mocked and cleaned by rinsing it with a saline solution to get rid of any discharge. The lesion was covered with sterile gauze and secured with a sterile roller bandage. At subsequent visits every three weeks, saline cleaning is used instead of debridement. After two weeks, the two-layer bandaging technique used for compression therapy was switched. The patient is advised to use class II below-knee graded compression stockings to avoid further breakdown and to have monthly follow-ups at the outpatient clinic until the ulcer has healed (full epithelization). Additionally, an appointment is made if surgical treatments are indicated to correct CVI.

4 layer compression

Prior to applying a bandage, the damaged region was assessed and photographed. Skin should always be clean, dry, and lightly moisturized. If necessary, a suitable wound dressing can be used underneath the compression bandage. The innermost sterile gauze dressing of the four-layer bandage is used to cover the ulcer. A non-elastic crepe bandage makes up the first two layers of the four-layer bandage, followed by a soft cotton layer. There is no compression offered by either of these layers. The elastic bandage is the third layer. During the patient's visit, the cohesive bandage, which makes up the fourth layer, was changed every three weeks. The layers are applied in a figure-of-eight with a 50% overlap at mid-stretch [6].

2 layer compression

Two-layer compression consists of a cohesive bandage on the second layer and an elastic crepe bandage on the first layer that gently adheres to the skin. The two layers that apply compression are breathable and light, keeping your skin comfortable and dry. The layers are applied in a figure-of-eight with a 50% overlap at mid-stretch [7].

Follow up

All patients were followed up for 6 months regarding: 1-Size 2- Shape (pigmentat).

Statistical Analysis

Microsoft Excel software is used to code, enter, and analyze data gathered over time, basic clinical examinations, laboratory tests, and outcome measurements. For analysis, the data were subsequently loaded into the Statistical Package for the Social Sciences (SPSS version 20.0) program. In accordance with the data type, qualitative variables were represented by numbers and percentages, while quantitative variables were represented by means ± standard deviations. The Chi square test (X2) was utilized to determine whether the differences were significant. quantifiable independent group differences as determined by the Mann Whitney or t test, combined with the sign test. For significant results, the P value was set at less than 0.05, and for very significant results, it was less than 0.001.

RESULTS

Table 1; showed that there was statistically non-significant difference between the studied groups regarding age or gender.

Table 2; revealed that there were no statistically significant differences between the groups under study in terms of smoking, comorbidities, prior vascular surgery history, or type of CVI. Regarding ulcer side, site, length, width, or surface area, there were no appreciable differences between the groups under study.

Table 3; demonstrated that the time it took for the groups under study to heal completely varied statistically significantly. By the end of the follow-up period, the majority of the patients in both groups had fully recovered (81% of the four layers compression group against 61.9% of the other group, with no discernible difference between them). Regarding the findings, there was no statistically significant difference between the groups under study.

Table 4; revealed that, in terms of the surface area of the ulcer before to compression technique and the size reduction on the third week of follow-up, The groups under investigation did not differ statistically, although there was a significant difference at the sixth, ninth, and twelfth weeks of followup. Both groups showed a statistically significant decrease in ulcer surface area over time, while the four layers compression group saw a larger decline.

Table 5; demonstrated that the negative effects of both compression strategies were not significantly different for the groups under study.

Table 6; revealed that the groups under study did not differ statistically in terms of their ability to withstand compression.

Figure 1 demonstrated a statistically significant positive relationship between the ulcer's duration, surface area, and time to full healing.

(1). Socio demographie characteristics among both studied groups							
		Studied groups with	Test	Р			
		N=42					
		Four layers Two layers					
		N (%)	N (%)				
	Gender:						
	Male	11 (52.4%)	9 (42.9%)	Fisher	0.211		
	Female	10 (47.6%)	12 (57.1%)				
	Age:			t-test			
	Mean ± SD	46.3 ± 9.18	45.8 ± 11.4	(0.712)	0.635		
	Range	25 – 55	20 - 50				

	Table (1): Socio-d	lemographic	characteristics	among both	studied g	roups
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Fisher=fisher exact test, t=independent sample t test

	Compression tec N=42	chnique			
Table	Four layers Tow layers		-X2	P	
	N (%)	N (%)			
Comorbidity:					
No	18 (85.7%)	16 (76.2%)	0.923	0.322	
Yes	3 (14.3%)	5 (23.8%)		NS	
Previous vascular					
operation:	19 (90.5%)	18 (85.7%)	0.898	0.252	
No	2 (9.5%)	3 (14.3%)		NS	
Yes					
Smoking:					
No	15 (71.4%)	14 (66.7%)	0.823	0.335	
Yes	6 (28.6%)	7 (33.3%)		NS	
CVI type:					
Primary	16 (76.2%)	13 (61.9%)	0.735	0.231	
Secondary	5 (23.8%)	8 (38.1%)		NS	
Ulcer characteristics					
Site:					
Left leg	15 (71.4%)	18 (85.7%)	0.763*	0.435	
Right leg	6 (28.6%)	3 (14.3%)		NS	
Side:					
Lateral	6 (28.6%)	4 (19%)	0.982*	0.515	
Medial	15 (71.4%)	17 (81%)		NS	
Ulcer length (cm):					
Mean ± SD	2.25 ± 0.86	2.17 ± 1.02	Ζ	0.324	
Median (Range)	3.2 (1.5-6.4)	3.5 (1-6.6)	1.23	NS	
Ulcer width (cm):					
Mean ± SD	1.85 ± 0.77	1.93 ± 0.64	Ζ	0.223	
Median (Range)	2.3 (1-5.5)	2.5 (1.5-5.6)	0.801	NS	
Ulcer surface area (cm ²):					
Mean ± SD	3.83 ± 1.33	3.21 ± 1.36	Ζ	0.125	
Median (Range)	4.45 (1.2-6.52)	3.75 (1-7.18)	0.961	NS	

Table (2): Comparison between the studied groups regarding past-history, risk factors and ulcer characteristics

Fisher: fisher exact test, *Chi-square test, Z: Mann-Whitney test, NS: P>0.05 is not statistically significant

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Table (3): Outcome of compression technique and Duplex findings among both studied groups.

	Compression technique N=42		Test	Р
	Four layers	Two layers	-	
	N=21 (%)	N=21 (%)		
Outcome				
Non-healing	4 (19.0)	8 (38.1%)	Fisher	0.389
Complete healing	17 (81.0%)	13 (61.9%)		NS
	N = 17	N = 13	t-test	
Duration to complete healing\w				
Mean ± SD	8.52 ± 2.89	12.92 ± 4.39	6.83	< 0.001
Range	6 – 12	10 - 16		HS
Duplex findings				
Venous reflux:				
No	6 (28.6%)	5 (23.8%)	F	1.0
SFJ	15 (71.4%)	16 (76.2%)		NS
Incompetent perforators	10 (47.6%)	8 (38.1%)	F	0.781
				NS

Fisher: fisher exact test, t independent sample t test, S: $P \le 0.05$ is statistically significant2 **Table (4):** Change in ulcer surface areas over follow-up time among both studied groups.

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	Compression technique N=42		Z	Р		
	Four layers Two layers					
	Mean ± SD	Mean ± SD				
Before compression	3.83 ± 1.33	3.22 ± 1.36	0.961	0.125 NS		
At 3 rd week	2.5 ± 0.98	3.01 ± 1.31	1.98	0.065 NS		
At 6 th week	1.63 ± 0.43	2.61 ± 1.01	-2.28	0.023 S		
At 9 th week	0.95 ± 0.42	1.79 ± 0.45	3.37	0.012 S		
At 12 th week	0.19 ± 0.27	0.49 ± 0.58	2.94	0.045 S		
P (Friedman test)	0.001 HS	0.04 S				

S: P<0.05 is statistically significant, HS: $P \le 0.001$ is highly significant, NS: P>0.05 is not significant Z Mann-Whitney test

Table (5): Adverse effect of compression technique among both studied groups

	Compression technique	X2	Р					
	N=42							
	Four layers Two layers							
	N (%)	N (%)						
No	15 (71.4%)	12 (57.1%)	0.819	0.524 NS				
Infection	1 (4.8%)	4 (19.1%)	F	0.343				
Itching	4 (19.1%)	1 (4.8%)	F	0.343				
Oozing	1 (4.8%)	4 (19].1%)	F	0.343				

F: Fisher exact test, x^2 : Chi-square test, NS: P>0.05 is not significant

Table (6): Tolerability to compression techniques among both studied groups.

Tolerability	Compression technique		Test	Р
	N=42			
	Four layers	Two layers		
	N (%)	N (%)		
Comfortable	18 (85.7%)	20 (95.2%)		
Non-comfortable	3 (14.3)	1 (4.8%)	Fisher	0.586 NS

F: Fisher exact test, NS: P>0.05 is not significant



Figure (1): Correlation between duration to complete healing and some of the studied parameters.

Case presentation

Case 1; Group (A): revealed a 50-year-old man's ulcer in the lateral region of his right leg, which was treated with four layers of compression bandages and had six inadequate perforators. The ulcer's measurements at the initial visit were 3 x 2 cm, or 4.71 cm². The ulcer measured 1.3 x 1.2 cm, formula = 1.2 cm², six weeks after compression. Formula =

0 indicates that the ulcer fully healed 12 weeks after compression.

Case 1; Group (B): demonstrates the 29year-old male patient's main venous ulcer in the left leg's lateral aspect, which has g4 incompetent perforators. Two layers of compression bandages were applied as treatment: The ulcer's measurements during the initial visit were 2.1 x 1.4 cm, or 2.2 cm². The ulcer measured 0.5 x 0.5 cm six weeks after compression. 0.19 cm² in size. The ulcer fully healed following 12 weeks of compression.

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1st visit to out patient clinic

After 6 weeks of 4 layers compression

After 9 weeks of 4 layers compression

Case (1) Group (A): The ulcer at the first visit it measured 3x2 cm, formula = 4.71cm². The ulcer after 6 wks post compression, it measured 1.3x1.2 cm, formula = 1.2 cm². The ulcer after 12 wks post compression, the ulcer completely healed, formula= zero.



1st visit at out patient clinic

After 6 weeks of 2 layers compression

After 12 weeks of 2 layers compression

Case (1) Group (B): demonstrates the 29year-old male patient's main venous ulcer in the left leg's lateral aspect, which has g4 incompetent perforators. Two layers of compression bandages were applied as treatment: The ulcer's measurements during

DISCUSSION

The gender disparities between the groups under investigation in our study are statistically not significant, and our findings are in contrast to those of investigations by Probst et al. [3] who found a higher prevalence of venous ulcers in female. And Shah et al. [6] revealed a male preponderance; the discrepancy in these results may be due to our study's smaller sample size. the initial visit were 2.1 x 1.4 cm, or 2.2 cm². The ulcer measured 0.5 x 0.5 cm six weeks after compression. 0.19 cm^2 in size. The ulcer fully healed following 12 weeks of compression.

The majority, according to data analysis for the age group, were between the ages of 20 and 55. According to our research Shah et al. [6] He discovers that 40 out of 100 fall into the age range of 31 to 45. and disapproval of a study carried out by Berenguer Pérez et al. [8] said that after the age of 65, the prevalence of venous leg ulcers (VLU) rises. This disparity may result from the fact that the working-class population in our nation, which includes those aged 20 to 55, is the most frequently impacted by long commutes, job, and the necessity to support their families at the expense of their own health.

There are statistically insignificant differences between the groups in our study with respect to smoking, comorbidities, prior vascular surgery history, and CVI type. Additionally, there were no discernible group differences or connections between the venous ulcer and other long-term conditions such diabetes or hypertension [9].

Our examination of the total number of follow-ups needed for both patient groups showed that most patients who received a four-layer bandage for VLU required more than four weeks of follow-up. However, all patients with a two-layer bandage required longer than four weeks for the ulcer to completely heal; this difference between the two groups was statistically significant (8.52 ± 2.89 for the four-layer group vs. 12.92 ± 4.39 for the twolayer group, p <0.001HS). These results were compared to studies carried by Shah et al. [6] claimed that, with a p-value of less than 0.001, the four-layer group needed substantially fewer followups (mean = 4.88) than the two-layer group (mean = 6.46).

Conversely, Shah et al. [6] discovered that the average time needed for the venous ulcer to completely close in all patients was 51.4±15 days; this time difference between the two groups was statistically significant (48.9±13.9 not vs. 54.3±15.1, P=0.438), Franks et al.[10] claimed that there was no discernible difference in healing between the two randomized groups, with 56% of them having healed after 12 weeks based on the bandaging technique used. This increased to 85% in the 4LB group after 24 weeks, while it was 83% in the 2LB group.

According to our research, the majority of patients in both groups had fully recovered by the end of the follow-up period (81% of the four layers compression group versus 61.9% of the other group; p = 0.389 NS), with no discernible difference between the two groups study Moffatt, et al [11]. According to Shan et al. [6], the study participants who were randomly allocated to the four-layer bandage system with follow-up reported ulcer closure in 88% of cases, compared to 77% of patients on the two-layer bandage. The four-layer group also required significantly fewer follow-ups than the two-layer group.

Gillet et al. disagreement in his complete analysis set (n = 88), he found that the two-layer bandage represents a viable alternative therapy in the management of venous leg ulcers based on its clinical efficacy, safety, and acceptability with potential benefits for lowering healthcare costs.

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The two-layer group showed a complete healing rate of 48.9%, while the four-layer group showed a rate of 24.4% [12].

Although Ashby et al. [13] found no evidence of a difference in reference ulcer healing rates between the two layer and four layer bandage groups, we conclude that the For venous leg ulcers, four-layer bandaging necessitates a much smaller number of follow-up visits than two-layer bandaging. Complete wound closure was attained in 48% and 38% of the 2 and 4 layer groups, respectively, according to Gillet et al.'s [12] analysis, confirming the 2LB system's non-inferiority in comparison to the 4LB method. The proportion of ulcers healing was similar between the two layer group (71%) and the four layer group (70%).

The results of Shan B et al. [6] Additionally, there was no discernible difference between the two groups' Doppler findings; 15 patients in the 4 layer group and 16 in the 2 layer group had incompetent SFJ; 10 patients in the 4 layer group and 8 patients in the 2 layer group had multiple incompetent perforators; 17 patients in the 4 layer group and 11 patients in the 2 layer group had incompetent SFJ; and multiple incompetent perforators were found in 12 patients in the 4 layer group and 20 patients in the 2 layer group.

The findings of our investigation showed that the groups' tolerance to compression varied statistically not significantly (p=0,58). Contrary to our research Gillet et al. [12], (Lazareth et al [9] and Jünger et al [14] In terms of comfort and tolerability, the two-layer system outperformed the four-layer system due to its ease of use, simplicity of application, and reduced bulk. However, Moffatt et al. [11] showed that patients had a larger percentage of patients whose ulcers closed during their randomized therapy because they tolerated the 4LB better than the 2LB and experienced considerably fewer treatment withdrawals.

There was no discernible difference between the groups in the overall number of adverse events (p=.53), which contradicts our findings Goka et al. [15] discovered that the two-layer group experienced one or more adverse events at a higher rate than the four-layer group (154/230, or 67%) compared to 130/224, or 58%; p=0.05). while Lazareth et al. [9] indicate that the two-layer bandage had a 17% adverse event incidence, while the four-layer bandage had a 25% incidence (p=0.99). Moffatt et al. The two-layer bandaging system had a significantly larger percentage of patients who had at least one device-related adverse incident (15 out of 54; 28%) than the fourlayer bandaging system (5 out of 54; 9%), suggesting that the latter has a higher frequency of adverse events (p = 0.01) [11].

Conclusion

A four-layer bandage is more effective at promoting healing and decreasing the size of the ulcer area than a two-layer one. Despite the fact that the four-layer bandage group healed the ulcer faster, further analyses show that the 2LB approach is not inferior to the 4LB system.

Conflict of interest

The authors declare no conflict of interest.

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