

MINISTRY OF HEALTH
OF THE RUSSIAN FEDERATION

Pavlov First Saint Petersburg
State Medical University

**USE OF
ELECTROSTIMULATOR
ABP-051
FOR NORMALIZATION
OF BLOOD PRESSURE
IN CLINICAL PRACTICE**

METHODICAL GUIDELINES

St. Petersburg
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The Guidelines for the use of physical therapy device ABP-051 intended for blood pressure management in patients with arterial hypertension and hypotension with the method of transcutaneous electric stimulation include the set of methods in which low-frequency pulse currents are used.

These treatment methods introduced to the present recommendations have demonstrated high efficacy in clinical practice both in monotherapy and potentiate the baseline drug therapy.

These Guidelines are intended for general practitioners, cardiologists, physiotherapists, specialists in physical and rehabilitative medicine and may be followed by patients after consultation with their medical specialists.

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■ INTRODUCTION

Nowadays, hypertensive disease (HD) is the one of most frequent cardiovascular disorders. The relevance of diagnostic and therapeutic problems related to HD is determined with the high morbidity (about one fourth of the global adult population) and its adverse effects on human health, working capacity and longevity.

Arterial hypotension is a medical condition characterized with the BP decrease less than 100/60 mm Hg. There is no unified arterial hypotension classification. However, there are clear distinctions between physiological and pathological BP decrease. The latter can be transitory or persistent, but it is always accompanied with the typical complaints and severe deterioration of patient health.

Low BP pathogenesis is based on the dysregulation of the vegetative nervous system, with the predominant parasympathetic segment tone, and impaired function of the higher vegetative centers responsible for vasomotor regulation, which leads to persistent decrease of the total peripheral vascular resistance.

If pathological arterial hypotension is combined with other symptoms of the vegetative dysfunction, this is an indication of primary or essential hypotension as a manifestation of neuro-circulatory dystonia (NCD).

Persistent arterial hypotension which is the principal disease symptom is considered as chronic arterial hypotension (CAH) and in accordance with ICD-10 treated as an individual nosological entity, that is: hypotensive disease.

The intensity of CAH depends on the rate and extent of BP decrease. However, internal medicine specialist should always bear in mind that the clinical picture of CAH crisis is often accompanied with ominous symptoms reminding of diffuse myocardial ischemia and cerebral ischemia, such as: cardialgias, all kinds of poorly tolerated cardiac rhythm disorders, cephalgias, profound weakness and dizziness, balance loss and malaise, hyperacusia, photophobia, etc.

CAH treatment is mainly focused on normalization of the vegetative nervous system balance. For that, a normalized life style is recommended; courses of herbal adaptogens (eleuterococcus, ginseng, schizandra, spikenard or Pantocrine) are made. If the symptoms aggravate due to nervous stresses, hypertensive drugs, sedatives and antidepressants are included to the therapy.

Until recently, one of the most effective methods for arterial hypotension treatment was therapy in sanatoria and health resorts. In sanatoria, a patient has a comprehensive therapy including non-drug treatment (massage, exercise therapy, physiotherapy and reflexotherapy) which may be not always implemented in routine everyday life due to the lack of time and arrangement problems. With the occurrence of portable devices for BP management, it became possible to overcome such inconvenience and difficulties since the treatment procedures are now available in home settings and at any time.

The implementation of new effective hypotensive drugs to the clinical practice in the recent decades helped to reduce BP effectively, while the range of BP disorders resistant to such therapy became slightly less extensive. It is known that increased blood pressure is caused mostly by the imbalance in relationship between per-minute blood circulation and peripheral vascular resistance. Per-minute blood circulation is determined as cardiac output depending, in its turn, on myocardial contractility, volume of the circulating blood and venous blood return. Peripheral vascular resistance depends on resistive artery tonicity and on the extent of vascular re-modeling (vascular constriction caused by hypertrophied media-intimal complex and excessively rigid vascular walls).

The changes in blood circulation regulation by the central nervous system and sympathetic nervous system which are closely related with the endocrine system activity, functional properties

of nephrones and their microcirculation are of the greatest importance for the blood pressure, increase in hypertension.

Nowadays genetically determined susceptibility is considered as the primary factor contributing to arterial hypertension which is represented as frequent disorders in the ion-transportation function and in cytoplasmic cell membrane structures. This induces shifts of regulation levels in calcium metabolism and changes in hormone-cell relationships which is shown as the greater activity of hypothalamus-pituitary gland-adrenal gland system, renin-angiotensin-aldosterone system, insular system and other systems. Calcium overload of cells increases contractile potential of smooth vascular muscles – the principal functional component for the increased peripheral resistance. Calcium overload also activates cellular proto-oncogenes (growth factors) resulting in hypertrophy and hyperplasia in smooth vascular muscles — the organic component of the peripheral vascular resistance. The vascular wall thickening and luminal constriction are the factors maintaining blood pressure on high levels.

Therefore arterial hypertension is caused by perverted baroreceptor relationships between cerebral centers, sympathetic nerves, resistive and capacitance vessels and heart, by more active renin-angiotensin mechanism, excessively secreted aldosterone and, finally, by depleted depressory mechanisms of kidneys (prostaglandine-E2, callicrein, bradykinin), vessels (prostaglandine-I2 or prostacyclin, callicrein-kinin- and dopaminergic vascular systems, endothelial relaxing factor) and heart (atrial natriuretic factor).

It is believed that important pathogenetical factors of arterial hypertension are: tissular insulin resistance (coupled with greater sodium re-absorption rates, greater activity of sympathetic nervous system, proto-oncogene expression and abating vasodilatory stimuli); more densely packed receptors of the vascular bed and myocardium and their higher sensitivity to adrenergic exposure under the influence of the excessive secretion of cortisol and thyroid hormones; changes in biological rhythm of the major endocrine systems and hence, in the rhythms of cardiovascular system regulation.

Nowadays, the special emphasis is made on contribution of endothelial dysfunction into pathogenesis of hypertensive disease: growth in endothelin synthesis and decrease in nitrogen oxide synthesis.

Many of the above listed pathogenetical mechanisms underlying the development and progression of arterial hypertension (endothelial dysfunction management, sympatheticotony, vasoconstriction, etc.) can be effectively managed by non-drug methods, among which low-frequency impulse currents play the leading role.

Diversified use of physical methods of arterial hypertension treatment is the modern trend in prevention, treatment and medical rehabilitation of patients of the cardiac profile. Based on that, the selection of optimal physical treatment methods is especially focused on the necessity to bear in mind an intricate complex of pathophysiological changes in the body system of a HD patient.

Based on that treatment of hypertonic patients is the multi-component in nature and requires an individualized approach. Treatment approach for each patient depends on many factors: predominant pathogenesis pathway and current stage of arterial hypertension. A decision on treatment of each HD patient should be based not only on blood pressure level, but also on the presence of other risk factors of cardiovascular diseases, concomitant nosological entities or disorders of the target organs.

Recently, electric stimulation with various current types in HD treatment is of the great practical importance. It helps to correct regulation processes of vascular tone and modulations of hemodynamic processes more targetedly.

The series of electric current impulses of various frequency provide selective effects upon sensitive nerve conductors and motor nerve conductors of spinal nerve roots and trophic fibers.

The exposure of alternating current impulses comparable in their parameters (in terms of shape and frequency) with action potential of single nervous fibers of a specific type causing electric neurons excitation leads to local changes in microcirculation and skin trophism by local and segment-reflex reactions.

When the electric stimulation of peripheral nerve conductors is made, the ascending impulse flows lead to activation in the major actinocceptive cerebral structures – central gray substance and raphe nuclei which receive polysynaptic afferent inlets, along A β -fibers predominantly. Such currents suppress the power of impulse flows in nociceptive nerve conductors, reduce amplitude of potentials induced in the raphe nuclei and induce production by brain stem neurons of endogenous opiates inhibiting pulse inputs entering the brain along thin A δ - and C-afferents. Stimulating vasomotor center neurons, the impulse currents effectively manage their functional properties. Experimental and clinical data on high efficacy of the electric stimulation in vascular tone management are the ground for the numerous attempts for its use in cardiology.

The improvement of physical treatment methods and development of new-generation physiotherapy devices allowing to implement the recent intellectual, rehabilitative and restorative technologies is an important task for the current physical therapy.

One of the recent medical device-building trends in modern physical therapy is the method of automated control over exposure parameters. Transcutaneous electrostimulator for blood pressure management ABP-051 (manufactured by Inferum LLC, Ekaterinburg, Russia) is one of the method-based devices.

ABP-051 is a portable device with the modern ergonomic design and intended for the use in treatment and prevention facilities, sanatoria and health resorts and health restoration centers, and also by patients themselves, outside of any healthcare facilities.

■ INDICATIONS FOR THE USE OF THE ELECTROSTIMULATOR

Electric stimulation with use of ABP-051 is indicated in combination with the basic drug therapy for the following patients with cardiovascular disorders:

- arterial hypertension of Stage I-II-III;
- hypotension;
- neurocirculatory dystonia of hypertensive, hypotensive and mixed type;
- ischemic heart disease, exertion angina of Functional Class I-II;
- vascular diseases and vascular injuries;
- angiospasm, obliterating endarteritis, Reynaud's disease;
- chronic cardiac insufficiency of Functional Class 1-2

For disease prevention and health support:

- physical and mental exhaustion;
- prevention of cardiovascular diseases;
- to provide general health improvement;
- in pre-menopause age.

■ CONTRAINDICATIONS

The major contraindications to electric stimulation with the use ABP-051 are:

- general debilitation (cachexia);
- severe atherosclerosis of cerebral vessels;
- hemorrhage or susceptibility to hemorrhages; fever condition (when patient's body temperature is higher than 38° C);
- epilepsy with frequently occurring fits, hysteria with severe convulsive fits, psychotic states with events of psychomotor agitation;
- open skin injuries in the application area;
- individual intolerance of the treatment procedures;
- implanted cardiac pacemakers.

HARDWARE

The methods for blood pressure management are implemented with transcutaneous electrostimulator ABP-051 for correction of blood pressure, manufactured by Inferum LLC (Ekaterinburg) (marketing authorization issued by the Federal Service for Surveillance in Healthcare: RZN 2016/3776 dated March 31, 2016; EC Certificate № 1942/MDD dated September 1, 2017).

The appearance of the device and its design are shown at Fig. 1

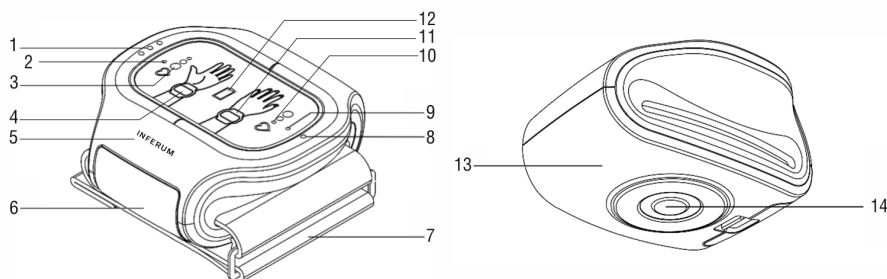


Fig. 1. ABP-051 appearance and design

- 1 – ON/OFF key, Program No 1 (contains three relief points on its surface, which facilitates the device use by people with impaired vision).
- 2 – LED indicator, Program No 1. After the LED starts flashing white, a sound signal occurs to state that Program No 1 operation is over
- 3 – Program No 1 symbol
- 4 – Symbol of the correct device installation on the forearm for Program No 1
- 5 – Company logo
- 6 – Battery compartment lid
- 7 – Cuff for fixing the device upon the wrist
- 8 – ON/OFF key, Program No 2 (contains one relief point on its surface)
- 9 – Light emitting diode, Program No 2. After the LED starts flashing white, a sound signal occurs to state that Program No 2 operation is over
- 10 – Program No 2 symbol
- 11 – Symbol of the correct device installation on the forearm for Program No 2
- 12 – Low battery indicator

Internal side of the device contains:

- 13 – Operational surface of the device body
- 14 – Skin electrodes

ABP-051 generates sequential series of two-phase electric impulses differing in frequency, stimulation time interval and exposure amplitude (Fig. 2).

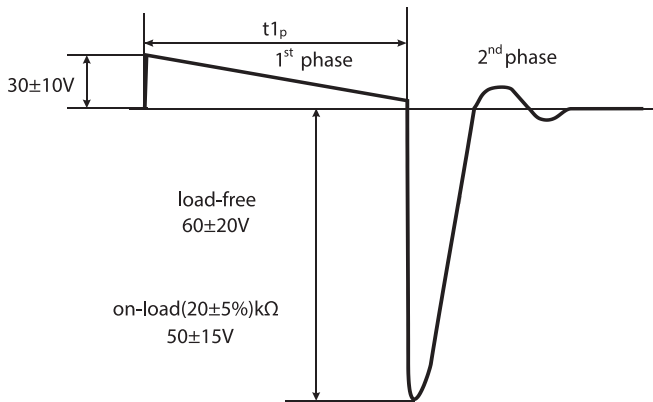


Fig. 2. Shape and parameters for a single impulse generated by ABP-051

Phase 1 of the impulse has fixed amplitude and duration equal to $30 \pm 10 \text{ V}$, ($16-32$) $\pm 6 \text{ mcs}$, while the Phase 2 – decaying sinusoid oscillations of $60 \pm 20 \text{ V}$, with their shape changing dependently on the rates of full electric resistance (impedance) in sub-electrode skin surface area. Decaying-pulse frequencies are dependent on the rate of skin impedance under the electrodes.

ABP-051 contains two automated software modes. Program No 1 is intended for management of high BP and systemic arterial hypertension, while Program No 2 – for management of low BP in arterial hypotension.

Main technical characteristics

Description		Characteristic value
Program No 1	Exposure purpose	Arterial hypertension
	Working impulse rates, Hz	9.2 and 77
	Total operation time, min.	5
Program No 2	Exposure purpose	Arterial hypotension
	Operation impulse rates, Hz	77 and 140, amplitude modulation with frequency of 4
	Total operation time, min.	6
Electric impulse amplitude (load-free)	Phase 1, V	30±10V
	Phase 2, V	60±20
Dimensions, not more than, mm		80x80x40
Electrostimulator weight (including the cuff and built-in electrodes (without power supply cells)), not more than, kg		0.3
Power consumption, not more than, mA		200
Supply voltage, V		3±0.6
Electric power supply source		Galvanic batteries, Type AAA (R03), 2 pcs.
Degree of the device body protection		IP41 pcs.
Degree of protection of the working units from electric current damage		Class: BF

■ TREATMENT METHOD

The treatment is made per the local stable method, with the fixed spatial placement of the electrodes within the projection of biologically active areas (Fig.3).

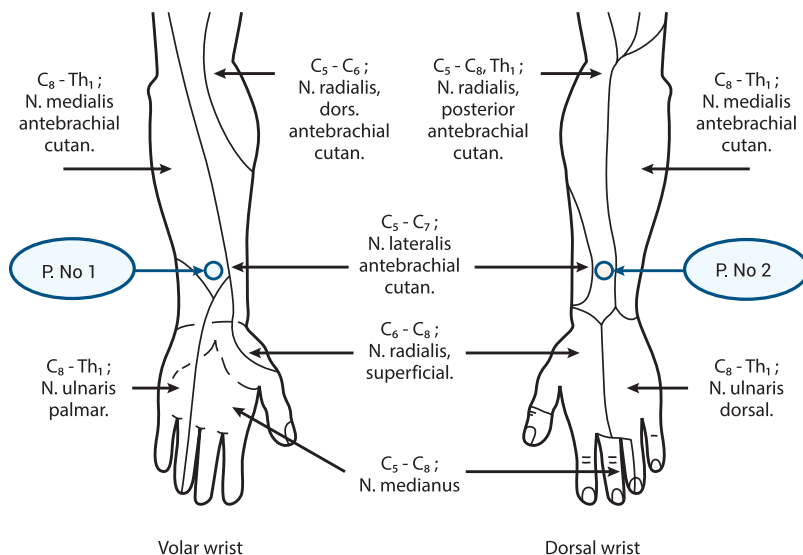


Fig. 3. Segmentary innervation and skin-sensitivity distribution on corrective exposure to peripheral nerves of the forearm and those of the left hand. ABP-051 electrode positions for treatment procedures with the use of: Program No 1 (P. No 1) and Program No 2 (P. No 2)

It is known that cardiovascular and vasomotor centers are represented by the dynamic network of CNS structures. They include sympathetic nervous system centers and preganglionic neurons C6, Th1-Th3 of the spine, parasympathetic nervous system centers represented by preganglionic neurons of vagus nerve nucleus, higher VNS centers and individual nuclei of hypothalamus, limbic system and cerebral cortex.

The pronounced morpho-functional relationships on the spinal level maintain on the segmentary and suprasegmentary levels of peripheral nervous system, the mechanisms of transformation of the ascending electric-pulse input flows from the somatic segment to the vegetative segment. The stellate ganglion plays a great role in differentiation of exposure areas and communicative topology (C6-C8; n. vagus; n. vertebralis; n. cardiacus cervicalis inferior).

The treatment procedures are made 1-3 times daily, total treatment course lasts for 10-14 days. After the targeted BP values are achieved - independently of BP level prior to the treatment – the procedure shall be made in high or low BP events. At the beginning of the BP treatment, course short-term transitory non-stable BP changes may occur over the time, to be followed by BP stabilization - steady BP decrease in hypertension or steady BP increase in hypotension.

In patients with arterial hypertension of Stage I (events of occasional BP increase up to not more than 154 mm Hg), the device can be used as monotherapy.

Recurrent regular electric stimulation courses are made in AH patients, one month after or earlier if clinically indicated.

In patients with arterial hypertension of Stage III, non-controllable hypertension (steadily persistent high SBP – above 180 mm Hg, persistent even in spite of the appropriate drugs taken), the number of daily treatment procedures and duration of the treatment course should be strictly determined under BP medical supervision.

■ PROCEDURE TECHNIQUE

Preparation for the treatment procedure

Electric stimulation procedures **should be made upon prescription of the attending** physician. Before the device is used, each patient should be warned that:

- Basic drug treatment should not be discontinued (adjusted) on their own in the period of BP management using ABP-051: after steady therapeutic effects are achieved, the applicable schemes of basic drug treatment may be adjusted only by the attending physician;
- Use of ABP-051 should be discontinued if any adverse effects develop such as vegeto-vascular syndrome, cephalgia or allergic reactions, to be followed by the medical specialist.

Before the treatment procedure, the patient should review the device and the nature of sensations by the treatment procedure, such as evident low-frequency pain-free vibration; intended treatment purpose should be explained to him/her; the patient should be recommended to take off all objects that he/she is wearing on the left arm/hand (wrist watch, rings, chains, etc.) and to free the distal third of his/her left forearm from the clothes.

Before the treatment procedure, the patient should take any body position convenient to him/her (either a sitting or supine position). The procedure is not made while the patient stays in a vertical position.

In case the patient has no sensations, and if his/her skin is dry, it is allowed to dampen the patient's wrist with a moist napkin or tampon moistened with water to ensure better contact between the device electrode and the skin in the exposure area.

During the procedure, the patient should never read, sleep, touch the device body or change the device position on his/her hand.

High BP management procedure (Program No 1)

This procedure should be made on the exposure areas located on the internal surface of the distal third of left forearm in patients with high BP (see Fig. 3).

Apply the device cuff to the patient's left hand so that orange-colored hand symbol on the device (Fig. 1, Position 3) is on the top and relocate the device upon the forearm, on the exposure area.

Fix the device at the lower third of the forearm so that right rim of the device is positioned in parallel to skin fold in the radiocarpal joint area (Fig. 4).

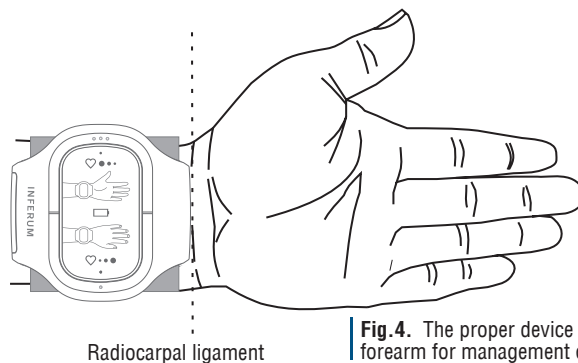


Fig.4. The proper device position on the left forearm for management of high BP

Fix the cuff in the exposure zone so that a close contact is maintained between device electrodes and the skin, while avoiding any blood flow disorders in the area. The patient should never feel any discomfort.

Turn the device on by pressing ON/OFF key, Program No 1 (Fig. 1, Position 1). The appropriate LED signal will appear flashing (Fig.1, Position 2), and high BP management mode will be activated. Afterwards, 5 minutes after the procedure and the appropriate sound signal, the device will be turned off automatically, and the appropriate LED signal will fade away.

To turn the device off manually (forcefully), press and hold ON/OFF key, Program No 1 (Fig.1, Position 1), pressed for more than 1 second; the device will be turned off, the sound signal will be heard, and the appropriate LED signal will fade away.

After the device is turned off, relax the cuff fixture and take the device off the patient's forearm.

After the treatment procedure, the patient should have rest for 20-30 min.

Low BP management procedure (Program No 2)

This procedure should be made on the exposure area on the posterior surface of the distal third of left forearm in patients with low BP (Fig. 5).

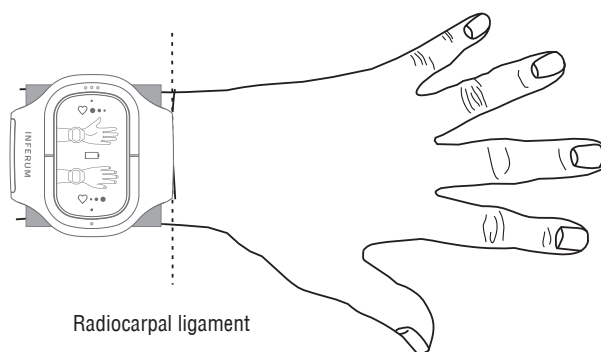


Fig. 5. The proper operation position of the device on the left forearm for management of low BP

Apply the device cuff to the patient's left hand so that the blue hand symbol on the device (Fig.1, Position 11) is below, and relocate the device upon the forearm, on the exposure area.

Fix the device at the lower third of the forearm so that right rim of the device body is positioned in parallel to skin fold in the radiocarpal joint area. (Fig. 5).

Fix the cuff in the exposure area so that a close contact is maintained between device electrodes and the skin while avoiding any blood flow disorders in the area. The patient should never feel any discomfort.

Turn the device on by pressing ON/OFF key, Program No 2 (Fig. 1, Position 8). The appropriate LED signal will appear flashing on the screen (Fig.1, Position 9), and low BP management mode will be activated. Afterwards, 6 minutes after the procedure and the appropriate sound signal, the device will be turned off automatically, and the appropriate LED signal will fade away.

To turn the device off manually (forcefully), press and hold ON/OFF key, Program No 2 (Fig.1, Position 8), pressed for more than 1 second; the device will be turned off, the sound signal will be heard, and the appropriate LED signal will fade away.

After the device is turned off, relax the cuff fixture and take the device off the patient's forearm.

After the procedure, the patient should have rest for 20-30 min.

After the treatment procedure

After each treatment procedure, clean electrodes of the device with a soft absorbent cloth slightly soaked in disinfectant solution (such as 3% aqueous hydrogen peroxide solution). Take precautions to avoid any liquid getting into the device.

Store the device with its electrodes dry.

■ USE AND STORAGE

Safety of the device conforms to the State Standard GOST 50267.0 for Class II, Type BF.

The device is even-surfaced, without any sharp protrusions, barbs or mechanical damages which may harm patients.

At least once a month, the electrodes and cuffs should be examined for soiling and cuff retention losses if any.

Per electromagnetic compatibility, the device conforms with State Standard GOST R MEK 60601-1-2-2014.

Depending on potential risk of its use, the device is classified as a product of Class 2a: low-rate risk products.

Materials from which ABP-051 is made (including its electrodes contacting directly a patient's skin) passed the applicable expertise, and their safety is proved by the toxicity report.

If any malfunctions are found in the device operation, it should not be used until they are eliminated.

Depending on its operational failure hazard, the device is of Class B under State Standard GOST R 50444.

Specifications for the device storage in the manufacturer's packaging, in the manufacturer's and final user's warehouses, conform to Storage Specifications 2 under State Standard GOST 15150.

■ EFFICACY OF THE MEDICAL TECHNOLOGY

Numerous research studies and practical observation have demonstrated high efficacy of electric stimulation for treatment of arterial hypertension and hypotension.

To determine efficacy of electric stimulation, 179 patients with hypertensive disease were studied. The study patient cohort was diagnosed with HD of Stage I or II; 29 of them – with that of Stage III. To identify HD stage, the classification of the US Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure was used (ACC/AHA, 2017). The duration of the pre-existing hypertensive disease in the patients was 6 months – 20 years (6.1 ± 5.1 years on the average).

The clinical status of the patients was assessed based on their complaints, case histories and objective examination. The instrumental study methods included daily BP monitoring, veler-gometry veloergometry with use of the computer processing system under the protocol of step-by-step, continuously increasing load, with the power increase on 10 W each minute. With the daily BP monitoring, the following values were calculated: average systolic BP, average diastolic BP and average hemodynamic BP during the day, daytime and night time.

After the electric stimulation course (10 treatment procedures), the intensity of subjective hypertensive manifestations in the HD patients decreased from 0.89 ± 0.17 to 0.24 ± 0.06 score points ($p < 0.01$). The extent of changes in the patients' subjective manifestations of the hypertensive disease, without any concomitant diseases, amounted to 53%-78% (66% on the average), while the proportion of AH manifestations significantly manageable achieved 81%.

Analysis of BP values in HD patients made by the standard Korotkov method showed significant decreases in average BP values (from 144.0 ± 5.1 to 132.6 ± 3.3 mm Hg) and in double multiplication on the loading height.

To assess efficacy of electric stimulation in hypotension management, 32 patients (predominantly, women) with the decreased pressure were studied. The pre-existing disease duration in the patients was one year – 30 years.

BP analysis in patients with the decreased BP showed the significant growth in average BP values: from $96.4 \pm 6.2/65 \pm 6$ up to $108.6 \pm 3.3/71 \pm 4.2$ mm Hg. Duration of the treatment course was 5-7 days.

It was shown that hypotensive effects produced by electric stimulation were cumulative. The prevailing tendency in changes of «pressor» reflex and vegetative status in the patients was dependent on their original vegetative tone that determined the «individual sensitivity» to the procedure.

These methodological recommendations/guidelines contain the research and practical data indicating the marked therapeutic effects in treatment courses by electric stimulation using ABP-051 device in patients with arterial hypertension and hypotension.

Methodological recommendations/ Guidelines developed for the technique of transcutaneous management of blood pressure can be effectively used both in various treatment and prevention facilities, sanatoria and health resorts, in the complex treatment of patients with arterial hypertension and hypotension, and in home settings.

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