

Efficacy of complex decongestive therapy on venous flow, internal saphenous diameter, edema, fat mass of the limbs and quality of life in patients with chronic venous insufficiency: A randomized clinical trial

Ana Martín Jiménez, PhD,^a Beatriz María Bermejo Gil, PhD,^b Alejandro Santos-Lozano, PhD,^c Francisco Jose Pinto- Fraga, PhD,^c Carolina García Barroso, PhD,^a Leonardo Raul Vittori, MD,^d Aurymar Fraino, MD,^e and Héctor Menéndez Alegre, MD,^c Ávila, Salamanca, and Valladolid, Spain

ABSTRACT

Objective: Demonstrate the effectiveness of complex decongestive therapy (CDT) in patients with chronic venous insufficiency (CVI).

Methods: A single-blind randomized controlled trial was conducted, where the participants were patients with CVI (n = 21/42) were assigned randomly to an experimental group (n = 11/22) or a control group (n = 9/18). A treatment of CDT (manual lymphatic drainage, intermittent pneumatic presotherapy, bilayer bandage) was applied to the experimental group for 4 weeks 2 days per week and no treatment was applied to the control group. The patients were evaluated at baseline (t0), 1 week after finishing the intervention (t1), and 6 weeks after the intervention (t2). The effectiveness of the treatment on symptoms and quality of life (QoL) (heaviness, pain and Chronic Venous Insufficiency Quality of Life [CIVIQ-20] questionary), edema, venous flow, and impedanciometry measurements was evaluated.

Results: An improvement in the patient's QoL was observed: there was a decrease in symptoms such as heaviness and pain, an increase in the average velocity of the left femoral vein and left internal saphenous vein (ISV), a decrease in the ISV diameter in both extremities and a decrease in body mass index and fat mass in both extremities. These results were maintained when following up at 6 weeks, except for the improvement of QoL.

Conclusions: CDT treatment improves the CIVIQ-20 and Venous Clinical Severity Scores. It also improves symptoms (pain and heaviness), venous flow velocity (superficial veins and deep veins [common femoral vein, femoral vein, popliteal vein]) and decreases body mass index, fat mass, and ISV diameter. (J Vasc Surg Venous Lymphat Disord 2025;13:102005.)

Clinical Relevance: This original research studied the effectiveness of complex decongestive therapy in patients with venous insufficiency and analyzes its effect on the reduction of symptoms, such as heaviness, pain and edema, the increase in venous flow rate and the quality of life of patients with this pathology. The importance of this publication lies in its originality—there are no previous studies with this design—and in the importance of demonstrating that there are alternatives for conservative treatment in patients with chronic venous insufficiency that is safe for the patient.

Keywords: Chronic venous insufficiency; Complex decongestive therapy; Physiotherapy; Manual lymphatic drainage; Multilayer bandage; Venous flow; Edema; Quality of life; Impedanciometry

Chronic venous insufficiency (CVI) of the lower extremities is associated with a wide clinical spectrum, ranging from asymptomatic but cosmetic problems to severe symptoms. This includes telangiectasis (or spider veins), reticular veins, varicose veins, edema,

pigmentation and/or eczema, lipodermatosclerosis, atrophie blanche, and venous ulceration.¹ There is a high prevalence of CVI worldwide, estimated to be between 22.00% and 25.95%.²⁻⁴ However, when talking about chronic venous disease in general, taking into

From the Faculty of Health Sciences, Catholic University of Ávila, Ávila^a: the Department of Nursing and Physiotherapy, University of Salamanca, Salamanca^b: the i+HeALTH, Department of Health Sciences, Miguel de Cervantes European University, Valladolid^c: the Traumatology Service of the Santa Teresa Hospital of Avila,^d the Radiology Service of the Medicalitas Clinic of Ávila,^e Ávila.

Correspondence: Professor Ana Martín Jiménez, PhD, Faculty of Health Sciences, Catholic University of Ávila, Spain, C/Canteros s/n, 05002 Ávila, Spain (e-mail: ana.martin@ucavila.es).

The editors and reviewers of this article have no relevant financial relationships to disclose per the Journal policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

Copyright © 2024 The Author(s). Published by Elsevier Inc. on behalf of the Society for Vascular Surgery. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

https://doi.org/10.1016/j.jvsv.2024.102005

account the milder stages of the disease, it is estimated that the prevalence is even higher, between 63.69% and 69.1%.^{2,5} This disease entails great costs for society and a decrease in productivity.⁶

Complex decongestive therapy (CDT) is the conservative treatment of choice for the treatment of upper and lower limb lymphedema. It is composed of manual lymphatic drainage (MLD), multilayer bandages, skin care, and active kinesitherapy; it can also be complemented with intermittent pneumatic pressotherapy and neuromuscular bandaging.⁷⁻¹⁰ This treatment can also be applied to patients with other circulatory return problems, such as CVI. Although these effects have been little studied, the effectiveness of CDT in reducing symptoms such as heaviness, pain and edema, improving venous flow (VF) and mobility of the joints of the lower extremity, and increasing the quality of life (QoL) of the patient has been demonstrated. 11,12 The efficacy of the techniques that make up CDT has also been proven separately, including MLD, 13-16 intermittent pneumatic pressotherapy,¹⁷⁻²⁰ active kinesitherapy or therapeutic exercise, 21-24 and neuromuscular taping. 25-27

Only Bakar et al¹¹ have studied the effectiveness of CDT as a whole in CVI and observed a decrease in pain and edema, as well as an improvement in the activities of daily living. However, this study did not have a control group, resulting in low methodological quality, and it did not examine variables such as VF.¹¹ Therefore, the objective of this study was to demonstrate the effectiveness of CDT in patients with CVI and quantify the results by measuring quantitative variables such as the VF of the main superficial and deep veins of the lower extremity, as well as the measurement of edema through bioimpedanciometry.

METHODS

A single-blind, randomized, controlled trial was conducted in patients with CVI at a physiotherapy center specialized in the treatment of venous and lymphatic vascular conditions in Ávila (center of Spain) between October 2022 and September 2023. An experienced vascular therapist carried out the selection phase, gathering data on gender, age, body mass index (BMI), profession, affiliation, personal and family history of vascular and other diseases, as well as lifestyle habits such as smoking, physical exercise, and its intensity. The same therapist then performed an exploratory clinical examination to identify patients with stages C1, C2, C3, or C4 (C1, telangiectasis or reticular veins; C2, varicose veins; C3, edema; C4, skin changes), following the criteria proposed by the American Venous Forum committee.²⁸ The examination was carried out in two positions (standing and supine) for both lower limbs to assess clinical signs of CVI and measure leg volume. The eligibility criteria for inclusion in the study were age between 35 and 75 years and the presence of mild, moderate, or

ARTICLE HIGHLIGHTS

- Type of Research: A single-blind randomized controlled trial.
- **Key Findings**: Complex decongestive therapy improves the quality of life in patients with mild and moderate chronic venous insufficiency (CVI) (C2-C4), and the symptoms that these patients develop, such as pain and heaviness in the lower limbs. These results are related to the improvement of venous flow velocity in superficial and deep veins and the decrease in the diameter of the internal saphenous vein and the fat mass of the limbs.
- Take Home Message: Patients with CVI may benefit from complex decongestive therapy treatment because one of the main conservative treatments to relieve CVI symptoms safely and without side effects.

severe CVI (grades C2, C3, and C4 on the Clinical, Etiologic, Anatomic, Pathophysiologic [CEAP] scale).²⁸ Patients with uncompensated acute cardiac, hepatic and renal disease, acute obstructive vascular disease, acute trauma, primary lymphedema (negative Stemmer sign), and acute skin infections were excluded. Additionally, patients who were currently receiving CDT treatment or had received it in the last 6 months were excluded from this study.

Of the 25 patients recruited from the accessible population, 21 met these selection criteria and were assigned randomly to either an experimental group (n = 12) for CDT application or a control group (n = 9). Participants in the control group did not received any treatment. The physiotherapist who selected the patients and collected the initial data randomized the participants and did not participate in the post-intervention data collection, in addition to being blinded to the treatment to which the patients were subjected and another physiotherapist collected data on the severity of the disease, symptoms, centimetric measurements (CM) of the limb. impedance measurements, and QoL of the patients. Finally, a specialist radiologist performed an ultrasound study of the lower extremities, diagnosing the participants and collecting VF measurements. The CDT intervention was performed by a vascular physiotherapist who was also masked to the outcome measures and initial examination findings.

Before starting the study, the participants were informed, and the entire process was conducted in accordance with Spanish legislation, and the study was approved by the Research Ethics Committee of the University of Salamanca, with file no. 955.

Evaluation procedure and variables studied. The main symptoms of the disease were assessed using the

Venous Clinical Severity Score (VCSS) questionnaire,^{29,30} where the following were assessed: pain (0, absent; 1, mild; 2, moderate; 3, severe) and heaviness and fatigue of the limb (0, none; 1, mild; 2, moderate; 3, severe).

The QoL of the patients was measured using the Chronic Venous Insufficiency Quality of Life (CIVIQ-20) questionnaire, 31,32 whose total score ranges from 10 to 100 points, with a higher score corresponding with a greater loss of the patient's QoL. Within this questionnaire, different dimensions are studied: pain (6-15), physical (10-25), social (6-15), and psychological (14-45).

Next, CMs were taken to measure the circumference of both extremities at three points: ankle (internal malleolus), leg (15 cm above the malleolus), and knee (at the level of Gerdy's tubercle). Patients were evaluated using segmental multifrequency bioimedancemetry (InBody S10, InBody, South Korea), collecting data on BMI, total body water (TBW), intracellular water (ICW), and extracellular water (ECW). Specific data for each extremity included TBW, ICW, ECW, fat-free mass, and fat mass (FM).

Finally, the gold standard test for the diagnosis of CVI was performed with a Doppler echo study³³⁻³⁶ in both extremities using a high-frequency linear probe (2-12 MHz) in B-mode, and color and pulsed Doppler. The type of insufficiency was diagnosed, which can be superficial (0, none; 1, mild; 2, moderate; 3, severe), deep (0, none; 1, mild; 2, moderate; 3, severe), or mixed. In addition, reflux was assessed (0, none; 1, reflux + retrograde flow >0.5 second) and the flow velocity (FV) of the femoral, common femoral, popliteal, internal saphenous or greater saphenous, and external saphenous veins was measured. Further, the diameter of the latter superficial veins at the level of their arch was measured.

Intervention procedure. The treatment of the experimental group consisted of an intensive program of CDT lasting 4 weeks, with two sessions held per week. Each session included the application of MLD maneuvers following the Leduc method (reabsorption and call) for 40 minutes on both lower extremities, intermitent sequential pneumatic compression therapy (35 minutes at 30-45 mmHg), bilayer bandages on the leg and foot with a layer of inelastic cotton, and a short elastic bandage (15 minutes). The total duration of the session was 1.5 hours.

- MLD^{11,13-16}: A protocol is carried out as per the Leduc method: recall maneuver in inguinal nodes and healthy areas above the edema, reabsorption maneuver in the edema area (leg, ankle, and foot), and recall maneuver from distal to proximal from the foot and ankle to the groin area.
- Intermittent pneumatic pressotherapy^{11,17-19}: It was applied on the lower extremities and abdomen, with a high-intensity foam bandage placed on the leg, ankle and foot to enhance the reabsorption of edema. A pressure of 30 to 45 mmHg was used based on the

- patient's tolerance and without causing any discomfort or adverse effects.
- Bilayer bandage^{11,18,37}: It was applied on the extremity up to the knee. An inelastic cotton bandage in a herringbone pattern followed by a short elastic bandage was placed on the ankle and leg in the shape of a herringbone (Rosidal K 8 cm and 10 cm). The bandage was kept until the end of the day or until the next day, depending on the patient's tolerance and without causing discomfort or paresthesia.

All participants completed treatment and were assessed after treatment. Only two patients did not complete the 6-week follow-up, which was considered in the statistical calculations.

Data analysis. Statistical analysis was carried out using RStudio (RStudio 2021.09.2+382 "Ghost Orchid" Release; fc9e217980ee9320126e33cdf334d4f4e105dc4f, 2022-01-04) for macOS. The following statistical techniques and tests were used.

- Descriptive analysis of qualitative variables was conducted with frequency tables and percentages. Contingency tables were used to cross-reference two variables.
- 2. Quantitative variables were explored with the main objective of verifying their adjustment to the normal Gauss bell curve. This included normal Q-Q graphs, asymmetry and kurtosis indices, and the Kolmogorov-Smirnov test of goodness of fit to normality, where only a significant deviation (P < .01) indicated that the variable was not normally distributed. At the same time, box plots were used to determine outliers (owing to the distance from the others in the sample), known as far out outliers.
- The quantitative variables were described using standard measures: measures of centrality: mean and median and measures of variability: observed range, standard deviation and interquartile range.
- 4. The repeated measures analysis of variance test was used to compare means over three time points (dependent on each other). A post hoc analysis was carried out using the paired Student t test for normally distributed variables.
- 5. For comparing two means (independent of each other), the Student *t* test was used. On the other hand, the Mann-Whitney test was used to contrast two medians (independent of each other).
- 6. The Friedman test was used to compare medians across three time points (dependent on each other). A post hoc analysis was carried out using a paired Wilcoxon test for normally distributed variables.
- 7. In cases where the conditions of normality were met, a repeated measures analysis (centimeter measurements) was carried out. However, in cases where these assumptions were not met, a Friedman test was carried out for the analyses based on time to determine time there were differences between the three moments. The post hoc analysis was carried

Table I. Demographic and clinical data

Demographic and clinical data	Control group (n = 9)	Experimental group (n = 11)				
Age, years	52.9 ± 7.8	56.2 ± 11.6				
CEAP classification: Clinical class						
C2: Troncular varicose veins		9.2 (1)				
C3: Edema	66.7 (6)	54.5% (6)				
C4: Skin changes	33.3 (3)	36.3 (4)				
Comorbidities						
Surgical removal of small and/or great saphenous vein	11.1 (1)	9.1 (1)				
Sclerotherapy	22.2 (2)	18.2 (2)				
History of deep venous thrombosis	0 (0)	9.1 (1)				
family history of venous insufficiency	77.8 (7)	81.8 (7)				
Arterial hypertension	22.2 (2)	27.3 (3)				
CVI treatments						
Compression stocking	22.2 (2)	27.3 (3)				
Medication to chronic venous disease	11.1 (1)	27.3 (3)				
Exercise						
No	11.1 (1)	18.2 (2)				
1 day/week	1.1 (1)	9.1 (1)				
2-4 days/week	33.3 (3)	18.2 (2)				
>4 days/week	44.4 (4)	54.5 (6)				
Smoking						
No	100 (9)	81.7 (10)				
Yes		8.3 (1)				
CEAP, Clinical, Etiologic, Anatomic, Pathophysiologic; CVI, chronic venous insufficiency. Values are mean ± standard deviation or % (n).						

out using a paired Wilcoxon test in the case of variables that did not meet the conditions of normality

RESULTS

Descriptive study of the data

Concerning age, gender, and lifestyle habits, the study was carried out with 21 patients (42 limbs), of whom 20 were female. The average age of the participants was 54.8 years. Regarding lifestyle habits, only 4.76% were smokers; 9.52% consumed alcohol moderately, 52.38% consumed alcohol occasionally, and 38.10% never consumed alcohol. Regarding physical exercise, 14.29% did not exercise, 9.52% exercised 1 day per week, 23.81 exercised 2 to 4 days per week, and 52.38% exercised every day. Most of the participants exercised at a light intensity (66.67%). Considering BMI analysis, only 26.98% of participants were within the normal weight range (normopese, 18.5-24.9); 23.81% and 46.03% were overweight (25.0-29.9) and obese (>30), respectively.

The clinical history of the participants showed that the majority (76.19%) had a family history of venous insufficiency and, of these, predominantly from the mother and her family (57.14%). Additionally, 9.52% had undergone surgery for venous insufficiency and 19.04% had received sclerotherapy. A large majority of patients (80.95%) did not take drugs to alleviate symptoms. As for use of compression stockings before the intervention, the majority of participants (71.4%) did not use them; 23.8% used them occasionally and only 4.8% used them continuously (Table I).

The clinical diagnosis of the participants, according to the CEAP classification, showed that most of the patients (61.93%) had edema (C3); 33.33% had skin alterations (C4) and only 4.76% had telangiectasias and reticular varicose veins (C2). Study participants were referred by a specialist physician during the patient recruitment period, and none classified as C5 met the inclusion criteria. When ultrasound diagnosis of the extremities was performed, we observed that a significant percentage of participants exhibited deep venous insufficiency in both the right and left extremities (42.86% and 57.14% mild, 33.33% and 23.81% moderate, and 9.52% and 9.52% severe, respectively). Additionally, a majority of participants showed mild to moderate superficial venous insufficiency in the right and left extremities (19.05% and 71.43% mild, 66.67% and 23.81% moderate, and 4.76% in the right extremity, respectively) (Table II).

Regarding the severity of venous insufficiency as determined by the VCSS questionnaire, the results showed the following distribution for the heaviness dimension: 4.76% reported no heaviness, 14.29% mild heaviness, 66.67% moderate heaviness, and 14.29% severe heaviness. Regarding the dimension of pain, 14.29% had no pain, 57.14% had mild pain, and 28.57% had moderate pain.

In addition to assessing edema with the patient's physical examination, participants' extremities were also classified using ECW/TBW impedanciometry measurements for each extremity separately. Normal values for the ECW/TBW ratio must be between the values 0.360 and 0.390. We found 13 edematous extremities and 29 nonedematous extremities. It is worth noting that these findings do not take into account the mild edema observed during physical examination, indicating a higher number of non-edematous extremities.

Last, on comparing the data of the control and experimental groups, it was observed that, in general, they were homogeneous, with no statistically significant differences between the two groups, except in CM and impedance measurements, which were significantly higher in the experimental group, except for BMI, ECW/ TBW. and FML.

Table II. Insufficiency classification

	Control grou	Control group (n = 18)		Experimental group (n = 22)		
Insufficiency classification	Right limb	Left limb	Right limb	Left limb		
Deep insufficiency						
No		1 (3.7)	3 (8.3)	1 (2.8)		
Mild	6 (22.2)	5 (18.5)	3 (8.3)	7 (19.4)		
Moderate	2 (7.4)	2 (7.4)	5 (13.9)	3 (8.3)		
Severe	1 (3.7)	1 (3.7)	1 (2.8)	1 (2.8)		
Superficial insufficiency						
No	1 (3.7)		1 (2.8)	1 (2.8)		
Mild	3 (11.1)	8 (29.6)	1 (2.8)	7 (19.4)		
Moderate	4 (14.8)	1 (3.7)	10 (27.8)	4 (11.1)		
Severe	1 (3.7)			1 (2.8)		
Values are number (%).						

Inferential study of the data

Qol. Patients in the experimental group showed improvements; the percentage of those with severe heaviness decreased from 16.7% at t0 to none at t1, but the results were not maintained at t2. Patients with moderate heaviness decreased from 75% at t0 to 25% at t1, with the results being maintained at 8 weeks. Meanwhile, patients with mild heaviness increased, and those without heaviness increased from 8.3% to 33.3% (Fig 1).

Regarding the pain levels, patients with moderate pain decreased from 25.0% to 8.3%, and those with mild pain decreased from 58.3% to 25.0%. Patients without pain increased from 16.7%. % to 66.7%, although these results were not sustained at the 8-week follow-up (Fig 2).

The CIVIQ-20 questionnaire results for patients with CVI indicate that, in the experimental group, a statistically significant improvement (P < .05) in all dimensions of the questionnaire—pain, physical, social, and psychological—was found between t0 and t1. This finding indicates an improvement in their QoL with the treatment. However, the results were not maintained 6 weeks after the end of the intervention, but only in the case of the physical dimension (Table III).

CM of the limb

There was no decrease in the CM of the ankle, leg, or knee in the experimental group as compared with the control group.

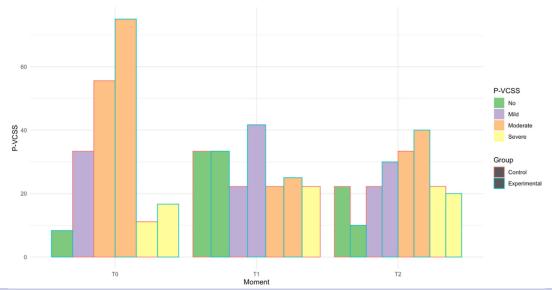


Fig 1. Venous Clinical Severity Score (VCSS) results (heaviness).

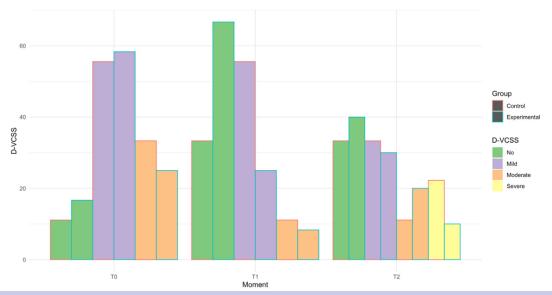


Fig 2. Venous Clinical Severity Score (VCSS) results (pain).

VF measures, reflux, and venous diameter

No significant statistical differences were found in the VF rate in the deep veins (CFV, FV and popliteal veins [PVs]), except in the left femoral vein (LFV) where almost significant differences were observed (P < .10).

Regarding the internal saphenous vein diameter (ISVD), we can affirm that there is a decrease in the ISVD of both extremities after applying the treatment, and this improvement is maintained at 6 weeks (Table IV).

Table III. Results of quality of life (QoL): Chronic Venous Insufficiency Quality of Life (CIVIQ-20)

	Contro	ol group (n = 9)	Experimental group (n $=$ 11)		
Variables	Mean ± SD	P value (effect size)	Mean ± SD	P value (effect size	
QoL (total CIVIQ_20)					
tO	29.6 ± 10.1		40.7 ± 14.3		
tl	35.9 ± 14.6	.045 (0.346)	26.0 ± 4.2	.002 (0.519)	
t2	28.8 ± 7.4		30.7 ± 11.0		
QoL (pain CIVIQ_20)					
tO	6.8 ± 3.3		6.7 ± 2.1		
tl	5.7 ± 2.6	.005 (0.597)	4.0 ± 1.3	.026 (0.306)	
t2	4.1 ± 0.9		5.5 ± 2.7		
QoL (physical CIVIQ_20)					
tO	10.0 ± 3.0		12.4 ± 4.1		
tl	10.1 ± 3.8	.405 (0.100)	6.3 ± 1.2	.002 (0.510)	
t2	9.0 ± 3.8		8.2 ± 3.4		
QoL (social CIVIQ_20)					
tO	6.2 ± 4.0		6.2 ± 2.6		
tl	6.1 ± 2.8	.005 (0.597)	3.7 ± 1.1	.018 (0.333)	
t2	4.1 ± 1.5		4.9 ± 2.4		
QoL (psychological CIVIQ_20)					
tO	11.1 ± 2.0		15.4 ± 7.4		
tl	14.0 ± 6.0	.483 (0.081)	11.3 ± 2.2	.016 (0.347)	
t2	11.3 ± 2.8		12.1 ± 3.4		

Table IV. Results of venous flow (VF) velocity (general group)

	Control group (n = 18)				Experimental group (n $=$ 22)			
Variables	Right limb	P value (effect size)	Left limb	P value (effect size)	Right limb	P value (effect size)	Left limb	P value (effect size)
VF velocity CFV (cm/sg)	RCFV		LCFV		RCFV		LCFV	
tO	4.0 ± 2.0	.005 (0.593)	3.4 ± 0.9		5.3 ± 2.1		6.0 ± 2.2	
t1	6.5 ± 2.2		9.3 ± 3.2	.001 (0.827)	7.2 ± 3.3	.558 (0.048)	6.2 ± 2.9	.297 (0.101)
t2	6.7 ± 2.0		7.7 ± 1.8		6.0 ± 2.0		8.0 ± 4.3	
VF velocity FV (cm/sg)	RFV		LFV		RFV		LFV	
tO	2.8 ± 0.7		3.2 ± 0.6		4.3 ± 2.6		4.9 ± 3.1	
tl	5.1 ± 1.7	.007 (0.556)	6.8 ± 4.7	.016 (0.457)	4.6 ± 1.9	.428 (0.071)	6.9 ± 3.4	.050 (0.250)
t2	4.6 ± 1.5		5.3 ± 1.4		4.3 ± 1.4		5.7 ± 2.8	
VF velocity PV (cm/sg)	RPV		LPV		RPV		LPV	
tO	2.4 ± 0.6		2.8 ± 0.6		2.9 ± 1.4		3.5 ± 1.9	
t1	3.3 ± 1.2	.110 (0.245)	3.9 ± 1.4	.074 (0.289)	3.8 ± 2.0	.266 (0.111)	3.9 ± 2.0	.234 (0.121)
t2	3.6 ± 1.4		3.6 ± 0.7		3.9 ± 1.1		4.9 ± 3.6	
VF velocity ISV (cm/sg)	RISV		LISV		RISV		LISV	
tO	2.5 ± 1.3		2.7 ± 0.9		3.6 ± 1.9		2.6 ± 1.9	
tl	3.8 ± 1.8	.092 (0.265)	3.5 ± 1.3	.459 (0.086)	4.5 ± 2.5	.368 (0.083)	3.1 ± 1.9	.076 (0.215)
t2	2.7 ± 0.6		3.1 ± 0.7		3.5 ± 1.7		3.6 ± 1.9	
Diameter ISV (mm)	RISD		LISD		RISD		LISD	
tO	6.3 ± 4.3		5.2 ± 1.7		5.9 ± 1.6		4.3 ± 2.0	
tl	6.2 ± 3.4	.236 (0.160)	5.2 ± 1.6	.103 (0.253)	5.5 ± 1.3	.011 (0.377)	4.6 ± 1.8	.076 (0.215)
t2	5.5 ± 2.9		4.8 ± 0.8		5.1 ± 1.0		4.4 ± 1.8	

LCFV, left common femoral vein; LISD, left internal saphenous diameter; LISV, left internal saphenous vein; LFV, left femoral vein; RCFV, right common femoral vein; RISD, right internal saphenous diameter; RISV, right internal saphenous vein; RFV, right femoral vein. Boldface entries indicate statistical significance.

Impedanciometry measures

No significant changes were observed in the general measurements of TBW, ICW, and ECW, or the measurements of FFM, ICW, and ECW in each of the extremities. Thus, we can affirm that the treatment applied to the patients in the experimental group does not imply any change in terms of the decrease in fluids and muscle mass, either in general or in each of the extremities.

Regarding BMI, there was a statistically significant decrease in the BMI in the patients of the experimental group who received treatment, which was maintained 6 weeks after treatment.

Considering the right FM and left FM, we can affirm that the FM in both limbs decreased significantly after treatment, which was maintained 6 weeks after treatment.

Statistical subanalysis of patients with edema and subanalysis by disease severity

Patients with edema. An analysis of the results of the group of patients who presented with edema, classified according to the impedanciometry data, was carried out. Significant and almost significant changes were observed in some of the VF measurements, such as an increase in the left common femoral vein (LCFV; P = .053), RPV/LPV (P = .030/P = .048), left ISV (LISV; P = .053), left internal saphenous

diameter (P=.095), and rigth external saphenous diameter (P=.016). There was a statistically significant decrease in BMI and right FM/left FM in the experimental group after the application of the treatment, but no significant changes were observed in the CM (Table V).

No further statistical analysis has been performed, because there is a high level of homogeneity between the characteristics of the participants, as well as in lifestyle habits and comorbidities, and because it would not be possible owing to the small sample size.

DISCUSSION

An improvement in the patient's QoL was observed, along with a decrease in symptoms such as heaviness and pain. There was also an increase in the average velocity of the LFV and LISV, a decrease in the ISVD in both extremities, and a decrease in BMI and FM in both extremities. These results are maintained when following up at 6 weeks, except for the improvement in QoL. In the analysis of patients with edema, improvements were observed in the mean velocity of LCFV and right venous popliteal/left venous popliteal, in addition to the findings observed in the general group. No significant decrease was noted in CM or edema measured with impedanciometry.

Table V. Results of venous flow (VF) velocity (edema group)

	Control group (n = 18)				Experimental group (n = 22)			
Variables	Right limb	P value (effect size)	Left limb	P value (effect size)	Right limb	P value (effect size)	Left limb	P value (effect size)
VF velocity CFV (cm/sg)	RCFV		LCFV		RCFV		LCFV	
tO	5.6 ± 3.0		3.0 ± 0.5	.097 (0.778)	5.4 ± 2.4		6.3 ± 2.0	
t1	7.9 ± 1.8	.264 (0.444)	9.5 ± 3.3		7.1 ± 3.3	.607 (0.063)	5.9 ± 3.1	.053 (0.367)
t2	6.3 ± 1.9		9.3 ± 0.3		6.4 ± 2.0		9.3 ± 4.6	
VF velocity FV (cm/sg)	RFV		LFV		RFV		LFV	
tO	2.6 ± 1.0		3.3 ± 0.7		3.8 ± 2.5		4.8 ± 3.2	
tl	5.2 ± 1.0	.097 (0.778)	4.3 ± 1.3	.050 (0.999)	4.9 ± 2.0	.223 (0.188)	5.9 ± 1.9	.135 (0.250)
t2	5.1 ± 2.4		6.0 ± 0.5		4.3 ± 1.6		5.9 ± 3.2	
VF velocity PV (cm/sg)	RPV		LPV		RPV		LPV	
t0	2.5 ± 0.9		2.7 ± 0.3		2.8 ± 1.6		3.4 ± 2.2	
tl	3.3 ± 0.6	.097 (0.778)	4.2 ± 0.7	.060	4.4 ± 2.2	.030 (0.440)	3.8 ± 2.1	.048 (0.379)
t2	4.0 ± 1.6		3.3 ± 0.5		4.1 ± 1.2		5.4 ± 4.4	
VF velocity ISV (cm/sg)	RISV		LISV		RISV		LISV	
t0	1.5 ± 3.0		3.0 ± 0.9		3.7 ± 2.0		2.7 ± 1.9	
tl	2.6 ± 3.8	.761 (0.091)	3.3 ± 1.0	.717 (0.939)	4.1 ± 1.7	.607 (0.063)	3.3 ± 1.8	.053 (0.367)
t2	2.2 ± 5.4		3.2 ± 1.1		3.6 ± 1.6		4.2 ± 1.7	
Diameter ISV (mm)	RISD		LISV		RISV		LISV	
t0	5.5 ± 1.9		4.0 ± 1.0		5.7 ± 1.7		4.8 ± 1.8	
tl	5.2 ± 0.9	.717 (0.111)	4.4 ± 0.8	.761 (0.091)	5.5 ± 1.4	.227 (0.185)	5.1 ± 1.3	.095 ± 0.294
t2	4.5 ± 0.5		4.6 ± 0.1		5.3 ± 1.1		4.8 ± 1.4	

LCFV, left common femoral vein; LISD, left internal saphenous diameter; LISV, left internal saphenous vein; LFV, left femoral vein; RCFV, right common femoral vein; RISD, right internal saphenous diameter; RISV, right internal saphenous vein; RFV, right femoral vein. Boldface entries indicate statistical significance.

evaluated with the CIVIQ-20 and VCSS questionnaires, where an improvement in the CIVIQ-20 scores was observed overall and across physical, social and psychological dimensions, as well as pain. This improvement was observed after treatment but was not maintained at the 6-week follow-up, except in the physical dimension. Heaviness and pain, measured according to the VCSS questionnaire, decreased significantly after treatment, and the results were maintained at the 6-week follow-up.

Several recent studies have evaluated the effectiveness of CDT and its components in CVI, consistently showing improvements in the QoL of patients and reduction in symptoms. Only Taradaj et al¹⁸ did not measure the QoL or the patient's symptoms. Almost all authors used the CIVIQ-20 or the VCSS questionnaires and the visual analog scale. 11,14,15,17,19,25-27,38 Some also used the Short Form-36,^{26,27} Hospital Anxiety and Depression Scale, Aberdeen Varicose Vein Questionnaire, and CEAP, although the last is usually used only to diagnose the patient. 28

CDT and edema. Edema was measured in different ways. First, it was determined whether the patient had edema with the physical examination. This was followed

by CM and a complete measurement with general and specific impedanciometry performed on each limb. No significant decrease in edema was found in the general analysis or in the subanalysis in patients classified as having edema with impedanciometry.

However, the patients included in the study did not present with phlebolymphedema; thus, the magnitude of edema was mild to moderate and localized only in the leg and ankle. Although patients reported that they noticed a decrease in edema in the legs, this result was not reflected in the measurements objectively, possibly owing to the distribution of extracellular fluid throughout the extremities. Moreover, the study participants did not exhibit very severe CVI. The difference between subjective relief of symptoms and the fact that there is no improvement in edema may be due to the characteristics of the participants, who present mild edema, although the measurement instruments used are specific and coincide in their results.

CDT and VF. Significant increases were observed in the LISV and LFV. Additionally, patients with edema showed significant increases in the LCFV and right venous popliteal/left venous popliteal. Average velocity values of other superficial and deep veins in both extremities showed an

increase but did not reach significance, perhaps owing to the small sample size or participant characteristics. In addition, significant variability was observed. in the average speed values of the control group, raising questions about this measurement.

When analyzing patients according to the severity of the disease, clear data indicate that the average velocity values of the superficial and deep veins were lower in patients with moderate to severe venous insufficiency. Thus, this value is correlated directly with the severity of the disease. However, there were no clear indications that physiotherapy treatment improves this variable, possibly owing to the study participants not having very severe CVI.

No other studies have measured VF velocity in the superficial veins (ISV) or deep veins (CFV, FV, and PV) of the lower extremity, making it difficult to compare results. Yamany and Hamdy¹⁷ measured VF velocity in the CFV only, whereas Mohamed et al¹⁹ measured it in the CFV and PV, each observing a combination of these variables. In contrast, Aguilar-Ferrándiz et al²⁶ and Molski et al¹⁶ measured VF with plethysmography, reporting positive results in their studies. Further studies are warranted to determine whether VF velocity increases significantly in each vein of the lower extremity.

CDT and **ISVD**. A significant decrease in the ISVD was observed in both extremities, which may be attributed to an increase in VF and a decrease in reflux. No study has taken this variable into account; thus, more research is required to corroborate these results.

CDT and FM. A significant decrease in BMI and FM of both lower extremities was observed after CDT treatment, which greatly benefits patients with CVI. There were no changes in other parameters, such as total water, ICW, and ECW, either globally or specifically in each limb. However, there was a decrease in FM in the limbs, which may be related to the decrease in BMI. It has been shown through this and past studies that patients with a higher BMI and FM have greater disease severity. Moreover, these results could also have applications within aesthetic physiotherapy.³⁹

In some studies, it has been shown that the relationship between BMI and FM and ISVD and VF is directly proportional, because patients with a higher BMI have a lower VF and a higher ISD.⁴⁰ In this study, improvements in VF, as well as decreases in BMI, FM, and ISD, were observed after CDT treatment in patients who, for the most part, are overweight or obese.

Limitations of the study. The main limitation of this study was having a small number of participants, which did not allow us to perform a subanalysis of patient data according to the severity of the disease. Additionally, although the experimental and control groups were generally homogeneous across their characteristics

and most of the collected data, the severity of the disease varied between C2 and C4, which could have influenced the results obtained, especially regarding edema reduction. Moreover, further research with longer follow-up periods is needed to better assess the effectiveness of CDT in treating CVI.

It would also be advisable to analyze a longer follow-up period for the patient in future research; in this study, the patient was only evaluated 6 weeks after the intervention. Other authors such as Mohamed et al,¹⁹ carried out a longer follow-up of 4 and 8 weeks and observed that the results of the treatment with pressotherapy were maintained, but to a lesser extent.

CONCLUSIONS

CDT treatment enhances the QoL of patients with CVI as evidenced by improved CIVIQ-20 and VCSS scores. It also alleviates symptoms such as pain and heaviness, improves VF velocity in both superficial veins (ISV) and deep veins (CFV, FV, and PV), and decreases BMI, FM, and ISD, thereby enhancing VF and patient symptoms. It is necessary to carry out more studies with longer follow-up periods to support these findings. These results are sustained when following up at 6 weeks, except for QoL improvement, which requires further investigation.

AUTHOR CONTRIBUTIONS

Conception and design: AMJ, BBG, ASL, FPF, CGB, LV, AF, HMA

Analysis and interpretation: AMJ, BBG, ASL, FPF, CGB, LV, AF, HMA

Data collection: AMJ, BBG, ASL, FPF, CGB, LV, AF, HMA Writing the article: AMJ, BBG, ASL, FPF, CGB, LV, AF, HMA Critical revision of the article: AMJ, BBG, ASL, FPF, CGB, LV, AF, HMA

Final approval of the article: AMJ, BBG, ASL, FPF, CGB, LV, AF, HMA

Statistical analysis: AMJ, BBG, ASL, HMA Obtained funding: AMJ, BBG, ASL Overall responsibility: AMJ

FUNDING

None.

DISCLOSURES

None.

REFERENCES

- Youn YJ, Lee J. Chronic venous insufficiency and varicose veins of the lower extremities. Kor J Intern Med. 2019;34:269–283.
- Vuylsteke ME, Colman R, Thomis S, Guillaume G, Van Quickenborne D, Staelens I. An epidemiological survey of venous disease among general practitioner attendees in different geographical regions on the globe: the final results of the vein consult program. *Angiology*. 2018;69:779–785.
- Rabe E, Goron F, Salmat G. The prevalence, disease characteristics and treatment of chronic venous disease: an international webbased survey. J Comp Eff Res. 2020;9:1205–1218.
- Kirsten N, Mohr N, Gensel F, Alhumam A, Bruning G, Augustin M. Population-based epidemiologic study in venous diseases in

- Germany prevalence, comorbidity, and medical needs in a cohort of 19,104 workers. *Vasc Health Risk Manag.* 2021;17:679–687.
- Cires-Drouet RS, Fangyang L, Rosenberger S, et al. High prevalence of chronic venous disease among health care workers in the United States. J Vasc Surg Venous Lymphat Disord. 2020;8:224–230.
- Ouriel K. Central venous pathologies: treatments and economic impact. Review Methodist DeBakey cardiovasc J. 2018;14.
- Bae SH, Kim WJ, Seo YJ, Kim JY, Jeon JY. Bioimpedance analysis for predicting outcomes of complex decongestive therapy for gynecological cancer related lymphedema: a feasibility study. *Ann Rehabil Med.* 2020;44:238–245.
- 8. Corum M, Basoglu C, Korkmaz MD, Yildirim MA, Ones K. Effectiveness of combined complex decongestive therapy and resistance exercises in the treatment of lymphedema associated with breast cancer and the effect of pain on treatment response. *Lymphat Res Biol.* 2021;19:383–390.
- Borman P, Yaman A, Yasrebi S, Pınar İnanlı A, Arıkan Dönmez A. Combined complete decongestive therapy reduces volume and improves quality of life and functional status in patients with breast cancer-related lymphedema. Clin Breast Cancer. 2022;22: e270–e277.
- Eretta C, Tridoni E, Isaia S, et al. Complex decongestive therapy in lymphedema: report from an Interdisciplinary Center. Veins Lymphatics. 2023;12.
- Bakar Y, Öztürk A, Calisal MA, Ertürk K, Daglar B. Complete decongestive physiotherapy for older people with chronic venous insufficiency. Top Geriatr Rehabil. 2010;26:164–170.
- 12. Jayaraj A, Thaggard D. The beneficial role of complex decongestive therapy in patients with symptomatic chronic iliofemoral venous obstruction with phlebolymphedema. *J Vasc Surg Venous Lymphat Disord*. 2023;12:1—9.
- dos Santos Crisóstomo RS, Candeias MS, Ribeiro AMM, da Luz Belo Martins C, Armada-da-Silva PAS. Manual lymphatic drainage in chronic venous disease: a duplex ultrasound study. *Phlebology*. 2014:29:667–676
- Crisóstomo RSDS, Costa DSA, Martins CDLB, Fernandes TIR, Armada-Da-Silva PA. Influence of manual lymphatic drainage on healthrelated quality of life and symptoms of chronic venous insufficiency: a randomized controlled trial. Arch Phys Med Rehabil. 2015;96:283—291
- Molski P, Kruczyński J, Molski A, Molski S. Manual lymphatic drainage improves the quality of life in patients with chronic venous disease: a randomized controlled trial. Arch Med Sci. 2013;9:452–458.
- Molski P, Ossowski R, Hagner W, Molski S. Patients with venous disease benefit from manual lymphatic drainage. *Int Angiol.* 2009;28: 151–155
- Yamany A, Hamdy B. Effect of sequential pneumatic compression therapy on venous blood velocity, refilling time, pain and quality of life in women with varicose veins: a randomized control study. J Phys Ther Sci. 2016;28:1981–1987.
- Taradaj J, Rosińczuk J, Dymarek R, Halski T, Schneider W. Comparison of efficacy of the intermittent pneumatic compression with a high- and low-pressure application in reducing the lower limbs phlebolymphedema. *Ther Clin Risk Manag.* 2015;11:1545–1554.
- Mohamed WAI, Badr NM, Fouad BE, Elsayed M, Abd M. Efficacy of intermittent pneumatic compression on blood flow in patient with varicose veins. Arch Pharm Pract. 2020;11:149–153.
- Barnhart H, Maldonado T, Rockson SG. Various therapies for lymphedema and chronic venous insufficiency, including a multimodal at-home nonpneumatic compression treatment. Adv Skin Wound Care. 2024;37:212–215.
- Ercan S, Çetin C, Yavuz T, Demir HM, Atalay YB. Effects of isokinetic calf muscle exercise program on muscle strength and venous function in patients with chronic venous insufficiency. *Phlebology*. 2018:33:261–266.
- 22. Ercan S, Çetin C, Yavuz T, Demir HM, Atalay YB. Evaluation of the isokinetic calf muscle strength and the range of motion of joint in C3 chronic venous insufficiency. *Vasc Specialist Int.* 2019;35:95–100.
- Araujo DN, Ribeiro CTD, Maciel ACC, Bruno SS, Fregonezi GAF, Dias F Al. Physical exercise for the treatment of non-ulcerated chronic venous insufficiency. *Cochrane Database Syst Rev.* 2016;2016: CD010637.

- Mutlak O, Slam MA, Dfield NS. The influence of exercise on ulcer healing in patients with chronic venous insufficiency. *Int Angiol.* 2018;37:160–167.
- 25. Aguilar-Ferrándiz ME, Moreno-Lorenzo C, Matarán-Peñarrocha GA, García-Muro F, García-Ríos MC, Castro-Sánchez AM. Effect of a Mixed Kinesio Taping-Compression Technique on Quality of Life and Clinical and gait parameters in postmenopausal women with chronic venous insufficiency: double-blinded, randomized controlled trial. Arch Phys Med Rehabil. 2014;95:1229—1239.
- 26. Aguilar-Ferrándiz ME, Castro-Sánchez AM, Matarán-Peñarrocha GA, Guisado-Barrilao R, García-Ríos MC, Moreno-Lorenzo C. A randomized controlled trial of a mixed Kinesio taping-compression technique on venous symptoms, pain, peripheral venous flow, clinical severity and overall health status in postmenopausal women with chronic venous insufficiency. Clin Rehabil. 2014;28:69–81.
- 27. Naci B, Ozyilmaz S, Aygutalp N, Demir R, Baltaci G, Yigit Z. Effects of Kinesio Taping and compression stockings on pain, edema, functional capacity and quality of life in patients with chronic venous disease: a randomized controlled trial. Clin Rehabil. 2020;34:783—793.
- 28. Lurie F, Passman M, Meisner M, et al. The 2020 update of the CEAP classification system and reporting standards. *J Vasc Surg Venous Lymphat Disord*. 2020;8:342–352.
- Catarinella FS, Nieman FHM, Wittens CHA. An overview of the most commonly used venous quality of life and clinical outcome measurements. J Vasc Surg Venous Lymphat Disord. 2015;3:333–340.
- Passman MA, McLafferty RB, Lentz MF, et al. Validation of Venous Clinical Severity Score (VCSS) with other venous severity assessment tools from the American venous Forum, national venous screening program. J Vasc Surg. 2011;54(6 SUPPL):2S—9S.
- Launois R, Mansilha A, Jantet G. International psychometric validation of the chronic venous disease quality of life questionnaire (CIVIQ-20). Eur J Vasc Endovasc Surg. 2010 Nov;40:783–789.
- 32. Thao Cuong L, Tat Bang H, Le An T, Thi Thien Nga L, Thanh Vy T. Quality of life of patients with chronic venous insufficiency of the lower extremities before and after endovascular laser ablation: a prospective pilot study using the chronic venous insufficiency quality of life questionnaire 20 (CIVIQ-20). Cureus. 2023;15:e41854.
- García Carriazo M, Gómez De Las Heras C, Mármol Vázquez P, Ramos Solís MF. Estudio de la insuficiencia venosa crónica mediante ecografía Doppler y realización de cartografía venosa. *Radiologia*. 2016;58:7–15.
- Berardi H, Ciccioli A. Examen Doppler de la insuficiencia venosa de miembros inferiores: consenso entre especialistas. Revista Argentina de Radiologia. 2014;79:72–79.
- **35.** Jaffer U, Normahani P, Lackenby K, Aslam M, Standfield NJ. Validation of a novel venous duplex ultrasound objective structured assessment of technical skills for the assessment of venous reflux. *J Surg Educ.* 2015;72:754–760.
- **36.** Caggiati A. Ultrasonography of skin changes in legs with chronic venous disease. *Eur J Vasc Endovasc Surg.* 2016;52:534–542.
- Torres-Lacomba M, Navarro-Brazález B, Prieto-Gómez V, Ferrandez JC, Bouchet JY, Romay-Barrero H. Effectiveness of four types of bandages and kinesio-tape for treating breast-cancerrelated lymphoedema: a randomized, single-blind, clinical trial. Clin Rehabil. 2020;34:1230—1241.
- Jayaraj A, Thaggard D. The beneficial role of complex decongestive therapy in patients with symptomatic chronic iliofemoral venous obstruction with phlebolymphedema. J Vasc Surg Venous Lymphat Disord. 2024;12:101686.
- Kraus AL, Rabe E, Kowall B, et al. Differences in risk profile associated with varicose veins and chronic venous insufficiency-results from the Bonn Vein Study 1. Vasa Eur J Vasc Med. 2024;53:145–154.
- Patel J, Shah P, Gandhi F. A study of chronic venous insufficiency in relation with body mass index and diameter of saphenofemoral junction and great saphenous vein. *Indian JVasc Endovasc Surg.* 2021:8:58.