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A survey study of the use of a subcutaneous implantable cardioverter-defibrillator in various clinical scenarios by expert electrophysiologists in Poland

Maciej Kempa, Barbara Opielowska-Nowak, Szymon Budrejko, Grzegorz Raczak

Department of Cardiology and Electrotherapy, Medical University of Gdansk, Poland

Abstract

Background: *A subcutaneous implantable cardioverter-defibrillator (S-ICD) has become a recognized alternative to a traditional transvenous implantable cardioverter-defibrillator (T-ICD). Despite the growing evidence of non-inferiority of S-ICD, there are no clear clinical guidelines for selection of either of the two available systems. The aim of the study was to analyze the decisions made in predefined typical clinical scenarios by Polish cardiologists experienced in the use of both S-ICDs and T-ICDs.*

Methods: *A group of 30 experts of cardiac electrotherapy experienced in the use of S-ICDs was recruited and invited to participate in a web-based anonymous survey. The survey questions regarded the proposed therapy in various but typical clinical scenarios.*

Results: *From the invited 30 experts representing 18 clinical centers, 25 completed the survey. 72% of them declared that the number of S-ICDs implanted at their center during the preceding 12 months exceeded 10, and 40% — that it was over 20. Rates of responders preferring S-ICD or T-ICD in various clinical scenarios are reported and discussed in detail.*

Conclusions: *Significant divergence of opinion exists among Polish experts regarding the use of a subcutaneous cardioverter-defibrillator. It is especially pronounced on the issue of the use of the system in middle-age patients, in case of complications of the hitherto ICD therapy, or the need of upgrading the existing cardiac implantable electronic device.* (Cardiol J 2023; 30, 2: 214–220)

Key words: implantable cardioverter-defibrillator, subcutaneous implantable cardioverter-defibrillator, sudden cardiac death, ventricular fibrillation, ventricular tachycardia

Introduction

A subcutaneous implantable cardioverter-defibrillator (S-ICD) is an efficient tool used to protect patients at risk of malignant ventricular tachyarrhythmias against sudden cardiac death [1]. According to the current guidelines of the European Society of Cardiology, it may be used alternatively to a transvenous cardioverter-defibrillator (T-ICD), unless the patient qualified for the device has indications for permanent cardiac pacing or a history of sustained ventricular tachycardia that can be treated with antiarrhythmic pacing [2]. According to the authors of the guidelines, the level of evidence behind that indication is low (level C). Despite the growing evidence of non-inferiority of S-ICD compared to T-ICD in terms of complication rate and risk of inappropriate interventions, there are no clear clinical guidelines for selection of either of the two available implantable defibrillator systems [3, 4].

Address for correspondence: Szymon Budrejko, MD, PhD, Department of Cardiology and Electrotherapy, Medical University of Gdansk, ul. Smoluchowskiego 17, 80–214 Gdańsk, Poland, tel: +48 58 3493910, e-mail: budrejko@gumed.edu.pl

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S-ICDs have been implanted in Poland since 2014 [5, 6], but the number of implantations has increased significantly in only just the last 3 years [7]. Despite legal regulations, the decision to choose S-ICD or T-ICD is made by the implanting cardiologist on an individual basis for each patient [8]. That decision is based not only on the personal experience of the physician, but also on other factors, such as the local availability of the method, its cost and the reimbursement regulations set by the National Health Fund. Such a setting may lead to the diversity of clinical decisions made by different clinicians in similar or even identical clinical cases. Therefore, it was decided to undertake an analysis of the accuracy and consistency of clinical decisions made in similar clinical scenarios involving potential implantable cardioverter-defibrillator (ICD) recipients.

The aim of the study was to analyze the decisions made in predefined typical clinical scenarios by cardiologists experienced in the use of both subcutaneous and transvenous ICDs.

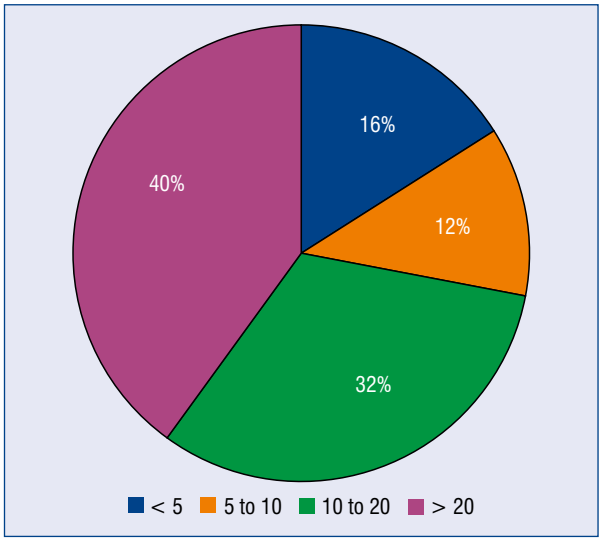

Figure 1. The number of subcutaneous implantable cardioverter-defibrillator devices implanted in centers of responders over the preceeding 12 months.

Methods

For the purpose of the study, a list of 30 Polish experts of cardiac electrotherapy experienced in the use of S-ICDs was established. That group was recruited among clinicians actively reporting data to the registry of S-ICD implantations held by the Heart Rhythm Section of the Polish Cardiac Society, and co-authoring publications based on the data from that registry.

They were invited by e-mail to participate in a web-based survey. The survey was completely anonymous to the extent that even the mere fact of completing the study or not by a given responder was confidential. The survey questions regarded the proposed therapy in various but typical clinical scenarios, as discussed in the following paragraphs (a complete list of questions and possible answers is reported as **Supplementary data**).

Data were collected and analyzed in a Microsoft Excel spreadsheet, and reported as rates and percentages.

Results and discussion

From the 30 experts invited, representing 18 clinical centers, 25 completed the survey. 72% of them declared that the number of S-ICDs implanted at their center during the preceding 12 months exceeded 10, and 40% — that it was over 20 (Fig. 1).

The majority of responders (92%) declared, that the choice of the device is not influenced by the history of sudden cardiac arrest (secondary prevention) as contrary to the primary prevention, unless the patient has a history of ventricular tachycardia potentially eligible for termination with antiarrhythmic pacing. That percentage is significantly higher (almost twice) than the value reported in another similar survey conducted in European countries several years ago [9]. At the same time, that observation confirms a previously recognized increasing tendency of Polish cardiologists to qualify patients for S-ICD devices in primary prevention [7]. Over 65% of S-ICD implantations in Poland are performed for primary prevention, and that data is in conformity with other reports concerning the European population [10]. That notion seems reasonable, as the history of sudden cardiac arrest is not considered to be a decisive factor for the choice of ICD type in the current guidelines. To quantify the potential future risk of the need for permanent cardiac pacing, other factors should be considered, such as the existing atrioventricular or intraventricular conduction disturbances, the stage of heart failure, and a history of prior cardiac surgery, as it was shown in the MADIT II and SCD-HeFT populations and in the study of de Bie et al. [11, 12]. In summary, the risk of conversion from the S-ICD to the T-ICD system due to the need for permanent cardiac pacing is low [13].

If an indication for pacing developed in an S-ICD patient, these responders would weigh their choice in relation to the mode of pacing. In case of

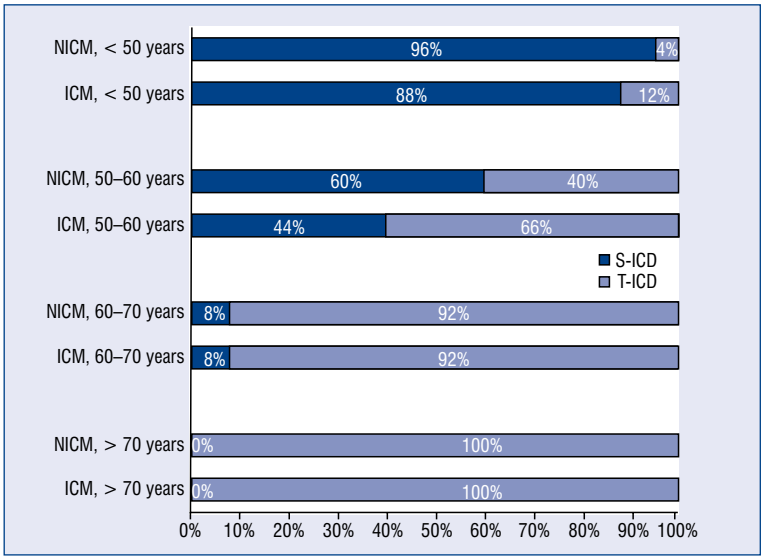

Figure 2. The choice between subcutaneous implantable cardioverter-defibrillator (S-ICD) and transvenous implantable cardioverter-defibrillator (T-ICD) in patients with non-ischemic cardiomyopathy (NICM) and ischemic cardiomyopathy (ICM) with no history of arrhythmia and no indications for permanent pacing for different age groups.

VVI pacing, as many as 56% of them would prefer to implant a single chamber ventricular pacemaker as a device concomitant to the S-ICD system rather than to extract the S-ICD and implant a transvenous system instead. The rate of responders preferring two coexisting cardiac implantable electronic devices (CIEDs) decreases with an increasing complexity of the pacing mode, and equals 44% and 32% for dual-chamber pacing and resynchronization therapy, respectively. Interestingly, in the opposite situation, that is if indications for prevention of sudden cardiac death occurred in a patient with a pacemaker already in place, a majority of responders would extract the pacemaker to replace it with a T-ICD system rather than implant an S-ICD in addition to the pacemaker. Such a solution was selected by 68% of responders for a VVI system and 72% for multi-lead pacing systems. Those results are surprising, taking into account the potential risk of transvenous lead extraction. Moreover, if an addition of an S-ICD system to a pre-existing pacemaker was planned, screening during paced rhythm would be possible prior to final decisions, and it might warrant appropriate sensing of the paced rhythm by the S-ICD device. On the other hand, if a pacemaker was added to the pre-existing S-ICD system, there would be a substantial risk of inappropriate sensing and inadequate interventions of the defibrillator due to the change in QRS morphology between paced and intrinsic rhythm. Such problems have been previously reported [14, 15].

It is noteworthy that the opinions of Polish experts diverge from the reported attitude of other researchers. French experts tended to choose the opposite options. The majority of them voted for S-ICD removal and replacement with a T-ICD in cases where permanent cardiac pacing was needed. But when a patient was already equipped with a pacemaker, most of them tended to add an S-ICD if needed rather than to extract the pacing system to replace it with a T-ICD [16]. Nonetheless, the use of S-ICD in patients with pacemakers and paced rhythm is possible and has been reported for transvenous, epicardial and leadless pacemakers [17–19].

The age of ICD recipients seems to be as important as the potential need for pacing when choosing between S-ICD and T-ICD. According to the present responders, the age of a patient was more important than the etiology of heart failure when choosing the device for primary prevention. The responses were similar for ischemic cardiomyopathy (ICM) and non-ischemic cardiomyopathy (NICM), detailed percentages are reported in Figure 2. The responders preferred S-ICD only slightly more frequently in case of NICM. Patients in the age range of between 50 and 60 years were most problematic. In that age group the experts were divided almost in half in terms of the choice of the type of ICD. But it is the young age of a patient that is crucial for S-ICD choice from the advent of that treatment method in Poland. It is consistent

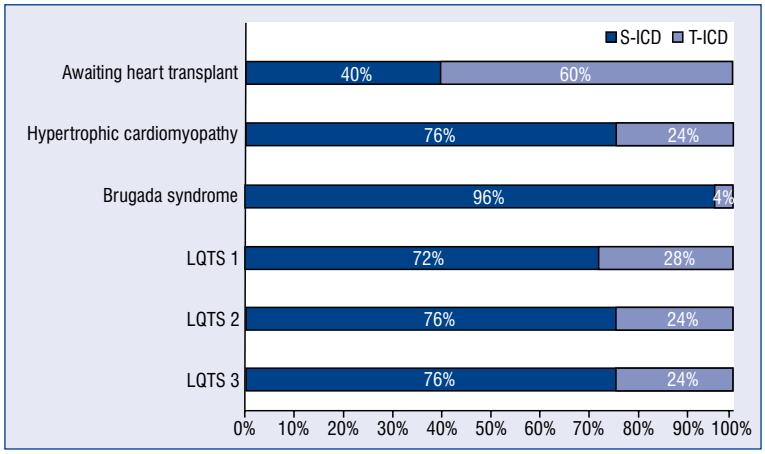

Figure 3. The choice between subcutaneous implantable cardioverter-defibrillator (S-ICD) and transvenous implantable cardioverter-defibrillator (T-ICD) in patients with indications for an implantable cardioverter-defibrillator, with no history of arrhythmia and no indications for permanent pacing in various clinical scenarios; LQTS — long-QT syndrome.

with the tendency observed in other European countries [9, 10, 20].

Inherited arrhythmia syndromes and hypertrophic cardiomyopathy are relatively frequent in the young population of potential ICD recipients. If such patients have indications for an ICD, most responders would choose S-ICD. In long QT syndromes (LQTS), depending on the type of LQTS, as many as 72–76% of responders would opt for an S-ICD. That rate reached 96% in case of Brugada syndrome and 76% for hypertrophic cardiomyopathy (Fig. 3). Although the agreement of responders to prefer S-ICD over T-ICD in those clinical entities was high, one should remember that subcutaneous systems have their limitations in those populations. The key issue is the risk of inappropriate sensing and interventions. Therefore, some researchers underline the importance of meticulous preimplant screening, and in some specific situations (for example in Brugada syndrome) — they advise performing an exercise test and pharmacological provocation tests [21, 22]. Careful screening allows avoiding future inappropriate interventions to a reasonable extent, and in the comparative analysis of S-ICDs and T-ICDs in that patient population, the efficacy of S-ICD was comparable to T-ICD with the benefit of a lower risk of lead failure [23]. One should mind though that in some channelopathies (e.g., LQTS 2) associated with bradycardia, the need for pacing may occur, especially in case of therapy with beta-blockers. The use of an S-ICD incapable of permanent cardiac pacing would not be advised in such a clinical setting [16].

A young population of potential ICD recipients has a relatively high representation of patients with congenital heart disease. Vascular anomalies and altered cardiac anatomy speak in favor of S-ICD in those patients. Importantly, the clinical studies underlying Food and Drug Administration approval of the S-ICD system, as well as subsequent updates of the relevant clinical guidelines, did not include patients below 18 years of age. The evidence behind the use of S-ICDs in children remains limited. The main issue associated with S-ICDs in that population is the relatively large volume of the device can, carrying the risk of surgical complications (such as pocket decubitus, but also lead erosion) [24, 25]. Implantation of the system may be limited by the small chest size of a patient, precluding the correct placement of the lead and device. Despite that fact, there are reports of S-ICD implantation in patients at the age of 4 to 5, with non-standard placement of the system components [26, 27]. The relatively fast heart rate in youngsters (both during sinus rhythm and supraventricular tachycardia) may lead to inappropriate interventions [25]. Despite those limitations, the available reports indicate that the rate of all the adverse effects is lower than 15% in the first-year post-implant, and the procedure becomes safer when the body mass index exceeds 20 kg/m^2 [25, 28, 29]. In patients with congenital heart disease and body mass lower than 30 kg only 56% of Polish experts would choose S-ICD. But over 30 kg of body mass the percentage of votes in favor of S-ICD increased to 72%. With the body mass over 40 kg and 50 kg, 84% and 92% respond-

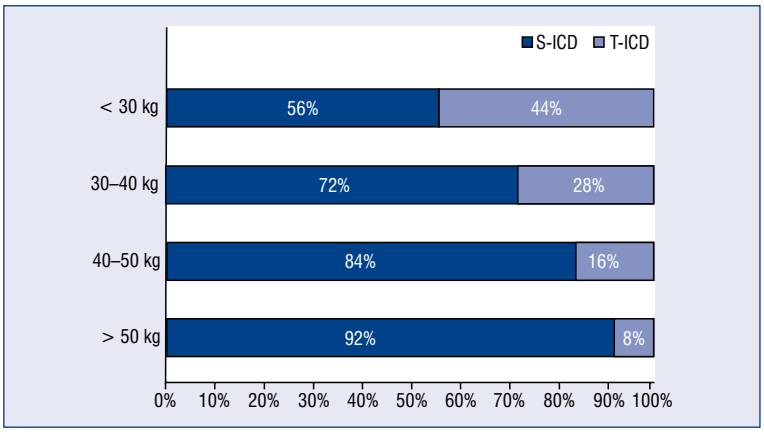

Figure 4. The choice between subcutaneous implantable cardioverter-defibrillator (S-ICD) and transvenous implantable cardioverter-defibrillator (T-ICD) in patients wih congenital heart disease (not precluding transvenous implant) qualified for an implantable cardioverter-defibrillator, with no history of arrhythmia and no indications for permanent pacing, for different weight categories.

ers, respectively, would opt for an S-ICD (Fig. 4). The Polish reports published so far confirm the efficacy and safety of such an attitude [14, 30].

Protection against sudden cardiac arrest of patients awaiting heart transplant is a complex issue. On one hand, an S-ICD seems to be an optimal solution due to the low risk of lead-related or systemic infection, it does not involve the vascular system and does not lead to lead-related thrombosis, which may be crucial for a patient's future treatment after heart transplant. On the other hand, if a patient is qualified for an assist device as a bridge to transplant, the S-ICD presence may be troublesome. Patients with assist devices are at risk of inappropriate interventions due to sensing issues, and of painful discharges in case of ventricular arrhythmias, which in the presence of an assist device may be well tolerated and treated with a shock before the loss of consciousness occurs. Despite those drawbacks, 60% of responders voted for S-ICD over T-ICD in the group of patients awaiting heart transplant. That question of the survey did not specify if the patients were already equipped with an assist device or potentially qualified for one.

Extraction of a CIED system is a cornerstone of therapy in many complications of cardiac electrotherapy, both infective and noninfective (e.g., lead damage). In case of high risk of infection, the American guidelines consider the use of S-ICD as class I recommendation, while in the European guidelines such a situation is considered to be a class IIb recommendation [2, 31]. According to the Polish expert consensus from 2018, the high risk of infection is among major indications for preference of S-ICD over T-ICD [32]. In the present survey though, 8% of responders did not consider a history of infective complications as justifying the replacement of the extracted T-ICD with an S-ICD. In case of lead extraction due to its failure, even if there was no need for permanent cardiac pacing or no history of ventricular arrhythmias requiring antiarrhythmic pacing, only 40% of responders would change the T-ICD system for a subcutaneous one. That percentage is relatively low, especially in the light of the opinion of the French experts, who unanimously opted for switching to an S-ICD in case of complications [16]. Similarly, the responders of the European Heart Rhythm Association (EHRA) survey also declared their preference of a subcutaneous system over transvenous one if the history of prior complications of transvenous electrotherapy was reported (80%) or a significant risk of infective complications occurred (63%) [9].

The expected divergence of opinions among Polish experts on the potential use of S-ICD system encouraged us to formulate a survey question regarding the most important reasons for not implanting S-ICD in cases, where it might be indicated. In response to that multiple-choice question the most frequent reason (68%) was the potential risk of the need for conversion from a subcutaneous to a transvenous system if indications develop in the future. But one third of responders also chose the financial reasons: 44% of them responded that they discontinued implanting S-ICDs due to the high cost of the system, and 28% due to the fear that the center will not receive reimbursement of the costs for the procedure (Fig. 5). Similar data was reported

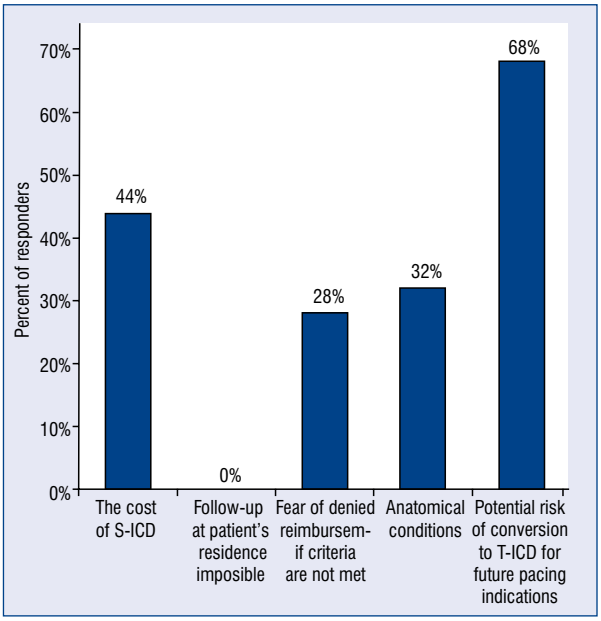

Figure 5. Main factors determining the preference of transvenous implantable cardioverter-defibrillator (T-ICD) over subcutaneous implantable cardioverter-defibrillator (S-ICD) in patients eligible for S-ICD (multiple choice question).

by the authors of the European survey, but in the present analysis those results are surprising, because the current regulations in Poland guarantee the complete reimbursement of S-ICD implantation procedure [8, 9]. Additional indications required to justify the choice of S-ICD and not T-ICD include the high risk of infective complications, the risk of lead failure, the risk of venous occlusion and the predicted long-life expectancy of the patient. Those requirements are consistent with the current guidelines from the scientific societies. The further limitation of S-ICD use in Poland is associated with the requirements for centers in terms of equipment and experience to include that method of treatment into their portfolio. That issue could not have influenced the responses to our survey, as all the participants represented centers meeting the requirements mentioned above and were themselves active implanters of S-ICD systems. Therefore, the financial issues and unjustified fear of lack of reimbursement are limiting the potential utilization of S-ICD in almost 30% of cases.

Conclusions

The results of the survey prove that a significant divergence of opinion exists among Polish experts regarding the use of a subcutaneous cardioverter-defibrillator. It is pronounced especially in the issue of the use of the system in middle-aged patients, in case of complications of the hitherto ICD therapy, or the need of upgrading the existing cardiac implantable electronic device.

Conflict of interest: None declared

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