



**PERCUTANEOUS ELECTRONEUROSTIMULATION IN THE TREATMENT OF
OCCLUSION LESIONS OF ARTERIES OF THE LOWER EXTREMITIES**

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Relevance. Ischemic conditions caused by occlusive-stenotic lesions of the main and peripheral arteries still occupy a significant part in the structure of diseases of the circulatory system. According to the Russian Society of Angiologists and Vascular Surgeons, the overall prevalence of chronic obliterating diseases of the arteries of the lower extremities (COLAE) varies within 3-10%, increasing to 15-20% among patients over 70 years of age. At the same time, the number of patients with severe degrees of ischemia of the affected limb is quite large. For example, 15-20% and according to some authors, 35-64% of patients with COLAE develop critical lower extremity ischemia (CLEI). The main method of treatment for this category of patients should be reconstructive surgery on the vessels. However, its implementation is not always possible due to the usually several levels of vascular occlusion, primarily damage to the distal arterial bed, as well as due to the high risk of surgical intervention. The impossibility of performing reconstructive vascular surgeries leads to a high percentage of primary amputations. Standard conservative therapy in such patients is usually ineffective. The generally accepted course of therapy helps to relieve the symptoms of CLEI in only 15-17% of patients and conservative treatment at the stage of terminal ischemia in 92% of patients does not give a positive result. Treatment of COLAE, including critical ischemia, is today one of the urgent problems of angiology and vascular surgery. Currently, the main role in the treatment of COLAE is given to reconstructive surgeries. It must be recognized that by now the possibilities of standard surgical methods of treating patients with distal forms of arterial bed lesions have been practically exhausted, which leads to a high percentage of amputations in this category of patients, to a low quality of life, to high costs for treatment and rehabilitation. All this dictates the need to improve surgical and complex conservative treatment, develop and implement new methods of treatment and rehabilitation of patients. In this regard, a search is underway for new approaches to solving this problem. In particular, the possibility of using genetic engineering technologies to stimulate angiogenesis in affected limbs, the use of intravascular laser irradiation of blood the use of plasmapheresis with photomodification of blood (E.S. Nazarova et al., 2006), osteotomy, osteotransplantation is being actively discussed. It should be especially noted that in recent years there have been reports of the successful use of electrical stimulation of the spinal cord in the treatment of CLEI. However, the high cost of treatment and implanted systems, the invasiveness of the method and possible complications limit its widespread use. In this regard, research in recent years has been aimed at developing non-invasive and less expensive technologies for electrical stimulation of the spinal cord.



Key words: *transcutaneous electrical neurostimulation, critical lower limb ischemia, chronic obliterating diseases of the arteries of the lower limbs, long-term intra-arterial catheter therapy.*

The aim of the study. To improve the treatment results of patients with chronic lower limb ischemia by using transcutaneous electrical nerve stimulation (TENS) of the spinal cord and lower limbs.

Material and methods. This work presents the results of examination and treatment of 106 patients with COLAE, who were treated in the vascular department and outpatients in the one-day surgical hospital of the 2-clinic of the TMA for the period 2004-2007.

The patients were divided into 2 groups. The control group - 38 patients who received conservative treatment, of which 23 (60.5%) patients with grade IIb ischemia received standard drug therapy, and 15 (39.5%) patients with CLEI used the traditional method of long-term intra-arterial catheter therapy (LIACT).

The main group consisted of 68 patients, who were divided into 3 subgroups according to the nature of the treatment they received. Subgroup 1 included 25 patients with grade IIb ischemia, who received only TENS as treatment. Subgroup 2 included 25 patients (14 with grade IIb ischemia, 11 with CLEI), who received standard drug therapy (SDT) together with TENS. Subgroup 3 included 18 patients with CLEI. They received TENS in combination with long-term intra-arterial catheter therapy (LIACT). No significant differences were found in the patients of these groups in terms of the occlusion level, age, and the presence of concomitant diseases. The criteria for choosing a treatment method for these patients were: impossibility of performing reconstructive surgery, severity of concomitant diseases, and patient refusal of surgery. TENS alone and in combination with other treatment methods was used only after explanation of the method and obtaining patient consent.

In the control group, there were 32 men (84.2%) and 6 women (15.8%). In the main group, there were 53 men (77.9%) and 15 women (22.1%). The age of patients ranged from 21 to 80 years in both groups. The average age in the control group was 56.5 ± 9.4 years, in the main group – 57.6 ± 8.9 years.

According to the Fontaine-Pokrovsky classification, grade IIb lower limb ischemia was observed in 23 (60.5%) patients in the control group, grade III ischemia in 4 (10.5%), and grade IV ischemia in 11 (29.0%) patients. In the main group, grade IIb ischemia was observed in 39 (57.3%) patients, grade III ischemia in 14 (20.6%), and grade IV ischemia in 15 (22.1%).

In the control group, 29 (76.3%) patients and 48 (70.9%) patients in the main group had various concomitant diseases.

It should be noted that 22 (55%) patients in the control group and 39 (57.3%) in the main group had previously undergone reconstructive, palliative, and organ-removing surgeries for lower limb ischemia. During the examination and treatment, patients underwent general clinical tests: general blood and urine tests, biochemical blood test, coagulogram, blood sugar, blood clotting time were determined. Before and after treatment, patients underwent: analysis of the dynamics of pain syndrome, ultrasound Dopplerography of the arteries of the lower extremities, measurement of regional systolic pressure (RSP) with calculation of the ankle-brachial index



(ABI), measurement of oxygen saturation in tissues - pulse oximetry (SpO₂), blood rheology study, study of the microcirculatory bed by biomicroscopy. 88% of patients included in our work earlier or upon admission underwent angiographic studies. The patients underwent transcutaneous electrical stimulation of the vertebral, paravertebral regions at the L1-L5 level and lower extremities with a low-frequency short-pulse high-amplitude current using the DiaDens-T electroneurostimulator (OOO RCART, Russia, Yekaterinburg). The stimulation duration was on average 20-35 minutes, the pulse frequency was 77-200 Hz. The course of treatment was 8-15 days, daily. Stimulation was performed in a lying position, first the lumbosacral region, then the lower extremities.

Results. All 23 patients with grade IIb ischemia received SDT for an average of 8.1 ± 1.1 days. Drug therapy included intravenous rheopolyglucin, trental, intramuscular nicotinic acid, subcutaneous heparin or fraxiparin, and thrombocardium or aspirin at a dose of 100 mg per day. When analyzing the effectiveness of SDT, it was noted that 4 (17.4%) patients out of 23 could be transferred to the previous group of ischemia grade - grade IIa (result +2 points) after drug treatment. In 15 (65.2%) of them with pain in the calf muscles of the affected limb when walking 50-100 m, after treatment they walked up to 200 m without pain, the feeling of numbness and coldness decreased or completely disappeared, but the ABI increased by less than 0.1 (result +1 point). Of the 23 patients, 4 (17.4%) did not show clinical improvement and within a year 2 (8.7%) of them underwent high amputation of the limb as a result of the development of critical ischemia. In patients receiving SDT with grade IIb ischemia, after treatment, ABI increased on average from 0.61 ± 0.08 to 0.67 ± 0.07 ($t=0.5$, $p>0.05$), and SpO₂ from 92.0 ± 0.01 to 94.0 ± 0.01 ($t=1.4$, $p>0.05$)

When analyzing the effectiveness of LIACT, it was found that 11 (73.3%) of 15 patients showed clinical improvement in their condition already on days 2-3 (result +1 point). Among patients with grade IV ischemia, 4 (26.6%) underwent high amputation of the affected limb due to ischemia progression on days 1-3 of LIACT for vital indications. In the remaining 11 (73.4%) patients, CLEI was relieved. 4 (26.7%) of them, after the appearance of the demarcation zone against the background of LIACT, economical amputations were performed and the supporting function of the leg was preserved.

However, remission of critical ischemia in 4 patients (26.6%) was short-lived and within a year they underwent high amputation, 1 of them died after amputation from myocardial infarction. As a result, within a year of 15 patients with CLEI who received LIACT, 8 (53.3%) underwent high amputation. The limb was preserved within a year in 47.7% of patients.

The initial ABI in these patients was 0.27 ± 0.1 , after treatment it increased to 0.57 ± 0.1 ($t=1.6$, $p>0.05$). A reliable increase in oxygen saturation in the tissues of the limb was noted, which indicates a significant improvement in the blood supply to the legs. SpO₂ from the initial, which was 82.3 ± 2.4 after treatment increased to 91.0 ± 3.4 ($t=2.07$, $p<0.05$). All patients in subgroup 1 were treated with TENS alone for 7 to 12 days, an average of 7.6 ± 0.9 days. Changes in the condition of patients who received TENS alone were noted on days 3-4.

In 5 (20.0%) patients in subgroup 1, both clinical and hemodynamic improvements were noted (result +2 points). In 17 (68.0%) patients, a change in ABI of less than 0.1 and minor clinical improvement (result +1 point) were noted. In 3 (12.0%) patients, the pain-free walking distance



did not change after treatment, the feeling of numbness and coldness decreased, but did not disappear completely, and in these patients, the RSP on the arteries of the lower leg did not change (unchanged). In 2 (8.0%) patients, a limb was amputated within 1 year due to progression of ischemia. The initial ABI in this subgroup was 0.56 ± 0.07 , after treatment it increased to 0.63 ± 0.07 ($t=0.73$. $p>0.05$). SpO₂ increased from 92.0 ± 0.008 to 95.6 ± 0.006 ($t=3.06$. $p<0.01$).

Patients of the 2nd subgroup received TENS in combination with SDT for 7 to 15 days, an average of 9.08 ± 2.02 days.

When analyzing the treatment results of patients of the 2nd subgroup, out of 14 patients with grade IIb ischemia, 7 (50%) of them showed an increase in ABI by more than 0.1, the pain-free walking distance increased to 300-400 m, the feeling of numbness and coldness completely disappeared or decreased dynamically (result +2 points). An increase in ABI by more than 0.1, but no clinical improvement or vice versa was noted in 6 (42.8%) patients (result +1 point). In 1 (7.2%) patient, neither clinical nor hemodynamic improvement was noted (unchanged). ABI in 14 patients of this subgroup increased on average from 0.52 ± 0.03 to 0.62 ± 0.03 ($t=2.0$. $p<0.05$), SpO₂ increased from 91.0 ± 0.01 to 95.03 ± 0.01 ($t=2.06$. $p<0.05$). 11 patients of subgroup 2 with CLEI received TENS together with SDT according to indications, the duration of the treatment course was on average 10.0 ± 2.9 days. As a result of treatment, 5 (45.4%) patients out of 11 showed an increase in ABI by more than 0.1, disappearance of pain at rest, a tendency for ischemic ulcers to heal, the appearance of a demarcation line in the gangrene zone (result +2 points) and 2 patients underwent economical amputations. Insignificant clinical improvement and an increase in ABI by more than 0.1 (result +1 point) were noted in 4 patients (36.4%), 2 of them began to do without analgesics, however, the remission was short-lived and within a year these patients lost the limb. The remaining 2 (18.2%) patients did not experience either clinical or hemodynamic improvement and they underwent amputation of the lower limb at the thigh level (unchanged). One patient died of a repeated myocardial infarction a month after treatment. The limb was preserved within a year in 45.5% of patients. The average ABI value in patients of subgroup 2 with CLEI was 0.36 ± 0.06 , after treatment it increased to 0.55 ± 0.05 ($t=2.13$. $p<0.05$), SpO₂ increased from 90.0 ± 0.01 to 94.1 ± 0.01 ($t=2.02$. $p<0.05$).

18 patients with CLEI who made up subgroup 3 received LIACT with TENS. LIACT was performed from 4 to 8 days, on average 6.61 ± 0.6 days. When analyzing the effectiveness of treatment in this subgroup, it was revealed that 15 (83.3%) patients showed clinical improvement on days 3-4 - pain decreased or disappeared, local skin temperature increased, cyanosis passed, edema completely subsided, sleep improved, a demarcation zone appeared (result +1 point), in connection with which 3 (16.6%) patients underwent economical amputations. In 3 (16.6%) patients, due to progression of ischemia on days 3-4 of treatment, high amputation of the limb was performed for vital indications. During the year, 2 more (11.1%) patients lost a limb, 2 (11.1%) underwent Sharp amputation. 1 (5.5%) patient aged 83 died of recurrent myocardial infarction 2 months after discharge. As a result, during the year, out of 18 patients with CLEI who received LIACT in combination with TENS, 5 (27.7%) patients underwent high amputation, the remaining 13 (72.3%) patients retained the limb.

ABI in these patients increased from 0.01 ± 0.02 to 0.5 ± 0.18 ($t=2.5$. $p<0.05$), and SpO₂ from 84.0 ± 0.03 to 91.4 ± 0.01 ($t=2.3$. $p<0.05$). When comparing the treatment results of patients with grade IIb ischemia in the control and main groups, it was noted that the results of subgroup



1 were better than the results of patients receiving standard drug therapy, and the percentage of treatment results in subgroup 2 was much better than in patients in the control and subgroup 1 (Table 1).

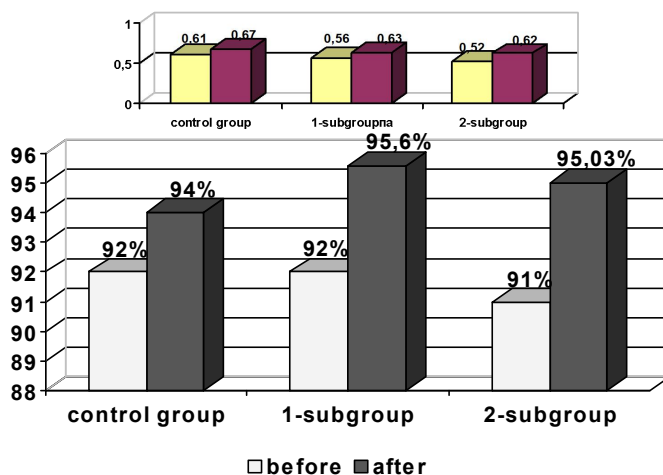
Table 1

Comparative evaluation of treatment results in patients with grade IIb ischemia.

	Treatment Method	Control group	Main group	
			1-subgroup	2-subgroup
		SDT (n=23)	TENS (n=25)	TENS+SDT (n=14)
+2	Moderate	4 (17,4%)	5 (20,0%)	7 (50%)
+1	improvement	15 (65,2%)	17 (68,0%)	6 (42,8%)
0	Minimal	4 (17,4%)	3 (12,0%)	1 (7,2%)

When analyzing hemodynamic changes in patients with grade IIb ischemia, a significant increase in ABI was noted only in subgroup 2 (Fig. 1), and SpO2 in patients in subgroups 1 and 2 (Pic. 2).

Pic. 1. ABI before and after treatment in patients with grade IIb ischemia





Pic.2 SpO2 before and after treatment in patients with grade IIb ischemia.

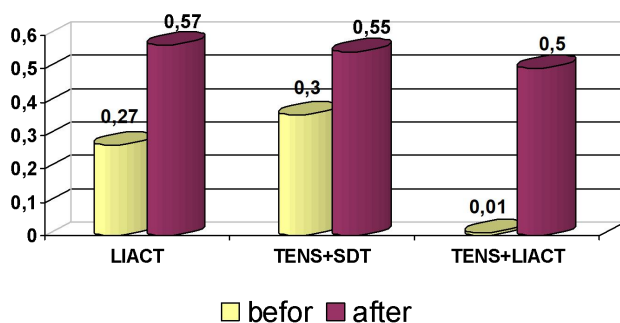
In a comparative analysis of the immediate results of treatment of patients with CLEI, a better result was noted in patients who received TENS in combination with LIACT (Table 2).

Table 2

Comparative assessment of the immediate results of conservative treatment of patients with CLEI.

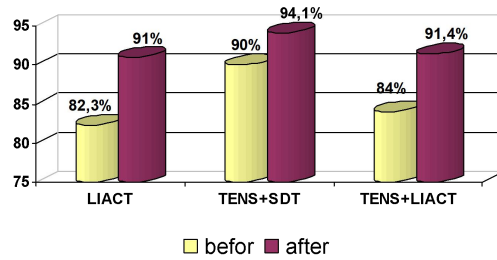
	Treatment Method	Control group	Main group	
			2-subgroup	3-subgroup
		LIACT (n=15)	TENS+SDT (n=11)	TENS+LIACT (n=18)
+2	Moderate	7 (46,6%)	5 (45,4%)	12 (66,6%)
+1	improvement	4 (26,7%)	4 (36,4%)	3 (16,7%)
0	Minimal	4 (26,7%)	2 (18,2%)	3 (16,7%)

Analysis of hemodynamic changes in patients with CLEI showed a significant increase in ABI in patients of the main group (Fig. 3), and SpO2 in patients of the main group and in patients receiving LIACT in the control group (Pic. 4)





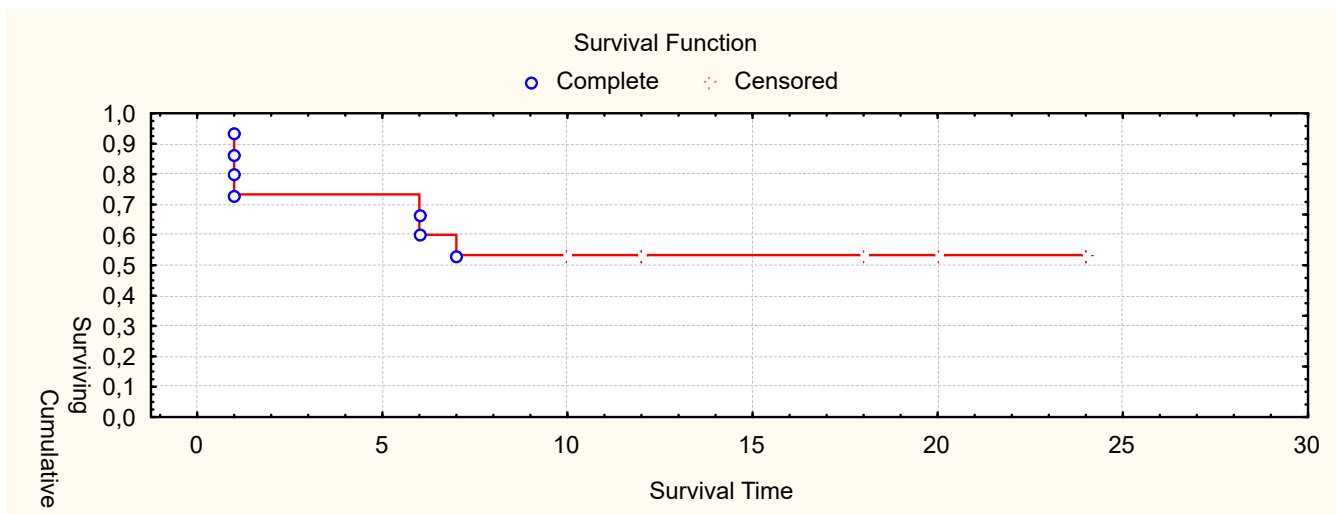
Pic. 3. ABI before and after treatment in patients with CLEI.



Pic. 4. SpO2 before and after treatment in patients with CLEI.

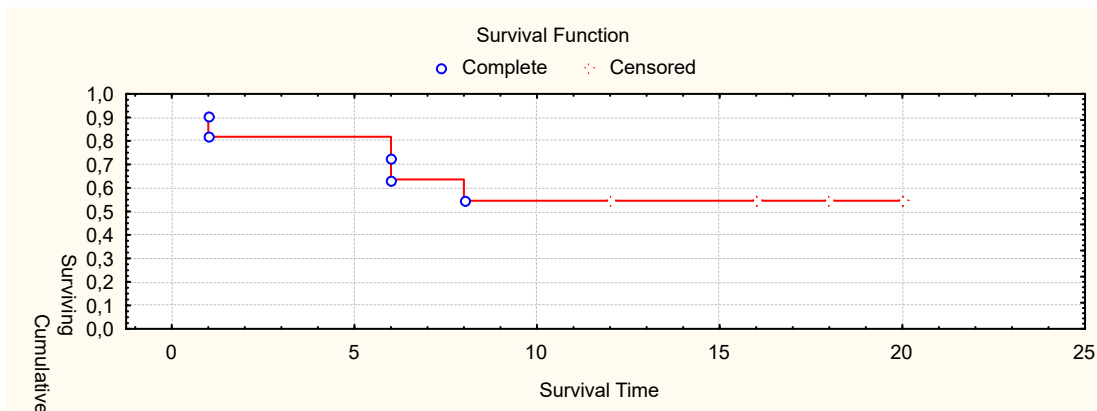
In a comparative analysis of the long-term results of patients with critical ischemia of the lower extremities using the actuarial method (life table method), the number of preserved limbs is higher in subgroup 3 (Pic. 5).

LIACT (n=15)



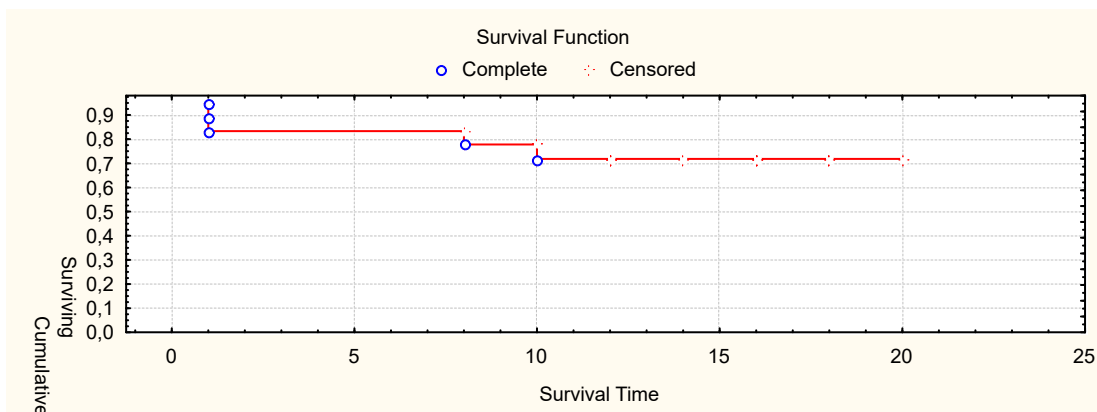
months months

TENS+SDT (n=11)



months

TENS+LIACT (n=18)



months

Pic. 5. Actuarial curves of preserved limbs in patients with critical lower limb ischemia.

The studies we conducted in patients with CLEI showed a significant violation of the initial parameters of the rheological properties of the blood in both groups. After the treatment, a decrease in blood viscosity was revealed in the control and main groups. A significant decrease in blood viscosity was observed in patients receiving TENS. At values of 4, 8, 12, 16 mm H₂O under applied hydrostatic pressure, blood viscosity in patients receiving SMT decreased by 1.26; 1.26; 1.23 and 1.32 times, in patients receiving LIACT by 1.21; 1.13; 1.22 and 1.32 times, in patients receiving TENS by 1.27; 1.41; 1.53 and 1.61 times, in patients receiving TENS+SDT by 1.22; 1.3; 1.34 and 1.41 times and in patients receiving TENS + LIACT by 1.3; 1.24; 1.3 and 1.39 times compared to the baseline data.

A decrease in blood viscosity in patients in both groups led to an acceleration of the blood shear rate at all hydrostatic pressure values, especially in patients of subgroup 1. Thus, the shear rate at hydrostatic pressure values of 4, 8, 12 and 16 mm H₂O increased in patients receiving SDT by 1.25; 1.28; 1.34 and 1.47 times, in patients receiving LIACT by 1.23; 1.14; 1.22 and 1.34 times, in patients receiving TENS by 1.28; 1.33; 1.43 and 1.58 times, in patients receiving TENS



+ SDT by 1.18; 1.31; 1.32 and 1.54 times and in patients receiving TENS + LIACT by 1.28; 1.26; 1.28 and 1.4 times compared to the initial data.

A significant decrease in blood viscosity in patients who received TENS, especially in patients of subgroup 1, prompted a study of the effect of electrical neurostimulation on the magnitude of the membrane charge of erythrocytes.

When determining the electrophoretic mobility (EPM) of erythrocytes and the zeta potential in patients who received only TENS, statistically significant shifts were revealed. In this case, the EPM of erythrocytes, initially $0.97 \pm 0.05 \mu\text{m/s-1/v-1/cm}$, after TENS increased to $1.15 \pm 0.05 \mu\text{m/s-1/v-1/cm}$ ($t=2.4$, $p<0.05$), and the zeta potential increased from $13.58 \pm 0.76 \text{ mV}$ to $16.23 \pm 0.77 \text{ mV}$ ($t=2.4$, $p<0.05$).

To analyze the state of microcirculation, we studied the morphological characteristics of the capillaries and the velocity of erythrocyte movement through the capillaries. In 37% of patients in the control group and in 47% of the main group, an increase in capillary density and an increase in the diameter of the capillaries is noted, but statistically insignificant. A reliable increase in the velocity of erythrocyte movement after treatment is noted in patients receiving TENS + SDT compared to patients receiving only SDT and in patients receiving TENS + LIACT compared to patients receiving only LIACT; in patients receiving only TENS, an increase in the diameter of the capillaries is noted on average from $9.1 \pm 0.6 \mu\text{m}$ to $10.6 \pm 1.4 \mu\text{m}$ and an increase in the velocity of erythrocyte movement from 0.132 ± 0.03 to 0.151 ± 0.05 (Table 3)

Table 3

Capillary diameter and red blood cell velocity.

	Treatment method	Diameter (μm)		Speed (mm/sec)	
		befor	after	befor	after
Control group	SDT	$8,4 \pm 0,5$	$10,2 \pm 1,3$	$0,124 \pm 0,03$	$0,143 \pm 0,05$
	LIACT	$8,7 \pm 0,3$	$11,3 \pm 0,4$	$0,091 \pm 0,02$	$0,174 \pm 0,04^*$
Main group	TENS	$9,1 \pm 0,6$	$10,6 \pm 1,4$	$0,132 \pm 0,03$	$0,151 \pm 0,05$

Continuation of table 3



TENS+	SDT	8,5±0,2	11,1±0,5	0,114±0,02	0,157±0,04*
TENS+	LIACT	8,8±0,3	12,3±0,3	0,098±0,02	0,221±0,03*

Note: * - differences between indicators before and after treatment are reliable ($p < 0.05$).

To summarize, it should be noted that after SDT, positive immediate results were noted in 82.6% of patients with grade IIb ischemia. However, when analyzing the long-term results, it was revealed that 17.4% of patients developed CLEI within a year. The quality of life in 21.7% of patients was assessed as unsatisfactory.

Significantly better results were obtained in patients using TENS. In the group of patients with stage IIb ischemia, who were treated with TENS in combination with SDT, 92.8% of patients showed positive dynamics, within a year only 7.1% developed CLEI, and in terms of quality of life, only 14.3% of patients consider their life unsatisfactory. Among patients with CLEI who received pure LIACT, 73.4% showed an improvement in their condition after treatment, 26.6% of patients underwent primary amputations, but within a year only 46.7% of patients preserved their limb.

In patients with CLEI, who received TENS in combination with LIACT, better results are noted than in patients who received only LIVACT as treatment. Improvement of the condition after treatment in this group was achieved in 83.3% of patients, primary amputations were performed in 16.6% of patients, and 72.3% of patients preserved their limbs within a year (Pic. 4.9).

The results of using TENS in its pure form in patients with grade IIb ischemia are practically no different from the results of SDT. Positive dynamics were noted in 88.0% of patients, within a year 12.0% developed CLEI, and 8.0% underwent high amputation.

Analysis of the obtained results led us to the conclusion that the use of TENS in combination with SDT in patients with grade IIb ischemia and the use of TENS in combination with LIACT in patients with CLEI is much more effective than their use in their pure form.

Based on the work performed, we have developed and proposed an algorithm for conservative treatment of patients with CLEI when surgical treatment is impossible.

Conclusion. Thus, TENS is indeed an effective method of treating patients with CLEI. The mechanism of action of TENS is associated with several points. Firstly, TENS leads to the removal of spasm and dilation of peripheral vessels, which was proven in our studies by Doppler. This leads to a decrease in peripheral resistance and an increase in blood flow to the distal parts of the limb.



Secondly, an increase in blood flow to ischemic tissues also occurs due to improved microcirculation. At the same time, its improvement occurs due to a decrease in blood viscosity and restoration of capillary circulation (an increase in the density and diameter of capillaries and an increase in the speed of erythrocyte flow). A decrease in blood viscosity is directly related to an increase in the negative charge of erythrocytes and an increase in their electrophoretic mobility.

In the framework of evidence-based medicine, it can be clearly said that TENS should be included in the complex of conservative treatment of patients with CLEI especially in cases where surgical treatment is impossible.

When using TENS, there is an improvement in blood supply to the lower extremities. This occurs due to: a) reflex vasodilation; b) an increase in the blood flow rate in arteries, capillaries and venules; c) a decrease in blood viscosity and erythrocyte aggregation. TENS leads to an increase in the zeta potential of erythrocyte membranes and the EPM of erythrocytes, which, in turn, decrease blood viscosity.

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