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Implantable cardioverter defibrillator: decision-making on turning off in patients with end-stage heart failure

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The use of implantable cardioverter defibrillators has become a common standard method of primary and secondary prevention of sudden cardiac death, prolonging the life of patients with cardiomyopathy. At the same time, with the disease and comorbidity progression, at the final stages of life, a difficult decision arises to turn off the device due to a shift in priorities from extending life to maintaining its quality. Heart failure patients eventually die due to the progression of the underlying disease, despite currently available advanced technologies. Whether certain life-sustaining treatment methods are still appropriate in the final stages of life is an important topic of discussion in this article. Palliation for patients with implantable cardioverter-defibrillators is a challenging issue for both patients and medical professionals. This article describes the different ways to turn off defibrillation devices based on patient status.

Key words: implantable cardioverter defibrillator, shock, terminal illness patient, death, heart failure.

Relationships and Activities: none.

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Currently, an implantable cardioverter defibrillator (ICD) is an effective therapy and prophylaxis in patients at high risk of sudden cardiac death (SCD) due to ventricular tachyarrhythmias (VTA). In 2013, over 85,000 ICDs were implanted in 46 European countries. Every year the number of implantations increases, which is associated with both an aging population and the shift from secondary prevention of SCD (implantation in patients with previous life-threatening arrhythmias or SCD) to primary prevention (implantation in patients only with an increased risk of arrhythmia or SCD) [1]. While ICD is effective in saving and therefore prolonging life, it creates problems for a patient such as fear, painful shocks, and helplessness due to the unpredictability of arrhythmias and subsequent shocks [2]. Defibrillator shocks can cause serious physical and psychological distress, and ICD benefits may do not outweigh these concerns, requiring consideration of turning off. Most often, this question arises in patients with end-stage heart failure (HF), cancer and other irreversible diseases. At the same time, not every European country has national legislation, directives, recommendations or consensus related to this issue.

The majority of patients with SCD more often (64%) are class II HF patients with moderate symptoms and need protection. The most symptomatic patients with class IV HF are much more likely to die from heart failure (56%), rather than suddenly from VTA (33%) [3]. That is why the current recommendations apply to patients whose life expectancy is >1 year with good functional status. The use of an ICD is not recommended for patients with class IV HF, refractory to therapy, without indications for cardiac resynchronization therapy (CRT), left ventricular assist device, or heart transplantation. Thus, severe HF is a contraindication to primary ICD implantation [4].

What about patients with progressive HF with previously implanted defibrillation devices? The study by Cleland J, et al. (2019) with a two-year follow-up of patients with ICD demonstrated an increase in mortality from congestive HF and sudden arrhythmia with an increase in class and in the end-stage phase. In the same phase, a significant decrease in the number of patients saved from sudden arrhythmic deaths was noted [5].

Patients with ICD can develop incurable disease due to progression of underlying heart disease or other chronic conditions. Terminally ill patients are more likely to develop conditions such as hypoxia, sepsis, decompensated HF, and electrolyte abnormalities, which predispose to tachyarrhythmias and, consequently, an increase in shock therapy frequency. Shocks are physically painful and contribute to psychological tension without prolonging life with good quality. Therefore, consideration of ICD deactivation is advisable when the patient's condition worsens and death is close [6].

Subanalysis of telemetry data from cardiac implanted electronic devices of deceased patients included in the MADIT-II trial found that 15 out of 55 (27%) patients received appropriate shock therapy at the last life phase and 1 patient (2%) received unwanted shocks; in 39 out of 55 patients (71%), ventricular tachycardia (VT) and shock therapy were not recorded [7]. According to a survey of 50 hospice workers in Oregon (USA), 64% of patients with ICD received unwanted shock therapy during the last phase of their life or even after death [8].

In the Almazov National Medical Research Center, patients with ICD and CRT devices for the SCD prevention are being observed. Since 2003, 2,248 implantations (primary, 1851) of such devices have been performed in patients from all regions of Russia. We analyzed the telemetry data of devices removed during autopsy of 18 patients who died in the clinic. At the time of hospitalization, the mean age of patients was 72,4±5,3 years, mainly men (15/18) with class III and IV HF. The left ventricular ejection fraction was 24,5±6,2%. Most of the deceased patients (13/18) had ischemic cardiomyopathy and the rest had dilated cardiomyopathy. Six patients had a history of VT; ICD implantation was performed for secondary prevention of SCD. The causes of death were mainly the progression of heart failure (n=12), severe pulmonary embolism (n=2), acute myocardial infarction (n=3), cancer (n=1). In only two patients, death was accompanied by recurrent VT with multiple ICD interventions in the form of antitachycardia pacing (ATP) and shocks (electrical storm) with progressive multiple organ failure (Figure 1). Five patients had prolonged paroxysmal or permanent atrial fibrillation. One of them had severe tachycardia with unwanted electrotherapy.

In addition, we analyzed the telemetry data of the ICD with remote monitoring of 20 deceased patients who were near the transmitter at the time of death. The system allows a detailed analysis of electrograms in episodes of VTA or atrial arrhythmias with a rapid ventricular contraction rate (Figure 2). During a telephone conversation with the relatives of the deceased, the circumstances, the cause of death and the presence of shocks immediately before death were clarified.

The overwhelming majority of patients (17/20) died without electrotherapy. Three patients had multiple shocks that aggravated the death. In most of the deceased patients, persistent cardiac arrhythmias were not recorded at the time of death. The cause of death, according to relatives, was progressive HF

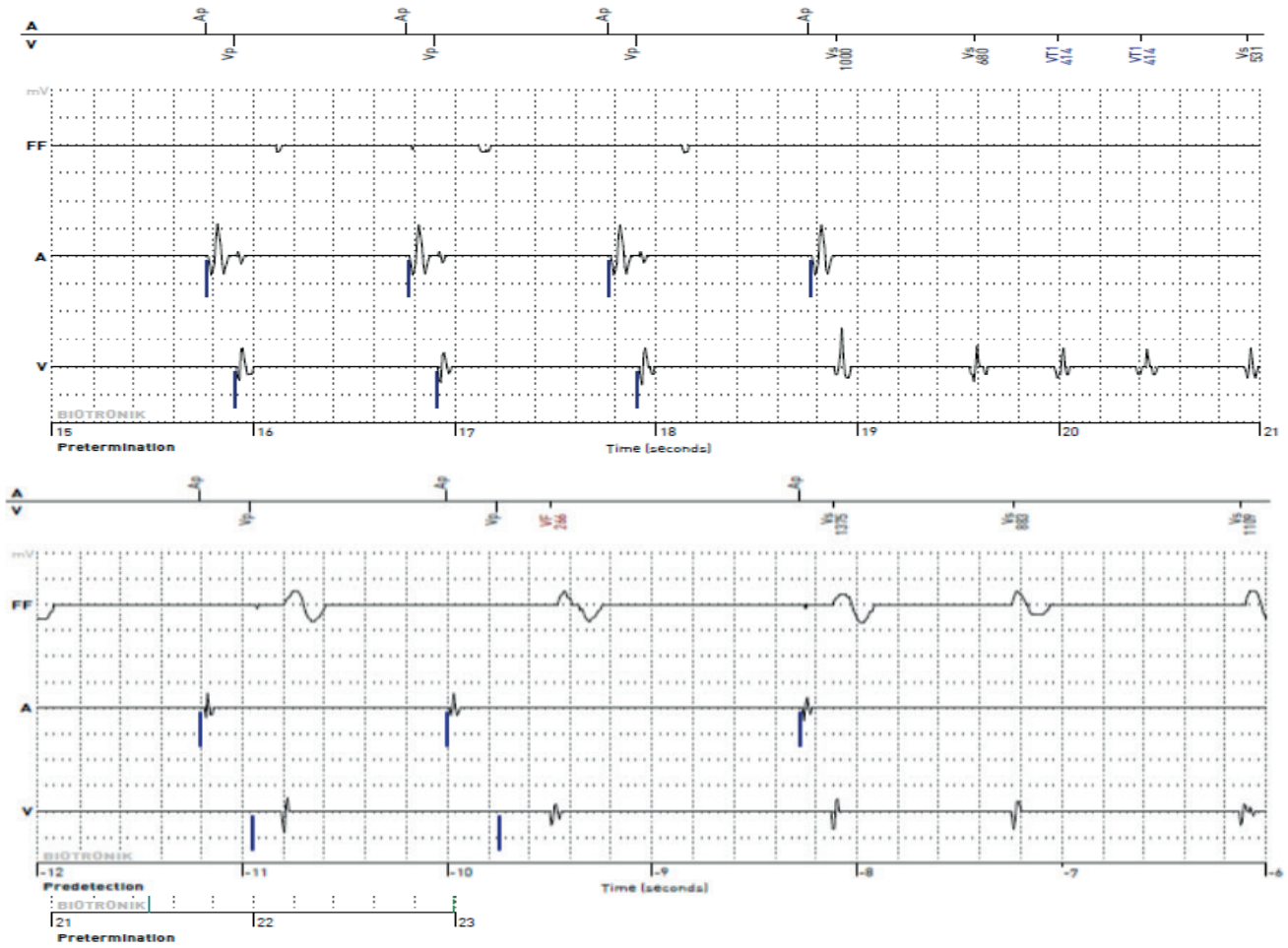

Figure 1. Recurrent VT with multiple ICD interventions in the form of antitachycardia pacing (ATP) and shocks (electrical storm).

(n=6), thromboembolism (n=3), stroke (n=4), cancer (n=3), acute myocardial infarction (n=3), and infection (n=1).

The presented analysis confirms the fact that, with the progression of the underlying disease, defibrillation is not always life-saving and sometimes it can even aggravate the critical condition. However, the small amount of available data does not allow for firm conclusion. More information could be obtained with the return of removed devices with a detailed analysis of the records. This will help developing criteria for risk stratification of critical events.

HF affects 2,4% of the adult population and >11% of patients over 80 years of age. The current treatments slow down but do not stop the disease progression. As a result, the prevalence of symptomatic HF increased, including prolongation of refractory end-stage heart failure. This definition describes a group of patients for whom symptoms, despite the recommended treatment, significantly limit daily life, and for whom long-term remission is unlikely [9]. The increasing prevalence and high burden of symptoms in patients with end-stage HF indicate a systematic and thoughtful approach to decision-making.

ICDs is fundamentally different from many life-saving therapies in patients with HF with reduced ejection fraction. Medication and CRT improve cardiac function, thereby reducing mortality and hospitalization rate and improving quality of life [10]. In contrast, ICDs improve survival by interrupting potentially fatal arrhythmias, but do not affect cardiac function or symptoms. In addition, cardioverter-defibrillators can create additional burdens for patients, especially due to unmotivated or unnecessary shocks and the prevention of quick death. Since the ICD use is a trade-off between a reduced risk of SCD and an increased risk of hospitalization, a possible decrease in the quality of life and long-term death from progressive contractility decrease, it is especially important to carefully discuss the absolute risks for a patient with and without an ICD.

There is a medical aspect, which may seem trivial, but is that all patients with/without an ICD, will die sooner or later. The annual mortality rate for patients

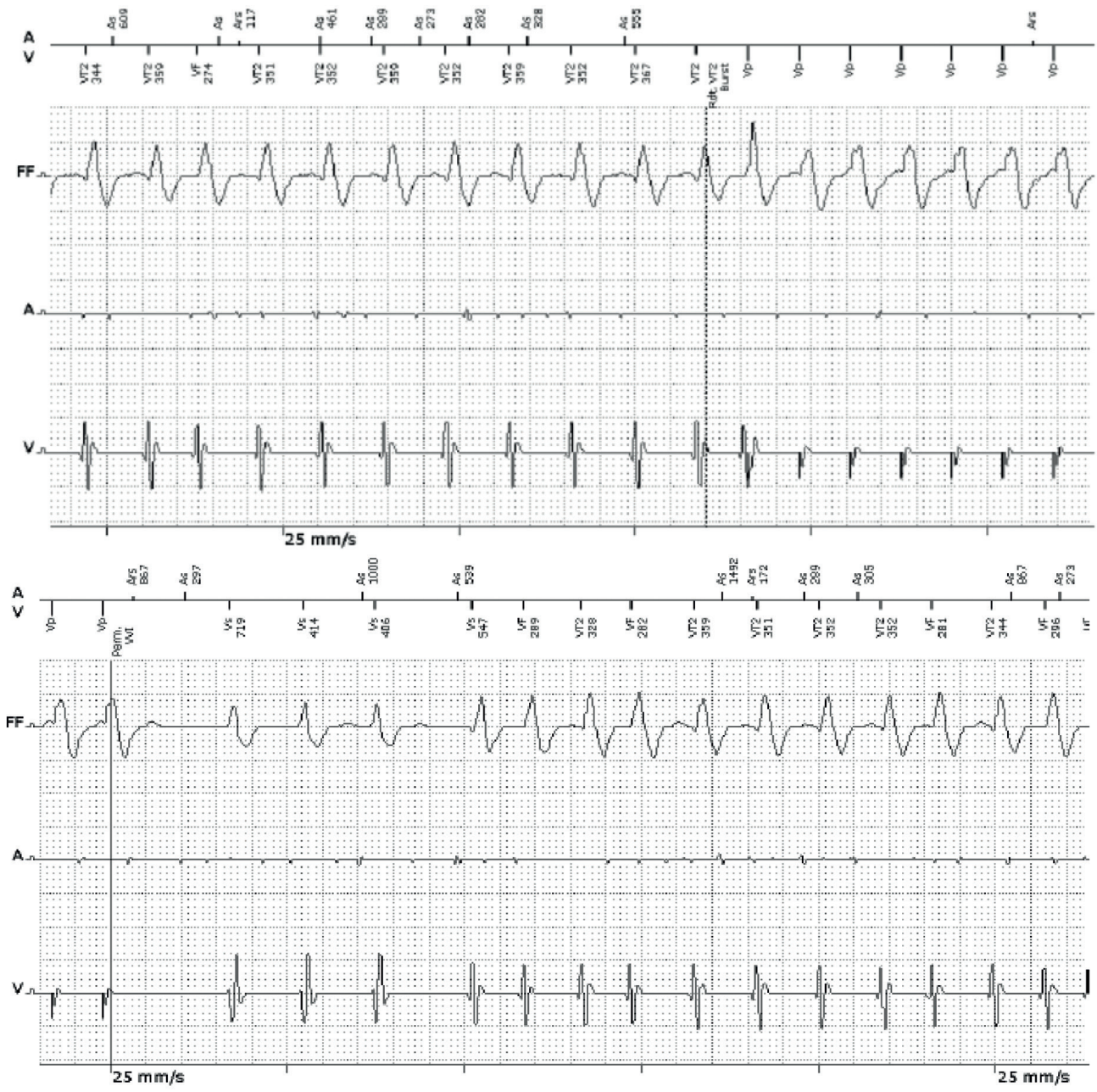

Figure 2. Episodes of VTA or atrial arrhythmias with a rapid ventricular contraction rate.

with ICD varies depending on the underlying disease (11,3% to 16,8%), and most of these patients die from the progressive HF [11].

Passive discontinuation of treatment: turning off the ICD

The option to deactivate the ICD should be discussed prior to implantation and again if significant changes in clinical status appear [6]. Currently, this is done very rarely. In a nationwide survey of 734 physicians, including 292 cardiologists, published by Goldstein N, et al (2010), only 60% of participants discussed ICD deactivation with patients and/or their families. The nationwide American survey of 900 hospice staff found that <10% of hospices have a clear policy on defibrillator deactivation, and >58% of hospices have had at least one patient who has suffered shock in the past year [12]. For a device near its end-of-battery life, the generator should not be changed without careful review of whether or not active defibrillation is consistent with overall goals of care and anticipated duration of good-quality survival [13].

Various ways to turn off ICD may be discussed. Thus, shock function and ATP can be completely

deactivated by reprogramming. Non-replacement of an ICD near its end-of-battery life should be considered (surgical removal is not recommended as it is painful and has potential unwanted complications).

Types of ICD deactivation

• Complete deactivation of all functions (detection and electrotherapy of tachycardia);

• Programming the device for monitoring only;

In patients with end-stage incurable HF, turning off all antitachycardia therapy should be considered, since any rapid VTA can result in sudden death without long-term suffering;

• Deactivate shock therapy only with maintaining ATP.

In stable patients and those with slow VT (100-160 bpm), tachycardia can lead not to death, but to an aggravation of the condition. In these cases, deactivation of shock therapy with maintaining ATP may be preferable, but it should be borne in mind that the rate of VT acceleration with ATP is 2 to 4%.

Deactivation of implantable electronic devices for pacing

Pacemakers prevent symptomatic bradycardia and asystole, which gives a patient a better quality of life and prevents worsening HF, and therefore is a means of achieving palliative care goals. In patients with CRT devices, severe HF usually accompanies an incurable illness. In this situation, CRT is mainly used as a symptomatic treatment and, therefore, should not be deactivate as there is a risk of a significant reduction in quality of life.

Ethical issues

Empirical ethical research shows that the judgments of patients and physicians do not always correspond to professional ethics. Patients tend to overestimate the potential of the ICD in preventing death, so they often view turning off the ICD as an act of suicide. Most patients are hesitant to accept ICD deactivation, even if death from another cause is not far off [14]. For a terminally ill patient who can make decisions, it is imperative that a physician discusses ICD deactivation in a timely manner. This will enable a patient to understand that failure to deactivate defibrillator can lead to excruciating death. Since deactivation may not have been discussed at the time of implantation, it is important that the issue is raised sensitively and at the appropriate time [15].

The parameters for device activation should be included in the informed consent prior to implantation, which should include the following points:

1. Before ICD/CRT-D implantation, the potential for impairing a patient's health to such an extent that deactivation should be discussed.

2. If a patient gives a do-not-resuscitate order or receives palliative care, a turning off should be discussed at the same time. Deactivation of shock therapy should at least be suggested.

3. The physician observing patients with implanted devices should be informed of significant health changes and worsening comorbidity at each patient visit.

What issues need to be discussed regarding ICD deactivation?

• ICD deactivation will not result in death;

• Demand pacing will be provided, but not therapy for VTA;

• Turning off ICD will not be painful and the ICD inability to function will not cause pain;

• Deactivation process will be similar to the examination in the clinic, where a patient is monitored after implantation.

Discuss ICD deactivation with a patient and/or immediate family member if:

— Resuscitation opportunities have been exhausted or a do-not-resuscitate order has been made;

— A patient's condition is deteriorating and turning off may be advisable;

— Moving to a hospice or home for the rest of life is planned.

At this stage, it may be appropriate to consider the palliative care, which involves a multidisciplinary team approach; caring for a patient, his family or closest friends; relief of pain and other symptoms; attention to emotional, psychological, and physical needs; improving the quality of life as high as possible.

Current пguidelines for the treatment of patients with HF and risk of SCD have focused on the indications for device implantation, but attention should also be paid to the technical, scientific and ethical aspects of turning off devices. It seems appropriate to develop a medical, bioethical, and legal consensus for deactivating ICD, keeping in mind that this applies to two different categories of patients: the cognitively intact and those deprived of legal capacity. Shared decision-making for advanced HF has become more difficult as the duration of illness and treatment options have increased. Carefully informed decisions should be chosen from medical options and should be consistent with the values, aims, and preferences of an informed patient.

Relationships and Activities: none.

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