ORIGINAL ARTICLES

УДК 616.12-008.46-036.12-037-036.88
https://doi.org/10.20538/1682-0363-2024-2-74-82

External validation of a multivariate model for predicting the risk of death in patients with chronic heart failure and an implantable cardioverter – defibrillator

Lebedeva N.B.[1], Parfenov P.G.[1], Ivanov V.I.[2], Egle A.P.[1], Galintsev Yu.V.[2], Kashtalap V.V.[1], Barbarash O.L.[1]

[1] *Research Institute for Complex Problems of Cardiovascular Diseases*
6, Sosnovy Blvd., Kemerovo, 650002, Russian Federation

[2] *Kemerovo State Medical University*
22a, Voroshilova Str., Kemerovo, 650056, Russian Federation

ABSTRACT

Aim. To perform external validation of a multivariate model for predicting the risk of death in patients with an implantable cardioverter – defibrillator (ICD) in an independent sample.

Materials and methods. The group for model development included 260 patients from the Implantable Cardioverter – Defibrillator Patient Registry who had an ICD implanted between 2015 and 2019. External validation of the model was carried out in an independent, prospective, observational cohort study of patients from the same registry, in whom an ICD was implanted between 2020 and 2021, a total of 94 patients, median age 66 (52;73) years, 73 (77.6%) men, 21 (22.4%) women. In 89 (94.7%) patients, an ICD was implanted for primary prevention of sudden cardiac death. Following a telephone survey and examination of medical records from hospital and clinic databases, data on the vital status (alive / dead) and causes of death were obtained during a 2.5-year follow-up. The actual and predicted mortality from the estimated multivariate model were compared.

Results. During the follow-up, a total of 26 (27.7%) patients died in the external validation group, which was comparable to the development group ($p > 0.05$). In the group of deceased, 15 (57.7%) people developed acute decompensated heart failure, 4 (14.8%) had myocardial infarction, 6 (23.1%) had pneumonia caused by a new coronavirus infection, and one (3.8%) patient died due to an infectious complication.

The diagnostic accuracy of the multivariate model for predicting the risk of death in patients with ICD in an independent sample was sufficient (the area under the curve (AUC) of the created model was 0.8). The sensitivity of the model was 76.2%, specificity – 76.1%. Previously, in the development cohort, AUC of the created model was 0.8, the sensitivity of the model was 75.7%, and the specificity was 80%. Model significance did not differ significantly between the development and external validation groups ($p = 0.102$, McNeil test).

Conclusion. The multivariate prediction model has sufficient statistical power to predict the risk of long-term death after ICD implantation, which was externally validated.

Keywords: implantable cardioverter – defibrillator, heart failure, prognostic model, death, validation

Conflict of interest. The authors declare the absence of obvious or potential conflict of interest related to the publication of this article.

Source of financing. The study was carried out within the basic research topic of Research Institute for Complex Problems of Cardiovascular Diseases "Developing innovative risk management models for cardiovascular diseases with account of comorbidity based on the study of fundamental, clinical, and epidemiological mechanisms and medical care organization technologies in conditions of the industrial region of Siberia" (state registration No. 122012000364-5 of 20.01.2022).

✉ *Lebedeva Nataliya B.,* lebenb@mail.ru

Conformity with the principles of ethics. All patients signed an informed consent to participate in the study. The study was approved by the local Ethics Committee at Research Institute for Complex Problems of Cardiovascular Diseases (Protocol No. 1 of 26.01.2015).

For citation: Lebedeva N.B. , Parfenov P.G., Ivanov V.I., Egle A.P., Galintsev Yu.V., Kashtalap V.V., Barbarash O.L. External validation of a multivariate model for predicting the risk of death in patients with chronic heart failure and an implantable cardioverter – defibrillator. *Bulletin of Siberian Medicine.* 2024;23(2):74–82. https://doi.org/10.20538/1682-0363-2024-2-74-82.

Внешняя валидация многофакторной модели прогнозирования риска смерти у пациентов с хронической сердечной недостаточностью и имплантированным кардиовертером-дефибриллятором

Лебедева Н.Б.[1], Парфенов П.Г.[1], Егле А.П.[1], Иванов В.И.[2], Галинцев Ю.В.[2], Кашталап В.В.[1], Барбараш О.Л.[1]

[1] Научно-исследовательский институт комплексных проблем сердечно-сосудистых заболеваний (НИИ КПССЗ)
Россия, 650002, г. Кемерово, Сосновый бульвар, 6

[2] Кемеровский государственный медицинский университет (КемГМУ)
Россия, 650056, г. Кемерово, ул. Ворошилова, 22а

РЕЗЮМЕ

Цель. Внешняя валидация многофакторной модели прогнозирования риска смерти у пациентов с имплантированным кардиовертером-дефибриллятором (ИКД) на независимой выборке.

Материалы и методы. Группа разработки модели была представлена 260 пациентами из Кузбасского регистра пациентов с имплантированным кардиовертером-дефибриллятором, которым ИКД был имплантирован в период с 2015 по 2019 г. Внешняя валидация модели проведена в когорте независимого проспективного наблюдения пациентов из этого же регистра, которым ИКД был имплантирован в период с 2020 по 2021 г., всего 94 пациента, медиана возраста 66 (52;73) лет, 73 (77,6%) мужчин, 21 (22,4%) женщина. У 89 (94,7%) пациентов ИКД был имплантирован с целью первичной профилактики внезапной сердечной смерти. Путем телефонного опроса, изучения медицинской документации баз данных стационаров и поликлиник были получены данные о статусе «жив/умер» и о причинах смерти в течение 2,5 лет наблюдения. Сравнивалась фактическая и прогнозируемая по оцениваемой многофакторной модели смертность.

Результаты. За период наблюдения в группе внешней валидации всего умерли 26 (27,7 %) пациентов, что было сопоставимо с группой разработки ($p > 0,05$). В группе умерших у 15 (57,7%) развилась острая декомпенсация сердечной недостаточности, у 4 (14,8 %) установлен инфаркт миокарда, у 6 (23,1%) – пневмония, вызванная новой коронавирусной инфекцией, 1 (3,8%) пациент умер из-за инфекционного осложнения.

Диагностическая точность многофакторной модели прогнозирования риска смерти у пациентов с ИКД на независимой выборке была достаточной (площадь под ROC-кривой (AUC) созданной модели составила 0,8). Чувствительность модели составила 76,2%, специфичность – 76,1%. Ранее на когорте разработки площадь под ROC-кривой (AUC) созданной модели составила 0,8; чувствительность модели – 75,7%; специфичность – 80%. Значимость модели в группах разработки и внешней валидации существенно не отличалась ($p = 0,102$, тест McNeil).

Заключение. Многофакторная модель прогнозирования обладает достаточной статистической мощностью для прогнозирования риска смерти в отдаленном периоде после имплантации ИКД, что подтверждено внешней валидацией.

Ключевые слова: имплантируемый кардиовертер-дефибриллятор, сердечная недостаточность, прогностическая модель, смерть, валидация

Конфликт интересов. Авторы декларируют отсутствие явных и потенциальных конфликтов интересов, связанных с публикацией настоящей статьи.

Источник финансирования. Работа выполнена в рамках фундаментальной темы НИИ КПССЗ «Разработка инновационных моделей управления риском развития болезней системы кровообращения с уче-

том коморбидности на основе изучения фундаментальных, клинических, эпидемиологических механизмов и организационных технологий медицинской помощи в условиях промышленного региона Сибири» (№ госрегистрации 122012000364-5 от 20.01.2022).

Соответствие принципам этики. Все лица подписали информированное согласие на участие в исследовании. Исследование одобрено локальным этическим комитетом КПССЗ (протокол № 1 от 26.01.2015).

Для цитирования: Лебедева Н.Б., Парфенов П.Г., Егле А.П., Иванов В.И., Галинцев Ю.В., Кашталап В.В., Барбараш О.Л. Внешняя валидация многофакторной модели прогнозирования риска смерти у пациентов с хронической сердечной недостаточностью и имплантированным кардиовертером-дефибриллятором. *Бюллетень сибирской медицины.* 2024;23(2):74–82. https://doi.org/10.20538/1682-0363-2024-2-74-82.

INTRODUCTION

According to recent data, the prevalence of severe chronic heart failure (CHF) in Russia has increased to 8.2% [1]. Low left ventricular ejection fraction (LVEF) is one of the main predictors of the development of life-threatening ventricular arrhythmias (VA) and the associated high risk of sudden cardiac death (SCD) [2]. Current clinical guidelines for the prevention of SCD consider LVEF lower than 35% as the main indication (class Ia evidence) for implantation of a cardioverter – defibrillator (ICD) for primary prevention of SCD [1, 3].

Therefore, the need for ICD for SCD prevention is very high. However, despite a steady increase in the number of ICDs implanted, Russia occupies last places in European ratings in the availability of interventional treatment for cardiac arrhythmia in the regions [4]. On the other hand, data from clinical practice indicate that patients with low LVEF are more likely to die from acute decompensated heart failure than from other causes, including SCD [5]. Thus, a prediction model that can assess mortality risk in patients with low LVEF before ICD implantation will help implement a patient-oriented approach to selecting patients for this type of medical care.

Clinical prognosis is based on available clinical data and the use of modern statistical methods and allows specialists to assess the risk of developing an event, making it an important area of research with a clear practical purpose. In this regard, in the medical field in general and in cardiology, in particular, an exponential growth in the number of prediction models has been seen. However, not all developed models undergo external validation. Thus, it was shown that out of 1,366 different models for predicting cardiovascular diseases, only 43.4% provided data on external validation [6]. Moreover, only single externally validated models have proven their clinical effectiveness by demonstrating that their use leads to improved results for patients and doctors.

The aim of this study was to perform external validation of a multivariate model for predicting the risk of death in patients with ICD in an independent sample.

MATERIALS AND METHODS

A multivariate prognostic model for determining the risk of nonarrhythmic death in patients with CHF and ICD was developed and internally validated as a result of a single-center, observational, prospective study based on data from the Kuzbass ICD Patient Registry. The registry consistently included all patients of the Kemerovo region who had ICD implanted from 2015 to 2019 and reached a total of 264 patients. The development of the registry and the informed consent form were approved by the local Ethics Committee and complied with the ethical principles of the Declaration of Helsinki. All study participants signed an informed consent upon admission to the hospital. When maintaining the registry, all the requirements of the Federal Law No. 152-FZ of 07.27.2006 “On Personal Data” were met.

The mean age of the patients included in the development group was 59 (53; 66) years, 214 (82.3%) were men, 28 (10.8%) were working. All patients were diagnosed with CHF. Median LVEF was 30 (25;36)%. A total of 158 (60.8%) patients received ICD for SCD prevention. Prior to ICD implantation, only 122 (46.9%) patients received triple combination therapy (renin – angiotensin – aldosterone system blocker (RAAS), mineralocorticoid receptor antagonist (MCRA), beta-adrenergic blocker (BAB)), according to the relevant clinical guidelines for the treatment of CHF.

To determine the most significant predictors of death during the follow-up period, a step-by-step logistic regression analysis with the inclusion of

the most important variables was performed (all variables can be assessed during patient screening), and prognostic models were developed for the risk of death, composite endpoint, and CHF progression. The regression equation was as follows: $y = a + b1 \times x1 + b2 \times x2 + ...bi \times xi$, where y is a dependent variable that can have two values: 0 – no event, 1 – event; a – constant; bi – regression coefficients; Xi – variables.

The probability of the event P was calculated according to the formula: $P = 1 / (1 + e^{-y})$, where P is predictive probability, e – exponent, whose approximate value equals to 2.718.

The verification of the null hypothesis regarding the validity of the model was carried out using the Hosmer – Lemeshow test; $p > 0.05$ indicated the validity of the model.

Following the development of the model, the qualitative assessment of the predictive probability of an event was conducted. When predicting death, the cut-off value was 0.2; for other events, it was 0.5.

Initially, the model included factors that had significant differences in comparison assessments. The parameters obtained during the model development using step-by-step regression are presented in Table 1.

Table 1

Regression coefficients used in the model for predicting the risk of low-term mortality (4 years) in patients with an implanted cardioverter – defibrillator

Parameter	Variables in the equation					
	B	Standard error	Wald	df	Significance	Exp (B)
P(PA) mmHg, X1	0.049	0.014	12.696	1	0.000	1.050
NYHA, X2	1.312	0.353	13.854	1	0,000	3.715
Type of prevention of SCD, X3	–1.396	0.370	14.203	1	0.000	0.248
Age, X4	0.054	0.017	9.596	1	0.002	1.055
RAAS + BAB+ MCRA, X5	1.244	0.380	10.737	1	0.001	3.470
BAB, X6	–1.626	0.681	5.701	1	0.017	0.197
Constant	–5.691	1.336	18.145	1	0.000	0.003

Note. P (PA) – systolic pressure in the pulmonary artery, NYHA – functional classification of heart failure proposed by New York Heart Association.

The probability of death was calculated as follows:

$$P = 1/(1 + 2.718^{-(-5.691 + 0.049 \times X1 + 1.312 \times X2 - 1.396 \times X3 + 0.054 \times X4 + 1.244 \times X5 - 1.626 \times X6)}) \times 100\%$$

P above 28% indicated a high risk of death.

Thus, the developed prediction model takes into account systolic pulmonary artery pressure above 45 mm Hg ($p = 0.000$), NYHA functional class ($p = 0.000$), type of SCD prevention ($p = 0.000$), triple combination therapy for CHF ($p = 0.001$), and therapy with BAB ($p = 0.017$). During internal validation, the Hosmer – Lemeshow test value for this model was $\chi 2 = 4.210$, $p = 0.838$, area under the curve (AUC) for the model was 0.8, sensitivity was 80%, and specificity was 75.7%, which indicated a high predictive ability. The model appears as a computer program for Microsoft Windows 9x / NT / 2000 / Vista, 7, 8 operating systems entitled "Calculator of mortality risks in patients with an implanted cardioverter – defibrillator" [7].

In order to externally validate this prediction model on an independent sample, 94 patients hospitalized at the Research Institute for Complex Issues of Cardiovascular Diseases for ICD implantation in 2020–2021 were included in a single-center, prospective study. The mean age of the patients was 66 (52; 73) years, 73 (77.6%) were men, 21 (22.4%) were women, 16 (17%) patients were still working. The comparative clinical characteristics of the groups and external validation of the model are presented in Table 2.

We assessed the risk of long-term mortality after ICD implantation in all patients using the developed model [7]. After that, we conducted a prospective follow-up with annual accumulation of data regarding the vital status of patients and causes of death. The follow-up period was 2.5 years.

Statistical processing of the results was carried out using the Statistica 10.0 (StatSoftInc., USA) and SPSS Statistics ver.23.0 (IBM, USA) software packages. The normality of data distribution was checked using the Shapiro – Wilk test. The Student's t-test was used to compare continuous variables with normal distribution; for the non-normally distributed data, the nonparametric Mann – Whitney U test was used. Discrete variables were compared using the $\chi 2$ test with the Yates correction. In case the number of variables was too small in one of the compared groups

(5 or less), the Fisher's exact test was applied. The data were presented as the median and the interquartile range *Me* (Q_{25}; Q_{75}) and as the absolute and relative values *n* (%). The differences were considered statistically significant at $p < 0.05$.

External validation was performed using the ROC analysis. By constructing curves, we analyzed the diagnostic accuracy of the model. Sensitivity and specificity were calculated for each diagnostic criterion. The diagnostic significance in different groups was compared by AUC values using the McNeil test. The classification and compliance assessment with actual events was performed using the Hosmer – Lemeshow test. The model was considered as adequate in the absence of significant differences ($p > 0.05$).

RESULTS

Comparative characteristics of the development and validation groups are presented in Table 2.

Table 2

Baseline clinical and anamnestic characteristics of the groups, *n* (%)

Parameter	Development, *N* = 260, 2015–2019	External validation group, *N* = 94, 2019–2020
Men	214 (82.3)	73 (77.6)
Age, years, *Me* (Q_{25}; Q_{75})	59 (53; 66)	66 (52; 73)
Still working	28 (10.8)	16 (17)*
CAD	194 (74.6)	76 (80.8)
PICS	156 (60)	58 (61.7)
Non-coronary diseases	66 (25.4)	18 (19.2)
LVEF, %, *Me* (Q_{25}; Q_{75})	30 (25; 36.5)	29.5 (24;37)
All types of AF	106 (40.8)	41 (43.6)
NYHA I–II	179 (68.8)	44 (46.8)*
NYHA III–IV	81 (31.2)	50 (53.2)*
Primary prevention of SCD	158 (60.8)	89 (94.7)*

Note. CAD – coronary artery disease, PICS – post-infarction cardiostenosis, AF – atrial fibrillation, *N* – number of patients. * $p < 0.01$.

The patients were comparable in gender, age, and etiology of CHF and LVEF. The external validation group had more severe cases of HF, and the majority of patients received ICD for SCD prevention (Table 2). Considering the fact that optimal drug therapy for CHF was an important prognostic factor, we carried out a comparative analysis of drug therapy in the development and external validation groups (Table 3)

Table 3

Frequency of prescription of drug therapy for heart failure prior to ICD implantation, *n* (%)

Drug	Development group, *N* = 260	External validation group, *N* = 94
ACEI	164 (57.3)	56 (59.5)
ARBs*	41 (14.3)	36 (38.2)
ARNI*	5 (1.7)	14 (14.9)
BAB	259 (90.6)	87 (92.5)
MCRA*	167 (58.4)	65 (69.1)
Amiodarone	144 (50.3)	54 (57.4)

Note. ACEI – angiotensin-converting enzyme inhibitor, ARB – angiotensin receptor blocker, ARNI– angiotensin receptor – neprilysin inhibitor, *N* – number of patients. * $p < 0.01$.

When comparing the drug therapy received before ICD implantation, it turned out that patients in the validation group were prescribed MCRA and RAAS inhibitors more often. However, only 122 (46.9%) patients in the development group and 49 (52.1%) patients in the validation group received triple combination CHF therapy ($p < 0.05$).

During the follow-up period, 54 patients died in the development group, and 4 patients were lost to follow-up and considered as dead; thus, the mortality rate in the group was 21.9%. Among these patients, 19 (35.2%) patients died in hospital, of which 3 (17.6%) had myocardial infarction, 1 (5.9%) had stroke, 13 (76.5%) died due to CHF and 2 (3.7%) died from pneumonia caused by novel coronavirus infection. Thirty-five (64.8%) patients died outside hospital, they suffered acute decompensated HF, and the cause of death was the underlying disease: 10 (27%) had dilated cardiomyopathy, 1 (2.8%) had rheumatic heart valve disease, and the remaining 24 (68.6%) had ischemic cardiomyopathy. The vast majority of deaths occurred in the first 1.5 years of the follow-up.

During the 2.5-year follow-up, 26 (27.7%) deaths were recorded in the external validation group, which is comparable to the development group ($p > 0.05$). Among the deceased patients, 15 (57.7%) developed CHF, 4 (14.8%) had myocardial infarction, 6 (23.1%) had pneumonia caused by novel coronavirus infection, and 1 (3.8%) patient died due to an infectious complication (sepsis).

The prognostic value of the developed model in the external validation group proved to be high (Figure).

The Hosmer – Lemeshow test for this predictive model was the following: $\chi 2 = 4.210$; $p = 0.838$. During the ROC analysis, AUC of the model was

0.8, indicating high predictive ability. Sensitivity of the model was 76.2%, and specificity was 76.1%. All these parameters confirmed the validity of the model.

The diagnostic value of the model in the development and external validation groups did not differ significantly ($p = 0.102$, McNeil test).

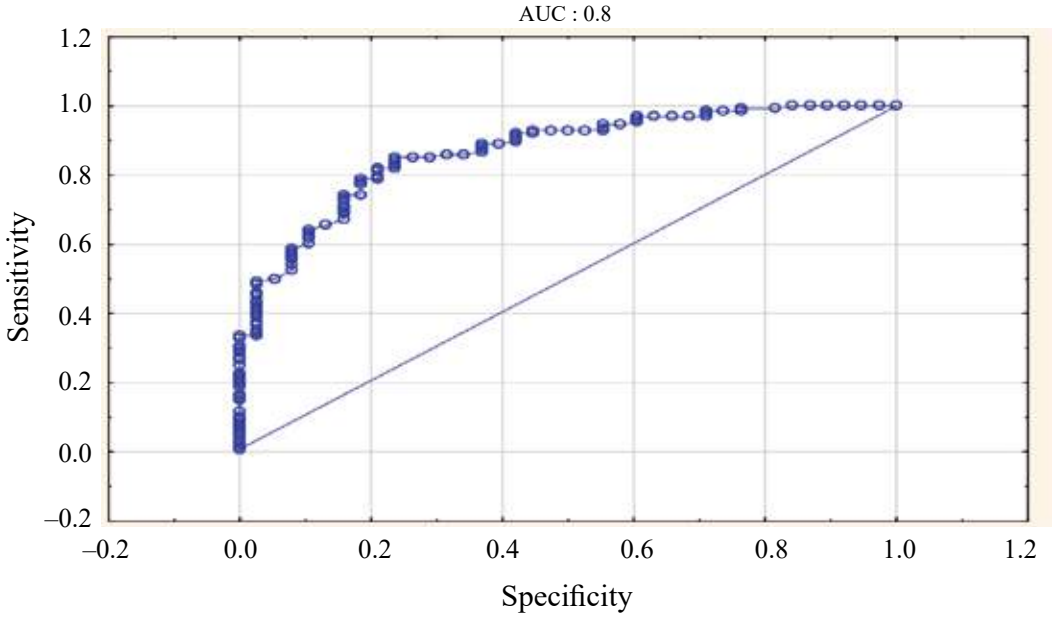

Figure. ROC curve for assessing mortality risk in patients with an implanted cardioverter – defibrillator in the external validation group

Table

Classification table

Patients		Predicted		
		Death		Percentage of correct predictions, %
		0	1	
Death	0	143	45	76,1
	1	15	48	76,2
Total percentage				76,1

Cut-off value was 0.280.

DISCUSSION

The data obtained in this study confirm that patients with low LVEF, including patients with ICD, die from CHF more frequently [8]. Currently, much attention is being paid to the issue of residual high mortality in patients with ICD and the search for predictors that would help identify ICD patients at high-risk of adverse outcomes [9–12]. In this regard, the possibility of predicting the risk of death becomes necessary when considering ICD implantation. In this context, the development of prediction models for application in clinical practice becomes relevant.

The MADIT-II risk score, intended for stratification of benefits of ICD implantation, includes eight predictors of the development of VA (male, age < 75 years, history of unstable ventricular tachycardia, heart rate >75 beats / min, systolic blood pressure < 140 mmHg, LVEF ≤ 25%, history of myocardial infarction and atrial arrhythmia) and seven predictors of nonarrhythmic death (age ≥ 75 years, diabetes mellitus, body mass index > 23 kg / m^2, LVEF ≤ 25%, NYHA class ≥ II, ICD instead of cardiac resynchronization therapy, atrial fibrillation, the level of the brain natriuretic peptide (BNP), and the duration of the QRS complex) [13]. Based on the combined analysis of these predictors, scientists developed a model for an individual assessment of a risk of developing VA compared to nonarrhythmic death. However, this scale was developed using data from studies conducted more than 20 years ago, its application is limited to patients with ischemic cardiomyopathy only, and the scale has not been validated in the Russian population.

Prior studies on the use of ICD are mainly aimed at determining the risk of developing VA and inappropriate ICD shocks in patients with CHF. Prospective Observational Study of Implantable Cardioverter – Defibrillators (PROSE-ICD) is one of the few studies to analyze predictors of mortality in patients with ICD. It included 1,189 patients with systolic HF who had ICD implanted for primary prevention of SCD. During the four-year follow-up, 343 (28.8%) patients died, and appropriate ICD shocks occurred in 137 (11.5%) patients. The study results showed that elevated levels of C-reactive protein, tumor necrosis factor alpha, BNP, troponin T, and iinterleukin-6 increased the risk of death ($p < 0.001$ for all parameters) [14]. To predict the risk of mortality, this study used biochemical markers that would not be routinely assessed in clinical practice. In addition, it has not been validated in the Russian population as well.

The well-known Seattle Heart Failure Model (SHFM), used to assess the life expectancy of patients with CHF at the outpatient stage, and the Meta-Analysis Global Group in Chronic (MAGGIC) Heart Failure scale are also based on the results of long-standing studies, do not take into account comorbid pathology, cannot be applied at the inpatient stage, and cannot be used to assess risks in patients with implanted devices, in particular, with ICD [15, 16].

In a study by T.E. Verstraelen et al. (2021) on the development and external validation of a model for predicting mortality in the ICD group (primary prevention of SCD) during a 2.7-year follow-up, 193 (13.4%) patients died in the development group and 223 (15.4%) patients died in the validation group, which is significantly different from the Russian population [10]. The predictors of all-cause mortality were age, diuretic intake, sodium and BNP levels, and intake of RAAS inhibitors. The C-statistic was 0.74 for both external and internal validation groups. Russian researchers are also actively working on the possibility of predicting outcomes in patients with CHF, however, almost all proposed methods include the need to determine either genetic markers or complex biochemical parameters, but do not include patients with ICD, thereby limiting practical application of these methods [17].

Therefore, currently there are no adequate ways to assess the risk of long-term nonarrhythmic mortality after ICD implantation in patients with CHF and low LVEF, suitable for use in the Russian clinical practice. The proposed and validated model for assessing the risk of nonarrhythmic death in patients with ICD differs from existing ones because it takes into account the presence of both factors (CHF with low LVEF and ICD), as well as comorbidity and adherence to optimal drug therapy (an important prognostic factor for the Russian population) to determine the prognosis.

The application of the prediction model involves the assessment of routine parameters included in a standard examination of a patient with CHF and does not require additional costs. It is important to note that this prediction model can and should be used before ICD implantation. It is supposed to identify the patients who would not significantly benefit from ICD implantation in the long term due to a high risk of SCD. In general, the predictive value of the studied model, estimated on the basis of an independent sample, is comparable with the results of the internal validation.

CONCLUSION

The presented multivariate model has sufficient prognostic power to predict the risk of death in patients with ICD in the long term, as confirmed by the external validation. However, risk stratification remains a difficult task, and based on the conducted research, identifying a group of patients who would not benefit from ICD implantation is still an issue. However, the proposed prediction model can provide clinical value by identifying cases in which ICD implantation could be delayed.

REFERENCES

1. Tereshchenko S.N., Galyavich A.S., Uskach T.M. Chronic heart failure. Clinical guidelines 2020. *Russian Journal of Cardiology*. 2020; 25(11):311–374 (in Russ.). DOI: 10.15829/1560-4071-2020-4083.
2. Wellens H.J., Schwartz P.J., Lindemans F.W., Buxton A.E., Goldberger J.J., Hohnloser S.H. et al. Risk stratification for sudden cardiac death: current status and challenges for the future. *Eur. Heart J.* 2014;35(25):1642–1651. DOI: 10.1093/eurheartj/ehu176.
3. Revishvili A.Sh., Neminushchiy N.M., Golitsyn S.P. All-Russian clinical guidelines for controlling the risk of sudden cardiac arrest and sudden cardiac death, prevention and first aid. M.: GEOTAR-Media, 2018:256 (in Russ.).
4. Bogachevskaja S.A., Bogachevskij A.N. Development of surgical and interventional arrhythmology in Russia over 10 years. Features of the functioning of the service in the Far East region. *Social Aspects of Population Health*. 2017;1(53):2 (in Russ.). DOI: 10.21045/2071-5021-2017-53-1-1.

5. Vinogradova N. G., Polyakov D. S., Fomin I. V. Analysis of mortality in patients with heart failure after decompensation during long-term follow-up in specialized medical care and in real clinical practice. *Cardiology*. 2020;60(4):91–100 (in Russ.). DOI: 10.18087/cardio.2020.4.n1014.
6. Adibi A., Sadatsafavi M., John P.A., Ioannidis J.P.A. Validation and Utility Testing of Clinical Prediction Models Time to Change the Approach. *JAMA.* 2020;324(3):235–236. DOI: 10.1001/jama.2020.1230
7. Boriani G., De Ponti R., Guerra F., Palmisano P., Zanotto G., D'Onofrio A. et al. Sinergy between drugs and devices in the fight against sudden cardiac death and heart failure. *Eur. J. Prev Cardiol.* 2021;28(1):110–123. DOI: 10.1093/eurjpc/zwaa015.
8. Looi K.L., Sidhu K., Cooper L., Dawson L., Slipper D., Gavin A. et al. Long-term outcomes of heart failure patients who received primary prevention implantable cardioverter-defibrillator: An observational study. *J. Arrhythm*. 2017;34(1):46–54. DOI: 10.1002/joa3.12027.
9. Piccini J.P., Zhang M., Pieper K., Solomon S.D., Al-Khatib S.M., Van de Werf F. et al. Predictors of sudden cardiac death change with time after myocardial infarction: results from the VALIANT trial. *Eur. Heart J.* 2010;31(2):211–221. DOI: 10.1093/eurheartj/ehp425.
10. Verstraelen T.E., van Barreveld M., van Dessel P.H.F.M., Boersma L.V.A., Delnoy P.P.H.M., Tuinenburg A.E. et al. Development and external validation of prediction models to predict implantable cardioverter-defibrillator efficacy in primary prevention of sudden cardiac death. *Europace*. 2021;23(6):887–897. DOI: 10.1093/europace/euab012.
11. Ilov N. N., Pal'nikova O. V., Nechepurenko A. A. Patients at high risk of sudden cardiac death: life after implantation of a cardioverter-defibrillator (single-center observational study). *Clinical and Experimental Surgery.* 2018;6 (3):98–106 (in Russ.). DOI: 10.24411/2308-1198-2018-13011.
12. Younis A., Goldberger J.J., Kutyifa V., Zareba W., Polonsky B., Klein H. et al. Predicted benefit of an implantable cardioverter-defibrillator: the MADIT-ICD benefit score. *Eur. Heart J*. 2021;42(17):1676–1684. DOI: 10.1093/eurheartj/ehaa1057.
13. Naksuk N., Akkaya M., Adabag S. Application of the Multicenter Automatic Defibrillator Implantation Trial II risk score in a nontrial setting. *Am. J. Cardiol*. 2013;112(4):530–532. DOI: 10.1016/j.amjcard.2013.04.019.
14. Cheng A., Zhang Y., Blasco-Colmenares E., Dalal D., Butcher B., Norgard S. et al. Protein Biomarkers Identify Patients Unlikely to Benefit from Primary Prevention ICDs: Findings from the PROSE-ICD Study. *Circ. Arrhythm Electrophysiol*. 2014;7(6):1084–1091. DOI: 10.1161/CIRCEP.113.001705.
15. Levy W.C., Mozaffarian D., Linker D.T., Sutradhar S.C., Anker S.D., Cropp A.B. et al. The Seattle Heart Failure Model: prediction of survival in heart failure. *Circulation*. 2006;113(11):1424–1433. DOI: 10.1161/CIRCULATIONAHA.105.584102.
16. Khanam S.S., Choi E., Son J.W., Lee J.W., Youn Y.J., Yoon J. et al. Validation of the MAGGIC (Meta-Analysis Global Group in Chronic Heart Failure) heart failure risk score and the effect of adding natriuretic peptide for predicting mortality after discharge in hospitalized patients with heart failure. *PLoS One*. 2018;13(11):e0206380. DOI: 10.1371/journal.pone.0206380.
17. Hazova E.V, Bulashova O.V., Malkova M.I., Oslopov V.N. A new approach to predicting outcomes in chronic heart failure. *Practical Medicine*. 2014:6(14);101–104 (in Russ.).

Authors' contribution

Lebedeva N.B. – conception and design, analysis and interpretation of the data, approval of the draft version of the article. Parfenov P.G. – keeping the registry, acquisition of the data, analysis and interpretation of the data, search for literature. Egle A.P. – keeping the registry, statistical processing and interpretation of the data. GalintsevYu.V. – keeping the registry, carrying out of the prospective stage of external validation group monitoring. Ivanov V.I. – statistical processing of the data, development of a multivariate prediction model, calculation of risks. KashtalapV.V. – critical revision of the manuscript for important intellectual data. Barbarash O.L. – conception of the study, editing of the article, final approval of the article for publication.

All the authors gave their consent to submission of the manuscript and agreed to bear responsibility for all aspects related to it.

Authors' information

Lebedeva Nataliya B. – Dr. Sci. (Med.), Associate Professor, Leading Researcher, Laboratory for Rehabilitation, Research Institute for Complex Problems of Cardiovascular Diseases, Kemerovo, lebenb@mail.ru, https://orcid.org/0000-0003-2769-3807

Parfenov Pavel G. – Junior Researcher, Laboratory for Myocardial Fibrosis, Research Institute for Complex Problems of Cardiovascular Diseases, Kemerovo, Pavel90548bars@mail.ru, https://orcid.org/ 0000-0003-0019-766X

Egle Albert P. – Resident, Research Institute for Complex Problems of Cardiovascular Diseases, Kemerovo, albert_egle@mail.ru, https://orcid.org/0009-0009-2547-0782

Ivanov Vadim I. – Cand. Sci. (Biology), Associate Professor, N.A.Barbarash Department of Normal Physiology, Kemerovo State Medical University, Kemerovo, trampviy@yandex.ru, https://orcid.org/0000-0003-2383-9768

Galintsev Yuriy V. – Student, Faculty of Medicine, Kemerovo State Medical University, Kemerovo, galinzev@mail.ru, https://orcid.org/0009-0002-5244-7245

Kashtalap Vasily V. – Dr. Sci. (Med.), Associate Professor, Head of the Department of Clinical Cardiology, Research Institute for Complex Problems of Cardiovascular Diseases, Kemerovo, v_kash@mail.ru, https://orcid.org/0000-0003-3729-616X

Barbarash Olga L. – Dr. Sci. (Med.), Professor, Academician of the Russian Academy of Sciences, Director, Research Institute for Complex Problems of Cardiovascular Diseases, Kemerovo, olb61@mail.ru, https://orcid.org/0000-0002-4642-3610

(✉) **Lebedeva Nataliya B.,** lebenb@mail.ru

Received 15.12.2023;
approved after peer review 26.02.2024;
accepted 06.02.2024