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Predictors of Unfavorable Prognosis in Patients with Heart Failure After Cardioverter-Defibrillator Implantation According to the Prospective Part of the Kuzbass Registry

Aim	Identification of clinical and instrumental predictors for non-arrhythmic death in patients with heart failure (HF) and implantable cardioverter-defibrillator (ICD).
Material and methods	Through a telephone survey and examination of medical records from hospital and polyclinic databases, data were obtained on the alive/dead status and causes of death for 260 patients with heart failure (HF) and ICD included in the Kuzbass Registry of Patients with ICD. The follow-up period was 1.5 years. Clinical and instrumental parameters entered into the registry before the ICD implantation were included in a univariate and multivariate step-by-step analysis using the logistic (for qualitative variables) and linear (for quantitative variables) regression with calculation of regression coefficients and construction of a prognostic regression model. The quality of the created model was assessed using a ROC analysis.
Results	During the observation period, 54 (20.8%) patients died. In 21 (38.8%) patients, death occurred in the hospital and was caused by acute decompensated heart failure in 15 (71.4%) patients, myocardial infarction in 3 (14.3%) patients, stroke in 1 (4.7%) patient, and pneumonia in 2 (9.5%) patients. 33 (61.2%) patients died outside the hospital; the cause of death was stated as the underlying disease associated with acute decompensated heart failure: in 9 (27.2%) patients, dilated cardiomyopathy; in 1 (3.0%) patient, rheumatic mitral disease; and in 23 (69.7%) patients, ischemic cardiomyopathy. According to the univariate regression model, the risk of death in the long-term period was increased by the QT interval prolongation (U 2.41, p=0.0161); elevated pulmonary artery systolic pressure (U 4.30, p=0.0000) and increased left atrial size according to echocardiography (U 2.98, p=0.0029); stage IIB HF (OR 2.41; 95% CI: 1.26–4.6), NYHA III–IV (OR 3.03; 95% CI: 1.58–5.81); chronic obstructive pulmonary disease (OR 5.24; 95% CI: 2.04–13.45); and lack of optimal drug therapy (ODT) for HF before ICD implantation (OR 2.41; 95% CI: 1.29–4.49). The multivariate analysis identified the most significant factors included in the prognostic regression model: pulmonary artery systolic pressure above 45 mm Hg, social status, chronic obstructive pulmonary disease, and lack of ODT for HF.
Conclusion	To ensure a maximum benefit from ICD, the factors that increase the likelihood of non-arrhythmic death should be considered before making a decision on ICD implantation. Particular attention should be paid to mandatory ODT for HF as the main modifiable risk factor for unfavorable prognosis.

Keywords	Heart failure; implantable cardioverter-defibrillator; prognosis; risk of death
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Introduction

Sudden cardiac death (SCD) and heart failure (HF) are closely related. In all randomized clinical trials (RCTs) evaluating the efficacy of implantable cardioverter defibrillators (ICDs) for the primary prevention of SCD, low left ventricular ejection fraction (LVEF) was the only high risk criterion. This is because the critical importance of myocardial contractile dysfunction, rather than induced or preceding ventricular arrhythmias (VAs), has been convincingly demonstrated in all studies [1]. Consequently, LVEF <35% is currently the sole predictor of a high risk of SCD, upon which the indications for implantable ICD therapy as a method of primary prevention of SCD are based in all existing guidelines, including the updated guidelines on HF [2]. Furthermore, it has been demonstrated that in the context of secondary prevention of SCD, patients with reduced LVEF benefit the most from ICD therapy [2].

Nevertheless, it is becoming increasingly evident that the current strategy for long-term SCD prevention, which relies on LVEF as a primary criterion for risk stratification, is not without flaws. The results of real-world clinical practice demonstrate that not all patients with reduced LVEF benefit from ICD implantation due to a high competing risk of non-

sudden death. In such cases, the allocation of healthcare resources for high-tech care is not cost-effective. The reasons for this situation are that the development of new approaches to the medical therapy of heart failure with reduced left ventricular ejection fraction (HFrEF) has led to a decrease in the incidence of sudden cardiac death (SCD) in this category of patients. Consequently, the role of low LVEF as a predictor of SCD has decreased [3]. Furthermore, some accumulated data indicate that LVEF alone is not a sufficient criterion for risk stratification of SCD and that additional examination methods are needed [4].

The issue of predicting adverse outcomes following ICD placement is also of great importance. Despite the apparent success of ICD therapy in preventing SCD, mortality in the group of patients with ICDs remains high. This is associated not only with inadequate pacing, but also with a high non-arrhythmic mortality rate in this group and, thus, a lack of discharges in 30–65% of patients with ICDs [5]. Consequently, the question of which tools can assist clinicians in evaluating the relative value of ICDs in improving patient prognosis on a case-by-case basis, while considering the individual ratio of risks associated with arrhythmic and non-arrhythmic death, is of particular relevance.

Objective

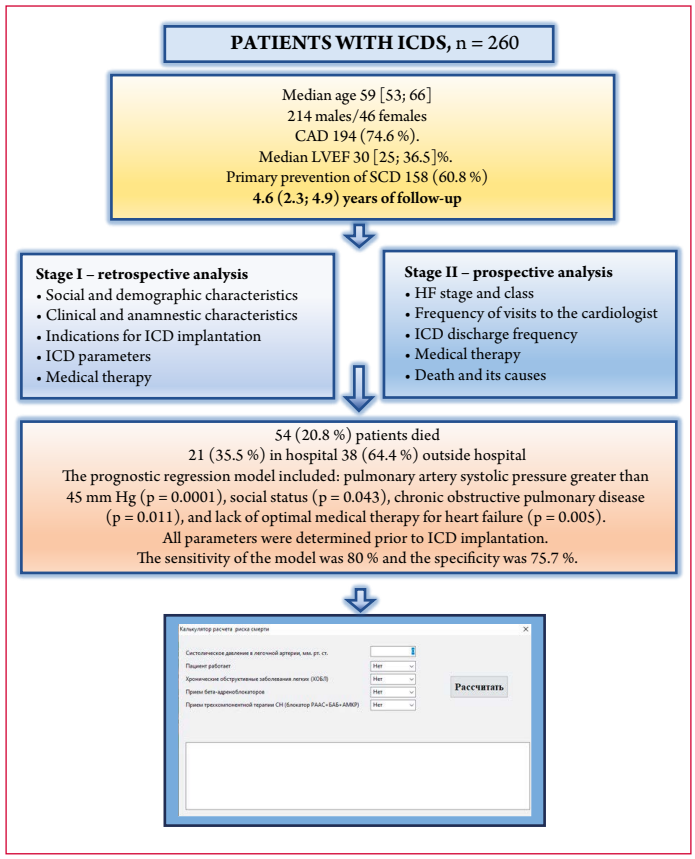
The objective of this study was to identify clinical investigation predictors of nonarrhythmic death in HF patients with ICDs.

Material and Methods

The study was conducted as part of a single-center retrospective prospective cohort study based on the data of the Kuzbass Register of patients with implanted cardioverter-defibrillators. This study consecutively included 286 patients hospitalized at the Research Institute of Cardiovascular Disease Complex Problems from 2015 to 2019 for ICD implantation. All requirements of the Federal Law No. 152 FZ «On Personal Data» as of July 27, 2006 were observed in maintaining the register. The details of the patients included in the registry have been previously published [6].

In accordance with the study protocol, all subjects in the registry were followed up prospectively. This entailed annual registration of their vital status, changes in their condition (stage and NYHA class of HF), frequency of visits to cardiologist, arrhythmologist, frequency of ICD discharges, drug therapy, rigid endpoints, and ICD-related events. In order to maintain the homogeneity of the sample, 22 patients undergoing cardiac resynchronization therapy were excluded from the analysis of the prospective stage. Of a total of 264patients, status as alive or deceased and hard endpoints were obtained for 260 patients by telephone survey and examination of medical records (discharge summaries, outpatient records, arrhythmologist notes, and data from residents' registration offices). Four HF patients with ICDs were lost to follow-up. Consequently, the analysis of the long-term stage included data on 260 patients with ICDs, all of whom had documented HF. The median follow-up period was 4.6 (2.3; 4.9) years. The characteristics of the group prior to cardioverter-defibrillator implantation are presented in Table 1.

Central illustration. Predictors of Unfavorable Prognosis in Patients with Heart Failure After Cardioverter-Defibrillator Implantation According to the Prospective Part of the Kuzbass Registry



MRA, mineralocorticoid receptor antagonist; BB, beta-blocker; SCD, sudden cardiac death; ICD, implantable cardioverter-defibrillator; CAD, coronary artery disease; HF, heart failure; RAAS, renin-angiotensin-aldosterone system; LVEF, left ventricular ejection fraction; COPD, chronic obstructive pulmonary disease.

Statistical processing

The statistical processing of the results was conducted using the Statistica 10.0 software suite for Windows (StatSoft Inc., USA) and the SPSS 10.0 software suite (IBM, USA). The normality of the distribution was evaluated using the Shapiro-Wilk test. A comparison of normally distributed continuous values was conducted using the Student's t-test. Non-normally distributed values were compared using the nonparametric Mann–Whitney U-test. Discrete variables were compared using the Yates' chi-squared test. When the comparison group comprised a small number of patients (5 and fewer), the two-sided Fisher test (F-test) was

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Figure 1. Kaplan–Meier survival curve

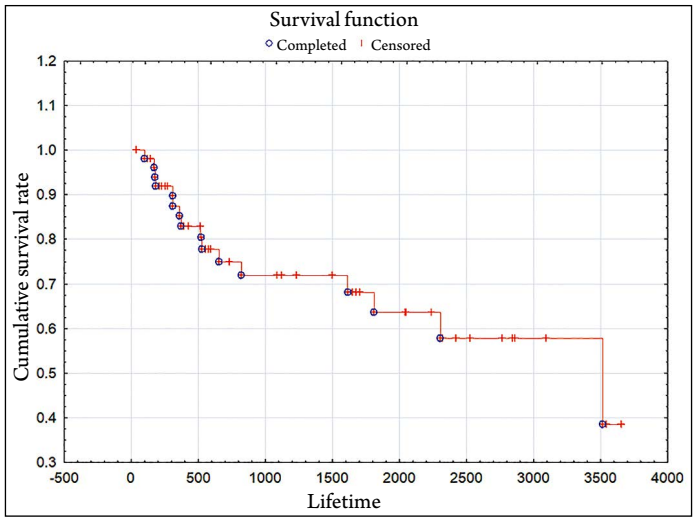

Table 1. Clinical and anamnestic characteristics of the group prior to the implantation of a cardioverter defibrillator

Parameter	n = 260 (100 %)
Male, n (%)	214 (82.3)
Age, years	59 (53; 66)
Employed, n (%)	28 (10.8)
Coronary artery disease, n (%)	194 (74.6)
Postinfarction cardiosclerosis, n (%)	156 (60)
Noncoronary myocardial diseases, n (%)	66 (25.4)
Arterial hypertension, n (%)	199 (76.5)
Diabetes mellitus type 2, n (%)	34 (13.1)
Chronic kidney disease, stage II-III, n (%)	83 (31.9)
Chronic obstructive pulmonary disease, n (%)	23 (8.8)
Chronic cerebral ischemia, n (%)	66 (25.4)
LVEF, %	30 (25; 36.5)
Atrial fibrillation, n (%)	106 (40.8)
CHF FC I, n (%)	35 (13.5)
CHF FC IIA, n (%)	147 (56.5)
CHF FC IIB, n (%)	76 (29.6)
CHF FC III, n (%)	2 (0.8)
NYHA FC I, n (%)	4 (1.5)
NYHA FC II, n (%)	175 (67.3)
NYHA FC III, n (%)	63 (24.2)
NYHA FC IV, n (%)	18 (6.9)
Primary prevention of SCD, n (%)	158 (60.8)

Data are presented as median with interquartile range – Me (Q25; Q75), number of patients – n (%); LVEF, left ventricular ejection fraction; CHF, chronic heart failure; SCD, sudden cardiac death.

employed. The differences were statistically significant at two-tailed $p<0.05$.

To identify factors associated with an unfavorable prognosis, univariate and multivariate stepwise analysis by logistic (for qualitative parameters) and linear (for quantitative parameters) regression method with calculation of regression coefficients was applied. The quality of the generated model was evaluated through the use of receiver operating characteristic (ROC) analysis, with the area under the ROC curve (AUC) serving as the primary metric. A regression equation was employed in the modeling process, and the probability of the event P was calculated. The model's validity was evaluated based on the percentage of correctly reclassified cases and the Somers' D test. The general consistency of the predictive model with real-world data was evaluated using the Hosmer-Lemeshow goodness-of-fit test. The threshold for the critical level of significance was set at $p=0.05$. The Kaplan – Meier method was employed to assess patient survival.

Results

During the follow-up period, 54 patients died, resulting in a mortality rate of 20.8% in the general group. Of these deaths, 32 (20.2%) occurred in the primary prevention group and 22 (21.6%) occurred in the secondary prevention group ($p>0.05$).

In the group of deceased, 21 (35.5%) patients died in hospital. Of these, 3 (14.3%) had myocardial infarction, 1 (4.7%) had stroke, 15 (71.4%) had acute decompensated heart failure (ADHF), and 2 (9.5%) died due to COVID 19 pneumonia. A total of 33 (61.2%) patients died outside the hospital. The underlying disease was the cause of death: dilated cardiomyopathy in 9 (27.2%) patients, rheumatic mitral valve disease in 1 (3.0%) patient, and the remaining 23 (69.7%) patients died of ischemic cardiomyopathy, which were associated with ADHF. Kaplan-Meier survival curve analysis revealed that the majority of deaths occurred during the first 18 months following ICD implantation (Figure 1).

The results of univariate regression analysis permitted the identification of several quantitative and qualitative clinical investigation factors that are determined prior to ICD implantation and are associated with the risk of death during the follow-up period (Table 2, 3).

According to the analysis, a statistically significant association with mortality during the follow-up period was found for the following clinical examination factors: QT interval prolongation, increased pulmonary artery systolic pressure (PASP) and increased left atrial (LA) volume by echocardiography. Patients who survived had slightly lower potassium levels and LV hypertrophy and were younger before ICD implantation; however, these differences did not reach a statistically significant level in this study (Table 2).

Table 2. Association of baseline clinical investigation findings with long-term mortality risk in heart failure patients with implantable cardioverter defibrillators

Parameter	Alive	Deceased	p
GFR, mL/min	72.41 (60.31; 88.73)	74.75 (59.9; 59.3; 2)	p = 0.9043
Potassium, mmol/L	4.7 (4.4; 5)	4.9 (4.6; 5.1)	p = 0.0590
QT, ms	0.4 (0.35; 0.43)	0.41 (0.38; 0.45)	p = 0.0161
HR, bpm	73 (64; 83)	71 (66; 87)	p = 0.6878
IVS, cm	1 (0.9; 1.0)	1 (0.9; 1.1)	p = 0.0806
QRS, ms	0.11 (0.1; 0.13)	0.1 (0.1; 0.12)	p = 0.1426
PASP, mm Hg	34 (30; 43)	45 (37; 54)	p = 0.0000
LA, cm	5.1 (4.6; 5.4)	5.3 (4.9; 5.6)	p = 0.0029
Age, years	59 (52; 66)	63 (55; 69)	p = 0.0771

Data are presented as median with interquartile range – Me (Q25; Q75); GFR, glomerular filtration rate; HR, heart rate; IVS, interventricular septum; PASP, pulmonary artery systolic pressure; LA, left atrium.

Table 3. Association of baseline clinical and anamnestic parameters with long-term mortality risk in heart failure patients with implantable cardioverter defibrillators

Parameter, availability	χ^2	OR	95% CI	p
Male sex	0.01	0.97	0.43–2.17	0.9351
Employed	0.23	0.83	0.38–1.79	0.631
Hypertension	1.64	1.71	0.75–3.89	0.1998
DM type 2, n (%)	0.85	1.46	0.65–3.25	0.3554
COPD	13.96	5.24	2.04–13.45	0.0002
CCI	0.89	1.38	0.7–2.72	0.3445
CKD	0.38	1.22	0.64–2.32	0.5394
CAD	0.41	1.26	0.62–2.59	0.5243
Revascularization	0.49	1.24	0.67–2.29	0.4852
MI	0.21	1.16	0.62–2.17	0.6432
LVEF < 35 %	0.49	1.32	0.61–2.87	0.4853
LVEF < 40 %	1.5	1.88	0.68–5.2	0.2214
HF IIB–III	7.32	2.41	1.26–4.6	0.0068
NYHA III-IV	11.73	3.03	1.58–5.81	0.0006
AF	0.09	0.90	0.44–1.81	0.7622
Lack of OMT	7.85	2.41	1.29–4.49	0.0051
Amiodarone administration	0.53	1.26	0.67–2.36	0.4645

DM, diabetes mellitus; COPD, chronic obstructive pulmonary disease; CCI, chronic cerebral ischemia; CKD, chronic kidney disease; CAD, coronary artery disease; MI, myocardial infarction; LVEF, left ventricular ejection fraction; HF, heart failure; AF, atrial fibrillation; OMT, optimal medical therapy; χ^2, chi-squared test; OR, odds ratio; CI, confidence interval.

Statistical analysis of qualitative variables revealed the following factors that increased the likelihood of mortality during follow-up: presence of HF stage IIB, NYHA class III, presence of chronic obstructive pulmonary disease (COPD), and absence of triple drug therapy (OMT) before ICD implantation (Table 3) [7].

To identify the most significant predictors of adverse long-term prognosis, we further performed stepwise logistic regression including the most important variables (all of which can be identified at patient screening) and developed prognostic models for the risk of death over 4 years of follow-up. Regression equation was used in modeling: $y=a+b1\times X1+b^2\times X2+\ldots bi\times Xi$, where: a is a constant; bi are regression coefficients; Xi are variables taking two values for qualitative indicators (0 – no event, 1 – there is an event) and numerical values for quantitative indicators. The probability of the event (P) was calculated:

$$P= 1/(1+e\text{-}y),$$

where P is the predictive probability, e is the exponent, whose approximate value is 2.718.

The verification of the null hypothesis of the coincidence of the theoretical and practical frequencies of the model (validity) was carried out using the Hosmer-Lemeshow goodness-of-fit test; the threshold of the critical level of significance $p>0.05$ indicates the validity of the model.

The ranges of qualitative assessment of the predictive probability of the event were calculated after model formation. For the prediction of death, a value of 0.2 was used as the cutoff. The results obtained in the development of the prognostic model to predict mortality risk are presented in Table 4. The formula for the prognostic probability of death is as follows:

$$P= 1/(1+2.718\ (2.960+ 0.088\times X1+1.333\times X2+ 1.819\times X3–2.729\times X4–1.480\times X5))\times 100\%,$$

where X1 is the systolic pulmonary artery pressure in mm Hg; X2 is the social status; X2=0 if the patient is employed, X2=1 if the patient is not employed; X3 is the presence of COPD, X3=0 if there is no COPD, X3=1 if there is COPD; X4 – administration of BBs, X4=0 if the patient is not taking BBs, X4=1 if the patient is taking BBs; X5 – administration of OMT, X5=0 if the patient is not taking OMT, X5=1 if the patient is taking OMT; P greater than 20% indicates a high risk of death.

The Hosmer-Lemeshow goodness-of-fit test for this predictive model was: $\chi^2=4,210$, $p=0.838$. In the ROC analysis, the area under the ROC curve (AUC) of the generated model was 0.8. This indicates a high predictive ability. The sensitivity of the model is 80%, the specificity is 75.7% (Figure 2).

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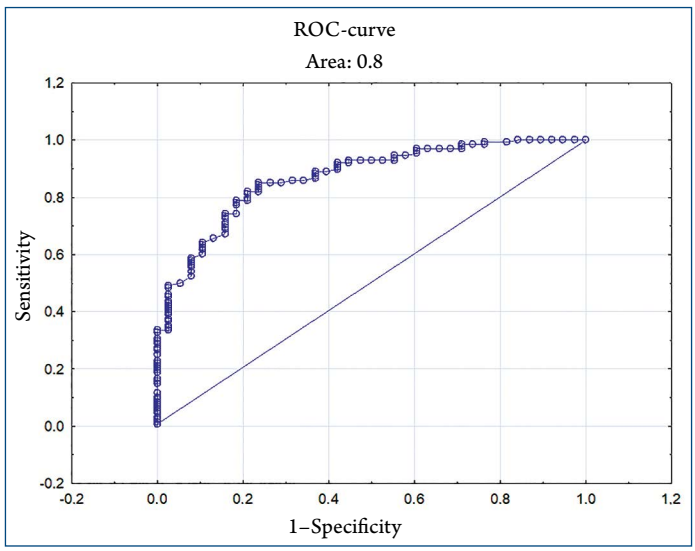
Table 4. Regression coefficients of the prognostic model of long-term mortality risk in heart failure patients with implantable cardioverter defibrillators

Parameters	Model parameters				
	B	Standard error	Wald	p	Exp (B)
PASP, mm Hg	0.088	0.020	18.701	0.000	1.092
Social status (X2)	1.333	0.659	4.090	0.043	3.793
COPD (X3)	1.819	0.718	6.411	0.011	6.163
BBs (X4)	-2.729	1.000	7.442	0.006	0.065
OMT (X5)	-1.480	0.531	7.770	0.005	0.392
Constant	-2.960	1.130	6.863	0.009	0.052

PASP, pulmonary artery systolic pressure; COPD, chronic obstructive pulmonary disease; BB, beta-blocker; OMT, optimal medical therapy; B – regression coefficient, Exp (B), standardized regression coefficient.

Figure 2. Predictive ability of the model (ROC curve) for estimating risk of death during follow-up in heart failure patients with implantable cardioverter defibrillators



The high validity of the obtained model is confirmed by all the above indicators.

For convenient use of this prognostic model in clinical practice, a computer program based on Microsoft Windows 9x/NT/2000/Vista, 7, 8 operating systems has been developed: «Calculator for Calculating the Risk of Death in Patients with Implanted Cardioverter Defibrillators» (certificate of state registration of a computer program No. 2022663830). After computer processing, a dialog box displays the predicted probability values and draws a conclusion about the risk of the predicted event (Figure 3).

Discussion

In contrast to other studies that showed greater efficacy of ICD therapy in the secondary prevention of sudden cardiac death, this study showed no significant differences in the incidence of fatal outcomes between the primary and secondary prevention groups [5]. This difference from the literature data is probably due to the characteristics of the cohort of this study, in which the primary and secondary prevention groups did not differ in terms of LVEF (it was reduced in both groups) and predominantly ischemic origin of HF, as well as other clinical and anamnestic characteristics [6]. Most patients died of ADHF. Other investigators also emphasize that patients with ICDs have an increased risk of HF rather than SCD after device disconnection and that they should pay special attention to the prevention and treatment of progressive LV dysfunction in the long term [5].

Researchers have made numerous attempts to create prognostic scores to personalize the consideration of arrhythmic and non-arrhythmic mortality risk in patients with reduced LVEF. Two scales for clinical benefit stratification of ICD therapy have been proposed based on the results of large RCTs: MADIT-II risk score and the Seattle Heart Failure Model (SCD-HeFT) [8, 9].

In the first case, the authors separately identified predictors of life-threatening arrhythmias and predictors of non-arrhythmic death, on the basis of which they developed a prognostic model for individual risk assessment of life-threatening arrhythmias versus non-arrhythmic death [8]. According to the MADIT II scale, the 3 year predicted risk of life-threatening arrhythmias was three times higher than the risk of non-arrhythmic death in the group with the highest ICD efficacy (20% vs. 7%, p<0.001) and similar to the risk of non-arrhythmic death in the group with the lowest ICD efficacy (11% vs. 12%, p=0.41). However, the authors also mention the need to confirm the results with contemporary registry studies [8]. For example, the frequency of prescribing OMT with concomitant use of renin-angiotensin-aldosterone system blockers, beta-blockers, and mineralocorticoid receptor antagonists was significantly higher in the MADIT RCT than in real-world practice [10]. Similar stratification results were seen with the second scale, where the benefit of ICD therapy was clearly absent in the group at high risk of all-cause mortality when groups were stratified by risk of 4 year all-cause mortality [9].

Importantly, both scales demonstrated that a simple clinical risk assessment could identify patients in whom primary ICD prevention of SCD would result in improved patient survival.

Currently, the paradigm shift in medical therapy has led to a significant increase in survival in patients with HFrEF, simply by reducing the incidence of SCD by 44%, which is comparable to the efficacy of ICD prevention according to the results of previous RCTs [11]. Thus, modern multicomponent drug therapy in HFrEF is a tool that can have a significant impact on

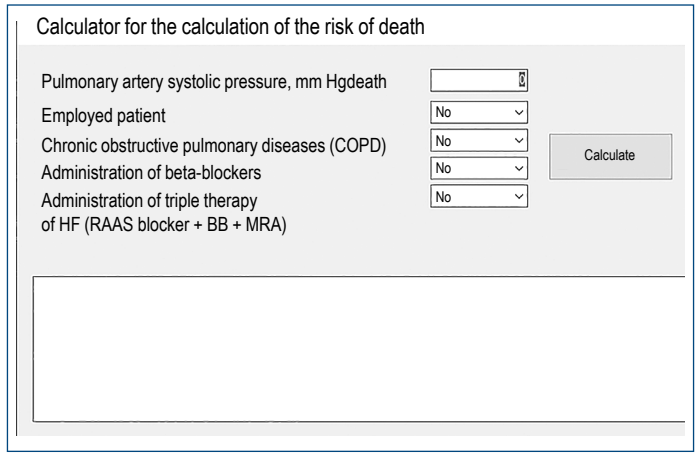
the role of ICDs in the primary prevention of SCD. For example, the results of a recent cost-effectiveness study of the combination of sacubitril/valsartan versus an ICD in patients with HFrEF showed that sacubitril/valsartan could result in 5.85 life-years saved and reduce the risk of hospitalization for HF by more than 20% in 1,000 patients with HFrEF over 10 years. Investigators conclude that sacubitril/valsartan is more cost-effective than an ICD because it increases survival at a lower cost [12].

There is a clear need for validated scales to determine the risk of all-cause mortality in patients with HFrEF and ICDs, and many studies have been devoted to finding predictors of adverse nonarrhythmic outcomes [13, 14]. For example, the LOHCAT RCT, which focused on secondary prevention of SCD, used QRS complex width as such a predictor [13]. Another study identified a panel of factors that increased the risk of all-cause mortality, including creatinine>200 mg/dL, LVEF<20%, and the presence of multifocal atherosclerosis [14]. There is a Russian model for predicting the risk of death in patients with CAD that takes into account electrocardiographic, echocardiographic, and coronary angiographic findings, as well as the severity of the underlying disease and the presence of comorbidities [15]. One of the most recent registry studies on this topic was conducted in Korea and showed that high brain natriuretic peptide levels, NYHA class, reduced glomerular filtration rate, and low body mass index were associated with death before the first motivated ICD discharge in the primary prevention group. The study concluded that the combination of negative prognostic factors for HF is useful for risk stratification in patients with an ICD used for primary prevention of SCD [16]. Another study showed that the risk of death after ICD implantation for the primary prevention is proportional to the severity of chronic kidney disease (CKD) [17].

The analysis of clinical investigation factors that increase the risk of nonarrhythmic death in the Russian cohort of patients with ICDs, performed in this study, showed for the first time the greatest prognostic significance of the complex of such factors as PASP, social status, history of COPD, and lack of OMT for HF; at the same time, beta-blockers were the most significant group in the studied cohort. Importantly, in patients with reduced LVEF, these factors were more significant than the conventional factors LVEF and HF severity. In this study, CKD severity and glomerular filtration rate were not included in the prognostic models, possibly due to the small number of patients with CKD in the study cohort.

The role of COPD in the prognosis of patients with ICDs is new, but the fact that the presence of COPD worsens the prognosis of patients with cardiovascular disease has long been known. Data from a recent analysis confirm that concomitant COPD increases the risk of adverse cardiovascular events by 1.56 times and also contributes to their earlier occurrence [18].

Figure 3. Example of using the calculator for estimating risk of death during follow-up in heart failure patients with implantable cardioverter defibrillators



An important finding of the study was the confirmation that the key to improving the prognosis of patients with HFrEF is to focus on achieving OMT for HF rather than implanting a cardioverter-defibrillator, since it is the lack of OMT that eliminates the efficacy of ICDs in reducing all-cause mortality. Therefore, in order to maximize the benefits of ICD therapy, efforts should be made to improve compliance with therapy in patients with HF and to strictly adhere to existing clinical guidelines for mandatory 3-month OMT before ICD implantation.

Conclusion

Elevated pulmonary artery systolic pressure, social status, history of COPD, and lack of OMT for HF were the main predictors of poor prognosis (death during 4 years of follow-up) in patients with HF and ICD.

Limitations

The created predictive model should be verified on an independent group to ensure the accuracy of the resulting formula.

No conflict of interest is reported.

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