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Стаття надійшла 26.12.2019 р.

DOI 10.26724/2079-8334-2020-4-74-40-44

UDC 616.12-008.331.1-085.225-036:615.817

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### DETERMINATION OF FACTORS EFFECTING ACHIEVEMENT OF THE TARGET BLOOD PRESSURE LEVEL IN PATIENTS WITH ARTERIAL HYPERTENSION AFTER THE ELECTRIC CARDIAC PACEMAKER IMPLANTATION

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The total of 119 patients (62 men and 57 women) aged  $69.5 \pm 11.6$  were observed at the one-year stage of maintenance drug therapy after implantation of electric cardiac pacemaker in DDD / DDDR, VVI / VVIR modes. Patients were divided into 3 groups with 1, 2 and 3 grades arterial hypertension. To determine the factors affecting the achievement of target blood pressure in patients with arterial hypertension after implantation of a pacemaker, potential factors that could be associated with achieving blood pressure control were compared. They were identified using univariate log-regression analysis and multivariate log-regression analysis. The results showed that the frequency of reaching the office arterial pressure,  $BP < 140/90$  mm hg, correlated with DDD, DDDR, VVI, VVIR pacemaker modes. In patients with implanted pacemaker, the most effective modes of antihypertensive therapy were the appointment of dual antihypertensive therapy: combination with an angiotension-converting enzyme inhibitor or angiotensin II receptor blocker with calcium channel-blocking agent and an angiotension-converting enzyme inhibitor or angiotensin II receptor blocker with diuretic.

**Key words:** arterial hypertension, cardiac pacing, correlation.

### Т.А. Дерієнко, І.В. Шоп, Т.М. Тихонова, Т.С. Главатських, Ю.В. Левадна, К.В. Шепітько ВИЗНАЧЕННЯ ФАКТОРІВ ВПЛИВУ НА ДОСЯГНЕННЯ ЦІЛЬОВОГО РІВНЯ АРТЕРІАЛЬНОГО ТИСКУ У ПАЦІЄНТІВ З АРТЕРІАЛЬНОЮ ГІПЕРТЕНЗІЄЮ ПІСЛЯ ІМПЛАНТАЦІЇ ЕЛЕКТРОКАРДІОСТИМУЛЯТОРА

Спостерігали 119 пацієнтів (62 чоловіка і 57 жінок) у віці  $69,5 \pm 11,6$  на річному етапі підтримуючої медикаментозної терапії після імплантації електрокардіостимулятора в режимах DDD/DDDR, VVI/VVIR. Пацієнти були розділені на 3 групи – 1, 2 і 3 ступінь артеріальної гіпертензії. Для визначення факторів, що впливають на досягнення цільового артеріального тиску у пацієнтів з артеріальною гіпертензією після імплантації електрокардіостимулятора, були зіставлені потенціальні фактори, які можуть асоціюватися з досягненням контролю за артеріального тиску. Ідентифікували за допомогою уніваріантного лог-регресійного аналізу та мультіваріантного лог-регресійного аналізу. Результати показали, що частота досягнення офісного артеріального тиску  $< 140/90$  мм рт ст корелювала DDD режимом кардіостимуляції, DDDR режимом кардіостимуляції, VVI режимом кардіостимуляції, VVIR режимом кардіостимуляції. У хворих із імплантованим електрокардіостимулятором найбільш ефективними режимами антигіпертензивної терапії виявилися призначення подвійної антигіпертензивної терапії у комбінації інгібітора ангіотензин-перетворюючого ферменту або антагоністів рецепторів ангіотензину із блокаторами повільних кальцієвих каналів та інгібітора ангіотензин-перетворюючого ферменту або антагоністів рецепторів ангіотензину II з діуретиком.

**Ключові слова:** артеріальна гіпертензія, електрокардіостимуляція, кореляція.

*The work is a fragment of the research project “Therapeutic support of patients with implanted pacemakers and cardioresynchronizing devices”, state registration No. 0119U102299.*

Today, arterial hypertension (AH) maintains one of the leading positions among the most common diseases of the cardiovascular system [1]. In particular, according to official statistics of the Ministry of Health of Ukraine, 32% of the adult population in Ukraine suffers from hypertension [1, 2]. Hypertension is a threatening risk factor for the development of various complications, and such as stroke, myocardial infarction, heart failure are recognized as the major causes of death and disability [10]. The risk of hypertension and the features of evolution, as well as mortality in this disease directly depend on the blood pressure (BP) levels and on the target organs' involvement in the pathology process. At the same time,

hypertension is the most common concomitant pathology in patients with implanted pacemaker (EC) [2]. In general, pacemaker implantation improves the quality of patients' life, synchronizes the work of the heart chambers, increases the left ventricular ejection fraction (LVTF) [6]. This is a factor that causes instability of systolic and diastolic blood pressure (CBP and DBP) [7], and as a consequence, the hypertension progression. The above justifies the feasibility of determining the factors influencing the achievement of the target blood pressure level in patients with hypertension after implantation of electric cardiac pacemaker (ECP).

**The purpose** of the study was to determine the factors influencing the achievement of the target blood pressure level in patients with hypertension after pacemaker implantation.

**Materials and methods.** On the basis of the ultrasound and clinical-instrumental diagnostics and minimally invasive interventions department at the SI "V.T. Zaitsev Institute of General and Emergency Surgery NAMS of Ukraine" 119 patients (62 men and 57 women) aged ( $69.5 \pm 11.6$ ) years were examined. All patients were implanted with electric cardiac pacemaker (ECP) from 2008 to 2016, stimulation was performed in the following modes: DDD (32 patients), DDDR (46 patients), VVI (35 patients), VVIR (6 patients).

Among the indications for ECP implantation were: atrioventricular blockade (AV blockade) – 81 patients (68%), sick sinus syndrome (SSS) – 21 patients (18%), permanent atrial fibrillation (PAF), in patients resistant to antiarrhythmic therapy after radiofrequency ablation (RFA) of the atrio-ventricular node (AV node) – 17 patients (14%), with DDD / DDDR and VVI / VVIR modes of stimulation.

According to the recommendations of the Ukrainian Association of Cardiology, 11 patients (9%) were diagnosed with grade 1 hypertension, 64 (54%) – with grade 2 hypertension, and 44 (37%) – with grade 3 hypertension.

The inclusion criterion was the presence of indications for permanent pacemaker implantation (PPI) and hypertension. The study excluded patients younger than 40 years of age with concomitant IV FC stable angina, IV FC CHF and / or III FC before ECP implantation, with stimulation of the right ventricle (RV) and / or left ventricle (LV) less than 50% during the year of observation.

Treatment of patients with implanted ECP was performed taking into account the provisions of the Draft Recommendations for implantation of electrical devices in cardiac arrhythmias and conductivity disorders of the Ukrainian Association of Cardiology [2] and in accordance with the recommendations of the European Society of Cardiology for pacemaker implantation and cardiac resynchronization [4]. Treatment of hypertension was carried out in compliance with the recommendations of the Ukrainian Association of Cardiology for prevention and treatment of hypertension [1] and in accordance with clinical recommendations for hypertension of the European Society of Hypertension and the Society of Cardiologists [9].

Drug therapy of hypertension in patients after ECP implantation was represented by: diuretics (furosemide, torasemide, hydrochlorothiazide),  $\beta$ -blockers (carvedilol, metoprolol, bisoprolol, nebivolol), calcium channel blockers (CCB) (dihydropyridine derivatives - amlodipine, nifedipine and phenylalkylamine derivatives - verapamil), angiotensin-converting enzyme (ACE) inhibitors (enalapril, lisinopril, ramipril), angiotensin receptor blockers (ARBs) II (losartan, candesartan). Among other means, there were used: anticoagulants (warfarin), non-vitamin K – oral anticoagulants, direct thrombin inhibitors (dabigatran etexilate) and direct Xa factor inhibitors (rivaroxaban), antiplatelet agents (acetylsalicylic acid, clopidogrel G), hydroxymethylglutaryl (HMG) inhibitors of coenzyme A (CoA) (statins) (atorvastatin, simvastatin), antiarrhythmic drugs (amiodarone).

The obtained data were processed after the formation of the database in Microsoft Excel (MS Office, 2016, USA), Statistica v.9 (USA). For each extent in their normal or abnormal distribution, either the mean value (M) and standard deviation (SD), or the median and interquartile interval, was determined respectively. Quantitative indices were presented as n (%). When comparing groups of patients according to the main indices (depending on the type of the analyzed indices distribution), an odd Student's t-test or Mann-Whitney U-test was used. The ANOVA method was used to establish differences between the three factors.

Bilateral Fisher's exact test and  $\chi^2$  test were used to analyze 2x2 conjugation tables. Potential factors that may be associated with the achievement of blood pressure control were identified first by univariate log regression analysis and then by multivariate log regression analysis. The odds ratio and the interquartile interval were determined, and the Wald index was used to compare the effect size. The results were considered significant at significance levels of  $p < 0.05$ .

**Results of the study and their discussion.** The results of the analysis revealed that before the ECP implantation, regardless of the hypertension grade in the medical treatment of patients with hypertension, ACE inhibitors and ARBs had the highest weighting factor. On the 3rd-5th days after implantation, it increased for beta-blockers (BAB) and diuretics in all groups of hypertension. During the one-year observation period, an increase in the weight factor for ACE inhibitors was found in the group of grade 1 hypertension, in the group

of grade 2 hypertension – for ACE inhibitors and ARBs, in the group of grade 3 hypertension – for ACE inhibitors, ARBs II and diuretics. There was also a decrease in weight factor for CBR and DBP, which indicates the efficacy of drug therapy.

During the study, a correlation analysis was carried out that established a correlation between the achievement of the target blood pressure level in patients with hypertension after ECP implantation and some demographic, hemodynamic parameters and features of hypertension drug therapy. The results of the analysis revealed that the frequency of achieving the target blood pressure correlated with age ( $r = -0.42$ ;  $P < 0.05$ ), diabetes mellitus ( $r = -0.52$ ;  $P = 0.001$ ), DDD pacing mode ( $r = 0.46$ ;  $P = 0.012$ ), DDDR pacing mode ( $r = 0.42$ ;  $P = 0.01$ ), VVI pacing mode ( $r = 0.38$ ;  $P = 0.01$ ), VVIR pacing mode ( $r = 0.32$ ;  $P = 0.04$ ), and the prescription of ACE inhibitors ( $r = 0.58$ ;  $P = 0.04$ ), ARBs II ( $r = 0.56$ ;  $P = 0.02$ ), BAB ( $r = 0.62$ ;  $P = 0.001$ ), diuretics ( $r = 0.56$ ;  $P = 0.001$ ), beta-blockers ( $r = 0.54$ ;  $P = 0.001$ ), dual antihypertensive therapy with ACE inhibitors or Angiotensin II receptor antagonist (ARA) with slow channel-blocking agent (SCBA) and ACE inhibitors or ARA II with diuretics ( $r = 0.68$ ;  $P = 0.001$  and  $r = 0.64$ ;  $P = 0.001$ , respectively), triple antihypertensive therapy with ACE inhibitors or ARBs with SCBA and diuretics ( $r = 0.76$ ;  $P = 0.0001$ ).

One of the purposes was also to identify the factors that had the greatest impact on achieving the target blood pressure level in patients with implanted ECP. To outline the influence of certain factors on the adequacy of blood pressure control in patients with hypertension and implanted ECP, which were included in the study, a uni- and multivariate log regression analyses were performed. Table 1 presents the factors effecting the achievement of the target blood pressure level in patients with hypertension after the ECP implantation. The results of uni- and multivariate log regression analysis, which is adjusted by a combination of antihypertensive drugs, are shown in table 1.

Table 1

**Factors effecting the achievement of the target blood pressure level in patients with hypertension after ECP implantation. The results of uni- and multivariate log regression analysis, which is adjusted by a combination of antihypertensive drugs**

Indices	Univariate log regression analysis			Multivariate log regression analysis		
	OR	IQI	P	OR	IQI	P
Age > 65 років	0.86	0.77-0.95	0.012	0.89	0.80-0.98	0.04
DDD mode ECP	1.05	1.02-1.09	0.02	1.05	1.01-1.10	0.044
DDDR mode ECP	1.04	1.01-1.09	0.04	1.07	1.02-1.11	0.035
VVI mode ECP	1.02	0.98-1.06	0.66	-	-	-
VVIR mode ECP	1.01	0.98-1.07	0.82	-	-	-
DM	0.85	0.73-0.97	0.001	0.86	0.78-0.95	0.01
ACE inhibitors	1.07	1.03-1.11	0.001	1.05	1.03-1.08	0.01
ARBs II	1.05	1.03-1.08	0.01	1.04	1.02-1.06	0.02
SCBA	1.08	1.04-1.10	0.024	1.05	1.02-1.09	0.034
BAB	1.02	0.99-1.04	0.72	-	-	-
diuretics	1.04	1.01-1.07	0.046	1.03	1.01-1.05	0.048

Note: DDD – atrioventricular non-frequency adaptive stimulation; DDDR – atrioventricular frequency adaptive stimulation; VVI – ventricular non-frequency adaptive stimulation; VVIR – ventricular frequency adaptive stimulation; BAB – beta- adrenergic blockers; SCBA – slow channel-blocking agent; ARBs II – angiotensin receptor blockers; DM – diabetes mellitus; IQI – interquartile interval; OR – odds ratio; P – significance of differences.

The data obtained indicate that the most important factors effecting the achievement of adequate control of blood pressure in patients with hypertension after the ECP implantation (except for the combination of ACE inhibitors or ARBs II with SCBA and ACE inhibitors or ARBs II with a diuretic) were: age > 65 years (OR = 0.89;  $P = 0.04$ ), diabetes mellitus (OR = 0.86;  $P = 0.01$ ), DDD ECP mode (OR = 1.05;  $P = 0.044$ ), DDDR ECP mode (OR = 1.07;  $P = 0.035$ ), as well as the prescription of ACE inhibitors (OR = 1.05;  $P = 0.01$ ), ARBs II (OR = 1.04;  $P = 0.02$ ), SCBA (OR = 1.05;  $P = 0.034$ ) and diuretics (OR = 1.03;  $P = 0.048$ ).

The study compared the effect size of various factors on the frequency of achieving adequate blood pressure control.

The results revealed that with the exception of factors related to the medical support of hypertension, the most weighting factor in achieving the target blood pressure level was DDDR mode of ECP, DDD mode of ECP and diabetes mellitus, the data are presented in table. 2.

Table 2

**Comparison of the various factors effect size on the frequency of achieving adequate control over blood pressure**

Factors	Wald index	95% CI	P
age > 65 years old	3.15	2.24 – 4.72	0.04
Diabetes mellitus	9.36	7.44 – 12.1	0.01

DDD mode of ECP	11.3	9.55 – 14.1	0.001
DDDR mode of ECP	19.6	18.5 – 22.4	0.001

Note: DDD – atrioventricular non-frequency adaptive stimulation; DDDR – atrioventricular frequency adaptive stimulation; P – significance of differences.

Based on the data obtained, in patients with hypertension at the yearly stage of observation after the ECP implantation, except for medical care and comorbid conditions – diabetes mellitus, DDDR mode of ECP is the most important factor contributing to adequate control of blood pressure, the data being new and not confirmed in the literature.

According to the obtained data, in patients with implanted ECP the most effective modes of antihypertensive therapy were prescription of dual antihypertensive therapy in combination with ACE inhibitors or ARA with SCBA and ACE inhibitors or ARBs II with diuretics ( $r = 0.68$ ;  $P = 0.001$  and  $r = 0.64$ ;  $P = 0.001$ , respectively), triple antihypertensive therapy with ACE inhibitors or ARBs II with SCBA and diuretic ( $r = 0.76$ ;  $P = 0.0001$ ), which partially meets the Recommendations of the Ukrainian Association of Cardiology for prevention and treatment of hypertension, but in patients without the implanted ECP. According to the obtained data, clinical and hemodynamic parameters are important criteria for predicting the results of medical intervention in patients with implanted ECP [7].

The results of the study showed that at the yearly stage after the ECP implantation in patients with hypertension prognostically significant indices of the drug therapy efficacy for the frequency of antihypertensive drugs prescription in the group of grade 1 hypertension were ACE inhibitors, in the group of grade 2 hypertension – ACE inhibitors and ARB II, in the group of grade 3 – ACE inhibitors, ARBs II and diuretics and weight factor reduction for CBP and DBP, indicating the efficacy of drug therapy, which is partially consistent with the data [6], but for patients with chronic heart failure and ECP implanted ones. The established data should be used in the selection of antihypertensive therapy in patients with hypertension after implantation of ECP. There are no data in the literature on prognostically significant indices of the drug therapy efficacy for the frequency of prescribing antihypertensive drugs depending on the grade of hypertension.

The results of our study showed that in response to the ECP implantation, the frequency of administration and doses of a number of drugs progressively increase. On the one hand, this suggests the need for a more thorough assessment of the indications for implantation and the choice of the ECP mode. On the other hand, it determines the features of drug management for patients with ECP in general. Thus, ECP does not cancel, but modifies drug therapy.

### Conclusions

1. The frequency of achieving office blood pressure  $<140/90$  mm Hg correlated with DDD pacing mode ( $r = 0.46$ ;  $P = 0.012$ ), DDDR pacing mode ( $r = 0.42$ ;  $P = 0.01$ ), VVI pacing mode ( $r = 0.38$ ;  $P = 0.01$ ), VVIR pacing mode ( $r = 0.32$ ;  $P = 0.04$ ).

2. In patients with implanted ECP, the most effective regimens of antihypertensive therapy were prescription of dual antihypertensive therapy in combination with ACE inhibitors or ARBs II with SCBA and ACE inhibitors or ARBs II diuretics ( $r = 0.68$ ;  $P = 0.001$  and  $r = 0.64$ ;  $P = 0.001$ , respectively).

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DOI 10.26724/2079-8334-2020-4-74-44-48

UDC 616.831-005+615.84

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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<sup>®</sup> electronic devices for biologically adequate movements control. The purpose of the study was to assess the functional capabilities of the TRENAR-01<sup>®</sup> 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<sup>®</sup> 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 головної 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<sup>®</sup> 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<sup>®</sup>. 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) спостерігалась 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