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CLINICAL STUDY ON THE EFFICACY OF THE DEVICE FOR ELECTROSTIMULATION WITH BIO-CONTROL IN REHABILITATION OF PATIENTS WITH MOTOR DEFICIENCY SUFFERED FROM CEREBRAL STROKE

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Vascular diseases of the brain nervous system are one of the main problems in the modern and, as predictions show, future medicine. At present, great importance in the processes of rehabilitation after a stroke is attached to neuroplasticity of the brain. This approach is implemented in a new class of TRENAR® electronic devices for biologically adequate movements control. The purpose of the study was to assess the functional capabilities of the TRENAR-01® software device in the restoration of voluntary movements in patients with impaired central motor neuron function due to the past acute cerebrovascular event. Clinical neurological examination and treatment of 30 cerebral stroke patients were carried out. 15 electrical stimulation procedures were performed with the TRENAR-01® device. After treatment in the group of patients with acute cerebral circulatory disturbance (23 patients) no effect on the motor deficiency regression was only observed in one case; in patients with long-term consequences of cerebral circulatory disorders (7 patients) there was a positive tendency in motor deficiency reducing. The efficacy of training the damaged limb movements according to the program, proceeding from voluntary reductions of symmetrical healthy muscles in paralyzed patients is reliably proved ($p < 0.005$). The "Donor" program is expedient at the early stages of rehabilitation in the absence of a cognitive disorder in the patient.

Key words: cerebral stroke, rehabilitation, motor deficiency, "Trenar-01" device, "Donor" program.

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КЛІНІЧНЕ ДОСЛІДЖЕННЯ ЕФЕКТИВНОСТІ МЕТОДУ ЕЛЕКТРОСТИМУЛЯЦІЇ З БІОКЕРУВАННЯМ У РЕАБІЛІТАЦІЇ ХВОРИХ З РУХОВИМ ДЕФІЦИТОМ ПІСЛЯ МОЗКОВОГО ІНСУЛЬТУ

Судинні захворювання нервової головного мозку – одна з основних проблем сучасної та, як показують прогнози, майбутньої медицини. В даний час велике значення в процесах реабілітації після інсульту надають нейропластичності мозку. Цей підхід реалізовано у новому класі електронних апаратів біологічно адекватного керування рухами ТРЕНАР. Мета дослідження: оцінювання функціональних можливостей програмного апарата ТРЕНАР-01® у відновленні довільних рухів пацієнтів з порушенням функції центрального мотонейрона внаслідок перенесеного гострого порушення мозкового кровообігу. Проведено клініко-неврологічне обстеження та лікування 30 хворих на мозковий інсульт. Проводилось 15 процедур електростимуляції на апараті ТРЕНАР-01®. Після проведеного лікування в групі пацієнтів з гострим порушенням мозкового кровообігу (23 хворих) відсутність впливу на регресію рухового дефіциту спостерігалась тільки в одному випадку; у пацієнтів з віддаленими наслідками перенесеного порушення мозкового кровообігу (7 хворих) спостерігалася позитивна динаміка у зменшенні рухового дефіциту. Достовірно доведена ($p<0,005$) ефективність тренувань рухів пошкодженої кінцівки за програмою, що виходить від довільних скорочень симетричних здорових м'язів у паралізованих хворих. Програма «Донор» доцільна на ранніх етапах реабілітації при відсутності у пацієнта порушень когнітивної сфери.

Ключові слова: мозковий інсульт, реабілітація, руховий дефіцит, апарат «Тренар-01», програма «Донор».

The work is a fragment of the research project "Improving the prevention, treatment and rehabilitation of patients with hypertension and coronary heart disease with comorbid pathology in outpatient and inpatient settings", state registration No. 0119U001045.

Despite some advances in the diagnosis and treatment of vascular diseases of the brain, which include ischemic stroke, the relevance of this problem is not reduced. Its importance is due to its high prevalence, high frequency of disability and mortality. According to the World Health Organization, about 6.3 million people die of stroke every year worldwide (10.8% of all deaths). The rate of disability from this disease is 3.2 per 1 thousand of population, with 1/3 of them being of working age [7, 15]. Thus, the consequences of a stroke are both a medical-social and an economic problem.

Currently, great importance in the rehabilitation process after stroke is attached to the neuroplasticity of the brain. It has been established that the brain contains self-replicating stem cells, which precursors of neurons, astrocytes and oligodendrocytes can be formed of, which are able to migrate, differentiate and integrate in the brain [12, 13]. The idea that nerve cells do not restore was rejected. The formation of new neuronal structures occurs in the adult brain with increasing physical activity, hypoxia, stress, endogenous

mental disorders, learning. Stimulation of neurogenesis is also observed in cerebral ischemia, trauma, the initial stages of neurodegenerative pathology [13].

The basis of neuroplasticity is the activation of previously uninvolved horizontal connections in the cerebral cortex, as well as changes in synaptic transmission [14].

Successful implementation of neuroplasticity is only possible with the preservation of subcortical links. A study of cerebral strokes showed that white matter lesions develop a persistent functional deficit [11]. The concept of neuroplasticity underlies the spatio-temporal functioning of the brain, modulations of functionally dynamic glio-neuro-synaptic networks under the influence of external and internal stimuli. It is proved that the functional organization of the neural structures in the cerebral cortex may be prone to modulation in the process of learning, as well as damage to the peripheral or central nervous system [10]. It was found that training in motor skills, depending on its intensity, can expand the cortical representation area of the muscles involved. It was also shown that when the motor area is damaged, a number of rehabilitation measures can reorganize the neuronal structure of the intact cortex adjacent to the focus, which plays an important role in restoring motor functions by activating structures of the intact cortex [5]. Activation of areas located in close proximity to the main motor area, indicates the recruitment of areas adjacent to the motor cortex to facilitate learning processes. Neurons working together form an associative link with each other, which is amplified. If the training continues, the respective links are strengthened. Cessation of training weakens the links in neurons and the brain needs to make room for new neural networks. The brain forms new habits and links within a week after starting regular training, but without training the acquired skill quickly disappears [6].

Modern tactics of restoring motor functions is to gradually refuse the drug treatment and inclusion into rehabilitation without drug methods of rehabilitation therapy. The regions adjacent to the damaged area take over its functions and connect the contralateral hemisphere to participate in the restoration [8, 9].

One of the methods of patients' rehabilitation after stroke is the method of electrical stimulation. There is a method of artificial movements correction by means of multichannel functional electric stimulation of muscles according to the natural program of human movements [14].

The described approach is implemented in a new class of electronic systems of biologically adequate motion control, represented by two modifications of digital medicine electronic devices: an apparatus for electrical stimulation with biocontrol and an apparatus for electrical stimulation with biological feedback [2].

The purpose of the study was to assess the functionality of the software apparatus with biologically adequate movement control for electrical stimulation with biocontrol for voluntary movements restoration in patients with central motoneuron dysfunction as a result of acute cerebrovascular event.

Materials and methods. Clinical and neurological examination of 30 patients with cerebral stroke was performed, including 22 patients with acute cerebrovascular event (ACVE) of the ischemic type (13-20 points by the NIHSS scale) – group 1, 8 patients with the ACVE year-old consequences (8-12 points by the NIHSS scale) –group 2. All patients had a persistent neurological deficit in the form of voluntary movement disorders with formation of central hemiparesis and hemiplegia.

All patients received etiotropic and symptomatic neurometabolic therapy according to the existing protocols.

All patients were subjected to the method of software electrical stimulation with biocontrol on the basis of the "Trenar-01" device for rehabilitation after stroke. The use of the "Trenar-01" device in 22 patients began from the 10th day of treatment (provided stable hemodynamic parameters), in 8 patients – from the moment of admission to the department. The course of electrical stimulation for both groups lasted 15 days. The duration of the procedure ranged from 15 to 20 minutes and depended on the body's response.

Registration of indices according to expert scales and electromyogram (μV) was performed at the initial examination (during hospitalization), on the 3rd, 6th, 9th, 12th, 15th procedures of electrical stimulation. Electromyogram parameters were recorded from both the affected and healthy extremities.

Statistical processing was performed using Microsoft Excel software package; mathematical - using STATISTICA 6.0 standard statistical packages.

Results of the study and their discussion. There are several programs of electrical stimulation with the "Trenar-01" device: "Synthesis", "Donor", "Memory", "Auto-memory". In the rehabilitation of patients with impaired voluntary movements who suffered a cerebral stroke with the formation of persistent neurological deficit in the form of central lesions of the corticomuscular pathway, with the formation of hemiparesis and hemiplegia, the "Donor" program was used. According to this program, the source of control influence for stimulation is the signal of the current integrated electromyogram (EMG) from the voluntary contraction of the healthy limb's healthy muscle, symmetrical to the affected one (functionally uninvolved in the stimulation process).

During the procedure, an electromyogram is "read" by the contractions of a healthy donor muscle, processed by the device, and in the form of a program to control the effects of electrical stimulation is applied to the affected limb, which causes its motor activity. To start working in the "Donor" mode, it is necessary to attach the electrodes to the appropriate muscle groups of a healthy limb, namely, the electrodes are fixed in the upper third of the forearm above the extensor muscle of the hand and fingers, for the lower limb – the first electrode is attached to the upper third. shin over the anterior tibial muscle, the second electrode is fixed in the external popliteal fossa in the area of the fibular nerve, then the device is turned on and according to the instructions for use of the "Trenar-01" device, a session of electrical stimulation treatment of symmetrical affected muscle is carried out to train movements of the affected upper or lower limbs.

Distribution of patients by age and gender is presented in table 1.

Table 1

Characteristics of patients groups by age and gender

Characteristics of patients	Group 1	Group 2	Total	Criterion χ^2
Number of patients/ group	22; 100 %	8; 100 %	30; 100 %	
Men	18; 81.8%. (63.4%-94.7%)% *****	3; 37.5% (9.5%-71.3%)% *	21;70% (51.9-85.3)% *****	P=0.051
Women	4;18.2% (5.3-36.6)% *****	5; 62.5% (22.-94.3)% *	9; 30% (14.7-48.1)% *****	P=0.051
Age, years Me (95% CI)	61 (55-65)	47 (28-69)	61 (51-69)	P=0.685

Note: * – determination of the particles' confidence interval (% CI), Fisher's angular transformation, integral estimation, Marascuilo-Lyakh-Guryanov procedure for multiple comparison by parts.

At the appropriate amplitude of the stimulation signal, the patient practically repeats the movements of his own healthy limb with the affected one. The patient independently controls and changes the training load, rhythm and strength of muscle contractions that are trained. The role of motivation in the process of afferent synthesis of voluntary contractions by a healthy limb and forced contractions by the damaged one is growing [1].

In order to assess the severity of neurological deficit in patients the following scales were used:

- Stroke Severity Scale of the US National Institutes of Health (NIHSS);
- Modified assessment scale of neurological motor deficit severity in patients who have suffered a stroke (developed by the authors using the Scandinavian stroke scale). The scale more effectively reflects the severity of neurological motor deficit.

Modified assessment scale for the neurological motor deficit severity in patients who have suffered a stroke.

1. Arm, strength of movements (assessed only on the affected side):
   Lifting with normal force – 6;
   Lifting with reduced force – 5;
   Raising the arm with bending the elbow – 4;
   Arm movements are only possible in the plane of support (without overcoming gravity) – 2;
   paralysis – 0.
2. Hand, strength of movements (assessed only on the affected side):
   Normal force – 64
   Reduced force of movement is preserved to the full extent – 44
   Some hand movements are preserved, but the fingers cannot be brought to the palm – 24
   Paralysis – 0.
3. Leg, strength of movements (assessed only on the affected side):
   Normal force – 6;
   Lifting a stretched leg with reduced force – 5;
   Lifting the leg with bending the knee – 4;
   Leg movements are possible only in the plane of support (without overcoming gravity) – 2;
   Paralysis – 0.
4. Muscle tone, degree of increase (assessed only on the affected side):
   Slight increase in muscle tone, which is manifested in the initial tension and rapid subsequent relief – 5;
   Slight increase in muscle tone, manifested by muscle tension less than in half of the passive movements total volume – 4;
   Moderate increase in muscle tone throughout the whole volume of passive movements, however, passive movements are easily carried out – 3;
   Significant increase in muscle tone, passive movements are difficult to carry out – 2;

The paretic part of the limb cannot be completely bent or unbent (extensor or flexor contracture, respectively) – 0.

The obtained data correspond to the following severity of neurological motor deficit:

23 – no disorders of voluntary movements;

18 – paresis of mild severity;

13 – paresis of moderate severity;

8 – deep paresis;

0 – plegia

In addition to the integrated quantitative assessment of the motor function deficit dynamics by expert scales, the dynamics of muscle strength was monitored by electromyogram (μV). For such an assessment, a technique was proposed that uses the technical capabilities of the "Trenar-01" device. The method of assessing muscle strength by electromyogram by the "EMG, dB" scale was developed by a researcher at the International Center Ivanov V.V.

Registration of indices according to expert scales and electromyogram (μV) was performed at the initial examination (during hospitalization), on the 3rd, 6th, 9th, 12th, 15th procedures of electrical stimulation. Electromyogram parameters were recorded from both the affected and healthy extremities.

As a result of the treatment, it was found that the indices of EMG, μV in both healthy and affected limbs increased (table 2).

Table 2

Dynamics of EMG, μV indices (Me (CI 95%) in the process of treatment procedures with the "Trenar-01" device, "Donor" program

Study stages	Initial examination	Procedure 3	Procedure 6	Procedure 9	Procedure 12	Procedure 15
EMG, μV healthy	126 (102-170)*	126(102-170)*	155(119-186)*	126(120-186)	168(119-186)*	168(119-186)
EMG, μV damaged	68(42– 102)*	85(42-102*)	93(68-136)*	120(69-132)	105(68-124)*	105(85-155)

Notes: * - statistically significant differences in EMG voltage in healthy and affected limbs by the Kruskal-Wallis test ($p \leq 0.01$), by the Dunn test ($p < 0.05$).

As can be seen from the presented data, in the process of treatment the strength and function of stimulated muscles increase, which permits to quickly normalize static and motor disorders, as well as approximates to the correct way of walking in patients with the ACVE consequences.

The current stage of rehabilitation technologies development for post-stroke movement training based on myoelectrostimulation is characterized by a biologically adequate approach. The concept of "adequacy" is regarded as an individual criterion for optimal movements formation and optimal reserve mobilization at different stages of recovery [6].

Based on processing and conversion of electromyographic (EMG) signals into light and sound informative signals, the theory of "figurative (visual and auditory) awareness" of muscular activity by visual and auditory analyzers of the cerebral cortex was developed. As a result of this conversion, EMG signals characterizing the key parameters of muscle activity (strength and speed of muscle contraction), previously unavailable, became available to consciousness in the form of "visual and auditory images" [1]. This permitted to activate additional reserves of the cortex motor area to restore motor functions.

It is known that the motor area, which is the cortical department of the proprioceptive sensory system, is simultaneously a place of projections convergence from all other sensory zones of the cortex and as a higher integration department of the mammalian brain is the "central apparatus of movement". Using not only the method of software electrical muscles stimulation in movement control systems, but also the method of biological feedback, as well as a combination of these methods helps to set movements in interaction with visual, auditory analyzers, permits to expand associative links between new functional formations that begin playing the role of lost structures in the patient's own movement control system. The method of biological feedback – visual and auditory, which is used both in parallel with other methods and as an independent method, permits to carry out conscious control of the training task, contributes to the efficacy of rehabilitation measures.

Programs such as "Donor" or "Threshold stimulation", "prepare" and make the damaged motor area more susceptible to control effects, enhance the efficacy of afferentation as the main way to form a new reflex system of supraspinal movement control instead of lost or distorted with pathology [1].

The study of the neurological deficit severity by the scales showed its reliable reduction, starting with the 9th procedure (table 3).

Table 3

Changes in the neurological deficit of patients in the dynamics of treatment (Me (CI 95%)

Scales	Initial exam.	Procedure 3	Procedure 6.	Procedure 9.	Procedure 12	Procedure 15
NIHSS	10 (6-15)*	9(6-14)	6 (5-11)	4 (2-7*)	4 (2-6)*	3(2-4*
MOSH n.d.	12 (5-13)**	12(6-15)	13(9-15)	17(11-18)**	18(17-20)**	18(16-20)**

Note: * - statistically significant differences in the number of points by the NIHSS scale according to the Kruskal-Wallis test ($p \leq 0.001$), by the Dunn test ($p < 0.01$); ** - statistically significant differences in the number of points by the MOSH n.d. scale according to the Kruskal-Wallis test ($p \leq 0.02$), by the Dunn test ($p < 0.05$).

According to studies, it can be concluded that in the group of patients with ACVE (23 patients) no effect on the motor deficit regression was only observed in one case when ACVE origin was of cardioembolic nature (with contraindications to systemic thrombolysis), in patients with long-term ACVE consequences (7 patients) there was a positive tendency in reducing motor deficit. The efficacy of training the injured limb's movements according to the program, which results in voluntary contractions of symmetrical healthy muscles in paralyzed patients, is reported by foreign researchers [3, 4, 15]. The "Donor" program is appropriate at the early stages of rehabilitation in the absence of the patient's cognitive impairment.

Conclusions

1. The use of the "Trenar-01" device for electrical stimulation with biocontrol, "Donor" mode in the rehabilitation of patients with motor deficits who have suffered a cerebral stroke, is appropriate to reduce the degree of paresis of the affected extremities and to restore voluntary movements.

2. The course of electrical stimulation by means of the "Trenar-01" device must protract at least 15 days.

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