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Electrical muscle stimulation with Veinoplus® device in the treatment of venous ulcers

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Aim. The aim of the study was to analyze the results of the electrical muscle stimulation (EMS) usage in patients with venous ulcers developed on top of a post-thrombotic syndrome (PTS).

Methods. Sixty patients (60 legs) with active venous ulcer (C6EsAsdpPr according to CEAP classification) were divided into two groups. In addition to the background therapy consisting of a standardized compression with ULCER X and intake of micronized purified flavonoid fraction (MPFF 1000 mg daily), all the patients in the main group underwent EMS with Veinoplus® V.I. for at least 3 times a day. Follow-up examinations were performed on days 30, 60 and 90. These included pain severity assessment with 100-mm Visual Analogue Scale (VAS), disease severity measurement with VCSS (Venous Clinical Severity Score) and ankle circumference above malleolus, as well as recording number of healed venous ulcers.

Results. At day 90 pain severity was reduced in both main and control groups. However, according to VAS pain reduction rates were significantly higher in patients of the main group (from 8.7 ± 0.6 to 1.9 ± 0.3 in the main group and 8.4 ± 0.6 to 3.9 ± 0.5 in the control group). At the end of the study, ankle circumference decreased from 270.9 ± 4.6 mm to 257.1 ± 4.2 mm in the main and from 269.7 ± 5.3 mm to 263.4 ± 5.2 mm in the control group. VCSS before treatment was 7.3 ± 0.6 in the main group and 6.8 ± 0.5 in the control group. By day 90 VCSS significantly decreased to 2.3 ± 0.4 and 4.6 ± 0.5 in the main and control groups respectively. Healing rates were significantly higher in the main group. On day 90, the number of open venous ulcers in the main group was 3 times lower than in the control group (4 vs. 12).

Conclusion. EMS demonstrated high efficacy and good tolerability and provided significant reduction in pain severity, VCSS score and ankle edema, as well as a 3-fold increase in the number of healed venous ulcers.

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Key words: Muscles - Varicose ulcer.

therapy, almost completely solved the problem of venous leg ulcers generated by superficial venous insufficiency. As for the post-thrombotic syndrome (PTS), an active surgical approach is usually ineffective because of hemodynamic characteristics and microcirculatory disturbances in this pathology. Compression therapy, aimed at improving calf muscle pump and to reduce dynamic venous hypertension, plays a central role in the treatment and prevention of venous ulcers associated with PTS, and it is usually accompanied by additional treatments, such as various wound dressings and certain venoactive drugs.¹⁻⁵

A new method aimed at enhancing venous outflow and based on electrical stimulation of the calf muscles has attracted considerable interest in recent years. Electrical muscle stimulation (EMS) has already demonstrated its efficacy in increasing linear and volumetric venous blood flow rates and alleviating vein-specific symptoms and chronic venous edema, as well as preventing deep venous thrombosis development and PTS.⁶⁻¹⁴ EMS was introduced in the new European and international guidelines as one of the treatments for chronic venous insufficiency (CVI) of CEAP class C3 (chronic venous edema).¹¹ In this report, we analyze the results of EMS usage in patients with venous ulcers developed on top of PTS.

Materials and methods

The study included 60 patients (60 lower extremities) (11 males and 19 females from 30 to 85 years old with mean age 63.8 ± 11.6 years) with

TABLE I.—Baseline characteristics of participating patients, according to the extended CEAP classification.

CEAP	N. of patients
C6EsAsdpPr 2,3,13,14,15,18	17
C6EsAdpPr 11,13,14,15,18	13
C6EsAdpPr 14,15,18	11
C6EsAsdpPr 3,5,11,13,14,15,18	10
C6EsAsdpPr 2,3,4,7,8,11,18	9
Total	60

CVI of CEAP class C6EsAsdpPr (PTS with active venous ulceration and complete recanalization of deep vein thrombosis) (Table I). Only patients with the presence of an open venous ulcer with an area of 5 to 10 cm², pain severity score of 5 or more by a 100-mm Visual Analogue Scale (VAS), Ankle-Brachial Index (ABI) not less than 0.8, Body Mass Index (BMI) under 30 kg/cm², and with no disorders and diabetes mellitus (blood glucose <6.0 mmol/L) were included in the study. Additionally, patients taking NSAIDs, hormones, calcium channel blockers and other drugs that can influence the lower extremity edema or reparative processes were not included.

As shown in Table II, the patients in the main and control groups did not differ significantly by any parameters that could affect the treatment's results.

The examination of the venous system of the lower extremities was performed with Logiq® Book XP and Vivid® q (GE Healthcare, Wauwatosa, WI, USA) devices. PTS's presence criteria were: thickening of the vein wall, avalvulation and reflux (over 0.5 seconds of duration) in the femoral, popliteal or posterior tibial veins in response to respiratory or manual compression tests in the standing and supine position of the patient.

All patients underwent standard regimens of compression, topical and pharmacological treatment. For compression therapy, the ULCER X kit (Sigvaris, Winterthur, Switzerland), designed to help healing venous ulcers, was used. Before putting on compression stockings, the surface of venous ulcer was covered with Hydrosorb® Comfort interactive hydrogel wound dressing (Paul Hartmann AG, Heidenheim, Germany). The micronized purified flavonoid fraction ([MPFF]; Detralex®, Laboratoires Servier, Suresnes, France) was administered at a daily dose of 1000 mg to all the patients as a systemic pharmacotherapy.

Patients were assigned either to the main group or to the control group using a random number generator. Patients from the main group received Veinoplus® V.I. devices for electrical muscle stimulation (Ad Rem Technology, Paris, France) with a set of replaceable electrodes. The EMS procedure required to be performed daily for at least 3 times a day. The protocol allowed application of the EMS up to 3 times a day, depending on the patient's feasibility. It was recommended to perform EMS under the following protocol: in sitting or supine position, the patient placed electrodes on the skin of posterior side of the affected ankle in the projection of the calf muscles, put on the lining and then the main compression stocking (Figure 1). After turning on the Veinoplus® device, the patient could choose the pulse intensity (from 1 to 50 V) to get clearly perceivable and visible contractions of the calf muscles without any pain or discomfort. If muscle contraction amplitude decreased due to habituation to the EMS procedures, the patient could increase the intensity of the impulses at his/her own discre-

TABLE II.—Comparative characteristics of patients in the main and control groups.

	All patients (N.=60)	Main group (N.=30)	Control group (N.=30)	P value
Gender, N. (male/female)	23/37	11/19	12/18	0.9
Age, years	63.8±11.6	67.1±12.2	60.6±10.3	0.1
BMI, kg/m ²	26.1±2.6	26.1±2.5	25.9±2.6	0.9
Duration of PTS, years	15.2±3.4	16.0±2.9	14.5±3.8	0.2
Duration of venous ulcer, months	9.8±2.3	9.7±2.4	9.9±2.3	0.8
Baseline area of venous ulcer, cm ²	7.7±1.3	7.9±1.4	7.5±1.2	0.4
Duration of daily static loads, hours	9.1±2.1	9.5±2.1	8.7±2.1	0.3
Baseline VCSS score	7.1±1.3	7.3±1.3	6.8±1.3	0.3
Confirmed relapse of DVT, N./%	13/43.3%	7/46.7%	6/40%	0.6
Continuous intake of vitamin K antagonists, N./%	11/36.7%	6/40%	5/33.3%	0.7
Regular compression therapy, N./%	17/56.7%	8/53.3%	9/60%	0.5

tion. The duration of EMS procedure was standard (30 minutes), and upon expiration of this time the built-in timer automatically turn off Veinoplus® V.I.

The contraindications for EMS were as follows: cardiac arrhythmias, metal implants in the lower extremities, pregnancy, history of severe traumatic brain injury, epilepsy and convulsive disorders. All patients provided written informed consent to participate in the study and received a diary in which they noted the time and number of performed EMS procedures.

All the methods used during the treatment are allowed in the Russian Federation and are officially registered for described indication, thus the approval of the local Ethics Committee was not required.

The treatment results were assessed on days 30, 60 and 90 using the following efficacy criteria: pain severity on a 100-mm VAS; circumference of the narrowest segment of the tibia (above the malleolus), measured using the Leg-O-Meter; Venous Clinical Severity Score (VCSS), and number of open ulcers.

Statistical analysis

Statistical data processing was performed with licensed statistical software package SPSS

Statistics 17.0 (Mann-Whitney test and Wilcoxon test for independent and dependent samples; Pearson's χ^2 test for qualitative variables).

Results

All patients participating in the study completed the treatment in accordance to the protocol. In the main group, the impulses of 30-50 V (average 42.5 ± 1.3 V) were required for effective EMS. No refusals from EMS due to the adverse side reactions were recorded, despite the fact that 11 patients performed EMS 3 times a day and 19 patients performed it 4-6 times a day.

At baseline, the pain severity was 8.7 ± 0.6 and 8.4 ± 0.6 scores in the main and control groups respectively. At the follow-up examinations on days 30, 60 and 90, a significant reduction in pain severity was observed in both the main group and the control group. However, the rates of pain reduction were significantly higher in patients of the main group (Figure 1).

Prior to the treatment, the ankle circumference measured at the narrowest part (above the malleolus) was 270.9 ± 4.6 mm and 269.7 ± 5.3 mm in the main and in the control group, respectively. During the follow-up, a significant progressive reduction in ankle circumference was observed

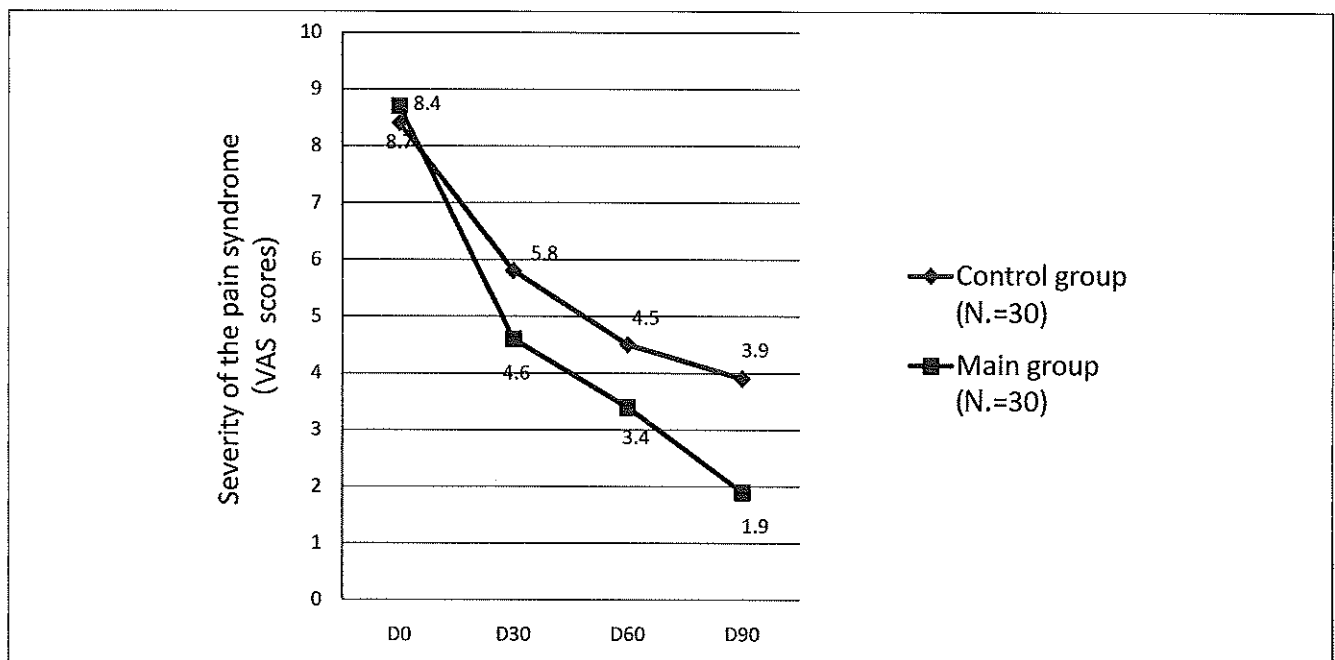


Figure 1.—Pain severity changes in the main and control groups from day 0 to day 90.

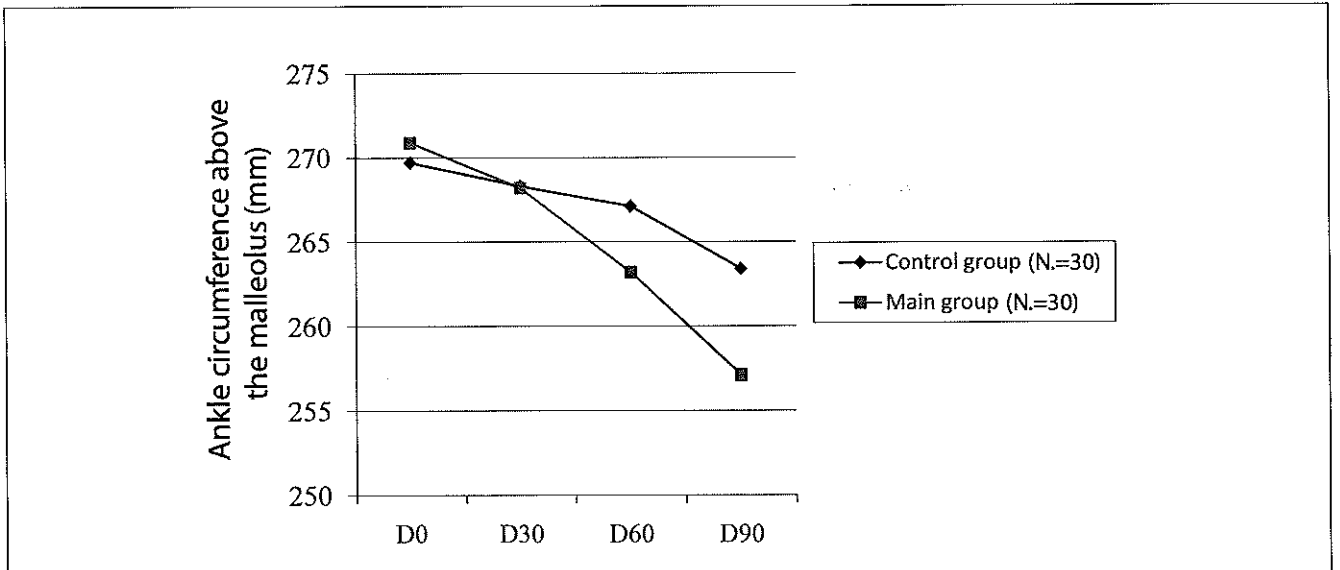


Figure 2.—Changes in ankle circumference from day 0 to day 90.

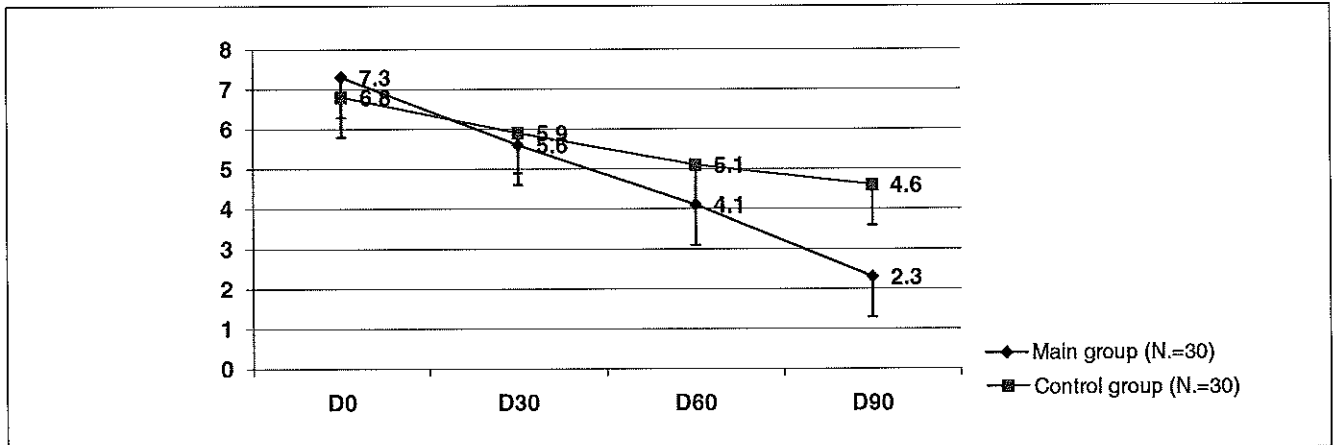


Figure 3.—Changes in VCSS from day 0 to day 90.

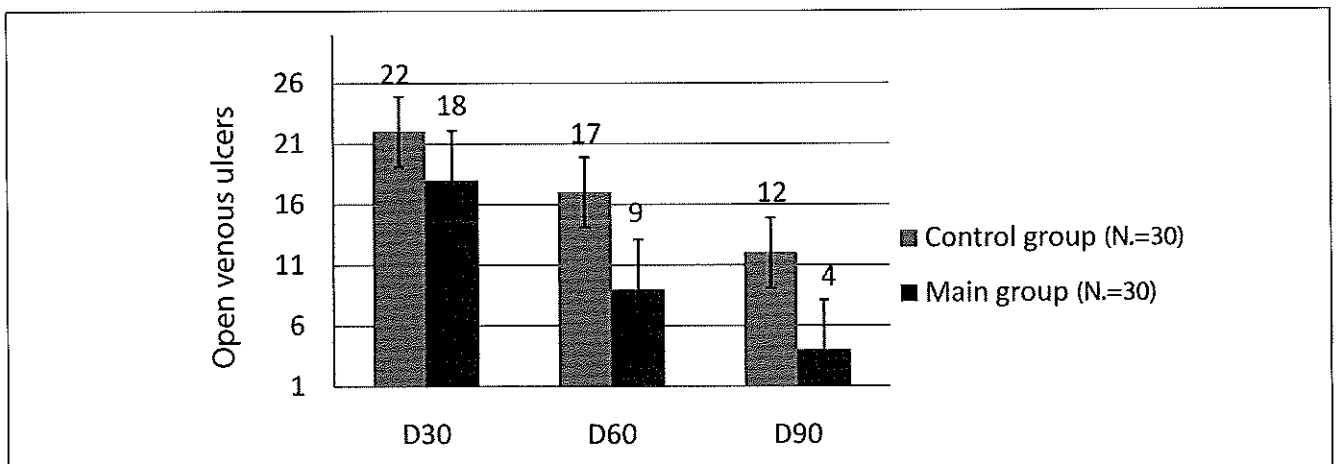


Figure 4.—The changes in the number of open venous ulcers from day 0 to day 90.

in both groups, but it was faster in those patients who underwent EMS (Figure 2).

A marked positive trend was observed in the VCSS, with significant differences *versus* baseline values in both the main and the control group (Figure 3). On days 30 and 60 the differences between the groups were significant ($P < 0.0001$), in favor of those patients who underwent the EMS treatment.

On the day 90, the number of open venous ulcers in the main group was 3 times lower than in the control group (4 *vs.* 12). For changes in the healing of venous leg ulcers in both groups, see Figure 4.

These findings suggest that EMS combined with compression and pharmacological therapy significantly reduces pain severity and chronic venous edema, and increases the rate of healing of venous ulcers associated with the PTS.

EMS's efficacy in the combination treatment of venous ulcers is well illustrated by the following clinical case.

Patient Sh., woman, 83 years old. She underwent total knee replacement of the right knee joint 12 years ago, complicated by thrombosis of the iliac, femoral, popliteal and tibial veins in the postoperative period, which was confirmed by ultrasound examination and CT. After a standard course of anticoagulant therapy, Sh. was administered warfarin and RAL standard class 2 compression stockings. In 3 years, the follow-up ultrasound examination revealed complete recanalization of deep vein thrombosis, and warfarin was discontinued. The regimen of compression therapy remained the same. Five years ago, the patient noticed a gradual increase in the ankle edema, induration and darkening of the skin above the medial malleolus. As the treating physician advised her, she took occasionally aspirin and various venoactive

drugs and used the ointments and gels. Thirteen months ago, after a home injury an ulcer appeared in the area of medial malleolus, and it rapidly increased in size. The skin around the ulcer became inflamed, and severe pain syndrome developed that worsened in the evening and was associated with sleep disturbances. To relief the pain, the patient had to take regularly NSAIDs, which led to the development and agranulocytosis, and, therefore, were discontinued. At examination of the medial malleolus, the venous ulcer of 10 cm² was identified. Ultrasonography revealed complete recanalization of the deep veins with continuous reflux in all deep venous segments. The pain syndrome was rated at 10 points by the VAS, and the ankle circumference above the malleolus was 265 mm. The patient was randomly assigned to the main group, and the usage of ULCER X kit and EMS procedures at least 3 times a day were recommended. At the follow-up examination on day 30, the patient reported pain reduction to 5 points and normal sleep restoration. After 90 days of treatment, the venous ulcer was completely closed, the signs of indurative cellulite decreased, and pain syndrome intensity was rated as 0 points. To maintain the achieved result, the wearing of class 3 compression stockings (RAL standard) was advised to the patient.

Discussion

EMS is a relatively new method of treatment for CVI. Previous studies show great efficiency of EMS for patients with symptoms of CVI and chronic venous edema. However, the exact mechanism behind that medical effect is not completely clear and requires further studies. It could be said that there are several mechanisms supporting each other. Among them, the direct activation of the calf muscle pump that enhance veins blood flow and drainage, the decrease of retrograde flow volume due to forced rhythm of muscular contractions, and influence upon microcirculation bed that reduces blood pres-



Figure 5.—Lower limb with active ulcer before treatment.



Figure 6.—Lower limb 90 days after treatment.

sure in its venous part. In the current study, the mechanisms of EMS are not discussed. Instead, this study shows significant positive effects of this treatment, such as the decrease of clinical symptoms and the healing of venous ulcers. This also means that EMS enhances microcirculation and tissue metabolism. Obviously, further studies are required for a better understanding of the medical mechanism of EMS and to develop optimal parameters for patients with different clinical classes of CVI.

Conclusions

EMS, thanks to an additional activation of the calf muscle pump in the setting of adequate compression therapy combined with pharmacological support, substantially reduces complaints and accelerates the healing of venous ulcers caused by the PTS. The ease of use, safety, availability and efficacy of EMS facilitate its widespread use in outpatients with severe forms of the CVI. Further studies are needed to determine the optimal regimens and clarify indications for the use of EMS in various forms and stages of chronic venous disease.

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