

Advantages, limitations and new perspectives on the implantation of subcutaneous cardioverter-defibrillator

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Abstract

Subcutaneous cardioverter-defibrillator (S-ICD) gained considerable place in sudden cardiac death (SCD) prevention. The main advantage of this device is the possibility of implanting it outside of blood vessel. The lack of permanent pacing and antitachycardia pacing (ATP) are its key limitations. New research is focused on creating an extravessel device that could combine the role of cardioverter and pacemaker. The main difficulty is the mutual interference of sensing.

Keywords: subcutaneous cardioverter-defibrillator (S-ICD) • ventricular pacing • sudden cardiac death

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Introduction

Sudden cardiac death (SCD) in the course of ventricular arrhythmias is the cause of 20% of deaths in Western countries [1]. In 2012 the United States Food and Drug Administration approved a subcutaneous cardioverter-defibrilla-

tor (S-ICD) developed by Boston Scientific as an alternative to transvenous defibrillators (TV-ICD) [2]. In Poland, the first S-ICD devices were implanted in 2014 at the Sterling Memorial Hospital in Łódź as well as at the Department of Cardiology and Electrotherapy of the Medical University of Gdańsk [3]. The aim of this study is to highlight the indications and

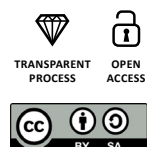
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contra-indications to the implantation of the S-ICD, the advantages and limitations of S-ICD and the perspectives for its development to include ventricular pacing and antitachycardia pacing (ATP).

Materials and methods

This is a narrative type of review, no statistical calculations were performed. Independent English and Polish-language literature search has been done by the first author (BON) using the ESC Guidelines, AHA/ACC/HRS Guidelines, the PubMed database and a review article published in "Kardiologia po Dyplomie." We used a query containing the keywords "S-ICD" or "Subcutaneous Cardioverter Defibrillator" and "EV-ICD" and other keywords relevant to the topics of our interest e.g. ventricular pacing, antitachycardia pacing (ATP), new perspectives. Authors focused on articles published in the last 7 years.

Results

The search retrieved 56 records. After review of the abstracts and full texts, 15 articles were included in the analysis.

Discussion

Advantages

The first official recommendations about S-ICD implantations were published in the European Society of Cardiology (ESC) guidelines in 2014 [4]. Therein it was recommended to implant S-ICD in patients with hypertrophic cardiomyopathy who qualify for cardioverter-defibrillator device and at the same time do not have indications for permanent cardiac pacing (class IIb recommendation). In 2015 a class IIa recommendation suggested S-ICD implantation as an alternative to TV-ICD for all patients who do not require permanent cardiac pacing, including cardiac resynchronization therapy (CRT) and antitachycardia pacing (ATP) [5]. An S-ICD device does not have transvenous leads, therefore it is a perfect option for patients who have a difficult vascular access (particularly those with vascular anomalies), venous thrombosis, history of electrotherapy complications (e.g. lead damage, lead extraction) or high risk of endocarditis (e.g. patients treated with immunosuppressants or dialysis). According to the 2017 AHA/ACC/HRS guidelines, S-ICD implantation is a class I recommendation [6].

In addition, S-ICD is also recommended for young patients with heart defects and ventricular arrhythmias. Due to their long expected lifespan, young patients have a high

risk of transvenous lead damage or cardiac device-related infective endocarditis (class IIb recommendation) [5]. S-ICD is also a very good solution for patients suffering from cardiac device-related endocarditis (CDE)

S-ICD is implanted at the operating room, usually under general anesthesia though local anesthesia is also an option. The first incision is made between the left mid- and posterior axillary lines in the 5th or 6th intercostal space. The pocket for the S-ICD device is usually made under the latissimus dorsi muscle, however subcutaneous or under the serratus muscle are also acceptable. The device can weigh 130 g and has the volume of 60 cm³. The defibrillating lead consists of 2 sensing rings and 8 cm-long shock coil. The next step consists of inserting the lead subcutaneously from the device pocket in the direction of the xiphoid process (2nd incision). The distal part of the lead is inserted along the left sternal margin and fixed near the jugular notch (3rd incision). Currently the two-incision technique is preferred, which is safer for patients as it omits the 3rd incision (superior parasternal incision). The three-incision technique may be performed in selected patients with high BMI. During this procedure the patient is exposed to little ionizing radiation, as fluoroscopy is needed only during the initial positioning of the lead and device can. Once the S-ICD is implanted and the patient does not have contraindications, a defibrillation test is performed using a single 65 J impulse. In case of ineffective defibrillation, a second test is automatically attempted using 80 J. In case of second failed defibrillation, it is necessary to revise the device and lead placement. Incorrect placement of the S-ICD device or lead relative to the heart are the most common causes of ineffective defibrillation. This is often due to implanting the S-ICD device too superficially [7].

The S-ICD device recognizes arrhythmia via analyzing the electric potentials recorded from the surface of the chest using one of 3 vectors: primary (between the proximal pole of the lead along the sternal margin and the body of the device), secondary (between the distal pole of the lead and the device can and alternate (between the two rings of the lead). Quality of the electric signals obtained from the heart is essential for correct function of the S-ICD device. Therefore, while qualifying the patient for S-ICD implantation it is necessary to screen the patient for correct arrhythmia recognition. This is done using the manufacturer's programming system to record and analyze the ECG obtained from precordial leads placed similarly to S-ICD leads and device. At least one of the 3 analyzed vectors should be accepted for use in future S-ICD implantation. The vector screening should be performed in several body positions – at minimum while supine and standing upright. During this screening the following parameters are automatically analyzed: voltage, R and T waves (their shape and relation to one another). In case of recognizing a ventricular arrhythmia, the implanted S-ICD device discharges 80 J of energy (up to 5 discharges during a single arrhythmia event) [8].

In January 2022 an analysis of a 5-years long follow-up of 984 patients with S-ICD from the EFFORTLESS register was published. Effectiveness of the high energy defibrillation was confirmed in this heterogenous study group. Relatively few patients required S-ICD removal and replacement with TV-ICD for the purpose of pacing. Episodes of arrhythmias that were either self-limiting or terminated by defibrillation were a predictor of future use of high-energy therapy. Early complications in the 1st year of follow-up were not predictive of late complications. In a 5-year registry the surgical site infections were rarely reported (3.2%), along with erosions (2.3%) and haematomas (0.9%). Lead damage were not observed in this registry [9]. Occasional damage were observed in the third-generation SQ leads. The implantation of a generator pocket between the serratus anterior and the latissimus dorsi muscles improves patients' comfort and reduce site complications. Intermuscular generator pocket and two-incision technique is now the standard of S-ICD implantation.

Limitations

Besides many advantages, an implanted S-ICD device also has limitations due to the lack of antitachyarrhythmic pacing. Another limitation is lack of permanent pacing function. Instead it can only provide pacing for up to 30 seconds, to treat bradyarrhythmia that began directly after defibrillation [5]. Furthermore, the S-ICD's arrhythmia detection based on R and T wave analysis might not be accurate enough for patients with broad QRS complexes in the course of ventricular pacing. Inadequate interventions are another significant problem in the treatment using S-ICD. Initially, 7-13% of interventions were inadequate. Thanks to new arrhythmia recognition algorithms it was possible to reduce inadequate interventions down to 4% during 18 month follow-up since implantation [10]. The most frequent surgical complication of S-ICD implantation are: dislocations of the lead or device can, pressure ulcers in the device pocket and problems with post-operative wound healing. As the operators gained more experience the number of these complications decreased to 3% [5, 11].

New perspectives

Research is underway with the aim of design an optimal implantable subcutaneous device that would combine the functions of a cardioverter-defibrillator and a pacemaker. In some cases, a decision was made to implant an S-ICD device in a patient who already has an implanted pacemaker or vice-versa. In several patients both devices functioned simultaneously without any interference in sensing. Furthermore, no inappropriate defibrillations were noted and none of the devices had to be removed during the 17-month

follow-up. However, studies with larger patient groups are needed in order to determine the indications for combining a pacemaker system with an S-ICD device [12].

The previously-mentioned limitation of S-ICD, lack of permanent pacing and ATP might be overcome by an extra-vascular (EV) ICD by Medtronic that is currently in clinical trials. In this EV-ICD system the defibrillating lead is implanted subternally which allows ATP and bradyarrhythmia pacing in addition to the detection and treatment of ventricular fibrillation [13]. In 2019 the first pilot EV-ICD implantations in 20 patients took place at 4 centers in Australia and New Zealand without any significant peri-operative complications. All patients underwent the defibrillation test and in 18 patients (90%) the arrhythmia was correctly sensed and sinus rhythm was restored. The average defibrillation threshold was 15 J, whereas pacing energy of < 10V was effective in > 95% of patients. One patient had ventricular tachycardia which was correctly sensed and terminated by ATP. Based on these results, the effectiveness of EV-ICD was comparable to the existing ICD systems [14].

After the promising results of the pilot study, Medtronic began a multi-center, prospective, non-randomized clinical trial that included 400 patients from 60 centers in Asia, Australia, Europe, Middle East, North America and New Zealand. Effectiveness of the defibrillation test is the hard endpoint. Lack of significant general and peri-operative complications suggests this device's safety. The results of this trial are currently analyzed and are likely to be published during this year's EHRA (European Heart Rythm Association) Congress [15].

Conclusions

S-ICD is an effective and safe method of preventing SCD. The main advantages of this device is its implantation outside of blood vessel, high effectiveness and relatively low incidence of early and late post-operative complications. Due to its limitations, S-ICD is currently dedicated for patients without indications for ventricular pacing and ATP. The possibility of combining S-ICD with a pacemaker is currently explored. The main limitations of this approach are the mutual interferences of sensing.

Funding

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Conflicts of interests

None.

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