REVIEW ARTICLE

The subcutaneous ICD as an alternative to the conventional ICD system: Initial experience in Greece and a review of the literature

Skevos Sideris a,*, Stefanos Archontakis b, Konstantinos A. Gatzoulis b, Aristotelis Anastasakis b, Ilias Sotiropoulos a, Petros Arsenos b, Alexandros Kiasiakogias a, Dimitrios Terentes a, Konstantinos Trachanas a, Eleftherios Paschalidis a, Dimitrios Tousoulis b, Ioannis Kallikazaros a

a State Department of Cardiology, Hippokration Hospital, 114 Vasilisis Sofias street, 11528, Athens, Greece
b First Cardiology Division, University of Athens, Medical School, Hippokration Hospital, 114 Vasilisis Sofias street, 11528, Athens, Greece

Received 8 November 2015; accepted 31 August 2016
Available online 2 February 2017

KEYWORDS
Sudden cardiac death; Ventricular tachyarrhythmias; Brugada syndrome

Abstract  The introduction of an implantable cardioverter defibrillator (ICD) in clinical practice has revolutionized our therapeutic approach for both primary and secondary prevention of sudden cardiac death (SCD), as it has proven to be superior to medical therapy in treating potentially life-threatening ventricular arrhythmias and has resulted in reduced mortality rates. However, implantation of a conventional ICD carries a non-negligible risk of peri-procedural and long-term complications associated with the transvenous ICD leads. The entirely subcutaneous implantable cardioverter defibrillator (S-ICD) has recently emerged as a therapeutic alternative to the conventional ICD for patients with various cardiopathies and who are at high risk of SCD. The main advantage is the avoidance of vascular access and thus avoidance of complications associated with transvenous leads. Patients without pacing indications, such as bradycardia, a need for antitachycardia pacing or cardiac resynchronization, as well as those at higher risk of complications from transvenous lead implantation are perfect candidates for this novel technology. The subcutaneous ICD has proven to be equally safe and effective...
compared to transvenous ICD systems in early clinical trials. Further technical improvements of the system will likely lead to the expansion of indications and widespread use of this technology. In the present review, we discuss the indications for this system, summarize early clinical experiences and highlight the advantages and disadvantages of this novel technology. In addition, we present the first two cases of subcutaneous cardioverter defibrillator system implantation in Greece.

© 2017 Hellenic Society of Cardiology. Publishing services by Elsevier B.V. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

1. Introduction

Despite the significant decrease in cardiovascular mortality over the past 20 years, the incidence of sudden cardiac death (SCD) in the general population is currently estimated at 50–100 per 100,000, and it accounts for approximately 300,000 deaths in the U.S. annually, with proportionate numbers in Europe. Since 1980, when they were first introduced in clinical practice, implantable cardioverter defibrillators (ICDs) have shown significant survival benefits in individuals at risk of sudden arrhythmic death.

The widespread use of the conventional ICD, however, is associated with significant procedural and long-term complications that are mainly associated with the use of a transvenous lead within the right ventricle. These include pneumothorax, cardiac perforation, pericardial effusion and tamponade, lead dislodgement, lead malfunction due to insulation failure or lead fractures, venous occlusion and systemic infections. A recent observational study reported a 1.5% rate of major complications. The incidence of complications appears to be higher in the pediatric population and in younger patients, who are expected to undergo multiple procedures. Recent data suggest a significant decrease in transvenous lead longevity from 91–99% at 2 years to 60–72% at 8 years. Moreover, the extraction of transvenous lead systems, which is occasionally required, is associated with significant procedural risks and high morbidity and mortality.

Recently, an entirely subcutaneous ICD system (S-ICD) has been developed to overcome many of the problems associated with conventional transvenous ICDs. In the present review, the current evidence, target population and other important issues regarding the advantages and disadvantages of S-ICDs are discussed.

2. Device features and implantation procedure

The S-ICD system is comprised of two basic components, i.e., a generator and an electrode lead (Fig. 1) that are both implanted subcutaneously.

- The pulse generator is placed over the fifth to sixth intercostal space between the left anterior and mid-axillary line (Fig. 2). The device is larger and weighs 145 g, which is approximately double that of a transvenous ICD. The generator is able to (a) provide up to five high-energy (80 J), non-programmable, defibrillation shocks per episode through the use of a constant tilt of 50% and a biphasic waveform and (b) deliver post-shock bradycardia pacing at 50 beats per minute, using a 200 mA biphasic transthoracic pulse for a period of up to 30 s if >3.5 s of post-shock asystole is detected. The estimated longevity is 5 years for the initial S-ICDs, though it exceeds 7 years for the latest generation models. Additionally, remote follow-up of the device is now available for new S-ICD models.

- The 3-mm lead comprises both sensing and defibrillating properties and is tripolar, consisting of three electrodes; these are the ICD can, a distal electrode on the tip of the defibrillator lead and a proximal electrode located approximately 8 cm from the tip of the lead. It is positioned such that the distal part is placed parallel and 1 to 2 cm to the left side of the sternum. The distal sensing electrode is localized at the junction of the sternum and the manubrium, while the proximal sensing electrode, which is the anchoring point for the lead, is positioned adjacent to the xiphoid process. Between the two sensing electrodes stands the 8-cm coil for defibrillation against the defibrillator can. Implantation is performed using three incisions (i.e., one for the lateral pocket and two parasternal incisions). The lead is tunneled from the lateral pocket through the parasternal incisions, guided by anatomic landmarks only, without the use of fluoroscopy. The superior parasternal incision is prone to exposure, and subsequently to infection, and it may be aesthetically undesirable to the patient. Thus, alternatively, a two-incision technique

Figure 1 The subcutaneous ICD system (image courtesy of Boston Scientific Corporation, with kind permission to reprint).
avoiding the superior parasternal incision, which was shown to be equally safe and efficacious to the three-incision technique, has been developed.\(^\text{14}\) Furthermore, in patients with a more centrally positioned heart, a right parasternal position of the lead may be preferred to include more left ventricular heart muscle in the defibrillation field and achieve optimal sensing.\(^\text{15}\)

Arrhythmia detection is performed using 1 of the 3 vectors that are formed between the three sensing poles of the system (Fig. 2); these consist of the primary vector (i.e., proximal electrode ring-to-can), the secondary vector (i.e., distal electrode ring-to-can) and an alternate vector (i.e., distal electrode ring-to-proximal electrode ring). The S-ICD automatically selects the most appropriate vector for rhythm detection according to the highest R amplitude and the most satisfactory R-wave/T-wave ratio to minimize the risk for double QRS counting and T-wave oversensing.\(^\text{13}\) However, polarity can also be switched manually.\(^\text{13}\)

In addition, to ensure patient eligibility for an S-ICD, it is recommended to perform a screening electrocardiographic (ECG) template to confirm a satisfactory R-wave/T-wave ratio pre-implantation in no fewer than two postures (Fig. 3).\(^\text{16}\) At least one of the three available sensing configurations has to be acceptable in both postures.\(^\text{13}\) However, recently it was demonstrated that 15% of candidates...
The subcutaneous ICD system

will not qualify for the S-ICD system due to the lack of an adequate vector.17

After the device has been successfully implanted, it is advised to always test the system effectiveness in the lab using a defibrillation test (DFT), although this is no longer necessary for the conventional ICD system.13 However, this practice is mandatory for the S-ICD because clinical experience and long-term follow-up data are limited and because the studies that established the safety and effectiveness of the system utilized defibrillation testing.13 During the DFT, conversion of induced ventricular fibrillation (VF) is tested using 65 J, though once implanted the S-ICD delivers a non-programmable 80-J shock to ensure a 15-J safety margin. If the DFT is unsuccessful, the shock vector is reversed. Occasionally, repositioning the generator or lead is necessary, and the defibrillation test is repeated until it is successful.

The detection zone is programmed from 170–250 beats per minute (bpm) with the device having a total storage capacity of 24 episodes (i.e., maximum of 120-s of recorded electrograms per event).13 Except from the shock zone, the capacity of 24 episodes (i.e., maximum of 120-s of recorded per minute (bpm) with the device having a total storage

As mentioned previously, the S-ICD system is able to deliver post-shock bradycardia pacing on demand for up to 30 seconds. However, the system does not provide long-term pacing and therefore is not adequate for patients with symptomatic bradycardia, with frequent ventricular tachycardia episodes that are likely to benefit from anti-tachycardia pacing (ATP), or who require for cardiac resynchronization therapy.13

3. Current evidence regarding safety and efficacy of the s-ICD: Present and future

Despite the fact that data and experience are still limited compared to conventional transvenous ICDs, S-ICD technology has expanded worldwide since its initial approval in Europe in 2009.

Results from initial trials were published in 2010 by Bardy et al, and they demonstrated short-term safety and efficacy of the S-ICD. In the pilot trial, which consisted of 6 patients, all 18 episodes of induced VF were successfully detected and defibrillated, although the defibrillation threshold was significantly higher than that of conventional ICD.13

However, most evidence is currently obtained from the Investigational Device Exemption (IDE) study,21 a prospective, non-randomized, multicenter, international trial, and the EFFORTLESS (Evaluation of FactOrs ImpacTing Clinical Outcome and Cost EffectiveneSS) S-ICD Registry,18 an ongoing, non-randomized, multicenter registry in approximately 50 investigational centers in Europe and New Zealand. To provide real world experience, the target sample size of the EFFORTLESS S-ICD Registry is 1,000 patients with at least 60 months of follow-up. In addition, supplementary evidence regarding the safety and efficacy of the S-ICD has been generated in several other trials.23–25 A recent meta-analysis of the IDE study and EFFORTLESS Registry included 882 patients who underwent S-ICD implantation and were followed for 651 ± 345 days. In that study, 111 spontaneous VT/VF events were treated in 59 patients. Of these, 100 (90.1%) events were terminated with 1 shock, and 109 events (98.2%) were terminated within the 5 available shocks, demonstrating that the S-ICD system has high efficacy.22 An overview of the different S-ICD trials is presented in Table 1. Although data on the long-term tolerability and safety of the treatment are currently lacking, initial results from these studies provide evidence for the safety and efficacy of the S-ICD system.

The ongoing Prospective Randomized Comparison of Subcutaneous and Transvenous Implantable Cardioverter-Defibrillator Therapy (PRAETORIAN) trial aims to recruit 700 patients with class I or IIa indication for ICD but without indication for pacing therapy from various centers at the Netherlands (estimated median follow-up: 30 months). This is the first randomized prospective study to compare the safety and effectiveness of the S-ICD to the conventional transvenous ICD system.28

4. Indications and patient selection

Because current evidence suggests that subcutaneous defibrillators are effective in preventing SCD, most patients
Table 1  Safety and effectiveness of the S-ICD system: overview of the different S-ICD trials.

<table>
<thead>
<tr>
<th>Patient number (n)</th>
<th>Age (years)</th>
<th>Follow-up</th>
<th>Underlying heart disease</th>
<th>Primary prevention</th>
<th>Success at conversion test of inducible VT/VF</th>
<th>Success at conversion of clinical VT/VF</th>
<th>Incidence of inappropriate shocks</th>
<th>Incidence of infection need for explantation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bardy et al7 (2010)</td>
<td>55</td>
<td>56 ± 13</td>
<td>10 ± 1 m</td>
<td>Ischaemic CM 67%</td>
<td>98% (ttt: 14.0 ± 2.5 s)</td>
<td>N/A</td>
<td>100%</td>
<td>9%</td>
</tr>
<tr>
<td>Lambiase et al18 (2014)</td>
<td>472</td>
<td>49 ± 18</td>
<td>558 d</td>
<td>Idiopathic dilative CM 18%</td>
<td>99.7% (ttt: 15.1 ± 3.8 s)</td>
<td>N/A</td>
<td>100%</td>
<td>7%</td>
</tr>
<tr>
<td>Weiss et al21 (2013) IDE study</td>
<td>314</td>
<td>51.9 ± 15.5</td>
<td>330 d</td>
<td>Other 15%</td>
<td>79.4% (ttt: 14.6 ± 2.9 s)</td>
<td>92.1%</td>
<td>97.4%</td>
<td>13.1% (o/s: 8%)</td>
</tr>
<tr>
<td>Burke et al22 (2015) EFFORTLESS/IDE pooled analysis</td>
<td>882</td>
<td>50.3 ± 16.9</td>
<td>651 ± 345 d</td>
<td>N/A (previous MI: 41.4%)</td>
<td>N/A</td>
<td>N/A</td>
<td>79.4%</td>
<td>90.1% 98.2%</td>
</tr>
<tr>
<td>Olde Nordkamp et al23 (2012) (Dutch cohort)</td>
<td>118</td>
<td>50</td>
<td>18 ± 7 m</td>
<td>N/A (previous MI: 41.4%)</td>
<td>N/A</td>
<td>N/A</td>
<td>79.4%</td>
<td>90.1% 100%</td>
</tr>
<tr>
<td>Jarmar et al24 (2013) (UK registry)</td>
<td>111</td>
<td>33</td>
<td>12.7 ± 7.1 m</td>
<td>N/A (previous MI: 41.4%)</td>
<td>N/A</td>
<td>N/A</td>
<td>79.4%</td>
<td>90.1% 100%</td>
</tr>
<tr>
<td>Köbe et al25 (2013)</td>
<td>69</td>
<td>45 ± 7</td>
<td>217 ± 138 d</td>
<td>N/A (previous MI: 41.4%)</td>
<td>N/A</td>
<td>N/A</td>
<td>79.4%</td>
<td>90.1% 100%</td>
</tr>
<tr>
<td>Dabiri Abkenari et al26 (2011)</td>
<td>31</td>
<td>53 ± 16</td>
<td>286 d</td>
<td>N/A (previous MI: 41.4%)</td>
<td>N/A</td>
<td>N/A</td>
<td>79.4%</td>
<td>90.1% 100%</td>
</tr>
<tr>
<td>Aydin et al27 (2012)</td>
<td>40</td>
<td>42 ± 15</td>
<td>229 d (median)</td>
<td>N/A (previous MI: 41.4%)</td>
<td>N/A</td>
<td>N/A</td>
<td>79.4%</td>
<td>90.1% 100%</td>
</tr>
</tbody>
</table>

M, months; d, days; CM, cardiomyopathy; MI, myocardial infarction; VT, ventricular tachycardia; VF, ventricular fibrillation; ttt, time to therapy; s, seconds; o/s, oversensing.
with an indication for ICD implantation could potentially be considered as candidates for the S-ICD. In the recently released (2015) Clinical Practice Guidelines for the Prevention of Sudden Cardiac Death of the European Society of Cardiology (ESC), the use of the S-ICD system is recommended as an alternative to transvenous ICDs when pacing therapy for bradycardia, cardiac resynchronization or antitachycardia pacing is not needed (Class IIaC). Moreover, the device may be useful, alternatively to the transvenous ICD system, when venous access is difficult, in young patients facing a lifetime of device therapy and in patients after the removal of a transvenous ICD system for infection (Class IIbC) (Fig. 4).

Aside from the contraindications related to pacing, at present, only speculation can be made regarding the suitability of the subcutaneous system in different patient groups. Current indications for S-ICD implantation are summarized in Table 2. Firstly, the S-ICD may represent a reliable therapeutic alternative when implantation of the conventional transvenous ICD system is either technically difficult and/or associated with increased procedural risk, such as in patients with complex anatomy (e.g., congenital heart disease), lack of venous access, history of lead infection, or those who are immunocompromised.

Moreover, young patients with a long life expectancy are also suitable candidates, as implantation of transvenous ICDs is associated with significant long-term risk of lead failure and a need for multiple reinterventions. The system has also been successfully used in children, though implantation in patients with low body mass index should be carefully considered due to the relatively large and heavy generator.

Furthermore, patients with ion channelopathies and hypertrophic cardiomyopathy (HCM), who are usually younger, those in whom the mechanism of SCD usually involves polymorphic VT or VF, and those with low risk of bradycardia and monomorphic VT requiring ATP theoretically constitute a group where S-ICD may be the preferable option. However, it should be noted that a higher rate of inappropriate shocks due to T-wave oversensing and double-counting has been recorded in these patients. For example, in patients with Brugada syndrome, although clinical efficacy of S-ICD has been demonstrated, inappropriate shock may be more common due to the characteristic QRS- and T-wave morphology and the frequent presence of supraventricular tachyarrhythmias.

Moreover, in a recent study, HCM, high body weight, prolonged QRS duration, and R:T ratio <3 in the lead with the largest T wave on 12-lead electrocardiogram were independently associated with screening failure. In the same study, it was demonstrated that 7.4% of patients with ICDs who had no indications for cardiac pacing would not have been
eligible for an S-ICD.31 Performing an exercise test with maximum tolerable capacity in these patients, as well as adopting a detailed patient screening practice with selection of the optimal sensing vector in different positions, may reduce the risk of T-wave oversensing. In contrast, in clinical practice, the majority of patients with an indication for ICD suffer from ischemic or idiopathic dilated cardiomyopathy. Clinical studies demonstrated significant safety and effectiveness of the S-ICD in these patients (Table 1), who were mostly recruited in the context of primary prevention of SCD. However, patients with ischemic cardiomyopathy are likely to present with monomorphic VT, for which ATP has proven highly effective at terminating. However, a recent Dutch study of 463 conventional ICD recipients, the majority with ischemic cardiomyopathy, demonstrated that 55.5% did not develop a pacing indication or receive appropriate ATP without subsequent shock from their device, and thus would have been suitable for an initial S-ICD implantation.32 Patients with a history of sustained monomorphic VT are more likely to need antitachycardia pacing, and thus a conventional ICD system is considered the preferable choice in the context of secondary prevention.32 Except for secondary prevention, other predictors for the unsuitability of an S-ICD were severe heart failure (NYHA class III/IV) and prolonged QRS duration.32 In addition, the finding that ICD shocks are associated with higher mortality and a reduction in the quality of life favors the use of ATP therapy. Data from the PainFREE Rx II Trial showed that empirical ATP for fast VT is as effective and safe as an internal shock.33 Of note, spontaneous termination of VT episodes was observed in 34% of patients in the shock arm. In contrast, all VTs were treated in the ATP group, and no spontaneous termination occurred, suggesting that a considerable proportion of ATP intervention that is delivered before a shock, may be unnecessary.33

In patients with the S-ICD system, a significant delay in the initiation and delivery of therapy, due to the more prolonged detection algorithm and charge time compared to conventional ICDs, has been observed (14.6 ± 2.9 s compared to 7.1 ± 1.6 s, respectively, in the IDE study).20,34 In addition, the 5–95% range of the transvenous ICD was narrow at 2.25–7.55 s, whereas for the S-ICD, a positively skewed distribution extending to 24 s of therapy was recorded.33 It has been suggested that a longer time to detect and deliver a shock likely affords greater leniency for VT events to self-terminate, and because these events would otherwise be treated with a shock and categorized as "appropriate" therapy, this may reduce the number of unnecessary shocks.32 The MADIT-RIT study demonstrated that both a high-rate programming strategy that treats only high ventricular rates and delayed conventional ICD therapy were associated with significant reductions in the first occurrence of inappropriate therapy, as well as a significant reduction in all-cause mortality.36 Several S-ICD studies demonstrated that time to therapy for appropriate shocks is within the range of prolongation in detection shown to be beneficial in MADIT-RIT (Table 1).20,21 Thus, the S-ICD was shown to mimic this programming strategy by providing high-rate zones of therapy and prolongation of detection-to-shock time to reduce inappropriate shock therapy due to self-termination of VT/VF, likely leading to a consequent reduction in mortality.20,34 However, debate continues regarding the risks and benefits of prolonged detection allowing for self-termination of VT/VF episodes and potentially reduced mortality from unnecessary ATP and shocks versus potentially higher risk of syncope or avoiding shocks through pace termination of VT.34

5. Inappropriate shock therapy

Despite the fact that prophylactic ICD implantation improved outcomes in patients with heart disease, inappropriate shocks, which have an incidence of 12–17%, remain a significant clinical problem.4–8,34 In addition, in the MADIT II trial, inappropriate shocks, but not

<table>
<thead>
<tr>
<th>Patient group</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with an indication for ICD implantation, when pacing for bradycardia, cardiac resynchronisation or antitachycardia pacing is not needed at the time of implantation and most probably at the future</td>
<td>Any type of underlying heart disease</td>
</tr>
<tr>
<td>Congenital heart disease</td>
<td>Patient’s preference is a determinative factor</td>
</tr>
<tr>
<td>Venous occlusion or thrombosis</td>
<td>Technically difficult with T-ICD</td>
</tr>
<tr>
<td>History of lead infection</td>
<td>Lack of venous access</td>
</tr>
<tr>
<td>Previous extraction of a transvenous system</td>
<td>Significant risk for infection with T-ICD</td>
</tr>
<tr>
<td>Immunocompromised individuals</td>
<td>Possibly, lack of venous access</td>
</tr>
<tr>
<td>Hemodialysis</td>
<td>Significant risk for infection with T-ICD</td>
</tr>
<tr>
<td>Young patients</td>
<td>Possibly, lack of venous access</td>
</tr>
<tr>
<td>Ion channelopathies</td>
<td>Need for multiple re-interventions</td>
</tr>
<tr>
<td>Hypertrophic Cardiomyopathy</td>
<td>Usually young patients</td>
</tr>
<tr>
<td>Early post-myocardial infarction phase (&lt;6 weeks) or early after diagnosis of dilated cardiomyopathy (&lt;3 months)</td>
<td>SC usually due to polymorphic VT/VF</td>
</tr>
</tbody>
</table>

SCD, Sudden Cardiac Death; VT, ventricular tachycardia; VF, ventricular fibrillation; T-ICD, transvenous ICD.
inappropriate ATP, were associated with increased mortality risk. Furthermore, studies interestingly demonstrated increased mortality in patients who received appropriate shocks, but not appropriate ATP. Supraventricular arrhythmias appear to be the commonest causes of inappropriate therapy in patients with transvenous ICD systems.

Regarding the subcutaneous ICD system, current data demonstrate a comparable rate of inappropriate shocks with transvenous ICDs (Fig. 5). Reported rates range between 7% and 16% (Table 1). In the IDE trial, the incidence of inappropriate therapy was 13.1% (41 patients) over a mean follow-up of 11 months. Oversensing was the commonest cause of inappropriate shocks, which occurred in 25 patients (8%), 22 of whom experienced T-wave oversensing. In 5.1% (16 patients), a shock was delivered due to supraventricular tachycardia. However, none of these inappropriate shocks were delivered in the conditional zone, indicating that programming of a conditional zone significantly reduces the risk of inappropriate shocks for supraventricular tachycardia (70% relative risk reduction). Moreover, in a cohort from the IDE trial, 226 subjects with dual-zone programming were compared with 88 subjects with single-zone programming. The 2-year inappropriate shock-free rates were 89.7% and 73.6% in the dual- and single-zone programming subgroups, respectively, suggesting that the use of dual- rather than single-zone programming is preferable. In patients with HCM and inherited channelopathies, the risk of inappropriate shocks was increased due to T-wave changes, particularly during exercise. An exercise stress test is recommended in these cases to assess the R-wave/T-wave ratio template changes and detect T-wave oversensing during exertion, and the sensing vector should be manually adjusted as necessary. Amelioration of the risk of T-wave oversensing could also be achieved by increasing the pre-implantation requisite of satisfactory R-wave/T-wave ratio templates to more than 1.

In the EFFORTLESS registry, 73 inappropriate shocks were recorded in 32 patients over an average follow-up of 18 months (inappropriate shock rate: 7%). Oversensing was the major cause of inappropriate shocks in 85% of the cases. Similarly to the IDE study, single-zone programming resulted in a higher inappropriate shock rate than dual-zone programming (12% versus 6.4%).

In summary, the existing data demonstrate a relatively high rate of inappropriate ICD shocks with the S-ICD system, though it is comparable to that of transvenous ICDs. In contrast to the transvenous ICDs, most of the inappropriate therapies appear to occur due to T-wave oversensing resulting in double counting (Fig. 5). The susceptibility to T-wave oversensing was demonstrated in a study utilizing a screening template designed to identify patients who are vulnerable to oversensing prior to insertion and showed that 8% of patients who already had an ICD would fail the screening test.

In contrast, a reduced inappropriate shock rate due to incorrect characterization of a supraventricular arrhythmia has been demonstrated with the S-ICD system compared to transvenous ICDs.

Figure 5 Inappropriate shock rates among patient populations with the subcutaneous ICD system in the IDE and EFFORTLESS trials and the transvenous ICD system in the MADIT II trial (pts: patients, SVT: supraventricular tachycardia, comprising atrial fibrillation, sinus tachycardia and other forms of supraventricular arrhythmias).
conventional ICDs. \textsuperscript{6,7,18,20,21,39} These clinical data are compatible with findings from the Subcutaneous versus Transvenous Arrhythmia Recognition Testing (START) trial, which compared arrhythmia detection by the S-ICD with single- or dual-chamber transvenous ICDs using simultaneous arrhythmia recordings. There was no significant difference in the sensitivity of detecting ventricular tachyarrhythmias between the S-ICDs and transvenous ICDs. However, specificity of the subcutaneous system for discriminating supraventricular arrhythmias was significantly better (98\% in S-ICD vs 76.7\% in single-chamber transvenous ICD vs 68\% in dual-chamber transvenous ICD), suggesting a potential reduction in inappropriate therapies with S-ICDs compared to transvenous ICDs.\textsuperscript{42}

6. Complications with the S-ICD system

The main advantage of the S-ICD system compared to conventional ICDs is the fact that it avoids vascular access (Table 3). Subsequently, perioperative complications are rare, and several complications associated with the implantation of a conventional ICD system and the presence of the transvenous lead, such as pneumothorax, cardiac tamponade and perforation, vascular lesions, and electrode dislocation, are avoided.\textsuperscript{43}

In IDE, the 180-day complication-free rate relating to the device, labeling and the insertion procedure was reported at

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Comments</th>
<th>Disadvantages</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>No vascular access required</td>
<td>Specific potential procedural complications omitted (eg cardiac tamponade, pneumothorax, vascular lesions) Suitable for patients with complex anatomy (eg congenital heart diseases) or no venous access</td>
<td>Pacing for bradycardia, ATP and CRT functions not available</td>
<td></td>
</tr>
<tr>
<td>No fluoroscopy required</td>
<td></td>
<td>Pulse generator larger/heavier, compared to conventional ICD Longevity shorter (~5 years) compared to conventional ICD Longer charge time &amp; time-to-therapy</td>
<td>New generation devices are significantly smaller/lighter Longevity of new generation devices &gt;7 years Prolongation of detection-to-shock time may reduce inappropriate shocks</td>
</tr>
<tr>
<td>No risk of bacterial endocarditis</td>
<td></td>
<td>Simpler diagnostic and therapeutic algorithms Remote monitoring not available</td>
<td>Available in new generation models Up-to-date evidence suggests efficacy and safety</td>
</tr>
<tr>
<td>Better discrimination of supraventricular arrhythmias</td>
<td></td>
<td>Limited clinical experience</td>
<td>Equivalent to conventional ICD</td>
</tr>
<tr>
<td>Simpler extraction procedure</td>
<td></td>
<td>Significant incidence of inappropriate shocks (mostly due to oversensing) Significant incidence of pocket infection Defibrillation test mandatory Pre-implantation ECG screening required Higher cost compared to conventional ICD</td>
<td>Equivalent to conventional ICD</td>
</tr>
</tbody>
</table>

Figure 6 The electrocardiogram of a 48-year-old female, revealing a characteristic spontaneous type 1 Brugada pattern (case 1).
92.1% (lower confidence limit: 88.9%). In addition, in EFFORTLESS, 15 system-related complications occurred in 14 patients (3%) in the first 30 days post-implant, which accounts for a peri-operative complication-free rate of 97%. At 360 days post-implantation, the documented system or implantation-related complication-free rate was 94%. Moreover, it has been reported that more complications occurred with the first implants, suggesting a physician-related learning curve. In accordance, in the Dutch cohort, the investigators observed that relatively more inappropriate shocks and device-related complications occurred in the first patients. Complication rates then improved with increased operator experience, optimization of screening for T-wave oversensing on exercise, use of a suture sleeve to prevent lead migration and reductions in implant time. Subsequently, they concluded that both physician-related and device-related learning curves existed.

The main complications associated with the S-ICD system were infection and suboptimal lead position. The rate of infection of the generator pocket ranges in trials from 2–10% (Table 1) and occasionally leads in explanation of the system. Interestingly, the incidence of infections may also be related to initial inexperience. In the IDE study, three of 4 cases of infection that required explanation of the system occurred in the first third of the study, a finding that was attributed to a learning curve.

Figure 7  Implantation of a subcutaneous ICD system in a 48-year-old female (case 1). Initially, an incision was made at the mid-axillary line between the 5th and 6th intercostal spaces (B). The lead was then tunneled from the lateral incision (C) through the two parasternal incisions (i.e., the xiphoid incision and from the xiphoid to the superior incision), and positioned parallel to the left edge of the sternum (D, E). The pulse generator was eventually connected to the subcutaneous electrode and secured in a pocket created at the level of the lateral incision (F, G). After implantation, a defibrillation test was performed and demonstrated inducible VF that was interrupted with a 65-J DC shock (I).
7. Conclusions

The subcutaneous ICD has emerged as a promising alternative to conventional ICD systems, as it avoids the potential periprocedural and long-term complications associated with the transvenous leads. Current evidence suggests that S-ICD is a highly effective and safe modality with comparable defibrillation success rate and similar rates of inappropriate shock delivery to conventional ICDs. Thus, a wide range of patients without pacing requirements, and particularly younger patients, may benefit. Ongoing clinical studies will help establish the S-ICD system’s long-term safety and efficacy and better define target patient groups. Recent developments in the field of leadless electrodes may expand the indications for S-ICDs.

8. Initial experience with the S-ICD system in Greece

We report the first two cases of a subcutaneous ICD implantation in Greece that took place in the electrophysiology laboratory of Hippokrateion General Hospital of Athens in October 2015.

The first patient was a 52-year-old Caucasian female who presented in the Emergency Department of our hospital due to relapsing syncope. The patient reported at least 3 syncopetic episodes within a period of 3 months. The electrocardiogram revealed a characteristic spontaneous type 1 Brugada pattern of a coved ST segment elevation of 4 mm in leads V1 and V2 followed by a negative T wave (Fig. 6). Physical examination and blood tests were insignificant. The echocardiographic examination was normal. Thus, the diagnosis of Brugada syndrome was established. According to the current recommendations, the patient was considered to be at high risk of SCD, and the decision was made to implant a subcutaneous ICD (Class IIa) (Fig. 6).1 Before implantation, a three-lead surface electrocardiogram was performed to assess the appropriateness of surface signals. The patient underwent ICD implantation (Boston Scientific Emblem S-ICD™ System) using the standard three-incision technique. Initially, an incision was made at the mid-axillary line between the 5th and 6th intercostal spaces. The lead was then tunneled from the lateral incision through the two parasternal incisions (i.e., the xiphoid incision and from the xiphoid to the superior incision), and positioned parallel to the left edge of the sternum. The pulse generator was eventually connected to the subcutaneous electrode and secured in a pocket created at the level of the lateral incision. The electrocardiogram was consistent with typical type 1 Brugada changes, showing a coved ST segment elevation of maximum 5 mm in the right precordial leads V1-V3 followed by a negative T wave (Fig. 9). Laboratory tests were all normal. Echocardiography did not reveal any abnormal features. A 24-hour ambulatory-ECG monitoring period revealed frequent premature ventricular beats and multiple runs of non-sustained VT of the same morphology. Recent ESC Clinical Practice Guidelines for the Prevention of Sudden Cardiac Death recommend ICD implantation in patients with a diagnosis of Brugada syndrome and syncopetic episodes (class IIa) (Fig. 9).1 The patient underwent a three-lead surface electrocardiogram screening followed by a subcutaneous ICD system implantation (Boston Scientific Emblem S-ICD). The procedure was similar to the previous patient, though this case used the two-incision technique, during which the parasternal part of the electrode was positioned using an 11 French peel-away sheath. The generator was, similarly to the previous patient, connected to the subcutaneous electrode and placed in a pocket created at the level of the lateral incision. A defibrillation test was performed post-procedurally that demonstrated inducible VF that was interrupted with

Figure 8 A post-implant chest radiography demonstrated optimal placement of the subcutaneous ICD system (case 1).

Figure 9 The electrocardiogram of a 22-year-old male, revealing a characteristic spontaneous type 1 Brugada pattern (case 2).
a 65-J DC shock. A chest-X-ray demonstrated optimal placement of the pulse generator and subcutaneous electrode (Fig. 10). The patient had an uneventful hospital stay and was discharged 3 days after the implantation.

**Funding sources**

All funds were provided by the National Health System.

**Disclosures/relationship with industry**

None.

**References**


18. Lambiase PD, Barr C, Theuns DA, et al. EFFORTLESS Investigators: Worldwide experience with a totally subcutaneous...


34. Lambiase PD, Srinivasan NT. Early experience with the subcutaneous ICD. *Curr Cardiol Rep.* 2014;16:516.


