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Original article

Compression Therapy for the Treatment of Venous Leg Ulcers: A Clinical Study

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Abstract:

Background: Venous leg ulcers (VLUs) are described as open lesions that develop between the knee and ankle joint in the presence of venous illness. This study's objective was to detect compression therapy influence on active VLUs healing in chronic VLUs patients. **Methods:** This study was carried out on a group of 50 patients who were treated with compression therapy. Patients were subjected to diagnostic duplex ultrasound assessment, the lower extremity deep and superficial venous systems, either unilateral or bilateral (according to the patient complaint) were examined by an imaging specialist using 7.5-9 MHz linear probe. **Results:** 25 to 65 years old was the age range with a mean ± SD of 42.9 ± 12.05 years. There were 20 (40%) males and 30 (60%) females. The median ulcer area was 80.5 with an IQR of 34.25 – 134. Ulcer duration ranged from 4 to 7 with a mean ± SD of 5.5 ± 1.22. Regarding healing, 2 (4%) patients achieved no healing, 5 (10%) patients achieved incomplete healing and 43 (86%) patients achieved complete healing. Regarding quality of life, 24 (48%) patients had negative quality of life, no patients had hematoma, 10 (20%) patients had delayed mobilization and 16 (32%) patients had pain. **Conclusions:** Treatment for VLU that is remarkably efficient is compression therapy. When using this treatment approach with VLUs, caution should be used. From the perspective of clinical treatment, research shows that compression systems are successful in helping patients recuperate, and a four-layer system may yield a positive outcome.

Keywords: Healing, Venous Leg Ulcers, Compression Therapy.

Introduction

VLUs are characterised as open lesions that develop between the knee and ankle joint when venous illness is present. They contribute to 60–80% of leg ulcers, making them the most prevalent aetiology. Between 0.18 percent and 1 percent of people have VLUs. When you reach 65 years old, the prevalence rises to 4%. They are known as chronic VLUs because, on average, 33–60% of these ulcers last longer than 6 weeks. These ulcers are the most severe manifestation of CVD like lipodermatosclerosis and varicose veins (1).

High venous pressure, turbulent flow, and insufficient venous return are the main causes of VLUs. The latter may result from venous reflux or venous blockage. The following are risk factors for developing CVD: recreational injectable drugs usage, phlebitis, primary venous system destruction (such as a history of deep venous thrombosis), venous valvular dysfunction and poor venous return due to underlying conditions (such as congestive heart failure and obesity) (2).

The two goals of venous ulcer therapy are to cure the ulcer and prevent a reoccurrence. When first-line methods fail, many second-line therapies can be attempted, but there is no universally approved second-line treatment standard. The conventional first-line clinical therapy is compression and debridement (3).

Compression stockings are the cornerstone of medical therapy for chronic venous insufficiency, whether it manifests as varicose veins or venous ulcers. The pressure amount created determines how successful compression therapy is, especially for treating ulcers. Severe venous disease typically requires high pressures. Although compression treatment has been found to increase the recovery rates of venous ulcer patients, relatively little is known about the pressures produced by the ready-to-wear compression stockings that patients are advised to use (4).

Four-layer bandage treatments heal 68–83 percent of wounds in 24 weeks, however they are known to have significant reoccurrence rates. Thus, early surgical repair of superficial venous reflux has been researched as a way to hasten ulcer recovery and prevent relapse. Nevertheless, the outcomes of open and endovenous treatments for incompetent great and short saphenous veins, and also perforator surgery, have been assessed in venous ulcers (5).

This study aimed to detect compression therapy influence on active VLUs healing in chronic VLUs patients.

Patients and Methods

This prospective clinical study was conducted on 50 patients undergoing treatment for lower limb venous problems (ulcers) in the General Surgery Department at Benha University Hospitals and El Matarya Teaching Hospital from 2018 to 2022 and they were treated with compression therapy to detect its

influence on active VLUs healing in chronic VLUs patients.

This study was done after approval by the institutional ethical committees and patients were informed about the study treatment modalities explained & informed consents were also obtained.

Inclusion criteria were Patients complaining of lower limb venous, active leg ulcers of venous aetiology, Ankle Brachial Pressure Index ≥0.8 and <1.3, Ulcer size of ≥1 cm^2.

The largest ulcer was chosen as the study's target ulcer when there were many ulcers detected.

Exclusion criteria were patients with DVT, severe peripheral arterial disease, vasculitis, and pregnancy.

All patients were subjected to a) Full history taking (Age, gender, medical comorbidities, and smoking), Onset and course of the ulcer, History of recurrent venous ulcers, History of recent DVT. b) Clinical examination: General examination, local examination of venous ulcer pointing to presence of ulcers at the gaiter area (C6), number and size of the ulcers, skin around ulcer, edges, floor of the ulcer and signs of inflammation or dermatitis. c) Investigations: routine laboratory investigations: complete blood picture, random blood sugar, prothrombin time, activity and INR.

Other findings that should be looked for are dermatitis and oedema related to lipo-dermatosclerosis and hyperpigmentation correlated with normal adipose tissue thickening and fibrosis under skin.

The patient is evaluated using a clinical severity score dependent on CEAP (anatomy, pathophysiology, clinical and aetiology). A classification system could direct how CVDs are evaluated. Patients with active, chronic ulcers (lasting longer than six months) received the highest CEAP severity score.

With the patient upright, the venous system's anatomy and pathophysiology were defined using duplex ultrasound scanning (TITAN; SonoSite, Bothell, Washington) to assess reflux in the superficial, deep, and perforating veins. As a benchmark, the linear array probe 5–10 MHz (Sonosite, L38) was employed. We employed the 5-2 MHz transducer, curved array to assess the deep veins, particularly in obese individuals (Sonosite, C60). The wall filter was adjusted to its lowest setting, and the Doppler range was set to 9 cm/s. To guarantee optimal sensitivity, the Doppler gain was raised. In order to assess the iliofemoral and saphenofemoral reflux, a Valsalva manoeuvre was employed.

By manually compressing and releasing the calf or foot, the popliteal vein, saphenopopliteal junction, and the perforators were examined. Reflux times greater than 0.5 seconds were deemed noteworthy. The popliteal and femoral veins were shut off at 0.5 seconds. A perforator's bidirectional flow was interpreted as a sign of its inefficiency. Pascal's law of elementary physics states that the pressure depends on the pressure gradient but not on the vessel's diameter. To remove proximal blockages, deep veins with reflux, lingering thrombi, or intraluminal septa were avoided. We evaluated the physiological modifications to flow velocity that femoral vein spontaneously produces. GSV.

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Tributaries leading to the contralateral saphenofemoral vein or pelvic veins ("spontaneous palma-like shunt").

Patients were subjected to diagnostic duplex ultrasound assessment, lower extremity deep and superficial venous systems, either unilateral or bilateral (according to the patient complaint) will be examined by an imaging specialist using 7.5-9 MHz linear probe.

Imaging:

Duplex scanning with comment on competency of SFJ, SPJ& perforators, patency & competency of deep venous system up to iliac vein and reflux from deep system to superficial system.

Procedures: Compression therapy.

Technique of compression therapy:

A soft wool bandage serves as the first layer of protection for the chin bine and ankle's bony points. The second layer was made of a crepe bandage. An elasticized bandage with compression was inserted as the third layer. The fourth layer adds more compression and secures the entire bandage. Conservative measures include compression therapy, elevation of leg and dressing of nicer. Only after the arteries have been evaluated by evaluating the ankle-brachial index should compression be used. This is because compression might harm the ulcer and the leg if the IHC arteries are severely damaged. could aggravate the disease. It would be excruciatingly painful. The leg and the ulcer should be completely cleaned prior compression is used, and the ulcer should be dressed simply with a dry, non-adherent dressing. The compression system is then chosen after measuring the ankle circumference. A soft wool bandage serves as the first layer of protection for the ankle and chin bone's bony points. The second layer is covered with a crepe bandage. An elastic bandage that will exert compression makes up the third layer. The fourth and final layer holds all of the bandages in place while adding additional compression.

Instruments and measures:

The following techniques were used to gauge the progress of wound recovery: Using a portable digital planimetry instrument, ulcer areas and percentage area decrease were estimated from acetate wound tracings. By measuring area, exudate, and the kind of tissue in the wound bed, the Pressure Ulcer Scale for Healing (PUSH) instrument for wound repair provides a more comprehensive assessment of recovery than just looking at the area (i.e., epithelial, granulating, slough or necrotic). Additionally, clinical information about the state of the wound's healing, such as the existence of oedema, eczema, inflammation, and infection symptoms, was gathered.

QL measures included:

QL Index: The five components that make up the QL Index, which was created for chronically ill individuals, measure the domains of activity, daily living, health support, and psychological attitude. Studies from Australia, Canada, and the USA have shown evidence of good validity and reliability. Chesterton et al. reported correlations ranging 074-084 for inter-rater reliability and coefficient = 077 for internal consistency (6). Medical Outcomes Study (MOS) Pain Measures: This seven-item survey

tracks pain impact on daily life and evaluates pain intensity, frequency, and duration. Two categories are covered by the self-report questions: pain impacts and severity. There has been good internal consistency observed.

Post-procedure follow-up: Follow-up visits were scheduled for one week, 1 month, 3 months, 6 months.

Clinical evaluation: change of ulcer size were assessed, ulcer complete healing, ulcer recurrence after healing.

All patients were advised to avoid straining, strenuous physical activity or Valsalva maneuver for the 1st 2 weeks, avoid prolonged car travel of more than 4 hours for 2 weeks to decrease the incidence of thrombo-embolic events.

Cases:

Case 1:

Before treatment: A 56-year-old female with a medical history of obesity and chronic venous insufficiency presented with a venous leg ulcer on her left lower leg that had been present for 6 months. The ulcer measured 2.5 cm x 3.0 cm and was located on the medial aspect of the ankle. The patient reported pain and discomfort associated with the ulcer and had difficulty walking due to the pain. Three months after treatment: After receiving compression therapy for 3 months, the patient reported significant improvement in the pain associated with the ulcer. The ulcer size had decreased to 1.5 cm x 1.5 cm and the patient reported an increase in mobility. Six months after treatment: At the six-month follow-up visit, the ulcer was completely healed, and the patient reported no pain or discomfort associated with the previous ulcer. Figure 1

Case 2:

Before treatment: A 63-year-old male with a medical history of hypertension and diabetes presented with a venous leg ulcer on his right lower leg that had been present for 8 months. The ulcer measured 2.0 cm x 2.5 cm and was located on the lateral aspect of the ankle. The patient reported pain and discomfort associated with the ulcer and had difficulty walking due to the pain. Three months after treatment: After receiving compression therapy for 3 months, the patient reported a decrease in the pain associated with the ulcer. The ulcer size had decreased to 1.0 cm x 1.5 cm, and the patient reported an increase in mobility. Six months after treatment: At the six-month follow-up visit, the ulcer was almost completely healed, and the patient reported minimal pain associated with the previous ulcer. The ulcer measured 0.5 cm x 0.5 cm, and the patient was able to walk without any difficulty. Figure 2

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A)

C)

B)

Figure 1: Case 1: A) Venous ulcer before treatment, B) After 3 months of compression therapy and C) After 6 months of compression therapy.

A)

B)

C)

Figure 2: Case 2: A) Venous ulcer before treatment, B) After 3 months of compression therapy and C) After 6 months of compression therapy.

Statistical analysis:

Statistical analysis was done by SPSS v26 (IBM Inc., Armonk, NY, USA). Shapiro-Wilks test and histograms were used to evaluate the normality of the distribution of data. Quantitative parametric data were presented as mean and standard deviation (SD). Quantitative non-parametric data were presented as the median and interquartile range (IQR). Qualitative data were presented as frequency and percentage (%).

Research Ethics Committee: Ms.18.1.2018

Results

Demographic data, comorbidities and clinical presentation of the studied patients were shown in Table 1.

The median ulcer area was 80.5 mm² with an IQR of 34.25 – 134 mm². Ulcer duration ranged from 4 to 7 days with a mean ± SD of 5.5 ± 1.22 days. HR ranged from 70 to 100 beats/min with a mean ± SD of 87.6 ± 9.13 beats/min. SBP ranged from 100 to 130 mmHg with a mean ± SD of 115.4 ± 9.94 mmHg. DBP ranged from 60 to 90 mmHg with a mean ± SD of 75.8 ± 9.06 mmHg. Hb ranged from 10 to 14.7 g/dL with a mean ± SD of 12.5 ± 1.28 g/dL. WBCs ranged from 4 to 10.9 $x10^3$/L with a mean ± SD of 7.9 ± 1.91 $x10^3$/L. PLT ranged from 150 to 349 $x10^3$/L with a mean ± SD of 252.8 ± 58.83 $x10^3$/L. INR ranged from 0.51 to 1.1 with a mean ± SD of 0.8 ± 0.18. Table 2

Table 1: Demographic data, comorbidities and clinical presentation of the studied patients.

	(n=50)
Age (Years)	42.9 ± 12.05 25 - 65
Sex	20 (40%) 30 (60%)
Weight (Kg)	67.7 ± 7.43 55 - 80
Height (m)	1.6 ± 0.05 1.55 - 1.7
BMI (Kg/m^2)	25.4 ± 2.88 19.03 - 31.65
Comorbidities	
HTN	19 (38%)
DM	10 (20%)
Previous leg ulcer	36 (72%)
Hyperlipidemia	6 (12%)
Cardiac disease	14 (28%)
Osteoarthritis	19 (38%)
Rheumatoid disease	19 (38%)
Smoking	17 (34%)

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Clinical presentation	
Pain	48 (96%)
Ulcer	50 (100%)
Heaviness	50 (100%)
Edema	44 (88%)
Pigmentation	40 (80%)
Dermatitis	39 (78%)

BMI: body mass index, DM: diabetes mellitus, HTN: hypertension

Table 2: Ulcer characteristics, vital signs, laboratory investigations of the studied patients.

Ulcer characteristics		(n=50)
Ulcer area (mm²)	Median	80.5
	IQR	34.25 - 134
Ulcer duration (days)	Mean ± SD	5.5 ± 1.22
	Range	4 - 7
Vital signs		
HR (Beats/min)	Mean ± SD	87.6 ± 9.13
	Range	70 - 100
SBP (mmHg)	Mean ± SD	115.4 ± 9.94
	Range	100 - 130
DBP (mmHg)	Mean ± SD	75.8 ± 9.06
	Range	60 - 90
Laboratory investigations		
Hb (g/dL)	Mean ± SD	12.5 ± 1.28
	Range	10 - 14.7
WBCs ($x10^3$/L)	Mean ± SD	7.9 ± 1.91
	Range	4 - 10.9
PLT ($x10^3$/L)	Mean ± SD	252.8 ± 58.83
	Range	150 - 349
INR	Mean ± SD	0.8 ± 0.18
	Range	0.51 - 1.1

HR: heart rate, SBP: systolic blood pressure, DBP: diastolic blood pressure, Hb: hemoglobin, WBCs: white blood cells, PLT: platelets, INR: international normalized ratio.

Regarding CEAP classification, all 50 (100%) patients were grade VI. Regarding VLU location, 14 (28%) patients had ulcer at medial malleolus, 12 (24%) patients had ulcer at lateral malleolus, 15 (30%) patients had ulcer at anterior face of the leg, and 9 (18%) patients had ulcer at other locations. Regarding VCSS, no patients had 0 score, 7 (14%) patients had 1, 37 (74%) patients had 2 and 5 (10%) patients had 3. Table 3

12 (24%) patients had GSV above knee while 38 (76%) had GSV below knee. 42 (84%) patients had Straight GSV shape while 8 (16%) had tortious one, 33 (66%) patients had medial perforators site while 17 (34%) had lateral one, 19 (38%) patients had competent duplex SFJ while 31 (62%) had incompetent one, 47 (94%) patients had competent duplex SVV while 3 (6%) had incompetent one, 45 (90%) patients had competent duplex SPJ while 5 (10%) had incompetent one and 50 (100%) patients had patent duplex deep vein. Table 4

Regarding healing, 2 (4%) patients achieved no healing, 5 (10%) patients achieved incomplete healing and 43 (86%) patients achieved complete healing. Figure 3

Regarding quality of life, 24 (48%) patients had negative quality of life, no patients had hematoma, 10 (20%) patients had delayed mobilization and 16 (32%) patients had pain. Figure 4

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Table 3: CEAP classification, VLU location and VCSS of the studied patients.

CEAP classification	(n=50)
Grade VI	50 (100%)
VLU location	
Medial malleolus	14 (28%)
Lateral malleolus	12 (24%)
Anterior face of the leg	15 (30%)
Other	9 (18%)
VCSS	
0	0 (0%)
1	7 (14%)
2	37 (74%)
3	5 (10%)

CEAP: clinical, etiological, anatomical, and pathophysiological, VLU: venous leg ulcer, VCSS: venous clinical scoring system.

Table 4: Duplex findings of the studied patients.

		(n=50)
GSV	**Above Knee**	12 (24%)
	Below Knee	38 (76%)
GSV shape	**Straight**	42 (84%)
	Tortious	8 (16%)
Perforators site	**Medial**	33 (66%)
	Lateral	17 (34%)
Duplex SFJ	**Competent**	19 (38%)
	Incompetent	31 (62%)
Duplex SVV	**Competent**	47 (94%)
	Incompetent	3 (6%)
Duplex SPJ	**Competent**	45 (90%)
	Incompetent	5 (10%)
Duplex deep vein	**Patent**	50 (100%)

GSV: great saphenous vein, SFJ: sapheno-femoral junction, SVV: small saphenous vein, SPJ: Sapheno-popliteal junction.

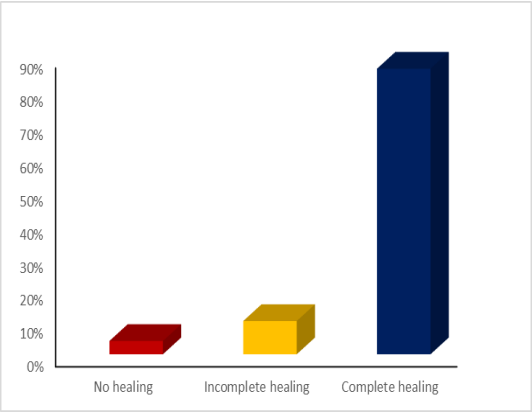

Figure 3: Healing of the studied patients.

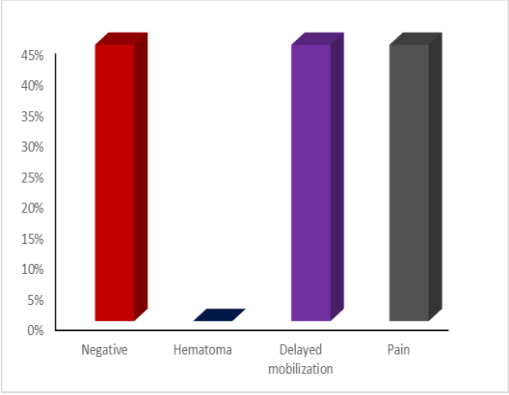

Figure 4: Quality of life of the studied patients.

Discussion

According to our results, the ulcer area had a median of 80.5 cm^3 with an IQR of 34.25-134 cm^3. Ulcer duration ranged from 4 to 7 with a mean ± SD of 5.5 ± 1.22 months.

A meta-analysis was performed by some authors (7) found that participants' ages ranged from 58.0 to 76.5 on average (median: 70.1 years). The participants' leg ulcers varied in length from 9.0 weeks to 31.6 months on average (median: 22.0 months), and the majority (64.8 percent; 901/1391) had ulcers that were between 5 and 20 cm^2 in size.

Interestingly, a study (8) declared that the ulcer area had a median (IQR) of 4.1 cm^2 (1–170) and a median duration of 23 weeks (1–364).

As is regularly observed in the numerous literatures, ulcer length stayed significantly related with recovery in various studied groups (9-12). For example, a study (11) described an ulcer with a length of more than three months as having a delayed recovery period, and a study (9) revealed that after 24 weeks of therapy, there was a 78% likelihood that ulcers larger than 10 cm^2 and persisting longer than 12 months would not cure. This persistent risk factor highlights the essential need for earlier detection of ulcers at high risk of inadequate repair results in order to carry out early therapies and stop the cycle that develops between lengthy duration and difficult to repair.

Prior to treating leg ulcers, hemodynamic dysfunction must be corrected (13). By using compression, walking, and leg elevation as conservative measures, or by surgically removing venous reflux, this can be accomplished. Compression treatment must be used properly to produce the optimum benefits. To counteract venous hemodynamic dysfunction (venous reflux, decreased venous pumping capacity), it should apply a high pressure while standing and working, starting from a lower and bearable supine pressure (14).

Regarding healing in the current work, 2 (4%) patients achieved no healing, 5 (10%) patients achieved incomplete healing and 43 (86%) patients achieved complete healing.

Regarding the ulcer healing outcomes, a study (8) reported that 84 percent of patients in the four-layer method and 72% of those wearing Class 3 hosiery were recovered following 24 weeks of therapy ($\chi^2 = 2.16$, $P = 0.14$). The average percentage reduction in the ulcer area was 96% (SD 15·6) for those in the four-layer bandage group, and 93% (SD 14.9) for those in the Class 3 hosiery group ($P = 0.27$).

A study carried out by some authors (10) found independent risk factors for the recovery and relapse of venous ulcers. This study comprised consecutive patients with an ABPI >0.85 who were evaluated by a specialised nurse-led leg ulcer service between January 1998 and July 2003. A Cox regression proportional hazards model was used to isolate independent risk factors from routinely measured variables for recovery and relapse. 1186 individuals and a number of 1324 legs were examined. The healing rate at 24 weeks was 76%, and the recurrence rate at 1 year was 17% (Kaplan-Meier life table analysis).

Regarding quality of life, 24 (48%) patients had negative quality of life, no patients had hematoma, 10 (20%) patients had delayed mobilization and 16 (32%)

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patients had pain. Some researchers (7) in their meta-analysis, found that during the 12-week to 12-month follow-up period, compression bandages or stockings versus no compression may enhance disease-specific life quality, but not other facets of general health status (four studies with 859 participants; low-certainty evidence). According to Finlayson et al. (8)**,** The QL Index scores had no discernible main effect or interaction effect, according to the general linear model repeated measures analysis. The Geriatric Depression Scale scores and the MOS Pain scores did not have any discernible interaction effects; but, the Geriatric Depression Scale scores showed substantial main effects, and there was a slight improvement over time from a mean score of 3.94 (SD =3.94) at baseline down to 3·88 (3.65), $F = 4.72$, $P = 0.035$, additionally, the MOS Pain Severity ratings increased from a mean score of 50.8 overall (SD =27.1) at baseline (on a scale of 0–100, where 0 = no pain and 100 = worst pain possible) to a mean score of 28·9 (SD 23.1) at 24 weeks from baseline ($F = 35.2$, $P < 0.001$).

Conclusion

Treatments for VLU that is remarkably efficient is compression therapy. In the case of VLUs, care should be exercised when using this treatment approach. From the perspective of clinical treatment, research shows that compression systems are successful in helping patients recuperate, and a four-layer system may yield a positive outcome.

Conflict of interest

None of the contributors declared any conflict of interest.

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