ROLE OF HIVAMAT® 200 (DEEP OSCILLATION®) IN THE TREATMENT OF THE LYMPHEDEMA OF THE LIMBS.

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Abstract

Background

The important goals achieved by the biomedical technologies lead us to search new mechanisms to contribute to the treatment of lymphatic pathologies. The aim of our study is to examine a new instrumental physiotherapeutic method characterized by the utilization of intermittent electrostatic fields with deep oscillation.

Methods

HIVAMAT® 200 operates at the level of the connective tissue using a pulsing electro-static field, producing an intense resonant vibration within the tissues involved. The repetition of this phenomenon in rapid succession generates rhythmic deformations of the tissue. This action permits fibre and tissue layers to reacquire motricity and malleability. Upon these premises we conducted a clinical and instrumental study in order to verify it's efficacy in the treatment of lymphedemas of the limb. From May to December 2005, 20 patients affected by lymphedema of the limbs underwent treatment with HIVAMAT® 200 in conjunction with II class elastic stockings.

Results

The results obtained in 20 patients confirmed that this method can have an important role in the treatment of such a complex disease. We achieved a statistically significant reduction in the circumference of the limbs and in the thickness of the subcutis.

Conclusion

The advantage of HIVAMAT® 200 lies in the combination of electricity and the various techniques of manual massage, thereby improving the results and the quality of treat-ment. Moreover, due to the potential for self-treatment, it is also possible to offer an on-going domestic therapy.

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Introduction

Lymphedema represents a chronic, inevitably progressive, and invalidating disease from a physical, functional and psychological point of view. For this reason, it requires a targeted approach, early diagnosis, and comprehensive follow up procedures. The crucial difference between the lymphedema with respect to the other vascular edemas is defined by it's constant progression in fibrosis. This is because lymphedemas have higher concentrations of proteins and these are responsible for the activation of the chain of inflammation (1).

Clinically, the more the element of inflammation is present, the more the lymphedema goes against connectivization and therefore fibrosis. Definition of the causes of the lymphatic disease and it's evolutive state, are also crucial elements to determine the timing and the methods of the therapeutic strategy (2,3). From the rehabilitative perspective this utilizes well-proven physiotherapeutic techniques which have been tested by numerous clinical studies in the university and medical sector (see guidelines CIF-2004 and CONSENSUS DOCUMENT ISL-2003) (4,5,6,7). All together they correspond to the Complex Decongestive Physiotherapy (CDP) in 2 phases of lymphedema, based on hygienic measures, skin cures, manual lymph drainage (MLD), compressive bandage application and decongestive exercises (8,9).

The aim of our study is to examine a new instrumental physiotherapeutic method characterized by the utilization of intermittent electrostatic fields with deep oscillation. HIVAMAT® 200 operates at the level of the connective tissue by a pulsating electrostatic field that generates an intense resonant vibration within the tissues involved. The mechanism is based on the creation of a semiconductor layer and a minimal electrostatic field between the hands of the therapist and the tissue of the patient. The repetition of this phenomenon in rapid succession generates rhythmic deformations of the tissue, which is being pumped throughout it's entire depth. This action permits fibre and tissue layers to reacquire motricity and malleability and improve tissue nourishment (increased production of ATP). HIVAMAT ® 200 acts principally on intercellular circulation at the level of the interstitial connective tissue. The effect of this treatment is the re-stabilization of the fluidity of circulation.

Materials & methods

From May to December 2005, 20 patients affected by lymphedema of the limbs underwent treatment with HIVAMAT® 200 in conjunction with II class elastic stockings. There were 16 females and 4 males with a mean age of between 30 and 60 years.
HIVAMAT® 200 was applied following the procedures of manual lymph drainage (MLD), which consists of the following phases: preparation of the central and peripheral lymph node stations, and then the successive drainage to lymph centers following the ways of lymphatic flow focusing on the areas of major lymph accumulation. The duration of treatment was 30 minutes, twice a week. Finally, every treatment was subdivided in 2 phases utilizing initially medium-high frequencies (25-80 Hz, 80-200 Hz) dissolving indurated tissue and stimulating the transportation of liquids, followed by low frequencies (25-80 Hz) characterized by a strong pumping effect and thus an effective interstitial drainage. After treatment the elastic stocking was applied on the affected limb.

As inclusion criteria of the study we considered the clinical conditions and the ecographic examination made by the Philips iu22 (10). Measurements of the circumferences of the limbs were made at 3 precise levels: above the ankle, at the upper 1/3 segment of the leg, and at the upper 1/3 segment of the thigh. For every patient such levels were determined by also considering the height from the ground, in order to have a constant and precise level of measurement. At the same levels ecographic examination was preformed in order to evaluate morphology and thickness of the subcutis before and after treatment. In this way we were able to evaluate qualitative modifications of the edema: the grade of edema, the state of connectivization of the subcutis and the presence of fluid lymph accumulation.

Moreover we excluded from the study all patients which were under edema specific or not pharmacological treatment. And we included patients which had finished a complex physical treatment at least 40 days before, in order to not evaluate patients that could have long-term benefits after an intensive treatment.

Results

After 8 weeks of treatment utilizing HIVAMAT® 200 and compressive stockings (known to not influence significantly edema's evolution) we evaluated both clinically and ecographically in these 20 patients the variations of the circumferences, the subcutaneous thickness and the qualitative variation of the subcutis layer affected by the lymphedema. In the evaluation of the circumference at the lower 1/3 segment of the leg before the treatment, we obtained data varying between 22.0 and 32.0 cm with a mean average of 25.9 cm. Measurement after treatment produced an average of 24.9 cm with peaks from 21 to 34 cm.

This average reduction of 1 cm was highly significant in the t student test ($p<0.001$). Evaluation of the circumferences at the upper 1/3 segment of the leg varied between 36 and 45 cm with a mean average of 39.3 cm. At the end of the therapeutic cycle we obtained values between 35 and 44 cm with a mean average of 38.4 Analysis of this data with the t student test demonstrated that the difference was statistically significant.

At the upper 1/3 segment of the thigh circumferences before treatment varied between 57.00 and 75.00 cm with an average of 63.6 cm. After 8 weeks of treatment that range was between 55.5 and 73.5 cm with an average of 62.0 cm, also significant (Table 1).

At the same level where circumferences were measured, we pinpointed ecographic windows in the medial upper and lower 1/3 parts of the leg, and at the upper 1/3 segment of the thigh.

Measurements of the subcutis thickness at the lower 1/3 segment of the leg before treatment had an average of 4.12 cm in a range between 3.5 and 5.09 cm. After treatment this value decreased to 3.97 cm (with a range between 5.41-3.34, again statistically significant ($p<0.000$).

At the upper 1/3 segment of the leg, before treatment, the average subcutis thickness was 6.26 (range between 5.73-7.16 cm). After treatment there was a decrease in thickness to 6.14 cm (a range between 5.57-7.00). This result was not significant.

The final measurement of the subcutaneous thickness was undertaken at the upper 1/3 of the thigh. The average value of the initial thickness was 9.86 (with a range from 8.83 to 11.7). At the end of treatment this was reduced to 9.67 (a range of 7.95-11.3). These results were statistically significant ($p=0.001$) (Table II).

We wanted to undertake a qualitative evaluation of the conditions of the subcutaneous layer and those which were the dominant features: edema, presence of lymphatic pools associated with the presence of lymph at the subcutaneous layer, fibrosis and sclerosis.

In all cases a substantial reduction was observed of the fibrotic component and, if pesent, of the sovrafascial edema. Clinically, this last result signified a major presence of a tender edema. This outcome allowed us, at the end of our study, to suggest a new intensive treatment to this group of patients. No side effects were observed, neither initially, nor subsequently, in the use of this machine.

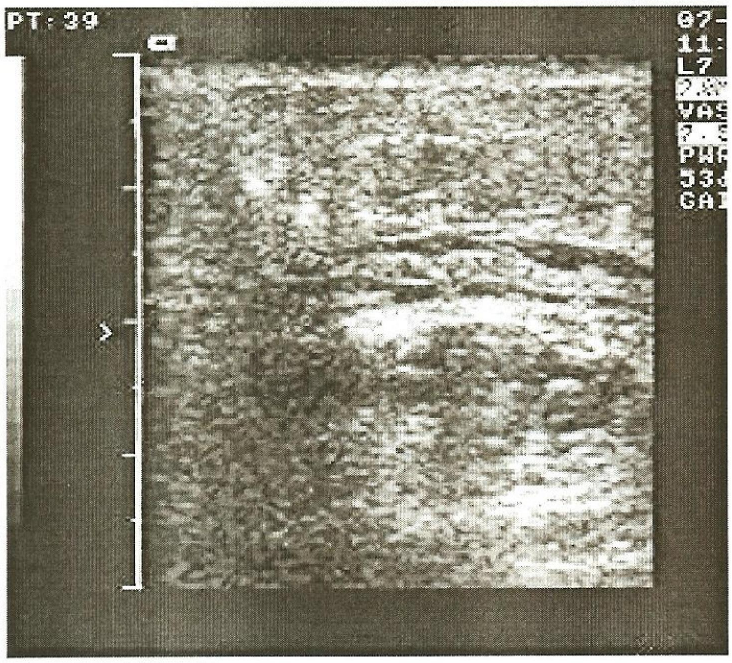

Photo 1: “Ecographic Window” of a Linfedematous limb with evident connectivization and presence of lymphatic pools.

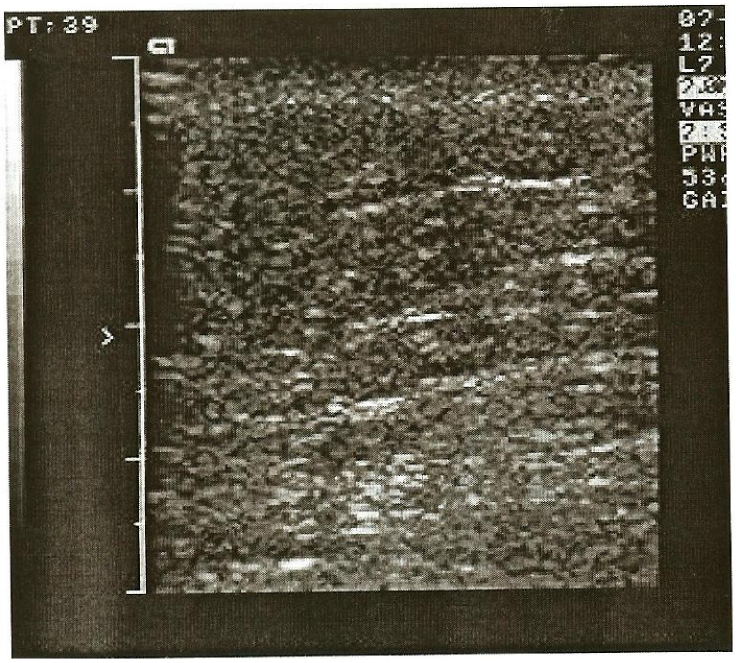

Photo 2: Same “ecographic window” of the previous patient: Evident reduction in the lymph accumulation and in connectivization.

Discussion

From the results obtained from our clinical research it is evident that, when confronted with a lymphedema, one cannot expect a clinical resolution of the disease, but only an improvement in the objective and subjective parameters. This aim was accomplished with the application of the deep oscillation method: With the HIVAMAT® 200 we achieved a statistically significant reduction in the circumference of the limbs affected. The type of clinical evaluation used, if applied rigorously, is able to confirm the result of any treatment aimed at improving lymphedemas.

We wanted to add both qualitative and quantitative ecographic evaluations by monitoring the structural aspects of the subcutis. As a result, the ecographic studies have also confirmed that the application of deep oscillation significantly reduces the thickness of the subcutis of the limbs.

Studies that utilize the deep oscillation method on lymphedemas of the limb are not described in the scientific literature. Our experience demonstrated that this treatment can positively influence the evolution of the lymphedematous limb.

Conclusions

Lymphedema represents a chronic, irreversible and debilitation condition with an inevitable progression. Instrumental tests are useful to confirm the diagnosis, determine residual lymphatic function, select and evaluate therapeutic methods. The goal of the treatment is to remove stagnating lymph in order to avoid the onset of subcutaneous fibrosis, prevent complications as lymphangitis, severe functional impairment, cosmetic embarrassment and amputation of the limb, and finally improve patient's quality of life. The non-invasive, conservative therapy represents the principal approach for lymphedema. Surgical procedures as lymphovenous anastomosis, are reserved for specific conditions and they are rarely indicated as primary therapeutic option.

The Complex Decongestive Physiotherapy (CDP) of lymphedema is commonly utilized as primary treatment and is based on hygienic measures, skin cures, manual lymph drainage (MLD), compressive bandage application and decongestive exercises.

HIVAMAT® 200 is a new instrumental physiotherapeutic method characterized by the utilization of intermittent electrostatic fields with deep oscillation stimulating the transportation of interstitial liquids and their components and permitting fibre and tissue layers to reacquire motricity and malleability. All these effects are achieved with a minimal external pressure.

In our experience, 2 or 3 week cycles of CDP constitute the optimum treatment for lymphedema of the limbs. Thus, in association with the deep oscillation method, able to stimulate transportation of interstitial fluids and their components, we can ensure an improvement of the quality of treatment, a reduction in treatment times with positive effects on the costs of patient management and an improvement of patient's quality of life. Furthermore, thanks to the possibility of self-treatment, it is possible to offer therapeutic continuity in the comfort of a patient's home.

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Table I

Measurement of the circumferences of the limb

SEGMENT	Mean average before treatment (cm)	Average post treatment (cm)	Range before treatment (cm)	Range post treatment (cm)
Lower 1/3 leg	25,9	24,9	22,0 – 32,0	21,0 – 34,0
Upper 1/3 leg	39,3	38,4	36,0 – 45,0	35,0 – 44,0
Upper 1/3 thigh	63,6	62,0	57,0 – 75,0	55,5 – 73,5

Table II

Measurement of the subcutaneous thickness

SEGMENT	Mean average before treatment (cm)	Average post treatment (cm)	Range before treatment (cm)	Range post treatment (cm)
Lower 1/3 leg	4,12	3,97	3,50 – 5,09	21,0 – 34,0
Upper 1/3 leg	6,26	6,14	5,73 – 7,16	5,57 – 7,00
Upper 1/3 thigh	9,86	9,67	8,83 – 11,7	7,95 – 11,3