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PRELIMINARY EVIDENCE OF EFFECTIVENESS OF TECAR IN LYMPHEDEMA

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ABSTRACT

Lymphedema of the lower limbs often contributes to the mobility impairment of morbidly obese patients. Defining novel cost-effective protocols is important for reducing treatment costs. The study aimed to assess if Capacitive and Resistive Energy Transfer (TECAR) can reduce edema and the minimum number of sessions needed to observe volume reduction. Forty-eight severely obese subjects (age range: 46-78 years; BMI >40 kg/m^2) with bilateral lower limb lymphedema were divided into three groups undergoing either manual lymphatic drainage, pressure therapy, or TECAR, in addition to a multidisciplinary rehabilitation program. They were compared to a control group composed by 12 women (age: 67.4 ± 8.9 years, BMI: 44.6 ± 4.1 Kg/m^2) undergoing only the rehabilitation program. A handheld laser scanner 3D system was used for volume measurements. In addition, patients were evaluated with a Timed Up and Go (TUG) test and pain/heaviness of the lower limbs with a Visual Analog Scale (VAS). A significant volume reduction was observed after 6 sessions of TECAR: specifically, in the whole limb (PRE: 9.7+2.8 dm^3; POST: 9.4+2.8 dm^3; $p<0.05$) and in the thigh (PRE: 3.5+1.3 dm^3; POST: 3.3+1.2 dm^3; $p<0.05$). The TUG and VAS for pain showed a significant improvement in all groups. Our preliminary results suggest that TECAR can provide a relatively early reduction of lower limb edema with improvement of patients' function and pain.

Keywords: lymphedema, TECAR, lymphatic treatments, rehabilitation, obesity

Chronic edema of the lower limbs is extremely common in severely obese patients and recent studies have shown that obesity can result in markedly impaired lymphatic function. (1,2) The typical pattern is development of edema first in the lower part of the legs which then may extend to include the whole leg. This condition is traditionally treated with decongestive physiotherapy, namely Manual Lymphatic Drainage Techniques, also in association with intermittent pneumatic pressure applied by means of biomedical devices including single-chamber and multi-chamber pumps. Lymphedema treatment also includes a range of interventions such as: exercise programs, multi-layered compression with short-stretch bandages, meticulous wound and skin care, adaptation of activities of daily living, training in following precautions, and use of life-long self-management techniques (3-8). The intensive phase of the treatment is followed by a maintenance phase consisting of daily use of standard or individually sized compression garments. Treatment of this chronic condition results in an economical burden for the patients and health care systems. Optimizing treatment modalities and defining cost-effective protocols for reducing edema and duration of cyclic treatments is an important goal in rehabilitation of lymphedema. Whereas pressure therapy and manual lymphatic drainage have been extensively studied, the effects of Capacitive and Resistive Energy Transfer (TECAR) has not been fully investigated in this field. We decided therefore to investigate its possible effect on edema reduction in short term use.

The aim of this study was therefore to measure and compare lower leg volumes in morbidly obese patients with lymphedema undergoing a multidisciplinary rehabilitation program and 3 different physiotherapy and physical agents modalities: TECAR, pressure therapy, and manual lymphatic drainage.

MATERIALS AND METHODS

Participants

The study design is a Randomized Controlled trial. Forty-eight severely obese women with chronic bilateral lower limb lymphedema were included. Patients had been admitted to our hospital for a 4-week multidisciplinary rehabilitation program including weight management, physiotherapy, diet, adapted physical activity, nutritional and psychological support, and medical supervision. Inclusion criteria were morbid obesity (BMI >40 Kg/m^2) and chronic bilateral lymphedema of the lower limbs. Patients presenting with thermal sensitivity disturbances, a pacemaker, pregnancy, arterial diseases, history of malignancy, current infections, venous thrombosis, or lymphangitis were excluded.

The participants were randomized into 4 groups with assignments generated using a computer program and presented in sealed, sequentially numbered envelopes. Three groups underwent the following treatments in addition to the 4-week multidisciplinary rehabilitation program, respectively: TECAR therapy (12 women, age: 63.0 ± 14.2 years, Body Mass Index (BMI) 46.1 ± 5.7 Kg/m^2); pressure therapy (12 women, age: 60.3 ± 12.9 years, BMI: 46.3 ± 5.5 Kg/m^2); lymphatic drainage (12 women, age: 61.4 ± 10.3 years, BMI: 48.0 ± 8.3 Kg/m^2). The fourth group (12 women, age: 67.4 ± 8.9 years, BMI: 44.6 ± 4.1 Kg/m^2) served as control group and underwent only the multidisciplinary rehabilitation program.

Patients were evaluated with a Timed Up and Go (TUG) test (9) and pain/heaviness of the lower limbs using a Visual Analog Scale (VAS) (10). Volume measurements of each leg with lymphedema were measured using a three-dimensional handheld laser scanner (LS3D) system (O&P Scan Rodin4D, Pessac, France). Laser peak power was 1 mw, wavelength 670 nm, and the product was in laser class I. The scanner procedure was performed by the same operator (CN) before and after each session.

All evaluations were scheduled before (pre-session) and after each week of treatment with the same modalities.

The experimental procedure was explained in detail to participants and the study carried out in accordance with the ethical standards of the institute, and with the 1964 Helsinki declaration and its later amendments. Written informed consent was obtained from all participants.

Treatments

All 48 participants performed a 4-week multidisciplinary rehabilitation program including 3 hours/day of the following standardized interventions: weight management with diet, physical activity and cognitive-behavioral interventions, and physiotherapy.

TECAR

A TECAR device (CIM 200, Fis Group) with a 0.8 – 1.0-1.2 MHz range of frequencies was used. This device has 2 independent channels and is provided with both traditional manual electrodes as well as large capacitive flexible automatic electrodes. Each channel has a power modulator and an absorption level display. The latter provides a real-time control of the quantity of energy provided to the biological tissue and facilitates choice of power output and geometric positioning of active and passive electrodes. TECAR was set on automatic, capacitive, medium-high power mode. Patients were in a sitting position during the treatment. The passive plate was positioned on the low back while the active plate was applied to the groin for 15-minute, 15 min on the popliteal cavity, and 15 min on the foot sole (a total of 45 minutes for the lower limb). Six 90-min sessions (45-min sessions for each limb) were conducted during the rehabilitation period daily.

Pressure therapy

A sequential pressure therapy with progressive distal-proximal pressure gradient was used (11). The compression-decompression cycle duration was 30 seconds (11). Pressure level was set at 40 mmHg. Patients underwent six 45-min sessions in supine position daily.

Lymphatic drainage

The manual lymphatic drainage (following Vodder) is a special massage technique in which very slow, rhythmic and mild-intensity pressures used are intended to accelerate the lymphatic drainage from the areas of stasis towards the drainage channels and also to free the interstitial tissue from fluid that has accumulated (12,13). Patients underwent six 60-min sessions of manual lymphatic drainage in supine position over the 4-week treatment period.

Control group

Patients in this group received no specific treatments for lower limb lymphedema reduction. They only underwent the 4-week multidisciplinary rehabilitation program 6 times a week as also followed by the other 3 groups.

Volume measurements

Volumes were measured using a novel instrument. In obese patients, identifying anatomical bony landmarks can be difficult because of regional bulging and skin folds, which make centimeter measurements operator-dependent and unreliable. For such reasons, we opted for an objective measurement of limb volumes with a 3D laser scanner (LS3D) (14). This method has been previously validated against the water displacement method, which represents the gold standard (15,16) and has some previous use in upper (17,18) and lower limbs (19).

A 3D handheld laser scanner system (O&P Scan Rodin4D, Pessac, France) was used. Resolution of this scanner model is 0.1 mm and the absolute accuracy is 0.75. The LS3D system consists of a receiver with laser scanner (wand probe), a transmitter and a signal-processing unit. Data were saved and processed using a commercial laptop. To guarantee the proper accuracy during the scanning phase, it was necessary to ensure subjects could maintain a stable position for the entire measurement duration – in general 2-3 minutes. To achieve this stability, participants were standing up with one straight leg as shown in *Fig. 1*.

The transmitter is used as a relative coordinate system by producing a magnetic wave so that the receiver could calculate its position and orientation in the space. In order to ensure a proper scanning, the transmitter was placed in correspondence of the lateral epicondyle of the femur. Overlapping sweeps of the whole limb were made with the scanner (typically 5-7 sweeps each acquisition). As the

Fig. 1: Positioning of patients for Laser Scanner measurement.

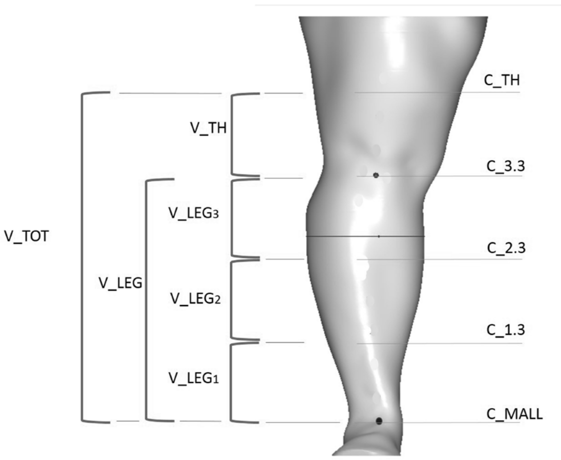

Fig. 2: 3D scanning protocol parameters: C_MALL=Malleolus circumference point, C_TH =Thigh circumference point, C_1.3 one third leg circumference point, C_2.3 two third leg circumference point, C_3.3 three third leg circumference point, V_TOT=Total Volume, V_LEG= Leg Volume, V_LEG2 two third leg sub volume, V_LEG3 three third leg sub volume, V_TH= Thigh Volume.

data were collected a three dimensional image is displayed immediately on the computer screen, and the data file was stored. Data were processed by a dedicated software - Rodin4D (version 5.6, Pessac, France).

The processing phase was divided into two main steps: 1) 3D surface definition: a triangular mesh was generated and a closed iso-surface was created, and 2) geometrical parameters definition.

Parameters

To develop the clinical scanning protocol, two types of parameters were defined: circumferential measures (C) and volume measures (V). In lymphedema, it is frequently hard to correctly identify reference points due to adiposity. The leg lengths were calculated adding the distance between malleolus and the center of the knee and a percentage of the thigh of 25%. The leg volume was then defined. In order to highlight different fat and swelling distributions, the leg length was divided into three parts. The correspondent circumferences were defined and the sub-volumes were calculated as shown in *Fig. 2* pre- and post-treatment.

Statistical Analysis

All previously defined parameters were computed for each participant. The Kolmogorov-Smirnov test was used to verify if the parameters were normally distributed. Because assumptions of normality were not fulfilled, median and quartile range relating to all indices were calculated. The Kruskal-Wallis was used to assess the differences among groups at the pre-session, and the Wilcoxon paired test between the pre- and post-sessions in order to determine whether a specific treatment introduced statistically significant changes in terms of TUG, VAS, and volume parameters. The significance level was $p < 0.05$. Statistical analysis was conducted using SPSS (version 19.0, SPSS Inc., Chicago, IL).

RESULTS

All participants included in the study showed good compliance and successfully completed the treatment protocols; two of the 12 patients in the control group could not be assessed with instrumental measure at the post-session.

The average percentage of weight loss after completion of the rehabilitation program was 5% in all of the participants with no differences between the four groups. *Tables 1 and 2* show the median (quartile range) of TUG and VAS and parameters obtained by laser scanner system (circumferences and volumes) for each group at pre and post.

At pre, no statistical difference was present among groups in terms of the functional/VAS assessments and circumferential/volume parameters ($p>0.05$).

TECAR

Data showed that both TUG and VAS improved significantly after the sixth TECAR session ($p<0.05$). Significant reductions in terms of volumes were found at week 1 (after 6 TECAR sessions). In particular, results showed a significant percentage edema reduction of the whole limb (V_TOT) and of the thigh volume (V_TH). In addition, a reduction in thigh (C_TH) and proximal level of the leg circumferences (C_3.3) was observed.

Pressure therapy

After the treatment, both TUG and VAS improved significantly ($p<0.05$). No significant reductions in terms of volumes and circumferences were found at week 1 (for a total of 6 sessions).

Lymphatic drainage

Both TUG and VAS improved significantly after 6 sessions of treatment ($p<0.05$). Significant but confined reduction in the middle part of the leg volumes (V_LEG2 parameter) was observed. No other volume changes were found after the six sessions.

Control group

In the controls, significant improvements were observed in both TUG and VAS pain ($p<0.05$). No significant changes were shown in terms of volumes and only a reduction of circumferences of the knee (C_3.3) was found at week 1 (for a total of 6 sessions).

DISCUSSION

Previous evidence has shown that combined physical and decongestive therapy (manual lymphatic drainage in association with intermittent pneumatic devices and compression bandages) could effectively reduce excessive leg volume due to lymphedema in the short term (5,20-23). Treating such chronic condition, however, can become costly in the long term and represents an economical burden both for the health systems and for the patients themselves. It appears therefore worth investigating novel rehabilitative modalities, among those that are not yet supported by sound scientific evidence, which may reduce duration of treatment and related health costs.

Despite initial and unpublished experimental evidence, the effects of TECAR on lymphedema of the lower limbs have not yet been clearly demonstrated. Among physical agents, capacitive diathermia, since the 90's, has been popular in sports medicine for prompt recovery of post-traumatic edema, inflammation, and pain. The term TECAR was later introduced to replace previous definitions of capacitive diathermia. There has been some published evidence of the effectiveness of TECAR in rotator cuff tendinitis (24) and painful cervical spine syndromes (25), but there is only very scanty evidence in the grey literature that TECAR is effective in reducing edema (26).

In this study we wanted to investigate whether TECAR can be an effective treatment modality in volume reduction in lower limb lymphedema in severely obese patients by

TABLE 1
Median (Quartile Range) Values of TUG and VAS at Pre- and Post-Session for the Assessed Groups

	TECAR Group		Pressotherapy Group		Lymphatic Drainage Group		Control Group	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
TUG (s)	21.8 (19.7)	13.3 (8.1)*	14.2 (6.4)	12.6 (6.8)*	14.5 (5.2)	12.8 (4.8)*	16.1 (5.7)	13.8 (5.2)*
VAS pain	73.9 (21.7)	47.2 (24.2)*	62.1 (25.5)	51.9 (24.4)*	42.5 (31.4)	30.8 (33.5)*	57.5 (30.2)	45.5 (26.1)*
VAS heaviness	78.3 (18.2)	45.0 (18.9)*	75.0 (16.7)	55.6 (30.7)*	50.4 (25.8)	39.2 (28.9)*	74.3 (26.3)	65.5 (26.1)

*= p< 0.05, pre vs. post session.

TABLE 2
Median (Quartile Range) Values of Volume and Circumferences Parameter for the Assessed Groups

	TECAR Group		Pressotherapy Group		Lymphatic Drainage Group		Control Group	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Volumes (dm³)								
V_TOT	9.7 (2.8)	9.4 (2.8)*	7.3 (1.5)	7.2 (1.6)	8.1 (2.2)	7.9 (2.2)	7.6 (0.9)	7.4 (0.8)
V_TH	3.5 (1.3)	3.3 (1.2)*	2.3 (0.6)	2.2 (0.6)	2.6 (0.7)	2.5 (0.8)	2.5 (0.3)	2.5 (0.3)
V_LEG	6.0 (1.5)	5.9 (1.5)	5.0 (0.9)	4.9 (1.0)	5.4 (1.6)	5.3 (1.5)	5.1 (0.7)	4.9 (0.6)
V_LEG1	1.0 (0.2)	1.0 (0.2)	1.1 (0.3)	0.9 (0.3)	1.1 (0.3)	1.0 (0.3)	0.9 (0.2)	0.9 (0.2)
V_LEG2	2.1 (0.5)	2.0 (0.5)	1.7 (0.3)	1.7 (0.4)	1.9 (0.6)	1.7 (0.7)*	1.7 (0.2)	1.7 (0.3)
V_LEG3	2.9 (0.9)	2.8 (0.9)	2.3 (0.4)	2.3 (0.4)	2.5 (0.8)	2.5 (0.7)	2.4 (0.4)	2.3 (0.3)
Circumferences (mm)								
C_TH	722.35 (191.2)	712.8 (106.9)*	623.3 (65.2)	605.3 (73.3)	646.2 (94.5)	639.6 (92.9)	630.9 (46.9)	624.6 (46.8)
C_1.3	376.6 (31.7)	375.3 (37.7)	359.8 (41.5)	355.6 (40.9)	376.1 (62.7)	370.8 (66.0)	358.7 (33.7)	354.5 (32.6)
C_2.3	502.9 (72.9)	499.5 (76.1)	463.4 (38.7)	454.2 (42.6)	495.7 (70.9)	483.4 (84.2)	477.2 (28.8)	473.3 (31.9)
C_3.3	612.6 (119.4)	604.3 (116.6)*	506.9 (41.7)	507.8 (44.5)	525.9 (79.2)	520.2 (74.8)	527.0 (41.4)	515.6 (38.0)*
C_MALL	305.3 (32.8)	307.7 (34.9)	354.8 (62.8)	357.6 (73.1)	366.5 (46.1)	369.6 (45.5)	343.4 (39.0)	342.9 (33.4)

C_MALL=Malleolus circumference point, C_TH =Thigh circumference point, C_1.3 one third leg circumference point, C_2.3 two third leg circumference point, C_3.3 three third leg circumference point, V_TOT=Total Volume, V_LEG= Leg Volume, V_LEG2 two third leg sub volume, V_LEG3 three third leg sub volume, V_TH= Thigh Volume. *= p< 0.05, pre vs. post session.

comparing its effects with those obtained with other widely used drainage techniques.

Our preliminary results show that at week 1 all the treatments induced significant improvements in terms of pain (VAS) and function (TUG), similarly to the control group undergoing only the 4-week multidisciplinary rehabilitation program.

As for volume parameters, 6 sessions of TECAR led to a significant reduction of the total volume of the lower limbs, particularly at thigh level. Improvements were observed also in terms of circumferences at proximal level of the leg, close to the knee. Some significant improvements confined to the middle part of the leg were observed after 6 sessions of manual lymphatic drainage, while pressure therapy showed no effects on volumes within this lapse of time. Such results are not surprising since it appears from the literature that the two latter modalities usually show their effects after longer treatment durations (i.e., 10-12 sessions for pressure therapy and up to 18 sessions for manual lymphatic drainage).

The mechanisms underlying the earlier lower limb volume reduction obtained with TECAR as compared to pressure therapy and manual lymphatic drainage are not clear and were beyond the scopes of this preliminary study.

TECAR electrodes were applied at the locations of lymphatic drainage vessels. By positioning the active electrode on the groin, we aimed at draining the proximal lymphatic station "congestion" at that level.

We know from specific literature (24-26) that the effects of TECAR are based on the use of bio-compatible energy which induces effects on cell metabolism. These may include: 1) effect on microcirculation: the induced microhyperemia affects the arterio-arteriolar deficit and increases capillary flow to reduce interstitial edema; 2) effect on adipocytes: improved microcirculation increases lipolysis and adipocytes turnover; 3) effect on the interstitial space: increased temperature reduces the consistency of the connective tissue and improves microcirculation and cellular exchanges; and 4) effect on the contraction of the smooth muscle cells of both venous and lymphatic vessels.

Different from other physical agents, including diathermia and intermittent pressure, TECAR acts as a condensator – it is possible to cyclically increase the density of electric charge close to each component of the condensator thus generating an alternating current. The therapeutic effect of TECAR could stem from the endogenous micro-hyperaemia and the homogeneous hyperthermia induced both at depth and superficially (24-26).

Our preliminary data suggests that TECAR might be a promising adjuvant for reducing volumes of the lower limbs in lymphedema, especially in consideration of its early effects. Combined with other treatments, use of TECAR might be able to shorten the duration of the treatment cycles periodically needed for this chronic condition.

Because of the excessive fat masses around the waist and thighs, obese patients generally rate higher scores on VAS scale related to pain and heaviness of the lower limbs. Decreases in lower limb volumes leads to a reduced subjective perception of heaviness in the legs and improves the range of motion of the lower limb joints. At post, obese patients reported a subjective improvement in mobility and general functional capacity and a reduced sensation of pain/heaviness in the lower limbs.

The study has several limitations. First, the relatively small number of participants resulted in limited strength of the clinical and statistical findings. Consequently, the external validity of our findings is reduced, and larger studies will need to confirm our results. Also, in this study we did not report data about variations in body composition after treatment.

The aim of the study focused on the possible effects of TECAR on lower limb volume reduction. We did not try to compare the effectiveness of different modalities – both pressure therapy and manual lymphatic drainage are known to need longer treatment durations.

This is the reason why the volume reduction observed after the 1-week treatments are not very remarkable (approximately 3% to 6%). However, these effects are observed after just 6 sessions of TECAR. These preliminary data suggest that TECAR is able to induce relatively early volume reduction in the lower limbs, thus promising to shorten the duration of the periodic treatment cycles and relative costs. Further studies should be conducted considering the medium-long term effects of treatment cycles and address the cost-effectiveness of various treatment modalities.

CONCLUSIONS

Our study consisted of a preliminary investigation on the short-term effects of TECAR on lymphedema in morbidly obese patients. We did not perform a cost-effectiveness analysis. However, we could speculate that due to reduced pressure on resources (i.e., physiotherapists for manual lymphatic drainage and long-term use of compressive bandages), implementation of TECAR may be promising in offering cost savings in the treatment of lymphedema. Also, since TECAR is an operator-independent modality, it may allow the treatment of more patients simultaneously which can further reduce pressure on resources.

CONFLICT OF INTEREST AND DISCLOSURE

All authors declare no competing financial interests exist.

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