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Electric Muscle Stimulation for Prevention of Venous Thromboembolism in Patients with Multiple Lower Extremity Trauma

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Abstract

Relevance. Patients with multiple lower extremity trauma are the group of a very high risk for the development of venous thromboembolism. Therefore, they need a set of measures to prevent this complication. The risk of developing hemorrhagic complications in the I–III periods of traumatic disease prevents many physicians from prescribing anticoagulants. In addition, the application of the external fixation apparatus makes the use of mechanical blood flow acceleration (elastic bandages, compression knitwear, intermittent pneumatic compression) impossible. ***The purpose of the study*** is to evaluate the effectiveness and safety of electric muscle stimulation (EMS) for venous thromboembolism prevention in the patients with multiple trauma and the use of external fixation for the lower limb fractures. ***Material and Methods.*** The analysis of treatment results of 31 patients with multiple lower limb trauma with the use of external fixation was carried. All the patients were men with average age of 29.3±5.1 years. The patients were divided into two groups by stratified randomization. The groups were comparable by sex, age, body weight, and injury severity. The patients of main group received EMS, in control group — the authors did not use the mentioned treatment. The EMS was carried out using a Veinoplus DVT according to the scheme: 60 min morning, afternoon and evening. Vascular ultrasonography of the lower extremities was performed for all patients before EMS and then every 7 days, as well as before each surgery. All patients underwent venous thromboembolism prevention with low molecular weight heparins, followed by switching to oral anticoagulants. ***Results.*** Side effects associated with the use of the EMS, as well as hemorrhagic complications were not detected. The velocity of blood flow in the popliteal vein in the patients, received EMS, was 9.7±0.7 cm/s before the session and 17.0±1.1 cm/s during the session (p<0.001). According to the vascular ultrasound, no venous thromboembolism was detected in the patients underwent the EMS. Deep vein thrombosis was diagnosed in the control group in 2 (13.3%) patients, and pulmonary embolism in 1 (6.7%). ***Conclusion.*** The use of EMS showed the absence of side effects and the development of hemorrhagic complications. The effectiveness of the EMS in the patients with external fixation was achieved due to a statistically significant (p <0.001) increase in the volumetric blood flow through the deep lower limb veins. The further study of the EMS in patients with multiple trauma, the development of optimal schemes for its use, depending on the severity of the injuries, will minimize the likelihood of developing venous thromboembolism in this category of patients.

Keywords: electric muscle stimulation, multiple trauma, thrombosis, venous thromboembolism prevention, external fixation apparatus.

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Introduction

Trauma is a leading cause of death and disability at a young age, and venous thromboembolism is the main cause of death in hospitalized trauma patients [1]. Forced bed rest or even immobilization of one limb turns off the muscle pump of the calf muscles and decreases the heart rate by 13% and venous blood flow by 47% [2]. The development of post-traumatic edema, damage to the vascular endothelium, and change in the blood rheological properties due to the blood flow decrease are observed in the overwhelming number of wounded and injured patients with multiple lower limb trauma and increase the risk of venous thromboembolism (VTE) [3].

The patients with of the pelvic, hip and lower limb fractures belong to the group of very high risk of developing VTE [4]. Depending on the method and effectiveness of prevention, the VTE rate in this group reaches 16–40% [5]. The comprehensive VTE prevention in the patients with femur fractures reduces the number of venous thromboses by 28.1% [6].

According to the Russian clinical guidelines for VTE diagnosis, treatment and prevention, the following mechanical means for preventing thrombosis are available: elastic bandages, compression knitwear, intermittent pneumatic compression, electric muscle stimulation (EMS) of the lower limb muscles, as well as the systems which provide ankle flexion-extensor movements [7].

The most common treatment of the patients with multiple trauma, including of the long bones gunshot fractures, is the application of external fixation (EF) [8]. Despite the current guidelines for VTE prevention [9], the risk of hemorrhagic complications stops many doctors from prescribing anticoagulant to the wounded and injured. In the patients with EF, the application of elastic bandages, pneumatic compression cuffs or compression knitwear is technically impossible. Therefore, if there is a risk of hemorrhagic complications, the only method of VTE preventing is to the increase of venous blood flow with EMS. In some patients, the EF continues for a long time, sometimes for more than a year. And all this time they require comprehensive prolonged VTE prevention.

A not completely resolved issue is the organization of vascular ultrasound (VUS) of the lower extremities in the patients with multiple trauma before prescribing VTE prevention. The problem is that most personnel at echelon 1 and 2 medical evacuation do not have a sufficient practical experience in conducting VUS in such patients. In addition, the heavy load of a doctor allows to study only 25% of those in need [10].

The purpose of the study to evaluate the effectiveness and safety of the EMS for prevention of VTE in the patients with multiple trauma on EF.

Material and Methods

Study design: two-center prospective randomized.

Patients

An analysis was made of the results of 31 injured with multiple lower limb trauma. The patients performed combat missions and were treated at the Main Military Clinical Hospital of the National Guard and the 2nd Military Clinical Hospital of the National Guard from 2017 to 2019. All of them were males. They regularly underwent a standard annual health assessment and recognized as medically ready for contract military service. The average age of the patients was 29.3±5.1 years. From the point of trauma, the patients were delivered to the hospitals from 30 minutes to 10 hours. During this period, anticoagulant therapy was not carried out. The time of the patients evacuation from other medical facilities was on average 7.5±1.2 days. There was no evidence of anticoagulant therapy in the patient's in-transit medical records. The coagulograms on admission showed the state of various degree hypercoagulation.

Criteria for inclusion in the study: the presence of a multiple injury with a fracture of one or more long bones of the lower extremities with EF.

Table 1

The Venous Segmental Disease Score

No.	Obstruction localization	Points
1.	Great saphenous vein (only if thrombosed from groin to below knee)	1
2.	Sural veins	1
3.	Popliteal vein	2
4.	Superficial femoral vein	1
5.	Profunda femoris vein	1
6.	Common femoral vein	2
7.	Iliac vein	1
8.	Inferior vena cava	1
	Maximum obstruction score	10

Exclusion criteria: the Venous Segmental Disease Score ≥1 and the indications for anticoagulants prescription (Table 1).

Obstruction a complete occlusion at some point in the segment or narrowing of at least half of the segment (>50%). Most segments are assigned one point, but some segments are rated higher according to their importance.

All the patients were divided into two groups by stratification randomization. The groups were considered comparable according to their gender, age, body weight, and severity of the injury on the basis of the homogeneity hypothesis under the Lehman Rozenblatt and Smirnov criteria. In the experimental group, EMC was performed, in the control was not (Table 2). The study design flowchart is shown in Figure 1.

The lower limb fractures characteristics is presented in Table 3.

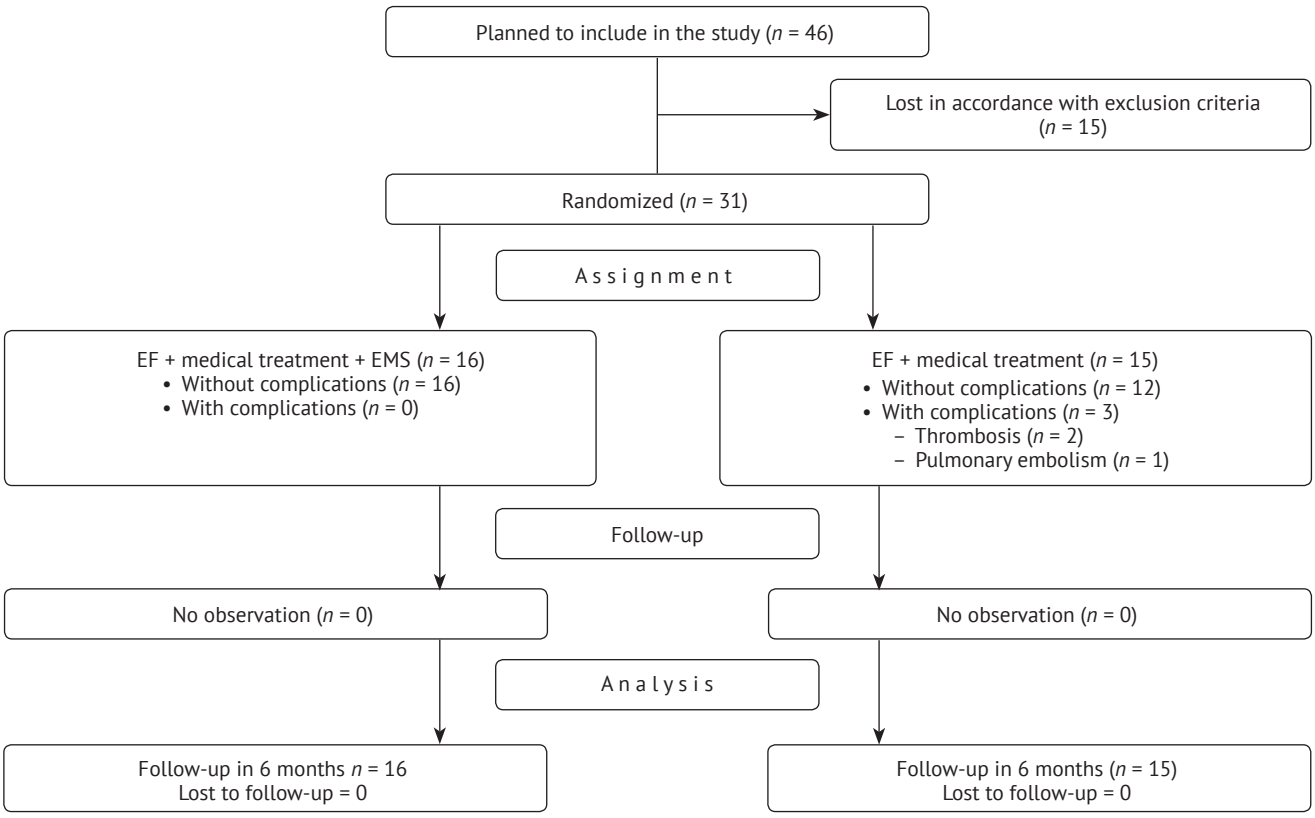

Fig. 1. Study design flowchart

Table 2

Characteristics of the experimental and control groups

Indicator	Experimental group (with EMS)	Control group (without EMS)
Number of patients	16 (51.6%)	15 (48.4%)
Age, years	28.1±3.9	30.3±5.7
Body mass, kg	84.5±5.1	79.9±4.3
Trauma severity according to Combat Surgery Department, Injury (Mechanical Injury) [12]	6.2±0.7	6.7±0.5
Injury Severity Score (ISS) [13]	22.3±3.9	23.9±2.7

Table 3

The lower limb fractures characteristics

Type of fracture	Localization	Experimental group (with EMS)		Control group (without EMS)		Total	
		n	%	n	%	n	%
Gunshot fracture	Femur	2	6.5	1	3.2	3	9.7
	Tibia	5	16.1	4	12.9	9	29
Open fracture	Femur	2	6.45	2	6.45	4	12.9
	Tibia	7	22.6	8	25.8	15	48.4
Total		16	51.6	15	48.4	31	100

Surgical Technique and EMS

After stabilization of the fracture by EF, 29 patients (93.6%) underwent intramedullary or transosseous osteosynthesis, 2 patients (6.4%) completed treatment in EF. The number of surgeries in both groups did not significantly differ. It amounted to 1–2 on lower limbs and 1–2 on other parts of the body. The hospitalization averaged 35.3±7.1 days for the patients of the experimental group and 36.1±6.3 for the control. Further follow-up in both groups was provided by a physician at the place of military service within six months after discharge from the hospital. EMS was performed using a Veinoplus DVT device. In order to evenly distribute the load on the leg muscles during the day, the procedure was performed according to the scheme: 60 min morning, afternoon and evening, a total duration of 180 min per day. A sticky fixing surface at the electrodes allowed them to be firmly fixed in the projection of muscles along the posterior side of the leg (Fig. 2).

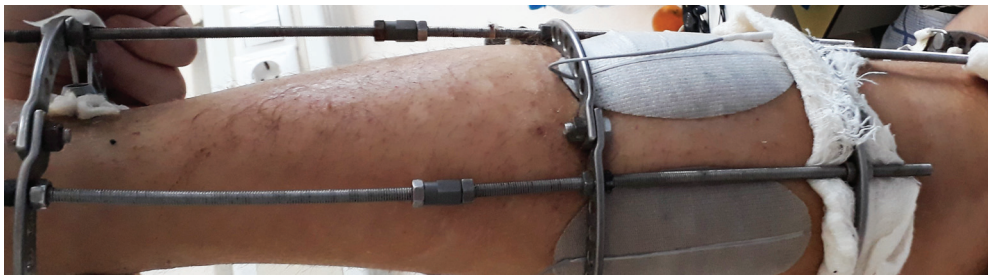

Fig. 2. Electrodes attachment method

For in-bed patients, one electrode was applied to one leg. After verticalization in the absence of damage to one of the legs, both electrodes were placed on the damaged leg. The electrical impulse strength was determined by the patient himself by pressing the "+" and "-" buttons until a slight tingling sensation under the electrodes. The duration of the EMS was determined by the presence of VTE risk factors and averaged 35.3±7.1 days.

The technical feature of Veinoplus DVT is the operation on a single battery, which makes it possible to use it in the field, in combat missions, and during evacuation of the wounded.

The VUS was conducted before using EMS to confirm the patency of the lower extremities superficial and deep veins, as well as to identify the possible thrombotic complications. The VUS performed using a portable ultrasound scanner MicroMaxx Sonosite with a linear sensor with a frequency of 10–5 MHz. The VUS was then carried out once every 7 days to assess the dynamics of the venous blood flow. Also, the VUS was fulfilled before each surgery.

Because the metal structure of the EF prevented the access to the typical points of visualization of the vessels, some techniques were developed and successfully tested to examine all the necessary zones (Fig. 3).

In some cases, the medical sonographer needed outside help.

The malleolar perimeter of both legs was measured with a centimeter tape 7 cm above the medial malleolus. In a results discrepancy of more than 2 mm (not related to the measurement error [14]), VUS was performed.

Fig. 3. Vascular ultrasound techniques in the patient with lower limb external fixation

All patients of both groups underwent VTE drug prevention with low molecular weight heparins followed by switching to oral anticoagulants (rivaroxaban) in recommended dosages [7, 9]. For the thrombotic process, the therapeutic doses of anticoagulants were used. According to the indications, two patients in the control group were examined for the presence of genetic pathology in the components of the hemostatic system: II, V, VII coagulation factors, fibrinogen, PAI-1, aggregation factors GP1BA, ITGB3, JAK2, SELPLG.

During the study, the attention was drawn to the skin side effects due to EMS in the form of electric current skin lesions under the electrodes. To assess the severity of hemorrhagic complications, the criteria recommended by the Scientific and Standardization Committee of the International Society on Thrombosis and Hemostasis were used [15].

The results evaluation

The evaluation of the results was carried out by comparing the recorded indicators of the venous blood flow in the patients of the experimental and control groups using statistical analysis.

Statistical analysis

Statistical processing of the results was carried out using the data processing package of the program Excel 2016 (Microsoft, USA) and the program Statistica 7.0 (StatSoft, USA). The results were presented as the median (Me) and the interquartile range (25–75% of the IQR). Comparison of quantitative indicators between the two groups was calculated using the Mann Whitney U-test. Differences between the groups were considered statistically significant at $p<0.05$.

Results

The application of electrodes on the posterior surface of the legs in the presence of EF did not cause any technical difficulties. There were no side effects associated with the contact of the electrodes and the EF parts. The data on the studied parameters in both groups are presented in Tables 4 and 5.

Table 4

The malleolar perimeter, cm

The study moment	Experimental group	Control group
On admission	24.2±0.5	25.2±0.5
Before discharge	23.8±0.3	24.5±0.3

Table 5

The popliteal vein blood flow in the experimental group, cm/c

The procedure session moment	1st day		7th day		14th day		21st day	
	Me	IQR	Me	IQR	Me	IQR	Me	IQR
Before EMS	9.7	9.6–9.9	9.8	9.6–10.0	9.8	9.6–9.9	9.9	9.7–10.1
During EMS	17	16.8–17.2	17.1	16.9–17.3	17.1	16.9–17.3	17.2	17.0–17.4
After EMS	12.1	11.9–12.3	12.2	12.0–12.4	12.2	12.0–12.4	12.3	12.1–12.5

The analysis of the obtained results showed a statistically significant increase in the popliteal vein blood flow during EMS in the experimental group (p<0.001) compared with the blood flow before the start of the EMS session at all stages of observation. It was also found that prior to the EMS, according to VUS, the venous sinuses of the leg muscles were not visualized. The signs of soft tissue edema were revealed in all patients. The blood flow in the venous sinuses was clearly recorded at low speed 9.1±3.7 days after the EMS started. In one patient, an organized intermuscular hematoma compressed the adjacent tissues was revealed by VUS.

Among the patients of the experimental group, according to VUS, VTE was not identified. In 2 (13.3%) patients of the control group, deep vein thrombosis of the leg on the injured side was revealed. And in one of them, segmental PE was developed on the 10th day after the injury (Fig. 4).

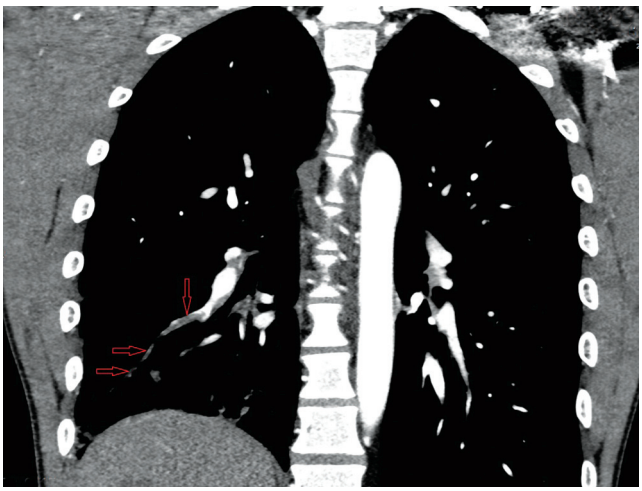

Fig. 4. CT signs of pulmonary embolism in segmental branches of the right pulmonary artery —non-occlusive thrombosis of S8 and S9 segmental branches of the right pulmonary artery. The blood clots indicated by arrows

Monitoring of blood coagulation parameters revealed a slight increase in the international normalized ratio to 1.3 and activated partial thromboplastin time (up to 44 seconds) in 2 patients with deep vein thrombosis who were on therapeutic dosages of anticoagulants recommended by manufacturers. The mentioned numbers did not reach the target values [7]. But the increase in the anticoagulant dose in these patients was not undertaken due to the high risk of hemorrhagic complications. The results of the study of congenital thrombophilia in these patients revealed in one of the patients a mutation in the fibrinogen gene (FGB 455 G > A). This mutation increased fibrinogen concentration in the plasma. In the other patient, a homozygous mutation PAI-1, reduced the level of fibrinolytic activity, and a mutation of the platelet fibrinogen receptor (L33P, T > C), increased the platelets aggregation, were detected.

The subjective assessment of the leg skin color on the side of the injury in the patients of the experimental group found its change from pale to pink by 11.3±0.7 days.

The patients follow-up within six months showed the absence of thrombotic complications.

Discussion

EMS is a relatively new method of VTE prevention. The chronological aspects of the EMS development and implementation are described in detail by Bogachev et al. [16]. The effectiveness of the EMC to accelerate venous blood flow [17] has been proved in the complex treatment of post-thrombotic disease, chronic venous and arterial failure, trophic ulcers [12, 18, 19], reduction the number of VTE in the surgical and trauma patients in the postoperative period [20, 21, 22], treatment of isolated leg fractures [1], prevention of postoperative muscle atrophy [23].

A search for publications on the use of the EMS for multiple trauma by the PubMed within the time frame from 2000 to 2019 by the keywords "electromuscular stimulation" and "electrical muscle stimulation" revealed 247 works. But no one of them was dedicated to VTE prevention after a multiple injury. We could not find any meta-analyses on the issue. A search in the eLIBRARY database showed that in the domestic scientific literature more attention has been paid to the use EMS in the surgical patients [24, 25], although the patients with trauma often have the higher risk of VTE. The only study conducted in trauma patients that we were able to find was devoted to the use of EMS in isolated leg injury [1].

Most researchers consider it appropriate to use mechanical methods (compression knitwear and intermittent pneumatic compression) for VTE prevention, however, they do not provide data on changes in blood flow during their use.

R. Jamieson et al. found that the blood flow in the common femoral vein at rest was 10 cm/s, and in 30 min after removing the compression stockings with a compression force of 18 mm Hg 13.9 cm/s [26]. When applying the method of intermittent pneumatic compression, the blood flow increased by 2.5–3.0 times: from 12 cm/s up to 33–68 cm / s depending on the model of the device used, however, such high rates led to a change in other characteristics of the blood flow [27].

Alencheva et al. found that the rate of the skin damage in the form of hyperemia, trophic disturbances and gangrene after compression knitwear and intermittent pneumatic compression reached 5.9% [28]. In our study, we did not see this side effect after EMS.

The organization of effective VTE prevention in patients with multiple trauma requires coordinated actions and mutual understanding of intensivists, trauma surgeons, vascular surgeons and medical sonographers of all hospitals where the treatment is carried out, as well as the continuity in the implementation of prevention and treatment. As a result of our study, it was not only established the effectiveness of EMS for the prevention of VTE in the patients with multiple lower extremities trauma, but also revealed important practical and organizational features of VUS for this category of patients. Thus, the serious organizational issues impeding the study were the need to transport the patient to an ultrasound room located in an adjacent building (if it is not possible to use a portable scanner), the associated risk of thrombotic mass migration during a patient shift, and the need for the medical sonographer time allocation for unscheduled procedure.

It should be noted that some patients after a multiple lower extremity injury were in the planned orthopedic surgery on large joints. Considering that some authors believed that VTE prevention scheme to minimize the risk of hemorrhagic complications was disputable [29], it is advisable to raise the issue of the possibility to extend the duration of the EMS use until the orthopedic stage of treatment is completed. In the hospital setting the EMS use in the long in-bed patients associated with replacing a power source problems. Thus, there is a need in EMC device powered by the electric network. This would eliminate the possibility of skipping the scheduled procedures due to battery replacement.

The study limitations

1. A relatively small number of observations.

2. The hospitals in which the study was conducted did not work in the compulsory medical insurance system.

3. A study on hereditary thrombophilia was conducted only for the patients with diagnosed lower limb DVT.

The use of the EMS showed the absence of side effects and hemorrhagic complications. The effectiveness of EMS in patients with EF

was achieved due to a statistically significant ($p < 0.001$) increase in the volumetric flow of blood through the deep veins of the lower extremities. Further study of the EMS for the wounded and injured with multiple trauma, the development of optimal schemes for its use, depending on the severity of injuries, will minimize the likelihood of VTE.

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Publication ethics

Patients gave voluntary informed consent to participate in the research study.

The study was approved by the local ethics committee.

Competing interests: The authors declare that there are no competing interests.

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