Vibrotherapy improves venous hemodynamics and metabolic profile in elderly with venous insufficiency: a randomized trial

La vibroterapia mejora la hemodinámica venosa y el perfil metabólico en ancianos con insuficiencia venosa: un ensayo aleatorizado

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Abstract

This randomized controlled trial investigated the effects of adjunctive vibrotherapy on elderly patients with chronic venous insufficiency. Sixty participants aged 65-85 were allocated to either a group receiving vibrotherapy combined with conventional physical therapy or a control group receiving only standard care over a twelve-week intervention period. The results demonstrated that while both groups showed improvements, the vibrotherapy group exhibited significantly superior outcomes across all measured parameters. These included enhanced venous hemodynamics on duplex ultrasound, improved lipid profiles with reduced LDL-C and triglycerides alongside increased HDL-C levels, and notable reductions in anthropometric measures including waist circumference and body mass index. Additionally, participants receiving vibrotherapy reported substantially greater improvements in quality of life assessments. The findings strongly support incorporating vibrotherapy as an effective non-pharmacological adjunct to conventional physical therapy regimens for managing chronic venous insufficiency in elderly populations, addressing both vascular and metabolic aspects of this condition while significantly enhancing patient quality of life.

Keywords: Elderly; Lipid profile; quality of life; vibrotherapy; Venous insufficiency; Waist circumference. duplex ultrasonograhy.8j

Resumen

Este ensayo controlado aleatorizado investigó los efectos de la vibroterapia adyuvante en pacientes de edad avanzada con insuficiencia venosa crónica. Sesenta participantes de entre 65 y 85 años fueron asignados a un grupo que recibió vibroterapia combinada con fisioterapia convencional o a un grupo control que recibió solo atención estándar durante un período de intervención de doce semanas. Los resultados demostraron que, si bien ambos grupos mostraron mejoras, el grupo de vibroterapia exhibió resultados significativamente superiores en todos los parámetros medidos. Estos incluyeron una hemodinámica venosa mejorada en la ecografía dúplex, mejores perfiles lipídicos con reducción de LDL-C y triglicéridos junto con mayores niveles de HDL-C, y reducciones notables en las medidas antropométricas, incluyendo la circunferencia de la cintura y el índice de masa corporal. Además, los participantes que recibieron vibroterapia informaron mejoras sustancialmente mayores en las evaluaciones de calidad de vida. Los hallazgos respaldan firmemente la incorporación de la vibroterapia como un complemento no farmacológico eficaz a los regímenes de fisioterapia convencionales para el manejo de la insuficiencia venosa crónica en poblaciones de edad avanzada, abordando tanto los aspectos vasculares como metabólicos de esta afección y mejorando significativamente la calidad de vida del paciente.

Palabras clave: Adulto mayor; Perfil lipídico; Calidad de vida; Vibroterapia; Insuficiencia venosa; Circunferencia de cintura. Ultrasonografía dúplex.8j

Introduction

Chronic venous insufficiency (CVI) refers to a status of impaired deep lower extremity circulatory flow due to inadequate functioning of their venous valves. Almost, CVI manifested by oedema, skin changes, fatigue, lower extremity pain and heaviness sense along legs, those often diagnosed via ultrasound imaging to detect venous reflux and pooling of blood in deep leg veins. Global incidence of CVI was reported by 1-17 among elder males, and 40% among elder females[1]. Venous insufficiency may develop into chronic leg ulcer and deep vein thrombosis. Venous thrombosis may damage the valves, and symptoms and signs of chronic venous insufficiency following a deep vein thrombosis (DVT) are called post-thrombotic syndrome[2].

Chronic venous diseases in most cases, are caused by the incompetence of the valvular action of venous walls. This activity describes the pathophysiology, etiology, and presentation of chronic venous insufficiency and highlights the role of the interprofessional team in the management of these patients[3]. Chronic venous insufficiency pathophysiology is due to either reflux (backward flow) or obstruction of venous blood flow. Chronic venous insufficiency can develop from the protracted valvular incompetence of superficial veins, deep veins or perforating veins[1]. Though it was suggested that vigorous exercise increased the risk for those with CVI to develop ulcers, physical activity was still considered important. There is a lack of research looking at the effects of Whole-Body Vibration (WBV) on individuals with CVI. Prior studies have demonstrated that CVI and varicose veins (VVs) treatments in patients ≥ 65 yield an overall benefit, however, there has been little data if octogenarians are undergoing these procedures and with what success[4].

Comprehensive CVI management supposed to base on its nature and severity in a gradual manoeuvre. Main therapeutic interventional goal should be to modulate discomfort, and odema, plus managing secondary ulcers, venous reflux, and varicose veins. Such therapeutic interventions may involve extended compressive therapy, weight modulation, therapeutic exercise training, as well vibrotherapy side by side with proper skin care including surgical management[1,5]. To our knowledge, no recent clinical trial has been conducted along Middle-East, Arab elder population investigating efficacy of vibrotherapy in management of chronic venous insufficiency in elderly patients. Therefore, this study was conducted to investigate vibrotherapy effect on venous insufficiency in elder population.

This randomized controlled trial was conducted on sixty participants suffering from chronic venous insufficiency selected from Physical Therapy Centre, Geriatric Care Center Hoda Talaat Harb, Helwan, and other geriatric care centers in Helwan, Cairo Governorate, Egypt, from March 2022 to March 2024. The study protocol was explained in details for each patient before the initial assessment and enrollment in the study and all patients signed an institutionally approved informed consent form that was approved by the Ethics Committee of the Faculty of Physical Therapy, Cairo University (PT REC/012/003160).

Study population

Sixty participants suffering from chronic venous insufficiency were diagnosed based on careful clinical examination by a certified physician. After the screening process, patients were eligible to participate in the study if they had (i) age ranged from 65 and 85 years; (ii)their laboratory lipid profile represented elevated values (iii) their waist circumference was > 88cm(iv) body mass index was ≥30kg/m²(v) they were of sedentary lifestyle. Patients were excluded if they exhibited anyof the following criteria: (i)neuropsychiatric conditions for example., epilepsy, depression or panic disorder; (ii) patients with orthopaedic or neurological problems that interfere with vibrotherapy (iii) diabetic micro vascular complications within the past three months (iv) kidney failure patients 'renal disease' (v) unstable chronic disease.

Randomization

Sixty-two participants were assessed for eligibility. However, two of them were excluded after being assessed for eligibility, one of them had exclusion criteria and the other one were unwilling to participate in the study because of personal reasons. Consequently, sixty of the sixty-two participants met the requirements for incorporation and were randomly assigned into two equal groups in number (n=30), (A& B). The randomization was done by random number generatorhttps://www.random.org/ , the patients had an equal chance of being allocated to either group. A blinded researcher saw the generator and allocated the patients according to their groups.

Outcome measures

The outcome measures were carried out for each patient individually, before and after 12 weeks of treatment by the same outcome assessor.

Standard Weight and Height scale:

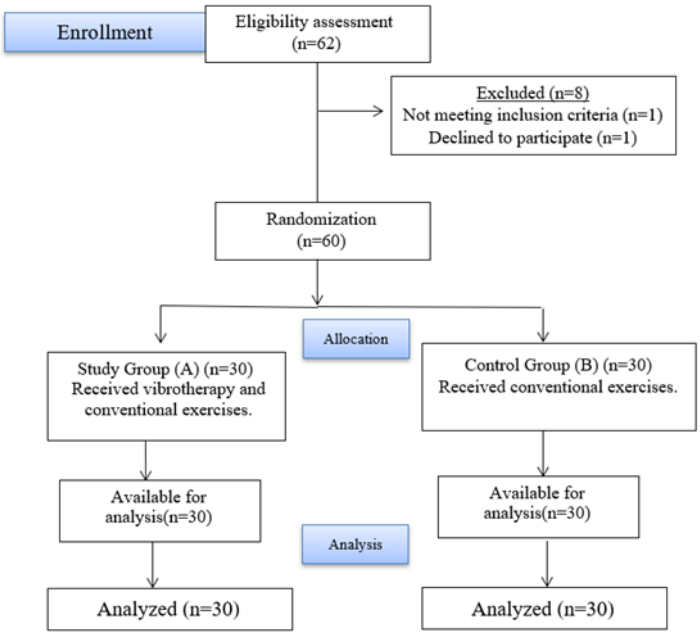
It is used to determine the participants' weight and height to calculate BMI for all participants before the beginning of the study for both groups (A&B), and after the end of the study. Body mass index (BMI) was calculated according to the following equation:

BMI=weight/ height² (kg/m²)[6].

Tape measurement:

It was used to measure waist circumference (WC) for all participants as a good predictor of obesity related health risks. Waist hip ratio (WHR) was measured in centimeters units, and recorded to the nearest centimeter then WHR was calculated by dividing WC to hip circumference (HC)[7].

Figure 1. Experimental Design of the Study



Semi-Chemistry AutoAnalyzer:

It is 'Bs-9200SemiChemistry Analyzer Small Auto Analyzer, China' that commonly used method for estimating blood analysis, including high density lipid, and low density lipids, triglyceride, total cholesterol, also triglyceride/ high density lipid cholesterol ratio. It measures lipid profile analysis for all participants before and after the end of the study while each participant was fasting more than eight hours. It generally demonstrates good reliability and validity when used under standardized conditions[8].

Score Risk Chart

Score risk chart was used to assess cardio vascular disease risk in asymptomatic persons. All patients were asked to complete the Arabic version of the chart by personal interview and then the investigator calculated the total score for each patient[9].

Borg RPE Scale

This scale was used to set the exercise intensity to be at moderate intensity which is represented from 12-14 on the scale. Borg RPE scale is used to subjectively quantify the intensity of exercise. It is a numerical scale that ranges from 6 to 20, where 6 means "no exertion at all" and 20 means "maximal exertion". When a measurement was taken, a number was chosen from the follow-

ing scale by an individual that best describes their level of exertion during physical activity using a valid reliable scale[10].

Quality of Life assessment using SF-36 questionnaire:

Each participant has been asked to fill out SF-36 questionnaire. The word of each question must be preserved exactly, and both the question and the answers must be listed in the same row[11].

Duplex ultrasonography

Duplex ultrasonography allows clear identification of specific venous segments and provides information on the patency of these segments (figure 23-25), the presence or absence of reflux, perforator veins, collateral channels, or patterns of recurrence.

The examination should be performed with the patient in a reverse Trendelenburg position at ≥ 30° or ≥ 60° incline or upright so that hydrostatic pressure in the veins is at its peak to aid venous distension. The leg under examination should be relaxed, slightly flexed at the knee and externally rotated.

Interventions

Patients were evaluated at baseline and after 36 physical therapy sessions on alternative days.

Each participant in study group (A), received vibrotherapy with pressure with enjoyable music program that consists of six steps[12];

- **Step 1;** Diaphragmatic Breathing Exercises were conducted from supine position with participants` knees flexed, in a slow-paced regular breathing pattern.
- **Step 2;** Active ankle range of motion (ROM) exercises were conducted from supine position, in form of ankle dorsi, and planter flexion for five minutes.
- **Step 3;**Vibrotherapy on venous course was conducted from toes up to knee.
- **Step 4;** Diaphragmatic Breathing Exercises were conducted from supine position with participants` knees flexed, in a slow-paced regular breathing pattern.
- **Step 5;** Active ankle range of motion (ROM) exercises were conducted from supine position, in form of ankle dorsi, and planter flexion for five minutes.
- **Step 6;** Diaphragmatic Breathing Exercises were conducted from supine position with participants` knees flexed, in a slow-paced regular breathing pattern.

- Prior to vibrotherapy session, all participants in group (A) have been instructed briefly and clearly about vibrotherapy, and its effect in order to gain their confidence and cooperation through the treatment procedures. Thevibrotherapy (vibra massage model 213 vibrator device) was properly settled up and adjusted according to the manufacturer's instructions. This might be involved adjusting the frequency, and intensity settings based on needs and severity level. The vibra massage model 213 vibrator 115volt, 15watts, 40 ampere, 60 cycle by John oster by Milwaukee Wisconsin co (produced by DGN Medical Company, China). It has capability of output 2 horses, heavy duty motor wattage: 220 W, operation frequencies: 5.0 Hz to 99.0 Hz[13].

All participants of study group A were instructed to begin with a brief warm-up for 5 minutes by doing diaphragmatic breathing exercises, then conducted active ankle ROM exercises to prepare their body for the vibrations[14]. Then, participants of study group A received vibrotherapy session with lower settings and gradually increased them until the desired frequency and amplitude (45 HZ) were been reached. Once the vibration was initiated, instructed each participant in study group A to relax and allowed the vibrations to pass through each participant`s lower extremity from toes up to knees. This was applied for 15 minutes per session[14]. After completing the session, each participant was instructed to cool down gradually by doing diaphragmatic breathing for 5 minutes followed by active ankle ROM exercises, followed by breathing exercises to help her body to return to a resting status.All participants were advised to drink plenty of water to be hydrated and recover after vibrotherapy session[14].

Sample size

The sample size for this study was calculated using the G*power program 3.1.9 (G power program version 3.1, Heinrich-Heine-University, Düsseldorf, Germany) for one tailed test. The effect size for the sample size calculation was obtained from the previous study done on the effect of whole-body vibration training with blood flow restriction on lower extremity muscle activity and hemodynamic variables. Based on F tests (multivariance analysis of variance [MANOVA]: effect and interactions, 51 patients were an adequate group size, with Type I error (α) 0.05, power (1-α error probability) 0.93, and effect size (Partial Eta square 0.436) calculated from a pilot study of 15 patients who received the same program between March 2022 to March 2024. To account for the likelihood of dropout, sixty patients were recruited (assuming a 20% dropout rate). The appropriate minimum sample size for this study will be 60 patients (30 patients in each group as a minimum)[15].

Data analysis

Statistical analysis was performed using SPSS version 25. Descriptive statistics including mean and standard deviation were computed for all demographic and outcome variables. The normality of data distribution was verified using the Shapiro-Wilk test, while homogeneity of variances between groups was confirmed through Levene's test. A paired T-test was applied to compare baseline characteristics between the two groups. For inferential analysis, within-group pre- and post-intervention comparisons were conducted using paired t-tests. A mixed MANOVA was employed to examine the effects of

time, treatment, and their interaction across all outcome measures. Post-hoc analyses incorporating Bonferroni correction were applied for multiple comparisons. The significance threshold was set at $p < 0.05$ for all tests.

Statistical analysis

The measured variables were statistically analyzed and compared utilizing the Statistical Package for Social Sciences (IBM SPSS, Inc., Chicago, IL) (version 25) for windows with an Alpha level set at 0.05. The Shapiro-Wilks test was used to verify that the data followed a normal distribution. Homogeneity of variances across both groups was carried out using Levene's test. Descriptive statistics, including mean ± SD, were quantified for all variables. An unpaired t-test was conducted for comparison of the mean values before and after each treatment intervention. Mean values before and after treatment of every group were compared using a paired t-test. Post-hoc tests using Bonferroni correction were performed for subsequent multiple comparison to protect against type I error. The level of significance for all statistical tests was set at $p < 0.05$. Tables (1), Fig. (2) represent the descriptive statistics for the patients` demographic data for both groups (A and B). according to the results there was no statistically significant difference among both groups in in the mean value of age ($p > 0.5$). Chi-square test revealed that there was non-significant difference between both groups in gender.

Within and between group`s analysis:

As presented in table 2, the mean values of both groups` (A and B) weight, BMI, waist circumference and waist/hip ratio significantly decreased posttreatment compared to pretreatment ($p < 0.001$). However, when comparing between both groups (A and B), there had been no significant statistical differences pretreatment, except in BMI ($p = 0.05$). Where there is a statistical significant decrease in all outcome measures posttreatment in favor to group A ($p<0.001$). In addition, regarding duplex ultrasonography there was no significant difference pretreatment ($p>0.5$). Where, there is a statistical significant decrease in all outcome measures posttreatment in favor to group A ($p < 0.001$).

As presented in Table 3, a highly statistical significant decrease in LDL-C, and triglycerides, posttreatment compared to pretreatment ($p < 0.001$). in addition, a high statistical significant increase in both HDL-C, and value of SF-36 questionnaire posttreatment compared to pretreatment ($p<0.001$). When comparing between both groups (A and B), there had been no significant statistical differences pretreatment ($p=0.05$). Where there is a statistical significant improve in all outcome measures posttreatment in favor to group A ($p < 0.001$).

Table 1: Baseline Demographic descriptive statistics and comparison of age between group A&B (n = 60)

		Group A (n=30)	Group B (n=30)	MD	t-value	p-value
		$\bar{x}$ ±SD	$\bar{x}$ ±SD			
Age (years)	Mean±SD	73.63± 5.24	75.53±4.09	-1.9	-1.612	0.118
Sex	Male	14 (47%)	12 (40%)		$\chi 2$ = 0.62	0.73
	Female	16 (53%)	18 (60%)			

SD: Standard deviation. **MD:** Mean difference, **t-value**: Unpaired t-value. **P-value**: Probability value.

Fig. (2): Frequency distribution of sex for groups A, and B

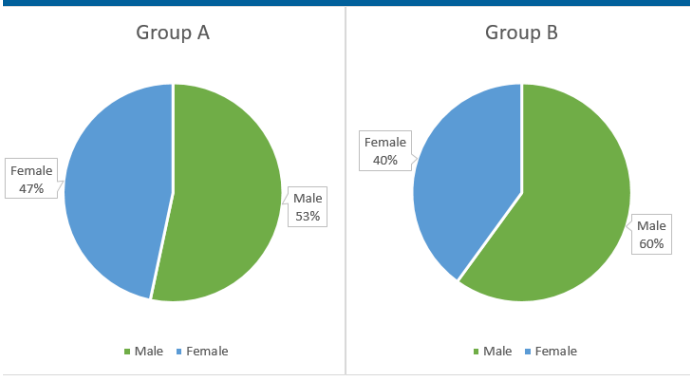


Table (2): Obesity outcome measures, and duplex ultrasonography pre and posttreatment for both groups (A& b).

Variable	Group A Mean±SD	Group B Mean±SD	MD	P-value	Sig*
Weight (kg)					
Pretreatment	71.67 ± 5.04	69.93 ± 3.71	1.74	0.132	**NS**
Posttreatment	73.63 ± 5.26	70.67 ± 3.82	2.96	0.001	**S**
Mean difference	-1.96	-0.74			
P-value	**0.0001**	**0.001**			
Sig.	**S***	**S**			
BMI (kg/m^2)					
Pretreatment	25.84 ± 1.82	24.63 ± 1.04	1.21	0.05	S
Posttreatment	26.54 ± 1.84	24.89 ± 1.02	1.65	0.001	S
Mean difference	-0.7	-0.26			
P-value	**0.0001**	**0.001**			
Sig.	**S***	**S**			
WC (cm)					
Pretreatment	112.6 ± 1.54	111 ± 1.67	1.6	0.06	**NS**
Posttreatment	97.9 ± 1.63	99 ± 1.84	-1.1	0.001	**S***
Mean difference	14.7	12			
P-value	**0.0001**	**0.001**			
Sig.	**S***	**S**			
WHR (%)					
Pretreatment	3.7 ± 0.47	3.7 ± 0.47	0	0.07	**NS**
Posttreatment	1.53 ± 0.51	2.43 ± 0.51	-0.9	0.001	**S**
Mean difference	2.17	1.27			
P-value	**0.0001**	**0.001**			
Sig.	**S***	**S**			
Duplex ultrasonography					
Superficial	n. (%)	n. (%)	**MD**	**P-value**	**Sig***
Pretreatment	22 (73.33°%)	23 (76.67%)	-1 (-3.34%)	0.077	NS
Posttreatment	18 (60%)	21 (70%)	-3 (10%)	0.001	S
Mean difference	-4 (-13.33%)	-2 (-6.67%)			
P-value	**0.0001**	**0.001**			
Sig.	**S***	**S**			
Deep					
Pretreatment	14 (46.67%)	15 (50%)	-1 (-3.33%)	0.075	NS
Posttreatment	9 (30%)	14 (46.67%)	-5 (-16.67%)	0.001	S
Mean difference	-5 (16.67%)	-1 (3.33%)			
P-value	**0.0001**	**0.001**			
Sig.	**S***	**S**			
Reflux					
Pretreatment	6 (20%)	6 (20%)	0.0	0.078	NS
Posttreatment	3 (10%)	5 (16.67%)	-2 (-6.67%)	0.001	S
Mean difference	-3 (-9%)	-1 (-3.33%)			
P-value	**0.0001**	**0.001**			
Sig.	**S***	**S**			

DUS: Duplex ultrasonography, **SD:** Standard deviation. **MD:** Mean difference, **t-value:** Unpaired t-value. **P-value:** Probability value. **BMI:** Body mass Index, **NS:** Non-significant, **WC:** waist circumference, **WHR:** Waist/ Hip Ratio, **P-value:** Probability value. **P-Value < 0.05** indicate statistical significance.

Table (3): Lipid profile, AND sf-36 Questionnaire values pre and posttreatment for both groups (A& b).					
Variable	**Group A Mean±SD**	**Group B Mean±SD**	**MD**	**P-value**	**Sig***
LDL-C (mg/dL)					
Pretreatment	160.8 ± 4.01	160.9 ± 4.49	-0.1	0.05	**S**
Posttreatment	119.7 ± 5.49	124.9 ± 1.99	-5.2	0.001	**S**
Mean difference	41.1	36			
P-value	**0.0001**	**0.001**			
Sig.	**S***	**S**			
HDL/C (mg/dL)					
Pretreatment	165.2 ± 3.82	165 ± 3.84	0.2	0.06	**NS**
Posttreatment	210.1 ± 3.83	203.3 ± 1.99	6.8	0.001	**S**
Mean difference	-44.9	-0.26			
P-value	**0.0001**	**0.001**			
Sig.	**S***	**S**			
Triglycerides (mg/dL)					
Pretreatment	176.7 ± 4.5	176.9 ± 3.03	-0.2	0.06	**NS**
Posttreatment	118.3 ± 5.04	123.6 ± 2.49	-5.3	0.001	**S**
Mean difference	58.4	53.3			
P-value	**0.0001**	**0.001**			
Sig.	**S***	**S**			
SF-36 Questionnaire values					
Pretreatment	80 ± 3.68	77.3 ± 4.78	2.7	0.05	NS
Posttreatment	91.1 ± 2.26	84.93 ± 3.15	6.17	0.001	S
Mean difference	-20.1	11.1			
% of Change	31.8%	26.3%			
P-value	**0.0001**	**0.001**			
Sig.	**S***	**S**			

LDL: Low-density lipoprotein. **HDL:** High-density lipoprotein. **SD:** Standard deviation. **MD:** Mean difference, **t-value:** Unpaired t-value. **P-value:** Probability value. **P-Value < 0.05** indicate statistical significance.

Discussion

The findings of this randomized controlled trial demonstrate that adjunctive vibrotherapy significantly enhances therapeutic outcomes for elderly patients with chronic venous insufficiency (CVI). Our results indicate that the group receiving vibrotherapy combined with conventional physical therapy (Group A) showed substantially greater improvements across all measured parameters compared to the control group (Group B) that received standard care alone. These improvements were particularly evident in venous hemodynamics, lipid profiles, anthropometric measures, and quality of life assessments. The mechanism behind these beneficial effects may be explained by vibrotherapy's ability to induce musculoskeletal activation by approximately 10-15%, particularly affecting endothelial compartments. Whole-body vibration (WBV) appears to function as a form of resisted exercise training that safely induces muscular exertion. This physiological response aligns with Piotrowska et al.'s findings[16] that oscillatory-cycloid vibration can beneficially impact lipid profiles by reducing total cholesterol and LDL cholesterol in hypercholesterolemic patients. The application of WBV modality stimulates reflexive musculoskeletal contractions that subsequently enhance venous flow[17].

Our results find support in previous research by Kienberger et al.[18], who conducted a randomized controlled trial demonstrating vibration training's positive effects on muscle strength in elderly women. Similarly, Xiong and Liu's recent clinical trial[19] reported WBV's effectiveness as a rehabilitation modality equivalent to low-intensity strength exercise, particularly for improving arterial stiffness in at-risk populations. These collective findings reinforce Uher's observation[20] that mechanical oscillatory-cycloid vibration applied to muscle bellies or tendons effectively stimulates sensory receptors, though the effects depend on multiple factors including vibration frequency, muscle properties, and body position. When considering CVI management in elderly patients, current therapeutic protocols typically involve patient education, mobilization, leg elevation, obesity prevention, venous compression stockings, and venoactive agents, with catheter-based or surgical interventions reserved for superficial venous insufficiency[21]. Treatment decisions must carefully consider risk-benefit ratios, clinical status, available options, and patient expectations focused on quality of life improvement[22]. Multiple factors influence optimal treatment strategy selection, including the CEAP classification stage, anatomical location, vein diameter,

treatment cost, symptoms, and age-dependent concomitant diseases[23].

While compression therapy remains a cornerstone of CVI management, with typical recommendations suggesting 20-30 mmHg elastic compression stockings with graduated pressure[24], our findings suggest that vibrotherapy represents a valuable adjunct approach. The intervention addresses the pathophysiological mechanism of CVI where increased lower-limb venous pressure during standing drives fluid into interstitial spaces[25]. Although current guidelines recommend external compression as first-line therapy[26], and trials have shown its benefit in reducing postprocedural discomfort following venous ablation procedures[27-30], our study indicates that incorporating vibrotherapy may provide additional therapeutic benefits. The significant improvements observed in both objective physiological measures and subjective quality of life indicators highlight vibrotherapy's potential as a comprehensive treatment approach for CVI in elderly patients. This non-pharmacological intervention addresses both vascular and metabolic aspects of the condition while significantly enhancing patients' quality of life[31,32]. Future research should focus on optimizing vibration parameters and establishing protocols for long-term maintenance of these therapeutic benefits.

Conclusions

This randomized controlled trial demonstrates that adjunctive vibrotherapy significantly enhances treatment outcomes for elderly patients with chronic venous insufficiency. The intervention group receiving vibrotherapy combined with conventional physical therapy exhibited substantially greater improvements in both hemodynamic and metabolic parameters compared to the control group receiving standard care alone. Specifically, the vibrotherapy protocol resulted in enhanced venous hemodynamics, improved lipid profile, reduced adiposity indicators, and superior quality of life measures. These findings suggest that mechanical vibration therapy activates musculoskeletal and endothelial responses that complement traditional physical therapy approaches. The study provides compelling evidence for integrating vibrotherapy into comprehensive management strategies for chronic venous insufficiency in elderly populations, offering a safe and effective modality that addresses both vascular and metabolic aspects of this condition. Further research should explore optimal vibration parameters and long-term maintenance of these therapeutic benefits.

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Patient consent statement:

Prior to the start of data collection, all participants provided their written, informed consent.

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