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SAFETY ISSUES OF SUBCUTANEOUS CARDIOVERTER-DEFIBRILLATOR SYSTEMS: IS EVERYTHING SO SIMPLE AND DEFINITELY?

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Aim. To evaluate the safety of subcutaneous cardioverter-defibrillator (SCD) systems.

Methods. Fifty-six patients underwent implantation of a SCD. The follow-up period for patients was 18 months. The number of early and late complications, as well as the number of episodes of shock therapy, were assessed.

Results. During observation, complications were recorded in 5 patients, which amounted to 0.9% of the total number of surgical interventions performed. Three complications occurred in the early postoperative period. In the late postoperative period, complications occurred in 2 (3.5%) patients. The number of inappropriate shocks in the total sample of patients was 6 episodes (10.7%).

Conclusion. SCD systems are effective for primary and secondary prevention of sudden cardiac death. Implantation of these systems is associated with a low number of perioperative complications, as well as a low percentage of inappropriate shock therapy.

Key words: subcutaneous cardioverter-defibrillator system; primary prevention of sudden cardiac death; secondary prevention of sudden cardiac death; chronic heart failure; inappropriate shocks

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Sudden cardiac death (SCD) is an outcome of sudden cardiac arrest in 50% of individuals 35-50 years of age. Usually, approximately 80%, SCD is attributed to the onset of ventricular fibrillation (VF) or ventricular tachycardia [1]. Additionally, the risk of SCD is strongly correlated with chronic heart failure (CHF) when accompanied by a left ventricular ejection fraction (LVEF) of less than 35% [2, 3]. The options for pharmacological prophylaxis in patients with chronic heart failure who are at risk of life-threatening arrhythmias are markedly limited. Thus, according to clinical guidelines for the treatment of CHF, patients with LVEF below 35% may be prescribed amiodarone as an antiarrhythmic drug. Taking this drug is associated with the development of various side effects, which often require its complete withdrawal. Implantation of a cardioverter-defibrillator (ICD) is recommended as a prophylaxis to prevent sudden cardiac death in at-risk patients [1, 4]. Implantation of a cardioverter-defibrillator for the primary prevention of sudden cardiac death in patients with chronic heart failure exhibits varying levels of evidence depending on the underlying etiology of the CHF. For patients with CHF of ischemic etiology, the recommendation for implantation of a cardioverter-defibrillator is supported by a high level of evidence. In contrast, for those with non-ischemic etiologies, the evidence is somewhat less robust, though ICD implantation remains indicated for most of these patients [1, 4].

Traditionally, patients have been offered implantation of transvenous ICD systems. However, these systems have many drawbacks and can be associated with various complications. There is a high rate of infectious complications associated with the implantation of intracardiac electrodes, often requiring complete system extraction. Currently, there is a generation of ICDs that are implanted subcutaneously. Such systems can help avoid several complications inherent to transvenous systems [4, 5]. A substantial body of research has demonstrated the efficacy of subcutaneous cardioverter-defibrillator systems [5-8]. One of the most significant studies, PRAETORIAN, aimed to compare the efficacy and safety of the two types of systems. A total of 849 patients were included. The follow-up lasted from 2011 to 2015. According to the study results, the incidence of the combined endpoint—consisting of implantation complications and the number of inappropriate shocks—did not differ significantly between the two groups. When considering complications separately, transvenous systems were significantly inferior to subcutaneous systems. However, the subcutaneous group experienced a significantly higher number of inappropriate shocks [5, 8, 9].

Another study, UNTOUCHED, included a larger number of patients (1116), these were patients with CHF with a LVEF less than 35%. In this study, the subcutaneous systems were more advanced with accurate arrhythmia discrimination algorithms. Thirty days following surgical intervention, 95.9% of patients achieved freedom from inadequate shocks, and 93.5% remained free from complications [5, 10]. At an 18-month follow-up, freedom from inappropriate shocks was maintained at 95.9%, and overall survival reached 94.9% [5, 11]. Until 2016, there were no implantations of these devices in Russia. Currently, approximately 200 devices have been implanted in the country, compared to over 100,000 devices globally [12]. In the Russian guidelines, the option of subcutaneous cardioverter-defibrillator implantation was first included in 2017. Since 2020, it has been featured in clinical recommendations for the management of chronic heart failure as an alternative to transvenous systems [4].

The purpose of this study is to present the results of a safety study on the use of a subcutaneous ICD system for the prevention of sudden cardiac death.

METHODS

The study included 56 patients who underwent implantation of a subcutaneous ICD system. Patients with class I and IIa indications for cardioverter-defibrillator implantation to prevent SCD, who did not require continuous pacing, antitachycardia pacing, or resynchronization therapy, were screened for study participation. Inclusion criteria were: age over 18 years, optimal pharmacological therapy for at least 3 months according to current guidelines for the underlying condition, positive preoperative screening using specialized software, and signed informed consent. Exclusion criteria were: patient refusal, acute illnesses that, in the physician's judgment, may compromise the safety or efficacy of the treatment, and medical conditions that limit the expected survival to less than 1 year. The follow-up period was 18 months. The incidence of intraoperative, early, and late complications associated with device implantation was assessed. The number of adequate and inadequate shocks was also assessed. Early complications were interpreted as complications that occurred during the period of the patient's hospitalization.

Technique of surgical intervention

Prior to the primary phases of the procedure, preoperative marking is performed using a non-sterile system. The incision sites are marked above the device pocket in the 4th to 5th intercostal space, between the anterior and mid-axillary lines on the left side, and in the paraxiphoid region when employing the double-incision technique. If the triple-incision technique is utilized, an additional incision site is marked 2.5 cm to the left of the sternal notch. The main stage is under endotracheal anesthesia with intravenous potentiation. After treatment of the operating field, incisions are made at the previously marked locations. Subsequently, a pocket is created between the latissimus dorsi and serratus anterior muscles. A lateral tunnel is created between the paramedian incision and the device pocket. A defibrillating electrode is then inserted. A vertical tunnel is created from the paraxiphoid incision using a tunneler and introducer, and the distal portion of the electrode is advanced along the left parasternal line. De-aeration of the vertical tunnel is conducted, followed by control fluoroscopy to assess the position of the electrode. Next, the electrode is secured and attached to the connector portion of the defibrillator. The device is positioned in the prepared pocket, secured, and the wound is then closed in layers. Next, defibrillation testing is performed.

Statistical analysis

Statistical analysis of data was performed using Excel 2010 application package and STATISTICA 10 statistical programs (StatSoft Inc., USA). Qualitative values are presented as absolute values and percentages. The following

Table 1.
Clinical and demographic characteristics of patients

Indicator	Value
Age, years	56 [47;62]
Male gender, n (%)	50 (89.3)
CHF NYHA FC I, n (%)	2 (3.5)
CHF NYHA FC II, n (%)	26 (46.5)
CHF NYHA FC III, n (%)	25 (44.6)
Postinfarction cardiosclerosis, n (%)	28 (50.2)
Dilated cardiomyopathy, n (%)	18 (32.1)
Hypertension, n (%)	6 (10.7)
LQTS, n (%)	3 (5.3)
Idiopathic VF, n (%)	1 (1.7)
Diabetes mellitus, n (%)	12 (21.4)
Paroxysmal AF, n (%)	6 (10.7)
Permanent AF, n (%)	19 (39.3)
Body mass index, kg/m^2	28 [25.8; 31.3]
Height, cm	175.6±8.01
QRS, ms	102 [96; 112]
LV ejection fraction, %	30 [26; 33.5]

Notes: hereinafter FC - functional class; CHF - chronic heart failure; LQTS - prolonged QT syndrome; VF - ventricular fibrillation; AF - atrial fibrillation; LV - left ventricle.

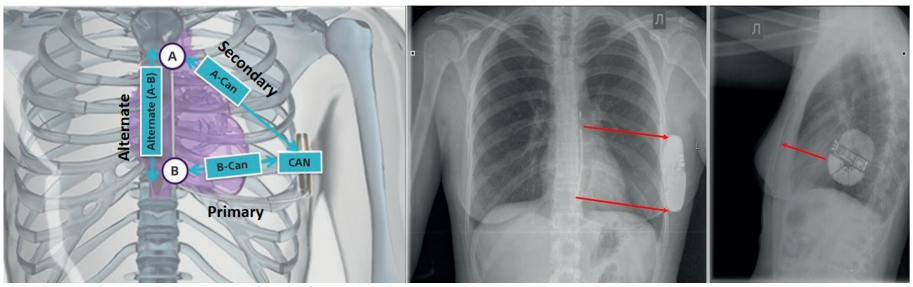

Fig. 1. Schematic arrangement of the system elements (left) and radiographs at the optimal position of the subcutaneous cardioverter-defibrillator system (right).

methods of statistical analysis were used: Mann-Whitney U-criterion. Sampling parameters reported in the table are presented as M (sd) and Me [Lq;Uq], where M is the mean, sd is the standard deviation, Me is the median, and Lq;Uq is the interquartile range. A difference was considered statistically significant at $p < 0.05$, while values of $0.05 < p < 0.10$ were interpreted as indicative of a trend.

RESULTS

The clinical and demographic characteristics of the patients included in the study are presented in Table 1.

Table 2.
Radiograph data of patients after S-ICD implantation (n=56)

Indicator	Value
Cardio-thoracic index, %	54 [52; 58.75]
Thoracotomy, n (%)	3 (5.3)
Direct projection	
Suboptimal position, n (%)	3 (5.3)
Suboptimal position, n (%)	14 (25)
Optimal position, n (%)	39 (70)
Side view	
Suboptimal position, n (%)	3 (5.3)
Optimal position, n (%)	53 (94.7)

In the studied cohort, 89.3% of patients were male. The primary indication for cardioverter-defibrillator implantation was the primary prevention of sudden cardiac death in chronic heart failure, accounting for 93% of cases. A small proportion of patients had indications for secondary prevention, including idiopathic ventricular fibrillation (1.7%) and hereditary channelopathies, such as long QT syndrome (5.3%). The predominant cause of chronic heart failure (CHF) was ischemic heart disease with postinfarction cardiosclerosis, affecting 50.2% of patients. Among those with non-ischemic etiology, over 30% had dilated cardiomyopathy (DCMP), while hypertension was identified as the cause of CHF in 10.7% of patients.

On the first postoperative day, all patients underwent radiography to evaluate the optimal positioning of the system. The electrode should be positioned 1-2 cm to the left of the midline of the sternum. The electrode is equipped with an 8 cm long shock coil. The distal part of the electrode, pole A, should be positioned at the junction of the manubrium and the body of the sternum. The proximal sensitive pole B is located at the xiphoid process. The body of the device should be positioned over the 6th rib, between the mid-axillary and anterior axillary lines. For optimal defibrillation, most of the left ventricular myocardium should be situated between the poles of the defibrillation system, which in turn establish three vectors for detecting cardiac electrical activity: primary, secondary, and alternative (Fig. 1).

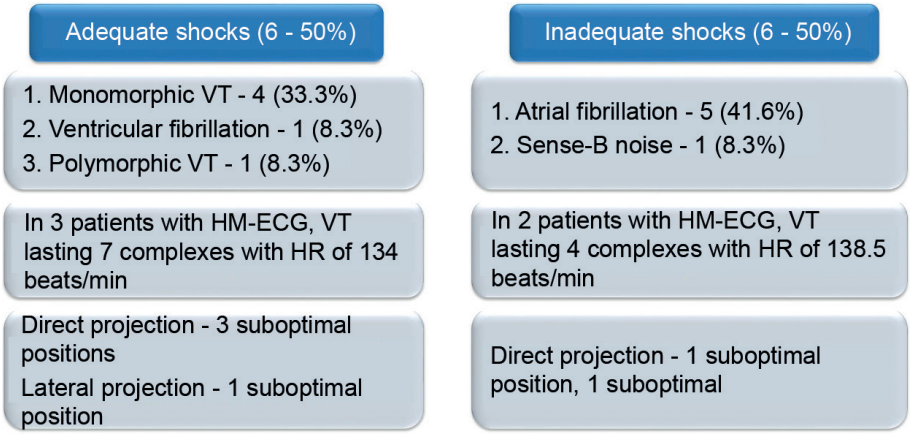

Fig. 2. Pattern of episodes of applied therapy in 56 patients with a subcutaneous cardioverter-defibrillator system over 18 months.

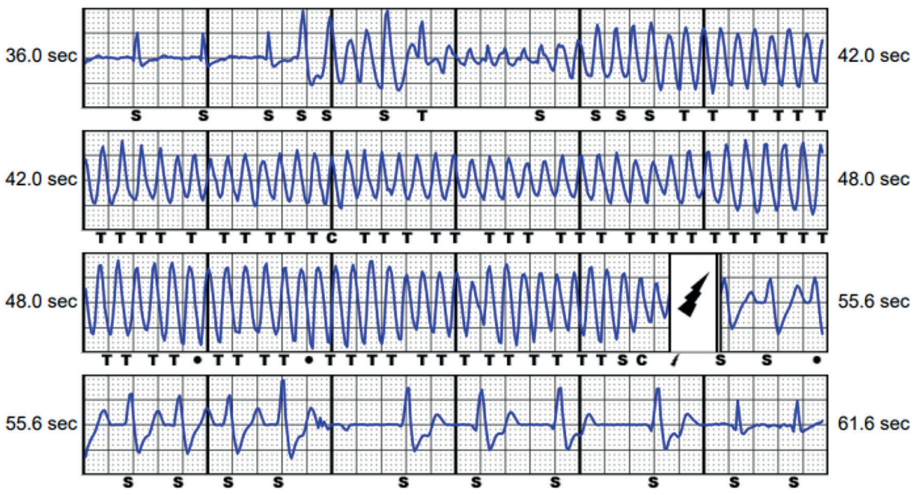

Fig. 3. Application of shock during an episode of ventricular fibrillation.

The radiologic assessment was conducted in two projections: anteroposterior and lateral. For each projection, specific criteria define the optimal position of the system. If these criteria are not met, the system position is deemed suboptimal. A suboptimal position of the system elements necessitates surgical correction if defects are identified during device testing, such as signal reading failures or ineffective defibrillation during testing.

All patients with chronic heart failure exhibited enlarged cardiac dimensions, particularly in the left chambers. Despite the elevated cardiothoracic index in this patient cohort, optimal system positioning was achieved in most cases. Additionally, 5.3% of patients had a history of thoracotomy, which significantly complicated the surgical procedure during the formation of the vertical tunnel for the electrode (Table 2).

During the 18-month follow-up period, complications were reported in 5 patients, representing 0.9% of the total num-

ber of surgical interventions. Three complications occurred in the early postoperative period, including: hematoma of the device pocket (2 cases, 3.5%) and the occurrence of noises during provocation tests, which necessitated repositioning of the electrode and a switch to the triple-incision technique (1 case, 1.7%).

In the late postoperative period, complications occurred in 2 (3.5%) patients. In the first case, infection was noted in the incision in the projection of the sternal process. Given the ineffectiveness of conservative therapy, the patient underwent system extraction. In the second case, shock application was noted against the background of polymorphic ventricular tachycardia; however, the patient also required correction of the device position due to registration noises.

One of the most critical criteria for evaluating the effectiveness and safety of a cardioverter-defibrillator is the ratio of adequate to inadequate shocks delivered. The overall pattern of episodes of applied therapy during follow-up is shown in Figure 2.

It is worth noting that both adequate and inadequate shocks occurred in equal numbers in the total sample of patients during the follow-up period. The main reason for inadequate therapy was tachysystolic form of atrial fibrillation (41.6%). These patients received adjustments to their rhythm-suppressive therapy, and the shock zones were recalibrated.

Before inclusion in the study, all patients underwent Holter monitoring to evaluate the presence and severity of ventricular rhythm disturbances. None of the patients had sustained episodes of ventricular tachycardia, which could be an indication for antitachycardia pacing. Despite meticulous patient selection, one reason for administering adequate shock therapy was the occurrence of monomorphic ventricular tachycardia (33.3%), which was treated with a cardioverter-defibrillator shock. Shock was also applied to polymorphic ventricular tachycardia (8.3%), and in 1 case to VF (8.3%) (Fig. 3).

It was of interest to analyze therapy episodes according to the indications for ICD implantation, namely primary and secondary prevention of SCD. In our study, there were only 4 patients with channelopathies and idiopathic VF in whom ICD implantation was performed as part of secondary prevention of SCD. Nevertheless, 24-hour ECG monitoring data revealed no sustained episodes of ventricular arrhythmias in these patients at the time of study inclusion. All patients had optimal system position according to chest radiography. There was 1 episode of adequate shock treatment applied to the VF.

In patients with indications for primary prevention of SCD, data were analyzed according to the etiology of CHF (Table 3). It is worth noting that the patients were comparable in terms of the main characteristics studied. This included an equal number of episodes of adequate and inadequate shock therapy in both groups (p=0.7). One reason for the occurrence of inappropriate shocks from a subcutaneous cardioverter-defibrillator is the rare phenomenon of noise detected by the B pole of the electrode.

A clinical case of the development of a B pole noise

This clinical case is the first description in the Russian-language literature. A 49-year-old patient with a history of ischemic heart disease, postinfarction cardiosclerosis, was indicated for implantation of a ICD as primary prevention of SCD. Given the absence of contraindications, the patient was implanted with a subcutaneous ICD system. The primary vector of subcutaneous ECG analysis was established. The early postoperative period was uneventful. According to chest radiography, the position of the system was suboptimal. No noise were recorded during provocative sampling.

A year later, the patient presented to the FGBU "E.I. Chazov NMICC" of the Ministry of Health of the Russian Federation with a complaint of receiving shock therapy despite being in complete well-being. Upon detailed questioning, it was determined that at the time of the therapy application, the patient was not engaged in physical activity and reported no sensations of palpitations or presyncope. During device interrogation, data were obtained on the applied shock to noncardiac activity (Fig. 4). After application of the shock, restoration of sinus rhythm registration

Table 3.

Characterization of the group of patients with indications for implantation of cardioverter-defibrillator as primary prevention of sudden cardiac death

	Patient groups		p
	Ischemic CHF (n=28)	Non-ischemic CHF (n=24)	
CHF FC I, n (%)	1 (3.6)	-	0.4
CHF FC II, n (%)	11 (39.3)	15 (62.5)	
CH FCF III, n (%)	16 (57.1)	9 (37.5)	
LV ejection fraction, %	30 [26.75; 33]	29 [25.75; 32.25]	0.5
LV EDD, cm	7.2 [6.5; 7.5]	7 [6.5; 7.5]	0.4
VT at 24-hour ECG (HM), n (%)	13 (46.4)	11 (45.8)	0.9
VT duration, complexes	6.6 ± 3.7	7.2 ± 3.5	0.3
VCR during VT, beats/min	141.5 ± 18.8	136.8 ± 15.7	0.5
Cardio-thoracic index, %	54 [52.5; 58.5]	56 [51.5; 59]	0.8
Aneurysm, n (%)	13 (46.4)	1 (4.2)	-
Thoracotomy, n (%)	2 (7.2)	-	-
Adequate therapy, n (%)	2 (7.2)	3 (8.3)	0.7
Inadequate therapy, n (%)	3 (10.7)	3 (16.6)	
Suboptimal, n (%)	2 (7.2)	1 (4.2)	-
Not optimal, n (%)	-	1 (4.2)	-

Notes: EDD, end-diastolic dimension; VT, ventricular tachycardia; HM, Holter monitoring; VCR, ventricular contraction rate.

was noted. At the time of initial device programming, the primary subcutaneous ECG reading vector was automatically selected. Since this issue with information analysis affected the B pole, the read vector was manually adjusted to the secondary vector. Thereafter, no repeat episodes of shock application were noted.

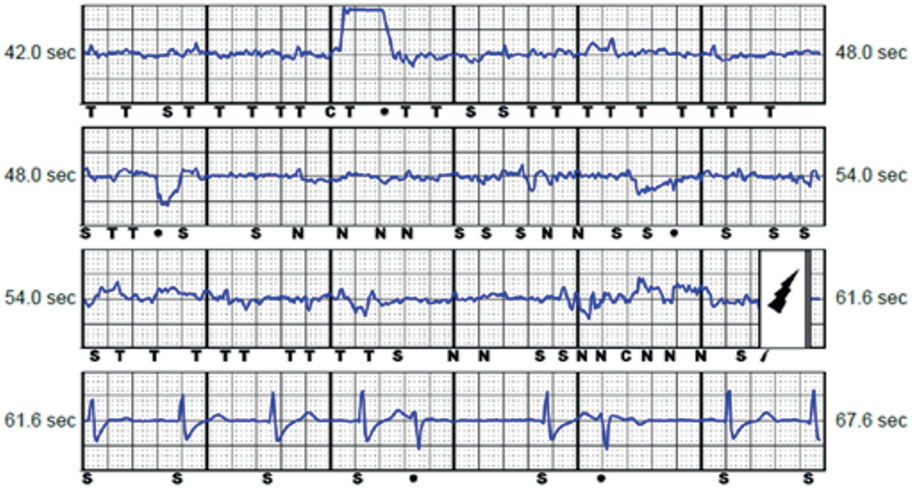

Fig. 4. Episode of shock application against a background of noncardiac activity.

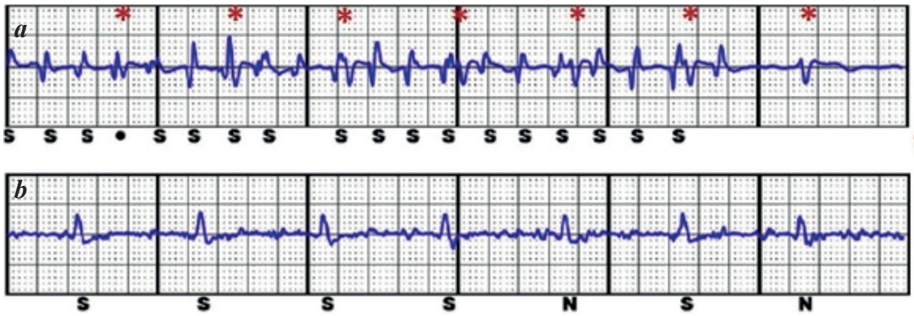

Fig. 5. Example of myopotential hypersensitivity during the TET-test: a - positive result (registration of myopotential hypersensitivity by the device is noted), b - negative result, * - QRS. Adapted from [15].

DISCUSSION

Subcutaneous ICD systems are devoid of some of the disadvantages inherent in transvenous systems. In particular, the use of this system reduces the risk of infectious complications. Also, the absence of intracardiac elements facilitates the procedure of system extraction, if necessary.

Worldwide studies prove that subcutaneous ICD implantation is associated with low complication rates. In our study, the total number of complications was 5 events (0.9%), whereas in the EFFORTLESS study, the complication rate was 12.2% (108 events out of 882 patients). The extremely low rate of device pocket hematoma development in the EFFORTLESS study (4 patients out of 108, or 0.4%) was consistent with the 3.5% rate observed in our study (2 patients out of 56) [7].

In our study, noise that necessitated correction of the electrode position occurred in 1 patient (1.7%), whereas the EFFORTLESS and IDE studies reported 8 such cases (0.8%) [7]. During the follow-up period in this study, infectious complications requiring system extraction were observed in 1 patient (1.7%). This rate is consistent with data from other sources, which report 17 such events (1.7%) [7, 8].

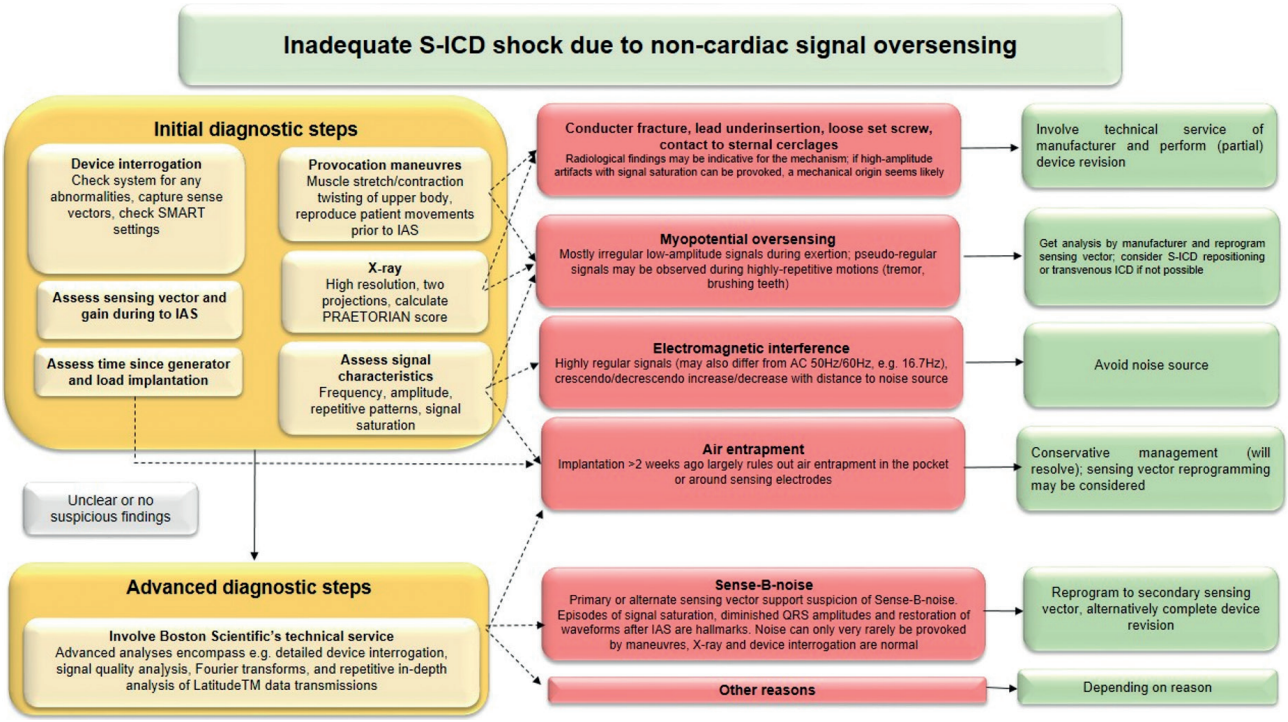

Fig. 6. Algorithm for the diagnosis and treatment of inadequate shocks of the subcutaneous cardioverter-defibrillator system. Adapted from [13].

In our study, inadequate shocks were recorded in 6 patients (10.7%). In comparison, the EFFORTLESS and IDE studies reported such complications in 6 patients (0.7%), while the PRAETORIAN study documented inadequate shocks in 41 patients (4.8%) [7, 8].

It is worth noting that in our observation adequate and inadequate shocks were equally distributed in groups of patients with ischemic and non-ischemic etiology of CHF (p=0.7). Thus, despite the different class of recommendations for ICD implantation, our data suggest that devices are necessary in patients of both etiologies of CHF. Regarding the profile of inadequate shocks, no correlation was found between the position of the subcutaneous ICD system, the technique of surgical intervention.

Unfortunately, the issue with noise on Pole B can result in the occurrence of inadequate shocks. Currently, it is not possible to predict the development of this problem in patients with an implanted subcutaneous defibrillator until a shock is administered. There are sporadic literature data on the B pole noise problem. This situation occurs in an extremely small number of patients in about 3% of cases [13]. According to the manufacturer's data, such episodes are rare and account for inadequate shock therapy in 0.42% of cases involving subcutaneous cardioverter-defibrillator implantation [14]. When the system was explanted, no pathology was found in the system components, according to the manufacturer. Treatment options for this condition include changing the readout vector to a secondary vector or complete system explanation [12].

In our study, out of 56 patients, this problem occurred in only one patient (1.7%). The issue associated with B pole noise does not fall under the category of myopotential hypersensitivity and represents a distinct problem. Currently, the solutions are limited to either changing the readout vector to a secondary one or de-implanting the system [8, 11].

Various exercise tests exist to detect myopotential hypersensitivity of the device. One of them is the tube exercise test (TET). Fig. 5 shows the report obtained by interrogating the subcutaneous ICD during TET. Noncardiac noise are seen under the letter "a", QRS complexes of the patient's own rhythm are marked with * [15].

In cases of myopotential hypersensitivity, the device records electrical activity from the muscles, which may be misinterpreted as ventricular tachycardia, leading to inappropriate shock applications. In the case of the noise at pole B, the noncardiac noises are not related to the work of the chest and shoulder girdle muscles and are significantly different from myopotentials. Fig. 6 shows the algorithm of action for diagnosis and treatment of inadequate subcutaneous ICD shocks.

CONCLUSION

Subcutaneous cardioverter-defibrillator systems are effective for primary and secondary prevention of SCD. High efficacy of these devices is noted in patients with various etiologies of chronic heart failure. Subcutaneous cardioverter-defibrillator systems are safe. The implantation procedure and follow-up results suggest minimal complications, inadequate shocks. The topic of studying subcutaneous cardioverter-defibrillator systems is an interesting and promising topic that requires further study.

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