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ORIGINAL ARTICLE

Influence of Manual Lymphatic Drainage on Health-Related Quality of Life and Symptoms of Chronic Venous Insufficiency: A Randomized Controlled Trial

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Abstract

Objective: To evaluate the efficacy of manual lymphatic drainage (MLD) in improving health-related quality of life (HRQOL), symptomatology, and physical status in patients with chronic venous insufficiency (CVI).

Design: Single-blind randomized controlled trial.

Setting: Health community attendant service.

Participants: Subjects with CVI (N=41) were randomly assigned to an experimental group (n=20; mean age, 54.6±11.3y) or control group (n=21; mean age, 46.8±11.1y).

Interventions: The experimental group completed 10 lower extremity MLD sessions over 4 weeks and 1 educational session. The control group only attended the educational session. Outcome measures were taken at baseline (t0), at the end of 4 weeks (t1), and after 2 months for follow-up (t2).

Main Outcome Measures: HRQOL was assessed with the Chronic Venous Insufficiency Quality of Life Questionnaire-20, symptoms (fatigue, heaviness) were assessed with a visual analog scale, severity of the disease was assessed with the Venous Clinical Severity Score (VCSS) (total score, score for each item), leg volumetry was assessed with perimeters, and plantar/dorsiflexion strength and ankle range of motion (ROM) were assessed with dynamometry.

Results: A significant interaction group × time effect was found for pain on HRQOL ($F_{2,78}=3.507$; $P=.035$; partial $\eta^2=.087$), clinical severity ($F_{2,78}=5.231$; $P=.007$; partial $\eta^2=.118$), especially for venous edema (assessed with the VCSS), fatigue ($F_{1.67,65.21}=4.690$; $P=.012$; partial $\eta^2=.107$), and heaviness ($F_{1.57,61.32}=9.702$; $P=.001$; partial $\eta^2=.199$), with the experimental group improving from t0 to t1 and t0 to t2 in all of these outcomes. No effect of MLD treatment could be found for ankle muscle strength, ankle ROM, and leg volume.

Conclusions: Short-term MLD treatment ameliorates CVI severity and related edema, symptoms, and pain HRQOL in patients with CVI.

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Chronic venous insufficiency (CVI) represents the most severe stage of chronic venous disease and is characterized by the presence of edema, skin changes, and venous ulcer.[1] The prevalence of CVI varies between 1% and 17% in men and 1% and 40% in women.[2] Patients suffering from this condition display diminished health-related quality of life (HRQOL),[3] especially in the most severe stages,[3] and severe symptoms (eg, pain, heaviness, fatigue), even in cases of uncomplicated varicose veins.[4]

Based on self-reported data, functional status is also affected in patients with CVI.[5] In addition, patients with CVI may also present gait changes,[6] impaired balance and weak ankle muscles,[6,7]

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and diminished ankle range of motion (ROM),[7,8] which might be associated with peripheral neuropathy or impaired calf muscle pump function.[9] Because of its multifactorial cause, CVI is responsible for high costs in health services.[10]

Manual lymphatic drainage (MLD) is a conservative treatment for lymphedema.[11] Despite doubts about its efficacy,[12,13] MLD seems to play an important role in lymphedema management by improving symptoms,[14,15] joint mobility,[16] and overall HRQOL.[14,15] Decongestive lymphatic therapy, which combines MLD with other treatments, including compression modalities, is generally effective in the treatment of lymphedema when related to cancer.[15] In addition, MLD has been used as a conservative treatment for CVI[17] because of its ability to increase venous blood flow in superficial and deep veins[18] and its ability to improve clinical severity and HRQOL when applied before surgery.[18] Associated with CVI, secondary lymphedema (venous lymphedema) may occur because of excessive interstitial fluid and an overloaded lymphatic system[19] or lymphatic pump failure.[20,21] In this case, MLD may stimulate the activity of the lymphatic system[22,23] and therefore might be used for the conservative treatment of venous lymphedema alone or in combination with other treatments.[17]

Despite the demonstrated effects of MLD, its long-term efficacy in treating CVI is unknown. Therefore, the purpose of this study was to evaluate the effect of MLD treatment on HRQOL, severity of the disease, symptoms, leg volume, ankle muscle strength (plantarflexion, dorsiflexion), and ankle dynamic ROM (both ankle muscle strength and ankle dynamic ROM are related to efficacy of the calf muscle pump function) in patients with CVI. We hypothesized the following: 4 weeks of MLD improves HRQOL and the clinical and physical status of patients with CVI, and these effects will remain at the end of a short-term follow-up (4wk).

Methods

Study design

A single-blind randomized controlled trial was conducted in patients recruited from a school-based health community attendant service between July and October 2013.

Before study enrollment, all participants were informed about the purpose and procedures of the study and signed an informed consent. The study received ethical approval by an ethics committee.

The demographic and clinical data of the participants are presented in table 1. All the participants had CVI with C3 to C5, according to the Clinical Etiologic Anatomic Pathophysiologic classification. Exclusion criteria included the presence of severe cardiac insufficiency, acute venous or arterial obstruction, arterial insufficiency, renal insufficiency, uncompensated thyroid dysfunction, pregnancy, neoplastic pathology, systemic or limb infection, recent musculoskeletal injury, or peripheral neuropathy affecting the lower extremity.

Out of the 125 prospective candidates, 50 met the eligibility criteria and were randomly allocated to the experimental group (n=25) or the control group (n=25). During the first visit, the participants were informed that they would be expected to complete 10 treatment sessions over a period of 4 weeks and another 3 sessions for assessments, starting within the following 2 months. Those conducting the assessments were blinded to group allocation, and the physical therapists applying the treatments were unaware of the results of the assessments.

After the first round of testing at baseline (t0), participants attended an educational session. Participants in the control group did not receive any further treatment during the time of the study. All participants were instructed to maintain their habitual CVI management scheme and their habitual daily life activities during the study. Participants were reassessed at the end of the MLD treatment program (t1) and after 4 weeks of follow-up (t2). Participants in the control group were tested at 4-week intervals. The timeline of the study, including sampling, testing, and intervention, is depicted in figure 1. Participants in the control group were also provided with the MLD treatment after t2.

List of abbreviations:

CI	confidence interval
CIVIQ-20	Chronic Venous Insufficiency Quality of Life Questionnaire-20
CVI	chronic venous insufficiency
HRQOL	health-related quality of life
MLD	manual lymphatic drainage
ROM	range of motion
VCSS	Venous Clinical Severity Score

Clinical examination and severity of the disease

CVI diagnosis was confirmed by venous duplex ultrasound scanning[a] (7mm linear array transducer; scanning frequency, 6−12MHz). Cutoff reflux duration was set at 1 second for the femoral and popliteal veins and 0.5 second for the other scanned veins.[1] The leg with the worse signs and symptoms of CVI was chosen for the subsequent tests. This procedure was repeated in each testing session to ascertain that major events (eg, venous obstruction) had not occurred.

Clinical history, CVI-related medication, and adherence to compression stockings were registered. The presence/absence of symptoms (fatigue, heaviness, itching, cramps, skin irritation) were also collected. The Clinical Etiologic Anatomic Pathophysiologic classification and Venous Clinical Severity Score (VCSS) (range, 0−30 from best to worst) were obtained following established guidelines.[1] The clinical data of the participants are presented in table 1.

HRQOL and symptoms

HRQOL was assessed by the Chronic Venous Insufficiency Quality of Life Questionnaire-20 (CIVIQ-20).[24] The scores for its 4 dimensions (physical, psychological, social, pain) and global HRQOL were obtained using a scale from 0 to 100 (best to worst). Symptoms (fatigue, heaviness) were additionally evaluated by a visual analog scale,[25] with scores from 0 to 10 (best to worst).

Leg volume

Leg perimeter (P) was measured while standing using a standard tape at the level of the malleolus (P0) and 10 (P1), 20 (P2), and 30cm (P3) above the lateral malleolus. The leg volume was calculated according to the following equation, corresponding to the sum of 3 volume cones estimated between P0 and P1, P1 and P2, and P2 and P3: