

**Clinical update**

# The subcutaneous implantable cardioverter defibrillator: state-of-the-art review

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The subcutaneous implantable cardioverter defibrillator (ICD) provides therapy for the prevention of sudden cardiac death while avoiding the numerous complications associated with transvenous leads. This relatively novel device employs an innovative approach to sensing and defibrillation from outside of the thoracic cage. Substantial data from cohort studies and registries have accrued and can be used to inform patient eligibility, implant technique, and efficacy compared with the standard transvenous ICD. This review serves to update the clinician as to current evidence and the nuances involved in the optimal utilization of this innovative technology.

## Keywords

Subcutaneous implantable cardioverter defibrillator • Sudden cardiac death • ICD implant

## Introduction

Sudden cardiac arrest is the most common cause of death in developed countries exceeding the mortality due to lung cancer, breast cancer, cervical cancer, colorectal cancer, diabetes, HIV, house fires, motor vehicle accidents, prostate cancer, suicides, and Alzheimer's disease combined.<sup>1,2</sup> In 2014, sudden cardiac arrest accounted for >1000 deaths per day.<sup>1,2</sup> The implantable cardioverter defibrillator has consistently been found superior to best available drug therapy for the prevention of sudden cardiac death in patients with previous cardiac arrest (secondary prevention) and in high-risk patients with depressed ventricular function or arrhythmogenic conditions (primary prevention).<sup>3</sup> For this reason, implantable defibrillators are the gold standard of prevention for sudden cardiac death prevention.

Implantable cardioverter defibrillator (ICD) system malfunction or associated medical complications are almost universally caused by the implanted lead: an intravascular polyurethane- or silicone-coated conductor. The lead is subject to repetitive mechanical motion in the vicinity of the tricuspid valve with each cardiac systole, stressing its component materials. Additionally, the lead is secured to the pectoralis muscle and enters the vasculature at or near the left axillary vein so that motion of the shoulder girdle and

manipulation during implantation provide additional acute and chronic mechanical stress. The lead failure rates approach 40% at 5 years, with marked variability depending on lead design.<sup>4,5</sup> Additionally, medical complications can arise secondary to the thrombogenic aspects of the intravascular lead. Staphylococcal and streptococcal bacteria species create biofilms in contact with leads, rendering antibiotics ineffective at eradicating device-associated infection, necessitating extraction.<sup>6</sup> Furthermore, the presence of leads in the blood pool can potentially transform localized infections into a systemic bacteraemia. The reaction elicited by foreign material (thrombosis, fibrosis, and adherence) also makes the removal of intravascular leads technically challenging, with the risk of venous perforation, valve disruption, hemothorax, and death. Moreover, thrombus has been found adherent to 30% of transvenous leads using intracardiac echocardiography, rendering their use contraindicated in patients with known veno-systemic shunts, and increasing the risk of thromboembolism three-fold in the presence of a patent foramen oval.<sup>5</sup> Lastly, the mere presence of a lead across the tricuspid valve can impinge leaflet motion, promote annular dilatation, and lead to clinically significant tricuspid regurgitation, which may impair the response to cardiac resynchronization.<sup>7</sup> Given the marked clinical efficacy of ICDs in preventing sudden death, and the number of complications stemming from transvenous leads, the

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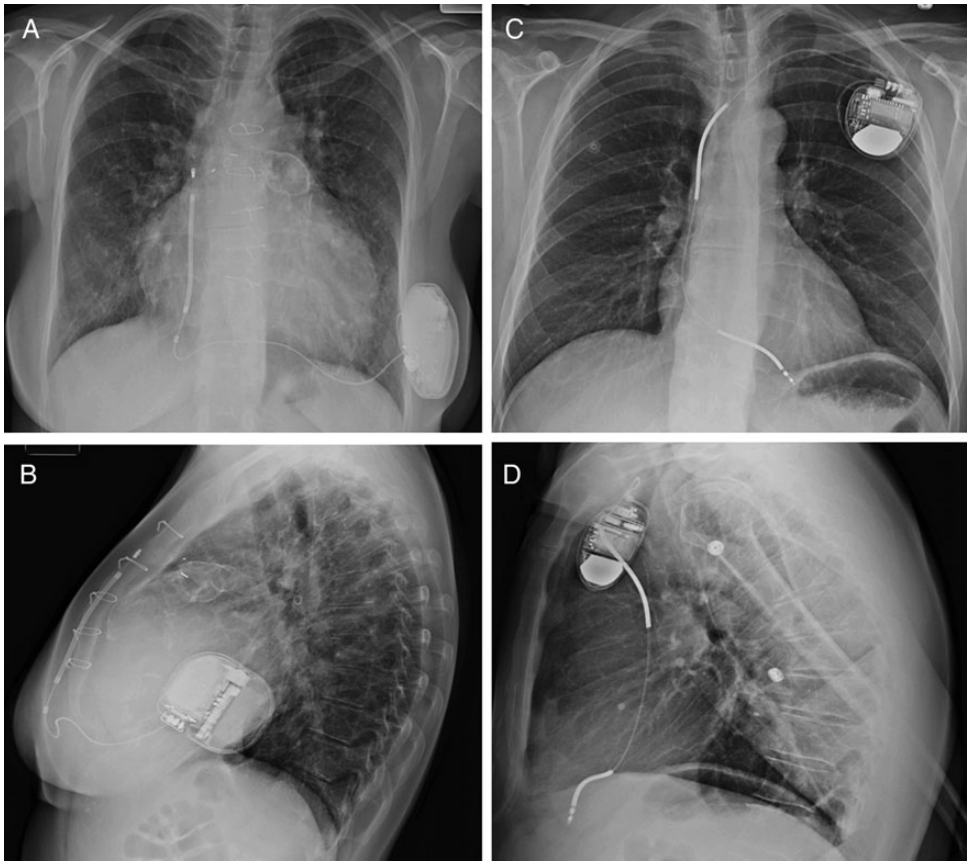
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subcutaneous ICD was conceived to deliver lifesaving therapy while avoiding the potential for these intravascular lead-related issues. Special design and functional differences were required to permit sensing and defibrillation with no lead touching the heart. The purpose of this article is to review the current status of the subcutaneous ICD (S-ICD) and potential future direction.

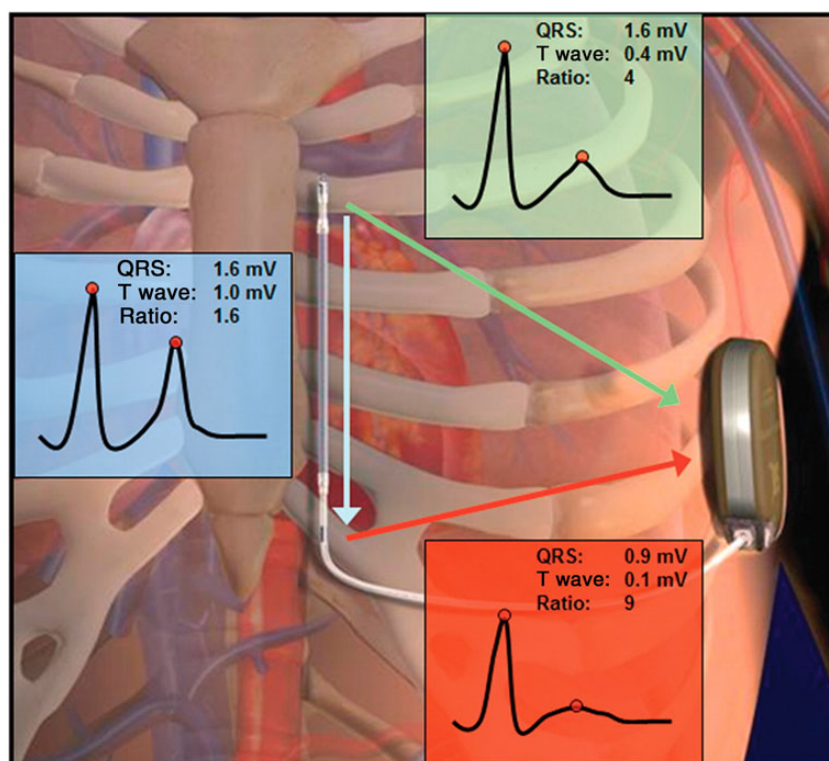
Overview of the subcutaneous implantable cardioverter defibrillator system

Unlike conventional transvenous defibrillator (TV-ICD) systems with an intravascular/intracardiac lead, the S-ICD is equipped with an extracardiac, extrathoracic, subcutaneous electrode. The defibrillation coil (8 cm long) lies directly between two sensing electrodes and the S-ICD generator acts as the 3rd electrode, used for sensing and defibrillation. The pulse generator serves as a mandatory component of the defibrillation pathway and as an optional electrode for sensing (Figures 1 and 2). The optimal position of device leads and generator for back-up pacing and defibrillation

has been comprehensively evaluated in animal and human subjects.<sup>8</sup> Two electrodes alongside the sternum and the S-ICD generator provide three possible sensing vectors (Figure 2). In contrast to the electrograms acquired with closely spaced endocardial electrodes, the S-ICD recording has a lower amplitude and frequency content and is more susceptible to postural variation. It resembles that of the precordial surface electrocardiogram (ECG) with distinct P-wave, QRS, and T-wave morphology, and the device software/algorithms must process the waveform to identify the QRS as distinct from the T wave and P wave. Pre-implant screening (discussed below) identifies individuals in whom such processing is not feasible based on the QRS amplitude and QRS to T-wave ratio. After S-ICD implant, the device will automatically choose the optimal vector to distinguish the QRS from the T wave—specifically to avoid double counting of each cardiac event. A baseline template is also stored using the optimal vector. The optimal vector can also be selected manually by the operator if so desired. The ability to appropriately identify the specific components of the cardiac electrical cycle in the S-ICD signal can be affected by coexistent factors that affect the P wave, QRS complex, and T wave, such as massive atrial enlargement,



**Figure 1** Posteroanterior (A) and lateral (B) chest radiograph taken from a patient with Eisenmenger's syndrome related to an unrestrictive ventricular septal defect. The subcutaneous implantable cardioverter defibrillator generator is seen in both views, located on the left side/anterior axillary line. In contrast to most patients, in whom the lead is placed to the left of the sternum, the patient underwent placement of the implantable cardioverter defibrillator coil on the right of the sternum based on the results of screening, during which the left-side position failed the screen. Figures (C) and (D) and corresponding cartoon show the positions of the pulse generator and leads in a transvenous ICD, for comparison.



**Figure 2** Diagram showing the positions of the sensing electrodes and pulse generator, which serve to create the vector for sensing of arrhythmia. Three options are available and can be independently programmed based on the ratio of the QRS to the T wave, to avoid oversensing of the latter. Adapted from Jarman et al.<sup>32</sup>

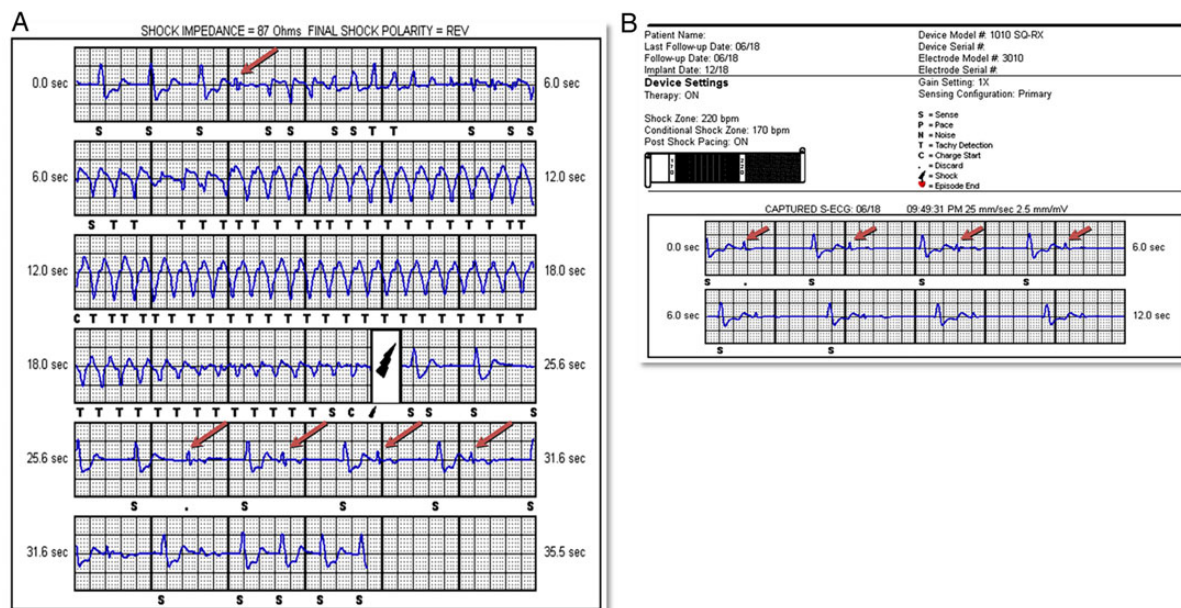
ischaemia, bundle branch block with QRS delay, and depolarization abnormalities, as well as by anatomical variations and posture, which may affect the relationship between cardiac position and sensing electrodes.

The original estimate longevity of the S-ICD was 5 years. In 2011, the initial developer of the S-ICD (Cameron Health) announced a medical device alert regarding premature battery depletion on their production device, which affected 9% of implants.<sup>9</sup> A second-generation device (the EMBLEM™ S-ICD System) has gone into production after approval by the relevant authorities. This defibrillator is 20% thinner than its predecessor and is projected to last 40% longer than the previous S-ICD system. The estimated longevity has been extended from 5 to 7.3 years.

An important limitation of the device in some regions remains the cost. In Europe, the price of the device is significantly higher than a standard single chamber transvenous ICD. The EFFORTLESS S-ICD Registry was designed to study quality of life and long-term resource utilization, but at the time of this writing, cost effectiveness analysis is not available. An important potential advantage of a device that does not contact cardiac tissue is magnetic resonance imaging (MRI) safety. Magnetic resonance imaging scanning with the S-ICD does appear feasible, but larger studies are necessary to confirm this. A cohort of 15 patients underwent a total of 22 MRI scans utilizing a 1.5 T magnet has been published, and no incident or device malfunction was observed.

## Detection and defibrillation

Since the S-ICD does not provide standard bradycardia pacing, it is not required to classify each individual cardiac event (Figure 3). Sensing and detection involve three steps. First, the sensed event detection phase identifies a QRS event and applies blanking and signal decay in an effort to avoid T-wave oversensing, in a process analogous to that used in TV-ICDs. It additionally includes filtering with a bandpass and notch filter. The notch filter is specific to geography (since different countries use either 50 or 60 Hz current) and is programmed based on the time zone selected in the programmer. Second, a certification phase employs algorithms that distinguish QRS electrograms from electromagnetic interference, myopotentials, T waves, and R-wave double counting. Lastly, during the rhythm decision phase, classification occurs using only on the corrected rate and duration [ventricular fibrillation (VF) zone] or the rate, duration, and morphology and QRS width compared with a baseline normal template (conditional zone). The conditional zone also uses a dynamic beat to beat analysis. With simulation-based assessment, the S-ICD's specificity for supraventricular arrhythmia discrimination is superior than that of the single- and dual-chamber TV-ICDs.<sup>10</sup> In practice, however, the inappropriate shock rate of the S-ICD is approximately twice that of the TV-ICD, predominantly due to T-wave oversensing. This rate has progressively declined with software refinements and systematic use of the conditional zone (discussed below).



**Figure 3** Subcutaneous implantable cardioverter defibrillator episode. (A) The initial rhythm is sinus with unifocal polyvinyl chlorides (PVCs), which in this sensing configuration are smaller than the normally conducted QRS complex. The first PVC (arrow) leads to polymorphic VT for ~4 s which then organizes to become monomorphic VT. Note the absence of markers for some of the electrograms recorded between 3 and 6 s. The rhythm is variable and the device is trying to 'catch up' with the high and low amplitudes presented. This is appropriate behaviour based on the slow rate detection profile that is in play. This algorithm is analogous to the automatic gain control used in transvenous devices. The device functioned appropriately with a return to sinus rhythm. S, sensed ventricular event in the normal heart rate range; T, tachycardia event. (B) Sinus rhythm with bigeminal PVCs, with morphology similar to stored episode initial PVC. The PVCs are not sensed—this is normal function.

During initial clinical testing, the S-ICD defibrillation threshold was confirmed to be significantly higher than TV-ICD (around 36 J compared with 11 J).<sup>8</sup> In light of this, the default shock delivered is 80 J, the maximum output. Polarity is programmable but will automatically reverse upon shock failure. At implant, VF is typically induced and a shock of 65 J delivered, thereby establishing a safety margin for defibrillation of 15 J. The average time from initial detection to an 80 J shock delivery is ~15 s.<sup>8,11,12</sup> Transthoracic anti-bradycardia ventricular pacing can be provided for up to 30 s after a shock if bradycardia is present (Figure 2).

## Patient selection, screening, programming, and troubleshooting

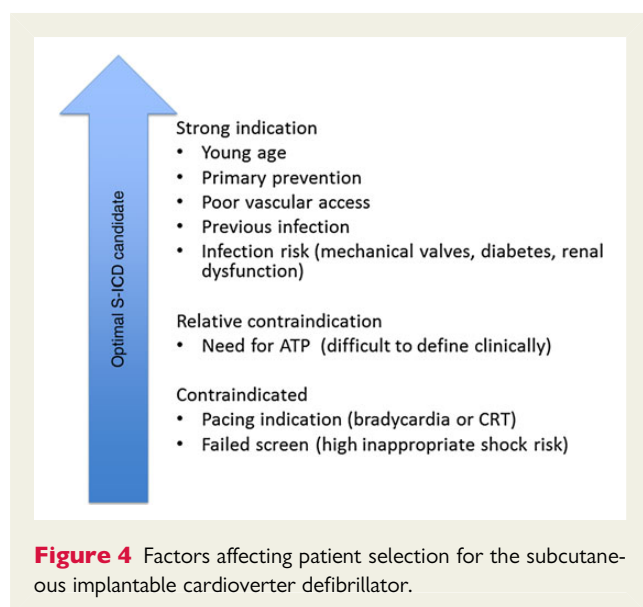
### Patient selection

Most ICD candidates with a primary prevention indication are suitable S-ICD recipients (Figure 4). Patients who require chronic pacing due to sinus node or atrioventricular node dysfunction should not be considered for the S-ICD. However, if a pacing need is absent at the time of implantation, the likelihood of developing such a requirement appears low.<sup>13,14</sup> While clinical experience is extremely limited, should an indication for right ventricular pacing develop post-S-ICD implant, a transvenous or leadless pacemaker may be

inserted. Patients with significant ventricular dyssynchrony related to a wide-left bundle branch block (QRS > 150 ms) with ejection fraction 35% or less who would benefit from cardiac resynchronization therapy (CRT) based on symptoms are better served with a CRT device. The importance of anti-tachycardia pacing (ATP) as an indication for a transvenous ICD remains controversial; while ATP is clinically effective, prolonging detection time or using a high rate cut-off may be equally effective, and predicting which individuals will benefit from ATP remains challenging. Utilizing data from SCD-HeFT,<sup>15</sup> ATP-terminated monomorphic tachycardia was found to be rare—occurring <2% per annum—which is interestingly less than the rate of failure of a transvenous lead.<sup>16</sup> Adenosine triphosphate itself does not appear to be without risk, and an analysis from the Altitude Study Investigators using data from the Latitude remote monitoring database recently provided concerning data that higher mortality was associated with ATP-treated ventricular tachycardia (VT) which accelerated the presenting ventricular arrhythmia.<sup>17</sup> Furthermore, one can argue that in the more recent era of higher detection rate programming for ICD's, and based on the results of the MADIT-RIT study,<sup>18</sup> several fold less ATP was utilized in the group with the higher rate detection zones. Importantly, this group sustained less shocks and a significantly lower mortality. These higher detection rate zones are standard for the S-ICD.

Nevertheless, patient selection has been slanted towards patients with prior ICD system infections, secondary prevention, or anatomy





with arteriovenous mixing placing the patient at risk for thromboembolic stroke from lead thrombus.<sup>19</sup> However, it may be that primary prevention ICD patients may stand to benefit more from the S-ICD, based on the unique extrathoracic position and the potential for less vascular and bloodstream complications. It is well recognized that even though many patient lives are saved in this group by primary prevention ICD therapy, a large proportion do not ever sustain a single episode of life-threatening ventricular arrhythmia. Until risk stratification for primary prevention improves, one can, therefore, argue that this latter group is exposed to less potential harm, in the absence of any clear benefit from the ICD.

## Screening

Pre-implant screening utilizing surface electrodes prior to device implantation is a crucial element in the clinical application of the S-ICD (Figure 5). Due to the high risk of inappropriate shock from T-wave oversensing, patients who fail the screen are not implanted with the S-ICD. Several groups have evaluated S-ICD eligibility based on standard screening approaches demonstrating that between 7 and 10% of patients fail, with a trend towards more ineligible patients when hypertrophic cardiomyopathy (HCM) or congenital heart disease is present.<sup>20–22</sup> Screening at rest as well as during exercise testing has been proposed to avoid oversensing of the T wave.<sup>23</sup> An elegant review of inappropriate S-ICD shocks found that seven of the eight T-wave oversensing events occurred during exercise and one during atrial fibrillation with a rapid ventricular response.<sup>23</sup> This prompted the investigators to evaluate all patients with inappropriate shocks due to T-wave oversensing with an exercise test during which each of the sensing vectors was assessed, and exercise repeated using the best vector. After optimization and template formation, no recurrent T-wave oversensing events occurred with follow-up beyond 1 year. This group, therefore, proposed an exercise screening test for patients at high risk of T-wave oversensing (right bundle branch block, digoxin use, and abnormal repolarization).<sup>23</sup> Unfortunately, there are still some patients with rate-related

aberrancy in whom T-wave oversensing cannot be reproducibly induced with an exercise test.

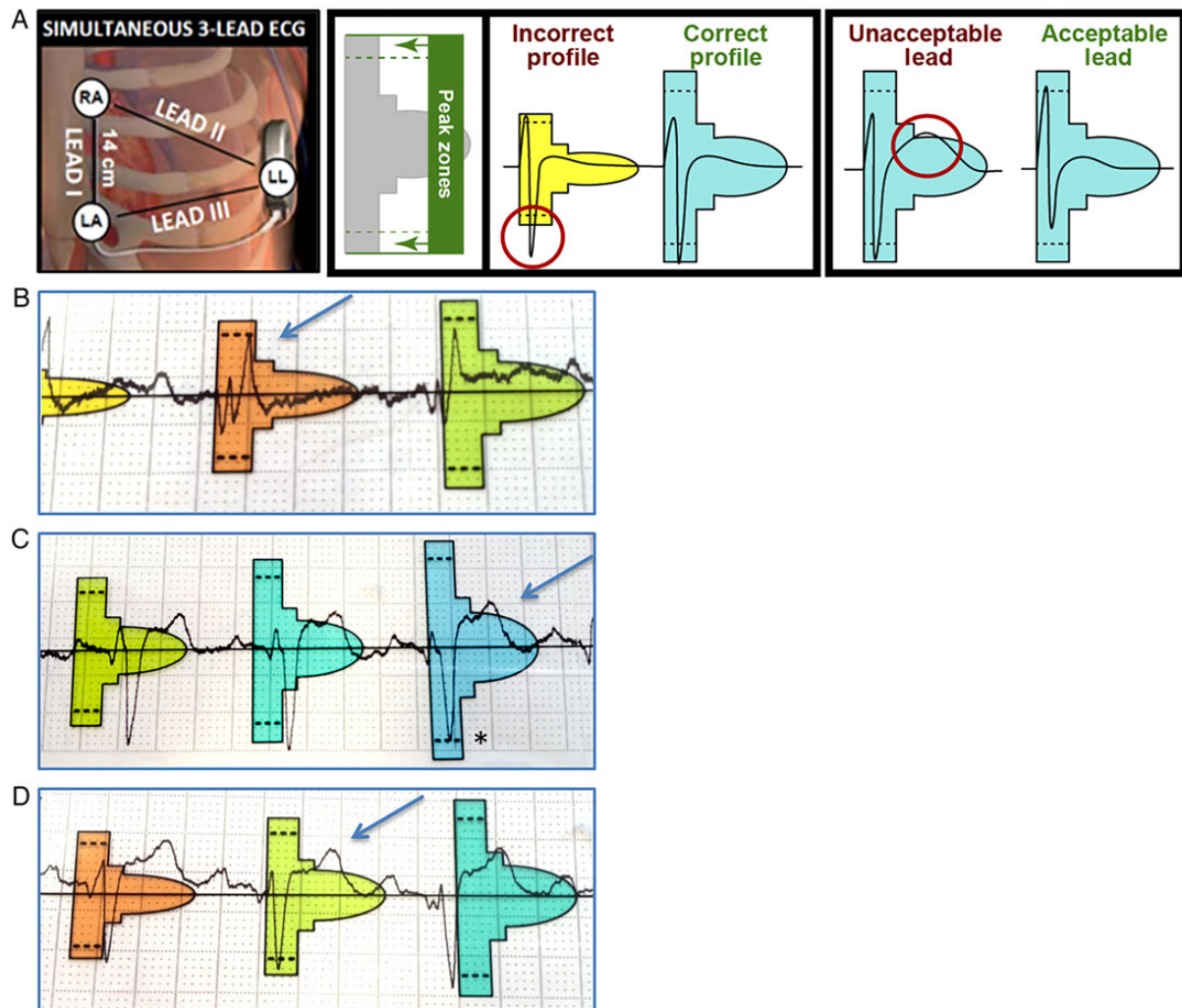
## Programming and troubleshooting

The S-ICD was designed to be highly automated. In contrast to TV-ICDs, which typically have over 100 programmable parameters,<sup>24</sup> the S-ICD has under 10. These include sensing vector, detection rate for each of two zones, and post shock pacing (on or off). Polarity of next shock and time delay to shock (smart charge) can be manually reset but will automatically adjust during operation. During early clinical experience, a single detection zone below 200 b.p.m. was programmed without rhythm discrimination, with inappropriate shock rates of ~20% at 3 years.<sup>25</sup> The introduction of dual-zone programming cuts the inappropriate shock rate at 3 years to 11.7%.<sup>25</sup> Analysis of the IDE trial data supports the important role of dual-zone programming, which resulted in a 70% reduction in inappropriate shocks for SVT compared with single zone programming.<sup>26</sup> TV-ICD trials have demonstrated the importance of higher detection rates and prolonged detection for shock reduction<sup>18,27</sup> and suggest that shocks may be related to unfavourable outcome.<sup>15,28</sup> A conditional detection zone at 200 b.p.m. and a non-conditional zone at 220 or 230 b.p.m. should be recommended.

Troubleshooting begins before implantation, with the ECG screen, as outlined above. When a patient presents with an inappropriate shock, review of the stored episode electrograms usually identifies the cause (Figures 6 and 7). Review of the chest X ray is helpful to insure lead position stability, but uncommonly identifies the cause (Figure 7). Interventions to prevent recurrent inappropriate shocks involve optimizing the sensing vector, adding a conditional zone if not present, modifying the detection rate, storing a baseline template during exercise testing, and addition of anti-arrhythmic drugs and occasionally, ablation (Figure 3). Rarely, surgical intervention to reposition the lead or pulse generator may be used. Anecdotally, S-ICD lead contact with sternotomy wires may lead to noise and inappropriate shock.

## Implantation techniques and considerations

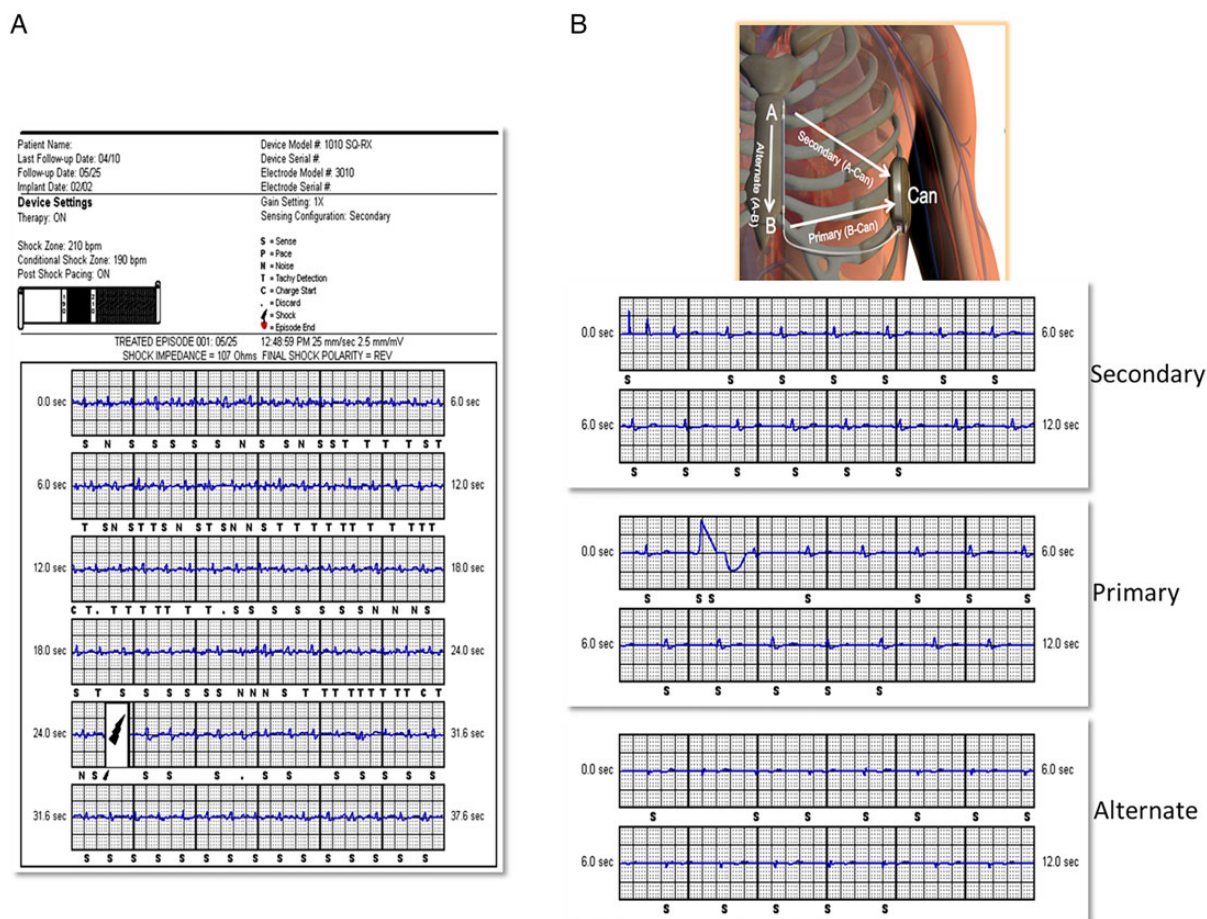
Implantation of the S-ICD is performed using a two or three incision approach. The greatest clinical experience is with the three incision approach, used in ~4000 implants. The implant technique is demonstrated in the Supplementary material online, Video S1. The initial incision is performed laterally, adjacent to the inframammary crease, between the anterior and mid-axillary lines at the level of the fifth or sixth intercostal space and is utilized to create the generator pocket. A second 1–1.5 cm incision is placed horizontally starting at the xiphoid at the midline, directed leftwards. A proprietary tool is employed to tunnel the lead from the device pocket to the xyphisternal incision. The electrode is secured at the xyphisternal incision with a suture sleeve. A similar process is then used to deliver the lead cephalad via a second tunnelling procedure parallel to the sternum, exiting out of a third superior incision (placed at the sternomanubrial junction). The lead is thus anchored at all three incision sites. A two-incision technique has also been developed and applied in hundreds of patients.<sup>29</sup> This approach does not require a



**Figure 5** Subcutaneous implantable cardioverter defibrillator implant screening. Electrocardiogram leads are placed: 1 cm lateral to the xiphoid process, 14 cm cranial to the xiphoid process, and either the fifth or sixth intercostal space on the left mid-axillary line. A ground electrode is also placed. The electrode configuration is designed to mimic the sensing vectors of the subcutaneous implantable cardioverter defibrillator. The screening electrograms are obtained in the supine and upright positions at gains of 5, 10, and 20 mV for a period of 10 s, and utilizing a template tool provided by the manufacturer, the waveforms are analysed—passing if only a single lead consistently falls within the designated area throughout a 10 s period (in both positions). (A) The position of the electrocardiogram leads during the screening process mimics the position of the defibrillator lead electrodes and generator. A far field electrocardiogram type waveform is generated and this is analysed with the use of the template tool provided by the company—to determine whether the sensing algorithm reliably detects QRS waveforms vs. P or T wave. (B) An example of a waveform which is acceptable, compared with (C) or (D) that show failure of screening based on the amplitude of T wave. The arrow indicates the complex being evaluated. In each case, note that the QRS complex amplitude fits between the dashed line and top or bottom of the template, asterisk in Figure C.

superior parasternal incision but instead utilizes a standard 11Fr peel-away sheath to deliver the lead from the xiphoid incision in a cephalad direction parallel to the sternum. By avoiding the superior chest incision, the risk of infection and pain associated with it are eliminated, but potentially at the cost of increased dislodgement as the lead is not affixed superiorly. Dislodgement has been rare in the early two-incision experience.<sup>23</sup> Since the superior incision is higher on the chest and more visible, its elimination is cosmetically appealing for some patients.

Although bacteraemia essentially has been eliminated with the use of the subcutaneous ICD, the risk of infection remains. The 2-year results from a pooled analysis of the IDE study and EFFORTLESS registry identified infection as the most common complication,<sup>25</sup> although S-ICD-related bacteraemia did not occur. Infection requiring surgical revision occurred in almost 2% of patients, and inadequate or prolonged healing or incisional, superficial infection occurred in another 0.6% of patients. Operator experience with implantation and management decreases infection rates and complications.<sup>25</sup> Since the S-ICD



**Figure 6** Inappropriate shock during sinus tachycardia. (A) The patient's rhythm was a sinus tachycardia throughout the recording with rates of 150–160 b.p.m. with a narrow QRS morphology. Baseline noise resulted in inappropriate tachycardia detection. The noise algorithm is active, indicated by the 'N' markers. However, in this case, the algorithm was unable to discern noise from true cardiac events, resulting in inappropriate shock delivery. Note that the sensing vector in use during the event was the secondary configuration, which spans the pectoralis muscle and may be more susceptible to noise. (B) Electrograms were checked in all three sensing configurations. Note that the alternate configuration, over the sternum, has the smallest amplitude, while the primary vector, which passes through less of the pectoralis, in this case provides a cleaner signal. The patient was reprogrammed to the primary vector.

is placed laterally in an infra-axillary location, shaving of the axilla and prepping widely may decrease infection risk. Whether the two-incision approach lowers the infection rate is not known. By its design, the S-ICD eliminates the risk of pericardial effusion and pneumothorax, while other acute major complications such as haematoma appear similar to that of the TV-ICD.

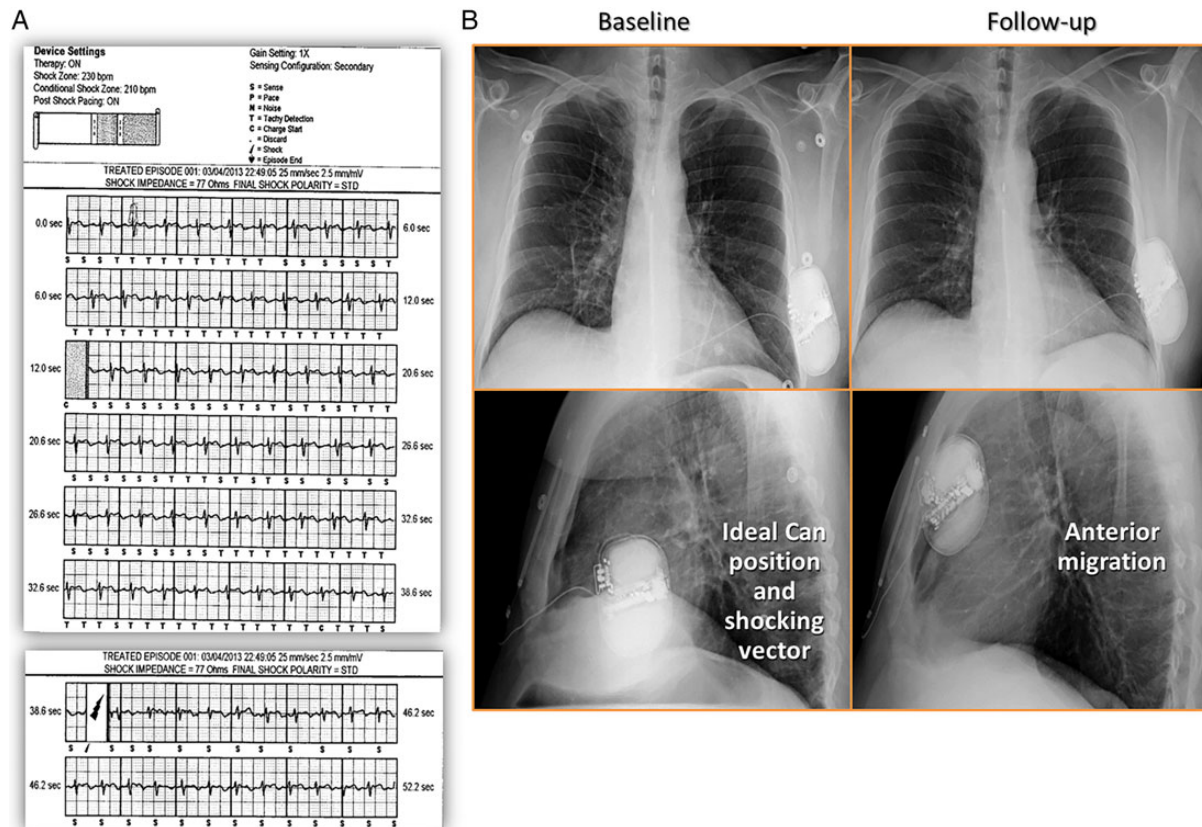
Nineteen of the 900 patients in worldwide registry have undergone implantation of a S-ICD despite the presence of a pre-existing bipolar pacemaker.<sup>25</sup> These patients underwent defibrillation testing at maximum output and with asynchronous mode pacing, and in follow-up, they were not found to have any high incidence of complications.

## Results of the clinical trials

Over the past decade, the S-ICD has been studied extensively using both prospective and retrospective approaches (Figure 8). The initial

clinical investigation<sup>8</sup> evaluated the defibrillation efficacy of various device configurations in 78 patients compared with a standard TV-ICD system to identify the optimal lead position for subcutaneous defibrillation. This study found that the S-ICD could reliably terminate induced and spontaneous VF, but that it required significantly more energy ( $36 \pm 19$  vs.  $11 \pm 9$  J) than a TV-ICD ( $11.1 \pm 8.5$  J). Longer term follow-up was evaluated in 55 patients over  $10 \pm 1$  months. Defibrillation testing was successful in all patients, and spontaneous sustained ventricular tachyarrhythmias were successfully detected and treated in all 12 episodes. Clinically significant adverse events included two pocket infections and four lead revisions. The ability of the device algorithm to recognize ventricular arrhythmias appropriately has been tested in a simulated environment against conventional single- and dual-chamber TV-ICDs in the START study.<sup>10</sup> In 64 patients, 46 ventricular and 50 atrial arrhythmias with ventricular rates  $>170$  b.p.m. were recorded by both





**Figure 7** T-wave oversensing leading to inappropriate shock. (A) Sinus tachycardia is present, and T wave is oversensed, leading the subcutaneous implantable cardioverter defibrillator to inappropriately calculate a heart rate in the tachycardia (T) zone. T-wave oversensing resulted in an inappropriate shock, following which the T waves are no longer oversensed. (B) Comparison of the post-implant baseline X ray with the follow-up film obtained after subcutaneous implantable cardioverter defibrillator shock demonstrates anterior migration of the subcutaneous implantable cardioverter defibrillator pulse generator. Since the pulse generator was part of the sensing vector, this likely resulted in the oversensing. Reprogramming to a different vector eliminated T-wave oversensing, and defibrillation testing confirmed efficacy.

S-ICD and TV-ICD leads. Appropriate detection of ventricular tachyarrhythmias occurred in 100% of S-ICD cases compared with >99% for the various TV-ICD devices.

The safety and efficacy of the S-ICD has been assessed in a number of studies (Figure 8). In the prospective multi-centre US IDE trial,<sup>11</sup> S-ICD implantation was attempted in 321 patients and successful in 314. Patients were followed up for a mean duration of 11 months. The 180-day system complication-free rate was 99% and induced VF was successfully terminated in all patients. All spontaneous ventricular arrhythmias were successfully converted; 13% of patients received an inappropriate shock. Eleven patients were withdrawn for S-ICD explantation, four of which were due to infection. Overall, a total of 18 patients experienced system infection, but no infections requiring explantation occurred in the final two-thirds of enrolment, highlighting the importance of proper patient preparation and operator experience. The 2-year results from the worldwide EFFORTLESS S-ICD Registry pooled together with the US IDE study were recently published.<sup>25</sup> This report provides comprehensive data on almost 900 patients. Spontaneous ventricular tachyarrhythmias were treated during 111 events, successfully in 98.2%,

with a minority requiring more than a single shock. The estimated 3-year inappropriate shock rate was ~13% with the majority occurring for T-wave oversensing (39%) or supraventricular tachycardia (24%). Device-related complications occurred in 11% of patients at 3 years, with no electrode failures and no systemic S-ICD-related infections. More specifically, this registry data provided the most complete description of real-world complications. Infection, without bacteraemia, appears to be the most common complication, while more experience with implantation and technique improvements were associated with reduced rates. Importantly, the major complication rates (haematoma, lead/device malposition/displacement) occurred in only 2% of patients—half of what is seen in some of the single- and dual-chamber ICD registries.<sup>25</sup> An ongoing randomized, multi-centre, prospective two-arm trial (PRAETOR-IAN)<sup>30</sup> is aimed at comparing the S-ICD with the TV-ICD with respect to inappropriate shocks and ICD-related complications, with the secondary endpoints of shock efficacy and patient mortality.

Two-year data from the registry mentioned above interestingly identified 125 episodes of VT/VF that self-terminated without associated syncope or mortality. This alludes to the reliability of the



		Olde Nordkamp, et al. 2012	Jarman, et al. 2013	Weiss, et al. 2013	Kobe, et al. 2013	Lambiase, et al. 2014
		multicenter, retrospective	multicenter, retrospective	multicenter, prospective	multicenter, prospective, matched control	multicenter, prospective/retrospective
n		118	111	321	69	472 (P 241/ R 231)
age		50±14	33 (10-87)	52±16	46±16	49±18
Follow-up		18±7 months	13±7 months	330 (17-715) days	217±138 days	558 (13-1342) days
Induced VF 65J	%	100%	100%	acute 100%; chronic 96%	95.5% (initial polarity 89.5%)	95%
Induced VF 80J	%	-	-	chronic 100%	-	99.7%
Spontaneous VT/VF	%	98.00%	100%	97%	100%	96%
Infection or skin erosion	n	9	11	6	1	18
Lead/Device Reposition	n	3	1	0	0	6
Inappropriate Shock	%	12.7%	15.3%	13.1%	7.2%	6.8%
Due to TWO	n	9	11	~22	3	~18
Due to SVT	n	1	1	16	0	7
Due to noise	n	1	5	3	2	4
Death	n	2 (cancer and heart failure)	1	8	1 (heart failure) (& 1 missing)	2

**Figure 8** Table summarizing studies of the SICD.

S-ICD algorithm deliberately delaying therapies in a time-dependent manner and thereby avoiding unnecessary shocks safely.<sup>25</sup> Delayed detection times of ventricular arrhythmias have been noted in small cohort studies, yet this does not appear to translate into any measurable morbidity or mortality from this particular device.

## Experience in specific syndromes and populations

### Experience in children

Despite the large generator size, the S-ICD has been placed in numerous children with channelopathies, cardiomyopathies, and congenital heart disease. On balance, the device implantation/operative complications appear to be fairly similar compared with other age groups.<sup>31,32</sup> One series has noted higher rates of inappropriate shocks due to T-wave oversensing,<sup>32</sup> yet newer programming approaches and software updates are likely to improve this rate significantly in this subset of patients.<sup>23</sup> Children and younger adults do typically sustain higher rates of inappropriate therapies due to sinus tachycardia and supraventricular tachycardia; the better discrimination ability in regards to these arrhythmias with the S-ICD holds promise for this group.

### Hypertrophic cardiomyopathy

Patients with HCM with an increased risk of sudden cardiac death frequently require ICD implantation at young ages. The S-ICD provides a potentially attractive treatment option, avoiding injury to the

vasculature in a group that uncommonly requires pacing. Whether the S-ICD provides equivalent defibrillation capacity in this group remains to be determined, yet eligibility for the S-ICD has been evaluated in a small cohort.<sup>33</sup> Abnormal T waves are commonly seen across this disease spectrum, providing obvious concern for inappropriate shocks from T-wave oversensing. Importantly, screening failure was found to be low in HCM patients, yet exercise was shown to unmask unsuitable patients formerly thought to be eligible at rest.<sup>33</sup> This suggests that all patients with severe ventricular hypertrophy, broad QRS, and abnormal T waves be thoroughly evaluated and that exercise screening be strongly considered.

## Conclusions and towards the future

The subcutaneous defibrillator represents an important advance in clinical medicine, offering life-saving defibrillation while limiting lead-related complications. Technical refinements including size reduction, increased battery longevity, and improved T-wave rejection will enhance its clinical utility. In the future, sufficient improvement in sensing function might eliminate the need for a separate screening ECG, enhancing clinical workflow and adoption. Patient care will also be tremendously augmented if the device can be utilized to record other cardiac activity: currently, there is no monitor zone, which can provide insight into slower ventricular or atrial arrhythmias and also chronotropy. Given its vantage point wrapped around the rib cage, much like a 12-lead electrocardiogram, we postulate that the S-ICD could serve as a remote monitoring hub to leverage emerging technologies to identify atrial fibrillation, acute ischaemia,

or electrolyte abnormalities.<sup>34,35</sup> The newest generation of S-ICD incorporates wireless connectivity to secure servers to deliver health-related information to remote caregivers. It has, however, been argued though that for a new therapy to be truly revolutionary, implantation and use should be simple, deployed at less cost and with non-inferior clinical outcomes.<sup>36</sup> Very few new therapies are initially significantly cheaper than their predecessors, and the S-ICD is not exception; however, with increased utilization, production volumes, and competition, much as with other cardiac implantable devices, cost will likely decline and functionality increase.

New therapies have been recently introduced or are emerging to overcome the current limitations of the S-ICD, and many more are in development. Coupling a subcutaneous ICD with a leadless cardiac pacemaker will overcome the current limited pacing support. Moreover, if the leadless pacemaker were epicardial, left atrial and left ventricular pacing could be introduced and linked to the S-ICD; alternatively use of a left ventricular seed would permit resynchronization.<sup>37</sup> With continued development, it is highly likely that within the next 5 years, a subcutaneous-based defibrillator will eliminate the system failures and medical problems currently associated with transvenous leads while offering the full complement of sudden death protection, resynchronization, anti-bradycardia pacing, and enhanced diagnostics for remote monitoring to transform the S-ICD into an integrated hub for health delivery that can be used for the long term.

## Authors' contributions

C.J.M., L.B., H.O., and P.A.F. performed statistical analysis; handled funding and supervision; acquired the data; conceived and designed the research; drafted the manuscript; and made critical revision of the manuscript for key intellectual content.

## Supplementary material

Supplementary material is available at *European Heart Journal* online.

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