

# The subcutaneous implantable cardioverter-defibrillator: A tertiary center experience

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## Abstract

**Background:** *The aim of the study was to evaluate subcutaneous implantable cardioverter-defibrillator (S-ICD) patients with regard to underlying etiology, peri-procedural outcome, appropriate/inappropriate shocks, and complications during follow-up.*

**Methods:** *All patients who underwent S-ICD implantation from February 2013 to March 2017 at an academic hospital in Vienna were included. Medical records were examined and follow-up interrogations of devices were conducted.*

**Results:** *A total of 79 S-ICD patients (58.2% males) with a mean age of  $44.5 \pm 17.2$  years were followed for a mean duration of  $12.8 \pm 13.7$  months. A majority of patients (58.2%) had S-ICD for primary prevention of sudden cardiac death. The most common of the 16 underlying etiologies were ischemic cardiomyopathy, non-ischemic cardiomyopathy, and idiopathic ventricular fibrillation. The lead was implanted to the left sternal border in 96.2% of cases, between muscular layers in 72.2%. Mean implant time was 45 min, 3 patients were induced, and all patients except one were programmed to two zones. Six (7.6%) patients experienced at least one appropriate therapy for ventricular arrhythmias and the time to first event ranged from 1 to 52 months. Seven patients experienced inappropriate shocks due to T-wave oversensing, atrial tachycardia with rapid atrioventricular conduction, external electromagnetic interference, and/or baseline oversensing due to lead movement. Four patients underwent revision for lead repositioning ( $n = 1$ ), loose device suture ( $n = 1$ ), and infection ( $n = 2$ ).*

**Conclusions:** *While S-ICDs are a feasible and effective treatment, issues remain with inappropriate shock and infection. (Cardiol J 2019; 26, 5: 543–549)*

**Key words:** arrhythmia, complication, subcutaneous implantable cardioverter-defibrillator, sudden cardiac death

## Introduction

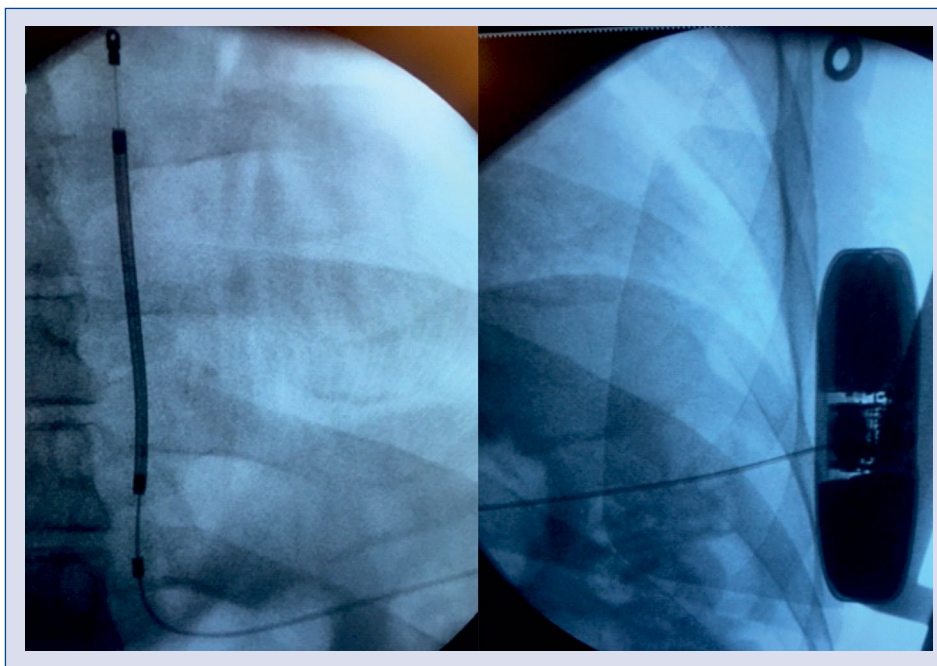
The entirely subcutaneous implantable cardioverter-defibrillator (S-ICD) offers an alternative to the transvenous/epicardial system in an effort to prevent sudden cardiac death. The advantages of implantation outside the thoracic cavity (Fig. 1) include: avoidance of cardiac complications (arrhythmias, perforation, tricuspid valve damage),

vessel-related problems (arterial puncture causing hematoma, venous thrombosis/obstruction), and tissue damage (pneumothorax, nerve palsus, shoulder dysfunction) [1]. Only brief fluoroscopy is needed to verify proper lead placement. The defibrillator lead is more robust and is expected to provide better long-term outcomes than transvenous leads, which manifest a 20% failure rate over 10 years and which extraction (if necessary) can bring serious complica-

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**Figure 1.** X-ray of the entirely subcutaneous implantable cardioverter-defibrillator system. Lead in the left sternal position and device in the left mid-axillary line.

tions, including death [2]. The use of an S-ICD is limited by its inability to provide antitachycardia pacing, cardiac resynchronization therapy, and bradycardia pacing, except for an immediate post-shock period; S-ICD systems are also comparatively expensive [1]. The pooled data from the landmark IDE and EFFORTLESS trials have proven the overall effectiveness of S-ICDs [3]. These promising results have been verified in external cohorts but further study in different settings is needed to justify more widespread use of S-ICD therapy [4–14].

The aim of this study was to evaluate patients who were implanted with an S-ICD at a tertiary center with regard to underlying etiology, peri-procedural outcome, appropriate/inappropriate shocks, and complications during follow-up.

## Methods

### Setting

The complete records of all S-ICD implants at Allgemeine Krankenhaus Wien, a University Hospital in Vienna, Austria were extracted from the database of the Medical University of Vienna, Department of Surgery, Division of Cardiac Surgery, Vienna, Austria. The first implant was performed in February, 2013 and the last in March, 2017.

### Data collection

Medical records were used to validate patient characteristics including the underlying etiology and follow-up. All device interrogations were stored in the database provided by Boston Scientific and evaluated for appropriate and inappropriate shocks.

### Ethics

The study complies with the Declaration of Helsinki and the local ethical committee approved the study.

### Variables

An appropriate therapy was defined as detection of ventricular tachycardia (VT) or ventricular fibrillation (VF) and subsequent shock. Inappropriate shocks were due to false classification of the arrhythmia (i.e. supraventricular tachycardias, oversensing of external signals, T-wave oversensing, or baseline drift due to movement of the lead tip). Prophylaxis after surviving cardiac arrest/VF or VT with hemodynamic compromise was a secondary prevention. Patients with a primary prevention indication were judged to be at an increased risk for life-threatening ventricular arrhythmias but without having had one.

## Statistical analysis

Numeric data were expressed as frequencies, percentages, means, and percentiles. Continuous variables were summarized as means, standard deviations (SDs), percentiles, and compared using t-tests. Fisher's test was used for categorical variables. A two-sided p-value of  $< 0.05$  was considered statistically significant. The database in Excel 2010 (Microsoft Corporation, Redmond, WA) was imported into SPSS version 22 (IBM, Armonk, NY).

## Results

### Patient characteristics

A total of 79 patients had an S-ICD implanted and were followed for a combined total of 1015 months (84.6 years). The follow-up time ranged from 3 days (3 patients were lost to follow-up) to 4.4 years, with a median of 7.0 months (mean  $12.8 \pm 13.7$  months). A majority were males ( $n = 46$ ; 58.2%). The median age at implant was 45 years (25<sup>th</sup> percentile 30 years and 75<sup>th</sup> percentile 57 years); mean age was  $44.5 \pm 17.2$  years with no significant sex difference (males 46.5 years and females 41.8 years;  $p = 0.217$ ).

Coronary artery disease was diagnosed in 21 (26.6%) patients and 11 (13.9%) patients had a history of atrial fibrillation at baseline or during follow-up. The underlying cardiac etiologies were cardiomyopathy in 45 patients (ischemic, non-ischemic dilated, peripartal, arrhythmogenic right ventricular, hypertrophic, and Takotsubo cardiomyopathy), amyloidosis in 1 patient, ion-channelopathies in 10 patients (Brugada syndrome and long QT syndrome), congenital disease in 5 patients (Ebstein's anomaly, Duchenne muscular dystrophy, Carnitine transporter deficiency), acquired structural heart disease in 2 patients (sarcoidosis, myocarditis), and idiopathic VF or nonsustained VT with syncope in 16 patients. Each etiology category with regard to primary ( $n = 46$ ; 58.2%) and secondary ( $n = 33$ ; 41.8%) indication prevention is reported in Table 1. The most common cause of implant for men was ischemic cardiomyopathy followed by dilated cardiomyopathy and for women idiopathic VT/VF and ischemic cardiomyopathy, respectively. Sex distribution with regard to primary (males 65.2%;  $n = 30/46$  and females 34.8%;  $n = 16/46$ ) and secondary indication — 48.5% ( $n = 16/33$ ) males and 51.5% ( $n = 17/33$ ) females which was not statistically different ( $p = 0.168$ ).

### Implant procedure

The subcutaneous lead was tunneled parallel to the left sternal border in 76 (96.2%) patients

and the remaining 3 cases were tunneled to the right based on preimplant screening. The S-ICD device was implanted between the muscular layers in 57 (72.2%) patients versus above the pectoral fascia in 22 (27.8%) patients. Early in the study, the 3-incision technique was sometimes used, but the 2-incision technique was used more frequently as the study progressed ( $n = 55$ , 69.6%).

Although the manufacturer recommends defibrillation threshold testing, it was performed in 1 of 3 patients. In all 3 cases, VF could be successfully induced (idiopathic VF, long QT syndrome, and ischemic cardiomyopathy).

Both the mean and median procedure times (skin-to-skin) were 45 min when performed without additional interventions such as bradycardia pacemaker implant, device extraction, epicardial leads, or concomitant tricuspid valve surgery.

### Programming

With one exception, all patients had two-zone programming. The lower zone was typically 200 bpm but was set to 190 bpm in 1 patient and 210 to 230 bpm in 14 patients, while the higher zone ranged 220–250 bpm. The primary vector was used in 57% ( $n = 45$ ), second vector in 32.9% ( $n = 26$ ), and alternative vector in 10.1% ( $n = 8$ ) upon hospital discharge. Notably, 10 patients switched from the primary to secondary vector after discharge, 2 patients from second to first vector, and 1 patient from alternate to primary vector. In 3 patients, the zones were changed during follow-up.

### Appropriate shock

Six (7.6%) patients experienced at least one appropriate therapy of VT/VF. In one of these patients there was an additional appropriate therapy. The annual incidence was 8.3% (7 episodes during 84.6 years, 83 events per 1000 years). In 6 out of 7 episodes the VT/VF converted at first attempt but in one episode a second shock (with reversed polarity) was needed.

The underlying etiologies of the 6 patients were ischemic cardiomyopathy ( $n = 3$ ), idiopathic VF ( $n = 2$ ), and arrhythmogenic right ventricular cardiomyopathy ( $n = 1$ ). In 5 of these patients the indication for the S-ICD was secondary prevention and in one, primary prevention. The time to first event ranged from 1 to 52 months.

### Inappropriate shock and complications

Seven patients experienced inappropriate shocks due to T-wave oversensing, atrial tachycardia with rapid atrioventricular conduction,

**Table 1.** Underlying etiology and primary versus secondary indication of 79 patients with an subcutaneous implantable cardioverter-defibrillator (S-ICD).

Etiology	Primary (n = 46)	Secondary (n = 33)	Total (n = 79)
Ischemic cardiomyopathy	16	6	22 (27.8%)
Non-ischemic dilated cardiomyopathy	7	4	11 (13.9%)
Peripartum cardiomyopathy	1	0	1 (1.3%)
Arrhythmogenic right ventricular cardiomyopathy	4	1	5 (6.3%)
Hypertrophic cardiomyopathy	4	1	5 (6.3%)
Takotsubo cardiomyopathy	0	1	1 (1.3%)
Amyloidosis	1	0	1 (1.3%)
Duchenne muscular dystrophy	1	0	1 (1.3%)
Carnitine transporter deficiency	0	1	1 (1.3%)
Ebstein’s anomaly	2	1	3 (3.8%)
Sarkoidosis	1	0	1 (1.3%)
Myocarditis	1	0	1 (1.3%)
Idiopathic ventricular fibrillation	0	15	15 (19.0%)
Idiopathic non-sustained ventricular tachycardia	1	0	1 (1.3%)
Long QT syndrome	3	3	6 (7.6%)
Brugada syndrome	4	0	4 (5.1%)

**Table 2.** Inappropriate subcutaneous implantable cardioverter-defibrillator (S-ICD) shocks: patient characteristics and causes.

Sex, age at shock	Etiology	Prevention	Reason
Female, 51 years	Idiopathic ventricular fibrillation	Secondary	T-wave oversensing due to decreased R-wave and change in morphology
Male, 69 years	Ischemic cardiomyopathy	Primary	Atrial tachycardia with rapid atrioventricular conduction
Female, 13 years	Hypertrophic cardiomyopathy	Secondary	T-wave oversense due to decreased R-wave and change in morphology
Female, 31 years	Idiopathic ventricular fibrillation	Secondary	Atrial tachycardia with rapid atrioventricular conduction after appropriate shock of ventricular tachycardia
Male, 41 years	Cardiac sarcoidosis	Primary	External electromagnetic inference in the bathroom
Male, 18 years	Long QT syndrome	Secondary	Oversensing of myopotentials due to lead movement (two incision technique)
Male, 54 years	Ischemic cardiomyopathy	Primary	Baseline oversensing of myopotentials due to lead movement (two incision technique)

external electromagnetic interference, and baseline oversensing of myopotentials due to lead movement (Table 2). Notably, in the 2 cases of baseline oversensing, the lead tip moved and they were both implanted using the two-incision technique (Table 1).

Four patients underwent revision of the S-ICD system. In 1 case lead position was checked on X-ray and deemed unacceptable. The incisions

were closed so it had to be re-opened in order to reposition the lead. In another case, the device suture in the pocket ripped off and had to be re-sewn. Furthermore, there were 2 cases of infection requiring explantation; 1 patient had no known risk factors for infection and the other was a diabetic on dialysis. One patient with severe amyloidosis died 2 months after implant but no post-mortem interrogation was performed.

## Discussion

This large sample confirms the age- and sex distribution of S-ICD reported in trials and other cohorts [3–14]. This is expected in a tertiary center sample where the underlying etiologies can vary and include rare diagnoses.

The relatively young age of S-ICD cohorts may be explained by the fact that physicians may be more likely to recommend these devices to patients with long life expectancies, who are able to pay higher device costs, and who may want to avoid adding hardware to the vasculature.

The lower percentage of females has been noted in several S-ICD studies and this cohort shares this finding [3–14].

### S-ICD therapy is effective

The 6 patients who experienced therapy were all converted in 7 episodes of VT/VF, which emphasizes the efficacy demonstrated by all major S-ICD cohorts [3–14]. This 7.6% proportion of patients during a mean follow-up of 12.8 months is in line with previous findings from diverse cohorts and the EFFORTLESS pooled data reported 5.3%, 7.9%, and 11.8% at 1, 2, and 3 years cumulative incidence of first appropriate therapy, respectively [3]. However, it should be remembered that not every appropriate therapy is indeed lifesaving, as ventricular arrhythmias may be self-terminating. Based on the MADIT-RIT study of transvenous ICDs, antitachycardia pacing was delivered to 22% of patients with conventional programming, 8% with high-rate programming, and 4% with delayed programming. However there was no difference among these three groups over 1.4 years with respect to the rate of shock therapy [15].

In the S-ICD, the 18/24 interval is fixed and the time to therapy is longer than in transvenous-ICDs, with overall time to shock therapy being about the same as modern transvenous-ICD programming.

### Inappropriate shocks do occur but may be avoided

Seven (8.9%) patients were affected by inappropriate shocks. This is in the lower range of other reported S-ICD cohorts [3–14]. The pooled analysis of IDE and EFFORTLESS registries reported 13.1% inappropriate shocks at 3 years; notably, 11.7% inappropriate shocks in dual-zone programming and 20.5% in single-zone programming [3]. The dual-zone allows discrimination based on QRS morphology in order to prevent shock due to supraventricular tachycardias [16]. The lower

incidence of inappropriate shocks in our cohort may be the result of adherence to manufacturer recommendations of prescreening and use of high-specificity sensing algorithms for supraventricular tachycardias [16].

Hypertrophic cardiomyopathy patients may fail the prerequisite of providing a QRS and T-wave morphology template and, in fact, 15% of patients in another study were ruled ineligible for this reason [16, 17]. However, T-wave oversensing remains a problem (2 patients in the present study) and was the most frequently encountered reason (39%) for inappropriate shock in the EFFORTLESS registry [3] and its risk is increased with hypertrophic cardiomyopathy [10]. There are ways to reduce the likelihood of T-wave oversensing, such as using exercise test settings and monitoring the reprogramming from secondary to primary (or alternative vector) configurations. T-wave oversensing is more likely with a low R/T ratio, bundle branch block, and repolarization abnormalities, which are most likely to occur during exercise [16]. A thorough preoperative screening is warranted and further improvement in the sensing algorithm would possibly decrease T-wave oversensing [18].

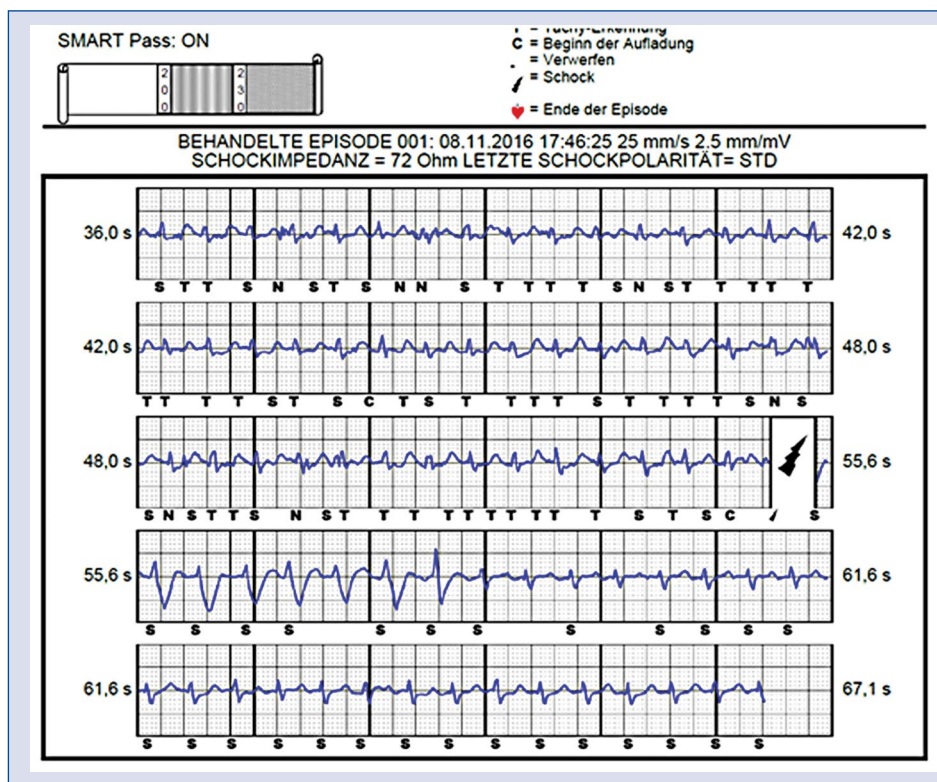
### Different spectrum of complications

The EFFORTLESS registry reports a 6.4% (1.7% infections) implant-related complications requiring surgical interventions during a mean follow-up of 558 days. Interestingly, there seems to be a learning curve in S-ICD implantation technique suggested by a decrease in complications over time [3].

Renal failure is prevalent in this population and is a known risk factor for infection in transvenous ICD recipients. In some S-ICD cohorts, 20% or more patients are on dialysis, a finding supported by a United States registry [19]. Note that compared to transvenous leads, S-ICD leads may be extracted with less risk to the patient.

Even though vascular access is not needed, surgical skills are important for proper lead placement and pocket formation. Intramuscular implant using blunt dissection in order to avoid skin erosion and discomfort [1, 20] is advocated herein. In the present cohort, mean implant time of 45 min was due to the fact that 96.2% of patients did not undergo defibrillation testing. In a study by Winter et al. [20], the average implant time was 65 minutes.

The two-incision technique was performed in 69.6% and has previously been described [1]. Nevertheless, the 2 cases of inappropriate shocks due to baseline oversensing called for careful attention in order to secure optimal long-term lead



**Figure 2.** Inappropriate subcutaneous implantable cardioverter-defibrillator (S-ICD) shock due to baseline oversensing caused by lead movement (two-incision technique).

placement (Fig. 2). This is similar to transvenous lead failure, which may impede appropriate shock but may also give rise to inappropriate shocks. Transvenous leads are susceptible to complications not only during implant but, unfortunately, increasingly so over time [2]. While there is still a risk of infection with an S-ICD system, endocarditis and myocardial/vessel damage may be ruled out. For this reason, an S-ICD may be a good choice for patients who had to have a transvenous ICD extracted due to infection.

**Strengths and weaknesses**

This study supports the use of S-ICD in selected patients who are at risk for sudden cardiac death, but short follow-up time remains a major limitation. To further compare S-ICD systems with transvenous ICDs, randomized controlled trials are needed to overcome the limitations of comparisons using historical cohorts or matched-controlled groups with heterogeneity in etiology, age, and comorbidities.

**Conclusions**

This patient cohort from a single tertiary center demonstrates the implant feasibility and therapeutic efficacy of the S-ICD, but inappropriate shocks and infection remain problems.

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