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THE ROLE OF DIAMAGNETIC PUMP (CTU mega 18) IN THE PHYSICAL TREATMENT OF LIMBS LYMPHOEDEMA. A CLINICAL STUDY

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INTRODUCTION

Lymphoedema represents a chronic pathology, that renders patients physically and psychologically disabled, it is not easy to control, and shows a marked tendency to spontaneously set in complications. For such reasons lymphoedema demands for a novel early, targeted and lasting diagnostic and therapeutic approach [1].

So far it is frequently claimed, in a completely misleading manner, that nor the lymphoedema physiopathology is clear or the corresponding treatment is satisfactory. Nevertheless, though the pathogenetic details are still an open question, the general principles of the disease's physiopathology are well known.

On one side, the main disorder may be characterized by a **"low output failure"** of the lymphatic system, that is, a general decreasing of the lymphatic flow. Such a disorder can be due to a congenital lymphatic dysplasia (primary lymphoedema) or to an anatomic obliteration, for example caused by a radical surgical resection or by radiotherapy, or again as a consequence of repeated lymphangitis with lymphangiosclerosis or, finally, produced by a functional insufficiency such that due to lymphangiospasm, paralysis and valvular insufficiency (secondary lymphoedema). In any case, the common feature is a disorder in the lymphatic transport mechanism, that decrease below the minimum capability required by the microvascular filtrate, that includes plasmatic proteins and cells that normally come out from the haematic network entering the interstice.

On the other side, the **"high output failure"** of lymphatic circulation occurs when an excess of capillary haematic filtrate overcomes the normal transport capability of the lymphatic system as for example happens in the liver cirrhosis (ascites), in the nephrosic syndrome (anasarca) and in the inferior limbs deep venous insufficiency (post-thrombophlebitic syndrome) and the severe phlebostasis [2]. The lymphatic injury, both primitive and secondary, worsen in time due to the creation of a vicious circle: LYMPHATIC DISORDER → INCREASE OF PROTEIN RICH INTERSTITIAL LIQUID → DECREASE OF PROTEOLYTIC CAPABILITY → INCREASE OF INTERSTITIAL CONNECTIVE → FIBROSIS [3]. In the subcutaneous tissue of patients affected by lymphoedema an increase of the amount of interstitial liquid, rich in proteins,is observed. To the increase a chronic phlogosis is associated (the monocyte-macrophage system and the fibroblast are activated), with a growth of the interstitial matrix. The lymph accumulates in the fascia, forming "holes" or "lymphatic lakes" and the three-dimensional retinaculum structure addresses molecules and lymph toward the cutis surface. The hydrophobic adipose lobules keep the water component off, so that it accumulates along the retinaculum. Finally, we observe an upsetting of the subcutaneous tissue, with the appearance of "comb" picture [4].

PULSED LOW-FREQUENCY ELECTROMAGNETIC FIELDS: The pulsed low-frequency (< 50 Hz) electromagnetic fields [5] belong to he class of non ionizing radiations, that is, they are characterized by an associated energy below 12 eV (electron-Volt). Such an energy is insufficient both to turn on ionization phenomena in molecules and to break even very weak chemical bonds. For this reason in the last decades these radiations have not been considered able to interact with biological systems and, as a consequence, the studies on this subject were scarce and information poor, especially when compared with the great amount of knowledge concerning the interactions among ionizing radiations and biological systems [6]. Only recently, due to the more and more common use of electromagnetic fields of different intensity and frequencies [7], a vast research activity [8-9-10-11-12-13-14-15] has started, addresses to the definition of their main biological and therapeutic effects, on which are based the exposition thresholds currently recommended (Tab. 1):

Table 1.

	Types of Radiation	Frequency	Wave Length	
Non-ionizing Radiation	Lowest Fields fz	0 Hz - 50 Hz	Over 6000 Km	- Dangerousness of Radiation +
	DIA System Low Frequency Electromagnetic Fields	50 Hz - 100 Hz	Over 3 Km	
	Magnetic Therapy High Frequency Radiations	100 KHz - 300 GHz	1 mm - 3 Km	
	Radio Transmission Marconi Therapy / Radar Therapy Infrared	> 300 GHz	780 nm - 1 mm	
	Physical treatment Visible light		380 nm - 780 nm	
	Phototherapy treatment Ultraviolet rays		10 nm - 380 nm	
	Tanning treatment		Under 10 nm	
Ionizing Radiation	X rays and Gamma radiation **Clinical diagnosis / Biological sterilization**			

DIAMAGNETISM: The diamagnetism works on hydrogen atoms. Indeed, when a hydrogen atom is covalently bound to a strongly electronegative atom, as for example the oxygen, the bond electrons tend to move toward the latter. As a consequence, the H atom assumes a partial but consistent positive charge. This charge, distributed in a small volume, lead to a high electric charge density. At this point, the hydrogen atom tends to bind with a partially negatively charged atom (the oxygen atom of a different water molecule) in this way acquiring a greater stability neutralizing its electric charge (Fig. 1)

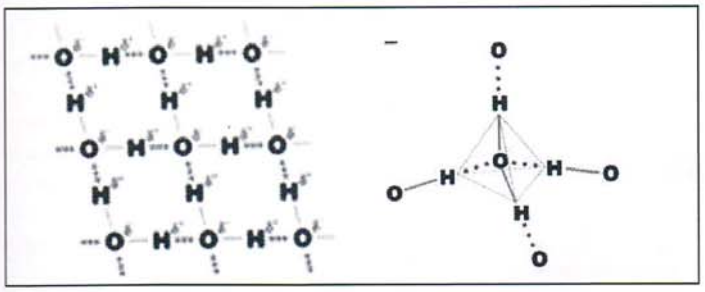

Fig. 1

A single water molecule does not feel any net force, since it is subject to the action of the surrounding molecules that are uniformly distributed in any direction of the three-dimensional space. The liquid water consists in a disordered network of molecules, bound together by relatively weak chemical bonds. Such a network is continuously subject to fluctuations that randomly break and create new bonds among the molecules. Due to these characteristics the water does not have a proper dipole magnetic moment and it is repelled by an external magnetic field (**diamagnetism**). The CTU Mega 18 is a device of molecular diamagnetic acceleration. It uses an energy of up to 200 Joule, generating high power (2 Tesla) pulsating fields and developing a water-repulsive force with the following main therapeutic aims:

- liquids transport;
- implant of pharmacologically active hydrosoluble molecules, bound to the water (salvation water);
- tissue biostimulation.

Liquids transport: As a result of diamagnetic repulsion, the free water in the extracellular compartments is fiercely pushed away from the field application site. The transport of extracellular liquids helps the oedema and post-traumatic effusions reabsorption and the scoriae removal, and stimulate the lymphatic circulation and related phenomena also thanks to the vasodilatation draining action produced by the diathermia coupled with CTU Mega 18. In addition, the magnetic field works on the intracellular liquids, increasing their mobility. The increase of the thermal molecular excitation supports the cells biochemical activity as well as the mitochondrial and phagic-lysosomal metabolic mechanisms. The result is a beneficial acceleration of all energetic, metabolic and cellular activities like ionic transport, scoriae removal and cellular breathing.

Implant of pharmacologically active molecules: The process works according to the principle of diamagnetic force that exerts a repelling force on the water. The handling can be obtained through a dilution in water (salvation water). Indeed, the magnetic fields do not produce effects of cutaneous polarization working as diffusion walls that otherwise appear with the use of devices operating with electric currents (ionophoresys, electroporation,

etc.). This permits a deeper action and a better uniformity in the drug distribution with respect to traditional systems.

Tissue biostimulation: A variable magnetic field crossing a conductor induces an electric current. The human body is a conductor, that when it is crossed by a magnetic field the phenomenon of biostimulation occurs. The action of magnetic fields is well described in terms of bioelectric parallelisms existing among cells [17], since it acts on the difference of electric potential on the membrane sides as well as on the orientation af the circulating atoms that behave as elementary magnetic dipoles [18-19].

* * *

The CTU-Mega 18 posses energetic transfer supplier for capacitive and resistive diathermia, that permits to produce a thermal effect having the following main characteristics:

- action on the microcirculation;
- action on the adipocytes;
- action on the mucopolysaccharidic gel;
- action on the interstitial weft.

Action on the microcirculation: The diathermia stimulates a microhyperaemia that permits to overcome the artery-arteriolar deficit and to increase the flow speed in capillaries. In this way the microcirculatory stasis is fixed and the interstice oedematous flooding [20].

Action on the adipocytes: The recovery of the microcirculation raises the thermal and enzymatic gradients, in this way reactivating the lipolysis. In addition, the friction caused by the shift currents of ionic charges moving in the tissue produces a localized and homogeneous increase in temperature, that restores the normal turn-over needed to maintain an active adipocytes metabolism.

Action on the mucopolysaccharidic gel: The diathermia returns the right fluidity to the gel both operating on its components and restoring the membrane selectivity that tunes the osmosis among the endoluminal, vasal and interstitial compartments. Such activity is further on magnified by the effects of the magnetic fields, thus justifying the improvement of the matrix "gel-sol" transition.

Action on the interstitial weft: The diathermia, while increasing the temperature, induces an increase in the macrophagic proteolytic activity, in this way reducing the compactness of the connective fibres with a consequent decrease of echogenicity [21].

MATERIALS AND METHODS

In the framework of the Vascular Surgery Operative Unit – University of Ferrara and of the "Oedema Centre" in Nola (NA) we evaluated 42 limbs affected by lymphoedema in 38 patients aged from 21 to 67 (average 47 ys). 34 patients were affected by monolateral lymphoedema (30 in the inferior, 4 in the superior limb) and 4 by bilateral lymphoedema, with oedema localized at inferior limbs. We built up two randomized groups. Patients in group 1 were treated with CTU Mega 18 together with 2nd class compression stockings; patients in group 2 were treated only with 2nd class compression stockings.
All patients were clinically evaluated using a standard procedure we proposed, see Table 2 [23], before recruiting, by an accurate clinical examination and instrumental exams (lymphoscintigraphy, soft tissues echography, echodoppler). In addition, the limb's circumference was measured in specific positions before and after the treatment (60 days).
Every patients were asked to fill an Inform and Consent form and submitted to an accurate case history interview using a clinical file devoted to CEAP-L Classification [23] that permitted us, at the end of the study, to get objective clinical conclusions. Moreover, specific exclusion causes to the diamagnetic pump treatment (epilepsy, peace makers, MR incompatible metallic component).

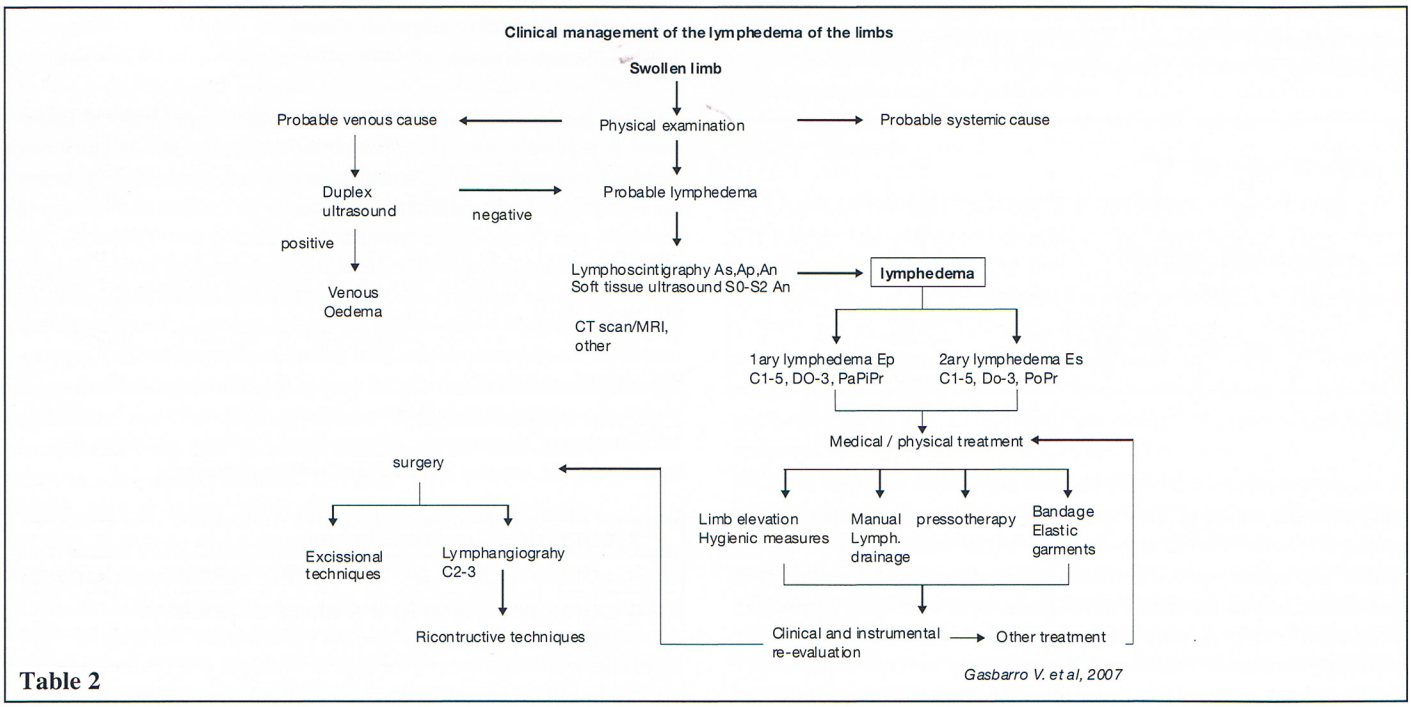

Table 2

All patients were then selected by C CEAP-L class (C stage of disease [1-5], localization and involvement grading) (Tables 3, 4, 5).

Table 3 - Clinical classification

C1	No oedema (pre clinical stage)	1 point
C2	Oedema that disappears with night rest	2 points
C3	Oedema that persists with night rest	3 points
C4	Fibrotic oedema	4 points
C5	Elephantiasis with skin lesions	5 points

Table 4

Lower Limb (LL)	Upper Limb (UL)
FOOT (1 point)	HAND (1 point)
LEG (1 point)	FOREARM (1 point)
THIGH (1 point)	ARM (1 point)
GENITAL (1 point)	SHOULDER (1 point)
TRUNK (1 point)	

Table 5

Group 1 (Diamagnetotherapy + Compression)	Group 2 (Compression)
C2 3 limbs	3 limbs
C3 15 limbs	14 limbs
C4 3 limbs	4 limbs

In a second step the patients, recruited according their class, were randomized to get homogeneous samples for a more reliable final evaluation. The echography was performed using a 7.5-10 MHz probe with Kontron Sigma and Philips 7.5-10 MHz devices. The exploited parameters were the subcutaneous tissue thickness, the presence of hyperechogenicity in the sub-cutis (signifying the presence of free lymph, that is, "lymphatic holes") [24]. We considered the interstitial trabecular meshworks that at this stage appear thickened, hyperechogenic and fragmented. Using a limb echographic mapping we observed high fibrosis and lymphatic accumulation areas; the same issues were evaluated after the therapy.
The application of diamagnetic therapy was performed according to the scheme:
Operative way: Liquid shift; Intracellular 20%; Extracellular 100%.
Diathermia with resistive system, electrical resistance of 500-1000 Ohm according to the measured impedance (the device is provided with an impedance detector that permits to highlight tissue areas with high resistance to magnetic fields, where it is necessary to increase the electrical resistance up to 1000 Ohm).

Executive procedure: The massage was performed following the lymphatic draining directions, in this way combining the advantage of the hand-made lymphatic drainage with the energy developed by the machinery [25].
The duration of diathermia application was 30-40 minutes and it was repeated three times per week for about two months (for a total of 20 applications).
The study was six months long in order to evaluate possible in-time negative effects of this therapeutic methodology.

Side effects: 4 patients (10% of the sample) showed, in the early stage of the therapy, a temporary warm sensation, nausea and urgent diuresis stimulus.

RESULTS

Clinical (limb's circumferences and consistency) and instrumental (soft tissues echography) controls showed a positive result in patients treated both by diathermia and compression with respect to those treated only by compression.

Clinical evaluation:

The clinical improvements, revealed by using the very reliable CEAP-L classification, are summarized in the following table 6.

Table 6

	Group 1 (T0)	Group 1 (T1*)	Group 2 (T0)	Group 2 (T1*)
C2	3	6	3	3
C3	15	15	14	15
C4	3	0	4	3

These results deserve an in-depth analysis. Indeed, even if they could appear of an ordinary level, they actually are not. In the group 1 (diathermia + compression) we obtained in the totality (3 limbs, 100%) of class C4 limbs a regression of trophic troubles like lymphatic ulcers. As a consequence of this improvement in the disease, they were declassed to a C3 class. This result is, in our opinion, of great clinical significance. The same happened to the three patients (20%) that moved from C3 class to the C2 one. On the other hand, by using only the compression therapy the clinical outcomes were basically irrelevant.
To make the results more meaningful we also used a clinical gravity score, that led to the following data (Tables 7, 8):

Table 7

CLINICAL GRAVITY SCORE
1 point for each area of the limb involved
1 point for each limb involved
2 points for other areas involved (genitals, shoulders)
1-4 points according to the stage of oedema
1 point symptomatic oedema
1-3 points according to the stage of disability

Table 8

Clinical gravity score	Group 1 (T0)	Group 1 (T1*)	Group 2 (T0)	Group 2 (T1*)
5	5	8	3	3
6	11	11	12	13
7	0	1	2	1
8	2	1	0	1
9	3	0	4	3

Instrumental evaluations:

Together with a decrease in the oedema volume, patients treated by diathermia + compression (Group 1) showed a meaningful decrease of tissue's consistency (hard oedema becoming soft oedema). In details, the echographis evaluations pointed out an improvement in the echographic derma and hypoderma structure, with more homogeneous and thinner connective shoots, an hypo-anechogenic appearance of the superficial loose cellular tissue, a reduction of the connection synechiae between derma and hypoderma and between hypoderma and superficial muscular fascia, with a consequent better excursion of the muscular district. In addition, at the end of each treatment cycle we observed a reduction of the lymphatic holes and lakes [26], with a consequent decrease of the circumference measures [cB (ankle) = –3 cm; cD (knee) = –4 cm; cG (thigh root) = –6 cm] (Fig. 2) e [cC (wrist) = –2 cm; cE (elbow) = –3,5 cm; cG (arm) = –5 cm] (Fig. 3) and most of all the transformation of a hard oedema in a soft one. In this way, the limb became more compressible (decrease in the tissue stiffness) leading to a better response to the compression therapy [27].

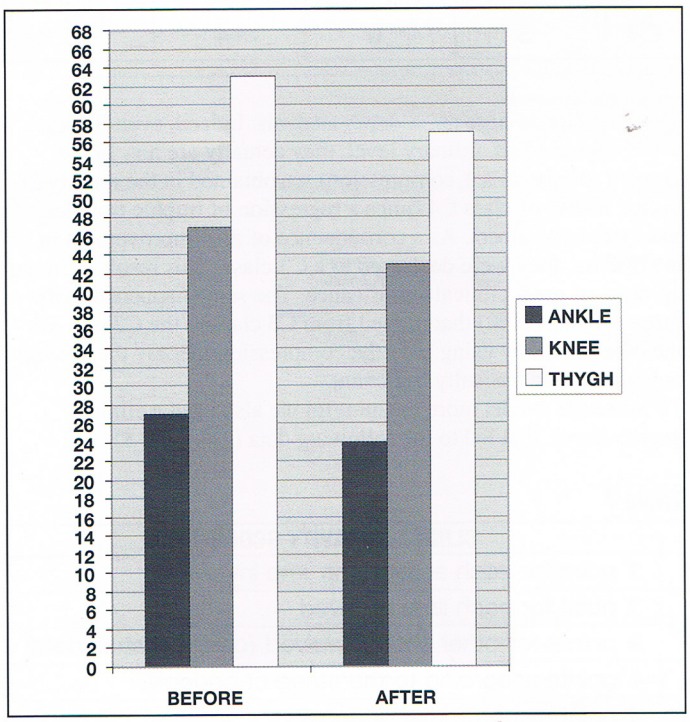

Fig. 2 - Average decrease in the inferior limb's circumferences measures.

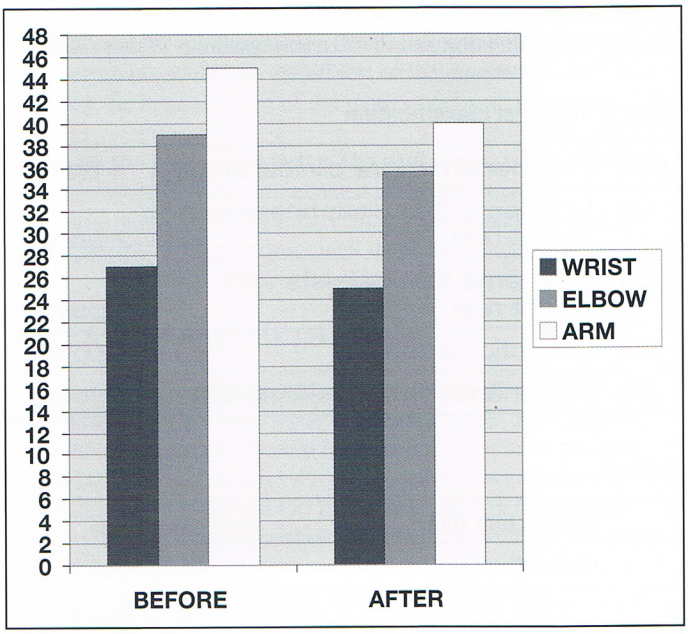

Fig. 3 - Average decrease in the superior limb's circumferences measures.

CONCLUSIONS

The data we obtained confirm the validity of the therapeutic approach (CTU Mega 18), even it is certainly integrable with all other therapeutic treatments of oedema, in general, and of lymphoedema, in particular [28]. It has shown its efficiency thanks to the different and synergic actions (diamagnetic force acting on the water, thermal effect and possible pharmacologic subcutaneous transport), that led to good results, both on clinical and on instrumental side. In particular, in Group 1 we observed a clear clinical improvement with respect to Group 2, testified by the CEAP-L classification and by the clinical gravity score, as well as an instrumental improvement pointed out by echographic images [29]. The safety [30] of the technique, moreover, has been benchmarked by the absolute irrelevance of registered side effects. In conclusion, the patients satisfaction and the objective improvement in both clinical and instrumental data, together with its simplicity, make the proposed technique, possibly integrated with other approaches, a new fundamental tool in the therapy of lymphoedema.

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