Original communication

The effects of adding physiotherapy to compression therapy on function and oedema in chronic venous insufficiency

Noemí Moreno-Segura[1], Mario Mateo-Martínez[2,3], Mariana Sánchez-Barbadora[1,4], and Rodrigo Martín-San Agustín[1]

[1] Faculty of Physiotherapy, University of Valencia, Valencia, Spain
[2] Health Emergency Services of the Valencian Community from the National Health System (SESCV), Valencia, Spain
[3] Fuensanta Health Centre, Valencia General University Hospital Consortium, Valencia, Spain
[4] Faculty of Health Sciences, Universidad Europea de Valencia, Valencia, Spain

Summary: *Background:* To compare the effects of conventional approaches based on compression stockings and preventive measures with a combined program including these techniques, together with therapeutic exercise and self-manual lymphatic drainage instructed by a physiotherapist on functionality, general physical activity, and oedema in individuals with chronic venous insufficiency. *Patients and methods:* A randomized controlled clinical trial with two parallel groups (conventional approach and conventional plus physiotherapy approach) and a single-blind design was conducted. Oedema (circumferences), functionality (6-Minute Walking Test and the Five-Repetition Sit-to-Stand Test), physical activity level (International Physical Activity Questionnaire), and prevention measures were assessed before and after the intervention. Repeated measures ANOVA was used for statistical analysis. A total of 55 participants composed the final sample (13 women and 42 men, mean age: 60.49 years [15.05]). *Results:* No significant changes were found for the main effect of time or group-time-adherence interaction in any variable, while circumference at 10, 20, and 30cm from the heel in both legs, and the 6-Minutes Walking Test showed a significant main effect for time in the conventional-approach group with high adherence. *Conclusions:* A multicomponent approach combining physiotherapy and medicine does not appear to be better than the conventional approach applied at primary care centres for improving functionality and oedema in patients with chronic venous insufficiency.

Keywords: chronic venous insufficiency, compression stockings, physiotherapy, therapeutic exercise, massage, conservative treatment

Introduction

Chronic venous insufficiency (CVI) is a condition characterized by impaired venous return due to valvular incompetence, with or without venous obstruction. It has a high global prevalence, estimated to range between 25–50% [1, 2], and its incidence increases with age and the absence of medical intervention [3]. Early diagnosis, symptomatic management, and, timely referral to a vascular surgeon are essential to prevent disease progression and complications [2, 3].

The most severe clinical consequences of CVI include deep vein thrombosis and venous ulcers [3, 4], along with symptoms such as nocturnal leg cramps, heaviness, evening swelling, and pruritus [3]. These symptoms significantly affect patients' functionality and quality of life [5].

Conservative treatment remains the first-line approach for mild to moderate CVI, typically involving the use of compression stockings, preventive measures, and pharmacological therapy. In more severe cases, non-conservative interventions such as endovenous ablation, sclerotherapy, or surgery may be indicated [6, 7]. However, despite this therapeutic framework, many CVI patients report insufficient symptom control and a lack of self-management strategies [8].

Among conservative options, compression stockings and pharmacological treatments are supported by the strongest evidence [9, 10]. Compression enhances venous return by increasing interstitial pressure and reducing oedema through improved muscle pump function [9]. Pharmacotherapy acts by decreasing capillary permeability, reducing inflammatory mediators, and improving venous tone [10]. However, adherence to both treatments is often low, especially among patients with comorbid conditions or obesity [11, 12]. Preventive strategies such as weight control, increased physical activity, smoking cessation, wearing loose clothing, and postural adjustments have also shown benefits in symptom management [13].

Physiotherapy has emerged as a promising adjunct treatment for CVI. On the one hand, therapeutic exercise, particularly targeting calf muscle strengthening, and circulatory massage are the main techniques under investigation [14, 15, 16]. Previous research suggests that regular ankle movements may enhance calf pump function, increase venous jet velocity, decrease the pressure on the luminal side of the valve leaflets and promote venous valve

closure [17, 18, 19]. Manual lymphatic drainage, which focuses on removal of tissue fluid (lymph) through very gentle, rhythmic, circular and pumping movements has shown benefits in reducing oedema and improving both superficial and deep venous blood flow [20, 21]. However, current evidence remains limited, with few high-quality studies, poorly standardized protocols, and inconclusive results regarding symptom relief [22]. Furthermore, existing studies have primarily focused on physiological outcomes rather than the functional or symptomatic improvements that matter most to patients. Thus, further research is needed to evaluate these physiotherapy-based interventions [23].

Therefore, the main objective of this study was to compare the effects of a conventional conservative approach (compression stockings and preventive measures) with a combined program that includes these components along with therapeutic exercise and self-manual lymphatic drainage, guided by a physiotherapist, assessing their impact on functionality, general physical activity, and oedema in individuals with CVI.

Patients and methods

Study design

This randomized controlled clinical trial followed a parallel group design and was single-blinded (evaluator blinded). Ethical approval was obtained from the Ethics Committee of the General Hospital of Valencia (register number: 137/2021). The study was conducted between March 2021 and August 2022.

Participants

Participants were recruited from a primary care centre (CS Fuensanta) affiliated with the General Hospital of Valencia in Spain. Medical records were screened for CVI diagnoses using ICD codes, identifying 143 potential candidates. A random sample, generated using an Excel spreadsheet of 100 participants, was selected and contacted for participation. Sample size calculation using G*Power software determined that at least 17 participants per group were needed to detect an effect size of 0.25, with 80% power and a 95% confidence level.

Inclusion criteria were: (a) diagnosis of CVI for at least one year and confirmed with the CEAP (Clinical-Etiological-Anatomical-Pathophysiological) scale at the first visit [24]; (b) age 18–85 years; and (c) access to email or mobile phone. Exclusion criteria included: (a) psychological conditions impairing participation – such as cognitive or emotional disorders that affect understanding or adherence to instructions, with the ability to comprehend and follow the exercise protocol verified through a brief interview; (b) physical comorbidities limiting activity performance (e.g. severe osteoarthritis, peripheral neuropathy, or lower-limb musculoskeletal disorders), with participants asked whether they could reach their knees to ensure adequate range of movement for self-manual lymphatic drainage, and lower-limb mobility observed and confirmed during the initial evaluation; (c) recent surgery (<6 months); (d) deep vein thrombosis; (e) active leg ulcer; and (f) pregnancy.

All participants provided written informed consent after being informed about the study's nature, procedures and objectives.

Procedures

Participants were randomly assigned to either the control group (CG) or the experimental group (EG). Group allocation was concealed using sealed envelopes. The intervention period lasted 16 weeks, during which participants were instructed to maintain their usual routines and medications.

Control group (CG)

Participants received standard conservative treatment. A brochure outlining general preventive recommendations based on Spanish primary care guidelines was provided [25]: These included advice on weight management, increased physical activity, smoking cessation, use of loose clothing, foot and skin care, cold water hydrotherapy, postural advice, and dietary advice to prevent constipation. Additionally, physicians prescribed graduated compression stockings (20–30 mmHg), to be worn for 6–8 hours per day [6].

Experimental group (EG)

In addition to receiving the CG intervention, EG participants engaged in a home-based program involving therapeutic exercise and self-massage, supervised by a physiotherapist. Two initial training sessions with the physiotherapist were followed by a home program, supported by instructional videos sent via mobile devices.

The exercise program included lower-limb mobility, stretching, and strengthening exercises in standing (step exercises, knee-to-chest movements, tiptoe, tiptoe steps, and walking on heels), sitting (fingers flexion-extension, feet separation and approximation, swinging the feet from toes to heels, knee extension with ankle dorsiflexion, tiptoeing, and adductor isometrics for 5 seconds) and supine position (ankle flexion-extension, circles with ankles, hip rotations, hip adductions and abductions, and pedalling) [16, 26, 27, 28]. Participants were instructed to perform 15–20 repetitions of each exercise, once per session, 3–4 times weekly, and to walk for at least 20 minutes daily at a light to moderate pace (i.e., purposeful walking rather than leisurely strolling). Although participants were encouraged to maintain this intensity, the actual walking intensity was not objectively monitored.

Self-manual lymphatic drainage involved venous and lymphatic drainage techniques along the saphenous veins and their pathways. Techniques included effleurage, fixed

circles on the medial thigh, behind the knee, mid-calf area and post-malleolar recesses, bimanual pumping, and plantar massage [20].

Participants in both groups received a diary to log their adherence. Follow-up was conducted via WhatsApp, with reminders sent weekly for the first month, biweekly during the second month, and monthly thereafter. Adherence was categorized as: very high (75–100%), high (50–74%), low (25–49%), or very low (<25%).

Outcome measures

Assessments were conducted at baseline (T0) and post-intervention (T1) by a blinded researcher.

Demographic information (age, sex, body mass index, and occupational status) and comorbidities (diabetes, hypertension, dyslipidaemia, cardiorespiratory conditions) were collected. Smoking status was evaluated using the Spanish version of the 6-item Fagerström questionnaire [29, 30]. CEAP classification and clinical variables related to CVI (fatigue, cramps, heaviness, pain, irritation, or tingling), prior thrombosis, and use of venotonic drugs were recorded. CVI severity was assessed with the Venous Clinical Severity Score (VCSS), which included 10 descriptors scored from 0 to 3, yielding a maximum of 30 points. This measure is validated and commonly used in clinical research [31]. All these variables were recorded only at T0.

Pre- and post-intervention measurements were taken to assess oedema, functionality, physical activity performance, prevention measures applied, and satisfaction with the treatment. All outcome measurements were taken during midday hours (12:00–16:00) to control for diurnal variation.

Oedema was quantified using right and left leg circumferential measurement at four standardized points (12 cm from the hallux, and 10, 20, and 30 cm from the heel to the knee). Total leg volume was estimated using the formula for partial volumes based on circumferences.

Functionality was assessed using standardized functional tests. The 6-Minute Walking Test (6MWT) measures the maximum distance walked in 6 minutes along a 30-meter marked corridor [32], where higher values indicate better functionality. The five-repetition sit-to-stand test (5STS) was employed to assess functional lower limb strength, balance and functional mobility. Participants were timed while performing 5 sit-to-stand transitions from a standard chair, with the arms crossed over the chest, where lower values indicate better functional performance [33].

The International Physical Activity Questionnaire (IPAQ) was administered to assess frequency and duration of physical activities, including walking, moderate to vigorous exertion, and sedentary time [34].

Adherence to prevention measures was quantified with a 10-item checklist (e.g., use of compression stockings, avoiding heat sources, cold water hydrotherapy, leg elevation, avoiding tight clothing). Each item received a binary score (0 or 1), with total scores ranging from 0 (no measures followed) to 10 (all measures followed).

Finally, participants' satisfaction with the intervention was assessed using a 10-point Likert scale (0 = least satisfied; 10 = most satisfied).

Statistical analysis

Statistical analyses were conducted using IBM SPSS Statistics software (Version 28.0, IBM Corp, Armonk, NY, USA). Continuous variables were summarized as means (SD), and categorical variables as frequencies. The Shapiro–Wilk test verified normality of distribution.

Baseline differences between groups were evaluated using unpaired t-tests. To assess intervention effects, two-way repeated measures ANOVA (Group × Time × Adherence) was conducted for each outcome. Where significant effects were found, Bonferroni-adjusted post-hoc t-tests (paired and unpaired) were used. Adherence was also considered as a categorical variable, classified as low or moderate-to-high. Participants who completed more than 50% of the prescribed sessions were categorized as having moderate-to-high adherence, whereas those below this threshold were considered to have low adherence.

Moreover, an additional analysis was performed excluding participants who showed low or very low adherence to the assigned treatment, as reported in their intervention diaries (11 in the CG and 10 in the EG).

Effect sizes were reported using Partial Eta squared (η^2), with thresholds as follows: small (0.01–0.06), medium (0.06–0.14), and large (>0.14). Cohen's d was also reported, with thresholds: trivial (<0.2), small (0.2–0.5), medium (0.5–0.8) and large (>0.8) [35]. A significance level of $p<.05$ was adopted for all tests.

Participants with low or very low adherence were excluded from the final analysis to ensure the validity of outcome comparisons.

Results

Of the 100 participants selected for the telephone screening, 10 did not meet the inclusion criteria or were excluded based on the exclusion criteria. Additionally, 16 declined participation, citing a lack of time to comply with the study protocol, and 4 did not attend the baseline assessment. Consequently, 70 participants were randomized into CG (n=35) and EG (n=35). For various reasons, detailed in Figure 1, 15 participants did not complete the intervention or post-intervention assessment. To perform the additional analysis with the patients who reported high adherence, 21 participants who showed low or very low adherence were removed (11 in the CG and 10 in the EG).

Sociodemographic and clinical characteristics

Table I shows the sociodemographic and clinical characteristics of the participants. The mean age was 60.49 years (SD=15.05), and the total sample included more men than

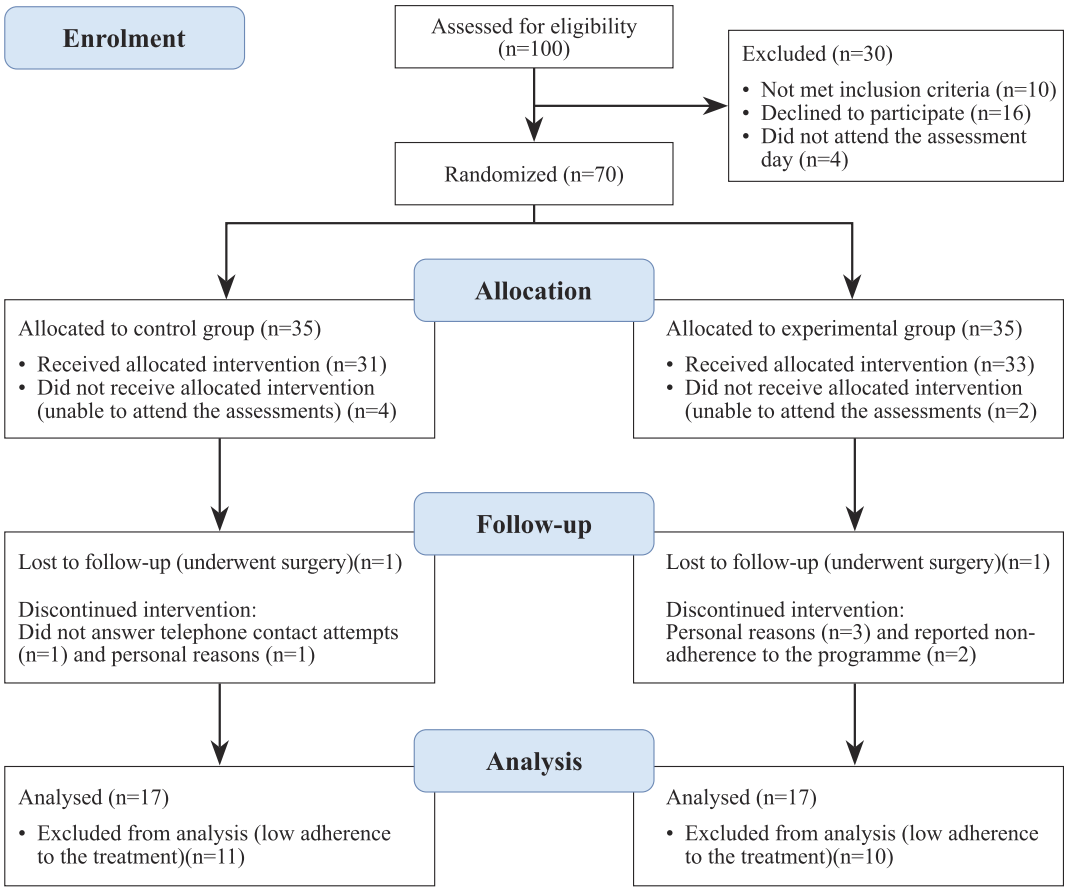

Figure 1. Flowchart of participant recruitment and inclusion in the study. Participants were screened for eligibility and then assigned to the experimental or control group. The final sample size at each stage is indicated. Arrows indicate progression through the study stages, and numbers represent the total participants at each stage.

women. The average body mass index was less than 30 kg/m^2 in both groups. While the majority of participants were retired, the final sample also included homemakers, cleaning staff, retail workers, healthcare workers, technicians, and unemployed individuals.

Regarding clinical symptoms, the severity of CVI was low, with mean VCSS scores of 6.00 in the CG and 5.93 in the EG. Most participants were non-smokers. The most frequently reported symptoms were heaviness and pain, followed by tingling and cramps. Only 4 participants had a history of deep vein thrombosis, and 12 had undergone varicose vein surgery but continued to experience symptoms. The most common comorbidities were hypertension and hypercholesterolemia. Both groups were comparable at baseline in terms of age, body mass index, clinical severity of CVI symptoms (VCSS), and smoking dependence (Fagerström test) (p>.05).

Adherence to the intervention

Adherence to the intervention was classified as low or very low in 11 out of 28 participants (39.29%) in the CG and in 10 out of 27 participants (37.04%) in the EG. A secondary analysis was performed excluding these participants from the analysis, as their low adherence was not representative of the appropriate application of the prescribed techniques (21 participants in total).

In the CG, adherence to the use of compression stockings was high in 4 participants (23.5%) and very high in 13 (76.5%). In the EG, adherence to compression stockings was high in 3 participants (17,6%) and very high in 14 (82.4%). Adherence to the therapeutic exercise program was very high across all EG participants (100%). Regarding self-massage techniques, 2 participants (11.8%) demonstrated high adherence, and 15 (88.2%) showed very high adherence.

Effects of the intervention

No significant baseline differences were found between groups in any of the outcome variables.

Leg circumference

The complete analysis showed no significant time effect or group × time × adherence interaction was found in any of the leg's circumference measures. Detailed data are showed in Table II.

For the right leg circumference at 12 cm from the hallux and 20 cm from the heel no time by group interaction was found. However, significant time-by-group interaction were observed at total circumference and 10 cm, 30 cm from the heel (p=.004; η^2=0.148, p=.026; η^2=0.09, p=.046; η^2=0.076, respectively) and significant time effects were observed at total circumference, 10 cm,

Table I. Sociodemographic and clinical characteristics of the patients

	Control group (n=28)	Experimental group (n=27)	Total (n=55)	p-value
Age (years)	62.11 (15.36)	58.81 (14.82)	60.49 (15.05)	.422
Sex (women/men)	7/21	6/21	13/42	–
Height (m)	163.35 (8.23)	165.26 (6.81)	164.29 (7.56)	.356
Weight (kg)	74.40 (18.80)	76.64 (15.39)	75.50 (17.09)	.632
BMI	25.54 (9.60)	27.67 (5.08)	26.58 (7.72)	.311
Job position:				
• Homemakers	3	5	8	–
• Cleaning workers	5	5	10	–
• Retail workers	3	1	4	–
• Hospital workers	1	2	3	–
• Technicians or engineers	3	2	5	–
• Unemployed	1	1	2	–
• Retired	12	11	23	–
Venous symptoms (yes):				
• Fatigue	13	12	25	–
• Cramps	10	7	27	–
• Heaviness	19	18	37	–
• Pain	15	18	33	–
• Irritation	13	13	26	–
• Tingling	14	15	20	–
Previous venous surgery (yes)	6	6	12	–
Previous deep vein thrombosis (yes)	2	2	4	–
Comorbidities (yes):				
• Diabetes	4	3	3	–
• High blood pressure	10	10	20	–
• Cardiorespiratory disease	5	1	6	–
• Cholesterol	10	11	21	–
Venotonic drugs (yes)	9	8	17	–
CEAP Classification Clinic				
• Telangiectasias	9	5	14	–
• Truncal varicose veins	7	10	17	–
• Edema	4	4	8	–
• Skin changes	5	6	11	–
• Skin changes + active ulcer	3	1	4	–
Etiology				
• Congenital	1	1	2	–
• Primary	26	26	52	–
• Secondary	1	0	18	–
Anatomy				
• Superficial veins	21	22	43	–
• Deep veins	5	4	9	–
• Perforator system	2	7	9	–
Pathophysiology				
• Reflux	23	23	46	–
• Obstruction	0	0	0	–
• Reflux and obstruction	4	4	8	–
• Not identifiable cause	1	0	1	–
VCSS	6.00 (5.25)	5.93 (3.67)	5.96 (4.50)	–
Fagerström Test	0.25 (0.89)	0.11 (0.58)	0.18 (0.75)	–

Notes. Data are expressed as mean (standard deviation). BMI: body mass index; CEAP: clinical-etiological-anatomical-pathophysiological; kg: kilograms; m: meters; VCSS: venous clinical severity score.

Table II. Results of right and left leg circumference (cm) measured at 12 cm from the hallux, 10, 20 and 30 cm from the heel

		T0	T1	T1–T0	p-value [ES]
Right leg					
Circumference 12 cm from the hallux	Total CG	24.86 (1.22)	24.66 (1.61)	-0.21 (0.76)	.080 (0.27)
	High Adh	24.76 (1.28)	24.49 (1.77)	-0.26 (0.89)	.120
	Total EG	24.85 (1.29)	25.06 (1.47)	0.21 (0.64)	.049
	High Adh	24.69 (1.41)	24.97 (1.65)	0.28 (0.73)	.077
Circumference 10 cm from the heel	Total CG	23.06 (2.06)	22.71 (2.02)	-0.35 (0.50)	<.001 (1.07)
	High Adh	22.75 (1.98)	22.31 (1.92)	-0.44 (0.37)	<.001 [1.17]
	Total EG	22.20 (2.06)	22.99 (2.14)	0.21 (0.51)	.21
	High Adh	22.52 (1.78)	22.26 (1.86)	-0.26 (0.60)	.051
Circumference 20 cm from the heel	Total CG	29.56 (3.45)	28.75 (3.37)	-0.81 (0.82)	<.001 (0.98)
	High Adh	29.70 (3.10)	29.02 (3.24)	-0.68 (0.86)	.003 [0.78]
	Total EG	29.65 (3.01)	29.04 (2.97)	-0.61 (1.23)	.008
	High Adh	28.51 (2.34)	28.23 (2.43)	0.28 (1.34)	.208
Circumference 30 cm from the heel	Total CG	37.47 (4.57)	36.48 (4.80)	-0.99 (1.78)	.003 (0.55)
	High Adh	37.62 (4.47)	37.07 (4.29)	-0.55 (0.63)	.001 [0.86]
	Total EG	37.47 (3.28)	37.12 (3.21)	-0.35 (0.68)	.006
	High Adh	36.58 (2.48)	36.27 (2.64)	-0.31 (0.83)	.077
Total circumference	Total CG	408.07 (51.08)	396.75 (52.75)	-11.32 (13.81)	<.001 (0.82)
	High Adh	403.88 (50.48)	393.06 (55.08)	-10.82 (16.36)	.007 [0.66]
	Total EG	412.04 (49.91)	411.89 (51.13)	-0.15 (12.97)	.477
	High Adh	398.06 (45.52)	398.50 (47.39)	0.44 (15.55)	.456
Left leg					
Circumference 12 cm from the hallux	Total CG	25.10 (1.47)	24.61 (1.58)	-0.48 (0.97)	.007 (0.50)
	High Adh	25.07 (1.64)	24.49 (1.89)	-0.58 (1.14)	.027 [0.51]
	Total EG	25.04 (1.52)	24.87 (1.36)	-0.17 (0.68)	.097
	High Adh	24.84 (1.39)	24.68 (1.53)	-0.17 (0.63)	.150
Circumference 10 cm from the heel	Total CG	23.09 (2.47)	22.79 (2.33)	-0.30 (0.52)	.003 (0.58)
	High Adh	22.80 (2.23)	22.54 (2.26)	-0.26 (0.52)	.030 [0.49]
	Total EG	23.37 (1.76)	23.18 (1.81)	-0.19 (0.61)	.059
	High Adh	22.73 (1.58)	22.56 (1.58)	-0.17 (0.62)	.148
Circumference 20 cm from the heel	Total CG	29.63 (4.06)	28.87 (3.76)	-0.76 (1.12)	<.001 (0.68)
	High Adh	29.75 (3.53)	29.15 (3.55)	-0.59 (0.76)	.003 [0.79]
	Total EG	29.74 (2.91)	29.20 (2.98)	-0.54 (1.08)	.007
	High Adh	28.49 (2.21)	28.17 (2.65)	-0.33 (1.19)	.147
Circumference 30 cm from the heel	Total CG	36.55 (7.49)	36.83 (4.26)	0.28 (5.76)	.399
	High Adh	37.70 (4.08)	37.02 (4.21)	-0.68 (0.85)	.002 [0.80]
	Total EG	36.97 (3.74)	37.23 (3.04)	0.25 (1.98)	.257
	High Adh	35.74 (3.53)	36.24 (2.56)	0.51 (2.56)	.220
Total circumference	Total CG	414.32 (60.90)	401.86 (57.07)	-12.46 (20.04)	<.001 (0.62)
	High Adh	410.24 (58.64)	396.88 (59.29)	-13.35 (21.19)	.010 [0.63]
	Total EG	417.00 (49.04)	411.26 (45.94)	-5.74 (14.94)	.28 (0.38)
	High Adh	402.50 (40.76)	397.75 (42.73)	-4.75 (14.90)	.111

Notes. Data are expressed as mean (standard deviation). T0: pre-treatment measures; T1: post-treatment measures; P: intra-group differences between T0 and T1; CG: control group; EG: experimental group; ES: effect size; High Adh: high adherence.

20 cm and 30 cm from the heel (p=.003; η^2=0.161, p<.001; η^2=0.35, p<.001; η^2=0.368, p<.001; η^2=0.241, respectively). Regarding the high adherence subgroup analysis, significant time effects were observed at 10 cm, 20 cm, and 30 cm from the heel (p<.001; η^2=0.34, p=.02; η^2=0.16, p=.002; η^2=0.27, respectively), without significant group-by-time interaction. Post-hoc analysis indicated significant reductions of 0.44 cm, 0.68 cm, and 0.55 cm, respectively, in the CG.

For the left leg, none of the variables measured showed a time by group interaction. However, significant time effect was found for total circumference, 12 cm from the hallux, 10 cm and 20 cm from the heel (p<.001; η^2=0.280, p=.009; η^2=.126, p<.001; η^2=0.296, p=.002; η^2=0.167, respectively). Regarding the high adherence subgroup analysis, circumference at 12 cm from the hallux showed neither a significant time effect nor group-by-time interaction. In contrast, measurements at 10, 20 and 30 cm from

Table III. Results of functional status

		T0	T1	T1–T0	p-value (ES)
6MWT (m)	Total CG	397.52 (93.28)	385.95 (85.99)	-11.57 (52.03)	.437
	High Adh	397.94 (84.29)	414.01 (84.68)	16.07 (35.02)	.04 [0.46]
	Total EG	395.15 (81.21)	399.59 (89.87)	4.44 (34.80)	.256
	High Adh	417.31 (80.53)	426.06 (84.99)	8.75 (38.41)	.348
5STST (s)	Total CG	14.10 (5.04)	13.78 (6.75)	-0.33 (3.31)	.309
	High Adh	14.16 (5.26)	13.71 (7.63)	-0.44 (4.07)	.582
	Total EG	13.53 (2.90)	12.21 (3.27)	-1.32 (2.56)	.007 (0.52)
	High Adh	12.79 (2.56)	11.62 (2.67)	-1.16 (1.67)	.140

Notes. Data are expressed as mean (standard deviation). T0: pre-treatment measures; T1: post-treatment measures; P: intra-group differences between T0 and T1; 5TSTST: 5 times sit-to-stand test; 6MWT: 6-minutes-walking test; CG: control group; EG: experimental group; ES: effect size; High Adh: high adherence.

Table IV. Results of physical activity performance and prevention measure applied

		T0	T1	T1–T0	p-value (ES)
Physical activity (METS)	Total CG	1896.20 (1681.58)	1619.36 (1392.42)	-276.84 (1266.23)	.129
	High Adh	2077.59 (1999.24)	2037.62 (1549.69)	-39.97 (1416.41)	.454
	Total EG	1277.89 (1177.96)	1448.28 (1322.08)	170.39 (1216.06)	.237
	High Adh	1221.18 (1129.14)	1172.30 (657.31)	-48.88 (1273.28)	.438
Prevention measures applied	Total CG	6.39 (1.99)	8.36 (1.34)	1.96 (2.01)	<.001 (0.98)
	High Adh	6.47 (2.21)	9.12 (0.78)	2.65 (2.15)	<.001 [1.23]
	Total EG	5.15 (1.63)	8.52 (1.67)	3.37 (1.76)	<.001 (1.91)
	High Adh	5.76 (1.56)	9.35 (0.70)	3.59 (1.42)	<.001 [2.53]

Notes. Data are expressed as mean (standard deviation). T0: pre-treatment measures; T1: post-treatment measures; P: intra-group differences between T0 and T1; CG: control group; EG: experimental group; ES: effect size; High Adh: high adherence.

the heel, as well as the total circumference, showed significant time effects (p=.028; η^2=0.15, p=.041; η^2=0.13, p=.012; η^2=.19; p=.008; η^2=0.20, respectively), with no group-by-time interactions. Post-hoc analysis revealed reductions of 0.58 cm, 0.26 cm, 0.59 cm, 0.68 cm, and 13.35 cm, respectively, in the CG.

Functional status (6MWT and 5STST)

In relation to functional capacity (Table III), no time × group × adherence, time x group nor time interactions were found (p>.05) for any of the tests measured. Regarding the high adherence subgroup analysis, the 6MWT showed a significant main effect for time (p=.04; η^2=0.15), while the 5STST did not show any significant time or interaction effects. Post-hoc analysis indicated a significant increase of 16.07 meters in walking distance for the CG.

Physical activity performance and prevention measures

Regarding physical activity levels, no time × group × adherence, time × group nor time interactions were found (p>.05). Regarding the high adherence subgroup analysis, the physical activity levels measured via IPAQ revealed no significant main effects for time or group-by-time interaction.

Regarding prevention measures, no time × group × adherence interaction was found; however, both a time × group interaction and a time effect were observed (p=.004; η^2=0.15, p<.001; η^2=0.674, respectively). The high-adherence subgroup analysis showed that scores from the preventive measures questionnaire revealed a significant main effect for time (p<.001; η^2=0.76), without a significant group-by-time interaction. Post-hoc analysis showed a significant increase in adherence to preventive measures of 2.65 points in the CG and 3.59 points in the EG. Detailed information is shown in Table IV.

Satisfaction with the treatment received

The mean satisfaction scores were 7.88 (SD=2.32) in the CG and 8.18 (SD=2.45) in the EG. Although the EG reported slightly higher satisfaction, the difference was not statistically significant (p=.388).

Discussion

This study aimed to evaluate whether the inclusion of a physiotherapist in primary care health centres – who provided instruction in home-based exercise programs (focused on lower limb strengthening and mobilization) and self-manual lymphatic drainage techniques – could enhance the conventional medical management of patients with CVI, which typically includes the use of compression

stockings and general preventive recommendations. The findings of this randomized clinical trial indicate that, although the program was well received by the participants, those who adhered only to the conventional approach showed improvements in several outcomes, including leg circumference and functional gait measures. However, no extra clinical improvements were observed in the experimental group.

The improvements observed in the CG were expected, as the use of compression stockings combined with preventive recommendations represents the *gold standard* for conservative CVI treatment when used alongside pharmacological interventions. Numerous studies have confirmed the benefits of this approach for reducing oedema, enhancing functionality, and alleviating CVI symptoms [36, 37, 38, 39]. However, we hypothesized that a multimodal approach integrating physiotherapy would yield superior outcomes, which was not supported by our results.

Regarding lower limb oedema, our findings indicate that participants in the CG experienced a reduction in leg circumference, whereas no such improvement was observed in the EG. These results contradict those of Kravtsov et al. [40], who reported a reduction in ankle oedema following a two-month lower limb strengthening program. However, their study involved only 22 participants performing exercises twice daily, in contrast to our protocol of three sessions per week. Similarly, De Jesús Leal et al. [41] reported a decrease in leg volume following a combined intervention of exercise and drainage massage in a single group of 10 patients. However, the absence of a CG in that study limits the ability to attribute changes solely to the intervention. On the other hand, Santos Crisóstonomo et al. [21] found no improvements in oedema following drainage massage applied by a physiotherapist, a result more consistent with our findings.

We hypothesize that the lack of oedema reduction in the EG may be attributable to the assessment method used – leg circumference – which may have been influenced by increases in muscle mass associated with the exercise program. This explanation is particularly plausible given that, although the EG presented lower baseline levels of physical activity compared to the CG, they showed better baseline performance in the 6MWT and 5STST, suggesting an initial capacity to achieve greater muscle gains. Moreover, after the intervention, physical activity levels were similar between groups. This study reinforces the need to employ more objective tools, such as ultrasound imaging, to differentiate between reductions in oedema and increases in muscle mass.

Regarding functional outcomes, our data showed that the multimodal approach had no effect on functional measures (5STST and 6MWT), while the CG demonstrated improved performance on the 6MWT. However, it is important to note that the mean improvements observed in our study (+ 16.07 in the CG and 8.75 in the EG) fall below the minimal clinically important difference (20–30 m) and the minimal detectable change (50 m) typically reported in the literature [42]. Therefore, while statistically significant, the clinical relevance of these changes appears limited. These findings align with those reported by Saliha Gürdal Karakelle [22] who found no functional improvements when comparing exercise to compression therapy. Possible contributing factors for these outcomes may include the emphasis on gait mechanics in the EG, which could have improved movement quality without increasing walking distance. Such improvements in gait pattern may also reduce the energy cost of walking, potentially translating into functional gains not reflected in the functional tests. However, we did not collect indicators of cardiovascular effort or physiological strain (e.g., heart rate, rate of perceived exertion), which limits our ability to confirm this mechanism. Future studies should incorporate these measures to better clarify the relationship between gait quality, energy expenditure, and functional performance. Moreover, the preventive recommendations were provided to both groups, which may have encouraged greater physical activity in the CG. Importantly, both groups showed increased adherence to preventive measures over the study period, and physical activity levels were maintained throughout. Additionally, differences in CVI severity between our primary care population and those recruited in previous studies conducted in vascular surgery units reported in other clinical trials may have influenced outcomes, too [43, 44].

This randomized controlled trial contributes several strengths to the current literature on CVI. To the best of our knowledge, this is the first randomized controlled trial to examine the inclusion of a physiotherapist in primary care consultations for CVI patients. Moreover, the study protocol was carefully designed to ensure randomization and double-blinding, and the intervention was grounded in established clinical guidelines and prior research on exercise, preventive strategies, compression therapy, and self-manual lymphatic drainage e [16, 25, 26, 27, 28].

Limitations

Nevertheless, several limitations must be acknowledged. First, the study sample was recruited from a single primary care centre, and the inclusion of only participants with access to email and mobile phones may have introduced selection bias, potentially limiting generalizability. Second, adherence rates were relatively low across the study, despite the implementation of various strategies to enhance adherence, such as a follow-up calendar, telephone reminders, and follow-up calls. It is possible that adherence would have been higher if the physiotherapy sessions had been conducted in person. However, given that CVI is a chronic condition, the intervention was intentionally designed to be feasible, accessible, and sustainable in the long term. Third, the study did not evaluate the isolated effects of each intervention component. Fourth, walking intensity was not objectively monitored, and participants' compliance with the recommended light-to-moderate pace could not be verified. Fifth, the self-administered manual lymphatic drainage used

in this protocol did not include proximal techniques targeting central lymph node regions, such as the neck, chest, or axilla, which are considered essential in current concepts (e.g. Vodder, Földi). Although drainage of the inguinal and leg regions was performed, the absence of these central techniques may have limited the effectiveness of the intervention. Therefore, future multicentre studies with larger sample sizes, improved adherence strategies or in-person sessions, and groups testing individual interventions are warranted to address these limitations and provide more definitive evidence in this field.

Conclusions

In conclusion, this study indicates that a multicomponent approach combining physiotherapy – consisting of home-based exercise and self-manual lymphatic drainage techniques – with standard medical care, including preventive recommendations and compression therapy, does not yield superior outcomes in functionality and oedema compared to the conventional approach routinely applied at primary care centres for patients with CVI. In fact, the conventional approach alone appears to offer better results in reducing leg circumference and increasing gait distance than the multicomponent intervention. However, all participants in both groups reported high levels of satisfaction with the treatment received, and no adverse effects were observed during the study period. These findings highlight the need for further multicentre randomized controlled trials with larger sample sizes to validate these results and explore the potential role of physiotherapy within comprehensive CVI management strategies.

References

1. Gómez Aguilar LM. Trastornos circulatorios de las extremidades inferiores (I). Clasificación, epidemiología, fisiopatología, clínica y complicaciones. Offarm. 2003;22:94–104.
2. García Alcalde L, Serralde Aguayo JA, Pontón Cortina A. Estudio de la insuficiencia venosa crónica. Cirugía Cardiovasc. 2024;(31):256–66.
3. Kienzl P, Deinsberger J, Weber B. Chronic Venous Disease: Pathophysiological Aspects, Risk Factors, and Diagnosis. Hämostaseologie. 2024;44:277–86.
4. Marquez RG, Desai K. Venous Interventions: Controversies in the Management of Acute Deep Venous Thrombosis and the Role of the Interventional Radiologist. Radiol Clin North Am. 2024;62(6):1003–11.
5. Ulloa JH, Lurie F, Santiago FR, Reina L, Wang J, Jindal R, et al. Systematic literature review and expert meeting report on health-related quality of life in chronic venous disease. Int Angiol. 2023;42(6):465–76.
6. Gloviczki B Peter, Lawrence P, Wasan S, Meissner MH, Almeida J, Brown KR, et al. The 2023 Society for Vascular Surgery, American Venous Forum, and American Vein and Lymphatic Society clinical practice guidelines for the management of varicose veins of the lower extremities. Part II: Endorsed by the Society of Interventional Radiology and the Society for Vascular Medicine. J Vasc Surg Venous Limphat Disord. 2023;12(1):101670.
7. Singh A, Zahra F. Chronic Venous Insufficiency. Treasure Island (FL): StatPearls Publishing; 2023.
8. Centre (UK) NCG. Patient perceptions and expectations. In National Institute for Health and Care Excellence (NICE); 2013 [cited 2024 Oct 19]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK328018/.
9. Rabe E, Partsch H, Hafner J, Lattimer C, Mosti G, Neumann M, et al. Indications for medical compression stockings in venous and lymphatic disorders: An evidence-based consensus statement. Phlebology. 2018;33(3):163–84.
10. Belczak SQ, Sincos IR, Campos W, Beserra J, Nering G, Aun R. Veno-active drugs for chronic venous disease: A randomized, double-blind, placebo-controlled parallel-design trial. Phlebology. 2014;29(7):454–60.
11. Ayala Á, Guerra JD, Ulloa JH, Kabnick L. Compliance with compression therapy in primary chronic venous disease: Results from a tropical country. Phlebology. 2019;34(4):272–7.
12. Chudek J, Kocełak P, Ziaja D, Owczarek A, Ziaja K. Compliance in pharmacotherapy in patients with chronic venous disorders. Int Angiol. 2012;31(4):393–401.
13. Soydan E, Yılmaz E, Baydur H. Effect of socio-demographic characteristics and clinical findings on the quality of life of patients with chronic venous insufficiency. Vascular. 2017;25(4):382–9.
14. Dogru-Huzmeli E, Fansa I, Cetisli-Korkmaz N, Oznur-Karabicak G, Lale C, Gokcek O, et al. Dancing: More than a therapy for patients with venous insufficiency. Vascular. 2020;28(2):189–95.
15. Padberg FT, Johnston MV, Sisto SA. Structured exercise improves calf muscle pump function in chronic venous insufficiency: a randomized trial. J Vasc Surg. 2004;39(1):79–87.
16. 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(4):261–6.
17. Bergan JJ, Schmid-Schönbein GW, Smith PDC, Nicolaides AN, Boisseau MR, Eklof B. Chronic venous disease. N Engl J Med. 2006;355(5):488–98.
18. Dymarek R, Ptaszkowski K, Słupska L, Rajfur J, Pasternok M, Taradaj J, et al. [Physiotherapy potentials improve the calf muscle pump function in chronic venous insufficiency]. Wiad Lek. 2014;67(2):112–8.
19. Vairo GL, Miller SJ, Rier NMCI, Uckley WBI. Systematic Review of Efficacy for Manual Lymphatic Drainage Techniques in Sports Medicine and Rehabilitation: An Evidence-Based Practice Approach. Journal of Manual & Manipulative Therapy. 2009;17(3):80E–89E.
20. Dos Santos Crisóstomo RS, Candeias MS, Ribeiro AMM, da Luz Belo Martins C, Armada-da-Silva PA. Manual lymphatic drainage in chronic venous disease: a duplex ultrasound study. Phlebology. 2014;29(10):667–76.
21. dos Santos Crisóstomo RS, Costa DSA, de Luz Belo Martins C, Fernandes TIR, Armada-da-Silva PA. Influence of manual lymphatic drainage on health-related quality of life and symptoms of chronic venous insufficiency: a randomized controlled trial. Arch Phys Med Rehabil. 2015;96(2):283–91.
22. Gürdal Karakelle S, Ipek Y, Tulin O, Alpagut İU. The efficiency of exercise training in patients with venous insufficiency: A double blinded, randomized controlled trial. Phlebology. 2021;36(6):440–9.
23. Araujo DN, Ribeiro CT, Maciel AC, Bruno SS, Fregonezi GA, Dias FA. Physical exercise for the treatment of non-ulcerated chronic venous insufficiency. Cochrane Database of Systematic Reviews. 2023;6(6):CD010637.
24. Zegarra TI, Tadi P. CEAP Classification of Venous Disorders. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 [cited 2025 Nov 20]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK557410
25. Carrasco Carrasco E Díaz Sánchez, Santiago. Recomendaciones para el manejo de la enfermedad venosa crónica en atención primaria. Torrejón de Ardoz: Id Médica; 2015.

26. Uhl JF, Gillot C. Anatomy of the veno-muscular pumps of the lower limb. Phlebology. 2015;30(3):180–93.
27. Orr L, Klement KA, McCrossin L, O'Sullivan Drombolis D, Houghton PE, Spaulding S, et al. A Systematic Review and Meta-analysis of Exercise Intervention for the Treatment of Calf Muscle Pump Impairment in Individuals with Chronic Venous Insufficiency. Ostomy Wound Manage. 2017;63(8): 30–43.
28. Yang D, Vandongen YK, Stacey MC. Effect of exercise on calf muscle pump function in patients with chronic venous disease. Br J Surg. 1999;86(3):338–41.
29. Arias-Gallegos WL, Huamani-Cahua JC, Choque-Vera R. Análisis psicométrico del test de Fagerström de dependencia a la nicotina en una muestra de estudiantes universitarios de Arequipa, Perú. Acta Med Peru [Internet]. 2019 Jan 3 [cited 2021 Sept 30];35(3). Available from: https://amp.cmp.org.pe/index.php/AMP/article/view/618
30. Becoña E, Vázquez FL. The Fagerström Test for Nicotine Dependence in a Spanish sample. Psychol Rep. 1998;83(3 Pt 2): 1455–8.
31. Passman MA, McLafferty RB, Lentz MF, Nagre SB, Iafrati MD, Bohannon WT, 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.
32. Gochicoa-Rangel L, Mora-Romero U, Guerrero-Zúñiga S, Silva-Cerón M, Cid-Juárez S, Velázquez-Uncal M, et al. Prueba de caminata de 6 minutos: recomendaciones y procedimientos. Neumología y cirugía de tórax. 2015;74(2): 127–36.
33. Goldberg A, Chavis M, Watkins J, Wilson T. The five-times-sit-to-stand test: validity, reliability and detectable change in older females. Aging Clin Exp Res. 2012;24(4):339–44.
34. Barrera R. Cuestionario Internacional de actividad física (IPAQ). Revista Enfermería del Trabajo. 2017;7(2):49–54.
35. Cohen J. Weighted kappa: nominal scale agreement with provision for scaled disagreement or partial credit. Psychol Bull. 1968;70(4):213–20.
36. Riebe H, Konschake W, Haase H, Jünger M. Advantages and disadvantages of graduated and inverse graduated compression hosiery in patients with chronic venous insufficiency and healthy volunteers: A prospective, mono-centric, blinded, open randomised, controlled and cross-over trial. Phlebology. 2018;33(1):14–26.
37. Naci B, Ozyilmaz S, Aygutalp N, Demir R, Baltaci G, Yigit C. 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(6):783–93.
38. Vayssairat M, Ziani E, Houot B. Efficacité versus placebo de la contention classe 1 dans l'insuffisance veineuse chronique des membres inférieurs [Placebo controlled efficacy of class 1 elastic stockings in chronic venous insufficiency of the lower limbs]. J Mal Vasc. 2000;25(4):256–62. French.
39. Hague A, Pherwani A, Rajagopalan S. Role of compression therapy in pathophysiology of the venous system in lower limbs. Surgeon. 2017;15(1):40–6.
40. Kravtsov PF, Katorkin SA, Volkovoy VV, Sizonenko YV. Vliyanie trenirovki myshechnogo komponenta myshechno-venoznoi pompy nizhnikh konechnostei na techenie varikoznoi bolezni [The influence of the training of the muscular component of the musculo-venous pump in the lower extremities on the clinical course of varicose vein disease]. Vopr Kurortol Fizioter Lech Fiz Kult. 2016;93(6):33–6. Russian.
41. Leal F de J, Couto RC, Silva TP da, Tenório V de O. Fisioterapia vascular no tratamento da doença venosa crônica. [cited 2024 Oct 26]; Available from: https://www.scielo.br/j/jvb/a/8ypFWZMgC4k4pS8qWYB5Q8d/?lang=pt
42. Perera S, Mody SH, Woodman RC, Studenski SA. Meaningful change and responsiveness in common physical performance measures in older adults. J Am Geriatr Soc. 2006;54(5):743–9.
43. Pereira DAG, Furtado SRC, Amâncio GPO, Zuba PP, Coelho CC, de Lima AP, et al. Association between heel-rise test performance and clinical severity of chronic venous insufficiency. Phlebology. 2020;35(8):631–6.
44. Cetin C, Serbest MO, Ercan S, Yavuz T, Erdogan A. An evaluation of the lower extremity muscle strength of patients with chronic venous insufficiency. Phlebology. 2016;31(3): 203–8.

History
Received September 15, 2025
Revision received November 23, 2025
Accepted December 5, 2025
Published online January 19, 2026

Acknowledgments
We thank the participants who attended the study sessions and their families for their support.

Conflict of interest
The authors declare that there are no conflicts of interest.

Open science
The raw data of this article will be made available upon request by the authors.

ORCID
Noemí Moreno-Segura
https://orcid.org/0000-0001-6061-5080
Mariana Sánchez-Barbadora
https://orcid.org/0000-0002-1416-5493
Rodrigo Martín-San Agustín
https://orcid.org/0000-0001-8201-0189

Correspondence address
Dr. Mariana Sánchez-Barbadora
European University of Valencia (SLU)
Faculty of Health Sciences
Paseo Alameda 7
46010 Valencia, Spain

mariana.sanchez@universidadeuropea.es