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Research article

Factors Associated with a Positive Hemodynamic Response to Cardiac Resynchronization Therapy

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AIM: This study aimed to conduct a comparative analysis of clinical, electrocardiographic, and echocardiographic factors in patients with chronic heart failure (CHF) with different hemodynamic responses to cardiac resynchronization (CRT) to assess the possibility of their use in predicting the positive effect of CRT.

MATERIALS AND METHODS: The study included 136 patients with New York Heart Association grade 3–4 CHF with a left ventricular ejection fraction of ⩽ 35%, QRS duration of ⩾ 150 ms, QRS duration of 130–149 ms, and QRS morphology of left bundle branch block (LBBB). For CHF treatment and primary prevention of sudden cardiac death, a cardioverter-defibrillator with CRT (CRT-D) function was implanted. The enrolled patients were followed up prospectively for 1 year to record the endpoint, namely, hemodynamic response to CRT, assessed by a decrease in the end-systolic volume of the left ventricle by ⩾ 15%.

RESULTS: During the 1-year follow-up, the primary endpoint was registered in 62 (46%) patients. With a one-way logistic regression, four indicators with the highest predictive potential ($p < 0.05$) and associated with the occurrence of the studied endpoint were identified. Based on the results of the multivariate regression analysis, a prognostic model was developed, which included three factors with the highest levels of statistical significance, namely, a history of indications of a previous correction of valvular insufficiency, QRS duration, and LBBB criteria according to Strauss. The diagnostic efficiency of the model was 73% (sensitivity, 80%; specificity, 68%). The electrocardiographic parameters of the Strauss LBBB criteria and QRS duration were independent predictors of the studied endpoint.

CONCLUSIONS: The developed multivariate prognostic model may be useful in the selection of patients with CHF reduced ejection fraction for implantation of devices with CRT function; the lack of external validation limits its application in practice.

Keywords: chronic heart failure; cardiac resynchronization therapy; response predictors; prognostic system.

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Оригинальные исследования

Факторы, ассоциированные с положительным гемодинамическим ответом на сердечную ресинхронизирующую терапию

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Цель исследования — провести сравнительный анализ клинических, электрокардиографических и эхокардиографических факторов у больных хронической сердечной недостаточностью (ХСН) с разным гемодинамическим ответом на проводимую сердечную ресинхронизирующую терапию (СРТ), оценить возможности их использования при прогнозировании положительного эффекта СРТ.

Материалы и методы. В исследование были включены 136 больных ХСН NYHA 3–4 функционального класса с фракцией выброса левого желудочка ⩽ 35% и длительностью QRS ⩾ 150 мс либо продолжительностью QRS 130–149 мс и морфологией QRS по типу блокады левой ножки пучка Гиса (БЛНПГ), которым для лечения ХСН и с целью первичной профилактики внезапной сердечной смерти была проведена имплантация кардиовертера-дефибриллятора с функцией сердечной ресинхронизирующей терапии (СРТ-Д). Включенные в исследование пациенты проспективно наблюдались в течение года для регистрации конечной точки — гемодинамического ответа на СРТ, оцененного по снижению конечного систолического объема левого желудочка на ⩾ 15%.

Результаты. В ходе 1-летнего наблюдения первичная конечная точка была зарегистрирована у 62 больных (46%). При однофакторной логистической регрессии выделено 4 исследуемых показателя с наибольшим прогностическим потенциалом ($p < 0,05$), связанных с возникновением исследуемой конечной точки. По результатам многофакторного регрессионного анализа была разработана прогностическая модель, в состав которой вошло три фактора, имеющих максимальные уровни статистической значимости: наличие в анамнезе указаний на ранее проведенную коррекцию клапанной недостаточности, продолжительность QRS, критерии БЛНПГ по Strauss. Диагностическая эффективность модели составила 73% (чувствительность 80%, специфичность 68%). Было обнаружено, что электрокардиографические показатели: критерии БЛНПГ по Strauss и продолжительность QRS — являются независимыми предикторами наступления изучаемой конечной точки.

Заключение. Разработанная многофакторная прогностическая модель может оказаться полезной в отборе больных ХСН с низкой фракцией выброса на имплантацию устройств с функцией СРТ, отсутствие внешней валидации ограничивает ее применение в практике.

Ключевые слова: хроническая сердечная недостаточность; сердечная ресинхронизирующая терапия; предикторы ответа; прогностическая система.

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INTRODUCTION

According to the Epidemiological Survey of Patients with CHF in Real Practice (EPOHA CHF study), the prevalence of chronic heart failure (CHF) in the Russian Federation has increased from 6.1% to 8.2% over the past 20 years [1], which explains the relevance of studying this medical problem.

The identification of disorders of interventricular and intraventricular conduction in patients with CHF led to the concept of cardiac resynchronization therapy (CRT) [2], which effectively eliminates electrical and mechanical dyssynchrony, improves the contractile function of the heart, and initiates reverse remodeling of the left ventricle [3]. Several studies have demonstrated that a decrease in left ventricular (LV) end-systolic volume (ESV) by ⩾ 15% is associated with a decrease in cardiovascular mortality in patients with CHF with reduced LV ejection fraction (CHF rEF) and therefore can be used as a reliable criterion for a positive hemodynamic response to CRT [4].

One of the most important and urgent problems in the use of CRT is insufficient response, which some researchers attribute to the inappropriate selection of patients for CRT. According to current recommendations, implantation of a CRT device is indicated for patients with CHF LVEF of ⩽ 35%, QRS duration of ⩾ 150 ms, or QRS duration of 130–149 ms and QRS morphology similar to left bundle branch block (LBBB) [5, 6]. This approach did not increase the number of patients who "responded" to CRT, which requires continued research in this field.

The work aimed to conduct a comparative analysis of clinical, electrocardiographic, and echocardiographic factors in patients with CHF with different hemodynamic responses to CRT and assess the possibility of their use in predicting the positive CRT effect.

MATERIALS AND METHODS

The presented material is a part of an ongoing single-center prospective clinical study conducted in accordance with the standards of Good Clinical Practice and the principles of the Declaration of Helsinki. The study protocol was approved by the local ethics committee of the Astrakhan State Medical University of the Ministry of Health of Russia (Minutes No. 3 of the LEC meeting dated 12/30/2021) and presented in the public register clinicaltrials.gov (NCT05539898). All patients under follow-up signed an informed consent to participate in the study.

Patient selection

The inclusion criteria were current indications for implantation of a biventricular implantable cardioverter-defibrillator (ICD) with CRT function (CRT-D) [5] and no history of sustained episodes of ventricular arrhythmias/sudden cardiac death. Exclusion criteria were as follows: hypertrophic cardiomyopathy, arrhythmogenic right ventricular dysplasia, verified hereditary channelopathies, and presence of indications for cardiac surgery (revascularization and correction of valvular insufficiency).

After testing for the inclusion/exclusion criteria, 180 patients who underwent CRT-D implantation were included in the study (Fig. 1). Device implantation was performed according to accepted methods [10]. A bipolar or

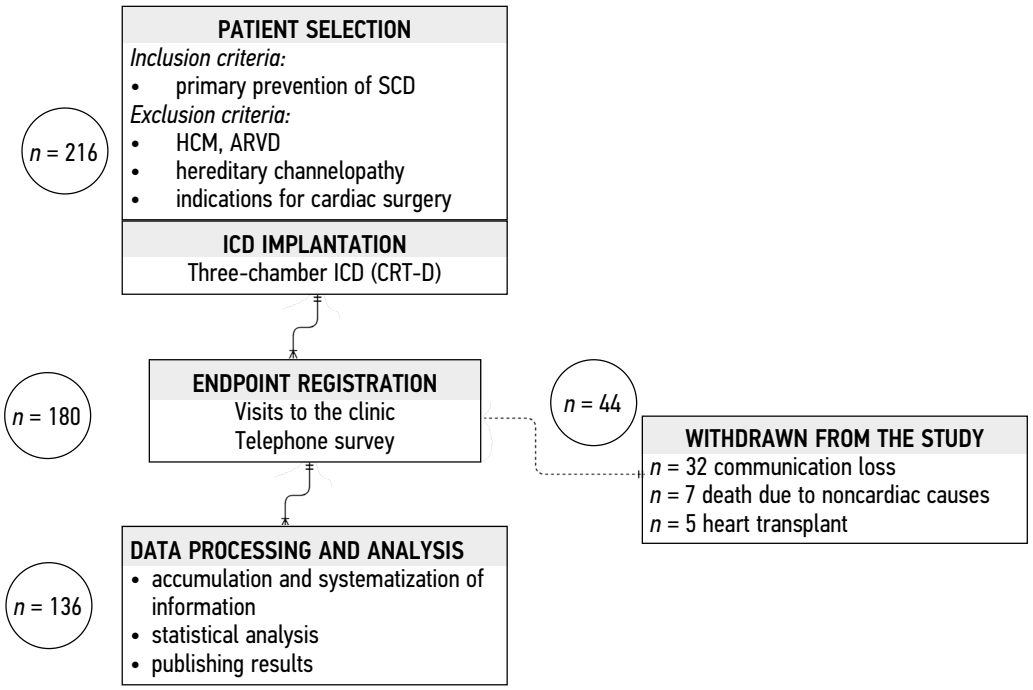

Fig. 1. Flow chart of the study design.

Note: ARVD, arrhythmogenic right ventricular dysplasia; CRT-D, implantable cardioverter defibrillator with cardiac resynchronization therapy function; HCM, hypertrophic cardiomyopathy; ICD, implantable cardioverter defibrillator; SCD, sudden cardiac death.

quadripolar LV lead was implanted using a delivery system into one of the coronary sinus veins. The lateral cardiac vein, which is usually located over the zone of late LV activation in patients with LBBB, was preferred for implantation.

To provide LV stimulation, a vector with a lower stimulation threshold and without stimulation of the phrenic nerve was chosen. Atrioventricular delay was performed to provide the maximum (approximately 100%) percentage of biventricular stimulation. Interventricular delay was determined by the minimum duration of the paced ventricular complex on the electrocardiogram (ECG). If delays can be selected, automatic algorithms of manufacturers were used [11]. ICD electrotherapy programming, protocol for recording and analyzing the ECG, and results of transthoracic echocardiography were described in detail previously [12, 13]. The presence of LBBB was determined according to the Strauss criteria [14].

Postoperative follow-up

Postoperative follow-up was performed for 12 months. The patients were invited to visit the clinic 3, 6, and 12 months after implantation. At this time, they were examined by a cardiologist, transthoracic echocardiography was performed, and if necessary, the programmed device parameters were corrected. In the case of cardiac decompensation, the patient can contact the investigator out of the schedule, the therapy was adjusted, and the clinical status was assessed jointly with cardiologists at the primary healthcare facility. Additionally, information about the occurrence of endpoints was obtained from the medical records, interviews of relatives, and messages analyzed from remote ICD monitoring (Medtronic Carelink, Biotronik HomeMonitoring).

The study endpoint was a hemodynamic response to CRT that was assessed by a decrease in LV ESV of ⩾ 15%.

Statistical analysis

Research data processed statistically using parametric and non-parametric analysis. Accumulation, adjustment, systematization of initial information, and visualization of the results were performed in Microsoft Office Excel 2010 spreadsheets. Statistical analysis was performed using IBM SPSS Statistics for Windows version 23 (IBM Corp., Armonk, NY, USA). Quantitative indicators were described and compared taking into account the distribution; those with normal distribution were assessed using the Kolmogorov–Smirnov test. When confirming the normality of the distribution, data were described using the arithmetic mean (*M*) and standard deviation. The comparison was performed using Student's *t*-test. In the absence of normal distribution, median (Me) and lower and upper quartiles (Q1–Q3) were indicated and were compared using the Mann–Whitney test. Nominal indicators were compared using Pearson's χ^2 test. When comparing relative indicators, the odds ratio (OR) was used as a quantitative measure of the effect. Significance was proven if the confidence interval (CI) was outside the border of no effect, which was taken as 1. The critical level of significance when testing statistical hypotheses was equal to 0.05. The multivariate prognostic model for determining the response to resynchronization therapy based on the studied ECG parameters was constructed using the binary logistic regression method. Independent variables were selected using the stepwise inverse selection method employing Waldovsky statistics as an exclusion criterion. The statistical significance of the resulting model was determined using Pearson's χ^2 test.

Nigelkirk's R2 was used as a measure of certainty, indicating the segment of the variance that can be explained by logistic regression. To assess the predictive value of the model and determine the threshold value of the resulting function at the cutoff point, receiver operating characteristics (ROC) analysis was performed with the calculation of the area under the curve.

RESULTS

A total of 136 patients completed the study protocol. The study endpoint was reported in 62(46%) patients. When analyzing the studied clinical and demographic indicators, the QRS duration, frequency of registration of Strauss LBBB, a history of previously performed surgical correction of valvular insufficiency, and permanent atrial fibrillation showed significant differences (Table 1).

These four factors were subjected to univariate and multivariate analyses (Table 2).

Using the binary logistic regression method, prognostic models were developed to determine the probability of hemodynamic response to CRT in patients with CHF rEF, based on the studied parameters.

The best predictive model was described by the following equation (1):

$$p = 1/(1+e^{-z})*100\ \%$$

$$z = -6.018 - 1.909*X_{valves} + 1.931*X_{LBBB} + 0.026*X_{QRS} \quad (1)$$

where p is the probability of cardiovascular death; X_{valves} — a history of correction of valvular insufficiency; X_{LBBB} — presence of LBBB according to Strauss; and X_{QRS} — duration of the QRS complex.

The resulting regression model was statistically significant (p = 0.001). Based on the value of Nigelkirk's determination coefficient, the model (1) takes into account 28.4% of the factors that determine the probability of a positive hemodynamic response to CRT.

The area under the ROC curve, which corresponds to the relationship between the prediction of the primary endpoint occurrence and the regression function value, was 0.768 ± 0.059 with 95% CI of 0.653–0.883 (Fig. 2).

The threshold value of function (1) at the cutoff point was 0.5. Values equal to or greater than this value corresponded to a good prognosis of a positive hemodynamic

Table 1. Comparative clinical and demographic characteristics of patients, depending on the endpoint achievement

Clinical indicator	All patients (*n* = 136)	Patients responding to CRT (*n* = 62)	Patients not responding to CRT (*n* = 74)	*P* 3–4
Age, years	56 (52–62)	56 (53–66)	55 (52–60)	0.844
Male sex, *n* (%)	108 (79)	46 (74)	62 (84)	0.250
BMI, kg/m^2	29.1 (25.7–31.8)	28.2 (25.6–32)	29 (26.6–32.1)	0.571
CHD, *n* (%)	42 (31)	16 (26)	26 (35)	0.287
PICS among patients with CHD, *n* (%)	24 (18)	8 (13)	16 (22)	0.270
DCM, *n* (%)	94 (69)	46 (74)	48 (65)	0.912
CHF grade 3, *n* (%)	119 (88)	56 (90)	63 (85)	0.221
CHF grade 4, *n* (%)	17 (13)	6 (10)	11 (15)	0.317
History of AH, *n* (%)	68 (50)	28 (45)	40 (54)	0.465
Diabetes mellitus, *n* (%)	28 (21)	8 (13)	20 (27)	0.128
Obesity, *n* (%)	54 (40)	24 (39)	30 (41)	0.878
Cerebral stroke, *n* (%)	10 (7)	2 (3)	8 (11)	0.238
CKD, *n* (%)	65 (48)	25 (41)	40 (54)	0.304
Anemia, *n* (%)	10 (7)	26 (10)	4 (6)	0.426
AF (paroxysmal/persistent), *n* (%)	32 (24)	20 (32)	12 (16)	0.103
AF (permanent form), *n* (%)	10 (7)	0	10 (14)	0.042
VTunst, *n* (%)	6 (4)	2 (3)	4 (5)	0.567
SBP, mm Hg	120 (110–130)	120 (110–135)	120 (110–135)	0.866
DBP, mm Hg	80 (70–80)	80 (70–80)	80 (70–80)	0.995
HR, bpm	75 (68–85)	76 (71–82)	75 (64–87)	0.445
PQ duration, ms	190 (160–200)	180 (160–190)	180 (160–200)	0.615
QRS duration, ms	170 (160–190)	180 (160–190)	160 (150–185)	0.035
Strauss LBBB, *n* (%)	110 (81)	58 (94)	52 (70)	0.015
LV end-systolic volume (mL/m^2)	95 (73–115)	95 (74–118)	82 (71–103)	0.182
LV end-diastolic volume (mL/m^2)	129 (102–156)	127 (110–154)	122 (100–135)	0.108
Simpson LV EF, %	29 (25–33)	29 (26–34)	30 (26–34)	0.710
LV relative wall thickness (cm)	0.31 (0.26–0.36)	0.30 (0.27–0.36)	0.32 (0.27–0.39)	0.348
LV mass index (g/m^2)	167 (137–205)	167 (136–185)	182 (133–221)	0.954
VLA (mL)	92 (76–120)	89 (84–93)	100 (79–104)	0.488
Pulmonary artery systolic pressure (mm Hg)	44 (31–56)	41 (30–53)	40 (31–55)	0.265
RVbas, cm	3.9 (3.4–4.5)	3.6 (3.5–3.6)	3.9 (3.5–4.6)	0.792
RVav, cm	3.3 (2.7–4.0)	2.5 (2.3–2.6)	3.0 (2.8–3.3)	0.410
TAPSE, cm	1.7 (0.8–1.9)	1.8 (1.7–1.8)	1.7 (1.2–1.95)	0.915
Surgical interventions on the heart:				
Revascularization (coronary bypass or percutaneous coronary intervention), *n* (%)	36 (26)	14 (23)	22 (30)	0.350
Valve insufficiency correction, n (%)	22 (16)	4 (6)	18 (24)	0.045
LV plastic surgery, *n* (%)	16 (12)	5 (8)	11 (15)	0.392
Quadripolar LV lead, *n* (%)	24 (16)	12 (19)	10 (14)	0.372
Received drug therapy:				
β-blockers, *n* (%)	136 (100)	62 (100)	74 (100)	0.913
ACE inhibitor/ARA II, *n* (%)	93 (68)	43 (69)	50 (67)	0.851
ARNI, *n* (%)	43 (32)	19 (31)	24 (33)	0.831
Mineralocorticoid antagonists, *n* (%)	121 (89)	54 (88)	67 (90)	0.154
Loop diuretics, *n* (%)	131 (96)	59 (95)	72 (97)	0.912
iSGCT-2, *n* (%)	11 (8)	5 (8)	6 (8)	0.381
Sotalol, *n* (%)	22 (16)	7 (11)	15 (20)	0.191
Amiodarone, *n* (%)	43 (32)	22 (35)	21 (29)	0.152

Note: Data are presented as absolute number of patients (%) or as *Me*(Q1–Q3) unless otherwise indicated. ACE inhibitors, angiotensin-converting enzyme inhibitors; AF — atrial fibrillation; AH, arterial hypertension; ARA II, angiotensin II receptor antagonists; ARNI, angiotensin receptors and neprilysin inhibitors; BMI, body mass index; CHD, coronary heart disease; CKD, chronic kidney disease; DBP, diastolic blood pressure; DCM, dilated cardiomyopathy; HR, heart rate; iSGCT-2, sodium-glucose cotransporter type 2 inhibitors; LVEF, left ventricular ejection fraction; PICS, postinfarction cardiosclerosis; SBP, systolic blood pressure; VTunst, unstable runs of ventricular tachyarrhythmias

Table 2. Relationship between the study factors and the primary endpoint

Factors	Univariate analysis			Multivariate analysis		
	OR	95% CI	*P*	OR	95% CI	*p*
AF (permanent form)	0.005	0.002–1.032	0.467	–	–	–
LBBB	6.135	1.242–30.292	0.026	6.896	1.310–36.307	0.023
QRS duration	1.026	1.002–1.050	0.034	1.026	1.000–1.053	0.048
Correction of valvular insufficiency in history	0.215	0.043–1.082	0.062	0.148	0.026–0.834	0.030

Note: AF, atrial fibrillation; CI, confidence interval; LBBB, complete blockade of the left bundle branch block; OR, odds ratio

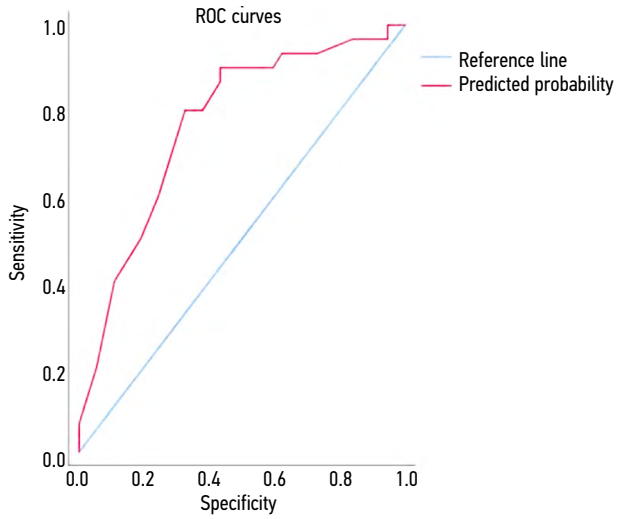

Fig. 2. ROC curve indicating the relationship between the probability of a hemodynamic response to CRT and the value of the regression equation obtained.

response to CRT. The sensitivity and specificity of the method were 80% and 68%, respectively.

DISCUSSION

Our results are consistent with the rate of positive hemodynamic response to CRT described in the literature. In previous major international multicenter studies involving a similar cohort of patients, this indicator (estimated as a decrease in LV ESV of ⩾15%) varied from 40% [15] to 56% [16].

In the course of achieving this aim, a model with a high prognostic metric (diagnostic efficiency of 73%) was proposed, which included one clinical and anamnestic factor and two electrocardiographic parameters.

The identification of the predictive potential of a history of indications of a previous correction of valvular insufficiency was quite unexpected. The authors who evaluated this factor revealed that it did not affect the efficiency of CRT [17]. Meanwhile, taking into account the close anatomical relationship between the large veins of the heart and the atrioventricular annuli [18], it can be assumed that during surgery for correcting the valvular heart disease, it is possible to change the anatomy of the venous bed of the heart, including that part that could be used as a target vein for the implantation of the LV lead. However, such a hypothesis was not evaluated in this study, which reduces the significance of the proposed explanation of the results.

An increase in the QRS interval duration on the surface ECG may reflect the degree of mechanical dyssynchrony, which, according to some authors, correlates directly with the probability of successful CRT [12, 19, 20]. In the present study, patients who responded positively to CRT had a longer QRS. This factor and the presence of the Strauss electrocardiographic criteria for LBBB were used as independent predictors of a decrease in LV ESV of ⩾ 15%.

Based on the analysis of computer models and data from electroanatomical mapping of the heart, the Strauss criteria, according to some researchers, have the best combination of sensitivity and specificity in predicting CRT response [21, 22]. The researchers explained the increase in the lower threshold of the QRS interval of ⩾130 ms in women and ⩾140 ms by the time required for the impulse to pass along the interventricular septum from the right ventricular endocardium to the LV endocardium and the subsequent spread of excitation and depolarization of the myocardium of the LV posterior lateral wall. This pattern of ventricular activation, characteristic of LBBB,

is also associated with the appearance of a double notch in lateral leads (V5, V6, I, aVL, and/or in V1 and V2) [14]. According to our findings, the verification of LBBB criteria according to Strauss increased the probability of a positive effect of CRT six times.

STUDY LIMITATIONS

This study is limited by its single-center setting. The developed model has not passed external validation, which limits its application in practice. The dynamics of LV ESV was assessed within 12 months after device implantation, and an increase in the follow-up period may increase the number of patients who responded to CRT.

CONCLUSION

The developed multivariate prognostic model may be useful in the selection of patients with CHF rEF for implantation of devices with CRT function. Among the parameters analyzed in the study, the Strauss electrocardiographic criteria for LBBB and QRS duration demonstrated an independent predictive potential to assess the probability of a positive hemodynamic response to CRT.

ADDITIONAL INFORMATION

Conflict of interest. The authors declare no conflict of interest.

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