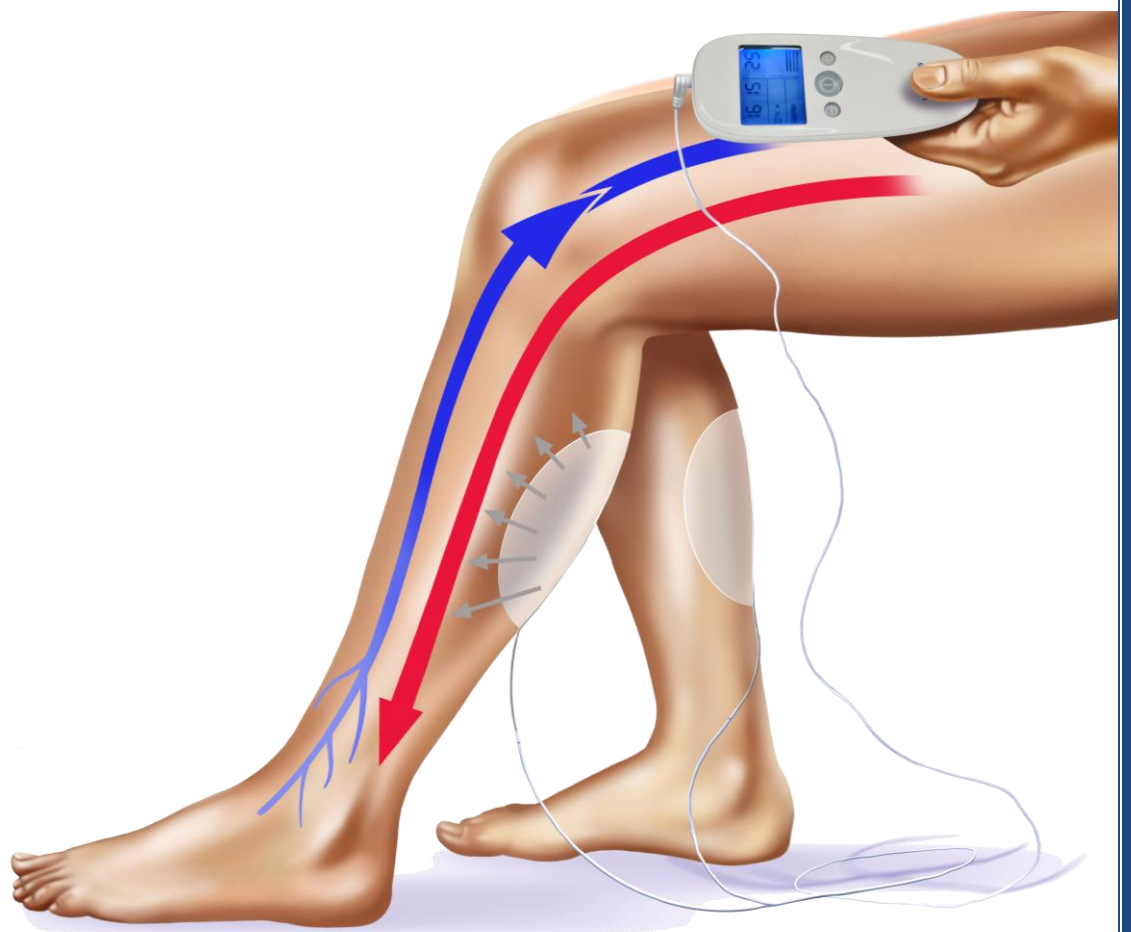


BOOK OF ABSTRACTS



VEINPLUS®

The Second Heart® Technology



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VENOUS STUDIES

ELECTRO- MUSCULAR STIMULATION WITH VEINOPLUS® FOR THE TREATMENT OF CHRONIC VENOUS EDEMA

Also presented at:

European chapter of the International Union of Angiology, Paris 2010

Russian Association of Phlebology, Moscow 2010

Mediterranean Congress of Venous Pathology, Nice 2010

DGP, Berlin 2010

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Objective: Electro-stimulation with VEINOPLUS® has recently emerged as a new technique to activate the calf muscle pump and improve symptoms of venous disease. The aim of this study was to determine in patients suffering from chronic edema of venous origin the efficacy of VEINOPLUS® treatment in terms of reduction of evening edema, diminution of pain, improvement of quality of life and also evaluate the durability of the treatment and its impact on venous hemodynamics.

Patients and methods: 30 patients (32 legs) aged 19-50 (mean 45.2 ±1.3) classified CEAP C3 with chronic evening venous edema were recruited (22 limbs: C3Sep and 10 limbs: C3EsPr). All patients were treated with CE-registered VEINOPLUS® neuromuscular stimulator during 30 days: 3 sessions per day (each session being 20 minutes) during 10 days, then 2 sessions per day during 10 days and one per day during the last 10 days. Main criteria was the circumference of the supramalleolar shin segment, measured with a tape in the evening, before treatment, daily and as control 5 days after treatment. As secondary criteria, patients were assessed on day 0 and 35 regarding pain on the Visual Analog Scale, Quality Of Life (QOL) according to CIVIQ questionnaire and venous Refilling Time (RT) measured by Photoplethysmography. Three months after the treatment, evaluation of symptoms was made again. No other means of treatment or prophylaxis were used.

Results: VEINOPLUS® treatment was well tolerated by patients. There was not drop out and patients did not change their lifestyle. After treatment, a total or partial reduction of evening edema was shown in 93.8% of limbs, the circumference of the supramalleolar shin diminished by 20,3mm (p<0.001), the number of painful legs reduced from 28 to 12 and the severity score was cut from 8.3 ±1.1 to 3.8 points ±0.9 (p<0.001), QOL was improved significantly as the score dropped from 34.5 ±7.8 to 17.2 points ±4.6 (p<0.001) and RT increased from 17.3 ±0.9 to 21.5 seconds ±1.1 (p<0.001).

Three months after VEINOPLUS® treatment a total remission of symptoms was observed in 50% of legs, despite absence of other treatment.

Discussion and conclusion:

VEINOPLUS® stimulation is an effective and well-tolerated therapeutic method for the treatment of chronic venous disease when it comes to treatment of chronic edema, for reducing pain and improving quality of life. VEINOPLUS® can be used as additional means in the treatment and the prevention of symptoms of chronic venous insufficiency. This study also reveals that stimulation of calf muscles with VEINOPLUS® can improve venous hemodynamics leading to a remission of symptoms. This finding should be investigated and confirmed in further studies.

EFFICACY AND OPTIMAL USE OF A PORTABLE ELECTRICAL MUSCLE STIMULATOR (VEINOPLUS) TO IMPROVE SYMPTOMS OF POST-THROMBOTIC SYNDROME

Poster Presented At: Scientific Symposium Of The Hemophilia & Thrombosis Research Society And North American Specialized Coagulation Laboratory Association Northwestern Memorial Hospital, Chicago 2010

Catherine Soriano, Stephan Moll, Allison Deal
University of North Carolina School of Medicine



Efficacy and Optimal Use of a Portable Electrical Muscle Stimulator (Veinoplus®) to Improve Symptoms of Postthrombotic Syndrome

Catherine Soriano, Stephan Moll, Allison Deal
University of North Carolina School of Medicine

Introduction

An estimated 330,000 people in the United States have postthrombotic syndrome (PTS)¹. Few studies have addressed the treatment of PTS². A 2003 Cochrane Review examined available data regarding treatment of PTS with compression stockings or mechanical devices (intermittent pneumatic compression units)³. The authors report that there may be some benefit to the mechanical device at higher pressures in treating PTS though the trial was too small and of too short a duration to draw strong conclusions. In regards to the ECS, the authors do not support, on basis of available evidence, treatment of PTS with ECS. Recently, a portable mechanical device has been shown to have a beneficial effect on the symptoms of PTS⁴. However, with only 32 patients enrolled, all of them with severe postthrombotic syndrome, and follow-up on treatment only having been 2 months, the study has been interpreted as too small, too short and too patient-selective to warrant advocating large-scale introduction of this device⁴. With few validated treatment options for PTS, further research and investigation is warranted given its significant morbidity.

Objectives

1. Estimate the clinical success⁵ of the device, defined by moderate improvement of symptoms, and an interest to continue using the device.
2. Estimate improvement in quality of life and objective findings of postthrombotic syndrome (Villalta scale).
3. Estimate the optimal electrical stimulation intensity that has the largest benefit for relief of symptoms.
4. Compute information needed to power a future study.

Design & Methods

Patient Data Collection
Twelve subjects with postthrombotic syndrome were given a Veinoplus device to use for 2 months as they saw fit and record their experience.

Measurements

Villalta scale: grades severity, from 0 to 3, of each of five symptoms (pain, cramps, heaviness, pruritus, paraesthesia) and six signs (edema, skin induration, hyperpigmentation, venous ectasia, redness, pain during calf compression)
VEINUS-QOL/Sym questionnaire: specific for patients with deep vein thrombosis

Design & Methods

Statistical Analysis
Severity of condition was measured by the Villalta scale, where increased scores indicate increased severity. The questionnaire produced two summary scores based on venous symptoms and quality of life. The Wilcoxon Rank Sum test was used to compare intensity levels.

Device

The Veinoplus device electrically stimulates leg muscles via motor nerves, causing calf muscle contractions which facilitates venous blood return from the legs. The small battery operated device uses two electrode pads that deliver low quantities of electrical energy for 20 minutes per treatment, with a user input variable intensity.



Results

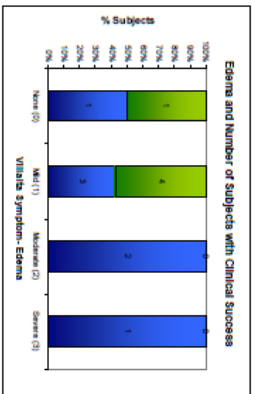
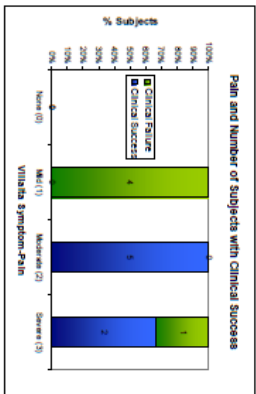
After using the device for eight weeks, **7 out of 12 patients (58%) had clinical success**. Eighty-three percent (10) of subjects increased their QOL score, while 75% (9) increased their symptom specific score. The Villalta score improved in 67% of subjects, with a median decrease of two points.

SUBJECT ID	Villalta Score		VEINUS-QOL		Change
	Before	After	Before	After	
1	no	9	50.25	57.05	6.74
2	no	7	57.45	67.19	9.74
3	yes	22	45.75	50.23	4.47
4	no	14	49.66	62.01	12.35
5	no	9	51.42	42.5	-8.92
6	yes	14	54.1	42.13	-11.97
7	yes	14	31.11	32.74	1.63
8	yes	10	49.25	54.87	5.61
9	yes	17	36.86	47.78	10.92
10	no	15	42.49	45.21	2.72
11	yes	6	47.25	71.37	24.01
12	yes	12	8	47.31	63.9
Median		12.50	11.17	44.92	53.08
					6.16

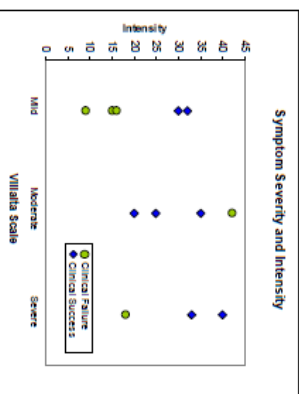
Results

At the end of the study period 4 (33%) subjects had a decreased calf circumference. Optimal intensity was found to be a range, with most of the subjects who had clinical success using an average intensity of 20-40.

Of the five symptoms that make up the baseline Villalta score, only pain appeared to have a significant association with clinical success; all 5 subjects who reported moderate pain had a clinical success, along with 2 of the 3 patients who reported a severe pain level (p=0.02). All 3 subjects with moderate or severe edema had clinical success, along with 5 of 7 subjects with moderate to severe cramps. No significant associations with clinical success were found for other potential predictors of success (symptom severity, body mass index, and calf circumference). However, for all subjects symptom severity was found to be correlated with intensity (rho=0.5, p=0.095) and calf circumference at baseline was strongly correlated with intensity (rho=0.7, p=0.07).



Results



Conclusion

The Veinoplus® electrical stimulation device appears to improve symptoms and QOL for patients with PTS. Although this study did not yield statistically significant results, given its small sample size, it provides the rationale and details needed for a larger trial. These initial findings are of clinical significance, as there are few treatments for patients with PTS. Veinoplus® is easy to use, small and portable, and had minimal disruptions in everyday life for most subjects. Elastic compression stockings and compression pumps could still be used in addition to using the Veinoplus®.

Future Directions

With the completion of this pilot study, we will be starting a phase 3 trial of the Veinoplus® device. This study will have a sample size of 60 subjects. It will be a randomized, placebo controlled, and double-blinded trial. For more information, or if you are interested in becoming a study site, please contact smoll@med.unc.edu.

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EFFECTS OF ELECTROSTIMULATION (VEINOPLUS) ON LOWER LIMBS VENOUS INSUFFICIENCY-RELATED SYMPTOMS DURING PREGNANCY. PRELIMINARY STUDY

Also presented at the European Venous Forum, Istanbul 2006

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Objective: To assess if electrostimulation of lower limbs relieves lower limbs venous insufficiency-related symptoms during pregnancy.

Patients and methods: A two-step study was conducted. First, a monocentric prospective preliminary study including 30 pregnant women was conducted to assess the effects of electrostimulation on foetal monitoring and uterine contractions. Then, a multicentric prospective non-randomised study including 58 pregnant women with a gestational age between 23 and 33 weeks of amenorrhoea was conducted to evaluate the electrostimulation treatment. This evaluation was based on a clinical examination performed pre- and post-treatment, a CIVIQ questionnaire filled out pre- and post-treatment and a daily diary filled out by the patient during treatment duration. Treatment duration was 21 days including two daily treatment sequences of 20 min. Three groups of patients were identified based on initial intensity of venous insufficiency-related symptoms (Group 1 minor symptoms, Group 2 moderate symptoms, Group 3 severe symptoms).

Results: Preliminary study showed no interference between electrostimulation and foetal cardiac rhythm, uterine contractions and maternal uterine and foetal umbilical arteries. Concerning the evaluation of the electro-stimulation: in Group 1, electro-stimulation significantly reduced heavy legs sensation ($p < 0,001$) and calves pain ($p = 0,02$) between the beginning and the end of the treatment. The four scores calculated with the CIVIQ questionnaire decreased after treatment and a significant reduction was noted for generalised pain feeling ($p = 0,04$) and psychological impact ($p = 0,03$). In group 2, a significant decrease was noted for tiredness ($p < 0,001$), heavy legs sensation ($p < 0,001$), calves pain ($p < 0,001$) and edema ($p = 0,02$) between the beginning and the end of the treatment. The four scores calculated with the CIVIQ questionnaires significantly decrease after 21 days of treatment. In group 3, a significant decrease of heavy legs sensation ($p = 0,03$) and calves and malleoli perimeters ($p < 0,05$) was noted. After 21 days of treatment, the four scores calculated with the CIVIQ questionnaire significantly decrease ($p < 0,05$). When comparing the three groups, beneficial effects of the treatment are most marked in group 2 regarding subjective symptoms, CIVIQ questionnaire scores and leg pain. According to the patients, effectiveness and tolerance of the treatment ranged from good to excellent in the three groups.

Discussion and conclusion:

Electrostimulation is an effective and well-tolerated treatment of lower limbs venous insufficiency-related symptoms in pregnant women. Its use during pregnancy did not show any effects on foetus and pregnancy.

USERS OF VEINOPLUS: AD REM TECHNOLOGY SURVEY ON SYMPTOMS, BEHAVIOUR AND SATISFACTION (2009)

Objectives

The “VEINOPLUS® Users” study was conducted only among individual French clients in order to find out their symptoms and their behaviour. The results presented here cover the 4 principal questions of the study, namely:

1. What is the user profile (age, gender, activity...)?
2. For what condition(s) and symptom(s) do they use VEINOPLUS®?
3. What is the behaviour of the users with regard to VEINOPLUS®?
4. What is their degree of satisfaction?

Methodology

The selected clientele gathers customers using VEINOPLUS® for more than 6 months and having repurchased electrodes from the company (whether or not the device had been purchased from the company). A questionnaire of 31 open and closed questions was submitted by telephone survey over a period of 8 weeks, in the 4th Quarter 2009. 100 individuals responded to the questionnaire, which is 32% of people called.

Results

Over 3/4 of the VEINOPLUS® users questioned (78%) were working or of working age. The average age of the users was 52 for women (25-84) and 50 for men (31-90).

The vast majority of regular users of VEINOPLUS® suffer from heavy legs feelings and/or painful legs (fig 1), very often associated with other symptoms. Lower limb edema affected around 50% of the people questioned and came in 2nd place among the symptoms cited.

It should also be noted that a little over 1/5 of women use VEINOPLUS® according to the seasons, particularly during hot periods. Over 50% of women combine VEINOPLUS® with compression. The device acts very effectively on heavy and/or painful legs (fig 2).

The level of satisfaction of users is also very significant concerning the effect of VEINOPLUS® on oedema, and particularly the reduction of its volume. The vast majority of users confirm an instant effect upon use of VEINOPLUS®, particularly among women. In total, around 88% of VEINOPLUS® users consider VEINOPLUS® to be indispensable and/or useful. These figures therefore indicate a high level of satisfaction.

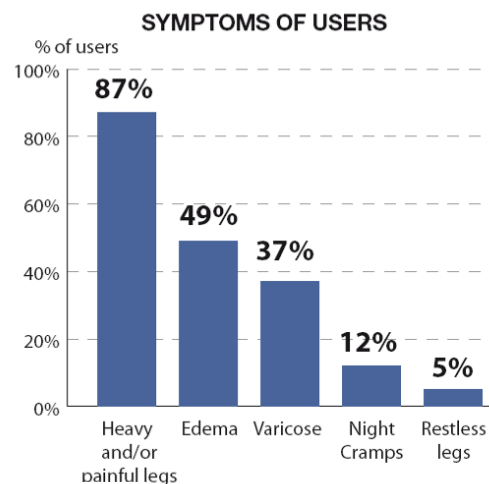


Fig. 1

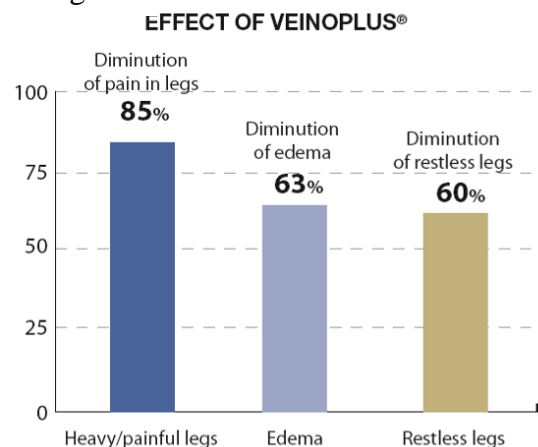


Fig. 2

Developed in collaboration with Dr. F. Becker (Geneva University Hospital) and Dr. P. Blanchemaison (Professor at University of Medicine, Paris).

ELECTRIC PULSE MUSCLE STIMULATION IN TREATMENT OF LOW PHYSICAL ACTIVITY PATIENTS WITH VENOUS STASIS ULCERS

Presented at European Wound Management Association Conference, Vienna 2012

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Aim: To assess effectiveness of joint use of long-term compression bandages (LTCB) and indirect electric pulse muscle stimulation (EPMS) in the context of conservative treatment of low physical activity patients with venous stasis ulcers (VSU) in the lower leg region.

Methods: A total of 17 low physical activity patients with VSU (C6, CEAP) with the following underlying somatic pathology: obesity, cerebrovascular accident after-effects, distorting osteoarthroses. Patients' average age was 74,7+13,6 years. Males amounted to 35,3%, females – 64,7%. In the course of the study we employed a combination of EPMS and LTCB approaches (primary zinc oxide saturated bandage and auxiliary 100% cotton bandage with 90% stretching property*). LTCB were applied for up to 7 days.

Prior to forming the bandage the skin at the back of lower leg was covered with self-attaching electrode with its terminal positioned outside the bandage. Having been briefed the patients used EPMS 3-10 times a day at their own discretion. Treatment efficiency was evaluated for four weeks.

Results: Hypostatic venous edemae of lower extremities were cut short within 3-10 days. In 23,5% of cases a full epithelialization of ulcerations was attained at the end of fourth week, in 47,1% of cases the area of ulcer size diminished in size by half and in 29,4% of cases the ulcers showed initial epithelialization stage.

Conclusion: Combination of EPMS and LTCB are effective method of VSU improvement of healing for low physical activity patients.

Portability, safety and ease of use of the technology, as well as the rate of exchange of LTCB (once a week), make this method applicable for at-home-treatment.

* Veinoplus®, made in France, Varolast®, Putterbinde®, made in Germany

CHRONIC (50 YEARS) VENOUS ULCER HEALING BY ELECTROSTIMULATION

Also presented at: American Venous Forum, San Diego 2007

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Patient M.G. born in 1935, in January 1953 was diagnosed with thrombosis of deep veins in the right leg. Bedridden for two months and treated with heparine and anti-vitamine K, developed thrombosis also in the left leg and multiple hematomas. Released from hospital in March 1953, readmitted in August 1953 with an ulcer of 8 cm in length, above right ankle. Treated with topical application of placenta and IV Novocaine + antibiotic.. July 1954 after 1 year of in-hospital treatments was released for at-home care with non-healing bilateral ulcers. Readmitted to hospital at the end of 1954 received bilateral skin grafts. From 1957 till 2002, the ulcers alternatively reopened or partially healed. In May 2002 was admitted to Hospital St. Michel with post-thrombotic syndrome with bilateral nonhealed venous ulcers. Presented no problem with ambulation. The ulcers were located on interior sides of ankles with open cryptogenic aspect and atonic separating borders. Treated with multilayer contention + detergent the ulcer on the left leg closed, but on the right leg remained open in spite of antibiotic therapy and enzymatic cleaning of the ulcer opening. Since November 2004 M.G was treated at home with the VeinOplus stimulator for 20 min. daily. After 3 months the open right ulcer has diminished

significantly (photo 1).After 6 months from the start of stimulation, the ulcer almost completely healed as shown on the Photo 2. Until May 2006 while continuing daily stimulations, no reoccurrence of active ulcers was observed. In May 2006 M.G. stopped the stimulation for personal reasons. In June 2006, the examining phlebologist observed reactivation and reopening of the ulcer. After one month, while reestablishing daily stimulations (20 minutes) with VeinOplus, the ulcer healed completely again. In conclusion, the results of healing venous ulcers are encouraging and are warranting to enter into controlled clinical studies on this subject.

Photo 1: 3 months after start of VeinOplus



Photo 2: 6 months after start of VeinOplus



ACTIVATION OF THE CALF MUSCLE PUMP ACTION BY ELECTRO-STIMULATION WITH VEINOPLUS DEVICE

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Purpose of the study

To study the effect of the electro-stimulation with the VeinoPlus[®] device on the physiopathology and quality of life patients suffering from distal venous stasis and also from insufficiency of saphenous veins.

Material and methods

The study carried out was of non-randomized experimental type. The inclusion criteria for patients were to have pains of venous origin and venous insufficiency classified as C0S or C1S or C2S according to classification CEAP and saphenous incompetence. A duplex Doppler Ultrasound scan was performed at the initial examination, to evaluate the VeinoPlus[®] physiopathological effects on the reflux. Then each patient filled out a QOL CIVIQ-2 questionnaire. The patients used the VeinoPlusT[®] for 20 minutes daily during three weeks. During the last exam the questionnaire CIVIQ 2 was filled out.

Results

Physio-pathological effects were studied on 20 patients. The VeinoPlus[®] electrostimulation restored physiological venous flow and drained the calf muscles of the blood accumulated there. The effect of VeinoPlus[®] stimulation on the quality of life was studied on 40 patients and demonstrated significant improvement of the quality of life of these patients.

Conclusion

VeinoPlus[®] by the way of electro-stimulation of calf muscles is of significant interest for venous insufficiency treatment. It ensures distal venous draining and significantly improves the quality of life of patients.

ARTERIAL STUDIES

CALF MUSCLE STIMULATION WITH THE VEINOPLUS® DEVICE, RESULTS IN A SIGNIFICANT INCREASE IN LOWER LIMB INFLOW WITHOUT GENERATING LIMB ISCHEMIA OR PAIN IN PATIENTS WITH PERIPHERAL ARTERY DISEASE.

Presented at XXV World Congress of the International Union of Angiology 2012

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3 : Institut National du Sport et de Education Physique; Paris

4 : Laboratoire de physiologie, Dakar, Sénégal.

OBJECTIVE: Increase in arterial inflow to the lower limbs is important to obtain functional improvement in peripheral artery disease (PAD) patients with claudication. The aim of this study was to assess the effect of electrical stimulation of calf muscles on arterial inflow and tissue oxygen content in PAD in the area of stimulation.

METHODS: Fifteen adult patients [mean (standard deviation) age, 62 (12) years; height, 165 (8)cm; weight, 76 (13) kg; lowest ankle-brachial index 0.66 (0.19)] with stable arterial claudication were recruited. All patients performed a treadmill test (3.2 km/h, 10% slope) associated with a transcutaneous oximetry test expressed as decrease from rest of oxygen pressure (DROP) index values (calf changes minus chest changes from rest) with a maximum walking distance (median [25th/75th percentiles]) of 295 [133-881] m. The DROP index on the symptomatic side was -25 [-18/-34] mm Hg. On another day the patients underwent electrical stimulation in the seated position on the leg that was the most symptomatic on the treadmill. After resting values were recorded, the gastrocnemius was stimulated for 20minutes at increasing contraction rates at 5-minute steps of 60, 75, 86, and 100bpm on the most symptomatic side. Arterial blood inflow with duplex Doppler ultrasound scanning of the femoral artery, DROP transcutaneous oxygen pressure value, and oxygen concentration (O(2)Hb) from the near-infrared spectroscopic signal of the calf were recorded on both sides. Patients were instructed to report eventual contraction-induced pain in the stimulated calf. Results are given as mean (standard deviation) or median [25th/75th percentiles] according to distribution, and the level of statistical significance was set at $P < .05$ on two-tailed tests.

RESULTS: Lower limb inflow (mL/min) was 64 [48/86] vs 63 [57/81] ($P > .05$) before stimulation, 123 [75/156] vs 57 [44/92] ($P < .01$) at 60bpm, 127 [91/207] vs 49 [43/68] ($P < .01$) at 75bpm, 140 [84/200] vs 57 [45/71] ($P < .01$) at 86bpm, and 154 [86/185] vs 55 [46/94] ($P < .01$) at 100bpm on the stimulated vs nonstimulated limb, respectively. No apparent decrease or significant leg difference was observed in DROP index or O(2)Hb values. None of the patients reported contraction-induced pain in the leg.

CONCLUSIONS: Electrical stimulation of calf muscle with the Veinoplus device results in a significant increase of arterial inflow without measurable muscle ischemia or pain. Potential use of this device as an adjuvant treatment to improve walking capacity in PAD patients remains to be evaluated.

KEY WORDS: Transcutaneous oxygen pressure, Claudication, Arterial disease, Near infra-red spectroscopy, NIRS, Electrical muscle stimulation, EMS.

**EXTENSIVE LOWER LIMB ULCERATION CAUSED BY IATROGENIC
ARTERIOVENOUS FISTULA AND PERIPHERAL ARTERIAL DISEASE: USE OF
VEINOPLUS CALF MUSCLE STIMULATION**

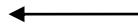
By Prof. K. Cassar,
Mater Dei Hospital, La Valette, Malta

Abstract:

We report the case of a gentleman with extensive arteriovenous ulceration of the right leg and foot secondary to an iatrogenic arteriovenous groin fistula in addition to occlusive disease at the level of the popliteal artery. The gentleman underwent an attempt at angioplasty of the popliteal artery which failed. He subsequently underwent surgical repair of the arteriovenous fistula as well as a popliteal to peroneal bypass graft using ipsilateral long saphenous vein. Postoperatively he was treated with Veinoplus electrical calf muscle stimulation twice a day for 20 days. The ulcer showed steady improvement and within 4 months had practically healed.

Case Report:

An 84 year old gentleman presented with a 6 month history of extensive ulceration of the right leg and foot (Fig 1). The ulceration in the foot affected the dorsal aspect and measured about 8cm in diameter. The ulceration in the leg was almost circumferential and extended from just above the ankle to the mid leg with large amounts of necrotic fat and slough. The foot and leg were very markedly swollen compared to the contralateral limb. He also had a fissure at the base of the 2nd and 3rd toes. There was also ulceration over the lateral malleolus and over the Achilles tendon. The patient was diabetic on insulin and oral hypoglycaemics. He also suffered from hypertension, renal impairment secondary to diabetic nephropathy, hyperlipidaemia and ischaemic heart disease. Several years previously he had undergone percutaneous coronary intervention through the right groin. Clinical examination revealed palpable femoral pulses with a palpable thrill over the right groin. The popliteal pulse was palpable above the knee but no distal pulses were present. The waveforms at the ankle on the right were monophasic continuous. Ankle brachial pressure indices were not performed in view of the extensive ulceration over the leg. An ultrasound scan revealed the presence of an arteriovenous fistula between the profunda femoris artery and the common femoral vein with high flow through it. The duplex scan also showed that there was a short popliteal artery occlusion. The gentleman was referred for right popliteal artery angioplasty through an antegrade approach. Unfortunately it proved impossible to cross the lesion. In view of this the gentleman was taken to theatre where he underwent repair of the arteriovenous fistula between the profunda femoris artery and the common femoral vein. At the same procedure he also underwent right popliteal to peroneal artery bypass grafting using ipsilateral reversed long saphenous vein. The extensive ulceration of the right leg and foot was debrided (Fig 2). Postoperatively he was treated with twice daily application of Veinoplus calf muscle electrical stimulation for 20 days. The ulcers made rapid progress and the marked swelling in the right lower limb improved dramatically. (Fig 3) He was well enough to be discharged after 20 days (Fig 4). His bypass graft continued to be scanned at 1 week, 6 weeks and 3 months post operatively. At the 3 month scan a stenosis was identified in the bypass graft and the patient underwent bypass graft angioplasty with a good technical result (Fig 6). The patient continues to be followed up with bypass graft surveillance. At 4 months post op the ulcers are practically healed and the initial swelling in the limb has improved dramatically (fig 5).



Conclusion:

We report a case of extensive ulceration of the right lower limb secondary to arterial and venous disease treated successfully with bypass surgery, repair of an arteriovenous fistula and surgical debridement of the ulcers. Veinoplus electrical calf muscle stimulation was used in the postoperative period to enhance healing and reduce swelling.



Fig 1: Extensive ulceration of the right leg and foot with necrotic fat and extensive skin loss



Fig 4: Right leg and foot 20 days after surgical intervention



Fig 3: Right leg and foot 12 days after surgical intervention



Fig 5: Right leg and foot 20 days after surgical intervention (full epithelialization)



Fig 2: Right foot and leg ulcer immediately after surgical debridement

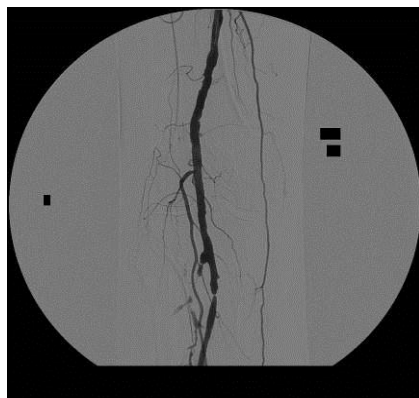


Fig 6: Right popliteal to peroneal vein bypass graft before and after angioplasty of graft stenosis

ELECTRIC PULSE CALF MUSCLE STIMULATION IN TREATMENT OF PATIENTS WITH DIABETIC FOOT SYNDROME

Presented at European Wound Management Association Conference, Vienna, 05/2012

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Aim: to determine efficiency of indirect electric pulse muscle stimulation (EPMS) in treatment of patients with diabetic foot syndrome (DFS).

Methods: A total of 24 patients with different types of DFS presented an edema of the afflicted limb that developed in the wake of inflammatory alterations. Patients' average age was 56,1 years; men/women – 6/18.

All patients had the afflicted limb immobilized, their glycemia condition was corrected, the patients were administered antibiotics, antineuropathy, anti-angiopathy and metabolism-promotional medication. At the same time in the main group (14 patients) the afflicted limb also receive EPMT*) 2-5 times a day. DFS degree as per Wagner was presented in the main (control) group as follows: II – 1 (1), III – 4 (3), IV – 8 (6), V – 1 (0). Observation period was 4 weeks.

Results: On average in the main group edema subsided on the first day by 45%, on the third day it dropped down some 40% more and on the 5th day edema were cut short completely. 12 patients (86%) did not present an edema relapse. In control group edema subsided on the first day by 10%, on the third day it reduced some 30% more and on the 5th day it decreased 20% more and later on stayed at this level.

Conclusion: The use of EPMS manifests in quick reduction of edema, positive changes in haemodynamics in afflicted areas which ultimately influences the general results of DFS treatment and reduces hospital stay.

Study report (2012)

ELECTROPULSE MUSCLE TONING BY THE VEINOPLUS DEVICE AS A PART OF COMBINATION TREATMENT OF PATIENTS WITH OBLITERATING ATHEROSCLEROSIS OF LOWER LIMBS ARTERIES.

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Aim of the study: This work contains a preliminary study of efficiency of Veinoplus portable apparatus in combination treatment of obliterating atherosclerosis for patients with chronic lower limbs ischemia. The received data indicate clinical efficiency of the device in combined therapy of chronic lower limbs ischemia.

Material and methods: 31 patients with different grades of chronic lower limbs ischemia received conservative vasodilating (Trental) infusion, and other pharmacological treatments. Hyperbaric oxygenation sessions were added for 17 patients. 13 patients underwent reconstructive operations on main arteries of lower limbs. Electropulse stimulation was also applied to the affected extremity muscles using the Veinoplus device in the treated group (21 people). The sessions were conducted during infusion vascular therapy (to improve perfusion of preparations in limbs tissue). The sessions were conducted 2 to 5 times a day.

Results: The results were estimated on the 1st, 5th, 10th day from the beginning of the therapy, then every 5 days (for patients after performing reconstructive surgery on the affected extremity arteries).

In the treated group, on the 5th day, 14 patients (66.67%) reported abatement of the pain syndrome at rest and during minimum walking, increase of the painless walk distance by 100 meters on the average (versus 50 m in control group). On the 10th day, 19 patients (90.48%) reported a positive effect: absence of pain in the affected extremity at rest (for 8 patients, versus 3 patients in the control group), reduction of trophic disorders sizes (for 5 patients versus 1 patient in the control group). Regarding the increase of the painless walking distance, in the treated group it increased by 300 meters (for 14 patients) and by up to 500 meters (for 5 patients). In the control group, it increased by 100 meters (for 6 patients); by up to 200 meters (for 3 patients) and by up to 300 meters (1 patient).

In the treated group, the edema of all 5 patients who underwent surgery decreased by 40% on the 1st day, by 50% on the 5th day, the edemas were eliminated on the 10th day and there were no recurrences of the edemas. In the control group, the edema was the same on the 1st day, decreased by 30% on the 5th day, 5 patients still had edema on the 10th day.

Conclusion: The Veinoplus electropulse muscle toning apparatus is appropriate for combination treatment of patients with chronic ischemia of lower limbs, especially of patients with critical ischemia (grades III and IV according to Fontaine-Pokrovsky classification). Electric muscle toning by means of the Veinoplus apparatus during treatment of arterial pathology of patients with chronic ischemia intensifies the effect of traditional therapy methods (vasodilating infusion therapy, hyperbaric oxygenation) and facilitates fast formation of collaterals. Portability, simplicity and safety of the technology make it possible to use the Veinoplus device in the outpatient setting.

Keywords: obliterating atherosclerosis, fitness walking, electropulse muscle toning, Veinoplus device.

Case report submitted to Ad Rem Technology (2011)

LOWER LIMB ULCER CASE REPORT WITH SEVERE ARTERIAL AND CHRONIC VENOUS DISEASE TREATED WITH A COMBINATION OF ELECTROSTIMULATION (VEINOPLUS) AND PROSTAGLANDINS.

Presented at European Venous Forum Workshop, Vienna 05/2011

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Introduction:

Ulcers with mixed venous and arterial components represent about 10% of cases and the more complicated the history of disease, the more difficult is the wound treatment. In affected patients, it is important to avoid compression, which is advised for pure venous ulcers. We report a case of ulcer on a complicated history of chronic venous and arterial disease treated with electrostimulation (EMS): VEINOPLUS and prostaglandins (PG).

Case presentation: We report here the case of a patient, Mr. MP, 56-years old.

History: Deep venous thrombosis (DVT) in left leg 15 years ago followed by 5 further DVT; the last one 5 years ago. Every episode was treated by warfarin (1 month). In 2009 a left popliteal aneurysm was diagnosed and repaired with vein graft which closed 10 weeks later despite warfarin. Critical ischemia and intermittent claudication (IC) at 100m were managed by stenting a stenosis in left superficial femoral artery which resulted in symptoms relief.

Consultation in June 2011: Patient presented IC at 50m without rest pain and a left leg ulcer present for 2 months. He was able to sleep horizontal at night without any pain. His left Ankle Brachial Index (ABI) was 0.35.

Investigations and Treatment: The duplex scan showed an occluded popliteal vein and a partially recanalized femoral vein with marked reflux at the ilio-femoral segment. Angiography showed occluded lower femoral and popliteal arteries but with good collaterals across the knee. Prescribed treatment was for outpatient management with PG E-1 daily infusion for 2 weeks, calf pump activation by EMS: VEINOPLUS in sitting position for 3-4 hours daily without warfarin discontinuation (INR 2.7).

Outcome: After 2 months (August 2011), swelling markedly reduced, ulcer healed and IC improved to 200m with no change in ABI.

Conclusion:

Management of mixed ulcers may not include compression as critical ischemia and limb loss may occur. It is therefore important to look for alternative ways of treatment. We describe the case of a mixed lower limb ulcer treated with electro-stimulation and PG that led to rapid healing of ulcer and improvement of IC. Possible contribution of EMS for treatment of leg wounds from both origins and the mechanisms underlying this action are worth further investigation.

Key words: mixed ulcer – electrostimulation

DVT STUDIES

THE EFFICACY OF A NEW STIMULATION TECHNOLOGY TO INCREASE VENOUS FLOW AND PREVENT VENOUS STASIS

Also presented at American Venous Forum, Amelia Island 2010

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Objectives:

Electrical stimulation of calf muscles has been shown to be effective in prevention of DVT. The aim was to determine: (a) dependence of venous blood velocity and ejected volume on the rates of stimulated calf contractions: (b) clinical factors affecting efficacy in healthy individuals.

Methods:

The maximum intensity stimulus tolerated was applied to calves of 24 volunteers. In popliteal veins, Peak Systolic Velocities (PSV), ejected volume per individual stimulus (Stroke Volume SV) and ejected Total Volume Flow per minute (TVF) of expelled blood were determined using ultrasound. Stimulation rates from 2 to 120 Beats Per Minute (bpm) were applied.

Results:

Mean baseline popliteal PSV was 10 cm/s. For stimulation rates between 2 and 8 bpm, the PSV was 10 times higher and reached 96-105 cm/s. Stroke volume (SV) per individual stimulus decreased in a similar fashion. With increasing rates of stimulation the TVF increased by a factor of 12 times (from 20 ml/min to 240 ml/min).

Conclusion:

Electrical stimulation is an effective method of activating the calf muscle pump.

Enhancements of popliteal blood velocity and volume flow are key factors in the prevention of venous stasis and DVT. Further studies are justified to determine the stimulation rates in those with a compromised venous system.

ELECTRICAL CALF MUSCLE STIMULATION COMBINED WITH LOW DOSE UNFRACTIONATED HEPARIN (LDUH) AND ELASTIC COMPRESSION (EC) VERSUS LDUH WITH EC ALONE IN THE PREVENTION OF POSTOPERATIVE DVT.

Presented at European Venous Forum2013 (Belgrade)

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Aim of the study:

Evaluate the potential effect of electrical muscle stimulation (EMS) of the calf in the prevention of postoperative DVT in high risk surgical patients. Evaluate efficacy and safety of EMS in patients with calf DVT.

Methods:

Prospective, non-randomized, controlled pilot study involving 80 surgical patients with high risk of VTE (According to “Russian clinical recommendations” based on ACCP8).

46 women and 34 men aged 40 to 85 (mean age: 64.9 ± 12.2)

Abdominal surgery: 44 patients. Neurosurgery: 36 patients. Among other additional DVT risks factors, 81% of patients had 3 or more additional risk factors, 78% rested in bed for at least 3 days, 45% had an active oncological disease, 69% were over 60 years-old. According to VTE prophylaxis patients were divided into two comparable groups. The protocol of VTE prophylaxis for the study group included electromuscular stimulation with Veinoplus device at >100 min per day (> 5 sessions), anticoagulation therapy with the use of a graduated compression bandage. In the control group, the prophylactic treatment consisted of the placement of a similar bandage and the prescription of direct anticoagulants without electromyostimulation

Design of the study protocol:

- Duplex ultrasound at baseline and every 3 days after surgery until discharge
- Ventilation-perfusion lung scintigraphy before discharge if any initial or new DVT detected
- Autopsy performed in all patients with fatal outcome



Results:

A single case of deep vein thrombosis (2.5%) in the absence of pulmonary embolism was documented in the study group whereas 10 patients of the control group developed thrombotic occlusion (25.0%), and two others (5.0%) presented with thromboembolism of the pulmonary arteries.

Conclusion: Addition of EMS using Veinoplus device at >100 min per day (> 5 sessions) to compression and LDUH decreases the incidence of postoperative DVT in high risk patients. Use of EMS in patients with calf DVT does not increase the rate of Pulmonary Embolism. The results need verification in a RCT.

Key words: venous thrombosis, pulmonary embolism, prophylaxis, surgery.



SPORTS STUDIES

RECOVERY AFTER HIGH-INTENSITY INTERMITTENT EXERCISE IN ELITE SOCCER PLAYERS USING VEINOPLUS SPORT TECHNOLOGY FOR BLOOD-FLOW STIMULATION

Also presented at: XXIXth National Congress of French Sports Medicine Society, Biarritz 2009

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Context: Electric muscle stimulation has been suggested to enhance recovery after exhaustive exercise by inducing an increase in blood flow to the stimulated area. Previous studies have failed to support this hypothesis. We hypothesized that the lack of effect shown in previous studies could be attributed to the technique or device used.

Objective: To investigate the effectiveness of a recovery intervention using an electric blood-flow stimulator on anaerobic performance and muscle damage in professional soccer players after intermittent, exhaustive exercise.

Design: Randomized controlled clinical trial. Setting: National Institute of Sport, Expertise, and Performance (INSEP).

Patients or Other Participants: Twenty-six healthy professional male soccer players.

Intervention(s): The athletes performed an intermittent fatiguing exercise followed by a 1-hour recovery period, either passive or using an electric blood-flow stimulator (VEINOPLUS).

Participants were randomly assigned to a group before the experiment started.

Main Outcome Measures(s): Performances during a 30-second all-out exercise test, maximal vertical countermovement jump, and maximal voluntary contraction of the knee extensor muscles were measured at rest, immediately after the exercise, and 1 hour and 24 hours later. Muscle enzymes indicating muscle damage (creatine kinase, lactate dehydrogenase) and hematologic profiles were analyzed before and 1 hour and 24 hours after the intermittent fatigue exercise.

Results:

The electric-stimulation group had better 30-second all-out performances at 1 hour after exercise ($P = .03$) in comparison with the passive-recovery group. However, no differences were observed in muscle damage markers, maximal vertical countermovement jump, or maximal voluntary contraction between groups ($P = .05$).

Conclusions: Compared with passive recovery, electric stimulation using this blood-flow stimulator improved anaerobic performance at 1 hour postintervention. No changes in muscle damage markers or maximal voluntary contraction were detected. These responses may be considered beneficial for athletes engaged in sports with successive rounds interspersed with short, passive recovery periods.

Key Words: quadriceps muscle, fatigue, athletes

POSITIVE EFFECTS OF LOW-FREQUENCY ELECTRICAL STIMULATION DURING SHORT-TERM RECOVERY ON SUBSEQUENT HIGH INTENSITY EXERCISE

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Purpose:

The aim of this study was to compare the effectiveness of blood flow stimulation (BFSTIM) with VEINOPLUS© device to active and passive recovery methods during a short-term recovery period between two exhausting exercises of short duration.

Methods:

Fourteen highly trained female handball players completed two successive ‘Yo-Yo intermittent recovery’ tests (level 2; YYIR2) elapsed by a 15 min recovery period during which they used one of the three recovery modalities presented in a random order (Active, BFSTIM or Passive). Performances (i.e. distance achieved) were measured at the end of each YYIR2 test. Blood lactate, pH and bicarbonates ions concentrations were measured or calculated before and immediately after the first YYIR2 test and every three minutes during the recovery. Heart rate, respiratory gas exchange and tissue saturation index (%TSI) of the lateral gastrocnemius were continuously recorded during the recovery phase.

Results:

In comparison to passive recovery, we observed a beneficial effect with BFSTIM (+13.0% ± 7.8%; ± 90% confidence limits) and a “possible” beneficial effect with active recovery (+4.0% ± 9.0%) on performance during the second YYIR2. BFSTIM and active recoveries versus passive recovery clearly showed a significantly faster return to baseline value of blood lactate, pH and bicarbonates ions concentrations during the recovery period ($P < .05$). Whereas %TSI was continuously lower, heart rate and oxygen uptake were higher with active recovery in comparison to the two others modalities.

Conclusion:

The results suggested that blood flow stimulation with VEINOPLUS© and, to a lesser extent, active recovery are effective interventions to improve recovery during short time periods and could be useful during half-time.

INFLUENCE OF POST-EXERCISE LIMB BLOOD FLOW STIMULATION ON PERFORMANCE RECOVERY

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Introduction: Elite sport requires athletes to complete multiple bouts of high-intensity exercise with limited rest periods that are not sufficient for full recovery. To facilitate the performance recovery, recovery therapies like active,1 immersion2 or neuroelectromyostimulation3 (NEMS) have achieved very good results. It has been hypothesized that the increase of blood flow with these strategies could accelerate the supply of oxygen rich blood, increase the flush of waste products and help reduce H+ levels associated with lactic acid build-up. Consequently, the assumption of a strong relationship between blood flow and high intensity performance recovery is often cited although never tested. Therefore, the aim of this study was to test this hypothesis by stimulating the blood flow at three different levels during a 30-min recovery intervention period between two sessions of multiple sprint interval (three 30-s WanT) exercise.

Methods : Thirty-seven trained athletes participated in a randomized controlled trial. Each session consisted of performing 3 x 30 WanT (bouts 1–3) followed by a randomly assigned 30-min recovery intervention of either: high blood flow (Veinoplus Sport®)(HBF), low blood flow (Cefar-Compex Theta 500®)(LBF); sham NEMS device (SHAM; that does not stimulate the blood flow) and passive recovery (PAS). A 30-s WanT was then repeated (bouts 4) and compared to bout 1 for peak power and mean power. Measures of blood flow, blood lactate and heart rate were recorded every 3 min throughout the recovery intervention period to monitor physiological responses.

Results: Blood flow was significantly higher in HBF group compared to PAS, SHAM and LBF groups. Examination of heart rate and blood lactate revealed no recovery effect. The recovery of mean power was likely beneficial in the HBF group compared with the SHAM group and very likely beneficial compared with the PAS group and the LBF group. The recovery of peak power in the HBF group was likely beneficial and very likely beneficial compared with the LBF group and the PAS group, respectively.

Conclusion: Stimulate total blood flow at a high velocity is a mean of preserving performance when repeating acute exhausting exercise interspaced by short recovery period. However this positive effect is not accompanied by a greater lactate removal.

Key words: Recovery, Blood flow, NEMS

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