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MEDICAL SCIENCES

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EVALUATION OF HEMODYNAMIC INDICATORS IN PATIENTS WITH CHRONIC HEART FAILURE AFTER IMPLANTATION OF PACEMAKER DEPENDING ON THE PRESENCE OF TYPE 2 DIABETES

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Abstract: The article investigated hemodynamic indicators in patients with chronic heart failure and concomitant type 2 diabetes mellitus at the one-year stage after pacemaker implantation.

The clinical effectiveness of implantation of a permanent pacemaker in patients with chronic heart failure and type 2 diabetes mellitus and monocourse of chronic heart failure has been established.

The superiority of heart rate, systolic and diastolic blood pressure among non-responders of the main group and improvement of the main indicators of echocardiography in response to implantation of a pacemaker was established.

Key words: pacemaker implantation, chronic heart failure, diabetes, hemodynamic indicators, clinical effectiveness

Introduction:

Chronic heart failure (CHF) accounts for a significant share in the structure of diseases of the circulatory system: in recent decades, an increase in the mortality rate

from CHF has been registrated, as well as an increase in the number of people aged 60–69 years with this pathology. Among the huge spectrum of modern methods of treatment of CHF, cardioresynchronization therapy stands out, which makes it possible to improve the patient's heart, reduce clinical signs of the disease, improve well-being, and also reduce morbidity and mortality [1, 2].

One of the diseases which significantly complicates the course of CHF, is capable of provoking the development of negative consequences and quite often appears as a "triggering" mechanism for the occurrence and development of CHF is diabetes mellitus (DM), in which, one of the leading components of the formation of CHF, regardless of its etiology, is heart remodeling, that is, structural changes of the LV, which include the processes of hypertrophy and dilatation of the myocardium. This, in turn, leads to changes and violations of both systolic and diastolic function. Prevention of cardiac remodeling is a leading factor in stopping the formation and progression of CHF. Unfortunately, in most patients with such changes, drug therapy is not accompanied by a significant improvement in their condition [2-10].

The purpose of the study: to assess hemodynamic indicators in patients with CHF and concomitant type 2 DM at the one-year stage after ECS implantation.

Materials and methods: On the basis of the department of ultrasound and clinical-instrumental diagnostics and mini-invasive interventions of the State Institution "Institute of General and Emergency Surgery named after V.T. Zaitsev of the National Academy of Medical Sciences of Ukraine" examined 203 patients with CHF aged 67.9 ± 6.9 years who had reasonable indications for implantation of a permanent ECS/artificial pacemaker, namely sinus node weakness syndrome; violation of AV conduction (AV blocks II and III degrees); violation of cardiac conduction (complete blockade of the left leg of the bundle of His); presence of ventricular arrhythmia with hemodynamic instability; symptomatic HF (II-III FC according to NYHA), despite optimal drug therapy; a decrease in the ejection fraction (EF) of the left ventricle (LV); dilated cardiomyopathy and others according to "Recommendations on electrocardiostimulation and cardiac resynchronization therapy. ESC 2013" [11]. Symptomatic atrial fibrillation (AF), which cannot be

controlled with medication, was considered as an additional indication for ECS implantation.

Exclusion criteria for the study were: minors or age over 90 years at the time of the examination, myocardial infarction within the next 90 days, presence of type 1 DM or taking insulin drugs, acute and significant decompensation of carbohydrate metabolism.

The distribution into the studied groups was carried out taking into account the presence of concomitant type 2 DM (according to the International Classification of Diseases of the XI revision - code 5A11 [12]): CHF patients with concomitant type 2 DM made up the main group (n = 102), while the control group was formed from patients with CHF without comorbid type 2 DM (n = 101).

All patients were implanted with a two-chamber ECS (Sorin (Italy), Vitatron (Holland), Medtronic (Ireland), St. Jude Medical (USA)) according to the standard method; during ECS implantation, the position of the electrodes in the LV was monitored using fluoroscopy. 203 ECS were implanted, 132 of which worked in DDD mode, 71 in DDDR mode.

Before ECS implantation and after 12 months. after surgery, patients underwent transthoracic echocardiography using different modes (M-modal, two-dimensional, Doppler) in accordance with the standard methodology recommended by the American Society of Echocardiography and the European Association of Cardiovascular Imaging [13-14]. In the course of echocardiography, the following were calculated: LV end-diastolic volume index (EDV), LV end-systolic volume index (ESV), unindexed LV EDV and LV ESV, LV ejection fraction (EF), degree of diastolic dysfunction (assessed using color Doppler tissue research), degree of mitral regurgitation.

Heart rate (HR) was measured using an ECG, which was recorded by a 12-channel computer electrocardiograph "Cardiolab 2000" KHAI-MEDYKA (Ukraine) at a speed of 50 mm/s.

Blood pressure (BP) was measured according to existing practical recommendations using the Korotkoff method using a Microlife BP AG1–20

tonometer (Switzerland) after a mandatory 5-min. resting in a sitting position in compliance with the general requirements for the location and application of the cuff of the device. Blood pressure was measured three times on each arm from 2 min. interval before each measurement, in further work the average values of systolic blood pressure (SBP) and diastolic blood pressure (DBP) were used [15].

Patients who, after the end of 12 months observations recorded a 15.0% decrease in the LV EDV, considered to be those who responded to ECS implantation; while patients who did not show an appropriate regression of the specified indicator were classified as non-responders.

The following software was used to maintain the database and carry out the above-mentioned calculations: database management in the Microsoft Excel 2013 program package and statistical calculations in the IBM SPSS 25.0 program package for Windows. To characterize the central tendency and the variability of quantitative traits (continuous or interval), the average value (M) and standard square deviation (SD, σ) were determined. The result was presented as M ± SD. Qualitative (binomial, ordinal, nominal) indicators were described in absolute and relative (percentage) values with calculation of standard deviation. The result was provided in the form of absolute and relative data (abs. (%)).

The threshold value of the level of significance in the paper was taken as 0.05 (p = 0.05) with the indication of the exact value of the level of confidence "p" with three decimal places. In the case of multiple comparisons, the Bonferroni correction was applied to correct the confidence level.

Results and discussion: The initial age data of the study patients are presented in fig. 1

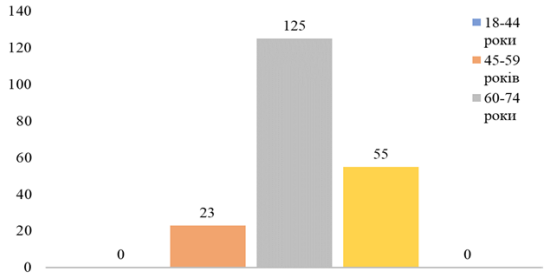

Fig. 1. Distribution of examined patients (n = 203) by age characteristics, abs.

As shown in fig. 1, the formed cohort was dominated by elderly patients (61.6%), there were a little less elderly patients (27.1%) and the least number of middle-aged people (11.3%).

The gender-age structure of the examined cohort of patients is presented in fig. 2, which demonstrates male dominance in all age cohorts.

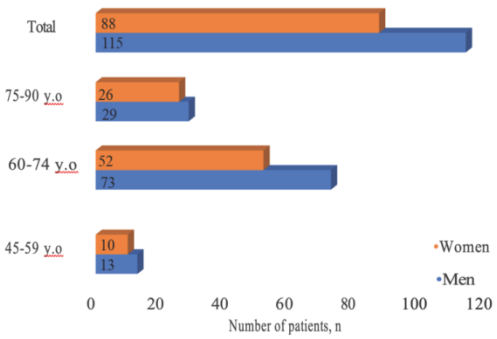

Fig. 2. Gender-age structure of examined patients (n = 203), abs.

Table 1

Characteristics of functional disorders of the heart rhythm of the examined patients according to the results of Echo-CG before implantation of ECS, M ± SD

Indicators	Group 1; n = 102	Group 2; n = 101	p
LV EF, %	47,6 ± 8,0	47,6 ± 7,6	0,961
LV ESS, см	4,3 ± 0,9	3,9 ± 0,8	< 0,001
LV EDS, см	5,7 ± 1,1	5,3 ± 1,0	< 0,001
LV EDV, $см^3$	165,3 ± 77,5	138,5 ± 65,1	< 0,001

As the table shows. 1, comorbid type 2 diabetes had a negative effect on such indicators as LV ESS, LV EDS, as well as LV EDV: these indicators probably exceeded those in the control group. It should be noted that despite the listed reliable intergroup differences, the average values of LVEF in the main group almost completely coincided with the specified indicator in the control group.

The results of the patients observation with heart failure and type 2 DM after implantation of ECS were obrained after 12 months. Mean heart rate values of responders and non-responders of the main group did not differ significantly, although quantitatively they prevailed among the latter (respectively, 45.31 ± 9.66 bpm and

47.13 ± 14.66 bpm; p = 0.657). At the same time, the mean values of SBP were also slightly higher in non-responders (156.13 ± 22.57 mm Hg) compared to patients who responded to ECS implantation (151.80 ± 18.77 mm Hg); however, the intergroup difference was also unreliable (p = 0.388). A similar trend was observed with regard to DBP indicators: its levels in the cohort of non-responders (87.04 ± 7.16 mm Hg) improbably (p = 0.195) exceeded the indicated indicators in the respondents (84.70 ± 8.34 mm Hg .) – Fig. 3.

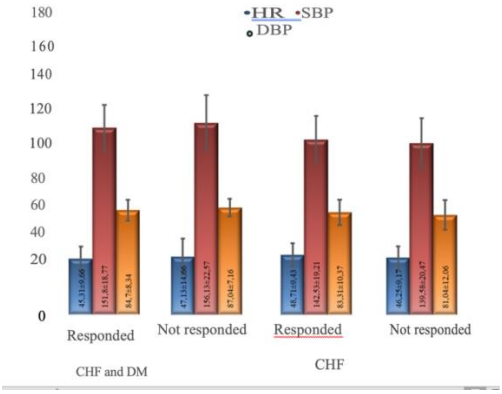

Fig. 3. Distribution of examined patients according to physical characteristics and effectiveness of ECS implantation, M ± SD.

In the control group, which was represented by patients with CHF without type 2 DM, the opposite pattern was observed: the average values of heart rate, systolic blood pressure, and diastolic blood pressure were slightly higher in the cohort of respondents: 48.71 ± 9.43 bpm, 142.53 ± 19.21 mm Hg. and 83.31 ± 10.37 mm Hg. in accordance. Among the non-responders, the indicators had slightly lower levels: 46.25 ± 9.17 bpm; 139.58 ± 20.47 mm Hg. and 81.04 ± 12.06 mm Hg., respectively; but in all cases the listed differences between responders and non-responders were not really significant.

It should be noted that the comparison of physical characteristics between the main and control groups made it possible to record a probable difference between the heart rate level in the cohort of respondents: the heart rate in patients with CHF without type 2 DM who responded to ECS implantation was significantly higher than the similar rate in people with CHF and type 2 DM: 48.71 ± 9.43 bpm. and 45.31 ± 9.66 bpm. (p = 0.014). The average SBP values in the cohort of patients

corresponding to the main group were significantly (p = 0.005) higher than the similar indicator in the control group: 151.80 ± 18.77 mm Hg. and 142.53 ± 19.21 mm Hg. At the same time, the levels of BP among the respondents of both groups probably did not differ (p = 0.732). Also, in the cohorts of non-responders in the main and control groups, there were no significant differences in the values of heart rate and DBP, while the level of SBP among non-responders with concomitant type 2 DM probably exceeded the specified indicator compared to non-responders with CHF without type 2 DM: 87.04 ± 7.16 mm Hg. and 81.04 ± 12.06 mm Hg. (Fig. 3).

It should be noted that the establishment of ECS contributed to a probable increase in LVEF both in the main and in the control groups. Also, there was a significant decrease in KDO and KSO indicators in the dynamics of treatment in both groups. At the same time, the conducted research determined that the course of CHF without DM was associated with more significant changes in the main characteristics of the Echo-CG of the examined patients: it was established that the absence of burden of CHF with concomitant 2nd type DM made it possible to achieve a significant decrease in the indicators of LV ESS, LV EDS and LV EDV (in in all cases p < 0.001) - table. 2.

Table 2

The value of the main indicators of Echo-CG of the examined patients in the dynamics of treatment, M ± SD

Indicators	Before treatment			After treatment			p_3	p_4
	Group 1; n = 102	Group 2; n = 101	p_1	Group 1; n = 102	Group 2; n = 101	p_2		
LV EF, %	47,62 ± 8,02	47,60 ± 7,57	0,961	53,50 ± 10,42	56,65 ± 8,21	0,385	< 0,001	
LV ESS, sm	4,27 ± 0,89	3,99 ± 0,84	< 0,001	3,78 ± 0,72	3,53 ± 0,73	< 0,001	< 0,001	
LV EDS, sm	5,65 ± 1,11	5,28 ± 1,04	< 0,001	4,97 ± 0,89	4,63 ± 0,84	< 0,001	< 0,001	
LV EDV, sm^3	165,25 ± 77,47	138,5 ± 65,06	< 0,001	122,02 ± 50,50	102,70 ± 43,17	< 0,001	< 0,001	
LV ESV, sm^3	87,17 ± 43,76	66,57 ± 56,95	< 0,001	64,76 ± 31,20	75,59 ± 59,84	0,317	< 0,001	0,668

Notes: p1 – reliability of the difference between the 1st and 2nd groups before treatment; p2 – between the 1st and 2nd groups after treatment; p3 – in the 1st group before and after treatment; p4 is the probability of difference in the 2nd group before and after treatment.

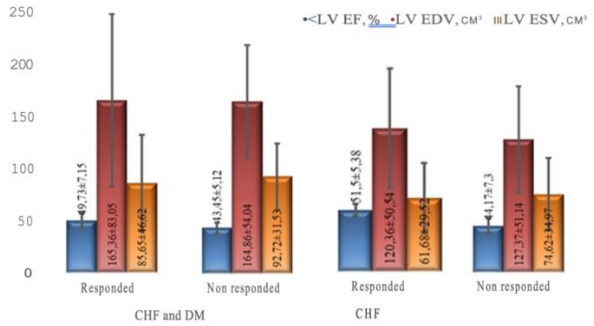

Fig. 4. Distribution of the examined according to the structural and functional parameters of the heart muscle depending on the efficiency of ECS, M ± SD.

At the same time, the analysis of changes in the main parameters of Echo-CG in the dynamics of observation depending on the effectiveness of ECS implantation made it possible to identify the features indicated in fig. 4. LV EF in patients with CHF and type 2 DM differed between responders and non-responders: 49.73 ± 7.15% and 43.45 ± 5.12%, respectively ($p < 0.001$). At the same time, although the LV EDV indicator was quantitatively superior among patients who responded to treatment, the difference was not significant ($p = 0.459$). At the same time, the value of LV ESV was higher among patients who did not respond to treatment, but the difference with the responders was not reliable ($p = 0.111$) - fig. 4.

In another group of subjects (with CHF without diabetes), a significant ($p < 0.001$) predominance of LV EF was determined among responders (51.50 ± 5.38 %), compared to non-responders (44.17 ± 7.30 %). The value of LV EDV was recorded at almost the same level among the subjects of the control group: 120.36 ± 50.54 cm3 and 127.37 ± 51.14 cm3, respectively ($p = 0.507$). The average value of LV ESV, at the same time, quantitatively prevailed among patients with no response to treatment (74.62 ± 34.97 cm3), but the indicator did not differ significantly ($p = 0.126$) in relation to responders (61.68 ± 29.52 cm3), Fig. 4.

In general, it should be noted that the comparison of the indicators of the responding patients and non-responding patients of the two studied groups determined the following patterns: LV EF did not reliably differ between the responding patients of both groups ($p = 0.726$). At the same time, the average values

of LV EDV and LV ESV significantly ($p \leq 0.001$) prevailed in corresponding patients with concomitant CHF and type 2 DM - fig. 4. The average values of LV EF of non-responding patients did not differ significantly between the studied groups ($p=0.537$), while the tendency for the average values of LV EDV and LV ESV to prevail among non-responding patients with concomitant CHF and type 2 DM remained: respectively, $p = 0.020$ and $p = 0.048$ - fig. 4.

Conclusions:

Based on the study and careful analysis of the clinical and instrumental characteristics of the effectiveness of pacemaker implantation and the features of medical support for patients with chronic heart failure and type 2 DM, it was:

1. The clinical effectiveness of implantation of a permanent pacemaker in patients with chronic heart failure and type 2 diabetes mellitus and the monocourse of chronic heart failure was confirmed.

2. The superiority of heart rate, systolic and diastolic blood pressure among non-responders of the main group was established (respectively, 47.13 ± 14.66 bpm; 156.13 ± 22.57 mm Hg and 87.04 ± 7, 16 mm Hg) compared to the counterparts (respectively, 45.31 ± 9.66 bpm; $p = 0.657$; 151.80 ± 18.77 mm Hg; $p = 0.388$ and 84.70 ± 8 .34 mm Hg; $p = 0.195$) in contrast to the control (respectively 48.71 ± 9.43 bpm, 142.53 ± 19.21 mm Hg and 83.31 ± 10.37 mm Hg – responders and 46.25 ± 9.17 bpm; 139.58 ± 20.47 mm Hg and 81.04 ± 12.06 mm Hg - non-responders).

3. A probable ($p < 0.001$) improvement of the main indicators of echocardiography in response to pacemaker implantation due to a probable increase in the left ventricular ejection fraction and end-diastolic and end-systolic sizes and end-diastolic and end-systolic volumes was found, especially among patients with the course of chronic heart failure without type 2 diabetes.

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