

# Effects of intermittent pneumatic compression treatment on clinical outcomes and biochemical markers in patients at low mobility with lower limb edema



Mirko Tessari, PhD,<sup>a</sup> Veronica Tisato, PhD,<sup>b</sup> Erika Rimondi, PhD,<sup>b</sup> Paolo Zamboni, MD,<sup>a</sup> and Anna Maria Malagoni, MD, PhD,<sup>a</sup> Ferrara, Italy

## ABSTRACT

**Objective:** We aimed to evaluate the effects of intermittent pneumatic compression (IPC) in patients at low mobility with leg edema.

**Methods:** A pilot, two-arm, randomized controlled clinical trial was performed. Fifty patients (age, 58.4 ± 9 years; male, 14), randomly allocated to a group (IPC) undergoing 1 month (n = 29) of an in-home cycle of IPC and to a control (C) group (n = 21), were studied. Leg edema was evaluated by measuring subcutaneous thickness (high-resolution ultrasound) and circumferences (metric tape), both assessed at different levels of the lower limbs, and volume (water plethysmography). Ankle range of motion (ROM, goniometer), quality of life (QoL) by the 36-Item Short Form Health Survey, and a pool of plasma inflammatory markers were also evaluated.

**Results:** Edema significantly decreased in the IPC group (for all outcome measures,  $P < .0001$ ), whereas it significantly increased in the C group ( $P < .0001$ ). Ankle ROM was significantly enhanced in the IPC group (dorsiflexion,  $P < .0001$ ; plantar flexion,  $P = .002$ ) and remained stable in the C group. QoL showed an improvement in the IPC group, particularly significant for the general health subscale ( $P = .004$ ), whereas no changes were highlighted in the C group. The two groups exhibited different trends and variations for some plasma inflammatory markers, mainly for granulocyte colony-stimulating factor.

**Conclusions:** In a sample of patients at reduced mobility with leg edema, IPC treatment was effective in reducing the edema, improving the ankle ROM, and determining a positive impact on QoL together with a slight modulation of some plasma inflammatory markers. (J Vasc Surg: Venous and Lym Dis 2018;6:500-10.)

**Keywords:** Compression devices; Intermittent pneumatic; Edema; Lymphatic disease; Mobility limitation; Venous insufficiency

Many chronic diseases, particularly neurologic ones, lead to progressive motor dysfunction along with long-term consequences due to the loss of mobility. Hypomobile patients, incapacitated or wheelchair bound for extended periods with their legs hanging down, can develop an impairment of the venous and lymphatic return.<sup>1-5</sup> In addition, in some neurologic disorders, a possible effect induced by the impairment of the autonomic reflexes on vascular functions could also have a role in affecting the venous system's functioning.<sup>6,7</sup> As a result, many patients affected by loss of

mobility experience lower limb edema,<sup>1,8</sup> affecting their general condition and raising thrombotic risk.<sup>9-12</sup> Moreover, the persistent venous hypertension generated by the stasis has recently been found to be associated with a pool of circulating inflammatory mediators,<sup>13-17</sup> even potentially implicated in the genesis of deep venous thrombosis (DVT).<sup>18,19</sup> Among the most suitable treatments to counter the peripheral venolymphatic stasis, intermittent pneumatic compression (IPC) seems to be a rational approach in immobile patients.<sup>20</sup> IPC is a noninvasive technique based on the application of inflatable sleeves exercising sequential and intermittent pressures reproducing the same physiologic mechanism of the calf muscle pump during walking. In addition to assisting in the reduction of swelling in the leg, IPC can also enhance the venolymphatic pump, which limits and restores the damaged microcirculation of the skin.<sup>20-25</sup> Its role in phlebology therapy, indicated by national and international guidelines, was stated in the treatment of venous ulcers and for DVT prophylaxis; in lymphology, it plays a key role in the integrated treatment of lymphedema.<sup>26-28</sup>

The aim of this study was to evaluate the effects of IPC therapy on clinical outcomes and quality of life (QoL) and modulation of plasma markers of endothelial

From the Department of Morphology, Surgery and Experimental Medicine, Unit of Translational Surgery, University Hospital of Ferrara, and Vascular Diseases Center,<sup>a</sup> and the Department of Morphology, Surgery and Experimental Medicine and LTTA Center,<sup>b</sup> University of Ferrara.

Author conflict of interest: none.

Correspondence: Mirko Tessari, PhD, Unit of Translational Surgery, University Hospital of Ferrara, Via Aldo Moro 8, 44124 Cona (FE), Italy (e-mail: [tssmrk@unife.it](mailto:tssmrk@unife.it)).

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.

2213-333X

Copyright © 2018 by the Society for Vascular Surgery. Published by Elsevier Inc. <https://doi.org/10.1016/j.jvs.2018.01.019>

inflammation in a group of patients at low mobility affected by edema of the lower limbs compared with a control (C) group.

## METHODS

### Study design and setting

A pilot, single-blinded, two-arm, parallel group, randomized controlled clinical trial was performed. The study was conducted in the Unit of Translational Medicine of the University Hospital of Ferrara, Italy. The study was approved by the ethical committee of Ferrara, Italy (study No. 140486).

### Participants

Sixty consecutive patients at low mobility as affected by lower limb edema referred to the vascular diseases outpatient clinic of the Unit of Translational Surgery of the University Hospital of Ferrara, Italy, were enrolled in the study from September 2014 to November 2015. All participants signed a written informed consent form.

**Inclusion criteria.** Patients aged between 18 and 65 years with reduced mobility as a result of a chronic disease affected by clinically relevant chronic lower limb edema (>6 months) were included in the study.

**Exclusion criteria.** Patients with DVT in the acute phase (<3 months), malabsorption syndrome, liver cirrhosis, nephrotic syndrome, heart failure (New York Heart Association class III-IV), connective tissue diseases, rheumatic diseases, primary aldosteronism, cancer, corticosteroids, immunomodulator and immunosuppressant therapy, pregnancy, dermatitis, and severe peripheral arterial disease (Leriche-Fontaine stage III-IV) were excluded from the study. Patients with leg ulcers were also excluded in order not to affect the plasma markers of the endothelial inflammation profile.

### Randomization

A block randomization with an allocation ratio of 1:1, experimental group and C group, was performed by an investigator with no involvement in the trial using a computer software system. Investigators involved in the enrollment were concealed from the allocation list until the moment of assignment.

### Interventions

Patients randomized to the experimental group (IPC group) underwent an in-home cycle of IPC (I-PRESS 4 LEG2; IACER Srl, Venice, Italy) following an established pattern in clinical practice for the prophylaxis of DVT in bedridden patients and for the reduction of lymphatic lakes in patients with lymphedema. This scheme consists of applying the device twice a day, each session lasting 50 minutes, with a setting of 50 mm Hg pressure, for 30 consecutive days. The pressure of 50 mm Hg was chosen according to the international guidelines related to the treatment of leg edema.<sup>29</sup> Such a pressure seemed able to significantly reduce leg edema without

## ARTICLE HIGHLIGHTS

- **Type of Research:** Pilot randomized controlled clinical trial
- **Take Home Message:** This pilot controlled study of 50 patients at low mobility with leg edema randomized patients to 1-month in-home intermittent pneumatic compression (IPC) treatment and to a control group. IPC treatment reduced edema, improved quality of life, and slightly modulated some plasma inflammatory markers.
- **Recommendation:** The study suggests that IPC treatment of low-mobility patients induces meaningful improvements in reducing edema, with a positive impact on quality of life and a slight modulation of some plasma inflammatory markers.

creating discomfort<sup>30</sup> and damaging lymphatics.<sup>31</sup> At baseline, each patient of the IPC group was trained to use the device. Patients were also periodically contacted by telephone to ensure the correct execution of the therapy. No intervention was provided for patients allocated to the C group. For both groups, patients were asked to not modify their medical or compression therapy and not to start physical therapy during the study period.

### Outcome measures

All outcome measures were evaluated at baseline (the day before start of IPC treatment for the experimental group) and after 30 days by the same investigators blinded to the patients' allocation, always in the morning at the same time of the day for each patient.

### Clinical outcome measures

**Subcutaneous thickness of the lower limbs.** The venous-lymphatic edema of the lower limbs was indirectly noninvasively measured by high-resolution ultrasound (MyLab 70 XV; Esaote Genoa, Italy) of the soft tissue with a 12 MHz linear transducer placed longitudinally on the leg. Subcutaneous thickness was measured as the distance between the posterior echogenic border of the dermis and the anterior echogenic border of the muscular fascia. The measurements were taken at eight fixed anatomic points where lymphatic lakes develop with landmarks that allow consistent measurement of the same region of the lower limbs, as follows: saphenofemoral junction; 5 cm below the saphenofemoral junction; middle of the thigh; lower third of the thigh; upper third of the calf; middle of the calf; perimalleolar area; dorsum of the foot.

**Circumferences of the lower limbs.** Circumferences were measured with a metric tape at standardized points of the lower limb according to international guidelines.<sup>1,3,8</sup> The points were the following: B, minimum circumference of the ankle; B1, circumference at

Download English Version:

<https://daneshyari.com/en/article/8672458>

Download Persian Version:

<https://daneshyari.com/article/8672458>

[Daneshyari.com](https://daneshyari.com)