УДК 616.12-036.886-08-039.71:616.12-008.46-089.843
https://doi.org/10.20538/1682-0363-2022-1-183-196

Implantable cardioverter-defibrillators in sudden cardiac death prevention: guidelines and clinical practice (literature review)

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ABSTRACT

Implantable cardioverter-defibrillators (ICDs) are considered to be the most beneficial in preventing sudden cardiac death (SCD), especially in patients with reduced left ventricular ejection fraction (LVEF). However, major large-scale randomized clinical trials on ICD effectiveness were conducted 20 years ago and do not reflect current realities. Modern ICDs and methods for treating heart failure have drastically improved. New clinical reality requires reconsideration of approaches to determining the risk of SCD and indications for ICD, personalization of device selection and programming, and identification of barriers that prevent ubiquitous use of the method in real clinical practice.

The article reviews the available evidence base on the use of ICDs, current clinical guidelines, complications following the device implantation, and any difficulties associated with ICD application in routine clinical practice.

Keywords: implantable cardioverter-defibrillators, sudden cardiac death, prevention, clinical practice

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

Source of financing. The authors state that they received no funding for the study.

For citation: Talibullin I.V., Lebedeva N.B. Implantable cardioverter-defibrillators in sudden cardiac death prevention: guidelines and clinical practice (literature review). *Bulletin of Siberian Medicine.* 2022;21(1):183–196. https://doi.org/10.20538/1682-0363-2022-1-183-196.

Имплантируемые кардиовертеры-дефибрилляторы в профилактике внезапной сердечной смерти: современные рекомендации по применению и реальная клиническая практика (обзор литературы)

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РЕЗЮМЕ

После завершения основных крупномасштабных рандомизированных клинических исследований около 20 лет назад, имплантируемые кардиовертеры-дефибрилляторы (ИКД) являются основой профилактики внезапной сердечной смерти (ВСС), особенно у пациентов с низкой фракцией выброса левого желудочка. За прошедшее время эволюционировали как сами устройства, так и методы лечения сердечной недостаточности. Новые медицинские реалии требуют пересмотра существующих подходов к определению риска ВСС, показаний для ее профилактики с помощью ИКД, индивидуализации выбора и программирования устройства, а также объективизации проблем, ограничивающих широкое применение метода в реальной клинической практике.

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В обзоре рассматриваются существующая доказательная база использования ИКД и позиции современных клинических рекомендаций, проблемы, возникающие после установки ИКД и пути их решения, а также вопросы применения ИКД в реальной клинической практике.

Ключевые слова: имплантируемые кардиовертеры-дефибрилляторы, внезапная сердечная смерть, профилактика, клиническая практика

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

Источник финансирования. Авторы заявляют об отсутствии финансирования при проведении исследования.

Для цитирования: Талибуллин И.В., Лебедева Н.Б. Имплантируемые кардиовертеры-дефибрилляторы в профилактике внезапной сердечной смерти: современные рекомендации по применению и реальная клиническая практика (обзор литературы). *Бюллетень сибирской медицины.* 2022;21(1):183–196. https://doi.org/10.20538/1682-0363-2022-1-183-196.

INTRODUCTION

Sudden cardiac death (SCD) is one of the most common causes of death worldwide, including young and able-bodied individuals. According to recent data, SCD accounts for 15–20% of all deaths worldwide [1]. Coronary artery disease (CAD) is known to be the most common pathology underlying SCD, followed by cardiomyopathies, inherited arrhythmia syndromes, and valvular heart diseases [2, 3].

During the past 3 decades, declines in SCD rates have not been as steep as for other causes of CAD deaths, with a growing fraction of non-ischemic SCD particularly among young population [4]. Although the effectiveness of prehospital resuscitation methods is improving throughout the world, the majority of individuals with sudden cardiac arrest will not survive, which makes prevention of SCD a highly relevant issue [1]. The mainstay of primary and secondary prevention of SCD is implantable cardioverter – defibrillator (ICD), since in 80% of cases the causes of sudden cardiac arrest are ventricular arrhythmias (VA), such as ventricular tachycardia (VT) or ventricular fibrillation (VF) [4].

EVIDENCE BASE FOR USING IMPLANTABLE CARDIOVERTER – DEFIBRILLATORS AND MODERN CLINICAL GUIDELINES

First implanted in individuals who experienced cardiac arrest due to VF, ICDs have been in use since 1980 [4]. Current guidelines for ICDs are based on the research data from clinical trials, such as Cardiac Arrest Study Hamburg (CASH); Canadian Implantable Defibrillator Study (CIDS), and Antiarrhythmics Versus Implantable Defibrillators (AVID) study, which have shown the benefits of ICDs compared with antiarrhythmic drug therapy, including amiodarone [5–7]. The total number of patients included in these randomized controlled trials (RCTs) was 1,963, the average follow-up was 3 years. However, all three trials were completed before 2005, therefore, they do not reflect the clinical realities of improved CAD and heart failure (HF) treatment.

According to the meta-analysis performed by S.J. Connolly et al., the use of ICDs for secondary prevention demonstrated a 50% decrease in the risk of SCD and a 28% decrease in the overall mortality [7]. Although secondary prevention ICDs proved to be more effective in patients with severe left ventricular (LV) dysfunction, all current guidelines recommend secondary prevention of SCD in case of VF / hemodynamically unstable VT in the medical history, irrespective of the left ventricular ejection fraction (LVEF).

The Russian Scientific Society of Clinical Electrophysiology, Arrhythmology, and Cardiac Pacing (2017) guidelines on the use of pacemakers, ICDs, cardiac resynchronization therapy devices, and implantable cardiac monitors have six indications for secondary prevention ICDs:

1) diagnosed VF or VF with adverse hemodynamic effects;

2) syncope of unknown origin, clinically similar to hemodynamically unstable VT or VF induced during an electrophysiology study (EPS);

3) unstable VT due to prior myocardial infarction (MI) with LVEF < 40% and sustained VT or VF induced during EPS;

4) sustained VT with LVEF < 45%, irrespective of a possibility to perform catheter ablation and its results;

5) recurrent sustained postinfarction VT with normal LVEF;

6) recurrent sustained non-coronarogenic VT, in case its eradication is unavailable [8].

To perform the implantation, the following conditions must be met: no transient causes of VA; 48 hours passed after MI; the patient receives optimal drug therapy (ODT); the predicted life expectancy of the patient exceeds 1 year [8]. The first recommendation is based on the findings of the three RCTs – CASH, CIDS, AVID [5–7] and corresponds to class IA indications. The second recommendation is based on the results of CIDS [6], in which one of the inclusion criteria was sustained VT with syncope. The third recommendation is based on the findings of the study performed by A.E. Buxton et al. on prevention of SCD in patients with CAD [9].

The study included 704 patients with MI, LVEF < 40%, and induced asymptomatic VT. The ICD therapy resulted in significant reduction of the SCD risk compared with standard therapy (odds ratio (OR) 0.24; 95% confidence interval (CI) 0.13–0.45; $p < 0.001$). The remaining recommendations mentioned are based on the expert consensus. The European Society of Cardiology (ESC) and the American Heart Association (AHA) take a more rigorous and reasonable approach to determining indications for secondary prevention ICDs in their guidelines [10, 11].

The ESC guidelines (2015) contain only two indications for secondary prevention ICDs: diagnosed VF or hemodynamically unstable VT in the absence of reversible causes of VT / VF (excluding the first 48 hours after MI, class IA) and recurrent sustained VT (excluding the first 48 hours after MI). In all these cases, patients should be on long-term optimal drug therapy and their life expectancy should exceed 1 year [10].

Thus, for secondary prevention ICDs, there is only one clearly defined class IA indication, based on the RCTs performed 10–15 years ago, while all other recommendations are based mainly on the expert consensus, confirming once again the existing gaps in the evidence base [10–12]. Subsequent RCTs focused on the effectiveness of ICD in patients at high risk of SCD as a primary prevention method, provided that there are no other diseases limiting the life expectancy to 1–2 years.

The guidelines for primary prevention are based on data of three relatively recent studies (Multicenter Autonomic Defibrillator Implantation Trial II (MADIT II), Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT), and Multicenter Unsustained Tachycardia Trial (MUSTT)). They demonstrated an increase in the life expectancy by an average of 2–6 years in ICD patients with reduced ejection fraction (rEF) and symptomatic HF compared with amiodarone-treated patients (amiodarone did not improve the prognosis) [13–15]. However, patients with reduced LVEF are still included in the primary prevention ICD group despite a lack of data on the impact of ICDs on the heart failure (HF) and non-sudden cardiac death [10–12].

Patients with CAD have an increased risk of SCD due to VA, especially with rEF. Two RCTs included patients with stable CAD prior to MI and reduced LVEF. The first study, MADIT II, included patients with NYHA class I–III HF and LVEF ≤ 30%. The follow-up period was 20 months, all-cause mortality was 14.2% in the ICD group, as opposed to 19.8% in the control group, with relative risk reduction of 31% [13]. The second study, SCD-HeFT, included patients with NYHA class II–III chronic HF and LVEF ≤ 35%. After 5-year follow-up, the absolute risk of death in the group with ICD was 7%, with relative risk reduction of 23% [14].

In the MUSTT study, all patients underwent an EPS for the induction of sustained VT, and 353 patients with induced VT were randomized into two groups – an antiarrhythmic therapy group and a placebo group. According to the results of 5-year follow-up, a significant decrease in SCD and all-cause mortality in the antiarrhythmic therapy group compared to the placebo group was revealed. However, a detailed analysis identified that the statistically significant reduction in mortality concerned only the ICD patients [15].

The clinical trials showed that ICDs had no positive impact on mortality in case the device was implanted in the early postinfarction period or during cardiac surgery [16, 17]. The results of a meta-analysis of RCTs in CAD patients (excluding studies in which the device was implanted during surgery or cardiac surgery) indicate a statistically significant

reduction of the risk of all-cause mortality with ICD by 24% compared with non-ICD therapy in this group [18]. Thus, cardiologists in Europe, the United States, and the Russian Federation have identical guidelines for primary prevention ICDs in patients with CAD, NYHA class II – III HF, and LVEF ≤ 35% after at least 3 months of optimal drug therapy and not earlier than 40 days after MI, if life expectancy exceeds 1 year [10–12].

The evidence base underlying guidelines for ICD therapy for non-ischemic HF is not as considerable as that for ischemic HF. Guidelines are based on the findings of Defibrillators in Non-Ischemic Cardiomyopathy Treatment Evaluation (DEFINITE) [19], SCD-HeFT [14], Cardiomyopathy Trial (CAT) [20], and Amiodarone Versus Implantable Cardioverter – Defibrillator: Randomized Trial in Patients With Non-ischemic Dilated Cardiomyopathy and Asymptomatic Nonsustained Ventricular Tachycardia (AMIOVIRT) [21] and a large meta-analysis performed by A.S. Desai et al. with a total of 1,854 patients [22]. Data from the DEFINITE study, which included 458 patients with non-ischemic HF, LVEF ≤ 35%, and Holter monitoring showing unstable VT, showed a statistically significant decrease in the SCD prevalence after 29-month follow-up, but no decrease in the all-cause mortality [19].

In the SCD-HeFT study mentioned above, nearly half of the patients had a non-ischemic HF [114]. The CAT and AMIOVIRT studies showed no statistically significant difference in survival of the patients from the ICD therapy and control groups [20, 21]. However, the meta-analysis of performed by M.J. Shun-Shin et al., which incorporated all the studies mentioned above, showed decreased all-cause mortality rate in the ICD group compared with the control group (OR 0.69; 95% CI 0.55–0.87; $p = 0.002$) [18].

The results of the Defibrillator Implantation in Patients with Non-Ischemic Systolic Heart Failure (DANISH) study (which included 1,116 patients with non-ischemic HF, LVEF less than 35%, and NYHA class II-IV HF, the average follow-up was 67.6-months) showed that ICD therapy had no positive impact on the all-cause mortality (the ICD group had 4.4 cases per 100 person – years versus 5.0 per 100 person – years in the control group, the differences were not significant). However, the frequency of SCD in the ICD group was 2 times lower. The main cause of HF was idiopathic cardiomyopathy (76% of cases). Moreover, this RCT showed that the benefits of ICD lessen with age and become minimal in elderly patients (68 years and older) [23]. In contrast to DEFINITE and SCD-HeFT, 96% of patients in the DANISH study were receiving renin – angiotensin – aldosterone system blockers (RAAS), 92% – beta-blockers, more than half – aldosterone antagonists (doses titrated sufficiently to achieve target levels), and 58% of patients in both groups received cardiac resynchronization therapy (CRT) for HF, which could have affected the results [14, 19, 23].

Despite the results of the DANISH study, a meta-analysis performed by L. Shen et al. showed that primary prevention ICDs in patients with non-ischemic HF are associated with statistically significant benefits in terms of survival, which are identical to those observed in patients with ischemic HF [24]. The current ESC, AHA, and Russian Clinical Guidelines indicate primary prevention ICDs for patients with non-ischemic HF, in case the following conditions are met: LVEF ≤ 35%, NYHA class II–III HF, patients after 3 months of optimal drug therapy, and a predicted life expectancy of more than 1 year [10–12].

There are a number of rare, genetically determined disorders associated with a high risk of SCD, such as hypertrophic cardiomyopathy (HCM), arrhythmogenic right ventricular dysplasia (ARVP), Brugada syndrome, long QT syndrome (LQTS), etc. RCTs on the effectiveness of ICD therapy in the prevention of SCD in these diseases have not been conducted. Currently, HCM is the main cause of SCD among young population [25].

According to the Russian Scientific Society guidelines, ICD therapy in HCM is indicated in patients with an estimated 5-year risk of SCD > 6% (IIA, B) or with the predicted benefit of ICD in the long term (IIB, B) [8]. These recommendations are based on the findings of two retrospective, cohort, observational studies that showed higher mortality, frequent inappropriate shocks, and complications in patients with HCM [26, 27]. The HCM Risk – SCD risk prediction model is used for 5-year SCD risk estimation, it establishes a non-linear relationship between the risk of SCD and the maximum left ventricular wall thickness. The effectiveness of this predictive model is being constantly improved [27].

In the latest Russian guidelines for sudden cardiac death risk assessment and prevention (2018), ICD placement due to HCM is indicated for patients with a predicted 5-year SCD risk of ≥ 4%, calculated using the HCM Risk – SCD model (class IB), as well as for patients with at least one major risk factor (IIA, B) [25].

Arrhythmogenic right ventricular dysplasia is an indication for secondary prevention ICDs in case of severe dysfunction of one or both ventricles (class IB) and in the presence of risk factors (syncope, moderate ventricular dysfunction, episodes of unstable VT, (IIA, B)) [8]. The basis for these indications was the result of the meta-analysis performed by A.F. Schinkel, which included 24 small studies and a total of 610 patients (average age 40.4 years; 42% of patients were women) with ARVP and primary / secondary prevention ICDs. The author noted a reduced risk of overall and cardiac mortality in the ICD group [28]. However, it should be noted that the ICD group had higher frequency of myocardial perforation [25].

The number of patients with LQTS is increasing worldwide [29]. P.J. Schwartz et al. in a prospective analysis of 233 patients with ICD and LQTS (41% of cases – secondary prevention ICDs) showed that within 4.6 years, 28% of patients received appropriate shocks, and 25% had complications associated with the device [29]. Predictors of appropriate ICD shocks included: age younger than 20 years, prior cardiac arrest, and a prolonged QTc (greater than 500 milliseconds). Appropriate shocks were not observed in the absence of these factors. The authors concluded that it is necessary to specify the criteria for ICD placement and consider other existing treatment options [29].

According to the recommendations of the Russian Scientific Society, in patients with LQTS, ICD placement is indicated after cardiac arrest (class IB), in case of syncope or unstable VT with prescribed beta-blockers (IIA, B), and with history of SCD in the family (IIC, C) [8]. The study by C. Jons et al. confirms high risk of SCD and the need for ICD placement in the presence of syncope with prescribed beta-blockers, especially in women and children [30]. Taking into account the fact that the development of the syndrome is associated with mutations in 13 genes, each associated with a different risk of SCD, the latest Russian guidelines for sudden cardiac death risk assessment and prevention clearly indicate genetic testing [25]. Primary prevention ICDs are recommended for LQT3, and secondary prevention ICDs (IB) – in case of LQT1, LQT2, LQT5, and LQT6 and a prior cardiac arrest [25].

In the Russian Federation, the prevalence of Brugada syndrome is estimated at 1 to 3 cases per 10 thousand population [31]. This disorder requires ICD therapy in case the patient has the following adverse outcome predictors: male, syncope or SCD in the family history, spontaneous ST segment elevation in leads V1–V3 with syncope, spontaneous ST segment changes, and Brugada type 1 ECG pattern (ST segment elevation of 2 mm or more, ending in a negative T wave) [8, 25]. There are no available data concerning the routine use of genotyping to assess the risk of SCD in patients with Brugada syndrome.

LVEF is still the only parameter strongly associated with SCD in patients with cardiovascular diseases [1, 2]. Thus, LVEF and the NYHA functional classification of HF have been used for more than a decade to determine the indications for primary prevention ICD. However, recent advances in prevention of HF with rEF (HFrEF) have allowed specialists to use complete neurohormonal blockade with renin – angiotensin – aldosterone system (RAAS) blockers and beta-blockers, revealed a new group of drugs – angiotensin-receptor-neprilysin-inhibitor (ARNI), and helped to improve CRT and coronary revascularization. Due to this fact, AHA guidelines (2017) included an additional criterion for revaluating parameters after 90 days, if revascularization is to be performed [11].

Currently, the prognosis in patients with HFrEF has significantly improved due to higher survival rates and lower risk of SCD, compared with 10–20 years ago. Analyzing the outcome of the last 12 RCTs that are not related to ICD, a significant decrease (44%) in the rate of SCD was observed in more than 40,000 patients with HFrEF, which was comparable to ICD therapy [24]. This decrease occurred simultaneously with a rise in prescription of ODT. Additionally, an analysis of 4,000 MADIT patients showed significant reduction of VT contribution to the overall mortality in ICD therapy over the past two decades. VT involvement in the overall mortality decreased from 21% in MADIT-II

(conducted in 1997–2001) to 14% in Multicenter Automatic Defibrillator Implantation Trial: Reduce Inappropriate Therapy (MADIT-RIT, conducted in 2009–2011). Presumably, ODT for CHF reduces cases of VT and SCD and increases survival rates [32]. This is validated by the results of a recent DANISH RCT on the effectiveness of primary prevention ICD in patients with non-ischemic HF [23].

Therefore, the above mentioned data determine the need for new large-scale RCTs to assess the effectiveness of ICD therapy, define the indications for it, and search for new biomarkers and predictors of SCD.

ICD IMPLANTATION-RELATED COMPLICATIONS AND THEIR PREVENTION

ICD-related complications can occur in the early and late postoperative period. Inappropriate shocks, infectious complications, and ICD malfunction are of particular interest due to their frequency.

According to the results of a recent study with a sample of more than 3,000 patients, the cumulative incidence of adverse events over 12 years of follow-up was: 20% – inappropriate shocks, 6% – infectious complications associated with an implanted device, and 17% – electrode failure. A population-based survey on the frequency of ICD-related infections in the United States (2016) showed that out of 191,610 placed ICDs, 8,060 caused infections (4.2%), hospital mortality was 4.7%, and the majority of patients (68.9%) with ICD-related infections had three or more comorbidities [33]. A much lower incidence of infectious complications (0.5–2.5%) was found by Russian observational studies, indicating relative safeness of the method [34, 35].

The problem of inappropriate ICD shocks is given a lot of attention in modern arrhythmology [4, 12, 35, 36]. There is growing evidence that ICD shocks lead to myocardial damage, contribute to the progression of left ventricular dysfunction (LVD), and multiply a risk of death by 1.9–5.6 times [24, 35, 36]. Moreover, social maladaptation, poor quality of life, anxiety, and depression can develop as the result of frequent shocks, worsening the course of the underlying disease. According to the data, 22–66% of patients complain about symptoms of depression, 31–83% of patients are concerned about anxiety within a year after ICD placement [37, 38], and the development of these mental health disorders is closely related to the frequency of ICD shocks [39]. Recent studies have shown that anxiety and depression in ICD patients have a bidirectional relationship with endpoints, such as hospitalization and death [40]. Currently, the cohort of patients with CHF and ICD is considered to have the most severe psychosocial distress and social maladaptation.

Data analysis suggests that compliance with the current recommendations on device programming, elaborated by the HRS / European Heart Rhythm Association (EHRA) / Asia Pacific Heart Rhythm Society (APHRS) / Latin American Heart Rhythm Society (LAHRS) in 2019, can help prevent inappropriate shocks and thereby reduce their frequency [41]. Optimal programming prolongs the time of arrhythmia detection, increasing the probability of triggering the antitachycardia pacing (ATP), rather than shock. Three RCTs (MADIT-RIT, Avoid Delivering Therapies for Non-Sustained Arrhythmias in ICD Patients III (ADVANCE III), and Programming Implantable Cardioverter – Defibrillators in Patients with Primary Prevention Indication to Prolong Time to First Shock (PROVIDE)) analyzed strategies of prolonging the tachycardia detection interval compared with conventional short detection intervals [42–44].

All three studies demonstrated that longer detection intervals were associated with a decrease in the frequency of inappropriate shocks. Moreover, improved survival rates in the groups randomized for prolonged detection were noted in MADIT-RIT and PROVIDE studies [42, 44]. T. Ananwattanasuk et al. compared two groups of patients with ICD: with programming according to recommendations and with random programming according to the doctor`s choice. The results showed that the first group experienced lower frequency of inappropriate shocks and had lower incidence of ICD therapy [45]. The results also demonstrated that only in 1/3 of patients in clinical practice ICDs were programmed in accordance with the existing recommendations [45].

Inappropriate ICD shocks might occur due to oversensing of the T-waves, atrial arrhythmia, R-waves, myopotential, electromagnetic noise, and sensing lead malfunction [46, 47]. Another common cause of inappropriate shocks is impaired detection and recognition of supraventricular tachycardia as

ventricular tachycardia, or a shock discharge instead of ATP [46, 47].

To solve this problem, modern ICDs use automatic algorithms for differentiation between arrhythmias, significantly reducing the frequency of inappropriate ICD shocks and recognizing supraventricular and ventricular arrhythmias, T-waves, noise, and interference. Non-compliance with the manufacturer's recommendations during programming can lead to an increase in the frequency of inappropriate shocks [48]. Medtronic Inc. have recently implemented algorithms to deliver the programmed number of ATP sequences during the charge after detection of arrythmia in the VF zone. The safety and effectiveness of this algorithm have been confirmed in a number of studies, moreover, they showed that the majority of episodes recognized as VF turned out to be VT that was treated with ATP therapy [49, 50].

Other similar algorithms for differentiating between types of arrhythmias are used in all modern devices, and subsequent studies have shown that their implementation can significantly reduce the number of inappropriate shocks [42, 51]. Devices made by different manufacturers differ significantly in their programming approaches, meaning there could be no standardized programming protocol. This particularity is reflected in the updates of the HRS/ EHRA / APHRS / LAHRS Expert Consensus [41]. According to the PainFree SmartShock Technology (PainFree SST) study, recently developed SmartShock technology (Medtronic Inc.) is comprised of six unique algorithms that effectively reduce the number of inappropriate shocks [52].

The development of new approaches to ICD placement based on the results of myocardial perfusion scintigraphy in patients with CAD is another way to reduce the stimulation threshold and the amplitude of the ventricular signal, allowing to prolong the longevity of ICD while minimizing the oversensing [53]. The compliance with current guidelines on the device programming and the use of modern ICD models proved to be an effective way to reduce the number of inappropriate shocks. Identifying the predictors of high-risk groups for frequent inappropriate shocks, specialists should take a more balanced approach to outlining the indications for ICD placement, its programming, and subsequent monitoring.

A significant contribution to the improvement of the follow-up efficiency after ICD placement is made by remote health monitoring (RHM) and telemetry technologies. Being a part of all modern devices, they can reduce the number of inappropriate shocks by appropriate programming. Data from numerous studies confirmed the effectiveness of RHM and telemetry technologies ((ALTITUDE (Long-term outcome after ICD and CRT implantation and influence of remote device follow-up), TRUST (Lumos-T Safely Reduces Routine Office Device Follow-Up), ECOST (Effectiveness and Cost of ICD follow-up Schedule with Telecardiology)) [54–56].

The large-scale ALTITUDE study (2006–2009) was devoted to the analysis of the advantages of RHM (69,556 patients) over conventional monitoring (116,222 patients) after the ICD placement. The results showed that implantation of the devices was associated with significant survival benefits during the first year – 92 and 88%, respectively, and it was RHM that ensured high efficiency of ICD in both groups ($p < 0.0001$) [54].A combination of telemetry and RHM allows for almost seamless process, providing daily self-monitoring of the implanted device and notifying the specialist in cases of abnormality, which could not be done using telemetry alone. The results of the TRUST study confirmed that RHM and telemetry are more effective than conventional follow-up visits, because patients were always under medical supervision [55]. In the ECOST study, cases of ICD therapy were identified as a secondary endpoint [56]. The results in the RHM group are explained by preemptive actions of the doctor that were taken after receiving an early warning via the RHM system. In the RHM group, 14.5% of device shocks were inappropriate, while in the control group the number was significantly higher, reaching almost 43% ($p < 0.001$) [56].

Another problem related to ICDs is the fact that, despite the 80% success rate of ICD therapy, the mortality rate in ICD patients continues to be high, which motivates researchers to further study the patterns and mechanisms leading to it. Thus, according to postmortem telemetry of 90 SCD cases in patients with ICD, 26% of patients died from uncorrected VT or VF, 29% – from post-shock electromechanical dissociation, 16% – from primary electromechanical dissociation, 13% – from inces-

sant VT or VF, and 7% – from VT or VF after ICD deactivation [57].

According to E. Cronin et al., only 33% of patients with primary prevention and 47% with secondary prevention ICDs receive appropriate shocks. Therefore, an upgrade in programming algorithms is required to differentiate life-threatening arrhythmias from other types of rhythm, cardiac, extracardiac, and external interferences. Monitoring ICD patients at high risk of SCD should be considered a priority [58]. According to the current guidelines, any inappropriate shock or non-response in the ICD patient with malignant arrhythmia is a reason for further studying SCD prevention methods, improving the device response, and verifying the population at risk [10–12].

For this purpose, several risk stratification systems were developed for ICD patients. However, most of them were focused on determining the risk of all-cause mortality in patients with reduced and preserved LVEF and were not widely used in clinical practice. The long-term follow-up withing the Leiden out-of-hospital cardiac arrest (LOHCAT) study (456 CAD patients with secondary prevention ICDs) added an adverse prognostic value to the QRS width [59]. D.B. Kramer et al. revealed that 2,717 patients with ICD had creatinine levels of more than 200 mg / l, LVEF < 20%, atherosclerosis, and an increased risk of mortality [60].

G.A. Gromyko et al. proposed a Russian system of risk stratification based on data of postinfarction patients, which included the following determinants: atherosclerosis, complete right bundle branch block, LV dilatation, stenosis of the anterior interventricular artery, and the value for the percentage of LV scar tissue. An important feature of this scoring system was the assessment of the relationship between the prognosis and the severity of the underlying and concomitant diseases [61]. Therefore, further validation and improvement of methods for ICD inefficiency assessment is another way to reduce medical and social losses for ICD patients.

DIFFICULTIES IN ICD APPLICATION IN CLINICAL PRACTICE

ICD therapy in real clinical practice is a complex issue. Firstly, there is an obvious gap between guideline recommendations and their clinical application in many countries, including the Russian Federation. Out-of-hospital all-cause mortality due to SCD reaches 39.4% worldwide [62]. There are no statistics available on the SCD-related death rate in the Russian Federation, but according to the latest estimates, 200,000–250,000 people die annually from cardiovascular diseases in the Russian Federation. The Sudden Cardiac Death in Patients with Coronary Heart Disease: Results of the Russian Multi-Center Epidemiological Study of Mortality, Morbidity, and Diagnostics and Treatment Quality in Acute CHD (RESONANCE) study revealed that the incidence of SCD is 156 (for men) and 72 (for women) per 100,000 population per year, although the real frequency of SCD might be higher [63].

For comparison, in the United States, the annual rate of SCD is 100 to 200 per 100,000 population [64]. This means that the number of ICD patients is too low, and there should have been more cases of ICD placement. The analysis showed that supply for surgical and interventional cardiology procedures in several regions of the Russian Federation is below average, while other regions are the most undersupplied in the world [65].

Only 66 clinics in the Russian Federation had cases of implanted ICDs in 2013. The total number of ICDs was 1,926 per year and the average was 0.05 ICDs per 100,000 population. The highest index was 0.06 per 100,000 in the Central Federal District (FD), and the lowest one was 0.01 per 100,000 in the North Caucasus FD [65]. According to recent data, the vast majority of ICD patients in the world belong to the primary prevention group, but even in countries where the ICD therapy is widespread, the implanted ICDs satisfy only 40–60% of the overall need [44]. There are several reasons for this situation: a high cost of the ICD device; ignorance or distrust of ICDs; lack of standards for patient selection and follow-up monitoring. Ultimately, doctors in the outpatient setting do not have necessary knowledge about the specifics of ICD patient management and experience of working with such patients due to their small number.

This leads to the second problem related to ICD patient management. Standard outpatient follow-up after implantation of the device implies complex cardiac care: echocardiography and ECG, compliance with medication treatment (including antiarrhythmic therapy), scheduled follow-up appointments with the arrhythmologist, and specialized

arrhythmological optimization of the device by the programmer (scheduled and in case of inappropriate shocks) [8].

Due to the occurrence of inappropriate shocks in 25% of patients, leading to premature depletion of the device battery, the need for unscheduled ICD follow-ups continues to persist. Other reasons for inappropriate shocks include device or lead malfunctions, excessive or insufficient sensing, and incorrect stimulation threshold [66]. However, many patients with ICDs do not receive such medical care, which was recognized, in particular, by HRS [67]. This problem has been especially relevant for the Russian Federation. The development of automated wireless RHM systems was a much-needed change in outpatient monitoring that helped to form the basis for new guidelines. Now all patients with ICD should be provided with RHM, which in turn reduces the number of follow-ups and justifies hospitalization in case of multiple malfunctions and is reasonable for evaluating the device performance and the battery life [67–69].

However, data from real clinical practice show that RHM data were never analyzed during the first year of ICD placement in 25% of patients [69]. Combined with the fact that the RHM system does not allow for reprogramming of ICD remotely, even more issues start to arise. They are primarily associated with a lack of standards and clinical guidelines for the use of RHM in the Russian Federation [68]. In many countries, neither clinics nor doctors receive monetary compensation for RHM / telemetry monitoring, despite the fact that these methods proved to be cost-effective and allow to increase the number of patients under medical supervision. Furthermore, this type of medical service is not funded by healthcare systems, which only complicates the work of specialists [57, 68, 69].

The difference in the ICD effectiveness according to foreign and Russian RCTs presents another significant problem. Data on the frequency of appropriate shocks in ICD patients in the Russian Federation indicate a lower number of effective responses compared with other RCTs, indirectly revealing the shortcomings of the selection process [35, 37]. According to A.S. Revishvili, 49% of patients did not receive single justified ICD therapy for 5 years, even though the frequency of inappropriate shocks was 39% [35]. Literature data indicate higher mortality rate among patients with both primary and secondary prevention ICDs in the Russian Federation compared with international statistics – 18.8 and 16% versus 12.7 and 14%, respectively [35, 70]. According to the study by M.A. Kamaliev et al., the survival rate in this category of patients during the year was 83.3%, which is a lower value than in international data on the annual survival of patients after ICD placement (92–98%) [71].

Therefore, studies on ICD therapy conducted in the Russian Federation indicate insufficient survival rate compared with international studies both in terms of the survival rate 1 year after ICD placement and in the long-term follow-up. It can be explained objectively by the level of healthcare system development and availability of medical care in certain regions; or subjectively by poor patient selection, non-compliance with recommendations on device programming or RHM, difficulties of outpatient management, and low adherence to ODT. However, these assumptions need to be confirmed by analyzing the cohort of patients with ICD in real clinical practice in every region of the Russian Federation.

Psychosocial rehabilitation is another problem of patient management in the Russian Federation. Depression and deterioration of the patient's quality of life after ICD placement can lead to a loss of contact with the specialist, which negatively affects survival [40]. The main sources of stress, anxiety, and depression can be both excessive information about the device, especially from other patients, as well as a lack of information [41]. Given these data, it may be useful to organize training sessions for ICD candidates – individual and group psychological counseling sessions, explanatory therapy, etc. The guidelines highly recommend assessment and treatment of psychosocial distress in ICD patients [10–12, 25]. Self-help groups and individual and group therapy have already proven to be effective in this cohort of patients [72].

However, such treatment options, including psychotherapy, are not available for patients with reduced mobility or financial difficulties [39, 72]. Research results have shown that online video and individual phone consultations can help in this situation [73, 74]. Given the availability and low cost, Internet-based consultation is a promising solution, even for elderly patients [40]. Supposedly, online consultations can be as effective as conventional

therapy for patients with ICD, and there is growing evidence in support of that [40, 73, 74].

Therefore, there are several ways to improve ICD patient management in the Russian Federation: active monitoring of the devices via implementation of the RHM system, optimization of drug therapy, promotion of drug compliance, application of modern ICD programming methods, raise of patient awareness (sessions, phone calls, monitoring diary), and psychological consultations and counseling, also via Internet-based technologies.

CONCLUSION

Significant progress has been made in the field of ICD therapy over the past two decades. As a result, there are currently multiple kinds of ICD devices to choose from [75]. Future efforts should be focused on improving methods of patient selection, which in turn requires large-scale RCTs against the background of ODT. It is also necessary to develop new comprehensive approaches to SCD risk stratification, based on the combined assessment of clinical risk factors on the basis of ECG, findings of medical imaging techniques, biomarkers, and genetic determinants, including patients with intermediate and preserved LVEF.

Evidently, ICD therapy has high relevance in healthcare. However, there are limiting factors for the Russian Federation, such as high cost of the device, distrust of the method due to ignorance of ICD benefits, lack of practical tools for risk assessment in SCD, and insufficient experience in managing patients with ICDs in the outpatient setting [75, 76].

Outlining problems associated with ICDs can assist in finding solutions among medical experts and device developers. One way to optimize ICD therapy is to create a registry of ICD patients, which can be crucial for developing cost-effective prevention strategies and bridging the gap between scientific data and limited healthcare resources.

REFERENCES

1. Hayashi M., Shimizu W., Albert C.M. The spectrum of epidemiology underlying sudden cardiac death. *Circ. Res.* 2015;116(12):1887–1906. DOI: 10.1161/CIRCRESAHA.116.304521.
2. Wong C.X., Brown A., Lau D.H., Chugh S.S., Albert C.M., Kalman J.M. et al. Epidemiology of sudden cardiac death: global and regional perspectives. *Heart, Lung and Circ.* 2019;28(1):6–14. DOI:10.1016/j.hlc.2018.08.026.
3. Garganeeva A.A., Okrugin S.A., Borel K.N., Efimova E.V. Prehospital mortality from acute myocardial infarction and possible ways to reduce it. *Complex Issues of Cardiovascular Diseases*. 2012;(2):28–33 (in Russ.). DOI: 10.17802/2306-1278-2012-2-28-33.
4. Link M.S. Sudden cardiac death in the young: epidemiology and overview. *Congenit. Heart Dis.* 2017;12(5):597–599. DOI: 10.1111/chd.12494.
5. Kuck K.H., Cappato R., Siebels J.R., Rupel R. Randomized comparison of antiarrhythmic drug therapy with implantable defibrillators in patients resuscitated from cardiac arrest: the Cardiac Arrest Study Hamburg (CASH). *Circulation.* 2000;102(7):748–754. DOI: 10.1161/01.CIR.102.7.748.
6. Connolly S.J., Gent M., Roberts R.S., Dorian P., Roy D., Sheldon R.S. et al. Canadian implantable defibrillator study (CIDS): a randomized trial of the implantable cardioverter defibrillator against amiodarone. *Circulation*. 2000;101(11):1297–1302. DOI: 10.1161/01.cir.101.11.1297.
7. Connolly S.J., Hallstrom A.P., Cappato R., Schron E.B., Kuck K.H., Zipes D.P. et al. Meta-analysis ofthe implantable cardioverter defibrillator secondary prevention trials. AVID, CASH and CIDS studies. Antiarrhythmics vs Implantable Defibrillator study. Cardiac Arrest Study Hamburg. Canadian Implantable Defibrillator Study. *Eur. Heart J.* 2000;21:2071–2078. DOI: 10.1053/euhj.2000.2476.
8. Revishvili A.Sh., Shlyakhto E.V., Popov S.V., Pokushalov E.A., Shkol'nikova M.A., Sulimov V.A., et al. Clinical guidelines for electrophysiological studies, catheter ablation, and the use of implantable antiarrhythmic devices. Russian Scientific Society of Specialists in Clinical Electrophysiology, Arrhythmology, and Cardiac Pacing (in Russ.). URL: http://webmed.irkutsk.ru/doc/pdf/vnoa.pdf
9. Buxton A.E., Lee K.L., Fisher J.D. Josephson M.E., Prystowsky E.N., Hafley G. A randomized study of the prevention of sudden death in patients with coronary artery disease. Multicenter Unsustained Tachycardia Trial Investigators. *N. Engl. J. Med.* 1999;341(25):1882–1890. DOI: 10.1056/NEJM199912163412503.
10. Priori S.G., Blomstrom-Lundqvist C., Mazzanti A., Blom N., Borggrefe M., Camm J. et al. ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: the Task Force for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death of the European Society of Cardiology (ESC). Endorsed by: association for European Pediatric and Congenital Cardiology (AEPC). *Eur. Heart J.* 2015;36(41):2793–2867. DOI: 10.1093/eurheartj/ehv316.
11. Al-Khatib S.M., Stevenson W.G., Ackerman M.J., Bryant W.J., Callans D.J., Curtis A.B. et al. 2017 AHA/ACC/HRS Guideline for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death. *Circulation*. 2018;138(13):272–391. DOI: 10.1161/CIR.0000000000000549.
12. Revishvili A.Sh., Neminushchiy N.M., Golitsyn S.P. All-Russian clinical guidelines for control over the risk of sudden car-

diac arrest and sudden cardiac death, prevention, and first aid. M.: GEO-TAR-Media, 2018:56 (in Russ.).
13. Moss A.J., Zareba W., Hall W.J., Klein H., Wilber D.J., Cannom D.S. et al. Multicenter Automatic Defibrillator Implantation Trial II Investigators. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. *N. Engl. J. Med*. 2002;346(12):877–883. DOI: 10.1056/NEJMoa013474.
14. Bardy G.H., Lee K.L., Mark D.B., Poole J.E., Packer D.L., Boineau R. et al. Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) Investigators. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. *N. Engl. J. Med*. 2005;352(3):225–237. DOI: 10.1056/NEJMoa043399.
15. Buxton A.E., Lee K.L., Hafley G.E., Pires L.A., Fisher J.D., Gold M.R. et al. MUSTT Investigators. Limitations of Ejection Fraction for Prediction of Sudden Death Risk in Patients With Coronary Artery Disease. Lessons From the MUSTT Study. *J. Am. Coll. Cardiol.* 2007;50(12):1150–1157. DOI: 10.1016/j.jacc.2007.04.095.
16. Hohnloser S.H., Kuck K.H., Dorian P., Roberts R.S,. Hampton J.R., Hatala R. et al. DINAMIT Investigators. Prophylactic use of an implantable cardioverter-defibrillator after acute myocardial infarction. *N. Engl. J. Med.* 2004;351(24):2481–2488. DOI: 10.1056/NEJMoa041489.
17. Steinbeck G., Andresen D., Seidl K., Brachmann J., Hoffmann E., Wojciechowski D. et al. IRIS Investigators. Defibrillator implantation early after myocardial infarction. *N. Engl. J. Med.* 2009;361(15):1427–1436. DOI: 10.1056/NEJMoa0901889.
18. Shun-Shin M.J., Zheng S.L., Cole G.D., Howard J.P., Whinnett Z.I., Francis D.P. Implantable cardioverter defibrillators for primary prevention of death in left ventricular dysfunction with and without ischaemic heart disease: a meta-analysis of 8567 patients in the 11 trials. *Eur. Heart J*. 2017;38(22):1738–1746. DOI: 10.1093/eurheartj/ehx028.
19. Hoch D., Goldberger J., Shalaby A., Sanders W.E., Schaechter A., Levine J.H. Defibrillators in Non-Ischemic Cardiomyopathy Treatment Evaluation (DEFINITE) Investigators. Prophylactic defibrillator implantation in patients with non-ischemic dilated cardiomyopathy. *N. Engl. J. Med.* 2004;350(21):2151–2158. DOI: 10.1056/NEJMoa033088.
20. Bänsch D., Antz M., Boczor S., Volkmer M., Tebbenjohanns J., Seidl K. et al. Primary Prevention of Sudden Cardiac Death in Idiopathic Dilated Cardiomyopathy The Cardiomyopathy Trial (CAT). *Circulation.* 2002;105(12):1453–1458. DOI: 10.1161/01.cir.0000012350.99718.ad.
21. Strickberger S.A., Hummel J.D., Bartlett T.G., Frumin H.I., Schuger C.D., Beau S.L. et al. AMIOVIRT Investigators. Amiodarone Versus Implantable Cardioverter-Defibrillator: Randomized Trial in Patients With Nonischemic Dilated Cardiomyopathy and Asymptomatic Nonsustained Ventricular Tachycardia – AMIOVIRT. *J. Am. Coll. Cardiol*. 2003;41(10):1707–1712. DOI: 10.1016/s0735-1097(03)00297-3.
22. Desai A.S., Fang J.C., Maisel W.H., Baughman K.L. Implantable Defibrillators for the Prevention of Mortality in Patients With Nonischemic Cardiomyopathy A Meta-analysis of Randomized Controlled Trials. *JAMA.* 2004;292(23):2874–2879. DOI: 10.1001/jama.292.23.2874.
23. Kober L., Thune J.J., Nielsen J.C., Haarbo J., Videbæk L., Korup E. et al. DANISH Investigators. Defibrillator implantation in patients with non-ischemic systolic heart failure. *N. Engl. J. Med.* 2016;375(13):1221–1230. DOI: 10.1056/NEJMoa1608029.
24. Shen L., Jhund P.S., Petrie M.C., Claggett B.L., Barlera S., Cleland J.G.F. et al. Declining risk of sudden death in heart failure. *N. Engl. J. Med*. 2017;377(1):41–51. DOI: 10.1056/NEJMoa1609758.
25. Shlyakhto E.V., Arutyunov G.P., Belenkov Ju.N., Boytsov S.A. National guidelines for risk assessment and prevention of sudden cardiac death. 2nd edition. M.: MeDpraktIka-M, 2018:247. ISBN 978-5-98803-397-4 (in Russ.).
26. O'Mahony C., Lambiase P.D., Quarta G. et al. The long-term survival and the risks and benefits of imptantabte cardioverter defibrillators in patients with hypertrophic cardiomyopathy. *Heart.* 2012;98(2):116–125. DOI: 10.1136/hrt.2010.217182.
27. O'Mahony C., Jichi F., Pavlou M., Monserrat L., Anastasakis A., Rapezzi C. et alA novel clinical risk prediction model for sudden cardiac death in hypertrophic cardiomyopathy (HCM risk-SCD). *Eur. Heart J.* 2014;35(30):2010–2020. DOI: 10.1093/eurheartj/eht439.
28. Schinkel A.F. Implantable cardioverter-defibrillators in arrhythmogenic right ventricular dysplasia/cardiomyopathy: patient outcomes, incidence of appropriate and inappropriate interventions, and complications. *Circ. Arrhythm. Electrophysiol*. 2013;6 (3):562–568. DOI: 10.1161/CIRCEP.113.000392.
29. Schwartz P.J., Spazzolini C., Priori S.G., Crotti L., Vicentini A., Landolina M. et al. Who are the Iong-QT syndrome patients who receive an implantable cardioverter-defibrillator and what happens to them?: data from the European Long-QT Syndrome Implantable Cardioverter-Defibrillator (LQTS ICD) Registry. *Circulation*. 2010;122(13):1272–1282. DOI: 10.1161/CIRCULATIONAHA.110.950147.
30. Jons C., Moss A.J., Goldenberg I., Liu J., McNitt S., Zareba W. et al. Risk of fatal arrhythmic events in long QT syndrome patients after syncope. *J. Am. Coll. Cardiol.* 2010;55(8):783–788. DOI: 10.1016/j.jacc.2009.11.042.
31. Blinova V.V., Bogdanova T.M., Il'in A.A., Nagoeva M.R. Brugada syndrome as a predictor of sudden cardiac death. *Current Issues of Science and Education*. 2019;2:141 (in Russ.).
32. Chernomordik F., Jons C., Klein H.U., Kutyifa V., Nof E., Zareba W. et al. Death with an implantable cardioverter-defibrillator: a MADIT-II substudy. *Europace.* 2019;21(12):1843–1850. DOI: 10.1093/europace/euz263.
33. Rennert-May E., Chew D., Lu S., Chu A., Kuriachan V., Somayaji R. Epidemiology of cardiac implantable electronic device infections in the United States: a population based cohort study. *Heart Rhythm.* 2020;17(7):1125–1131. DOI: 10.1016/j.hrthm.2020.02.012.
34. Ilov N.N., Palnikova 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.

35. Revishvili A.Sh., Neminushchy N.M. Implantable cardioverter-defibrillator therapy at the present stage: improvement and standardization of the method. *Bulletin of Arrhythmology.* 2017;87:33–41 (in Russ.).
36. RychkovA.Yu., Kuznetsov V.A., Deryagina E.L., Horkova N.Yu. Frequency of motivated responses of implanted cardioverter defibrillators in patients with chronic heart failure. *Bulletin of Arrhythmology*. 2015;81:10–14 (in Russ.).
37. Thylen I., Moser D.K., Stromberg A., Dekker R.A., Chung M.L. Concerns about implantable cardioverter-defibrillator shocks mediate the relationship between actual shocks and psychological distress. *Europace.* 2016;18(6):828–835. DOI: 10.1093/europace/euv220.
38. Van Den Broek K.C., Habibovic M., Pedersen S.S. Emotional distress in partners of patients with an implantable cardioverter defibrillator: a systematic review and recommendations for future research. *Pacing Clin. Electrophysiol.* 2010;33(12):1442–1450. DOI: 10.1111/j.1540- 8159.2010.02885.x.
39. Sears S.F., Ford J. Seeking innovation in the delivery of psychosocial care for ICD patients. *European Heart Journal.* 2020;41(11):1212–1214. DOI: 10.1093/eurheartj/ehz167.
40. Lemon J., Edelman S., Kirkness A. Avoidance behaviors in patients with implantable cardioverter defibrillators. *Heart Lung.* 2004;33(3):176–182. DOI: 10.1016/j.hrtlng.2004.02.005.
41. Stiles M.K, Fauchier L., Morillo C.A., Wilkoff B.L. 2019 HRS/EHRA/APHRS/LAHRS focused update to 2015 expert consensus statement on optimal implantable cardioverter-defibrillator programming and testing. *Heart Rhythm*. 2020;17(1):220–228. DOI: 10.1016/j.hrthm.2019.02.034.
42. Moss A.J., Schuger C., Beck C.A., Brown M.W., Cannom D.S., Daubert J.P. et al. MADIT-RIT Trial Investigators. Reduction in appropriate therapy and mortality through ICD programming. *N. Engl. J. Med*. 2012;367(24):2275–2283. DOI: 10.1056/NEJMoa1211107.
43. Gasparini M., Proclemer A., Klersy C., Kloppe A., Lunati M., Ferrer J.B. et al. Effect of long-detection interval vs standard-detection interval for implantable cardioverter-defibrillators on antitachycardia pacing and shock delivery: the ADVANCE III randomized clinical trial. *JAMA.* 2013;309(18):1903–1911. DOI: 10.1001/jama.2013.4598.
44. Saeed M., Hanna I., Robotis D., Styperek R., Polosajian L., Khan A. et al. Programming implantable cardioverter-defibrillators in patients with primary prevention indication to prolong time to first shock: results from the PROVIDE study *J. Cardiovasc. Electrophysiol.* 2014;25(1):52–59. DOI: 10.1111/jce.12273.
45. Ananwattanasuk T., Tanawuttiwat T., Chokesuwattanaskul R., Lathkar-Pradhan S., Barham W., Oral H. et al. Programming implantable cardioverter defibrillatorin primary prevention: guideline concordance and outcomes. *Heart Rhythm.* 2020;17(7):1101–1106. DOI: 10.1016/j.hrthm.2020.02.004.
46. Powell B.D., Asirvatham S.J., Perschbacher D.L., Jones P.W., Cha Y.M., Cesario D.A. et al. Noise, artifact and oversensing related inappropriate ICD shock evaluation: ALTITUDE noise study. *Pacing Clin. Electrophysiol.* 2012;35(7):863–869. DOI: 10.1111/j.1540-8159.2012.03407.x.
47. Borne R.T., Varosy P.D., Masoudi F.A. Implantable cardioverter-defibrillator shocks. *Epidemiology, Outcomes, and Therapeutic Approaches JAMA Intern. Med*. 2013;173(10):859–865. DOI: 10.1001/jamainternmed.2013.428.
48. Gold M.R., Ahmad S., Browne K., Berg L., Thackeray B.L., Berger R. Prospective comparison of discrimination algorithms to prevent inappropriate ICD therapy: Primary results of the Rhythm ID Going Head to Head Trial. *Heart Rhythm.* 2012;9(3):370–377. DOI: 10.1016/j.hrthm.2011.10.004.
49. Schoels W., Steinhaus D., Johnson W.B., O'hara G., Schwab J.O., Jenniskens I. et al. En Trust Clinical Study Investigators.Optimizing implantable cardioverter-defibrillator treatment of rapid ventricular tachycardia: Antitachycardia pacing therapy during charging. *Heart Rhythm*. 2007;4(7):879–885. DOI: 10.1016/j.hrthm.2007.03.008.
50. Koneru J.N., Swerdlow C.D., Wood M.A., Ellenbogen K.A. Minimizing inappropriate or «Unnecessary» implantable cardioverter-defibrillator shocks appropriate programming. *Circ. Arrhythm. Electrophysiol.* 2011;4(5):778–790. DOI: 10.1161/CIRCEP.110.961243.
51. Wilkoff B.L., Williamson B.D., Stern R.S., Moore S.L., Lu F., Lee S.W. et al. Holloman and PREPARE Study Investigators Strategic Programming of Detection and Therapy Parameters in Implantable Cardioverter-Defibrillators Reduces Shocks in Primary Prevention Patients Results From the PREPARE (Primary Prevention Parameters Evaluation) Study. *J. Am. Coll. Cardiol.* 2008;52(7):541–550. DOI: 10.1016/j.jacc.2008.05.011.
52. Auricchio A., Schloss E.J., Kurita T. et al. Low inappropriate shock rates in patients with single and dual/triple chamber ICDs using a novel suite of detection algorithms: PainFree SST Trial Primary Results. *Heart Rhythm*. 2015;12(5):926–936. DOI: 10.1016/j.hrthm.2015.01.017.
53. Atabekov T.A., Batalov R.E., Krivolapov S.N., Sazonova S.I., Khlynyn M.S., Levintas A.D., et al. A new approach to cardioverter-defibrillator implantation in patients with coronary artery disease. *Russian Journal of Cardiology.* 2019;(3):32–38 (in Russ.). DOI: 10.15829/1560-4071-2019-3-32-38.
54. Saxon L.A., Hayes D.L., Gilliam F.R., Heidenreich P.A., Day J., Seth M. et al. Long-term outcome after ICD and CRT implantation and influence of remote device follow-up: the ALTITUDE survival study. *Circulation.* 2010;122(23):2359–2367. DOI: 10.1161/CIRCULATIONAHA.110.960633.
55. Varma N., Epstein A., Irimpen A., Schweikert R., Love C. TRUST Investigators. Efficacy and safety of automatic remote monitoring for ICD follow-up: the TRUST trial. *Circulation.* 2010;122(4):325–332. DOI: 10.1161/circulationaha.110.937409.
56. Guédon-Moreau L., Lacroix D., Sadoul N., Clémenty J., Kouakam C., Hermida J.S. et al. ECOST Investigators. Costs of remote monitoring vs. ambulatory follow-ups of implanted cardioverter defibrillators in the randomized ECOST study. *Europace*. 2014;16 (8):1181–1188. DOI: 10.1093/europace/euu012.
57. Mitchell L.B., Pineda E.A., Titus J.L., Bartosch P.M., Benditt D.G. Sudden death in patients with implantable cardioverter defibrillators: the importance of post-shock electromechanical dissociation. *J. Am. Coll. Cardiol.* 2002;39(8):1323–1328. DOI: 10.1016/s0735-1097(02)01784-9.

58. Cronin E., Jones P., Seth M., Varma N. Right ventricular pacing increases risk of appropriate implantable cardioverter-defibrillator shocks asymmetrically. *Circ. Arrhytm. Electrophysiol.* 2017;10(10):1–7. DOI: 10.1161/CIRCEP.116.004711.
59. Borleffs C.J.W., van Erven L., Schotman M., Boersma E., Kiès P., Borger A.E. et al. Recurrence of ventricular arrhythmias in ischaemic secondary prevention implantable cardioverter defibrillator recipients: long-term follow-up of the Leiden out-of-hospital cardiac arrest study (LOHCAT). *European Heart Journal.* 2009;30(13):1621–1626. DOI: 10.1093/eurheartj/ehp234.
60. Kramer D.B., Friedman P.A., Kallinen L.M., Morrison T.B., Crusan D.J., Hodge D.O. et al. Development and validation of a risk score to predict early mortality in recipients of implantable cardioverter-defibrillators. *Heart Rhythm.* 2012;9(1):42–46. DOI: 10.1016/j.hrthm.2011.08.031.
61. Gromyko G.A. Kazakov A.I., Chetverikov S.Yu., Didenko M.V., Pasenov G.S., Yashin S.M. Using QRS analysis to determine the risk of ventricular arrhythmias in patients with ischemic heart disease and implanted cardioverter defibrillators. *Bulletin of Arrhythmology*. 2013;72:14–18 (in Russ.).
62. Mendis S., Pushka P., Norrving B. et al. World Health Organization, World Heart Federation. Global Atlas on Cardiovascular Disease Prevention and Control. World Health Organization, Geneva, 2011. URL: https://apps.who.int/iris/handle/10665/44701
63. Yakushin S.S., Boytsov S.A., Furmenko G.I., Nikulina N.N., Akinina S.A. Sudden cardiac death in patients with coronary heart disease based on the results of the Russian multicenter epidemiological study of morbidity, mortality, quality of diagnosis, and treatment of acute forms of CHD (RESONANCE). *Russian Journal of Cardiology.* 2011;2:59–64 (in Russ.). DOI: 10.15829/1560-4071-2011-2.
64. Myerburg R.J. Sudden cardiac death: exploring the limits of our knowledge. *J. Cardiovasc. Electrophysiol.* 2001;12(3):369–381. DOI: 10.1046/j.1540-8167.2001.00369.x.
65. Bogachevskaya S.A., Bogachevskiy A.N. A 10-year overview of surgical and interventional arrhythmology in the Russian Federation over the past 10 years. Features of the service in the Far Eastern region. *Social aspects of Public Health (electronic journal).* 2017;1 (in Russ.). DOI: 10.21045/2071-5021-2017-53-1-1.
66. Beau S., Greer S., Ellis C.R., Keeney J., Asopa S., Arnold E. et al. Performance of an ICD algorithm to detect lead noise and reduce inappropriate shocks. *J. Interv. Card. Electrophysiol.* 2016;45(2):225–232. DOI: 10.1007/s10840-015-0081-6.
67. Wilkoff B.L., Auricchio A., Brugada J., Cowie M., Ellenbogen K.A., Gillis A.M. et al. Heart Rhythm Society (HRS), European Heart Rhythm Association (EHRA), American College of Cardiology (ACC), American Heart Association (AHA), European Society of Cardiology (ESC), Heart Failure Association of ESC (HFA), Heart Failure Society of America (HFSA). HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices (CIEDs): description of techniques, indications, personnel, frequency and ethical considerations: developed in partnership with the Heart Rhythm Society (HRS) and the European Heart Rhythm Association (EHRA); and in collaboration with the American College of Cardiology (ACC), the American Heart Association (AHA), the European Society of Cardiology (ESC), the Heart Failure Association of ESC (HFA), and the Heart Failure Society of America (HFSA). Endorsed by the Heart Rhythm Society, the European Heart Rhythm Association (a registered branch of the ESC), the American College of Cardiology, the American Heart Association. *Heart Rhythm.* 2008;10(6):707–725. DOI: 10.1093/europace/eun122.
68. Drozdov I.V. Baranov A.V., Amiraslanov A.Yu. Experience in using remote health monitoring systems in patients with implanted cardioverter defibrillator. *Bulletin of Arrhythmology.* 2015;82:38-42 (in Russ.).
69. Al-Khatib S.M., Mi X., Wilkoff B.L., Qualls L.G., Frazier-Mills C., Setoguchi S. et al. Follow-up of patients with new cardiovascular implantable electronic devices: are experts' recommendations implemented in routine clinical practice? *Circ. Arrhythm. Electrophysiol.* 2013;6(1):108–116. DOI: 10.1161/circep.112.974337.
70. 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.
71. Kamaliev M.A., Almukhanova A.B., Bapayeva M. Medical effectiveness after implantation of a cardioverter-defibrillator. *Bulletin of Kazakh National Medical University.* 2018;3:283–284 (in Russ.).
72. Maia A.C., Braga A.A., Soares-Filho G., Pereira V., Nardi A.E., Silva A.C. Efficacy of cognitive behavioral therapy in reducing psychiatric symptoms in patients with implantable cardioverter defibrillator: an integrative review. *Braz. J. Med. Biol. Res*. 2014;47(4):265–272. DOI: 10.1590/1414-431X20133418.
73. Andrews G., Basu A., Cuijpers P., Craske M.G., McEvoy P., English C.L., Newby J.M. Computer therapy for the anxiety and depression disorders is effective, acceptable and practical health care: an updated meta-analysis. *J. Anxiety Disord.* 2018;55:70–78. DOI: 10.1016/j.janxdis.2018.01.001.
74. Schulz S.M., Ritter O.R., Zniva P., Nordbeck C., Wacker M.J. Efficacy of a web-based intervention for improving psychosocial well-being in patients with implantable cardioverter-defibrillators: the randomized controlled ICD-FORUM trial. *European Heart Journal*. 2020;41(11):1203–1211. DOI: 10.1093/eurheartj/ehz134.
75. Bokeria L.A., Neminushchiy N.M., Mikhailichenko S.I. Implantable cardioverters-defibrillators as a specific method for preventing sudden cardiac death: development and standardization of the method. *Emergency Cardiology*. 2018;2:22–34 (in Russ.). DOI: 10.25679/EMERGCARDIOLOGY.2018.18.2.003.
76. Lampert R., Wang Y., Curtis J.P. Variation among hospitals in selection of higher-cost, higher-tech, implantable cardioverter-defibrillators: data from the National Cardiovascular Data Registry (NCDR) implantable cardioverter/defibrillators (ICD) registry. *Am. Heart J.* 2013;165(6):1015–1023. DOI: 10.1016/j.ahj.2012.12.003.

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Received 29.06.2020;
approved after peer review 16.02.2021;
accepted 25.05.2021