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Aims	The subcutaneous implantable cardioverter defibrillator (S-ICD) was introduced to overcome complications related to transvenous leads. Adoption of the S-ICD requires implanters to learn a new implantation technique. The aim of this study was to assess the learning curve for S-ICD implanters with respect to implant-related complications, procedure time, and inappropriate shocks (IASs).
Methods and results	In a pooled cohort from two clinical S-ICD databases, the IDE Trial and the EFFORTLESS Registry, complications, IASs at 180 days follow-up and implant procedure duration were assessed. Patients were grouped in quartiles based on experience of the implanter and Kaplan–Meier estimates of complication and IAS rates were calculated. A total of 882 patients implanted in 61 centres by 107 implanters with a median of 4 implants (IQR 1,8) were analysed. There were a total of 59 patients with complications and 48 patients with IAS. The complication rate decreased significantly from 9.8% in Quartile 1 (least experience) to 5.4% in Quartile 4 (most experience) ($P = 0.02$) and non-significantly for IAS from 7.9 to 4.8% ($P = 0.10$). Multivariable analysis demonstrated a hazard ratio of 0.78 ($P = 0.045$) for complications and 1.01 ($P = 0.958$) for IAS. Dual-zone programming increased with experience of the individual implanter ($P < 0.001$), which reduced IAS significantly in the multivariable model (HR 0.44, $P = 0.01$). Procedure time decreased from 75 to 65 min ($P < 0.001$). The complication rate and procedure time stabilized after Quartile 2 (>13 implants).
Conclusion	There is a short and significant learning curve associated with physicians adopting the S-ICD. Performance stabilizes after 13 implants.
Keywords	Implantable cardioverter-defibrillator • Subcutaneous implantable cardioverter-defibrillator • S-ICD • Learning curve • Complications • Inappropriate shock

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What's new

- There is a learning curve for physicians adopting the S-ICD.
- The complications rate decreased from 9.8 to 5.4%.
- Performance stabilizes after 13 implants.
- Inappropriate shocks (IASs) decreased during the study due to higher rates of dual-zone programming but were not related to physician experience.
- The use of dual-zone programming will help new implanters achieve low IAS rates.
- Procedure time stabilized at 65 min after 13 implants, which is similar to dual-chamber transvenous ICD implant durations.

Introduction

The subcutaneous implantable cardioverter defibrillator (S-ICD) was introduced to overcome complications related to transvenous leads. The available evidence from S-ICD studies shows a complication rate similar to transvenous implantable cardioverter defibrillator (ICD) therapy but includes the learning curve of Physicians becoming familiar with this new technology.[1–3]

It is widely accepted that increasing experience improves performance, particularly when adopting a new procedure. The introduction of the S-ICD required implanting physicians to adopt a new implant technique and different modes of ICD programming.[4,5] The pulse generator of the S-ICD is positioned in the left lateral axillary line on the chest wall and uses a subcutaneous sensing and defibrillation lead, whereas conventional transvenous ICDs use endocardial leads. The S-ICD requires more energy for defibrillation, which increases the size of the pulse generator. Tunnelling the lead in this new position and larger size of the pulse generator and pocket require a different surgical approach than for transvenous implants.

The association between operator experience and the impact on adverse events is well documented.[6] For cardiovascular procedures, operator training and volume have been associated with patient outcomes, including mortality in percutaneous coronary intervention procedures and infection and mechanical complications in transvenous ICD implants and replacements.[7–9] Olde Nordkamp *et al.* observed more inappropriate shocks (IASs) and complications in initial experience per implanting centre compared with later experience in a Dutch S-ICD cohort.[10]

The aim of this study was to assess the learning curve for individual S-ICD implanters with respect to implant-related complications, procedure time, and IASs. We hypothesized the presence of a learning curve with the introduction of the S-ICD. Therefore, complications, implant procedure duration, and IASs were expected to decrease with increasing experience of the implanter, with stabilization after a given learning interval.

Methods

Study cohort

The design of this pooled cohort has been described in detail elsewhere, but briefly: the pooled cohort consists of a total of 889 patients, 568 patients from the EFFORTLESS registry (NCT01085435), 308 from the IDE study (NCT01064076), and 13 patients who were in both studies.[1,11,12] Data were collected until 12 November 2013 for the ongoing EFFORTLESS registry. The IDE study follow-up ended on 14 February 2012. Participation in both studies complied with the Helsinki declaration and required approval of local ethics or institutional review boards and informed consent. The device programming, including the use of the morphology-based discrimination algorithm, was at the physicians' discretion.

Endpoints

Endpoints included in the analysis were complications, procedure time, and IASs. Complications were defined as those related to the implant procedure and required surgical intervention. Complications unrelated to the implant procedure that did require a surgical intervention were excluded (inability to communicate with the device $n = 1$, IASs $n = 12$, and premature battery depletion $n = 1$). Procedure time was collected for patients enrolled in the EFFORTLESS registry and was defined as the time between incision and closure of the wound (skin-to-skin time). Inappropriate shocks were defined as shocks for any reason but ventricular tachyarrhythmias. Classification of complications and treated events were reported by the site, and appropriateness of therapy or detection was adjudicated by the sponsor (EFFORTLESS) or Clinical Events Committee (IDE). The complication rate and IAS rate were assessed by calculating Kaplan–Meier estimates at 180 days post-implantation.

Experience

Outcomes with S-ICD therapy were analysed for individual implanter experience: per implanter, all patients were chronologically ranked and subsequently distributed in quartiles. The first quartile of patients represents the initial experience of implanters, whereas the last quartile represents implant procedures when implanters had the most experience. During the EFFORTLESS study, the device was commercially available in Europe outside of the study. Therefore, the manufacturer's device tracking database was used to adjust the implant ranking for implants done outside of the EFFORTLESS study per individual implanters. The data presented in this study only represent patients who participated in the EFFORTLESS or IDE study.

Statistical analysis

The appropriateness of pooling the two studies was assessed by evaluation of the study as a predictor of each endpoint. Descriptive statistics are reported using the mean $\pm$ standard deviation for continuous variables and numbers with percentages for dichotomous variables unless otherwise indicated. Differences in baseline characteristics were tested using a Student's *t*-test or ANOVA for parametric numerical variables and Fisher's exact test for dichotomous variables unless otherwise indicated. Kaplan–Meier analyses and log-rank test were used to assess event rates across groups.

Univariable models were fit to assess which patient and programming characteristics were associated with each of the three endpoints. Cox proportional hazard models were used for the outcomes of complications and IASs. A general linear model was fit for the outcome procedure time. Each variable that was significant at the 0.10 level was included as a candidate for the final multivariable model for each outcome. Backward selection was used in a multivariable Cox proportional hazards model with a significance level for retention in the model of 0.10. All statistical analyses were performed using SAS version 9.3 (SAS Institute, Cary, NC). *P* values of <0.05 were deemed statistically significant.

Results

Study population

From August 2009 to November 2013, 889 patients were enrolled in both studies. There was no evidence that endpoints significantly differed by study (complications *P* = 0.47, IASs 0.12). Procedure time was only collected in the EFFORTLESS registry.

Of these 889 patients (73% men, mean age 50 ± 17 years), 70% received an S-ICD for primary prevention and 38% had ischaemic heart disease. A total of 882 implants were performed in 61 implanting centres by 107 implanters with a median of 4 implants (IQR 1,8). The remaining seven patients were not implanted. Most implanters in this cohort performed a total of 4 implants (Quartile 1) and 11 implanters performed more than 28 implants (Quartile 4). Additionally, there were 187 implants outside the EFFORTLESS study identified in the manufacturer's device tracking database that were used to adjust the implant order per individual implanter. The patient characteristics per quartile of increasing implant experience are summarized in *Table 1*.

Complications

There were 59 patients with 72 complications at 180 days follow-up. Of these complications, infections and suboptimal implantation were most common (*Table 2*). The median time from implant to complication was 18 days (mean 45 ± 71). The complication rate decreased almost by half from 9.8 to 5.4% (*P* = 0.019) over the experience quartiles (*Figure 1*). The absolute risk reduction, therefore, was 4.4% between Quartiles 1 and 4, and the relative risk reduction was 44.8%. The largest decrease was seen between Q1 and Q2. The complication rate stabilized in Quartile 3, which represents >13 procedures per implanter and indicates the end of the learning

curve. In a Cox proportional hazard model for complications, increasing experience reduced the occurrence of complications per quartile (HR 0.78, *P* = 0.045, *Table 3*).

In the univariable model, there was a non-significant trend towards fewer complication over the years 2009–2013 (*P* = 0.07). However, implant year was not retained in the multivariable model (*Table 3*). Implant year also did not interact with physician experience (Supplementary material online, *Figure S1*). No individual complication type was observed to drive the decrease in complications (Supplementary material online, *Table S1*).

The complication rate in implanter's first four S-ICD patients for those who ended as relatively high-volume implanters (>5 implants, 50% of implanters) was compared with lower-volume implanters in the study (1–5 implants, 50% of implanters). Higher-volume implanters had a similar complication rate (9.4%, 95% CI 5.6–15.7%) in the first four implants to lower-volume implanters (10.2%, 95% CI 5.8–17.6%, *P* = 0.429).

Procedure time

A sub-analysis among 434 EFFORTLESS patients for whom skin-to-skin procedure time was available showed a decrease from ~75 ± 34 min in Quartile 1 to 65 ± 23 min in Quartile 4 (*P* < 0.001), which stabilized in Quartiles 3 and 4 (*Figure 2*). A generalized linear model for procedure time showed that the decrease in procedure time did not remain significant (*P* = 0.81) after adjustment for confounders: implant year, age, congenital heart disease, and prior ICD (*Table 4*).

Inappropriate shocks

In this cohort, there were a total of 107 IASs in 48 patients during the first 180 days. Seventy-one per cent of the IASs were related

Table 1 Patient characteristics per experience quartile

Characteristic (number of implants)	Quartiles				
	Q1 (1–4)	Q2 (5–12)	Q3 (13–28)	Q4 (>28)	*P* value
Number of patients	248	203	222	216	
Implanters[a]	95	48	25	11	
Age (years)	51.0 ± 17.0	47.3 ± 17.9	48.6 ± 16.4	53.9 ± 15.8	<0.001
Female (%)	62 (25.1)	54 (26.7)	65 (30.2)	60 (28.2)	0.653
Primary prevention (%)	180 (72.9)	135 (67.5)	145 (67.4)	150 (71.1)	0.503
QRS (ms)	107 ± 27	103 ± 21	104 ± 22	108 ± 25	0.224
LVEF (%)	38 ± 17	40 ± 18	42 ± 18	37 ± 17	0.59
BMI	28.5 ± 6.7	28.5 ± 7.2	28.0 ± 6.9	27.9 ± 5.6	0.764
Congestive heart failure (%)	128 (52.0)	80 (40.2)	73 (34.0)	88 (41.3)	0.001
AF (%)	40 (16.3)	23 (11.6)	40 (18.6)	40 (18.8)	0.154
NYHA Classes III and IV (%)	33 (26.8)	21 (28.8)	26 (44.1)	28 (38.9)	0.070
Diabetes (%)	62 (25.2)	25 (12.6)	33 (15.3)	36 (16.9)	0.004
COPD (%)	18 (7.3)	4 (2.0)	21 (9.8)	13 (6.1)	0.007
Hypertension (%)	129 (52.4)	70 (35.4)	71 (33.0)	61 (28.6)	<0.001
Dual-zone programming (%)	152 (64.1)	154 (79.0)	176 (83.4)	207 (95.8)	<0.001
Conditional zone rate	195 ± 20	201 ± 20	201 ± 21	195 ± 14	0.79

LVEF, left ventricular ejection fraction; BMI, body mass index; CHF, congestive heart failure; HCM, hypertrophic cardiomyopathy; AF, atrial fibrillation; NYHA, New York Heart Association classification; COPD, chronic obstructive pulmonary disease.
[a]Implanters can contribute to more than one quartile.

Table 2 Complications in the first 6 months

Description	Number of events
System infection	16
Electrode movement	7
Suboptimal electrode position	7
Erosion	5
Discomfort	4
Haematoma	4
Suboptimal pulse generator and electrode position	4
Adverse reaction to medication	3
Inadequate/prolonged healing of incision site	3
Incision/superficial infection	3
Pulse generator movement/revision	3
Suboptimal pulse generator position	2
Failed defibrillation threshold test	2
Acute hypoxic respiratory failure	1
Incomplete electrode connection to the device	1
Near syncope/dizziness/shortness of breath/confusion	1
Pleural effusion	1
Pneumothorax	1
Seroma	1
Suspected worsening of ischaemia	1
Suture discomfort	1
Undersensing	1
Grand total	**72**

Table 3 Multivariable Cox proportional hazard model for complications

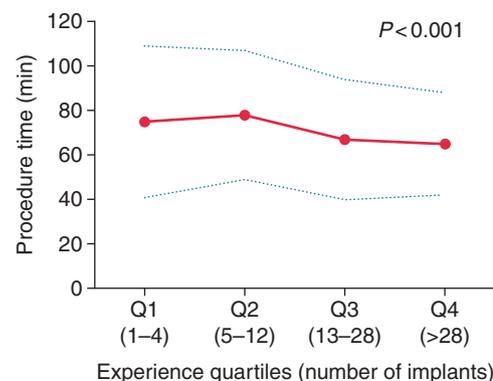| Characteristic	Hazard ratio (95% CI)	P value
Physician experience (per quartile)	0.78 (0.61, 0.99)	0.045
BMI (per 5 units)	1.15 (0.98, 1.34)	0.090
Age (per 5 years)	0.89 (0.82, 0.96)	0.005
Atrial fibrillation (yes vs. no)	1.91 (1.00, 3.67)	0.051

Figure 2 Skin-to-skin procedure time by experience quartiles. Q1: Experience Quartile 1 (implants 1–4); Q2: Experience Quartile 2 (implants 5–12); Q3: Experience Quartile 3 (implants 13–28); Q4: Experience Quartile 4 (implants >28). Solid line is mean, and dashed lines are ± 1 SD. P value is trend test.
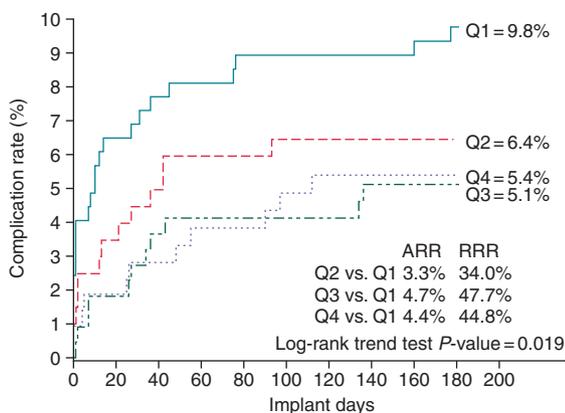

Figure 1 Kaplan−Meier analysis of experience quartiles and complications at 180 days. Q1: Experience Quartile 1 (implants 1–4); Q2: Experience Quartile 2 (implants 5–12); Q3: Experience Quartile 3 (implants 13–28); Q4: Experience Quartile 4 (implants >28); ARR, absolute risk reduction; RRR, relative risk reduction. P value is Kaplan−Meier trend test.

Table 4 Generalized linear model for procedure time

Characteristic	Effect (95% CI)	P value
Intercept	101.2 (91.1, 111.3)	<0.001
Physician quartile (per quartile)	0.3 (−2.4, 3.1)	0.807
Implant year (per year starting in 2009)	−6.7 (−9.2, −4.1)	<0.001
Age (per 5 years)	−1.7 (−2.4, −1.0)	<0.001
Congenital disease (yes vs. no)	26.1 (8.3, 43.9)	0.004
Prior ICD (yes vs. no)	8.9 (2.0, 15.8)	0.011

64 to 96% ($P < 0.001$). In a Cox proportional hazard model for IASs, increasing experience was not found to be a predictor for the decrease of IASs (HR 1.01, $P = 0.96$) (Table 5). However, dual-zone programming was significantly associated with fewer IASs (HR 0.44, $P = 0.01$).

Discussion

Main findings

This study describes the learning curve for individual S-ICD implanters in the two largest cohorts to date regarding implant-related complications, procedure duration, and IASs. The main finding of this study is
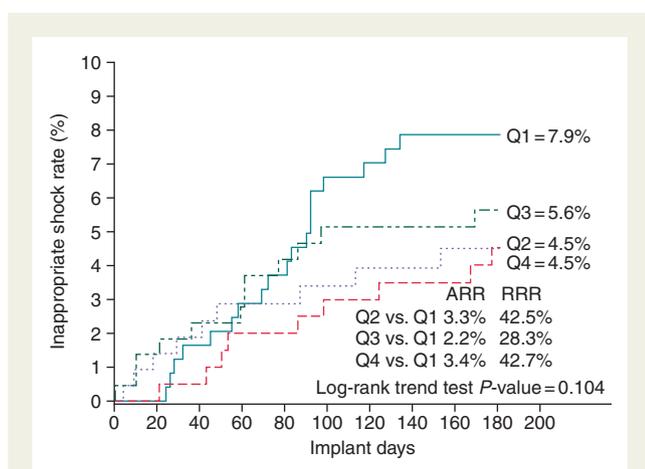
to cardiac oversensing, 19% to supraventricular tachycardias, and 10% to non-cardiac oversensing. The median time between implant and the occurrence of the first IAS was 98 days (141 ± 105). There was a non-significant trend towards fewer IASs from 7.9 to 4.5% from Quartile 1 to Quartile 4 ($P = 0.10$) (Figure 3). Dual-zone programming increased significantly over the experience quartiles from

Figure 3 Kaplan−Meier analysis of experience quartiles and IASs at 180 days. Q1: Experience Quartile 1 (implants 1−4); Q2: Experience Quartile 2 (implants 5−12); Q3: Experience Quartile 3 (implants 13−28); Q4: Experience Quartile 4 (implants >28); ARR, absolute risk reduction; RRR, relative risk reduction. *P* value is Kaplan−Meier trend test.

Table 5 Multivariable Cox proportional hazard model for IASs

Characteristic	Hazard ratio (95% CI)	P value
Physician quartile (per quartile)	1.01 (0.77, 1.32)	0.958
Age (per 5 years)	0.91 (0.83, 0.99)	0.028
Programming zones (dual vs. single)	0.44 (0.24, 0.82)	0.010
NYHA class (II−IV vs. I)	2.09 (1.13, 3.88)	0.020

that implant-related complications significantly decrease from 9.8 to 5.4% with increasing experience of the individual implanter, and stabilized in Quartile 3, which represents >13 procedures per implanter. The unadjusted procedure duration decreased over the experience quartiles, but it did not remain significant after multivariable adjustment for baseline characteristics. There was a non-significant decrease of IASs over the experience quartiles, which was primarily explained by the increase in dual-zone programming of the S-ICD.

Complications

The complication rate decreased almost by half when the earliest experience (Quartile 1: first four procedures per implanter) was compared with the latest experience in this cohort. The largest reduction was seen between Q1 and Q2, indicating that most of the learning happens in the implanter's first four cases. It is possible that this result was driven by individual physicians who had a low complication rate in their early experience vs. implanters that may have experienced a higher complication rate early and stopped implanting. To explore whether this effect was driven by individual physicians, the complication rate in the first four implants per individual implanter was assessed.

High-volume implanters had a similar complication rate in the first four implants as those who implanted fewer S-ICDs. This indicates that the complication rate during the earliest experience is similar for all implanters, and individual physicians who became high-volume implanters did not have a lower complication rate in their early experience. If the low-volume implanter would have continued to increase their experience, they may reduce their complication rate to the level of high-volume implanters.

In the 2-year follow-up of the combined EFFORTLESS and IDE study, which included the earliest commercial and investigational experiences, Burke *et al.* found a complication rate of 7.7% at 180 days.[1] That study showed that the complication rate reduced over time. In the current study with the same cohort, the difference in implant period did not remain significant in the multivariable model, whereas experience of the implanters did. Therefore, this analysis of the same cohort indicates that the complication rate of 7.7% was elevated by the early learning curve of individual implanters and that the rate for experienced implanters is lower.

Procedure time

The procedure time decreased significantly from 75 ± 34 to 65 ± 23 min over the experience quartiles in the unadjusted analysis (*Figure 2*). Interestingly, in the multivariable model, each increase in experience quartile did not significantly reduce procedure time, but each increment in implant year did. This indicates that the implant procedure has become more efficient over time, such as by the introduction of the two-incision technique that omits the superior parasternal incision.[13] In the unadjusted analysis, the procedure time increased in the second quartile to 78 min compared with 75 the first quartile, which may be explained by the presence of a proctor during implants in Q1. In the presumed implants without a proctor (Q2−Q4), the trend of reduction in procedure time reduction is clearer. When procedure time in Quartile 4 is compared with unpublished data from MADIT-CRT, it is longer than in single-chamber ICDs, 65 ± 23 vs. 51 ± 25 min, respectively ($P < 0.001$), and similar to dual-chamber ICDs 63 ± 30 min ($P = 0.414$).[14]

Inappropriate shocks

There was a non-significant trend towards fewer IASs with increasing experience of the individual implanter. In the multivariable model, this trend was caused by increased dual-zone programming over the experience quartiles. The discrimination algorithm in the conditional zone between 170 and 250 beats per minutes has proved to be equally good at detecting ventricular arrhythmias and superior with respect to discrimination of supraventricular arrhythmia in a head-to-head comparison study published in 2012.[5] Roughly half of the cohort of this study was implanted prior to this publication, which may explain the increase in dual-zone programming. The increased use of dual-zone programming can be considered as learning at a global level enabling knowledge to be transferred to new implanters. Potential other confounders such as discrimination algorithm improvements and reduction of myopotential oversensing after introduction of the suture sleeve may have contributed, but these variables were not collected in both studies. Improvement of the discrimination algorithm may continue to reduce the IAS shock rate but need to be proved in prospective studies.[15] Future

studies into programming of rate cut-off values for the conditional and unconditional zones are warranted in order to optimize sensitivity and specificity of the detection of ventricular arrhythmias.

Clinical implications

This study has several implications for training and instruction of new S-ICD implanters. First, we observed rapid improved performance by implanters resulting in a stable complication rate after 13 implants. The complication rate decreased for all implanters after four implants. Complications occurring during the early experience should encourage the implanter to analyse and adjust the workflow where needed and continue the learning process. Interruption of implants in response to complications stops the learning process and diminishes the impact of skills acquired up to that point.

There was no individual implanters learning curve with respect to IASs and procedure time. Strategies to reduce IASs can be transferred to new implanters.[16,17] Therefore, the IAS rate in Quartile 4 in this analysis is achievable for new implanters from their first procedure.

Study limitations

This study has several limitations. First, this is a retrospective cohort analysis that can only establish associations and not determine causation. Implant experience may, therefore, be a surrogate marker for an unidentified confounder. Other confounders that may influence the learning curve for individual implanters such as differences in transvenous ICD implant experience/volume or the number of implants that were performed in the presence of a proctor were not part of the current analysis.

Conclusions

There is a short and significant learning curve associated with physicians adopting the S-ICD. The complication rate of 9.8% decreased with increasing experience of individual implanters and stabilized after 13 implants per implanter at 5.4%. The reduction of IASs and procedure time likely reflects a global learning effect.

Supplementary material

Supplementary material is available at *Europace* online.

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