ТЕХНОЛОГИИ ВОССТАНОВИТЕЛЬНОЙ МЕДИЦИНЫ И МЕДИЦИНСКОЙ РЕАБИЛИТАЦИИ

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The Lymphatic Pump Technique for the Treatment of the Lower Limb Lymphedema

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Abstract

Lymphedema is a condition occurring when the lymphatic system fails to efficiently transport the lymph, thus creating a fluid accumulation in the interstitial space. As of today, the rehabilitation treatment for lymphedema relies on the principles of Complete Decongestive Therapy (CDT), a series of treatments designed to favor the reabsorption of the lymph by the lymphatic system and to restore the functionality of the affected limb. From an osteopathic point of view, interesting results have been obtained through Lymphatic Pump Technique (LPT), a series of oscillatory techniques applied to different areas of the body such as chest, abdomen and feet. A few LPT studies on animals have shown a significant improvement not only in the lymphatic system efficiency (an increase of 271% in lymph flow) but also in the immune system.

Aim. From the scientific evidence derived from such studies, in this paper we propose a clinical trial aiming to demonstrate the benefits that this technique can bring to human beings in a specific rehabilitation process following a lower limb lymphoedema.

Material and methods. An indirect volumetric measurement of lymphedematous limbs according to the segmental technique was performed on six subjects having a history of CDT treatments with different clinical histories, age, gender, work and sport characteristics. The results of the study group treated with the LPT were compared to the results of the same subjects who previously underwent CDT treatment only. The LPT was applied in 8 sessions for two weeks, i.e. for the period of time scheduled for normal physiotherapy rehabilitation including CDT.

Results. The average volume before CDT was 9470.6 ml while after treatment was 8429 ml. The mean volume before CDT associated with LPT was 9608.5 ml, whereas after treatment the mean was 8267 ml with a significant reduction in lymphoedema.

Conclusions. Despite the small number of cases examined, the treatment described in this project has led to positive and statistically significant results, in terms of absorption of lymphedema, especially reducing the volume of the limb. LPT is safe as it is a non-invasive technique, performed with the application of light forces, and integrates perfectly with the CDT.

Keywords: complete decongestive therapy, lymphatic pump treatment, lymphedema

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Lymphedema is a serious and potentially debilitating condition that happens when the lymphatic system fails to efficiently transport the lymph, resulting in the accumulation of protein-rich fluid in the interstice [1]. Despite being a fairly common problem, gauging the exact incidence of lymphedema is difficult, since a portion of the people affected by the lighter forms of edemas do not seek medical advice. The number of people suffering worldwide a form of lymphedema is believed to range from 140 to 250 million [2] of wich 90% are cases of lower limb edemas, while just 9% affect the upper limbs. The genital organs can also be affected by edemas but, in this case, the lymphedema is usually connected with the lower limb.

In industrialised countries, the main causes of lower limb lymphedema are lymphadenectomies and/or radiation therapy for cancer treatment, while in developing countries lymphedema is mainly caused by parasitic infections. As far as upper limb lymphedema is concerned, mastectomy due to breast cancer is the cause in the great majority of cases.

There are two kinds of lymphedema: primary and secondary lymphedema. Primary lymphedema is rare and causes the absence or congenital deformity of the lymphatic vessels. This pathology mainly affects children (1 child every 100,000 suffers from it [3] but it can also develop during adulthood (19% of cases) [4]. The most common sites are the lower limbs (91.7%), where half of the time the edema affects just one leg instead of appearing bilaterally [5]. As far as the secondary lymphedema is concerned, it is caused by a damage of the lymphatic vessels developed later in life. It is known that pelvic and abdominal neoplasia constitute a strong risk factor; specifically, the likelihood for the occurrence of lymphedema after lymphadenectomy and/or radiation therapy for the treatment of different kinds of cancer is: 13% prostatic cancer, 18% uterine cancer, 25% melanoma, 28% vulvar cancer, 25% sarcoma, 30% penis cancer and 42% cervix cancer [6]. It is important to notice that the incidence of lower limb and genitals lymphedema decreases in all those cases in which a biopsy of the inguinal sentinel node is chosen over a complete lymphadenectomy (1.9% of cases) [7]. Complete Decongestive Therapy (CDT) is well recognized as a conservative lymphedema treatment method [8, 9].

It consists of treatment of the skin in order to decrease the risks of infection in areas affected by edema, Manual Lymph Drainage (MLD), use of multilayer elastic compression bandages, use of compression socks, ultrasounds, shock waves, press therapy and specific exercises aimed at the full recovery of the affected limb [10].

Following the International Guidelines, lymphedema should be treated through a CDT in two stages. The first stage aims to reduce the amount of interstitial fluid and therefore the volume of the affected limb [11, 12], whereas the second stage aims to maintain-/-improve upon the results obtained during the previous phase.

The central point of the first stage of CDT is the MLD: this technique focuses on the mobilization of the interstitial fluid from the affected area towards the main lymphatic collectors [13]. This is achieved through light pressure, generally around 30-40 mmHg (lower than the 70-80 mmHg used during body massage). In this way it is possible to increase lymph circulation without increasing blood flow (hyperemia). Pressure is applied tangentially to the affected area in order to induce stretching of the skin with the direction towards the closest lymph nodes, releasing in first instance the proximal lymph nodes and then moving the external ones.

There is some evidence that MLD in early stages following breast cancer surgery may help prevent progression to clinical lymphedema. MLD may also provide additional benefits in volume reduction for mild lymphedema. However, in moderate to severe lymphedema, MLD may not provide additional benefit when combined with CDT [14].

Together with MLD, compression bandaging is also of paramount importance. Low elastic compression bandaging is applied at the end of the session in order to maintain the volume reduction achieved during the treatment. The bandage also increases the pressure of interstitial fluid, resulting in an increase of lymphatic reabsorption [12].

However, there is a lack of clear guidelines regarding the proportioning of the compressive action in relation to the clinical condition. In this context, Dr. Giovanni Farina has developed a procedure based on "resolutive algorithms" that allows the determination of the appropriate compression strategy. The procedure performed with these directives results to be an optimal research tool of immediate and practical clinical commitment [15].

Finally, in order to improve the effectiveness of the CDT, elastic isotonic exercises are performed and assigned to the patients. These aim to activate the skeletal muscle pump mechanism and to increase the venous and lymphatic return of the lymphedematous segment [12].

Osteopathy is a manipulative therapy, recognized by the World Health Organization (WHO), which has as its objective the improvement of physiological functions and the maintenance of homeostasis [17].

The osteopathic professionals have long used Lymphatic Pump Technique (LPT) to improve circulation, reduce edema and help weaken infectious diseases [18].

There are different types of LPT. This study will take into consideration the thoracic, abdominal and breech variants.

More specifically, thoracic lymphatic pumping temporarily reduces intra-thoracic pressure, increasing chest expansion and increasing respiratory recoil in exhalation. Abdominal lymphatic pumping transiently increases abdominal pressure, thus increasing the thoracoabdominal pressure gradient of the lymphatic flow. Podalic lymphatic pumping is thought to improve lymphatic and venous drainage.

Recent studies in anesthetized dogs have shown that LPT increases the flow of lymph, the number of leukocytes and the flow of inflammatory mediators [18, 19]. Regarding the lymphocyte count present in the lymph of the thoracic duct during the execution of the technique, after 10 minutes one can encounter an increase of 251% of neutrophils, of 116% of monocytes and of 111% of lymphocytes with a decrease of 73%, 72% and 56% respectively. With a second application of the technique there is an increase of 402% of neutrophils, 181% of monocytes and 240% of lymphocytes compared to the values present before the first execution of the technique.

Other studies on mice show that an application of LPT, lasting 4 minutes and with the frequency of about one second per compression, increases the flow of lymph from 24 ± 5 µl-min to 89 ± µl-min and at the same time has also a notable increase in the flow of lymphocytes inside the kilo cistern [20, 21]. Furthermore, there are no differences between the results obtained with the abdominal lymphatic pumping technique and the thoracic pumping technique [22].

Recently it has been highlighted how the osteopathic manipulative treatment at the lymphatic system is effective in patients suffering from pneumonia, improving the respiratory and circulatory capacity at the lymphatic level and reducing the hospitalization time, the use of antibiotics and respiratory imbalances [23].

The study protocol described in this paper aims to demonstrate the benefits that can bring to the human being, within the specific area of the rehabilitation of lymphedema

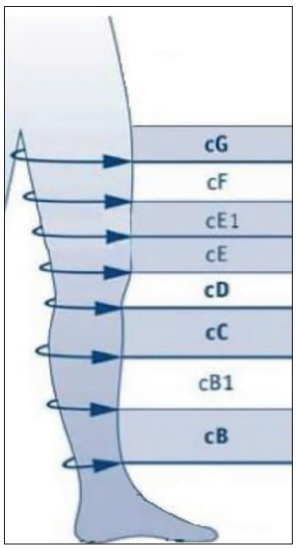

Fig. 1. *Points of reference to evaluate the lymphedematous lower limb*

of the lower limb. The hypothesis that we want to verify is that the LPT (thoracic, abdominal and podalic) induces the reactivation of the lymph flow and the mobilization of lymphocytes in the lymphatic system also at the peripheral level, promoting the reabsorption of liquids and interstitial substances and, in fact, reducing lymphedema of the lower limb. LPT is a technique that is easy to learn and quick to perform and, if this hypothesis is confirmed, it would be possible to insert it into the rehabilitation treatment routine of lymphedema. It is also a minimally invasive technique that does not involve any risk or side effect on anyone who underwent it [24].

Aim. The aims of this preliminary pilot study are to know if LPT treatment is safe for the patient, it integrates correctly with the gold standard and can be used together with CPT treatment to increase the absorption of lymphedema.

Material and methods

Type of study. A controlled pilot study.

Inclusion criteria

The study included subjects of both sexes with diagnosis of lymphedema in the lower limb, regardless of the type, the cause, the extent and the degree of lymphedema. Subjects with specific conditions such as: ongoing lymphangitis, non-compensated cardiac problems, nephropathies or deep venous thrombosis/TPV, bilateral lymphedema were excluded.

Outcome. The outcome of the study was the indirect volumetric measurement of lymphedematous limbs according to the segmental technique [25]. This measurement is an innovation in phlebology and was developed and validated in 2013 by Dr. Giovanni Farina, a physiotherapist working at the Clinical Institute Città Studi Milano, and defined, in procedural terms, according to criteria conceded by the multicentre study group and multispecialist of the Italian Society of Oncological Lymphology SILO.

Giovanni Farina has defined the points of reference to evaluate the lymphedematous limb with the patient lying supine (fig. 1). Once having defined the points of reference, the measurements of the circumferences have been carried out by using the dynamometric tape measure, also developed and recently patented by Giovanni Farina. In addition to giving a quantitative measure of the circumference and reducing intra and inter operator variability, this instrument allows to objectively determine the degree of tissue resistance to compression on all the points examined in the segmental technique giving information on the degree of organization of lymphedema.

When the reference points and the size of the respective circumferences are obtained, the total volume of the limb is calculated as the sum of the various segments, each of them similar to a truncated cone (fig. 2). By applying the formulas for the calculation of volumes of geometric solids, we obtain:

Where C1 and C2 are the circumferences of radius r1 and r2, respectively. It should be noted that the more the shape of the different limb segments differs from that of the theoretical solid on which the formula is based, the greater the error.

Study procedures

A sample of subjects underwent LPT together with CDT including MLD and compression lasting two weeks (study group, tab. 1). The results of the indirect volumetric measurement of the lymphedematous limbs according to the segmental technique were compared with those obtained after two weeks of CDT alone (control group, tab. 2).

The LPT was applied in 8 sessions for two weeks, i.e. for the period of time scheduled for normal physiotherapy rehabilitation: MLD sessions are on average 30-45 minutes long and occur 5 times per week. The LPT was applied without distinction always after the MLD or after the multilayer compression bandage, never before these procedures.

LPT involves three distinct phases [22]:

– thoracic lymphatic pumping technique (ThLPT), the patient lies in a supine position. The operator positions himself/herself at the patient's head and, with his/her hands resting on the patient's subclavia area, performs rhythmic compressions directed downwards on the patient's chest, with a frequency of about one per second;

– abdominal lymphatic pumping technique (AbLPT), the patient lies in a supine position. The operator places his/her hands under the patient's costal arch and performs compression-relaxation cycles upwards. The speed of execution is about 20-30 compressions per minute and the compressions must be performed in a more delicate way than the previous ones;

– podalic lymphatic pumping technique (FeLPT), the patient lies in a supine position. The operator places his/her hands at the 2/3 distal of the plantar surface of the patient's feet and performs rhythmic compressions in the cranial direction, thus bringing the feet into dorsiflexion with a frequency of 50 compressions per minute.

$$V = \frac{1}{3}\pi (r_1^2 + r_1 r_2 + r_2^2)h = \frac{1}{12\pi}(C_1^2 + C_1 C_2 + C_2^2)h$$

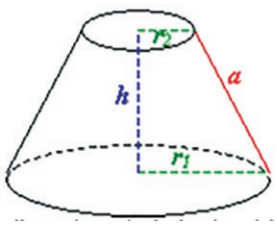

Fig. 2. *Total volume calculation*

Table 1. *Study group steps*

T0	– First meeting with the patient for taking charge during which the privacy policy documents and the informed consent to the treatment are delivered – Indirect volumetric measurement of the lymphedematous limbs according to the segmental technique is performed and the lower limbs are photographed
T1	– Standard physiotherapy treatments are carried out – The LPT technique is performed according to the times defined for the two weeks of treatment
T2	Indirect volumetric measurement of the lymphedematous limbs according to the segmental technique is performed and the lower limbs are photographed

Table 2. *Control group steps*

T0	– First meeting with the patient for taking charge during which the privacy policy documents and the informed consent to the treatment are delivered – Indirect volumetric measurement of the lymphedematous limbs according to the segmental technique is performed and the lower limbs are photographed
T1	– Standard physiotherapy treatments are carried out – The LPT technique is performed according to the times defined for the two weeks of treatment
T2	Indirect volumetric measurement of the lymphedematous limbs according to the segmental technique is performed and the lower limbs are photographed

Table 3. *Results of circumference evaluation and limb volume*

Subject	CDT Cir. pre	CDT Vol. pre	CDT Cir. post	CDT Vol. post	CDT+LPT Cir. pre	CDT+LPT Vol. pre	CDT+LPT Cir. post	CDT+LPT Vol. post
1	374.5	11,283.30	365.1	10,754.20.	360	10,878.10	354.9	10,628.10
2	334.5	9680.4	321.5	8963.2	321.7	8985	305.3	8100
3	325.8	8510.1	307.9	7668	323	8345.6	307.6	7674
4	344.4	9923	329.4	9082.1	350.5	10520.8	332.3	9516.7
5	356.3	9484.3	336.6	8418.2	395.8	11519.1	386.3	8337.5
6	349	7942.3	296.9	5688.1	338.3	7402.5	287.5	5345.7
μ	347.4	9470.6	326.2	8429.0	348.2	9608.5	329.0	8267.0
σ	17.08	1165.59	23.86	1685.84	27.73	1609.02	36.62	1791.93

Note: *μ = average ; σ = standard deviation*

Table 4. *Study group results*

CDT+LDP	Δ (cm)	Reduction (ml)
1	5.1	250.1
2	24.7	885.0
3	32.0	671.6
4	54.2	1004.1
5	90.2	3181.6
6	73.7	2056.8

Table 5. *Control group results*

CDT	Δ (cm)	Reduction (ml)
1	9.4	529.1
2	37,5	717.1
3	34.8	842.1
4	43.5	841.0
5	50.7	1066.1
6	84.4	2254.2

Table 6. *Control group sample statistics*

Statistical analysis		Average	N°	Standard deviation	Standard average error
1	Circumference CDT pre	347,.417	6	17.0772	6.9717
	Circumference CDT post	326.233	6	23.8624	9.7418
2	Volume CDT pre	9470.567	6	1165.5910	475.8505
	Volume CDT post	8428.967	6	1685.8372	688.2401

Table 7. *Control group statistical significance results*

	Coupled differences							
	Average	Standard deviation	Standard average error	Confidence interval on the difference in 95%		t	gl	P-value
				Inferior	Superior			
Circumference CDT pre Circumference CDT post	21.1833	15.5748	6.3584	4.8386	37.5281	3.332	5	0.021
Volume CDT pre Volume CDT post	1041.6000	619.5113	252.9144	391.4627	1691.7373	4.118	5	0.009

Table 8. *Study group sample statistics*

		Average	N°	Standard deviation	Standard average error
1	Circumference CDT+LPT pre	348.417	6	27.7330	11.3219
	Circumference CDT+LPT post	328.983	6	36.6248	14.9520
2	Volume CDT+LPT pre	9608.517	6	1609.0166	656.8783
	Volume CDT+LPT post	8267.000	6	1791.9289	731.5519

Table 9. *Study group statistical significance results*

		Coupled differences					t	gl	P-value
		Average	Standard deviation	Standard average error	Confidence interval on the difference in 95%				
					Inferior	Superior			
1	Circumference CDT+LPT pre Circumference CDT+LPT post	19.2333	16.2156	6.6200	2.2161	36.2506	2.905	5	0.034
2	Volume CDT+LPT pre Volume CDT+LPT post	1341.5167	1082.5887	441.9650	205.4095	2477.6238	3.035	5	0.029

The LPT duration depends on tissue congestion. The technique continues until the tissue texture of the right and left sides of chest, abdomen and foot are similar.

It was found that the duration for each phase did not exceed 4 minutes and decrease with the application of the following treatments.

The operators were three osteopaths at «SOMA Istituto Osteopatia Milano».

Data collection and analysis

The outcome compared on the study and control sample was the indirect volumetric measurement according to the segmental technique detected after two weeks of treatments. For each of these metrics the effect of the treatment were evaluated through an appropriate hypothesis test with significance p <0,05. The statistical analysis of the outcome was performed using the Student's t-test because the authors used a within-subjects study design with a normal distribution of the variables, i.e. averages of continuous data.

Results

Six subjects were enrolled in the study group with a history of CDT treatments with different clinical histories, age, gender, work and sport characteristics. The results of the study group treated with the LPT technique were compared with the results of the same subjects who previously underwent CDT treatment only.

The average of the circumference before CDT was 347.4 cm while after treatment was 326.2 cm. The average circumference before CDT associated with LPT was 348.2 cm, whereas after treatment was 329 cm. The average volume before CDT was 9470.6 ml while after treatment was 8429 ml. The mean volume before CDT associated with LPT was 9608.5 ml, whereas after treatment was 8267 ml.

The standard physiotherapeutic treatment (CDT) associated with the manual treatment with LPT increased the reduction of the volume of the limb affected by lymphedema, while regarding the circumference of the limb, there were no major variations between the study group and the control group (tab. 3-5).

Criticality and limits of the study

Two critical issues are highlighted in the design of the project. The first is that the evaluator that detected the parameters at the beginning and at the end of the treatment, which should be blinded, was instead to be an active part of the treatment itself as regards the procedures of CDT. The second limit was due to the impossibility of creating a control trial CDT vs LPT because the treatment took place in a hospital that had to guarantee the standard treatment (CDT) to the patients.

The study was also not randomized, since the control group was composed of the same patients also belonging to the study group. A further limitation was the reduced number of subjects.

Discussion

The data obtained from this work, despite the smallness of the sample under examination, show there is no substantial difference in the reduction of the lymphedematous limb circumference between the study group (CDT+LPT) and the control group with only CDT (Tab. 3, 6, 8).

Instead the data demonstrate how the association of the CDT standard treatment with the LPT manipulative technique amplifies the increase in lymphatic drainage, thus reducing the average volume of the lymphedematous limb (Tab. 3, 6, 8).

We can see how statistical significance exists between the circumference variables and volume for the control group (CDT only).

So the differences that are noticed between pre and post treatment are not due only to the case but also to an event between the two times: in fact the p-value obtained for both cases is below the threshold of significance of 5% (Tab. 7, 9).

As can be seen from Tables 8 and 9, there is statistical significance between the circumferential variables and volume for physiotherapeutic and osteopathic treatment.

Given the results obtained, the hope is to raise the sample unit, thus reinforcing the significance obtained, with the aim of making the LPT osteopathic treatment an integral part of the rehabilitation process of patients suffering from lymphedema.

Conclusion

The goals of this pilot study were to determine whether LPT treatment is safe for patients, whether it integrates correctly with the gold standard, and whether it may be used in conjunction with CPT treatment to boost lymphedema absorption. The results obtained are encouraging showing that LPT can be a safe and effective treatment for lower extremity lymphedema. In light of the findings, further studies are needed thus reinforcing the result obtained with the aim of making the LPT osteopathic treatment an integral part of the rehabilitation process of patients suffering from lymphedema.

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