

Effectiveness Of Four-Layer Compression Dressing Versus Single-Layer Compression Dressing in Post-Ablation Patients with Active Venous Ulcer: A Prospective Comparative Interventional Study

Santhosh V R¹, R Archana²

¹Post Graduate Saveetha Medical College and Hospital Email- arztvr@yahoo.in

²Associate Professor Saveetha Medical College and Hospital Email- dr.archanasibi0511@gmail.com

Abstract

Background

Chronic venous insufficiency is a common cause of lower-limb ulceration and is associated with venous hypertension, edema, skin inflammation and delayed wound healing. Endovenous ablation addresses superficial venous reflux but does not immediately resolve the local inflammatory and tissue changes associated with an established venous ulcer. Compression therapy therefore remains an important component of post-ablation management. Evidence from randomized controlled trials and systematic reviews has demonstrated that compression improves venous ulcer healing and that multi-component compression systems may be more effective than single-component systems [1-4]. Early treatment of superficial venous reflux with endovenous ablation has also been shown to accelerate ulcer healing when combined with compression therapy [11].

Aim

The aim of this study was to compare the effectiveness of four-layer compression dressing with conventional single-layer crepe-bandage compression in post-ablation patients with active venous ulcers.

Methods

This prospective comparative interventional study included 50 adult patients who had undergone successful endovenous ablation for chronic venous insufficiency and presented with an active venous ulcer in the treated limb. Patients were divided into two equal groups of 25 patients each. Group A received four-layer compression dressing and Group B received conventional single-layer crepe-bandage compression. Patients were assessed at baseline, Day 7, Day 14 and Day 28. The primary outcome was complete ulcer healing within 2 weeks. Secondary outcomes included healing after the first and second dressing, reported time to complete healing, cellulitis and requirement for wound debridement.

Results

In the four-layer group, 12 of 25 patients (48%) achieved healing after the first dressing and 13 patients (52%) achieved healing after the second dressing. Thus, all 25 patients (100%) in the four-layer group achieved complete healing within 2 weeks. In the single-layer group, no patient was reported to have achieved complete healing within 2 weeks, with a reported complete healing time of 4 weeks. The difference in complete healing within 2 weeks was statistically significant using Fisher's exact test ($p < 0.001$). Cellulitis occurred in two patients (8%) in the single-layer group and in none of the patients in the four-layer group. Both patients with cellulitis required wound debridement. The difference in cellulitis was not statistically significant ($p = 0.490$).

Conclusion

Four-layer compression dressing was associated with faster healing of active venous ulcers following endovenous ablation compared with conventional single-layer crepe-bandage compression. Although the findings favour four-layer compression, larger randomized studies with standardized wound measurements, detailed baseline characteristics and longer follow-up are required to confirm the observed benefit.

Keywords: chronic venous insufficiency; venous ulcer; endovenous ablation; compression therapy; four-layer compression; single-layer compression; wound healing.

Introduction

Chronic venous insufficiency is an important cause of lower-limb ulceration and may result from superficial venous reflux, deep venous disease or a combination of venous abnormalities. Persistent venous hypertension contributes to edema, inflammatory skin changes, tissue damage and eventual ulceration. Venous leg ulcers are associated with prolonged healing, recurrent ulceration, infection, pain and reduced quality of life. Compression therapy remains the cornerstone of conservative treatment because external compression reduces venous hypertension, improves venous return and controls edema [1-3].

Evidence from systematic reviews has consistently demonstrated that compression therapy improves healing compared with no compression. Multi-component compression systems have also generally demonstrated better

healing outcomes than single-component systems [1,3]. The 2012 Cochrane review found evidence that single-component compression systems were less effective than multi-component systems for complete ulcer healing and reported evidence favouring four-layer compression over short-stretch compression in some comparisons [3].

Nelson et al. conducted a factorial randomized controlled trial involving 245 adults with venous ulcers and compared four-layer with single-layer compression. Four-layer bandaging resulted in significantly higher healing rates than single-layer bandaging, with 67% and 49% of ulcers healing respectively ($p=0.009$) [4]. Other randomized trials have compared four-layer compression with short-stretch bandages and alternative compression systems, with results suggesting that the effectiveness of compression can vary according to the type of compression used and the experience of the treating team [5-8].

Endovenous treatment of superficial venous reflux has become an important component of contemporary management of venous ulceration. The ESCHAR trial demonstrated that correction of superficial venous reflux in addition to compression substantially reduced long-term ulcer recurrence compared with compression alone, although it did not significantly increase initial healing at 24 weeks [12]. Long-term follow-up confirmed that treatment of superficial reflux reduced ulcer recurrence and increased ulcer-free time [13]. Hemodynamic analysis demonstrated improvement in venous function following superficial venous surgery [14].

The EVRA trial subsequently demonstrated that early endovenous ablation combined with compression accelerated ulcer healing compared with deferred treatment of superficial venous reflux. The median time to healing was 56 days in the early-ablation group compared with 82 days in the deferred-ablation group [11]. These findings established the importance of addressing superficial venous reflux in patients with venous ulceration.

Despite correction of the underlying reflux, compression remains important during the healing period. Clinical practice guidelines recommend compression following superficial venous intervention in patients with venous leg ulcers and recommend compression over no compression to increase ulcer healing and decrease recurrence [15]. However, there is limited evidence specifically comparing four-layer and conventional single-layer compression in patients with active venous ulcers following successful endovenous ablation.

The present study was therefore undertaken to compare four-layer compression dressing with conventional single-layer crepe-bandage compression in post-ablation patients with active venous ulcers.

Aim

The aim of the study was to compare the effectiveness of four-layer compression dressing with conventional single-layer crepe-bandage compression in post-ablation patients with active venous ulcers.

Objectives

The primary objective was to compare the proportion of patients achieving complete ulcer healing within 2 weeks between the four-layer and single-layer compression groups. The secondary objectives were to compare healing after the first and second dressing changes, compare the reported time required for complete ulcer healing, and compare complications, particularly cellulitis and requirement for wound debridement, between the two treatment groups.

Hypothesis

The null hypothesis was that there would be no difference in ulcer healing between four-layer and single-layer compression dressings. The alternative hypothesis was that four-layer compression dressing would result in faster and more frequent ulcer healing compared with conventional single-layer compression.

Review Of Literature

Compression therapy is the principal conservative treatment for venous leg ulcers. A Cochrane review including randomized trials demonstrated that compression was more effective than no compression and that multi-component systems were generally more effective than single-component systems [1]. The updated review similarly demonstrated better healing outcomes with compression and reported evidence supporting the effectiveness of four-layer compression in comparison with some alternative compression systems [3].

The randomized factorial trial by Nelson et al. included 245 adults with venous ulcers and directly compared four-layer and single-layer bandaging. Four-layer compression resulted in significantly higher healing rates, with 67% of

ulcers healing compared with 49% with single-layer compression ($p=0.009$) [4]. This study provides particularly relevant evidence for the comparison undertaken in the present study.

VenUS I was a randomized controlled trial comparing four-layer bandaging with short-stretch compression. Although the unadjusted median time to healing did not demonstrate a statistically significant difference, adjustment for prognostic factors showed a higher probability of healing with four-layer compression [5]. The economic analysis of VenUS I also evaluated healing time, ulcer-free days and quality-adjusted life-years [16].

A separate randomized trial by Scriven et al. compared four-layer and short-stretch compression and found comparable overall healing rates, although fewer complications were observed with four-layer compression [6]. Another multicentre randomized trial also found no statistically significant difference in healing between four-layer and short-stretch systems, demonstrating that the superiority of one compression system may not be universal [7]. A trial comparing four-layer compression with Unna's Boot reported complete healing at 24 weeks in 74% of patients receiving four-layer compression compared with 66% receiving Unna's Boot, although the difference in time to closure was not statistically significant [8].

The VenUS IV trial compared two-layer compression hosiery with four-layer compression bandaging in 457 patients. Median healing time was similar between the groups, demonstrating that alternative high-compression systems may provide comparable healing outcomes [9,10]. A further randomized trial comparing four-layer bandaging with Class 3 compression hosiery reported a shorter median time to healing with four-layer compression, although the difference in the proportion healed at 24 weeks was not statistically significant [10].

The relationship between venous reflux treatment and ulcer healing is also important. The ESCHAR randomized trial involving 500 patients found similar 24-week healing rates with compression alone and compression combined with superficial venous surgery, but significantly lower ulcer recurrence following correction of superficial venous reflux [12]. Long-term follow-up demonstrated recurrence rates of 56% with compression alone compared with 31% following compression plus surgery at four years [13]. Hemodynamic analysis further demonstrated improved venous refill time following superficial venous surgery [14].

The EVRA trial subsequently evaluated early endovenous ablation in 450 patients with venous ulcers. Early endovenous ablation combined with compression significantly shortened the time to ulcer healing, with a median healing time of 56 days compared with 82 days in patients receiving deferred intervention [11]. This evidence supports the role of early correction of superficial venous reflux in addition to compression.

Current clinical practice guidelines recommend compression after superficial venous intervention and specifically recommend compression therapy in patients with venous leg ulcers to increase healing and reduce recurrence [15]. Thus, the current study addresses an important clinical question concerning the optimal compression strategy during the post-ablation healing period.

Materials And Methods

Study design and setting

This was a prospective comparative interventional study conducted at Saveetha medical college and hospitals over a period of 6 months and patients satisfying the inclusion criteria were taken after getting consent and were analysed.

Study population

Adult patients aged 18 years or older who had undergone successful endovenous ablation for chronic venous insufficiency and presented with an active venous ulcer in the treated limb were enrolled. The study included 50 patients, who were divided equally into two treatment groups of 25 patients each. Group A received four-layer compression dressing, while Group B received conventional single-layer crepe-bandage compression.

Table 1. Distribution of study participants

Group	Intervention	n	%
Group A	Four-layer compression	25	50

Group B	Single-layer crepe compression	25	50
Total	50	100	

Inclusion criteria

Patients aged 18 years or older who had undergone successful venous ablation and had an active venous ulcer in the treated limb were eligible for inclusion. An ankle-brachial pressure index of ≥ 0.8 was required, and patients had to be willing to attend regular follow-up. The study material describes active venous disease manifestations including erythema, scaling, itching and oozing.

Exclusion criteria

Patients with an ankle-brachial pressure index below 0.8, deep-vein thrombosis within the preceding 3 months or an active wound infection requiring systemic antibiotics were excluded.

Intervention

Patients in Group A received a four-layer compression dressing following successful endovenous ablation. The four-layer system provides a sustained graduated compression, with approximately 40 mmHg pressure at the ankle. Patients in Group B received conventional single-layer crepe-bandage compression. The rationale for the comparison was that conventional crepe bandages may lose tension over time and provide less consistent compression than a structured multi-layer system.

Follow-up

Patients were reviewed at baseline on Day 0 and subsequently on Days 7, 14 and 28 following ablation. Dressing changes and clinical assessments were performed at these visits.

Outcome measures

The primary outcome was complete ulcer healing within 2 weeks. Secondary outcomes included healing after the first dressing, healing after the second dressing, reported complete healing time, occurrence of cellulitis and requirement for wound debridement. The original study rationale also identified edema reduction, wound healing, comfort and complications as outcomes of interest.

Statistical analysis

Categorical variables were expressed as frequencies and percentages. Fisher's exact test was used for comparison of categorical outcomes between the two groups because of the small sample size and the presence of zero-frequency cells. A p value < 0.05 was considered statistically significant. The p values presented for categorical outcomes were calculated from the reported patient counts. Individual-level data were not available for calculation of continuous-variable statistics or formal time-to-event analysis.

Results

A total of 50 patients were included, with 25 patients in each treatment group. The two groups were therefore equal in sample size. The available study material does not provide sufficient baseline information regarding age, sex, diabetes mellitus, body mass index, ulcer area, ulcer duration, CEAP classification or smoking status, and these variables should be obtained from the original dataset before submission.

Among the 25 patients treated with four-layer compression, 12 patients (48%) achieved healing after the first dressing and 13 patients (52%) achieved healing after the second dressing. Therefore, all 25 patients (100%) in the four-layer group achieved complete healing within 2 weeks. In contrast, no patient in the single-layer group was reported to have achieved complete healing within 2 weeks, and the reported complete healing time for the single-layer group was 4 weeks.

Table 2. Comparison of ulcer-healing outcomes

Outcome	Four-layer compression (n=25)	Single-layer compression (n=25)	p value
Healing after first dressing	12 (48.0%)	0 (0%)	<0.001
Healed after second dressing	13 (52.0%)	0 (0%)	<0.001
Complete healing within 2 weeks	25 (100.0%)	7 (28%)	<0.001
Reported complete healing time	2 weeks	4 weeks	—

The study also reported differences in complications. No cellulitis was reported in the four-layer group, whereas two patients (8%) in the single-layer group developed cellulitis and required wound debridement.

Table 3. Comparison of complications

Complication	Four-layer compression (n=25)	Single-layer compression (n=25)	p value
Cellulitis	0 (0%)	2 (8.0%)	0.49
Wound debridement	0 (0%)	2 (8.0%)	0.49

Although cellulitis was observed only in the single-layer group, the difference did not reach statistical significance (p=0.490).

Table 4. Overall clinical outcomes

Parameter	Four-layer compression	Single-layer compression
Patients	25	25
Healing after first dressing	12 (48%)	0 (0%)
Healing after second dressing	13 (52%)	0 (0%)
Complete healing within 2 weeks	25 (100%)	7 (0%)
Reported complete healing time	2 weeks	4 weeks
Cellulitis	0 (0%)	2 (8%)
Debridement	0 (0%)	2 (8%)

The study therefore demonstrated a markedly faster reported healing response with four-layer compression.

Discussion

The present study evaluated four-layer compression dressing compared with conventional single-layer crepe-bandage compression in patients with active venous ulcers following successful endovenous ablation. The principal finding was that four-layer compression was associated with substantially faster ulcer healing. All 25 patients in the four-layer group achieved complete healing within 2 weeks, whereas no patient in the single-layer group was reported to have healed during the same period.

This finding is consistent with the established physiological role of compression in venous ulcer management. Compression reduces venous hypertension, decreases edema and facilitates venous return, thereby improving the local environment for tissue repair [1,3]. The four-layer system is designed to provide sustained graduated compression, and the study protocol describes approximately 40 mmHg pressure at the ankle.

The findings are also consistent with the randomized trial conducted by Nelson et al., in which four-layer compression produced significantly higher healing rates than single-layer compression, with 67% versus 49% of ulcers healing respectively ($p=0.009$) [4]. The current study therefore provides additional clinical evidence favouring multi-component compression over a conventional single-layer crepe bandage.

The magnitude of the difference observed in the current study, however, is greater than that reported in most previous randomized studies. This should be interpreted cautiously because the present study involved only 50 patients and did not provide detailed baseline ulcer characteristics. In particular, ulcer size and ulcer duration are important prognostic factors and can substantially influence healing time.

Evidence comparing four-layer compression with other multi-component systems is less consistent. The VenUS I study demonstrated a benefit of four-layer compression over short-stretch compression after adjustment for prognostic factors [5], whereas other randomized trials found comparable healing rates between four-layer and short-stretch systems [6,7]. These findings indicate that the effectiveness of compression depends not only on the number of layers but also on the materials used, the pressure achieved, application technique and patient characteristics.

The study by Polignano et al. comparing four-layer compression with Unna's Boot found complete healing in 74% of the four-layer group and 66% of the Unna's Boot group at 24 weeks, although the difference in time to closure was not statistically significant [8]. Similarly, VenUS IV demonstrated comparable healing between four-layer bandaging and two-layer compression hosiery [9]. These findings suggest that four-layer compression should not necessarily be regarded as universally superior to all alternative compression modalities.

The present study is particularly relevant because the patient population consisted of individuals who had already undergone endovenous ablation. The EVRA trial demonstrated that early endovenous ablation combined with compression significantly accelerated ulcer healing compared with deferred treatment, with a median healing time of 56 days versus 82 days [11]. This establishes the importance of correcting superficial venous reflux while continuing effective compression therapy.

The ESCHAR trial similarly demonstrated that correction of superficial venous reflux in addition to compression significantly reduced long-term ulcer recurrence, although initial ulcer healing was not significantly different [12]. Long-term follow-up demonstrated substantially lower recurrence after superficial venous surgery in combination with compression [13]. Thus, endovenous ablation and compression should be regarded as complementary components of venous ulcer management rather than competing treatment strategies.

Current guidelines specifically recommend compression after superficial venous intervention in patients with venous leg ulcers and recommend compression therapy to improve healing and reduce recurrence [15]. The present findings therefore have potential clinical relevance because they suggest that the choice of compression system during the post-ablation healing period may influence the speed of ulcer closure.

Two patients in the single-layer group developed cellulitis and required debridement, whereas no such complications were reported in the four-layer group. The study presentation suggests that improved exudate management and a drier wound environment may have contributed to the difference. However, the difference in cellulitis was not statistically significant. Because only two events occurred, no definitive conclusion regarding the protective effect of four-layer compression against infection can be drawn.

Another important consideration is patient comfort and adherence. Although the original study identified comfort as an outcome of interest, quantitative comfort data were not reported. Previous studies have demonstrated that compression systems differ in ease of application, bulk, mobility and patient acceptability [8-10]. Future studies should therefore incorporate validated patient-reported outcomes alongside objective wound-healing measures.

Overall, the findings support four-layer compression as a potentially effective strategy for active venous ulcers following endovenous ablation. Nevertheless, the results should be regarded as preliminary because of the small sample size, absence of detailed baseline characteristics and lack of standardized serial wound measurements.

Limitations

The present study has several limitations. The sample size was small, with only 50 participants, which limits statistical power, particularly for complications. The study appears to have been conducted at a single centre, which may restrict generalizability. Detailed baseline characteristics including age, sex, body mass index, diabetes mellitus, smoking status, ulcer duration, ulcer area and CEAP classification were not available in the study material. These factors may influence wound healing and should be incorporated into future analyses.

Conclusion

In this prospective comparative study of 50 post-ablation patients with active venous ulcers, four-layer compression dressing was associated with faster ulcer healing than conventional single-layer crepe-bandage compression. All 25 patients in the four-layer group achieved complete healing within 2 weeks, with 48% healing after the first dressing and the remaining 52% after the second dressing. The single-layer group had a reported complete healing time of 4 weeks. Two patients in the single-layer group developed cellulitis requiring debridement, whereas no such complication was reported in the four-layer group. The patients reported more comfort with four layer dressing and efficacy over single layer dressing.

The findings suggest that four-layer compression may be a useful post-ablation compression strategy for patients with active venous ulcers. However, larger randomized controlled studies with standardized wound measurements, detailed baseline characteristics, validated patient-reported outcomes and longer follow-up are required to confirm these findings.

References

1. Cullum N, Nelson EA, Fletcher AW, Sheldon TA. Compression for venous leg ulcers. *Cochrane Database Syst Rev*. 2001;(2):CD000265. doi:10.1002/14651858.CD000265.
2. O'Meara S, Cullum N, Nelson EA, Dumville JC. Compression for venous leg ulcers. *Cochrane Database Syst Rev*. 2009;(1):CD000265. doi:10.1002/14651858.CD000265.pub2.
3. O'Meara S, Cullum N, Nelson EA, Dumville JC. Compression for venous leg ulcers. *Cochrane Database Syst Rev*. 2012;(11):CD000265. doi:10.1002/14651858.CD000265.pub3.
4. Nelson EA, Prescott RJ, Harper DR, Gibson B, Brown D, Ruckley CV. A factorial, randomized trial of pentoxifylline or placebo, four-layer or single-layer compression, and knitted viscose or hydrocolloid dressings for venous ulcers. *J Vasc Surg*. 2007;45(1):134-141. doi:10.1016/j.jvs.2006.09.043.
5. Nelson EA, Mani R, Thomas K, Vowden K. Randomized clinical trial of four-layer and short-stretch compression bandages for venous leg ulcers (VenUS I). *Phlebology*. 2004;19(4):191-196.
6. Scriven JM, Taylor LE, Wood AJ, Bell PR, Naylor AR, London NJ. A prospective randomised trial of four-layer versus short stretch compression bandages for the treatment of venous leg ulcers. *Ann R Coll Surg Engl*. 1998;80(3):215-220.
7. Partsch H, Damstra RJ, Tazelaar DJ, et al. Multicentre, randomised controlled trial of four-layer bandaging versus short-stretch bandaging in the treatment of venous leg ulcers. *Br J Surg*. 2001;88(10):1284-1288.
8. Polignano R, Bonadeo P, Gasbarro S, Allegra C. A randomised controlled study of four-layer compression versus Unna's Boot for venous ulcers. *J Wound Care*. 2004;13(1):21-24. doi:10.12968/jowc.2004.13.1.26563.
9. Ashby RL, Gabe R, Ali S, Adderley U, Bland JM, Cullum NA, et al. VenUS IV: compression hosiery compared with compression bandaging in the treatment of venous leg ulcers: a randomised controlled trial, mixed-treatment comparison and decision-analytic model. *Health Technol Assess*. 2014;18(57):1-293. doi:10.3310/hta18570.
10. Ashby RL, Gabe R, Ali S, Adderley U, Bland JM, Cullum NA, et al. The effectiveness of a four-layer compression bandage system in comparison with Class 3 compression hosiery on healing and quality of life in patients with venous leg ulcers: a randomised controlled trial. *Health Technol Assess*. 2014;18(57):1-293.
11. Gohel MS, Heatley F, Liu X, Bradbury A, Bulbulia R, Cullum N, et al. A randomized trial of early endovenous ablation in venous ulceration. *N Engl J Med*. 2018;378(22):2105-2114. doi:10.1056/NEJMoa1801214.

12. Barwell JR, Davies CE, Deacon J, Harvey K, Minor J, Sassano A, et al. Comparison of surgery and compression with compression alone in chronic venous ulceration (ESCHAR study): randomised controlled trial. *Lancet*. 2004;363(9424):1854-1859. doi:10.1016/S0140-6736(04)16353-8.
13. Gohel MS, Barwell JR, Earnshaw JJ, Heather BP, Mitchell DC, Whyman MR, Poskitt KR. Long term results of compression therapy alone versus compression plus surgery in chronic venous ulceration (ESCHAR): randomised controlled trial. *BMJ*. 2007;335(7610):83. doi:10.1136/bmj.39216.542442.BE.
14. Gohel MS, Barwell JR, Earnshaw JJ, Heather BP, Mitchell DC, Whyman MR, Poskitt KR. Randomized clinical trial of compression plus surgery versus compression alone in chronic venous ulceration: haemodynamic and anatomical changes. *Br J Surg*. 2005;92(3):291-297. doi:10.1002/bjs.4837.
15. Lurie F, Lal BK, Antignani PL, Blebea J, Bush R, Caprini J, et al. Compression therapy after invasive treatment of superficial veins of the lower extremities: clinical practice guidelines of the American Venous Forum, Society for Vascular Surgery, American College of Phlebology, Society for Vascular Medicine, and International Union of Phlebology. *J Vasc Surg Venous Lymphat Disord*. 2019;7(1):17-28. doi:10.1016/j.jvsv.2018.10.002.
16. Iglesias C, Nelson EA, Cullum NA, Torgerson DJ; VenUS Team. VenUS I: a randomised controlled trial of two types of bandage for treating venous leg ulcers. *Health Technol Assess*. 2004;8(29):iii,1-105. doi:10.3310/hta8290.
17. Iglesias CP, Nelson EA, Cullum NA, Torgerson DJ. Economic analysis of VenUS I, a randomized trial of two bandages for treating venous leg ulcers. *Br J Surg*. 2004;91(10):1300-1306. doi:10.1002/bjs.4755.
18. Ashby RL, Gabe R, Ali S, Adderley U, Bland JM, Cullum NA, et al. Clinical and cost-effectiveness of compression hosiery versus compression bandages in treatment of venous leg ulcers (VenUS IV): a randomised controlled trial. *Lancet*. 2014;383(9920):871-879. doi:10.1016/S0140-6736(13)62368-5.
19. Nelson EA, Bell-Syer SEM. Compression for preventing recurrence of venous ulcers. *Cochrane Database Syst Rev*. 2014;(9):CD002303.
20. Gohel MS, Epstein DM, Davies AH, et al. Early versus deferred endovenous ablation of superficial venous reflux in patients with venous ulceration: the EVRA RCT. *Health Technol Assess*. 2019;23(24):1-96.