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CLINICAL AND ANAMNESTIC CHARACTERISTICS OF PATIENTS WITH AN IMPLANTED CARDIOVERTER-DEFIBRILLATOR IN REAL CLINICAL PRACTICE (DATA FROM THE KUZBASS REGISTER)

Aim To study the consistency of the practice of management, selection and routing of patients at high risk

of sudden cardiac death (SCD) selected for cardioverter-defibrillator implantation (CDI) with current clinical guidelines and to evaluate the quality of subsequent outpatient follow-up and treatment based on a

retrospective analysis of clinical amnestic data from the Kuzbass Registry of Patients with CDI.

Material and methods The study was based on the Registry of Patients with Implanted Cardioverter Defibrillator and included

successive data of 28 patients hospitalized to the Kizbass Cardiological Center from 2015 through 2019. Social and clinical amnestic characteristics, indications for CVI, and concomitant drug therapy were analyzed retrospectively. Statistical analyses were performed with the Statistica 10.0 software (Statsoft,

USA).

Results Median age of patients was 59 (53; 66) years; 239 (83.6%) men were included; 29 (10.1%) people

were employed, CHI was performed in 182 (63.6%) patients for prevention of SCC, and for secondary prevention in 104 (36.4%) patients. 208 (72.7%) patients were diagnosed with ischemic heart disease (IHD), and 145 (67.9%) of them underwent myocardial revascularization. Noncoronarogenic diseases were found in 78 (27.3%) patients, and most of them were diagnosed with dilated cardiomyopathy. All patients had chronic heart failure (CHF); half of them had stage IIA CHF. Median left ventricular ejection fraction was 30 (25; 36,5) % according to echocardiography using the Simpson method. Comorbidity was found in 151 (52.8%) patients. 128 (44.8%) patients received a triple neurohormonal blockade for CHF treatment; titration to target doses was not performed in any of them. Antiarrhythmics

were administered to 150 (52.4%) patients.

Conclusion According to the data from the Kuzbass Registry of CVI, the main patient cohort consisted of men of pen-

sion age with IHD and CHF. Before CVI, more than a half of them had not received an optimum drug therapy and not all of them had received target lesion revascularization. Creating and analysis of Registries of CHI patients is an effective method for identifying existing problems in patient management before CVI

and for optimizing their subsequent follow-up and treatment.

Keywords Prevention of sudden cardiac death; implantable cardioverter defibrillator; registry of patients

For citations Lebedeva N.B., Talibullin I.V., Temnikova T.B., Mamchur S.E., Barbarash O.L. Clinical and anamnestic

characteristics of patients with an implanted cardioverter-defibrillator in real clinical practice (data from the Kuzbass register). Kardiologiia. 2021;61(8):40–47. [Russian: Лебедева Н.Б., Талибуллин И.В., Темникова Т.Б., Мамчур С.Е., Барбараш О.Л. Клинико-анамнестические характеристики пациентов с имплантированным кардиовертером-дефибриллятором в реальной клинической практике

(данные Кузбасского регистра). Кардиология. 2021;61(8):40–47]

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In modern cardiology the prevention of sudden cardiac death (SCD) is a matter of pressing concern [1, 2]. Considering that ventricular arrhythmias (VA) are the main mechanism of SCD and require immediate defibrillation, with only 5% of in-hospital sudden deaths, the main method of preventing SCD is prevention. This may be primary in patients at high risk of SCD or secondary in patients who have experienced an episode of hemodynamically significant ventricular arrhythmia [3]. Thus, the data obtained from a 34-year observation of patients after acute myocardial infarction (MI) indicates that there is no decrease in the number of prehospital SCD cases over the specified period.

This leads researchers to conclude that it is necessary to strengthen SCD prevention [4].

Thus, the main ways of reducing SCD frequency are to search for highly specific and highly sensitive predictors of SCD and the corresponding risk factors, to develop corrective methods, and to take actions aimed at the specific prevention of SCD. There are no safe antiarrhythmic drugs, so the gold standard for both primary and secondary prevention of SCD is implantable cardioverter-defibrillators (ICD) [5]. This method is constantly evolving, including the modification of devices (mainly to reduce the number of inadequate shocks and to extend battery life), the



development of subcutaneous ICDs, and the follow-up monitoring of patients with the active introduction of remote monitoring systems and telehealthcare [5–8].

At the same time, real-world clinical practice faces many challenges associated with the use of ICD. These range from the cost of the device given the limited funding opportunities of compulsory health insurance (CHI), poor accessibility in different Russian regions, difficulties in referring patients to this high-technology medical care, the lack of clear standards for the outpatient management and resources for the development of the system of individual ICD remote monitoring [9–11].

In addition, there are significant differences between the findings of randomized clinical trials, used as a basis for indicating a particular treatment, and the results of their application in real-world clinical practice [9, 11].

ICD patient registries are one way of improving the efficiency of ICD use in real-world clinical practice. Maintaining and analyzing such a registry allows for evaluation of the following factors: the baseline demographic and anamnestic data of patients selected for ICD implantation; the compliance of indications for ICD implantation with existing clinical guidelines; the demand for ICD therapy; changes in the clinical condition of patients; their safety; and the quality of follow-up outpatient management and treatment. Thus, such registries will make it possible to collect sufficient information on the management and condition of patients with ICD. Analysis will make this method of SCD prevention available precisely for the category of patients who will benefit the most from ICD therapy.

In the Kemerovo region (Kuzbass), a registry of patients with ICD was developed, in order to assess the existing features of ICD therapy and its compliance with the clinical guidelines. The objective of this study was to examine the compliance of the management, selection, and routing of patients at high risk of SCD selected for ICD implantation, with the existing clinical guidelines, as well as to evaluate the quality of outpatient follow-up and treatment based on a retrospective analysis of clinical and anamnestic data from the Kuzbass registry of patients with ICD.

Material and methods

The study included 286 patients admitted to the Kuzbass Cardiology Center for ICD implantation from 2015 to 2019, consecutively recorded in the Registry of Patients with Implantable Cardioverter Defibrillators. In the Kemerovo region, ICD implantation is carried out only in the Kuzbass Cardiology Center.

The registry is a proprietary software-based database of patients with ICD, and allows for the possibility of generating reports. The software allows patient data to be recorded: case history; drug therapy; clinical and laboratory findings; various scores and tests; features of outpatient management; ICD programmer's reports; and history of cardiovascular events [12]. The study was carried out following the Declaration of Helsinki. Upon admission all patients signed the informed consent approved by the local ethics committee. The registry met all the requirements of Federal Law No. 152 FZ «On Personal Data» dated July 27, 2006. During the analysis all patient data was labeled and used in a depersonalized manner.

This paper presents the results of the retrospective part of the registry: analysis of social, clinical, and anamnestic characteristics; indications for ICD implantation; and concomitant drug therapy.

The findings were processed using Statistica 10.0 (StatSoft Inc., USA). The Kolmogorov-Smirnov test was applied to determine the normality of the distribution of quantitative variables. The continuous variables with normal distribution were compared using the Student t-test. The non-parametric Mann-Whitney U-test was used to compare continuous values with non-normal distribution. Discrete variables were compared using the Yates χ^2 test. The two-tailed Fisher test was used, if the expected value was less than 10 in at least one cell in the contingency table. The differences were statistically significant with two-tailed p < 0.05.

Results

In the Kemerovo region, cardioverter-defibrillator implantation has been carried out since 2007. Since 2013, more than 40 implantations have been carried out on an annual basis. From 2015 to 2019, 286 patients had ICDs implanted in Kuzbass, an average of 2.1 per 100 thousand of the Kemerovo region's population. 67% were Kemerovo residents (from 56.5% in 2015 to 78.3% in 2018). Table 1 shows that there were no fundamental changes in the population of Kuzbass during the observation period, and the number of ICD implantations doubled in 2019.

The majority of patients (n=245 (85.6%)) were referred for ICD implantation from other departments of the Kuzbass Cardiology Center, where they were being treated for the background diagnosis. The main clinical and anamnestic characteristics of patients included in the registry are presented in Table 2. The median age was 59 (53; 66) years (the youngest patient was 19 years old, and the oldest was 83 years). The vast majority of patients were male. In terms of social status, unemployed patients predominated. 10.1% were employed at the time of ICD implantation.

CAD was the main substrate of high risk of SCD with more than half of the patients having a history of MI: 71 (24.8%) patients after percutaneous coronary intervention (PCI) with stenting; 38 (13.3%) patients being subjected to coronary artery bypass grafting; and 13 (4.5%)



both types of interventions. Thus, 122 (42.6%) patients had a history of myocardial revascularization. Coronary angiography before ICD implantation was performed in 174 (60.8%) patients. 87 of them had significant (more than 50%) coronary stenosis, while 23 patients underwent PCI before ICD implantation. Thus, 64 patients with coronary stenosis did not undergo myocardial revascularization before ICD implantation. Myocardial revascularization was performed in a total of 145 (67.9%) patients with CAD. The main reasons for failure to perform revascularization were the absence of clinical manifestations of angina pectoris or distal coronary lesions.

Non-coronarogenic myocardial diseases caused a high risk of SCD in 78 (27.3%) patients. The majority of 61 (21.3%) patients presented dilated cardiomyopathy (DCM). Rare nosologies included hypertrophic cardiomyopathy (HCM) (2 (0.7%)), acquired heart defects (11 (3.8%)), and arrhythmogenic right ventricular cardiomyopathy (ARVC; 4 (1.4%)).

All patients experienced chronic heart failure (CHF). Half of the cases were CHF stage IIA, 34.6% of CHF stage IIB, while patients with NYHA functional class (FC) II predominated. One patient with CHF stage III was on the waiting list for orthotopic heart transplantation.

The vast majority of patients had left ventricular ejection fraction (LVEF) < 40% (Figure 1). The median LVEF according to the Simpson method was 30 (25; 36.5) %.The minimum LVEF was 19.1%, and the maximum LVEF was 60.2%.

Most patients had arterial hypertension (AH), and one-third had signs of peripheral atherosclerosis with the involvement of brachiocephalic or lower-leg arteries. A total of 151 (52.8%) patients had comorbidities: chronic kidney disease (CKD) grade II–III; diabetes mellitus (DM) type 2; and chronic obstructive pulmonary disease (COPD) (Table 2).

ICD indications were determined using the European (2015) and Russian (2017) guidelines for the prevention of SCD. According to these guidelines the main indication for the primary prevention of SCD is a decrease in LVEF less than 35%, HF NYHA FC II–III of ischemic and non-ischemic origin. A hemodynamically significant VA episo-

de was the main indication for the secondary prevention [13, 14]. According to the registry, ICDs were more often implanted for the primary prevention of SCD (Table 2). Persistent ventricular tachycardia (VT) or cases of ventricular fibrillation (VF) occurred in 104 (36.4%) patients in the secondary prevention group, in 40 (38.5%) and 64 (61.5%) patients, respectively. All patients in the secondary prevention group were treated in the Kuzbass Cardiology Center when hemodynamically significant VAs were registered.

According to the results of 24-hour ECG monitoring before ICD implantation, 251 (87.8%) patients had VAs of various grades. 178 (62.2%) patients had paroxysmal unstable VT, which was significantly more common in the primary prevention group (Table 3). In the secondary prevention group, the data of the subsequent 24-hour ECG monitoring, presented in the table, was analyzed, as well as the episode of persistent VT/VF.

As expected the comparative analysis of the frequencies of VAs, depending on HF FC in the absence of differences in the total frequency of VAs, revealed that paroxysmal VT was more common in groups with higher CHF FCs (Table 4).

Various forms of atrial fibrillation (AF) were recorded in 119 (41.6%) patients: a permanent form in 65 (54.6%) patients; persistent AF in 27 (22.7%) patients; and paroxysmal AF in 27 (22.7%) patients. Other types of supraventricular arrhythmias were rare (9 (3.1%) patients).

Figure 1. Distribution of patients depending on the left ventricular ejection fraction

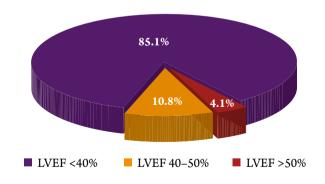


Table 1. Number of cardioverter-defibrillator implanted arranged by years

Year	Number ICDs	Population of Kuzbass	ICDs/100 thousand people	Population of Kemerovo	ICDs/100 thousand people
2015	46	2724990	1.7	549159	4.7
2016	48	2717627	1.8	556920	5.9
2017	46	2688120	1.7	558973	6.1
2018	46	2695028	1.7	558662	6.4
2019	100	2673796	3.7	556382	10.4

ICD, implantable cardioverter defibrillator.



Table 2. Main clinical and anamnestic data of patients included in the registry

59 (53; 66)
239 (83.6)
182 (63.6)
104 (36.4)
29 (10.1)
208 (72.7)
171 (59.9)
78 (27.3)
89 (31.1)
219 (76.6)
38 (13.3)
89 (31.1)
24 (8.4)
69 (24.1)
30 (25; 36.5)
119 (41.6)
41 (14.3)
146 (51.0)
98 (34.3)
1 (0.3)
4 (1.4)
176 (61.5)
83 (29.0)
23 (8.1)

CAD, coronary artery disease; PICS, postinfarction cardiosclerosis; AH, arterial hypertension; DM, diabetes mellitus; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; CCI, chronic cerebral ischemia; LVEF, left ventricular ejection fraction; AF, atrial fibrillation; CHF, chronic heart failure.

Single-chamber ICDs were implanted in 113 (39.5%) patients. Dual-chamber ICDs were installed in 151 (52.8%) patients, while another 22 (7.7%) patients had devices for cardiac resynchronization therapy with ICD function implanted for the corresponding indications.

Analysis of drug therapy before ICD implantation showed that 210 (73.4%) patients received renin-angiotensin-aldosterone system (RAAS) inhibitors (angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARB)), 259 (90.6%) patients received beta-blockers, while 167 (58.4%) patients received mineralocorticoid receptor antagonists (MCRA) (Table 5).

Only 128 (44.8%) patients received triple neurohumoral blockade. In either case doses were not titrated to target doses (Table 6).

Diuretics, statins, and antithrombotic therapy were administered to most patients, and digoxin was rarely prescribed. Antiarrhythmic drugs, mainly amiodarone, were administered to 150 (52.4%) patients, while sotalol was prescribed in some cases despite the presence of heart failure.

All patients were discharged with recommendations for cardiological follow-up, scheduled examination of the ICD by an arrhythmologist in the counseling outpatient clinic within 3 months, then at least once every 6–12 months, or in the event of ICD shocks. In neither case was remote monitoring and remote telemetry systems.

Discussion

There are no official SCD statistics in the Russian Federation. It is estimated that 200–250 thousand people a year suddenly die of cardiac causes in the Russian Federation.

Table 3. Comparative characteristics of the frequencies of various ventricular rhythm disturbances in the groups of primary and secondary prevention based on 24-hour electrocardiogram monitoring

Parameter	Primary prevention group, n=182	Secondary prevention group, n=104	p
VAs grades 1–2 (Lown), n (%)	16 (8.7)	11 (10.5)	0.364
VAs grades 3 (Lown), n (%)	32 (17.5)	18 (17.3)	0.950
VAs grades 4 (Lown), n (%)	129 (70.9)	49 (47.1)	0.001
VAs grades 5 (Lown), n (%)	4 (2.1)	1 (0.9)	0.441

VA, ventricular arrhythmia.

Table 4. Comparative characteristics of the frequencies of various ventricular arrhythmias depending on the heart failure functional class

Parameter	NYHA FC I, n=4 (100%)	NYHA FC II, n=176 (100%)	NYHA FC III, n=83 (100%)	NYHA FC IV, n=23 (100%)	p
VAs, total, n (%)	3 (75.0)	158 (89.8)	68 (81.9)	21 (91.3)	p=0.258
VAs grades 1–2, n (%)	1 (25.0)	14 (7.9)	2 (2.7)	-	$p_{I-III}=0.016$ $p_{I-II}=0.025$
VAs grade 3, n (%)	-	39 (22.2)	11 (13.2)	_	p _{II-III} =0.091
VAs grades 4–5, n (%)	2 (50.0)	105 (59.6)	55 (66.3)	21 (91.3)	$p_{I-IV} = 0.032$ $p_{II-IV} = 0.004$

VA, ventricular arrhythmia.



The RESONANCE trial showed SCD incidence of 228 cases per 100 thousand people per year, of which 156 cases are male patients [15]. As a comparison, in the United States, where overall cardiovascular mortality is significantly lower than in the Russian Federation, SCD is also about 200 individuals per 100 thousand people [16]. The true rate of SCD is most likely to be much higher in the Russian Federation. However, based on the available data, the real need for ICD as the main method of SCD prevention significantly exceeds the actual number of implantations performed. SCD is a worldwide public health problem.

In terms of the accessibility to interventional arrhythmology outside the metropolitan areas, the Russian Federation is lagging behind Europe [17]. In 2011, ICD implantation was performed in 62 Russian hospitals. By 2013, this figure had increased to 66. Thus, in the Russian Federation there has been a steady increase in the number of ICDs implanted from 0.88 per 100 thousand people in 2011 to 1.34 per 100 thousand in 2013 with 0.05 hospitals per 100 thousand people [17]. In 2013, the highest rate of ICD implantations was observed in the Siberian Federal District (3.12 per 100 thousand people) with less than the Russian average number of hospitals (0.03 per 100 thousand people) [17]. In 2013, ICD implantation rate was 1.7 per 100 thousand people in the Kemerovo region with 0.04 hospitals per 100 thousand people, higher than in the Russian Federation as a whole for the same year. At the same time, in 2019, there was a significant increase in the number of implantations in Kuzbass - from 1.7 to 3.4 per 100 thousand people. This figure is still not enough to satisfy the existing need. It should be noted that no more than 60% of the real demand for ICD implantation is met even in those countries where it is most common [17]. The main limitations for the use of ICDs is their high cost, the insufficient number of highly specialized hospitals and specialists providing this type of care. A contributory factor is the lack of knowledge among primary care physicians about the selection criteria for patients at high risk of SCD and the lack of effective approved routing schemes for such patients [15].

According to this registry, ICD implantation is performed mainly in male patients over 60 years of age, presenting chronic heart failure with reduced ejection fraction (HFrEF) due to CAD with comorbidities. Half have a history of myocardial infarction and have undergone coronary revascularization. At the same time, according to one of the trials, the prevalence of HFrEF is higher among female patients [17]. Our findings show the specifics of patient selection and routing for ICD implantation. For example, the main flow of patients referred for this type of high-technology care (85.6% of patients) was created in hospital, while the percentage of outpatients was significantly less.

Raising the awareness of physicians about this type of SCD prevention, the establishment of CHF clinics, the introduction of regulatory algorithms for the outpatient selection of patients will increase the accessibility of ICD therapy in other categories of the population.

The guidelines for the treatment of stable coronary artery disease regulate the need for CAG in the decision whether to perform myocardial revascularization in patients with HFrEF. According to the registry such a condition is fulfilled in the Kemerovo region [17]. Half of the patients who underwent CAG shortly before ICD implantation had significant coronary stenosis. However, only 25.6% underwent revascularization. The failure to perform revascularization was mainly due to the lack of indications or technical reasons.

90% of patients with ICD worldwide are subject to primary prevention of SCD [18]. The registry reflects the current global trend. Given that the risk stratification of

Table 5. Frequencies of prescribing drug therapy before cardioverter-defibrillator implantation

Drug	Main group, n=286
ACE inhibitors, n (%)	164 (57.3)
ARBs, n (%)	41 (14.3)
ARNIs, %	5 (1.7)
Beta-blockers, n (%)	259 (90.6)
Statins, n (%)	209 (73.1)
MCRAs, n (%)	167 (58.4)
Diuretics, n (%)	184 (64.3)
Digoxin, n (%)	12 (4.2)
Amiodarone, n (%)	144 (50.3)
Sotalol, n (%)	6 (2.1)
Antiplatelet agents, n (%)	145 (50.6)
OACs, n (%)	117 (40.9)
CCB, n (%)	41 (14.3)

ACE, angiotensin-converting enzyme, ARB, angiotensin II receptor blocker; ARNI, angiotensin receptor-neprilysin inhibitor; MCRA, mineralocorticoid receptor antagonist; OAC, oral anticoagulant; CCB, calcium channel blocker.

Table 6. Compliance of the prescribed doses with the recommended doses

Drug	Lowest dose	Recommended dose
ACE inhibitors, n (%)	132 (80.4)	5 (3.0)
ARBs, n (%)	31 (75.6)	2 (4.9)
ARNIs, %	0	5 (100)
Beta-blockers, n (%)	44 (16.9)	29 (18.9)
Statins, n (%)	28 (13.4)	18 (8.6)

ACE, angiotensin-converting enzyme; ARB, angiotensin receptor blocker,

ARNI, angiotensin receptor-neprilysin inhibitor.



primary SCD is based on LVEF, the main group of patients with ICD are those with LV systolic dysfunction. The bestpossible drug therapy is essential in this cohort, in order to ensure the longest survival. According to all existing guidelines, this condition must be met before the decision whether to perform ICD implantation is taken. For example, ESC, ACC/AHA/HRS, and RCO recommendations determine the level IA class of indications for ICD in CHF NYHA FC II-III with CAD, LVEF < 35% after at least 3-months of the best-possible drug therapy of HF, but no earlier than 40 days after MI with a life expectancy of more than a year [13, 14, 19]. Analysis of this registry showed that compliance with the principles of best-possible drug therapy is a pressing matter for real-world clinical practice. Given that all patients had HF, mainly with HFrEF and FC II and higher, according to the current guideline they should have received triple neurohumoral blockade with RAAS inhibitors, betablockers, and MCRAs. The doses of RAAS inhibitors and beta-blockers should have to be titrated to the maximum tolerable doses or until the target values of blood pressure, and heart rate were achieved [20, 21]. Real-world clinical data suggest that this condition is never met. This fact is very important in terms of understanding the correct selection of patients for ICD implantation and the need to focus efforts on improving outpatient CHF management. Moreover, according to our study, when considering the 24-hour ECG findings, the frequency of high-grade VAs and AF requiring active antiarrhythmic therapy, targeting a reduced number of ICD shocks, inter alia, exceeds the actual prescription rate of antiarrhythmic drugs.

Another problem identified by the registry analysis is the low detection rate of non-ischemic causes of SCD during patient selection. Cases of ICD implantation in ARVC, which constitute the main high-risk group for SCD of nonischemic origin, are rare in Kuzbass. At the same time, the prevalence of these diseases is significantly higher. For example, when modern diagnostic methods such as MRI, CT, and genetic testing are used, it is 1:200-500 for HCM, or 1:167 [22-24]. The prevalence of ARVC ranges from 1:5000 to 6:10000 [25, 26]. Consequently, given the fact that these nosologies are asymptomatic for a long time, the detectability of these conditions is impaired. Such patients are likely not to be referred for ICD therapy in due time. For example, SCD in ARVC occurs in approximately 3-10% of patients under the age of 65, and it may become the first and only manifestation of this disease [26].

Outpatient management of ICD patients currently involves: regular cardiological examinations including echocardiographic and electrocardiographic control: efforts to maintain adherence to the background drug treatment; and specialized routine ICD control using a programmer by an arrhythmologist [7, 14]. In addition, unreasonable

ICD shocks, which according to the literature occur in a quarter of patients, required unscheduled ICD monitoring [7]. Systems of remote monitoring and remote telemetry can significantly improve outpatient monitoring of patients with implanted devices, including ICD [7, 27, 28]. At the same time, such patients do not often receive remote monitoring even in the presence of remote monitoring and remote telemetry systems for various reasons. This fact has been confirmed by the Heart Rhythm Society (HRS) [29]. This problem is especially urgent for Russia. For example, remote monitoring and remote telemetry systems were not used in this registry largely due to the lack of funding and organizational solutions for monitoring and interpreting data from remote monitoring systems.

Thus, analysis of the retrospective part of the Kuzbass registry of patients with ICD enabled us to collect new real-world clinical data on ICD therapy in the Russian Federation. This was based on the use of the example of a separate region, including poor outpatient involvement in the selection of patients at high risk of SCD, insufficient detection of non-ischemic causes of SCD, inconsistency with existing clinical guidelines regarding the prescription of the best possible drug therapy, and existing problems concerning the use of remote monitoring and remote telemetry systems.

Conclusion

According to the Kuzbass registry, the main category of patients with implantable cardioverter-defibrillators is retired males with coronary artery disease and chronic heart failure. More than half do not receive the best possible drug therapy, and not all of them undergo full myocardial revascularization before cardioverter-defibrillator implantation, which contradicts the existing guidelines for the proper indications. This situation reflects the existing problems of selecting and routing patients to this type of high-technology medical care, as well as shortcomings in the observation and treatment of patients with chronic heart failure with reduced left ventricular ejection fraction, i.e., the main cohort of the high risk of sudden cardiac death. The development of registries of patients with implantable cardioverter-defibrillators and the analysis of their clinical prospects will enable us to assess the quality of implantable cardioverter-defibrillator therapy in real-world clinical practice, as well as its compliance with the existing standards and guidelines. This will eventually lead to the development of new tactics for predicting the efficacy of implantable cardioverter-defibrillator therapy, as well as identification of the best ways of improving the quality of care for patients at high risk of sudden cardiac death.

Limitations

The study was limited by the single-center design.



Funding

The study was performed as a part of basic project of the Research Institute for Complex Problems of Cardiovascular Diseases: «Scientific substantiation of an integrated approach to development and implementation of modern methods for diagnostics and interventional treatment of complex heart rhythm and con-

ductivity disorders in order to improve quality of life and prognosis of patients with cardiovascular diseases». (State reg. #Nº AAAA-A16116011910162 9 of 19.01.2016).

No conflict of interest is reported.

The article was received on 08/04/2021

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