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MULTIPURPOSE APPROACH TO THE TREATMENT OF CHRONIC HEART FAILURE: IMPLANTATION OF SYSTEM SUBCUTANEOUS CARDIOVERTER-DEFIBRILLATOR AND CARDIAC CONTRACTILITY MODULATION DEVICE. A CASE REPORT

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A clinical case of patient with implanted system subcutaneous cardioverter-defibrillator and cardiac contractility modulation device is described. No violations were identified in the joint operation of the devices.

Key words: subcutaneous cardioverter-defibrillator system; primary prevention of sudden cardiac death; chronic heart failure; cardiac contractility modulation.

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Chronic heart failure (CHF) with reduced left ventricular ejection fraction (LVEF) is characterized by a steadily progressive course. Despite the diversity and efficacy of medical therapy, surgical intervention is often required for these patients. Individuals with CHF are at a high risk of sudden cardiac death (SCD). In the general population, the majority of CHF patients belong to functional class II, where SCD remains the leading cause of death, according to research data[1, 2]. Additionally, the risk of SCD is significantly higher among patients with coronary artery disease.

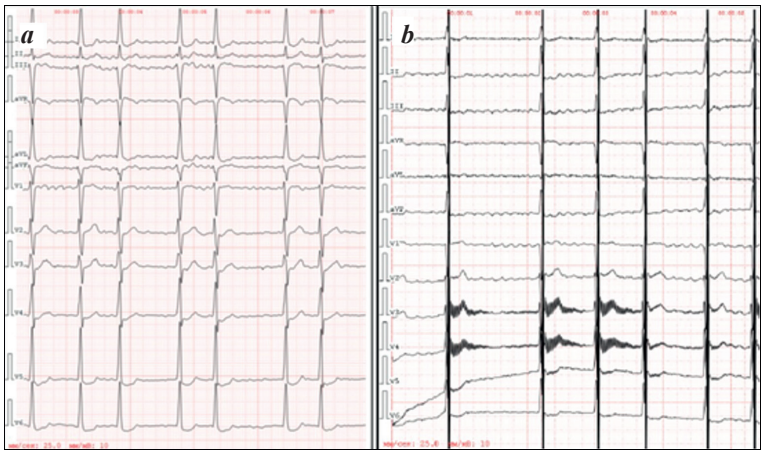

Fig. 1. Patient's ECG after implantation of the CCM device: without CCM therapy (a) and during CCM therapy delivery (b).

To prevent SCD, both primary and secondary, the implantation of an implantable cardioverter-defibrillator (ICD) is commonly employed [3]. Until recently, transvenous ICD systems were the sole option available. In these systems, the defibrillation lead is endocardial, delivered via the subclavian and superior vena cava into the right ventricle, where it is anchored at the apex. However, the transvenous placement of these system components can lead to various complications, such as thrombosis and occlusion of major vessels, fractures of endocardial leads, worsening of tricuspid valve insufficiency, and infectious complications. These issues often necessitate serious interventions, including complete extraction of the ICD system [4].

As an alternative to transvenous ICDs, subcutaneous ICD (S-ICD) systems can be offered to patients. This device has been available in the Russian Federation since 2016. Subcutaneous systems are designed for younger patients, those who do not require antibradycardia or antitachycardia pacing, or resynchronization therapy[5, 6]. The implantation of S-ICDs is associated with a lower incidence of infectious complications. Moreover, due to the absence of intracardiac components, there is no impairment of tricuspid valve function compared to trans-

venous ICD systems, even in the presence of other implanted devices[5–8].

A significant proportion of CHF patients have a normal QRS complex duration, precluding the use of resynchronization therapy for their treatment[9]. Currently, a technique known as cardiac contractility modulation (CCM) is available for patients with CHF, reduced LVEF, and narrow QRS complexes[10, 11]. This treatment involves the implantation of a device consisting of an implantable pulse generator and two ventricular leads anchored in the interventricular septum. The implantation technique is like that for standard pacemakers or transvenous ICDs. The device delivers high-amplitude stimulation during the absolute refractory period of ventricular depolarisation, which does not trigger subsequent contraction. Consequently, the CCM device does not affect heart rhythm. This stimulation increases phospholamban phosphorylation, thereby raising calcium levels in cardiomyocytes, ultimately enhancing myocardial contractility[11, 12].

Experience with the combined use of S-ICD systems and CCM devices in the global literature is limited, which prompted the consideration of this clinical case.

Clinical case description

A 51-year-old patient with CHF and reduced left LVEF, accompanied by atrial fibrillation (AF). The medical history included hypertension diagnosed in 2002 and type 2 diabetes mellitus diagnosed in 2005. In 2012, the patient presented with symptoms of exertional angina, and coronary angiography revealed a haemodynamically significant stenosis of up to 90% in the left anterior descending artery. Percutaneous transluminal coronary angioplasty with stenting was performed.

In 2015, symptoms of exertional angina recurred, leading to coronary angiography and angioplasty of the circumflex artery due to significant stenosis. In 2018, the patient experienced the first paroxysm of AF, with a noted reduction in LVEF to 29%. CHF was diagnosed, and therapy was initiated. In 2019, in-stent restenosis was detected in the left anterior descending artery, which required endovascular intervention. In September 2020, the patient was hospitalised with complaints of exertional dyspnoea.

At admission, the patient was on comprehensive CHF therapy, including valsartan/sacubitril, bisoprolol, furosemide, digoxin, eplerenone, rivaroxaban, atorvastatin, and empagliflozin, alongside medications for comorbidities. The admission ECG showed AF with a ventricular rate of 72–135 bpm and a QRS complex duration of 100 ms. Blood tests revealed an NT-proBNP level of 4217 pg/mL.

Transthoracic echocardiography (TTE) indicated significant chamber dilation, including a left atrial volume of 219 mL with an indexed volume of 91.3 mL/m². The left ventricular myocardium demonstrated reduced contractile function (LVEF 26%) without clearly defined zones of regional wall motion abnormalities. Given the history of extensive coronary artery disease and to exclude post-infarction myocardial fibrosis while evaluating myocardial perfusion, scintigraphy with 99mTc-MIBI at rest was performed. The study revealed small focal perfusion defects

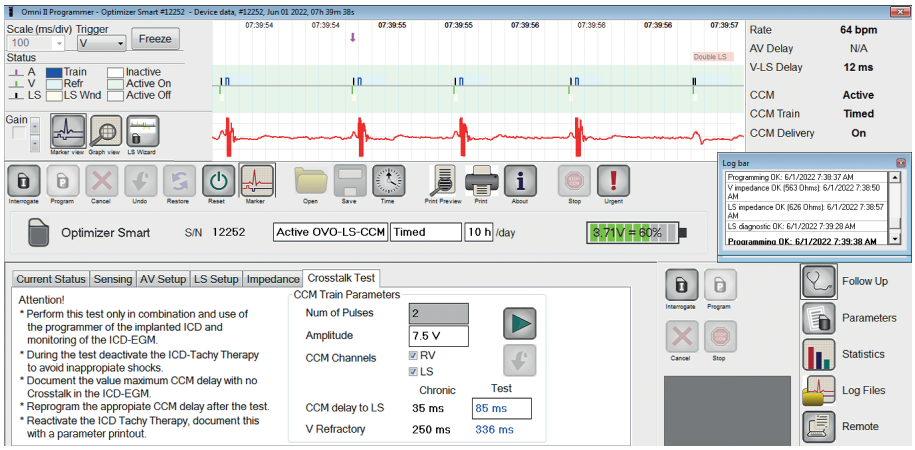

Fig. 2. Cross-talk testing: programmer data.

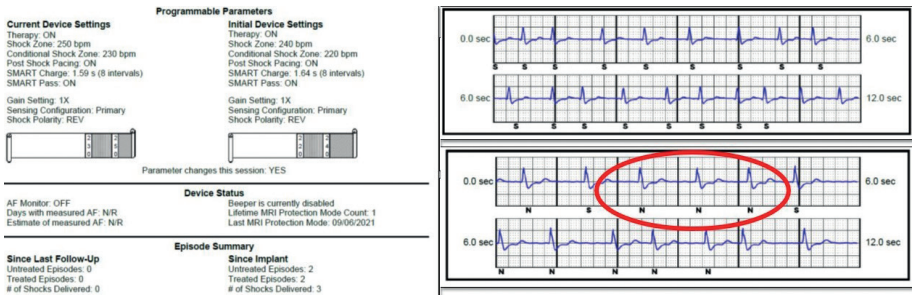

Fig. 3. Programmer data from the subcutaneous ICD system: absence of double counting of CCM therapy signals.

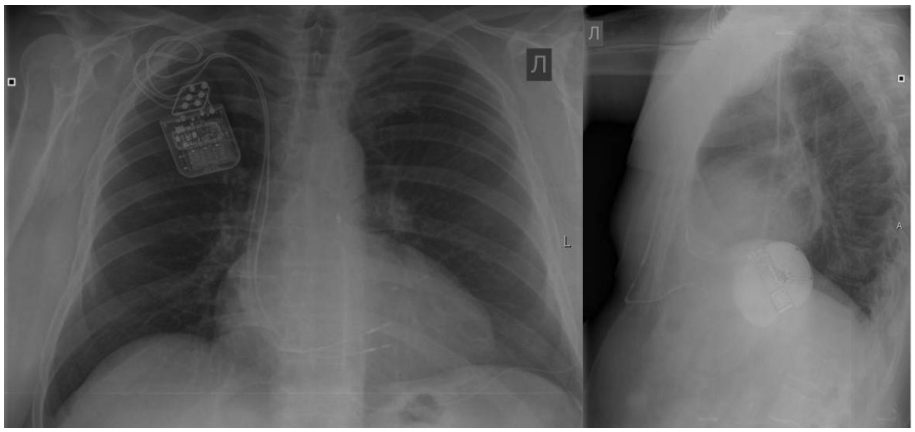

Fig. 4. Chest X-ray of the patient after implantation of the CCM device and subcutaneous ICD system.

in the apex, portions of the apical and mid-anterior wall segments, and basal segments of the inferior wall, totalling 10–12% of the left ventricular surface area, alongside significantly reduced left ventricular contractility.

Considering the diagnosis of coronary artery disease and CHF with reduced LVEF, despite optimal medical therapy for over three months, the patient was indicated for ICD implantation as primary prevention of SCD. Given the patient's relatively young age, lack of indication for antibradycardia or antitachycardia pacing, and the absence of a need for cardiac resynchronisation therapy, a subcutaneous ICD system was implanted.

In April 2021, the patient contracted COVID-19. By May 2021, they reported worsening dyspnoea and the development of oedema in the feet and lower legs. They were rehospitalised with decompensated CHF involving both systemic and pulmonary circulations. Aggressive diuretic therapy was administered, but the patient experienced severe hypotension (70/40 mmHg) and a reduced urine output. Dobutamine and noradrenaline therapy were initiated, leading to stabilisation of their condition. Echocardiography showed a further decrease in LVEF to 25%.

The patient was discharged with recommendations for close follow-up. After three months, LVEF remained reduced at 25%, and no shock therapy events were recorded during ICD checks. The lack of improvement indicated the need for CCM therapy. Given the satisfactory perfusion in all interventricular septal segments, as shown by myocardial scintigraphy, electrodes were implanted in the upper and middle thirds of the interventricular septum, an optimal choice for CCM electrode placement. Figure 1 illustrates the functionality of the CCM device recorded during a standard resting 12-lead ECG.

Intraoperative testing included cross-talk assessments to exclude interference between the CCM device and the ICD. Such interference could lead to misinterpretation of CCM impulses as ventricular tachycardia or fibrillation, potentially triggering inappropriate ICD shock therapy (Fig. 2). No cross-talk was observed during ICD testing (Fig. 3). Figure 4 shows a chest X-ray of the patient after the implantation of both devices.

Six months after the CCM device implantation, a follow-up echocardiogram showed an improvement in LVEF from 25% to 35%, with reductions in cardiac chamber sizes: left ventricular end-diastolic volume decreased by 43%, end-systolic volume by 53%, and left atrial volume by 8%. NT-proBNP levels decreased more than tenfold, to 325.3 pg/mL.

However, six months after treatment, the patient reported an ICD shock. Device interrogation revealed an episode of atrial fibrillation with rapid ventricular response (Figure 5), during which shock therapy was delivered. The ICD parameters were adjusted, and the beta-blocker dose was increased.

DISCUSSION

Currently, interventional treatment methods are widely employed in clinical practice for managing CHF, alongside pharmacotherapy. Device implantation plays a crucial role in improving patient prognosis. With increased life expectancy and advancements in CHF treatment, the number of patients requiring multiple implanted devices is rising. However, there is limited data on the interaction between different devices. The presence of multiple intracardiac leads may increase the risk of complications.

In the presented clinical case, the patient had indications for both CCM and ICD implantation. At present, no device combines CCM therapy and ICD functions into a single system. According to clinical guidelines, patients with CHF who are not candidates for cardiac resynchronisation therapy (CRT) require ICD implantation for the prevention of SCD. Additionally, CCM device implantation may be considered to improve patient outcomes, as recommended in CHF management guidelines. Subcutaneous ICD (S-ICD) implantation is preferred for patients with pre-existing CCM devices to minimise the risk of complications associated with more than two intracardiac leads. There are only a few documented cases of such combinations in the literature. These cases highlight the issue of potential interference between the two implanted devices and strategies to prevent cross-talk, wherein CCM signals could be misinterpreted by the ICD as ventricular arrhythmias, triggering inappropriate shockslo-

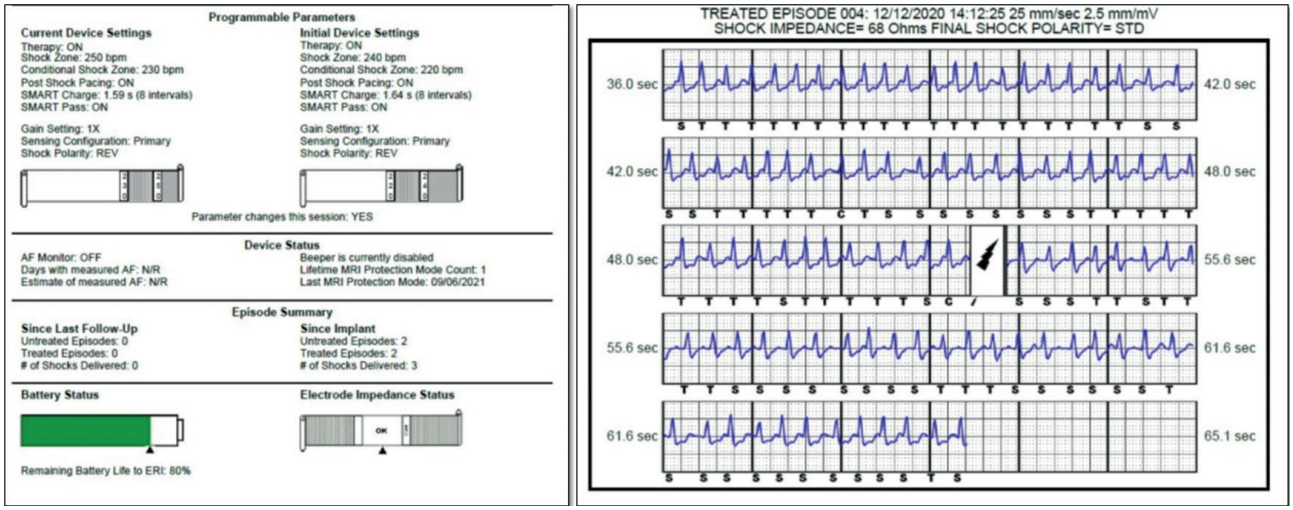

Fig. 5. Programmer data from the subcutaneous ICD system: segment showing shock delivery during tachysystolic AF.

cal study reported on 20 patients with CCM and S-ICD devices. All patients underwent intraoperative cross-talk testing to rule out interference between the implanted systems. This standardised procedure involved simultaneous activation of both devices to assess the QRS configuration and the CCM device's spikes as detected by the S-ICD. Various CCM stimulation delays and durations were temporarily programmed. The mean follow-up duration was 34.3 months. Functional class improved significantly from 2.9±0.4 to 2.1±0.7 ($p<0.0001$), and quality of life scores improved from 50.2±23.7 to 29.6±22.8 points on the Minnesota Living with Heart Failure Questionnaire ($p<0.0001$). LVEF increased from 24.4±8.1% to 30.9±9.6% ($p=0.002$). Over an average 22-month observation period with both devices active, three patients experienced a total of six episodes of sustained ventricular tachycardia, all successfully treated by the ICD's first shock. No damage or dysfunction of the CCM device was observed during defibrillation. One patient received an inappropriate ICD shock unrelated to CCM therapy, and another underwent explantation of both devices after receiving a mechanical circulatory support device .

As demonstrated rience and the limited international data available, interference between the devices does not occur. The S-ICD, like its transvenous counterpart, incorporates arrhythmia discrimination algorithms. Notably, the CCM device automatically halts therapy delivery when the ventricular rate exceeds 110 bpm, as per its programmed settings, reducing the likelihood of interference in cases of atrial fibrillation with rapid ventricular response.

Algorithms for discrimination of subcutaneous ICD arrhythmias

One of the auxiliary tools in the device's logic for accurately identifying arrhythmias is the SMART Pass function. This feature activates an additional high-frequency filter that reduces oversensing while maintaining an adequate sensing margin. Notably, SMART Pass has been shown to reduce the number of inappropriate therapies by over 40%. This function is activated when the measured ECG signal amplitude during configuration is at least 0.5 mV. The device continuously monitors signal amplitude and deactivates SMART Pass if sensing inadequacy is suspected [15].

The device prevents inappropriate therapy by recognizing noise and avoiding multiple counting of individual cardiac cycles. This is achieved through automatic signal analysis that includes detection, event certification, and decision-making phases. During the detection phase, the device uses a detection threshold to identify events. This threshold is continuously and automatically adjusted based on the amplitude of recently detected electrical events. The device also modifies parameters to enhance sensitivity for detecting fast rhythms. Events identified in the detection phase are examined in the certification phase, where they are classified as certified cardiac events or suspected artifacts (e.g., muscle activity or external signals) [15].

In the subcutaneous ICD system, two programmable tachycardia zones are available: the "Charge Zone" and the "Conditional Shock Zone." In the "Charge Zone," heart rate is the sole criterion used to determine the need for electrical shock therapy. In the "Conditional Shock Zone," additional parameters, such as heart rate and morphology, are analyzed to evaluate the appropriateness of delivering therapy. This zone differentiates treatable events from others, such as AF, sinus tachycardia, or supraventricular tachycardias.

A reference template of the normal sinus rhythm (NSR) is created during device initialization. This NSR template is used in the "Conditional Shock Zone" to identify treatable arrhythmias. In addition to morphology comparison with the NSR template, the device conducts other morphological analyses to detect polymorphic rhythms. The morphology and QRS complex width are used to identify monomorphic arrhythmias, such as ventricular tachycardia. If the "Conditional Shock Zone" is enabled, arrhythmias are considered treatable according to a decision-making algorithm (Figure 6) [15].

For patients with paroxysmal AF, the device also features an AF Monitor function, which alerts clinicians to AF episodes lasting at least six minutes within a day. These six minutes can consist of a single episode or several shorter ones. AF detection relies on groups of 192 peaks, with at least 80% of the peaks in a group needing to indicate AF for the group to be counted. Consequently, the AF Monitor function may underestimate total AF duration in cases of certain arrhythmia types or brief episodes[15].

All the algorithms aim to minimize inappropriate shocks, which is particularly crucial when used alongside a CCM device. To avoid cross-talk between CCM therapy signals and intrinsic QRS complexes, intraoperative cross-talk testing is necessary. Additionally, if CCM signals are detected by the subcutaneous ICD, adjustments can be made to stimulation amplitude, the number of CCM therapy impulses, or the daily duration of CCM stimulation to ensure adequate stimulation percentages.

In the presented case, an episode of AF with tachysystole was within the "Shock Zone," leading to an inappropriate device discharge. Conducting a telemetry assessment of the device and reprogramming the subcutaneous ICD prevented further inappropriate shocks. Post-defibril-

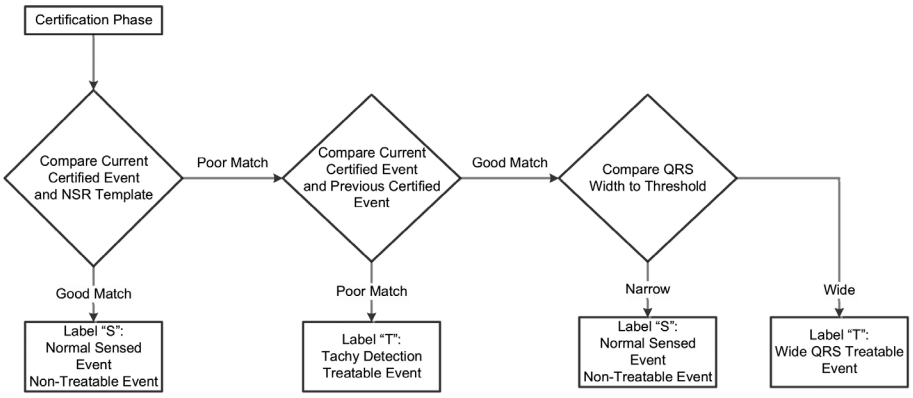

Fig. 6. Decision-making scheme for shock therapy delivery, illustrating the device's internal logic. Adapted from [15].

lation checks of the CCM device revealed no disruptions in its function. No interactions between the two devices that could impair their operation were observed. Thus, with proper monitoring and timely adjustments of modern CHF treatment devices, patients can receive the necessary therapy without adverse effects or diminished quality of life.

CONCLUSION

Modern treatment of chronic heart failure is inseparable from the use of interventional methods that extend patient survival and improve quality of life. The simultaneous use of multiple devices necessitates precise indication determination and careful monitoring to ensure their safe interaction. This clinical case illustrates the feasibility of combining implantable cardioverter-defibrillator and cardiac contractility modulation systems in a patient with CHF and atrial fibrillation. The global accumulation of experience with complex device implantation continues to grow. Advances in device management techniques will enable the application of non-pharmacological treatments for CHF in a broader range of patient categories in the future.

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