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ADDITION OF INTERMITTENT PNEUMATIC COMPRESSION TO CONVENTIONAL TREATMENT IMPROVES VOLUME REDUCTION BEFORE LYMPHATIC SURGERY FOR LOWER LIMB LYMPHEDEMA: A PILOT STUDY

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ABSTRACT

This study assesses the impact of an advanced intermittent pneumatic compression device (IPC - Lympha Press® Optimal Plus) when added to Complete Decongestive Therapy (CDT) compared to CDT alone on volume reduction of limbs with lymphedema. The goal is to maximally reduce edema in preparation for microsurgery. Fifty subjects scheduled for Multiple Lymphatic-Venous Anastomosis (MLVA) were randomly (sequentially) assigned to experimental or control group: 25 (21 females and 4 males) in the experimental IPC group and 25 (20 females and 5 males) in the control group. The two groups were similar in age, sex distribution, and type of lymphedema. Results indicate the IPC group reported greater volume loss than the control group (p= 0.00137) comparing final vs. initial limb volume. The average percentage edema volume loss achieved with added IPC was two times greater (11.7%) than in the control group (5.0%). When differences in treatment duration were accounted for, the IPC group achieved consistently greater proportional volume loss (12.83% vs 6.30%) than conservative therapy alone. In our pilot study, IPC added to CDT resulted in greater proportional volume loss and provides better preparation for MLVA surgery.

Keywords: lymphedema; intermittent pneumatic compression; complete decongestive therapy

Lymphedema is a chronic, disabling, and progressive disorder, characterized by reduced or blocked lymphatic flow in the upper and/or lower limbs. This condition affects about 140-250 million people worldwide (1,2), with increasing incidence due to improved diagnostic capabilities. The growth in the number of patients treated for lymphedema indicates a need for research to improve and innovate rehabilitation protocols, so that patients may achieve the best possible outcome in terms of limb volume reduction and quality of life. Although there is published data on the effects of various treatment modalities, very little exists on combinations of these treatments (3,4).

Two types of lymphedema are found:

TABLE 1
Lymphedema Staging (2,3)

Stage I	
A	Latent lymphedema, without clinical evidence of edema but with impaired transport capacity (provable by lymphscintigraphy)
B	Initial lymphedema, totally or partially decreasing by rest and draining position
Stage II	
A	Increasing lymphedema
B	'Column shaped' limb fibrolymphedema
Stage III	
A	Properly called elephantiasis
B	Extreme elephantiasis, with total disability

primary and secondary. Primary lymphedema has a congenital basis and is due to structural malformations of the lymphatic vessels and/or lymph nodes. It generally affects both limbs. Secondary lymphedema is usually caused by lymphadenectomy and radiation therapy for cancer treatment. To a lesser extent, it may also be due to major cardiac surgery, chest surgery, organ transplantation, bariatric surgery, minor surgery – varicose veins, inguinal hernias, lipomas, biopsies, and trauma, with parasitic infections being the largest cause worldwide. In most cases of obstructive secondary lymphedema, only one limb is affected. (4,5) Proper lymphedema staging is essential for correct treatment and our group utilizes a system based on the International Society of Lymphology. Details are shown in *Table 1*.

Lymphoscintigraphy is the gold standard for lymphedema diagnosis: it identifies the lymphatic origin of the edema and provides useful information on lymphedema staging and etiology. Transport index (TI) is used to classify lymphatic flow. A score below 9 indicates normal TI and a score ≥9 indicates pathological TI (6,7).

International guidelines recommend complete decongestive therapy (CDT), which is a multimodal, conservative therapy. This therapy consists of two phases: an intensive phase of limb volume reduction and a maintenance phase (3). The intensive phase consists of skin care, manual or mechanical lymphatic drainage, multi-layer functional compressive bandaging, and active kinesiotherapy. The maintenance phase includes medical compression stockings, manual self-drainage, isotonic exercise, and intermittent pneumatic compression therapy at home, as well as outpatient follow-up (8,9).

An additional treatment method – advanced intermittent pneumatic compression (IPC) – has been added to the protocol we use in our clinic as part of the preparation for lymphatic microsurgery. This 12 to 24-chamber system (Lympha Press® Optimal Plus, Mego Afek) has a pressure range of 20 to 90 mmHg and mimics the action of muscle pumps by applying intermittent, sequential compression to the treated area. This therapy can also be administered independently by the patient at home.

These decongestive therapies are administered as part of preparation of patients for lymphatic microsurgery, with the goal of reducing the volume of the lymphedematous limb as much as possible prior to surgery. During this process, the patient's limbs are assessed frequently by a multidisciplinary team, consisting of a physician, a physiotherapist, a nurse, and a podiatrist. Although we have found the addition of IPC to be effective in reducing limb volume in patients, we have not randomly studied this addition or found

Fig. 1. Photograph of the opto-electric Peromenter (400T model Pero-System).

studies in the literature (10,11) and the aim of this pilot study is to examine the combination compared to conventional treatment alone.

MATERIALS AND METHODS

Patients

This pilot study was conducted at Campisi Clinic in Genoa, Italy, between January 2021 and February 2022. Male and female patients aged between 18 and 80 years diagnosed with primary and secondary lower limb lymphedema and expected to undergo MLVA were included. Exclusion criteria included patients with vascular problems, presence of lipedema, genital/truncal lymphedema, morbid obesity, pregnancy, or advanced cancer. All human subject work was approved by an internal commission and the authors conformed to the ethical guidelines of the 1975 Declaration of Helsinki. Informed consent was obtained from all subjects.

Procedure

Before starting treatment, each patient was examined by a specialist physician-surgeon who took their medical history and assessed their health condition. They were then prescribed a diagnostic lymphoscintigraphy. Based on the results of this test and their transport index (TI), the physician assessed whether the lymphedematous limb was caused by lymph transport deficiency and whether the patient was a candidate for surgery. Two groups were then developed: the experimental group – referred to as the 'IPC group' – and the control group. Patients were randomly assigned to either groups regardless of their clinical characteristics and socioeconomic variables in the order of arrival to their first visit.

The experimental group was treated with advanced IPC (Lympha Press® Optimal Plus and Lympha Pants), in addition to the standard modalities we use as part of our standard in-clinic CDT program: multilayer bandaging, skin care, exercise, and mechanical lymphatic drainage with Endermologie (LPG®). The control group was treated with standard in-clinic CDT only: multilayer bandaging, skin care, and mechanical lymphatic drainage with Endermologie.

Each patient in both groups underwent at least 11 consecutive days of in-clinic therapy immediately before surgery when the final measurement was taken. Aside from the mandatory 11 consecutive therapy days, each patient in both groups underwent an average of 20 days of additional therapy, spread over up to two months prior to surgery according to the patient's ability to travel to the clinic. For those patients who could not stay 3 or 4 consecutive weeks in the clinic, these therapy days were performed according to the patient's schedule, with some receiving therapy in clinic once or twice a week. However, for all patients, the mandatory 11-day consecutive therapy period was performed immediately prior to surgery.

An Opto-electrical Perometer 400T (*Fig. 1*) was used to assess any limb volume changes during therapies. For each patient, volumetric measurements were taken at the beginning

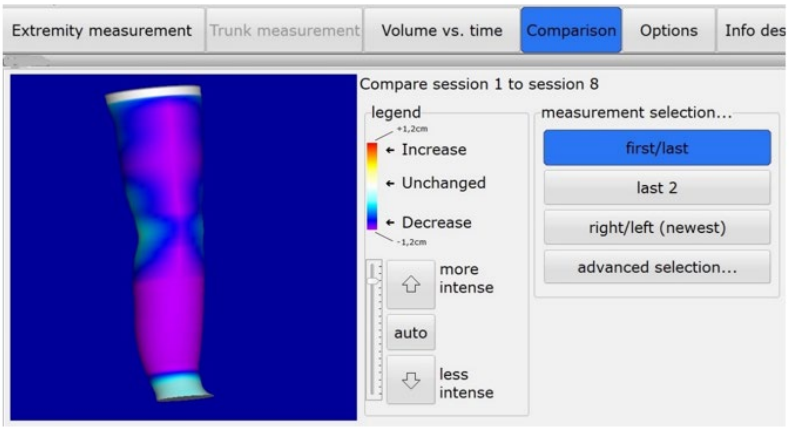

Fig. 2. Example output from the Peromenter software depicting an image of the limb segment and highlighting the changes from previous measurements.

Fig. 3. Photograph of a typical patient treatment using the Lympha Press Optimal Plus® with the Lympha Pants.

and at the end of treatment. Both limbs were measured in patients with primary lymphedema, whereas only the affected limb was measured in patients with secondary lymphedema. Prior to assessment, patients removed all clothing and jewelry in the area to be measured. The volume is expressed in milliliters (ml). Standardized front and back photos were taken at the end of treatment. The Perometer has been proven to be a valid tool to measure the volume of lymphedematous limbs and data was collected by experienced lymphedema specialists. Measurements were taken with the patient standing upright (orthostatic position). The perometer measures circumferential transitions every 4 cm along the leg. The total leg volume is then calculated by the device software (*Fig. 2*). According to scientific literature, the Perometer is a method of measurement that guarantees high reliability both intra-rater (0.989 interclass correlation; 95% confidence interval, 0.98-0.99) and inter-rater (0.993 interclass correlation; 95% confidence interval, 0.99-1.01), compared to other volumetric evaluations for lymphedema (12,13,14).

Treatments

Intermittent Pneumatic Compression

The IPC experimental group was treated with an advanced intermittent pneumatic compression therapy system with 24 chamber compression trousers (*Fig. 3*). This system treats the lower body, including the entire trunk, abdomen, hips, genital area, and both limbs. This IPC system starts treatment with a therapy sequence based on the principles of manual lymph drainage, applying an initial proximal pressure on the trunk, preparing the lymph vessels of the thoracic-inguinal region to receive lymph from the distal areas.

receive lymph from the distal areas. Compression then proceeds from distal to proximal with a sequential movement, holds briefly, and then releases. This progression promotes the emptying of terminal lymphatic vessels, improves lymphatic vessel filling upon release of compression, enhances edema clearance and protein absorption, and increases lymphatic flow during and even after therapy (15). It has been shown to reduce limb volume significantly both when used in clinic and in the home (16). This device works with a pressure ranging from 20 mmHg to 90 mmHg. The patients in the experimental group underwent two hours of daily IPC therapy with a pressure range of 45 to 50 mmHg.

Multilayer Compression Bandages

Multilayer compression bandaging is the most widely used therapy in the treatment of lymph stasis of the limbs due to its effective draining function. The decongestive effect of multilayer bandages is achieved by the pressure applied to the skin, which in turn increases blood flow velocity within venous vessels and lymph flow within lymphatic collectors. This mechanism also increases interstitial pressure, with a corresponding increase in the absorption of interstitial fluids by initial lymphatic capillaries and a decrease in fluid infiltrate. This bandaging must be correctly performed by applying decreasing compression, ensuring that there are no folds and, where necessary, duly protecting any skin areas at risk. This type of bandaging must be performed only by trained and experienced healthcare professionals (17). Multilayer bandaging was applied to patients in both groups every 48 hours.

Skin care

Some skin characteristics – such as texture, elasticity, and hydration – are changed by lymphedema. The skin in the area affected by lymphedema may be slightly pale and cold. In case of consistent and long-lasting lymphedema, the dermis and skin may become hard and fibrotic due to fatty material buildup. Lymphatic vessels may become inflamed (so called lymphangitis). In this case, there may be rashes on the skin, which can be tender to the touch, warm, also accompanied by other symptoms of general malaise and fever. Therefore, it is necessary to frequently check the skin in order to avoid excessive stress. Several specific creams prescribed by the treating doctor are applied before compression bandaging (18).

Mechanical Lymph Drainage

Endermologie by LPG® is a mechanical lymphatic massage, performed by an operator using a hand-held massage roller exerting sequential suction for a dual, vertical and horizontal, stimulation of the connective tissue (dermis and subcutis). (19) The use of this device in combination with other therapies can improve limb volume reduction compared to standard care. By improving lymphedema, fluid accumulation is minimized, and better skin care ensured. This therapy is carried out every 48 hours, after removing the multilayer bandage.

Statistical Analysis

The two groups of patients were analyzed to determine whether they were statistically homogeneous in terms of age, gender, distribution of lymphedema type, initial volume, and time between the two measurements. For this analysis, the Kolmogorov-Smirnov test, Fisher's Exact Test and Pearson's Chi-squared test were performed. The two groups were found to be homogeneous, with no significant differences *(Table 3*).

Next, the relationship between the logarithm of the number of days and the percentage change in volume was considered. Analyzing the relationship between treatment duration and frequency, a sub-optimal distribution was observed, since distribution 'tails' are greater than exponential distribution (heavy-tailed distribution). Using the logarithm of the number of days, a Gaussian distribution was obtained. The percentage change in volume reduction was taken into account since

TABLE 2
Treatments Applied to Experimental and Control Groups

EXPERIMENTAL GROUP	CONTROL GROUP
IPC	
multilayer bandaging	multilayer bandaging
skin care	skin care
mechanical lymphatic drainage	mechanical lymphatic drainage

TABLE 3
General Characteristics

	IPC Patients	Control group Patients	P value
No.	25	25	
Age, Average Years	47.2	42.84	0.6652
Sex, (No.)			
Male	4	5	1
Female	21	20	1
Type of Lymphedema (No.)			
Primary (Bilateral)	7	6	1
Secondary (Unilateral)	18	19	1

absolute change depends on the initial value. The linear model was discarded as, in the case of subjects with bilateral lymphedema, some of the observations came from different legs of the same patient, and therefore could not be considered independent. To continue the analysis, a mixed-effect model was selected. The Satterthwaite method was used to calculate treatment impact.

RESULTS

In this study, 25 patients were included in the experimental IPC group (21 females and 4 males) 7 with primary lymphedema and 18 with secondary lymphedema, and 25 patients in the control group (20 females and 5 males), 6 of them had primary lymphedema and 19 secondary lymphedema. The two groups were similar with regard to age (mean IPC vs. control age: 47.2 years vs. 42.8 years (p=0.6652), sex distribution (male p=0.3971) and (female p=0.5494), and type of lymphedema (primary p=0.3208) and (secondary p= 0.5224). Participants' characteristics are presented in *Table 2*.

Limb volume measurements of the patients both at the beginning and at the end of treatment were taken using the Perometer (*Tables 4 and 5*). Subjects in the CDT group exhibited a mean reduction of -474.87 +/- 837.65 (SD) mls and subjects in the CDT+IPC group exhibited a mean reduction of -1035.72 +/-670.99 (SD) mls. The percent change in final limb volume (100 times beginning volume minus final volume / beginning volume) was evaluated. Using mixed-effect modeling to account for multiple limbs per subject, the percent volume decrease for each group is presented in *Fig. 4* with error bars representing one standard error. The IPC group's volume decreased by 6.7 percentage points more than the control group (p=.0005) with 95% confidence interval 3.2 to 10.3 (11.7% reduction for IPC group, 5.0% reduction for the control group)

However, as described above, the treatment duration for the patients differed somewhat, and the data shows that the volume change depends quite strongly on the amount of time that elapsed (*Fig. 5*). In particular, the volume change reduces down to a minimum at

TABLE 4
Volume Measurements of the Lower Limbs in Milliliters (ml) in IPC Patients

First Measurement (ml)		Final Measurement (ml)	
Right Leg	**Left Leg**	**Right Leg**	**Left Leg**
-	5480 ml	-	4271 ml
9136 ml	-	7100 ml	-
-	8720 ml	-	8205 ml
-	11228 ml	-	9750 ml
8889 ml	-	8063 ml	-
7945 ml	7581 ml	6899 ml	6787 ml
-	9110 ml	-	8083 ml
7459 ml	7291 ml	7251 ml	7065 ml
7163 ml	-	6157 ml	-
9606 ml	9266 ml	8277 ml	7913 ml
7909 ml	-	7276 ml	-
8743 ml	-	7606 ml	-
-	12029 ml	-	9573 ml
6821 ml	-	6453 ml	-
-	10416 ml	-	9349 ml
9603 ml	-	9167 ml	-
5971 ml	6082 ml	5479 ml	5558 ml
7137 ml	-	6543 ml	-
-	9440 ml	-	8399 ml
9963 ml	-	8905 ml	-
11044 ml	-	7872 ml	-
10882 ml	10509 ml	9940 ml	9482 ml
10704 ml	10221 ml	8432 ml	8800 ml
9723 ml	-	8781 ml	-
10545 ml	10022 ml	10134 ml	9925 ml

TABLE 5
Volume Measurements of the Lower Limbs in Milliliters (ml) in the Control Group

First Measurament (ml)		Last Measurament (ml)	
Right Leg	**Left Leg**	**Right Leg**	**Left Leg**
7314 ml	7094 ml	6872 ml	6691 ml
8279 ml	-	8335 ml	-
9876 ml	12244 ml	9581 ml	11018 ml
9332 ml	-	8777 ml	-
3525 ml	-	3423 ml	-
-	16022 ml	-	13508 ml
-	7255 ml	-	6181 ml
-	12280 ml	-	10380 ml
5858 ml	5822 ml	5739 ml	5711 ml
7726 ml	-	7705 ml	-
7084 ml	-	7316 ml	-
5571 ml	-	5459 ml	-
9789 ml	-	9010 ml	-
6630 ml	-	6491 ml	-
9295 ml	9196 ml	9176 ml	9128 ml
6638 ml	-	6634 ml	-
9700 ml	-	9160 ml	-
11116 ml	-	11152 ml	-
5989 ml	5917 ml	6273 ml	6099 ml
16487 ml	-	14150 ml	-
9762 ml	-	9535 ml	-
-	6688 ml	-	6391 ml
14347 ml	14748 ml	15248 ml	15152 ml
8482 ml	-	7202 ml	-
14313 ml	-	12161 ml	-

around 44 days then climbs back upward, and this pattern is apparent for both groups. To account for the varying durations, a quadratic model was used with a different intercept allowed for each group. This analysis reported nearly the same group difference that was seen without controlling for time: 6.3 percentage points more volume reduction in the IPC group (p=.001) with 95% confidence interval 2.8 to 9.8.

Regardless of number of days of treatment (duration), the average volume loss of the patients receiving IPC and CDT was consistently 6.3% higher than the patients who received CDT only. The maximum volume loss was achieved for both groups at 44 days of therapy. According to the fitted model, after 44 days, the control group's volume decreases most significantly – by 6.55% on average whereas the treatment group decreases by 12.83% on average (*Fig. 5*). We select 44 days (represented by the green line in *Fig. 5*) because the two curves of the proportional volume change reach their maximum value.

DISCUSSION AND CONCLUSION

In recent years, the number of patients with lymphedema undergoing treatment for this disorder has steadily increased (1). with lymphedema undergoing treatment for this disorder has steadily increased (1). Research should thus develop new therapeutic paths with proven scientific evidence to improve the condition of the limb(s) affected by lymphedema with the ultimate goal of increasing the quality of life of affected patients. The Consensus Document on the Diagnosis and Treatment of Peripheral Lymphedema issued by the International Society of Lymphology - ISL (3) recommends CDT as the therapeutic strategy to be adopted for this condition in the first

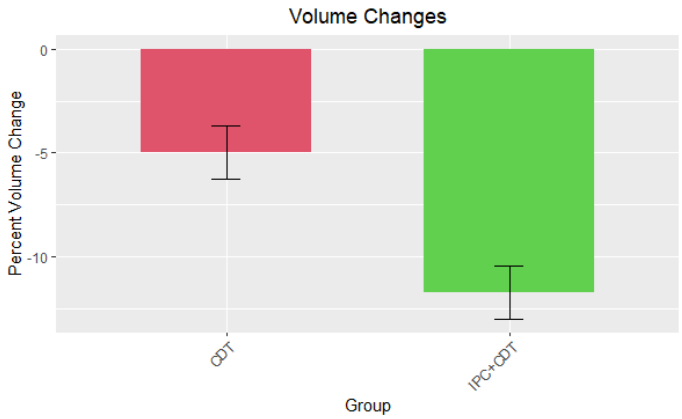

Fig. 4. Percent volume change for the CDT and the CDT-IPC groups. Measurements used a mixed-effect modeling to account for multiple limbs per subject and were calculated using the first and last measurement for each subject. Error bars are 1 standard error.

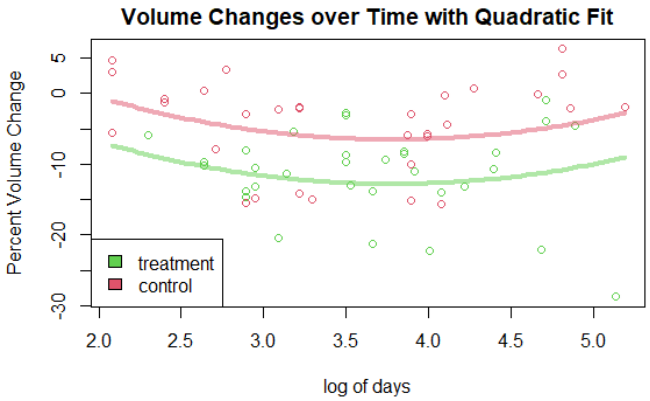

Fig. 5. Quadratic regression curves of percent volume change for subjects in the control (CDT) and experimental (CDT+IPC) groups. The maximum value of reduction was achieved at 44 days before the curve rises again.

intensive phase and in the second maintenance phase. In recent years, research has been investigating the effectiveness of new combination therapies to best improve or slow down the disease. Limb volume reduction is an important goal of lymphedema therapy and ultimately has an impact on the patient's quality of life. Reduction of limb edema volume prior to surgery is important for maximizing success of the operative procedure. This study fits into this context and aims to investigate IPC impact on volume reduction of a patient's limb prior to surgery.

IPC was performed at the Campisi Clinic in conjunction with other treatments designed to reduce the volume of the lymphedematous limb as much as possible before undergoing MLVA surgery. With this derivative microsurgical technique, an anastomosis is fashioned between lymphatic vessels and veins (lymphatic-venous anastomosis), so as to promote lymph drainage into the venous circulation, such as occurs physiologically.

The aim of this study was to assess the additional impact of IPC on limb volume reduction, compared to conventional therapy

alone. To carry out this analysis, a heterogeneous group of 50 patients was divided into two groups: a treatment group – which received IPC in addition to conventional therapy – and a control group, receiving conventional therapy alone. The two groups were not significantly different in terms of gender, age, and distribution in lymphedema type. The aim of our analysis was to better understand the actual contribution of IPC when considering the number of days of therapy and the proportional decrease in limb volume compared to baseline. The two variables are indeed positively correlated. It was observed that the proportional volume loss is greatest after 44 days of therapy.

Using a mixed model effect, the average IPC effect on proportional limb volume loss was observed to be 6.3% greater than with conventional therapy alone. The 95% confidence interval is included between 2.8% and 9.8% additional proportional limb volume loss. In particular, at day 44th of therapy, we observed that the average expected volume loss in the control group was 6.55 % versus 12.83 % in the treatment group.

Based on the results of our pilot trial, the data support that adding IPC to traditional treatments contributes to significant improvement compared to conventional treatment. This may be important since the device can also be used by the patient at home without professional healthcare assistance.

A main limitation of our study is that it is a pilot study applied only to a small series of patients. In addition, we did not use the fully conventional CDT treatment which consists of a therapist applying the MLD instead of our device. In addition, our subjects were treated for an average of 20 days over time before the 11 consecutive days. These differences may be due to our selection of subjects that are eligible for microsurgery and not patients with severe lymphedema in general. Further studies on the effect of IPC alone without the support of other treatments might be useful to assess its direct impact on lymphedema for those patients in preparation for lymphatic surgery.

CONFLICT OF INTEREST AND DISCLOSURE

All authors declare no competing financial interests exist.

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