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Whether to implant a defibrillator or not? The Possibility of Using the MADIT-ICD Benefit Score Calculator in Real Practice

Aim	To study the predictive capabilities of the MADIT-ICD Benefit Score calculator in assessing the benefit of implantable cardioverter defibrillator (ICD) placement for the primary prevention of sudden cardiac death (SCD).
Material and methods	This study included 388 patients with NYHA II–IV functional class chronic heart failure (CHF) with a left ventricular ejection fraction (LVEF) ≤35% who underwent ICD placement for the primary prevention of SCD. Patients were followed up for two years to record the endpoints of first-time paroxysmal sustained ventricular tachyarrhythmia (VT) or non-arrhythmic death.
Results	According to the results of calculation with the MADIT-ICD Benefit Score calculator, 276 (71%) patients had a high risk of VT (score ≥7) and 150 (39%) had a high risk of non-arrhythmic death (score ≥3). 336 (94%) patients would benefit from an ICD: 148 (38%) with a high level of probability and 218 (56%) with a medium level of probability. According to the incidence of endpoints, VT episodes predominated in the low-ICD benefit group (36%), while the high-ICD benefit group had a relatively high incidence of non-arrhythmic death (12%).
Conclusion	The results obtained for a cohort of Russian patients with CHF and reduced LVEF indicated that the use of the MADIT-ICD Benefit Score in routine clinical practice does not improve the stratification of SCD risk compared to the traditional approach to selecting patients with CHF for ICD based on the LVEF value.
Keywords	Chronic heart failure; acute decompensated heart failure; ventricular tachyarrhythmia; implantable cardioverter defibrillator; predictors; MADIT-ICD Benefit Score
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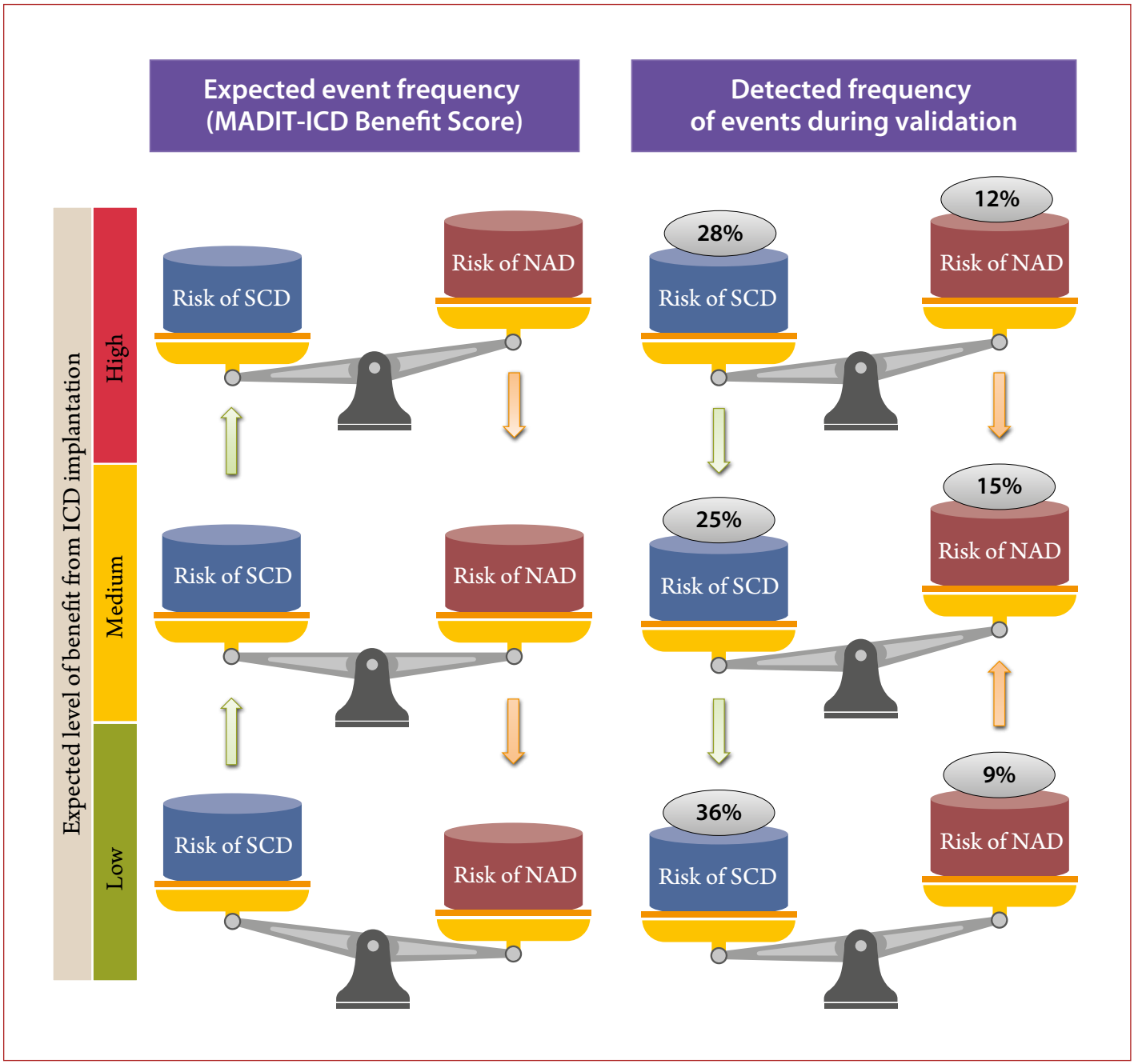
Implantable cardioverter-defibrillator (ICD) implantation is a life-saving treatment intended to control paroxysmal ventricular tachyarrhythmia (VT) and restore central hemodynamics [1]. The widespread use of this approach has not proven to be effective. This is partly due to the shortcomings of arrhythmia risk assessment algorithms, which primarily rely on left ventricular ejection fraction (LVEF) [2]. On the other hand, despite extensive observational data, no effective prognostic system has been developed to predict the risk of acute decompensated heart failure (ADHF) progressing to a terminal stage that is refractory to ICD therapy.

However, it would be wrong to say that there have never been attempts to create such systems. For example, Li et al. [3] proposed to estimate the benefit of ICDs based on LV risk stratification using the ESTIMATED scale (LGE Based Prediction of SCD Risk in Nonischemic Dilated Cardiomyopathy). It involves quantifying gadolinium accumulated in the myocardium using cardiac magnetic resonance imaging. This approach was only formulated for patients with nonischemic cardiomyopathy and did not allow predicting nonarrhythmic mortality. In contrast, Barsheshet et al [4] proposed a set of clinical, laboratory and electrocardiographic parameters to predict all-cause mortality in patients with ICDs without cardiac resynchronization therapy (CRT) function. The Seattle Heart Failure Score, a prognostic calculator adapted to predict survival in chronic heart failure (CHF) patients with ICDs, is certainly worth mentioning [5]. Contrary to the high diagnostic capabilities described in the original papers, none of the known prognostic algorithms have been incorporated into the standard of care for patients with CHF [6].

In 2020, a group of authors from the United States developed the MADIT-ICD Benefit Score calculator based on clinical data and endpoints from four

Central illustration. Whether to implant a defibrillator or not?
The Possibility of Using the MADIT-ICD Benefit Score Calculator in Real Practice



Multicenter Automatic Defibrillator Implantation Trial (MADIT) studies, namely MADIT-II [7], MADIT-CRT [8], MADIT-RIT [9], and MADIT-RISK, involving more than 4,500 patients with CHF [10]. The authors proposed a calculator that takes into account the presence of predictors of VT (male sex, age < 75 years, heart rate (HR) > 75 bpm, systolic blood pressure (SBP) > 140 mm Hg, LVEF ≤ 25%, history of unstable VT, myocardial infarction, atrial arrhythmias) and predictors of nonarrhythmic death (age ≥ 75 years, body mass index < 23 kg/m^2, LVEF ≤ 25%, CHF class ≥ II, use of CRT, history of diabetes mellitus and atrial arrhythmias). The calculator provides information on the benefit of ICD therapy based on the likelihood of VT or nonarrhythmic death.

The results of ROC analysis after external validation showed additional prognostic information provided by the proposed prognostic models (C-statistic for prediction of VT – 0.75; for prediction of nonarrhythmic death – 0.67).

Importantly, it was emphasized immediately after publication that a broad evaluation of the proposed predictors of the onset of VT and nonarrhythmic death should be performed in patient cohorts from different countries [11]. The scale has not been validated in our country, which provides the rationale for this study.

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Objective

To evaluate the predictive ability of the MADIT-ICD Benefit Score calculator in assessing the benefit of ICDs for the primary prevention of sudden cardiac death (SCD).

Material and Methods

Patient selection

The study was conducted in accordance with Good Clinical Practice guidelines and the Declaration of Helsinki. The study design was approved by the local ethics committee of Astrakhan State Medical University (Minutes No. 3, dated December 30, 2021) and registered in a public database (clinicaltrials.gov NCT05539898). All patients who were followed up signed informed consent to participate in the study.

Between 2013 and 2020, patients with CHF class II–IV and LVEF ≤ 35% were included in the study. Most CHF class IV patients did not have an indication for CRT and were on the heart transplant waiting list. Patients with hypertrophic cardiomyopathy, arrhythmogenic right ventricular dysplasia, proven hereditary canalopathies, indications for cardiac surgery (revascularization, correction of valvular insufficiency) were not included in the study.

Investigated indicators

Patients underwent standard clinical examination. To calculate the MADIT-ICD Benefit Score, we collected medical history, measured HR and SBP during the baseline examination, performed transthoracic echocardiography to calculate LVEF, and conducted a 6-minute walk test to determine CHF class [10].

Postoperative follow-up

Patients included in the study received optimal pharmacological therapy for CHF and were followed for 2 years by cardiologists at the implantation center, with visits at 3, 6, 12, 18, and 24 months. Clinical status was assessed and ICD testing was performed during clinic visits. The protocol for ICD programming, as well as endpoint observation and registration, has been previously described by the authors [12, 13]. In cases of cardiac decompensation, the patient was promptly contacted by the investigator, therapy was adjusted, and clinical status was reassessed in collaboration with community-based cardiologists. Information on the occurrence of endpoints was obtained from medical records and interviews with family members. Two endpoints were registered: the onset of sustained VT attacks (≥ 30 seconds) detected in the VT monitoring zone or VT attacks requiring electrotherapy (anti-tachycardia stimulation or shock

Table 1. Clinical and demographic characteristics of the included patients (n = 388)

Parameter	Value
Age, years	57 [51–62]
Male, n (%)	324 (84)
BMI, kg/m2	29 [26; 33]
CAD, n (%)	190 (49)
PICS among CAD patients, n (%)	142 (37)
DCM, n (%)	198 (51)
CHF class II, n (%)	82 (21)
CHF class III, n (%)	278 (72)
CHF class IV, n (%)	26 (7)
History of hypertension, n (%)	216 (56)
Diabetes mellitus, n (%)	78 (20)
History of obesity	138 (36)
Stroke, n (%)	28 (7)
CKD, n (%)	182 (47)
History of anemia, n (%)	24 (6)
AF (paroxysmal/persistent), n (%)	108 (28)
AF (permanent), n (%)	26 (7)
VT unst, n (%)	36 (9)
SBP, mm Hg	120 [110; 130]
DBP, mm Hg	80 [70; 80]
HR, bpm	78 [68; 90]
LVEF (Simpson), %	29 [25; 33]
Cardiac surgery, n (%)	
Revascularization (coronary artery bypass grafting or percutaneous coronary intervention)	164 (42)
Correction of valvular incompetence	74 (19)
LV repair	36 (9)
Received drug therapy, n (%)	
Beta-blockers	388 (100)
ACE inhibitors/ARBs	264 (68)
ARNIs	124 (32)
MRAs	345 (89)
Loop diuretics	372 (96)
SGLT2 Inhibitors	31 (8)
Sotalol	54 (14)
Amiodarone	132 (34)
ICD, n (%)	
Cardiac resynchronization therapy ICDs	224 (58)
Dual-chamber ICDs	164 (42)

Data are presented as absolute numbers of patients and percentages (n (%)) or as Me [Q1; Q3]. PICS, postinfarction cardiosclerosis; DCM, dilated cardiomyopathy; VTUnst, unstable ventricular tachyarrhythmia runs; ARNI, angiotensin receptor-neprilysin inhibitor; MRA, mineralocorticoid receptor antagonist; SGCT2, sodium glucose co-transporter type 2; ICD, implantable cardioverter-defibrillator.

Table 2. Predictors of VT under investigation

Parameter	All patients (n = 388)	Patients without VT (n = 284)	Patients with VT (n = 104)	p3–4
LVEF ≤ 25 %, n (%)	102 (26)	74 (26)	28 (27)	0.903
Atrial arrhythmia, n (%)	134 (35)	96 (34)	38 (37)	0.723
HR > 75 bpm, n (%)	212 (55)	148 (52)	64 (62)	0.243
SBP <140 mm Hg, n (%)	314 (81)	234 (82)	80 (77)	0.390
History of myocardial infarction, n (%)	142 (37)	96 (34)	46 (44)	0.182
Age < 75 years, n (%)	386 (99)	284 (100)	102 (98)	0.098
Male, n (%)	324 (84)	232 (82)	92 (88)	0.260
History of unstable VT, n (%)	36 (9)	22 (8)	14 (13)	0.224
Risks of VT, score	7 [6; 9]	7 [6; 8]	8 [7; 9]	0.084
High risk of VT (≥ 7), n (%)	276 (71)	196 (69)	80 (77)	0.282

Data are presented as absolute numbers of patients and percentages (n (%)) or as Me [Q1; Q3].
VT, ventricular tachyarrhythmia; p3-4, coefficient of significance of the differences between the groups compared.

Table 3. Predictors of nonarrhythmic death being investigated

Parameter	All patients (n = 388)	Patient survivors (n = 336)	Deceased patients (n = 52)	p3–4
Cardiac resynchronization therapy ICDs, n (%)	224 (58)	196 (58)	28 (54)	0.666
CHF class ≥ II, n (%)	388 (100)	336 (100)	52 (100)	–
Diabetes mellitus, n (%)	78 (20)	64 (19)	14 (27)	0.351
BMI < 23 kg/m2, n (%)	28 (7)	22 (7)	6 (12)	0.360
Atrial arrhythmia, n (%)	134 (35)	114 (34)	20 (38)	0.651
LVEF ≤ 25 %, n (%)	102 (26)	76 (23)	26 (50)	0.003
Age > 75 years, n (%)	1 (< 1 %)	1 (< 1 %)	0	0.693
Risk of nonarrhythmic death, score	2 [1; 3]	2 [1; 3]	3 [2; 4]	0.010
High risk of nonarrhythmic death (≥ 3), n (%)	150 (39)	122 (36)	28 (54)	0.069

Data are presented as absolute numbers of patients and percentages (n (%)) or as Me [Q1; Q3].
ICD, implantable cardioverter-defibrillator; p3-4, coefficient of significance of the differences between the groups compared.

Table 4. Diagnostic efficacy of the scales being studied

Endpoint	Predicted number of outcomes, n (%)	Actual number of outcomes, n (%)	PPV, %	NPV, %	Se, %	Sp, %
Onset of VT	276 (71)	80 (21)	28.99	78.57	76.92	30.99
Nonarrhythmic death	150 (39)	28 (7)	18.67	89.92	53.85	63.69

PPV, positive predictive value; NPV, negative predictive value; Se, sensitivity; Sp, specificity; VT, ventricular tachyarrhythmia.

therapy), and nonarrhythmic death. Deaths unrelated to arrhythmias or other non-cardiac conditions, including accidental deaths, were classified as nonarrhythmic deaths. Therefore, the reported deaths were most likely caused by ADHF.

Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics v.26. The accumulation, correction, systematization of baseline data, and visualization of the results were conducted in Microsoft Office Excel 2010. The data were analyzed using both parametric and non-parametric methods.

Quantitative data were described and compared based on their distribution, which was assessed using the Kolmogorov-Smirnov test. If the distribution was confirmed to be normal, the data were described using means (M) and standard deviations (SD), and comparisons were made using the Student's t-test. If the distribution was not normal, the median (Me) and the interquartile range [Q1; Q3] were used, and comparisons were made using the Mann-Whitney test. Nominal variables were compared using Pearson's chi-squared test. The significance threshold for statistical hypotheses was set at 0.05. To evaluate the effectiveness of the scales of interest, we calculated sensitivity (Se), specificity (Sp),

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positive predictive value (PPV) and negative predictive value (NPV) and performed ROC analysis to calculate the area under the curve (AUC).

Results

In total, 388 patients completed the postoperative per-protocol follow-up (Table 1).

Arrhythmia developed in 104 patients (27%), and nonarrhythmic death occurred in 52 patients (13%). Based on the data obtained, the patients were grouped, and a comparative analysis of previously proposed predictors of VT and nonarrhythmic mortality was conducted [10]. Univariate analysis revealed that these parameters lacked prognostic potential for the arrhythmic outcomes of interest (Table 2). Surviving patients had lower scores on the nonarrhythmic death prediction scale (p = 0.01), whereas patients who died of ADHF were more likely to have a low LVEF (Table 3). In the studied patient cohort, LVEF ≤ 25% was found to increase the odds of death threefold (odds ratio [OR] 3.4; 95% confidence interval [CI] 1.5–8.0; p = 0.003).

ROC curve analysis revealed that the area under the curve (AUC) indices indicate a low informative value for the investigated diagnostic scales (Figure 1).

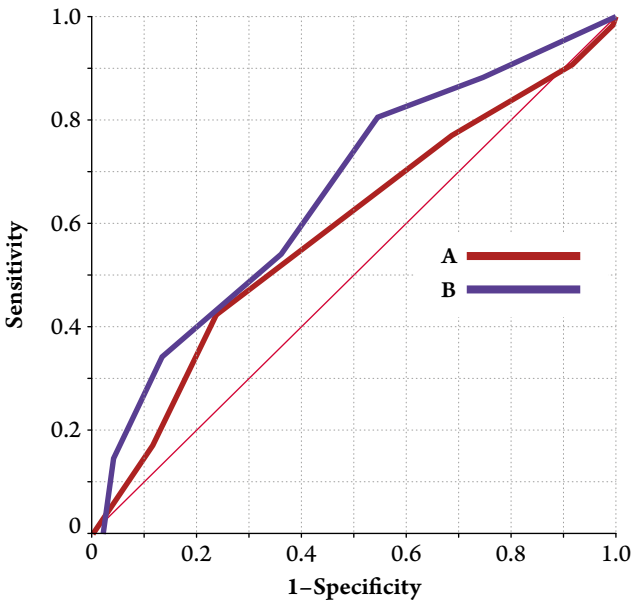
Based on the MADIT-ICD Benefit Score risk calculation, 276 patients (71%) were at high risk of VT (≥7), 150 patients (39%) were at high risk of nonarrhythmic death (≥ 3), and 366 patients (94%) were expected to benefit from an ICD, with 148 (38%) having a high probability of benefit and 218 (56%) having a medium probability. The diagnostic value of the calculator is presented in Table 4. Figure 2 illustrates the actual frequency distribution of endpoints across groups with different levels of ICD benefit.

Discussion

Simultaneously addressing two prognostic tasks – calculating the risk of VT and nonarrhythmic death – is of clear practical importance in the context of primary SCD prevention. This approach would likely reduce the percentage of ICD placements that do not provide immediate ICD therapy, while increasing ICD coverage for patients who are more likely to survive an episode of arrhythmic SCD. It is believed that this approach can only be implemented with a comprehensive evaluation of laboratory test results and clinical examination data [2]. An example would be the MADIT-ICD Benefit Score based on a retrospective analysis of data from the Multicenter Automatic Defibrillator Implantation (MADIT) trials in which subjects (n=4,503) had ICDs or CRT ICDs (n=1,831 (41%)).

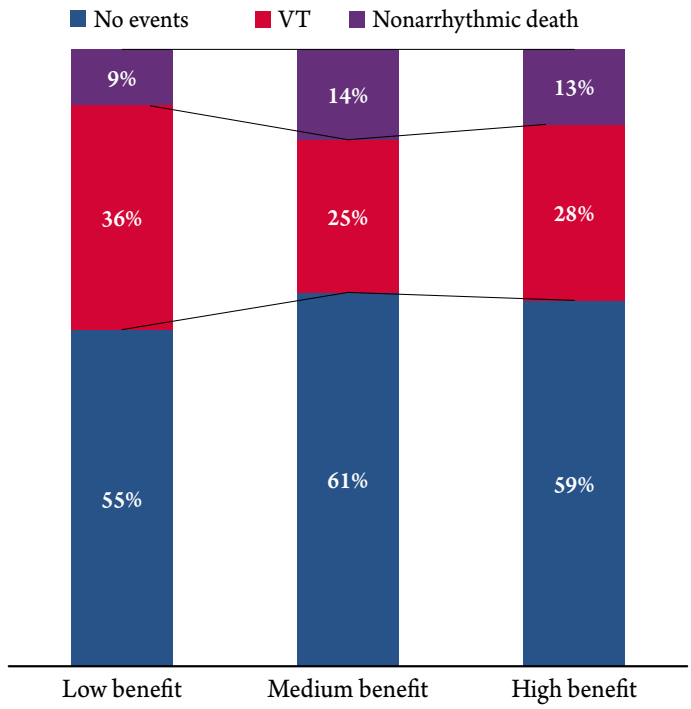
We conducted the first external validation of the MADIT-ICD Benefit Score using data from a Russian cohort of CHF patients with reduced LVEF. Of the

Figure 1. ROC curve showing the diagnostic efficacy of the scales under study for predicting the onset of VT (A) and nonarrhythmic death (B)



	Onset of VT (A)	Nonarrhythmic death (B)
Area under the ROC curve	0.580	0.655
Standard error	0.048	0.058
p value	0.089	0.011
95 % confidence interval	0.486–0.674	0.542–0.768

Figure 2. Study endpoints (absolute values) in groups with different levels of benefit from the implantation of cardioverter-defibrillators (according to the MADIT-ICD Benefit Score calculator)



VT, ventricular tachyarrhythmia.

8 predictors of VT and 7 predictors of nonarrhythmic death proposed by the authors, only LVEF ≤25% demonstrated independent prognostic ability, with its presence tripling the odds of a fatal outcome in the studied patient cohort.

The AUC values we obtained were lower than those reported by the scale developers: 0.58 compared to 0.71 (internal validation) and 0.75 (external validation) for VT, and 0.66 compared to 0.68 (internal validation) and 0.67 (external validation) for nonarrhythmic death. The difference is particularly noticeable in predicting VT probability, which, according to our data, is related to the calculator's low specificity (31%).

Figure 2 illustrates the imperfect stratification of the benefit of ICD implantation according to the MADIT-ICD Benefit Score calculator: the low-benefit group should be characterized by a high risk of nonarrhythmic death and a low risk of VT, the high-benefit group should be expected to have a high probability of VT with a low risk of mortality, and the other cases should be expected to have an average benefit of the procedure. Similar results were observed by German researchers. After finding no statistically significant differences in endpoints within the general cohort of CHF patients with LVEF < 35%, the authors demonstrated the scale's prognostic value in patients with ischemic CHF [14].

It is important to note that the calculator was developed using data from the MADIT studies conducted between 2002 and 2012, with external validation based on findings from the RAID study, which was completed in 2017 [15]. It is possible that significant changes in optimal drug therapy could limit the MADIT-ICD Benefit Score's effectiveness in predicting adverse outcomes in CHF. The heterogeneity in approaches to endpoint registration may also play a significant role. For example, in the MADIT II, MADIT RISK, and MADIT CRT trials, LV paroxysms were verified in case of ≥180 events per 1 min in the ICD detection zones, in the MADIR RIT trial, ≥145 events per 1 min, and in the protocol we used, the minimum LV detection was ≥160 events per 1 min. For the validation in this study, we considered this endpoint to be cardiovascular death in the absence of documented VT, i.e., a fatal outcome that was most often caused by ADHF.

Conclusion

The proposed prognostic calculator MADIT-ICD Benefit Score was validated in a cohort of Russian patients with chronic heart failure for the first time. The practical significance of this calculator lies in its ability to provide pre-implantation information on the correlation between the risk of ventricular tachyarrhythmia and the probability of nonarrhythmic death in the short term. The results suggest that using the MADIT-ICD Benefit Score in routine clinical practice does not enhance risk stratification for sudden cardiac death compared to the traditional approach, which selects chronic heart failure patients for cardioverter-defibrillator implantation based on left ventricular ejection fraction.

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