

# Comparison of efficacy of the intermittent pneumatic compression with various pressures in reducing the primary lower extremity venous lymphedema of menopausal patients

## *Porównanie skuteczności sekwencyjnego masażu uciskowego o różnym ciśnieniu w leczeniu pierwotnego obrzęku żylny-chłonnego kończyn dolnych u pacjentek w okresie menopauzalnym*

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### Summary

**Introduction:** The primary lymphedema and chronic venous insufficiency are important medical problems in women during menopause. Intermittent pneumatic compression has been accepted as a supplemental therapy for many years. However, due to the diversity of the clinical view of venous lymphedema and difficulties in the diagnosis, there is still no uniform and fully reliable treatment algorithm and international consensus.

**Aim of the study:** To compare the efficacy of pneumatic compression of various pressure for the treatment of lower extremity venous lymphedema in menopausal patients.

**Material and methods:** The study included 33 patients with chronic venous insufficiency and bilateral primary lymphedema of the lower limbs. Group A consisted of 10 patients aged from 46 to 56 years (mean age 51.2 years) who had used monthly therapy, treatments consisting of manual lymphatic drainage, multi-layer bandaging and intermittent pneumatic compression with a pressure of 120 mm Hg. Group B consisted of 10 patients aged from 45 to 58 years (mean age 53.3 years) who had identical basic treatment as group A, and intermittent pneumatic compression with a pressure of 60 mm Hg. Group C (control) consisted of 13 patients aged from 44 to 57 years (mean age 52.8 years) who were using only primary treatment without intermittent pneumatic compression.

**Results:** It was found out that the greatest reduction in edema in patients undergoing compression settings with a pressure of 120 mm Hg. Comparison of the percentage reduction in edema showed a statistically significant advantage for group A to groups B and C, both for changes in the right ( $p = 0.01$ ) and left limb ( $p = 0.01$ ). Results in patients undergoing intermittent pneumatic compression with a lower pressure (60 mm Hg) were similar to those obtained in the control group.

**Conclusions:** Intermittent pneumatic compression with a pressure of 120 mm Hg significantly helps to reduce the venous lymphedema in patients with menopause. It appears that the procedures with a pressure of 60 mm Hg are ineffective.

**Key words:** intermittent pneumatic compression, venous lymphedema, menopause.

### Streszczenie

**Wstęp:** Pierwotny obrzęk chłonny oraz przewlekła niewydolność żylna stanowią istotny problem leczniczy u kobiet w okresie menopauzalnym. Wciąż poszukuje się skutecznych fizykalnych metod terapeutycznych.

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**Cel pracy:** Porównanie skuteczności sekwencyjnego masażu uciskowego o różnym ciśnieniu w leczeniu pierwotnego obrzęku żylny-chłonnego kończyn dolnych u pacjentek w okresie menopauzalnym.

**Materiał i metody:** Do badania włączono 33 pacjentki z przewlekłą niewydolnością żylną oraz z obustronnym pierwotnym obrzękiem chłonnym kończyn dolnych. Grupę A stanowiło 10 chorych w wieku 46–56 lat (średni wiek 51,2 roku), u których zastosowano miesięczną terapię przeciwobrzękową składającą się z zabiegów manualnego drenażu limfatycznego, kompresjoterapii oraz sekwencyjnego masażu uciskowego o ciśnieniu wyjściowym 120 mm Hg. Grupę B stanowiło 10 chorych w wieku 45–58 lat (średni wiek 53,3 roku), które poddano identycznemu leczeniu podstawowemu jak w grupie A oraz sekwencyjnemu masażowi uciskowemu o ciśnieniu wyjściowym 60 mm Hg. Grupę C (kontrolna) stanowiło 13 chorych w wieku 44–57 lat (średni wiek 52,8 roku), u których zastosowano jedynie terapię podstawową – bez sekwencyjnego masażu uciskowego.

**Wyniki:** Stwierdzono, że największe zmniejszenie obrzęku miało miejsce u chorych poddanych zabiegom sekwencyjnego masażu uciskowego o ciśnieniu 120 mm Hg. Porównanie procentowej redukcji obrzęku wykazało znamienne statystycznie przewagę grupy A w stosunku do grup B i C zarówno dla zmian w kończynie prawej ( $p = 0,01$ ), jak i lewej ( $p = 0,01$ ). Rezultaty u pacjentek poddanych sekwencyjnemu masażowi uciskowemu o niższym ciśnieniu (60 mm Hg) były zbliżone do uzyskanych w grupie kontrolnej.

**Wnioski:** Sekwencyjny masaż uciskowy o ciśnieniu zewnętrznym 120 mm Hg istotnie wspomaga redukcję obrzęku żylny-chłonnego u chorych w okresie menopauzalnym. Wydaje się, że zabiegi o ciśnieniu 60 mm Hg są nieskuteczne w terapii przeciwobrzękowej u pacjentek z przewlekłą niewydolnością żylną.

**Słowa kluczowe:** sekwencyjny masaż uciskowy, obrzęk żylny-chłonny, menopauza.

## Introduction

Lymphedema is an abnormal accumulation of stagnant protein-rich fluid in the interstitial matrices of the limbs. The high concentration of protein causes the colloid osmotic pressure to increase, which accelerates fluid transfer into the interstitial space. Lymphedema may be present in the extremities, trunk, abdomen, head and neck, external genitalia, and inner organs. Lymphedema of the lower limbs, which occurs in patients with chronic venous insufficiency is a result of circulatory tissue fluid, lymph and venous blood disorders in the extremity. Patients with venous lymphedema may experience pain, swelling, tightness and heaviness in the affected area, reduction in motion in joints and the documented side effects include cosmetic and functional problems, cellulitis, and other infections, as well as lymphangiosarcoma [1, 2].

The results of most studies show a much higher morbidity associated with the primary lower extremity venous lymphedema among women than men. Previous observations [3-5] indicate a possible effect of hormonal contraception and pregnancy on the emergence of symptoms of chronic venous insufficiency in women, including in the form of edema.

According to some reports it is concluded that the incidence of venous insufficiency among women is about three times higher than in men in the same age range (pregnancy leads to an increase in the risk even four-six times). In addition, it is believed that the number of documented cases of lymphedema of lower limbs in women is about 6 million (4.6 million from the age group of 40-60 years), of which 60% of patients have chronic venous insufficiency [5, 6].

Decongestive lymphatic therapy is a common management for venous lymphedema. A program combining skin care, manual lymphatic drainage, exercise,

and compression therapy (multilayer bandage or garment) is recognized as the best practice in management. Taking into consideration personal and medical resources in clinical practices, intermittent pneumatic compression as a supplemental therapy is often given to patients to improve the effectiveness of lymphatic therapy. It is a mechanical method of delivering compression to swollen limbs. Pneumatic compression has been accepted as a standard supplemental therapy for many years. However, due to the diversity of the clinical views of venous lymphedema and difficulties in diagnosis, there is still no uniform and fully reliable treatment algorithm and international consensus. For example, some authors recommend pressure from 40 to 60 mm Hg [7, 8] for pneumatic compression, others suggest much higher values from 80 to 130 mm Hg [9, 10]. This fact significantly impedes the treatment process in use of this method.

The aim of the study was to compare the efficacy of intermittent pneumatic compression of various pressure for the treatment of lower extremity venous lymphedema in menopausal patients. The study endpoints were to determine the difference in limb volume before and after therapy in each group and comparison of changes between all groups.

## Material and methods

This study was approved by the Research Ethics Committee of the Medical University of Silesia in Katowice, Poland (protocol number NN/6501/101/06). The present study was done at the Limf-Med Clinics in Chorzow, Poland, and was carried out from September 2009 to July 2012.

Participating subjects met the following inclusion criteria: 1) women, 2) gave written informed consent

to participate in the study, 3) chronic venous insufficiency and 4) bilateral primary lower limb lymphedema. They were women in menopause, who on the basis of the interview have had time signs of menopause for more than 2 years. Participants have not had menstruations for at least a year. All subjects were non-smokers. Women could not use solarium for six months preceding the study. Patients who qualified to the study due to the venous lymphedema and thromboembolic complications risk, did not use the hormone replacement therapy. The exclusion criteria were: 1) an ankle brachial pressure index (ABPI) lower than 0.8, 2) diabetes, 3) cancer, 4) peripheral nerve injury, 5) rheumatoid arthritis, 6) ventricular arrhythmia, 7) cardiac pacemaker, 8) skin infection, 9) after steroid therapy, and 10) after vein surgery. The 11) secondary lymphedema, 12) pulmonary edema and 13) congestive heart failure, 14) chronic renal failure were exclusion criteria in our protocol, too.

In total, 33 women were included in this study. Participants were randomly allocated to three groups A, B and C.

Group A consisted of 10 patients aged from 46 to 56 years (mean age 51.2 years) who had used monthly therapy, treatments consisting of manual lymphatic drainage, multilayer bandaging and intermittent pneumatic compression with a pressure of 120 mm Hg.

Group B consisted of 10 patients aged from 45 to 58 years (mean age 53.3 years) who had identical basic treatment group A, and intermittent pneumatic compression with a pressure of 60 mm Hg.

Group C (control) consisted of 13 patients aged from 44 to 57 years (mean age 52.8 years) who were using only primary treatment, without intermittent pneumatic compression.

All women were treated in outpatient clinics, where for a period of 4 weeks they had comprehensive physical therapy (manual lymphatic drainage, multilayer bandaging) and standard drug therapy (micronized purified flavonoid fraction 450 mg diosmin, 50 mg hesperidin, 2 tablets of 500 mg once daily). Manual lymphatic drainage was applied by a therapist to develop the central

techniques on "venous angles" – in subclavian vein area on chest), referred to the receptaculum chyli and retroperitoneal nodes (combined with exercises of diaphragmatic breathing) and finally the whole drain segmented limbs. The massage lasted for 50 minutes and was performed once a day, 3 times weekly. After the manual lymphatic drainage (before patients stand up and limbs were in a low position) used a multilayer bandaging of external pressure of 40-50 mm Hg. The first layer was applied to the skin directly with a Tubula orthopedic sleeve. Then, a supporting bandage Matoplast was applied to the toes and on foot. Another layer was cotton RoltaSoft covering the whole limb. The external layer consisted of short-stretch Hartmann bandages, which were applied for 20-24 hours.

Additionally, patients in groups A and B received 12-chamber intermittent pneumatic compression therapy (Fig. 1). The Flowtron Hydroven 12 System device was applied to compress the cuff covers to the foot, lower leg, knee and thigh. Patients were subjected to a pressure of 120 mm Hg in group A and 60 mm Hg in group B. Ventricular filling time in each chamber was 15 s. A single setting lasted for 45 min; during treatment patients were lying. The treatment was performed once a day, 3 times a week (every other day).

To assess the volume of limb, an optoelectronic Perometer 400 T, co-operating with a personal computer was used. This method allowed us to estimate the measuring error as only 0.5%. The assessment technique was based on a special ring, equipped with a system of 378 LED diodes (emitting the infrared radiation). Within the ring there were also optical sensors that receive electromagnetic stimuli. In the course of measuring, the limb was located inside the ring on the diode-sensor lines. The registered light pulses on the detectors were turned into electronic signals. The ring was moved during measurement to cover the entire lower limb (Fig. 2). Measurements of the limb volume were made for all three groups of patients before and after therapy.

The  $\chi^2$  independence test (greatest reliability level) and non-parametric Kruskal Wallis one-way analysis, which is an element of a module of the analysis of variance, were used for comparing indicators, which characterized patients in all comparative groups. Outcome measurements were compared between the groups using Kruskal Wallis analysis of variance and within the groups – using non-parametric Wilcoxon signed-rank test. Two-sided "p" (level of significance) values of less than 0.05 were considered to be statistically significant.

## Results

The participant demographics assessed before randomization are shown in Tables I and II. All groups were homogenous as regards initial edema size and other factors that characterize the patients ( $p > 0.05$ ).



Fig. 1. Intermittent pneumatic compression with 12 chambers

The average volume of the right lower limb in women from group A (pneumatic compression with a pressure of 120 mm Hg) was 18 034.11 cm<sup>3</sup>, and decreased after treatment to 10 051.15 cm<sup>3</sup> ( $p = 0.00001$ ). The average volume of the lower extremity was 18 008.21 cm<sup>3</sup> before, and significantly reduced to 10 124.02 cm<sup>3</sup> after one month's therapy ( $p = 0.00001$ ).

The average volume of the right lower limb in women from group B (procedures with a pressure of 60 mm Hg) was 17 921.33 cm<sup>3</sup>, and decreased after treatment to 14 641.02 cm<sup>3</sup> ( $p = 0.0002$ ). The average volume of the lower extremity was 17 890.97 cm<sup>3</sup> before, and 14 570.76 cm<sup>3</sup> after a month's therapy ( $p = 0.0002$ ).

In turn, the average volume of the right lower limb in women from group C (control group) was 17 908.41 cm<sup>3</sup>, and after treatment 15021.22 cm<sup>3</sup> ( $p = 0.0002$ ). The average volume of the lower extremity was 17 789.99 cm<sup>3</sup> before, and decreased to 14 789.06 cm<sup>3</sup> after a month's therapy ( $p = 0.0002$ ).

In the study we observed the most significant decrease in edema in patients undergoing compression settings with a pressure of 120 mm Hg. The comparison of the percentage reduction in edema showed a statistically significant advantage for group A to groups B and C, both for changes in the right ( $p = 0.01$ ) and left limb ( $p = 0.01$ ). Results for patients undergoing intermittent pneumatic compression with a lower pressure (60 mm Hg) were similar to those obtained in the control group (Tables III and IV).



Fig. 2. Optoelectronic ring and perometer

Table I. Characteristics of women in comparative groups

Parameter		Group A	Group B	Group C	Level of significance $p$
number of patients		10	10	13	> 0.05
age (years)	average	51.2	53.3	52.8	> 0.05
	min-max	46-56	45-58	44-57	
	SD	4.2	5.3	4.1	
BMI (kg/m <sup>2</sup> )	average	31.2	30.4	30.1	> 0.05
	min-max	24.2-34.2	22.5-32.8	24.8-32.9	
	SD	6.2	5.9	6.1	
duration of disorder (years)	average	11.2	10.6	9.8	> 0.05
	min-max	2.2-17.1	2.5-13.3	4.8-15.4	
	SD	9.8	7.9	7.1	
initial edema (cm <sup>3</sup> )	average	18034.1	17921.3	17908.4	> 0.05
	min-max	2022.2-1598.1	22033.5-14431.3	24005.1-14402.4	
	SD	5679.8	70 072.2	90 093.1	
edema stage by Olszewski classification* (number of patients) R-right leg, L-left leg	IIa	3 R/3 L	3 R/3 L	5 R/4 L	> 0.05
	IVa	5 R/4 L	4 R/4 L	4 R/5 L	
	IVc	2 R/2 L	3 R/3 L	4 R/4 L	

\*stage IIa (soft, plastic edema of the foot and crural area), stage IVa (soft, plastic edema of the whole leg), stage IVc (edema with dermatitis, lymphadenitis, tissue fibrosis of the whole leg)

**Table II.** Characteristics of chronic venous insufficiency

Scale CEAP* (number of patients) R-right leg, L-left leg	Group A	Group B	Group C	Level of significance p
C <sub>3</sub> E <sub>p</sub> A <sub>S2,3</sub> P <sub>R</sub>	6 R/7 L	6 R/7 L	7 R/7 L	> 0.05
C <sub>4</sub> E <sub>p</sub> A <sub>S2 D13</sub> P <sub>R</sub>	2 R/2 L	2 R/2 L	4 R/4 L	> 0.05
C <sub>4</sub> E <sub>p</sub> A <sub>S2,3 D13,14 P18</sub> P <sub>R</sub>	2 R/1 L	2 R/1 L	2 R/2 L	> 0.05

\* C<sub>3</sub>E<sub>p</sub>A<sub>S2,3</sub>P<sub>R</sub> (edema, primary etiology, venous reflux in upper and lower segments of the greater saphenous vein), C<sub>4</sub>E<sub>p</sub>A<sub>S2 D13</sub>P<sub>R</sub> (edema, primary etiology, venous reflux in upper segments of the greater saphenous and femoral vein), C<sub>4</sub>E<sub>p</sub>A<sub>S2,3 D13,14 P18</sub>P<sub>R</sub> (edema, primary etiology, venous reflux in upper/lower segments of greater saphenous, popliteal and femoral veins, saphenofemoral and saphenopopliteal junctions)

## Discussion

The intermittent pneumatic compression has been suggested as a promising treatment option for acute (post-operative, post-burn) edema, chronic venous insufficiency, cellulite and chronic disorders like venous or lymphatic ones, but there are still many controversies connected with pressure values.

Olszewski [9] maintains that lymphatics contract rhythmically with a frequency depending on the volume of inflowing tissue fluid. In regions with a high capillary filtration rate and tissue fluid formation, the frequency is high. The recorded pressures at rest, irrespective of whether in the lying or upright position, with free proximal flow (lateral pressure) range between 7 and 30 mm Hg and during foot flexing between 10 and 30 mm Hg. The pulse amplitude is 3 to 20 mm Hg and 5 to 17 mm Hg, respectively. The pulse frequency is 0.6 to 6/min and 2 to 8/min, respectively. The resting end pressures with obstructed flow (e.g. corresponding to lymphatic obstruction in postsurgical lymphedema or in primary venous lymphedema) range between 15 and 55 mm Hg and during foot flexing 15 to 50 mm Hg. The pulse amplitude is 3 to 35 mm Hg and 3 to 14 mm Hg, respectively. The pulse frequency is 2.5 to 10/min and 3 to 12/min, respectively.

It means that the external low pressure value during pneumatic compression procedures (under 80 mm Hg) has no effect on lymph pressures. In obstructive lymphedema, only few lymphatic collectors remain patent. The recorded pressures during rest range from 5 to 45 mm Hg depending on the remaining contractility force of the damaged lymphatic musculature. During calf muscular contractions, pressures are generally low ranging from 10 to 25 mm Hg, although well-conducted intermittent compression may in some cases generate pressures of above 200 mm Hg. The author [9] recommends only high pressure range: 100-160 mm Hg and time: 40-60 minutes. In his opinion, lower values are useless, which is similar to our view of the results arising from the study.

However, Ponikowska *et al.* [7] argue that the pressure range of the pneumatic compression must not

**Table III.** Comparison a percentage change in edema between groups (right leg)

	Group A	Group B	Group C
Average (%)	46.23	20.03	18.46
SD (%)	12.13	7.09	6.76

p (A vs. B) = 0.01; p (A vs. C) = 0.01; p (B vs. C) > 0.05

**Table IV.** Comparison a percentage change in edema between groups (left leg)

	Group A	Group B	Group C
Average (%)	44.58	19.77	17.89
SD (%)	10.57	8.07	6.89

p (A vs. B) = 0.01; p (A vs. C) = 0.01; p (B vs. C) > 0.05

exceed 40-50 mm Hg, as higher performance may result in damage to the lymphatic vessels, and have adverse consequences on the damaged venous valves in the forms of lymphedema in patients with venous insufficiency, and may not be well tolerated by excessive pressure on the pain receptors in the skin. The researchers noticed the decrease in the limb volume from 9231 cm<sup>3</sup> to 7490 cm<sup>3</sup> (p = 0.024) after three weeks' therapy (5 procedures, once daily from Monday to Friday). A single procedure lasted for 30 minutes. The weakness of this study was lack of the control (placebo) group and much smaller edema sizes compared to our study.

Similar recommendations were also presented by Woźniowski and Kolodziej [8], explaining that the higher pressure in the pneumatic compression therapy than 60 mm Hg should not be applied to patients with venous lymphedema, because higher parameters can be painful and damage the skin vessels (lymphatic pre-collectors in the skin circulatory system). These authors applied the external pressure of 50 mm Hg in 10 patients during one month's treatment, but also without control groups and comparing to other pressure values. The mean volume decreased by about 10% (p = 0.034). For example, in our control group (without intermittent pneumatic compression), the edema was reduced by about 12-15%. It means that it is extremely difficult to conclude about the efficacy of pneumatic compression procedures without estimation the placebo effect.

The additional problem in venous lymphedema of menopausal patients is pain feelings and quality of life [9-15]. In our study, the external pressure of 60 mm Hg did not reduce in a significant way venous lymphedema of the lower limbs. In the group of patients with 120 mm Hg, we noticed a significant reduction. Moreover, high pressure was well tolerated by patients and did not cause discomfort and pain.

In recent literature (Pubmed, Medline, PEDro), we have found only one article and Szolnok *et al.* [16] recruited 38 menopausal women with lipedema to

the study with 19 patients undergoing treatment and 19 serving as a control group using exclusively moisturizers. Treatment consisted of once daily manual lymph drainage (MLD), intermittent pneumatic compression, and multilayered short-stretch bandaging performed throughout a 5-day-course. Pain was evaluated with a 10-item questionnaire, a pain rating scale (PRS), and the Wong-Baker Faces scale. Treatment resulted in a significant reduction in pain with a decrease in mean scores of all three measures. In the control group, only PRS showed a significant decrease. The study results indicated that this treatment regimen not only reduces leg volume and capillary fragility, but also improves pain intensity in patients with lipedema.

Also, Taiwan researchers [17] included in their study thirty-one patients with infrapopliteal diffuse or multiple segmental lesions. Based on receipt of intermittent pneumatic therapy (3 hours daily for 3 months), patients were allocated to a study ( $n = 23$ ) or control ( $n = 8$ ) groups. The 6-minute walking test, transcutaneous oxygen tension ( $TcPO_2$ ), and quality of life (QOL) evaluated with the Short-Form 36 questionnaire were measured at the beginning and end of the study. In the QOL analysis, scores for physical functioning, physical and emotional role functioning, bodily pain, and general and mental health showed significant changes after pneumatic compression therapy. In the 6-minute walking test, duration, and the initial and absolute claudication distances were significantly increased in the study group. The  $TcPO_2$  was also significantly increased in the distal end of the target limb after therapy. Authors concluded that patients at a high risk of amputation with infrapopliteal diffuse or multiple segmental lesions can improve their walking ability,  $TcPO_2$  of the target limb and QOL after intermittent compression therapy.

In the literature there are no randomized controlled studies with menopause patients and venous lymphedema. We will continue our study. To date we have analyzed only a pilot group of menopausal patients with primary lymphedema and chronic venous insufficiency, further studies will be provided.

## Conclusions

The intermittent pneumatic compression with a pressure of 120 mm Hg significantly helps to reduce the venous lymphatic edema in patients with menopause. It appears that the procedures with a pressure of 60 mm Hg are ineffective.

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