Electrical calf muscle stimulation with Veinoplus device in postoperative venous thromboembolism prevention

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***Aim*. The aim of this pilot study was to evaluate the potential effect of electrical calf muscle stimulation (EMS) in the prevention of postoperative deep vein thrombosis (DVT) in high risk patients and to assess efficacy and safety of EMS in patients with calf DVT.**

***Methods*. This was a prospective non-randomized controlled study involving 80 patients over the age of 40 having major surgery (44 abdominal and 36 cranial or spinal surgery; duration more than 60 min under general anesthesia). Patients were divided into 2 comparable groups: main (N.=40) and control (N.=40). In both groups graduated middle stretch compression bandage with compression level 20-40 mmHg was applied and low dose unfractioned heparin (LDUH) injections (5000 U s.c. 3 t.i.d) were started on 1st or 2-5th day after surgery and continued until discharge. The time of starting LDUH was comparable in both groups. In addition, electrical calf muscle stimulation (EMS) with Veinoplus device was performed for not less than 5 periods of 20 minutes per day (total >100 minutes) in the main group. Control of venous patency was performed with duplex ultrasound obligatory at baseline (first 24 h after surgery) and then every 3 days until discharge.**

***Results*. The incidence of DVT was 2.5% in the main group and 25% in the control group (P=0.007). In patients without DVT at baseline it was 3% *versus* 21% (P=0.025). Patients with baseline thrombosis who underwent EMS did not have any new cases of DVT and PE, while in patients without EMS thrombosis progression was observed in 43% cases also without pulmonary embolism (not significant).**

***Conclusion*. EMS with Veinoplus device at >100 min per day (>5 sessions) can decrease the rate of postoperative DVT in high risk patients. Using of EMS in patients with calf DVT does not increase the rate of PE. These findings need to be confirmed in a randomized controlled trial.**

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Key words: **Venous thromboembolism - Venous thrombosis**

Venous thromboembolism (VTE) causes significant morbidity and mortality; approximately one million VTE episodes are registered every year in the European Union member countries, and over one-third of them are fatal PE.[1] These complications are particularly common among hospitalized patients, with VTE events accounting for approximately 96 in every 1000 hospitalizations per year.[2]

Blood stasis is one of the three essential components in the pathogenesis of intravascular clot formation, as described by Rudolph Virchow, making it the key target for the prevention of VTE. Elastic and pneumatic compression, which has been shown to be highly effective clinically, is most commonly used to prevent stagnation of venous blood. The use of compression knitwear alone is only effective in patients with a low to moderate risk of postoperative VTE, with less efficacy in high-risk patients.[3-7] While intermittent pneumatic compression leads to a significant reduction in the risk of VTE in high-risk patients even when used for prophylaxis alone, there may be poor compliance among both patients and health care professionals.[8-11]

Electrical muscle stimulation of the calf (EMS) is an emerging alternative method which can be used to reduce stasis in the veins of the lower limbs. The use of EMS for the prevention of VTE was first proposed in the second part of the 20th century, when postoperative DVT was demonstrated to originate in the soleal sinuses,[12, 13] and the mechanism of muscular-venous pumping in the lower leg was described.[14] Intraoperative use of EMS was found to be effective in reducing the incidence of DVT,[15-19] but it was too painful to be used in the postoperative period.[19]

However, with modern technology EMS is

re-emerging in the clinical arena as a new safe and well tolerated method. Portable electric calf stimulators that can significantly increase venous blood velocity [20-23] are now available.

The main goal of this pilot study was to assess the potential efficacy of electrical muscle stimulation of the calf in the prevention of postoperative DVT in high-risk patients. The secondary goal was to evaluate the safety of EMS in patients with baseline deep vein thrombosis confined to the calf.

Materials and methods

Study design

We performed a prospective, non-randomized controlled trial in surgical patients at high risk of developing postoperative VTE. The exclusion and inclusion criteria are shown in Table I. This study was approved by the Ethics Committee of the Russian National Research Medical University named after N. I. Pirogov.

Patient characteristics

A total of 80 patients (34 men and 46 women) aged between 40 and 85 years (mean age 64.9±12.2) were recruited. All of them had either abdominal surgical (44 cases) or neurosurgical (36 cases) disorders (Table II), for which they underwent major surgical intervention (Table III), rendering them high-risk for VTE. Major surgery was defined as an operation lasting over 60 minutes using general anesthesia. VTE risk was assessed in accordance with the "Russian clinical recommendations for the diagnosis, treatment, and prevention of venous thromboembolism events" based on the ACCP 8 guidelines.[24] The postoperative VTE high-risk group included all patients aged over 60 years who had had a major abdominal or neurosurgical operation, as well as patients aged between 40 to 60 years who had extra risk factors in addition to surgical intervention.

Prior to the study, all participants were assessed using clinical, sonographic, and laboratory examinations, which always included duplex ultrasound scanning of the inferior vena caval

TABLE I.—*Inclusion and exclusion criteria used in this study.*

Inclusion criteria	Exclusion criteria
Aged >40 years	Acute proximal DVT
Major surgery performed	Implanted cava-filter or performed IVC plication
High-risk of postoperative VTE	Regular preoperative anticoagulation
Informed consent given	Coagulopathy (not related to DIC)
	Thrombocytopenia
	Postoperative anticoagulation needed at therapeutic doses
	Hemorrhagic diathesis
	Chemotherapy
	Cardiac pacemaker
	Severe cardiac arrhythmia
	Lower limb soft tissue infection
	Ankle-brachial index <0.9 or >1.3
	Fatal outcome within first five days of study observation

DIC: disseminated intravascular coagulation; IVC: inferior vena cava.

TABLE II.—*Underlying condition in study patients.*

Underlying condition	N.
Intestinal gangrene	6
Purulent peritonitis	9
Malignant gastrointestinal tumors	27
Complicated gastric and duodenal ulcers	2
Cerebral and meningeal tumors	12
Parenchymal intracranial hemorrhage	12
Non-traumatic subarachnoid, subarachnoid-parenchymal hemorrhage	8
Traumatic intracranial hemorrhage	4
Total number of patients:	80

TABLE III.—*Surgical interventions performed in study patients.*

Surgical interventions	N.
Laparotomy with resection of gastrointestinal tract	27
Laparotomy with the removal of inflamed organs	7
Laparotomy with digestive anastomosis applying	9
Laparotomy, gastrostomy	1
Osteoplastic trepanation, intracranial tumor resection	12
Osteoplastic trepanation, aneurysm clipping	8
Osteoplastic/resection/burr-hole trepanation, evacuation of haematoma	11
External ventricular drain	5
Total number of surgical interventions:	80

TABLE IV.—*The additional VTE risk factors occurrence rate.*

Risk factor	Rate
Age over 60	69%
Overweight and obesity	34%
Varicose veins	34%
Estrogen medication use	1%
Chronic heart failure	20%
Bed rest more than 3 days	78%
Sepsis	25%
History of past VTE	5%
Active oncological disease	45%
Lower extermity paralyses	30%
Femoral vein catheterization	10%
Three and more additional risk factors	81%

system. The primary ultrasound examination served to evaluate the superficial and deep lower limb veins for patency, as well as to detect any signs of valvular insufficiency in the superficial and deep veins.

The clinical assessment was focused on the identification of conventional VTE risk factors, including excessive body weight, varicose veins, chronic heart failure, the use of procoagulant medication, history of past VTE, active oncological disease, lower extremity paralysis, sepsis, and catheterization of leg deep veins. Thorough clinical evaluation revealed, in addition to major surgery, one to seven additional VTE risk factors in every patient (mean number, 3.5±1.2 risk factors). Risk factor occurrence rates are presented in Table IV. Three or more additional risk factors were found in 81.2% of all cases.

Laboratory evaluation included standard blood coagulation tests and other appropriate tests, depending on the nature of the underlying condition.

All patients were divided, depending on their postoperative VTE prevention protocol, into two groups: a main group (40 patients), in which electrical stimulation of the calf muscles was extensively used; and a control group (40 patients) in which the VTE prevention protocol did not include EMS. The main and control groups were well matched with regard to the main clinical parameters, as presented in Table V.

Study protocol

The VTE prevention protocol included EMS, use of graduated compression bandages, and administration of low dose unfractioned heparin (LDUH) in the main group. EMS was not used in the control group, only equivalent graduated compression bandages and LDUH.

EMS was performed using "Veinoplus" model 2.1 pocket-size portable muscle stimulator (Ad Rem Technology, France) powered by a 9 volt battery. The "Veinoplus" device generates low frequency (250 Hz) alternating electrical current with modulated periods of impulse duration, which result in short lasting (50 ms) muscle contractions.

The rate of stimulated muscle contractions ranges from 60 to 105 beats per minute, corre-

TABLE V.—*Main and control study group comparison.*

Characteristics	Main group (N.=40)	Control group (N.=40)	P	Statistical method
Age	65.8±12.5	64.1±12.0	0.832	Student's *t*-test
Men	15	19	0.498	Fischer's exact test
Abdominal surgical patients	23	21	0.822	Fischer's exact test
Number of additional risk factors	3.5±1.3	3.5±1.1	0.806	Mann-Whitney test
Patients having ≥3 risk factors	32	33	1.0	Fischer's exact test
Duration of a surgical intervention (h)	3.70±1.96	2.9±1.3	0.012	Student's *t*-test
Total observation duration (days)	12 (10;16)	14 (10;20.8)	0.293	Mann-Whitney test
SAPSII score at baseline	39.1±16.1	41.8±13.9	0.266	Student's *t*-test
Length of ICU stay (days)	3 (2.0;6.8)	5 (3.0;13.0)	0.102	Mann-Whitney test
VTE detected at baseline	5	7	0.755	Fischer's exact test
LDUH injections started on POD 1	23	22	1.0	Fischer's exact test
LDUH injections started on POD 2-5	17	18		
Overall mortality	6	8	0.770	Fischer's exact test

sponding to frequencies from 1 to 1.75 Hz, thus ensuring at least 1500 effective contractions over period of 20 minutes.

EMS procedure in the main group was performed not less than 5 times per day (total >100 minutes) with a target frequency of ten times per day on a schedule of every two hours, from 6 am to 12 am, with a six-hour break overnight. Individual self-sticking "Vein Pack" electrodes were fixed over the gastrocnemius muscle region for the EMS procedure throughout the patient's hospital stay. Compression bandages were applied over the electrodes. In the case of bed-ridden and unconscious patients, nurses and hospital attendants activated the device according to the required regimen. As the patients regained mobility and recovered consciousness, they activated the apparatus by asking health care personnel to control the device. Impulse power was determined on an individual basis and increased until the patient was able to achieve painless, extensive flexion of the foot at the ankle joint without forced movement of the entire extremity.

"Stülpa Rollen" and "Rolta" lining (Paul Hartmann, Germany) were used with the compression bandage to protect the skin from damage, and to cover protruding bone parts in order to avoid injury of the underlying skin. Graduated compression bandages were applied to all study groups using medium-extension "Pütterbinde" material (Paul Hartmann, Germany), by means of the eight-shaped technique or the classical Pütter technique. The bandage was placed following under-bandage pressure monitoring with a portable "Kikuhime" manometer (TT MediTrade, Denmark). The target pressure at point B (the most narrow part of the shin) was 20-40 mmHg, decreasing gradually in the proximal direction to 10-12 mmHg. The bandage was adjusted once every 48-72 hours, or more frequently if indicated.

LDUH injections were administered to the both groups (5000 units s.c. three times per day). The therapy was started either on the first postoperative day or 2-5 days after surgery in patients with unstable hemostasis in the affected area. The times of LDUH administration did not differ between the main and the control groups, as presented in Table V.

The prophylactic program was initiated in accordance with the described protocol during the first 12 hours after surgery and continued throughout the patient's stay in the hospital. The time points of the study are presented in Table V. Immediately after operation patients were in an intensive care unit due to the type of surgical procedures they received. Their mean SAPS II scores were 40.5±15, with no statistically significant difference between the groups.

Interpretation of results

Compression sonographic scanning of blood vessels was performed regularly using "LOGIQ e" and "Voluson E8" devices (General Electric, USA) to evaluate the efficacy of the prophylactic program in the postoperative period. Particular attention was directed to the state of the soleal veins. Ultrasound examination was performed within the first 24 hours after surgery and then repeated every 3 days throughout the hospital treatment.

For patients shown to have a venous thrombus, ventilation-perfusion scintigraphy of the

lungs was performed to determine the presence or absence of PE. All patients who died underwent autopsy.

The endpoints of the study were the presence or absence of VTE events verified on every third day after surgery and the overall incidence of VTE throughout the inpatient treatment.

A positive result meant no signs of "fresh" thrombus on ultrasound vascular scanning, no signs of PE on lung scintigraphy and no signs of VTE on autopsy in dead study subjects. A "fresh" venous thrombus meant involvement of new venous segments in patients already diagnosed with calf thrombosis, as well as any thrombotic occlusion in patients without such occlusion at the baseline check.

Statistical analyses

Statistical analyses of obtained data were performed using IBM SPSS Statistics (version 19). Numerical data were presented either as means with their standard deviations, or as medians with interquartile ranges. Mean values were compared using the *t*-test (age, duration of operation, number of risk factors), and the non-parametric Mann-Whitney test (length of ICU stay, duration of observation) for parametric and non-parametric data, respectively. Proportions are presented as values with their 95% confidence intervals (CIs), calculated using the standard method or according to Wilson. To compare such values, we used the chi-squared test with Yates' correction and Fisher's two-tailed exact test. To compare cumulative DVT free survival rate in both groups we used log rank test. P values below P<0.05 were considered statistically significant.

Results

Baseline ultrasound scanning revealed DVT in 20 patients. A proximal location or extension was found in eight subjects, and therefore these patients were not enrolled in the study. In the remaining 12 patients, the thrombotic process involved the calf veins only. These patients were recruited into this study: 5 in the main group, and 7 in the control group.

Throughout the hospital observation period, "fresh" venous thrombosis was verified in one patient in the main group (2.5%; 95% CI: 0.4-12.9%), and in 10 controls (25%; 95% CI: 14.2-40.2%, P=0.007, Fischer's exact test). The rates of occurrence of proximal DVT were 0% in the main group, and 5% (95% CI: 1.4-16.5%) in the control group (P=0.494, Fischer's exact test). The overall PE incidence was 0% in the main group, and 5% (95% CI: 1.4-16.5%) in the control group without significant differences (P=0.494, Fisher's exact test). The sites of "fresh" DVT are presented in Table VI. Isolated involvement of the calf gastrocnemial and soleal sinuses prevailed in the control group and accounted for 70% (95% CI: 41.6-98.4%) of all thrombotic events.

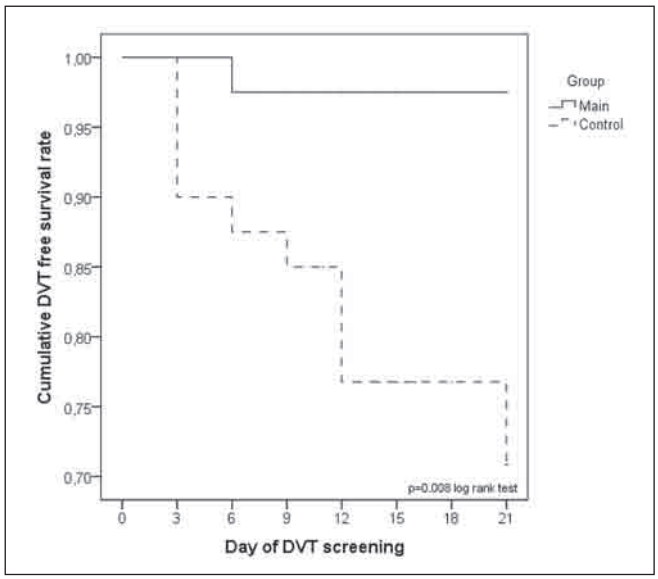

Figure 1.—Cumulative DVT free survival in all patients (N.=80).

TABLE VI.—*The sites of detected "fresh" venous thrombosis.*

Sites of "fresh"venous thrombosis	Main group (N.=40)	Control group (N.=40)
Calf muscles sinus(es)	0	7
Calf muscle sinuses with the extention to the tibial and peroneal veins	1	1
Total thrombosis of leg veins up to the inguinal fold	0	1
Thrombosis of the great saphenous vein at thigh level	0	1
Total:	1	10

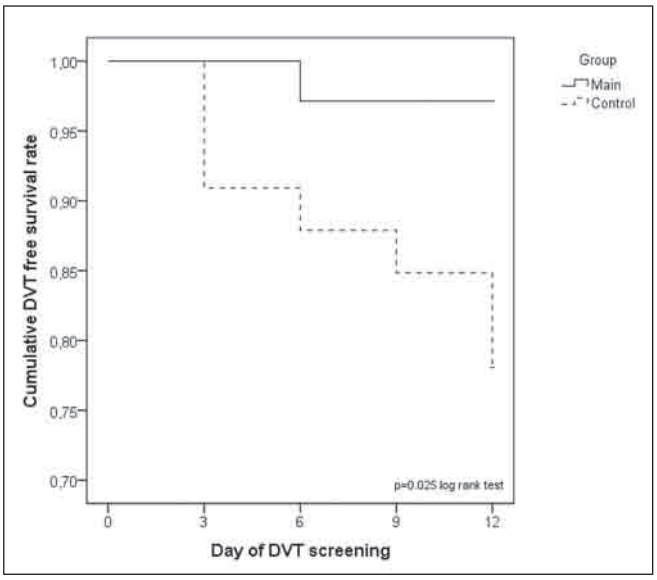

Figure 2.—Cumulative DVT free survival in patients without DVT at baseline (N.=68).

The time to DVT development among all patients is presented in Figure 1. The comparison of cumulative DVT free survival rates in the main and control groups showed a statistically significant advantage of the main group (P=0.008, log rank test).

The separate analysis of results in patients without baseline DVT (N.=68) has also shown the advantages of EMS: the total number of postoperative thrombosis significantly reduced from 21% (95% CI: 9.7-39.8%) to 3% (95% CI: 0.5-15%, P=0.025, Fischer's exact test), and the cumulative DVT free survival rate was significantly higher in the main group (Figure 2, P=0.025, log rank test).

The history of 12 patients with baseline calf DVT is presented in Table VII. All the patients had a high risk of postoperative bleeding and therefore received not therapeutic but prophylactic doses of anticoagulants. There were no new cases of venous thrombosis and pulmonary embolism in patients underwent EMS. However, three patients without EMS showed progression of thrombosis without PE. This difference was not statistically significant. In patients in which EMS was used in the presence of calf DVT a positive clinical and sonographic effect was observed: the thrombotic process did not spread proximally, and signs of vein recanalization were observed after 10 to 14 days of EMS.

The overall mortality rates did not significantly differ between the main and control groups, being 15% (95% CI: 3.9-26.1%), and 20% (95% CI: 7.6-32.4%), respectively. All deaths in the main group were due to progression of the underlying condition and its complications; there was no evidence of VTE at autopsy. In the control group, two patients died of sub-massive or massive PE (5%; 95% CI: 1.4-16.5%), whereas all other deaths were caused by the underlying condition and its complications.

There was 100% compliance with EMS in the study subjects, with no refusal to have this treatment. With regard to health care personnel, the mean rate of device use was 6.7±1.5 times per day in the intensive care unit, and 6±1.6 times per day in the specialized departments, with a target frequency for the main group being 10 periods per day. Therefore, compliance of health care personnel was 60-70%. In view of the observed positive effects, we concluded that six or seven 20-minute periods per day was the appropriate frequency to ensure a favorable effect in high-risk patients.

We observed no specific complications while using EMS. Injuries of the shin skin because of compression bandage like redness and blistering developed on the anterior surfaces of the ankle joints and the tibia in two main group and control group subjects (5%; 95% CI: 1.4-16.5%), although these did not require any specific treatment.

Discussion

Here we present, for the first time, the use of state-of-the-art portable electrical stimulation of the calf muscles to prevent VTE events. We demonstrate high clinical efficacy using this technique in a very severely ill patient population.

TABLE VII.—*The history of patients with DVT at baseline (N.=12).*

	Initial DVT	Fresh DVT	PE
Main group	5	0	0
Control group	7	3	0
P value (Fischer's exact test)	-	>0.05	-

A large and statistically significant reduction in the rate of postoperative venous thrombosis was demonstrated through the use of frequent EMS sessions (more than five times per day) in addition to a standard complex VTE prevention program. This was most likely due to the ability of EMS to effectively evacuate blood from the calf veins, and prevent venous blood stagnation.[20] The mechanism of action may also be due to changes in blood flow acceleration and the associated shear stress increment, which is known to promote activation of the anti-thrombotic properties of the endothelium.[25] As shown in an experimental study, EMS using the "Veinoplus" apparatus to ensure 60 to 105 muscle contractions per minute increases popliteal vein peak blood flow velocity four or five times, to 40-50 cm/s on average. This is comparable to the magnitude of acceleration achieved using intermittent pneumatic compression devices, and can be expected to cause similar activation of the blood fibrinolytic system.[22, 26, 27] However, this presumption needs further experimental validation.

The study subjects were high-risk surgical patients, who represent as many as 40% of all surgical in-patients;[28] this technique using this methodology is therefore widely applicable to routine surgical practice. The majority of them had a combination of conditions predisposing to thrombosis, which significantly increases the risk of VTE.[29-34] Our (not published jet) results show that the simultaneous presence of three or more risk factors of thrombosis produces a tenfold increase in the occurrence of VTE events in the postoperative period, even on a background of standard preventive measures. These patients characteristically had an unfavorable baseline prognosis for the underlying condition, which was reflected by the mean SAPS II score (40.5±15 points), thus resulting in high postoperative mortality. This bias towards patients most predisposed to the development of VTE was likely to have been responsible for the high frequency of postoperative VTE events, in spite of the use of a standard complex prophylactic program that included elastic compression and LDUH injections. Notwithstanding the high VTE rate, the majority of cases of thrombosis were isolated involvement of the calf muscle veins, which have not been convincingly shown to be clinically important.[35-39] In addition the data confirm the value of combined modalities in prevention of postoperative VTE.

The limitations of this trial include the absence of randomization, its small size, and the inability to use EMS alone as the only means of VTE due to the need to be compliant with currently clinical protocols. However, these promising initial clinical findings demonstrating the successful use of the "Veinoplus" instrument for the prevention of postoperative VTE suggest that a large-scale, prospective, randomized clinical trial is warranted, in particular in patients in whom anticoagulant therapy and compression therapy are contraindicated.

Conclusions

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. Using EMS in patients with calf DVT does not increase the rate of PE.

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