Long-term complications in patients implanted with subcutaneous implantable cardioverter-defibrillators: Real-world data from the extended ELISIR experience

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BACKGROUND Recently, the Food and Drug Administration issued a recall for the subcutaneous implantable cardioverter-defibrillator (S-ICD) because of the possibility of lead ruptures and accelerated battery depletion.

OBJECTIVE The aim of this study was to evaluate device-related complications over time in a large real-world multicenter S-ICD cohort.

METHODS Patients implanted with an S-ICD from January 2015 to June 2020 were enrolled from a 19-institution European registry (Experience from the Long-term Italian S-ICD registry [ELISIR]; ClinicalTrials.gov identifier NCT0473876). Device-related complication rates over follow-up were collected. Last follow-up of patients was performed after the Boston Scientific recall issue.

RESULTS A total of 1254 patients (median age 52.0 [interquartile range 41.0–62.2] years; 973 (77.6%) men; 387 (30.9%) ischemic) was enrolled. Over a follow-up of 23.2 (12.8–37.8) months, complications were observed in 117 patients (9.3%) for a total of 127 device-related complications (23.6% managed conservatively and 76.4% required reintervention). Twenty-seven patients (2.2%) had unanticipated generator replacement after 3.6 (3.3–3.9) years, while 4 (0.3%) had lead rupture. Body mass index (hazard ratio [HR] 1.063 [95% confidence interval 1.028–1.100]; $P < .001$), chronic kidney disease (HR 1.960 [1.191–3.225]; $P = .008$), and oral anticoagulation (HR 1.437 [1.010–2.045]; $P = .043$) were associated

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with an increase in overall complications, whereas older age (HR 0.980 [0.967–0.994]; $P = .007$) and procedure performed in high-volume centers (HR 0.463 [0.300–0.715]; $P = .001$) were protective factors.

CONCLUSION The overall complication rate over 23.2 months of follow-up in a multicenter S-ICD cohort was 9.3%. Early unanticipated device battery depletions occurred in 2.2% of patients, while lead fracture was observed in 0.3%, which is in line with the expected rates reported by Boston Scientific.

KEYWORDS ICD complications; Lead complications; S-ICD; S-ICD recall; Subcutaneous implantable cardioverter-defibrillator

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Introduction

In recent times, the subcutaneous implantable cardioverter-defibrillator (S-ICD) has become a valid alternative to the transvenous implantable cardioverter-defibrillator (TV-ICD) for sudden cardiac death prevention. Despite their life-saving role, TV-ICDs are associated with short- and long-term complications leading to considerable morbidity and mortality, such as lead failure and infections.[1,2] If TV-ICD–related infection rates may vary between 0.67% and 1.49% over a 3- to 12-month follow-up period,[3] lead failure rates significantly differ according to the lead type, the year of implantation (with older leads more likely to fail), and the follow-up duration. Indeed, if the Riata[4] and Fidelis[5] leads have shown the highest rates of lead failure (up to 25%) and they have thereby been recalled, when assessing the most used leads (Durata, Endotak Reliance, Sprint Quattro Secure, and Linox), the estimated rates of freedom from lead failure at 5 years ranged from 97.7% to 98.9%.[6] In this analysis, the authors used lead replacement as a surrogate for lead failure, which may indeed have led to an underestimation of total lead failure events. In a recent meta-analysis including Fidelis, Riata, Durata, Endotak, and Quattro leads, an overall incidence of lead failure of 2.23%/y, 1.17%/y, 0.45%/y, 0.36%/y, and 0.29%/y, was reported, respectively.[7]

Although S-ICDs have failed to show lower rates of infection and are associated with a higher risk of pocket-related complications, they have been extensively used in recent years because of a lower rate and a safer management of lead and major procedure-related complications[1,8] as well as because of an easier management of both, especially in the event of lead extraction.[9,10] Recently, Boston Scientific Inc. (Marlborough, MA) recalled the S-ICD subcutaneous electrode (model 3501) because of the risk of fractures at a specific level (distal to the proximal sense ring). Twenty-seven cases of lead body fractures at this location have been reported, with 1 death as a result of that specific lead complication; although the S-ICD generator and electrode were not returned for a postmortem analysis, a contributing role related to malfunctioning could not be excluded.[11] Moreover, the manufacturer identified approximately 38,350 active S-ICDs (models A209 and A219) with a certain likelihood of a low-voltage capacitor causing accelerated battery depletion as well as of moisture entrance into the S-ICD generator, potentially causing a short circuit when the device delivers high-voltage shocks. Thus, the Food and Drug Administration (FDA) has identified this recall as a class I recall.[12] Nevertheless, to date, no independent real-world analysis has been run on S-ICD–related complications. Therefore, the aim of this study was to evaluate all device-related complications over time as well as the need for reinterventions to manage them.

Methods

The ELISIR project (Experience from the Long-term Italian S-ICD registry; ClinicalTrials.gov identifier NCT0473876) is a multicenter, open-label, independent, and physician-initiated observational registry. At the time of writing, 19 public and private health care institutions from 4 countries in Europe were involved in the registry. The project was approved by each institutional review board and drafted in accordance with the tenets of the Helsinki Declaration.

Registry population and data collection

From January 2015 to June 2020, all consecutive patients undergoing implantation of an S-ICD device were retrospectively enrolled in the registry. For every patient enrolled, demographic characteristics and baseline data comprising cardiovascular risk factors, arrhythmic substrate, periprocedural data, device programming, and outcome data were collected. For patients undergoing defibrillation testing, ventricular fibrillation (VF) was induced using transthoracic 50-Hz burst pacing. No specifics regarding shock energy and the use of either general anesthesia or deep sedation for the procedure were given. In all patients for whom a postimplant 2-view chest radiograph was available, the PRAETORIAN score was calculated and patients were classified having a low-, intermediate-, or high-risk of conversion failure according to the score definition.[13]

Follow-up and outcome definition

A follow-up strategy was left to each center's policy, with most patients being evaluated at 1, 6, and 12 months and every 6 months thereafter. Remote device monitoring was used if accepted by each country regulatory policy; all patients provided specific informed consent. All device-related complications were collected over the entire follow-up period, as well as the need for reinterventions to manage them and the subsequent length of hospital stay. As per registry protocol, *complications* were defined as follows: major pocket hematoma requiring a transfusion or a pocket revision, pocket infection, air entrapment causing inappropriate shocks, lead displacement affecting device functioning and requiring reintervention, lead fracture, lead infection, device extraction, device

replacement for excessive inappropriate shocks, *unexpected early battery depletion* (defined as within 5 years from implantation in patients with a low arrhythmic burden at follow-up), and unexpected pneumothorax. *Early complications* were defined as any of the aforementioned complication presenting within the first 48 hours of device placement. Arrhythmia episodes and therapy delivered, either appropriate or inappropriate, were collected during follow-up. Cardiovascular and total mortality were also documented. The *primary outcome* of the study was defined as the occurrence of any device-related complication since implantation through the entire follow-up period. As secondary analysis, the following outcomes were assessed: freedom from sustained ventricular arrhythmic events, freedom from inappropriate shocks, rate of ineffective shocks, and overall mortality.

Event definition

An *appropriate shock* was defined as therapy delivered because of correctly diagnosed shockable rhythm. An *inappropriate shock* was defined as shock delivered owing to (1) a supraventricular tachycardia, (2) oversensing of either cardiac or noncardiac signals, and (3) any other cause resulting in a device shock in the absence of clinical arrhythmia. An *ineffective shock* was defined as a shock delivered on an adequately recognized shockable rhythm, ineffective to terminate ventricular tachycardia (VT)/VF. An *untreated arrhythmia* was defined as VT/VF not treated by the device owing to (1) undersensing of the cardiac signal during VT/VF, (2) misclassification of VT/VF due to the device discrimination algorithm, and (3) VT/VF presenting at a lower rate than the cutoff value for device intervention, as established by defibrillator programming.

Predictors definition

S-ICD implantation learning curve was considered completed after the placement of 10. A center was considered a high-volume center after the performance of 13 procedures/y for at least 3 years in a row.[14]

Statistical analysis

All analyses were performed using Stata version 14.0 (StataCorp LLC, College Station, TX). Continuous variables were expressed as mean ± SD if normally distributed or as median (interquartile range). Categorical variables were expressed as count (percentage). Comparisons between categorical variables were performed using the exact χ^2 or Fisher exact test, as appropriate. Associations between predictors and time-dependent outcomes were tested using univariate Cox regression models; time intervals were set as time elapsed from device implantation to either the event or last available follow-up. A parsimonious model including only variables reaching $P < .10$ in univariate analysis was built to adjust for confounders. Event-free survival and cumulative complication rates were reported using Kaplan-Meier curves. All 2-tailed P values $<.05$ were considered significant.

Results

Patient population

A total of 1254 patients were enrolled in the present study. The median age of the population at device implantation was 52.0 (41.0–62.2) years, with 77.6% of patients being male. Device implantation occurred as the primary prevention of sudden cardiac death in 786 patients (62.7%) of the cohort. Most implantation procedures were performed using the 2-incision technique (90.3%). The devices were most commonly placed in an intermuscular position between the musculus serratus anterior and the musculus latissimus dorsi (81.1%). Adequate postprocedural radiological imaging to assess the PRAETORIAN score was available in 836 patients (66.6%). The vast majority of the cohort showed a low risk of conversion failure (n = 679). The baseline characteristics of the cohort are reported in Table 1. Periprocedural characteristics have been reported in Online Supplemental Table 1. The median follow-up of the study was 23.2 (12.8–37.8) months. Complete follow-up data are provided in Table 2.

Primary outcomes

The primary outcome was observed in 117 patients (9.3%) for a total of 127 device-related complications; 30 (23.6%) of these were managed conservatively, while the remaining 97 (76.4%) required reintervention (Figure 1). Pocket-related complications were the most common (n = 54), with pocket hematoma representing 25.2% of the overall complications. A total of 27 patients (2.2%) had unanticipated generator replacement after a median of 3.6 (3.3–3.9) years. Overall complications were evenly distributed when the investigated cohort was split into a young and an old patient subgroup (9.8% vs 5.6%, respectively; $P = .108$). High-volume centers presented lower rates of complications than did non–high-volume centers (8.5% vs 12.8%; $P = .041$) (Figure 2). Body mass index (BMI; adjusted hazard ratio [aHR] 1.063 [95% confidence interval 1.028–1.100]; $P < .001$), chronic kidney disease (CKD; aHR 1.960 [1.191–3.225]; $P = .008$), and the use of oral anticoagulation (aHR 1.437 [1.010–2.045]; $P = .043$) were significantly associated with an increased risk of any complication at follow-up, while older age (aHR per year 0.980 [0.967–0.994]; $P = .007$) and the performance of the procedure in a high-volume center (aHR 0.463 [0.300–0.715]; $P = .001$) were protective factors. When assessing individually infective and noninfective S-ICD complications instead, CKD (aHR 2.436 [1.057–5.615]; $P = .037$) and development of a pocket hematoma (aHR 6.075 [2.426–15.207]; $P < .001$) were associated with infective complications while a higher BMI (aHR 1.059 [1.014–1.105]; $P = .009$), the use of oral anticoagulation (aHR 1.738 [1.207–2.505]; $P = .003$), and the performance of the procedure in a high-volume center (aHR 0.315 [0.182–0.547]; $P < .001$) were predictors of noninfective complications. Table 3 summarizes the entire univariate and multivariate Cox regression analysis. Figure 3 represents graphically univariate analysis of predictors of overall and by type complications.

Table 1 Baseline characteristics (N = 1254)

Characteristic	Value
Age (y)	52.0 (41.0–62.2)
Male sex	973 (77.6)
BMI (kg/m^2)	25.0 (23.0–28.0)
Diabetes	186 (16.8)
Hypertension	484 (38.6)
Sports practice	99 (12.3)
CKD	209 (16.7)
LVEF (%)	43.0 ± 15.9
Primary prevention implant	786 (62.7)
Underlying cardiac disease	
Ischemic cardiomyopathy	387 (30.9)
Dilated cardiomyopathy	283 (22.6)
Hypertrophic cardiomyopathy	115 (9.2)
Arrhythmogenic cardiomyopathy	58 (4.6)
Brugada syndrome	125 (10.0)
Idiopathic VF	132 (9.6)
Alcoholic cardiomyopathy	6 (0.4)
Valvular cardiomyopathy	37 (2.9)
Other	111 (8.8)
Atrial fibrillation	246 (19.6)
Paroxysmal	149 (11.9)
Persistent	55 (4.4)
Permanent	42 (3.6)
Removal of the previous TV device	153 (12.2)
β-Blockers	901 (71.8)
Anti-arrhythmic Drugs Class I-C	35 (2.8)
Amiodarone	148 (11.8)

Values are presented as mean ± SD, median (interquartile range), or n (%).

BMI = body mass index; CKD = chronic kidney disease; LVEF = left ventricular ejection fraction; TV = transvenous; VF = ventricular fibrillation.

*Percentages were calculated for patients for whom data were available.

Table 2 Follow-up data (N = 1254)

Characteristic	Value
Follow-up time (mo)	23.2 (12.8–37.8)
Patients experiencing device-related complications	117 (9.3)
Device-related complications	127 (100)
Within 48 h	15 (11.8)
Not requiring reintervention	4 (3.1)
Pocket hematoma	1 (0.8)
Air entrapment	3 (2.4)
Requiring reintervention	11 (8.7)
Pocket hematoma	5 (3.9)
Lead displacement	5 (3.9)
Subcutaneous emphysema	1 (0.8)
After 48 h	112 (88.2)
Not requiring reintervention	26 (20.5)
Pocket-related complications	20 (15.7)
Pocket hematoma	18 (14.2)
Pocket infection	2 (1.5)
Air entrapment	6 (4.8)
Requiring reintervention	86 (67.7)
Lead-related complications	21 (16.5)
Lead displacement	5 (3.9)
Lead rupture	4 (3.1)
Lead infection	12 (9.5)
Pocket-related complications	28 (22.0)
Pocket hematoma	14 (11.0)
Pocket infection	14 (11.0)
Unanticipated generator replacement	27 (21.3)
Excessive inappropriate shocks	8 (6.9)
Noninfective peri-generator skin erosion	2 (1.5)
Patients experiencing appropriate shocks	118 (9.4)
Patients experiencing inappropriate shocks	112 (8.9)
Reason for inappropriate shocks	
AF	17 (1.4)
TWO	55 (4.4)
Myopotentials	18 (1.4)
Atrial tachycardia	3 (0.2)
VAD interference	1 (0.1)
Lead problem	6 (0.5)
Air entrapment	9 (0.7)
Twiddler's syndrome	2 (0.2)
Patients experiencing ineffective shocks	12 (1.0)
Deaths	42 (3.4)
Cardiovascular death	29 (2.3)

Values are presented as median (interquartile range) or n (%).

AF = atrial fibrillation; TWO = T wave oversensing; VAD = ventricular assist device.

Secondary outcomes

One hundred eighteen patients (9.4%) received at least 1 appropriate shock. Arrhythmia-free survival is shown in Online Supplemental Figure 1. A total of 12 ineffective shocks were observed, with multiple shocks required for arrhythmia termination in 8 patients and 4 requiring resuscitation maneuvers and external defibrillation. In the study cohort, 112 patients (8.9%) received inappropriate shocks during study follow-up. T-wave oversensing (4.4%), muscle noise (1.4%), and atrial fibrillation episodes (1.4%) were the most common triggers of inappropriate shocks. Overall mortality in the registry was 3.4%, with end-stage heart failure being the leading cause (1.5%). No device-related deaths were observed. Regression analysis results for all other secondary outcomes have been reported in Online Supplemental Table 2.

Discussion

This is the first large independent multicenter cohort study assessing S-ICD complications in the real-world setting after the issue of the Boston Scientific recall by the FDA.[11,12]

The main results of our study are as follows:

1. Over a median follow-up time of 23.2 months, 9.3% of patients experienced device-related complications. Pocket-related complications were the most common, with pocket hematoma representing the leading one.
2. The rate of unanticipated generator replacement was 2.2%, with a median replacement time below 4 years. Four patients (0.3%) experienced lead fracture, requiring lead replacement.
3. Management of all device-related complications was safe, with no device-related deaths observed.
4. One hundred eighteen patients (8.9%) experienced inappropriate shocks, with T-wave oversensing and atrial fibrillation being the most common triggers. Advanced

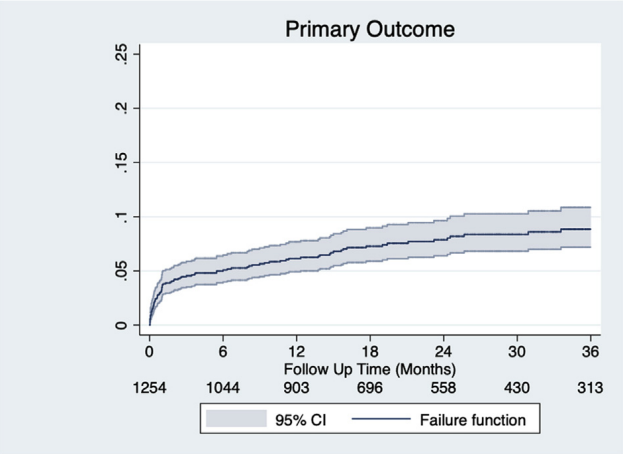

Figure 1 Cumulative incidence of primary outcome (complication rate) over time. CI = confidence interval.

age and the use of the SMART Pass algorithm were protective factors from inappropriate shocks.

5. Younger age, higher BMI, CKD, and the chronic use of oral anticoagulants were the main predictors of all complications at follow-up. Procedure performance in a high-volume center was associated with a significant reduction in overall complications.

Device- or lead-related complications and the current FDA recall

Long-term complications in TV-ICD are currently estimated around 5%, with infections and lead-related adverse events being the most common.[15] TV-ICD infections or lead-related complications might result in endocarditis or lead extraction, with nonnegligible mortality rates, especially with older devices. The S-ICD technology was indeed developed specifically to reduce device-related complications and to manage these issues more easily. Although the periprocedural complication rate was close to 10% for unexperienced operators, a halving of the complication rates after the initial learning curve phase was observed. In our analysis, the S-ICD complication rate at follow-up was noteworthy (9.3%), similar to TV-ICD but, as expected, with a much more favorable outcome profile, with no device-related deaths being reported, though hospitalization and reinterventions were required. Patients requiring lead extraction and repositioning did not experience significant postoperative consequences. Different from the report of Knops et al[14] on periprocedural complications, the overall long-term complications had no trend toward improvement with operators' experience in our study while the overall center volume seemed to have a significant impact, especially on noninfective complications.

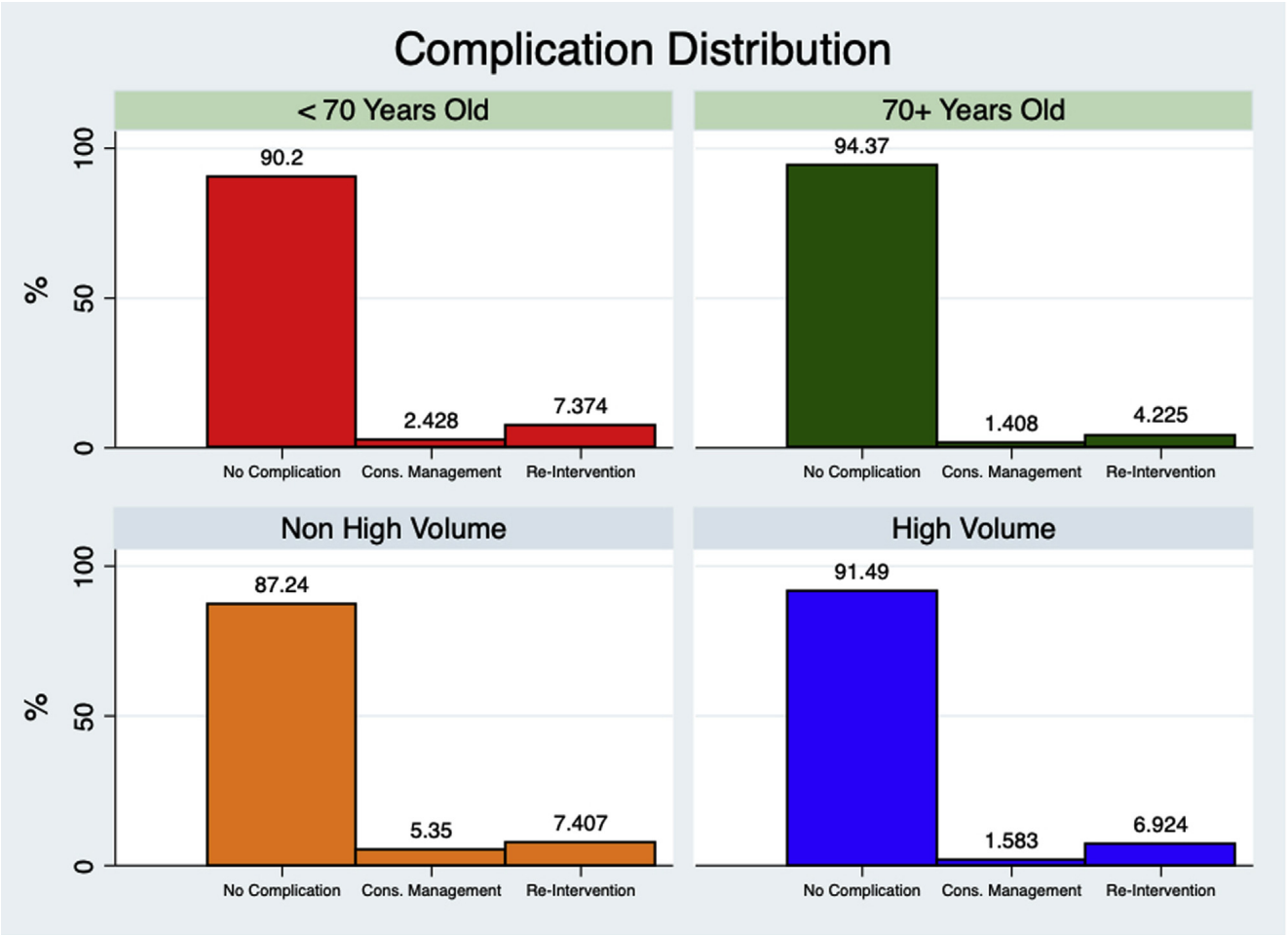

Figure 2 Complication rate distribution by age (≥70 and <70 years) and by center volume. Cons = conservative.

Table 3 Univariate and multivariate Cox regression analysis for device related complications

Characteristic	HR	CI	*P*	aHR	CI	*P*
Primary combined outcome						
Age	0.989	0.978–1.000	**.064**	0.980	0.967–0.994	**.007**
Male sex	1.144	0.725–1.806	.562			
Hypertension	0.916	0.629–1.335	.651			
BMI	1.055	1.021–1.090	**.001**	1.063	1.028–1.100	**<.001**
Diabetes	0.767	0.428–1.374	.373			
CKD	1.821	1.202–2.759	**.005**	1.960	1.191–3.225	**.008**
LVEF	1.002	0.991–1.014	.693			
Two-incision technique	0.917	0.548–1.533	.741			
Intermuscular placement	0.729	0.486–1.095	.128			
Patients on OAC	1.391	1.015–1.905	**.040**	1.437	1.010–2.045	**.043**
High-volume center	0.634	0.420–0.957	**.030**	0.463	0.300–0.715	**.001**
Learning curve completed	1.152	0.714–1.859	.561			
Infective complications						
Age	0.982	0.959–1.005	.121			
Male sex	1.625	0.564–4.686	.369			
Hypertension	1.074	0.501–2.300	.854			
BMI	1.064	0.999–1.132	***.052***	1.042	0.974–1.114	.232
Diabetes	1.013	0.347–2.953	.980			
CKD	3.871	1.830–8.189	**<.001**	2.436	1.057–5.615	**.037**
LVEF	0.963	0.938–0.989	**.005**	0.974	0.948–1.002	.070
Two-incision technique	0.695	0.257–1.880	.867			
Intramuscular placement	0.809	0.344–1.903	.628			
Patients on OAC	1.284	0.672–2.453	.449			
Pocket hematoma	7.711	3.094–19.217	**<.001**	6.075	2.426–15.207	**<.001**
High-volume center	1.464	0.507–4.226	.481			
Learning curve completed	0.914	0.344–2.428	.857			
Noninfective complications						
Age	0.994	0.980–1.009	.460			
Male sex	1.167	0.651–2.093	.603			
Hypertension	1.081	0.674–1.731	.746			
BMI	1.051	1.008–1.095	**.018**	1.059	1.014–1.105	**.009**
Diabetes	0.672	0.306–1.478	.323			
CKD	1.843	1.092–3.114	**.022**	1.504	0.844–2.682	.166
LVEF	0.999	0.985–1.015	.995			
Two-incision technique	0.743	0.380–1.452	.385			
Intramuscular placement	0.615	0.369–1.026	***.063***	0.744	0.416–1.334	.322
Patients on OAC	1.645	1.182–2.286	**.003**	1.738	1.207–2.505	**.003**
High-volume center	0.457	0.279–0.746	**.002**	0.315	0.182–0.547	**<.001**
Learning curve completed	0.894	0.488–0.639	.717			

Bold values indicate statistical significant ($P < .05$).

aHR = adjusted hazard ratio; BMI = body mass index; CI = confidence interval; CKD = chronic kidney disease; HR = hazard ratio; LVEF = left ventricular ejection fraction; OAC = oral anticoagulation.

Indeed, we hypothesize that the importance of the center volume extends beyond the simple number of procedures performed by the single operator, but also accounts for experienced, better periprocedural flow, and a proactive hospital inward environment. Our data seem to strongly point toward the centralization of S-ICD procedures into high-volume centers to reduce overall complications and related downsides.

In addition to the crude complication rate, the type of complications should be discussed. The PRAETORIAN trial showed comparable complication rates between S-ICD and TV-ICD, with subcutaneous devices presenting more surgical complications and transvenous devices presenting more lead-related complications.[16] Our study partially confirmed these findings. The main reasons for S-ICD complications in our study were indeed surgical, with pocket-related complications being the most frequent. However, we also detected a nonnegligible number of lead-related complications, with around 20% of all complications being lead related. We observed a similar rate of lead fracture to that declared in the medical device advisory recently published by Boston Scientific (0.3%),[11] alongside several lead dislodgments and infections (Figure 4). Until recently, the S-ICD lead reliability was proposed as the cornerstone for its broad clinical adoption, with only rare case reports of lead-related complications. However, despite the reported fractures, the long-term performance of S-ICD leads still remains significantly better than that of endovascular leads.[10,17] Additionally, the big advantage of S-ICDs over TV-ICDs is represented by the relative safety with which leads can be explanted and replaced, with virtually no mortality risk for the patient.

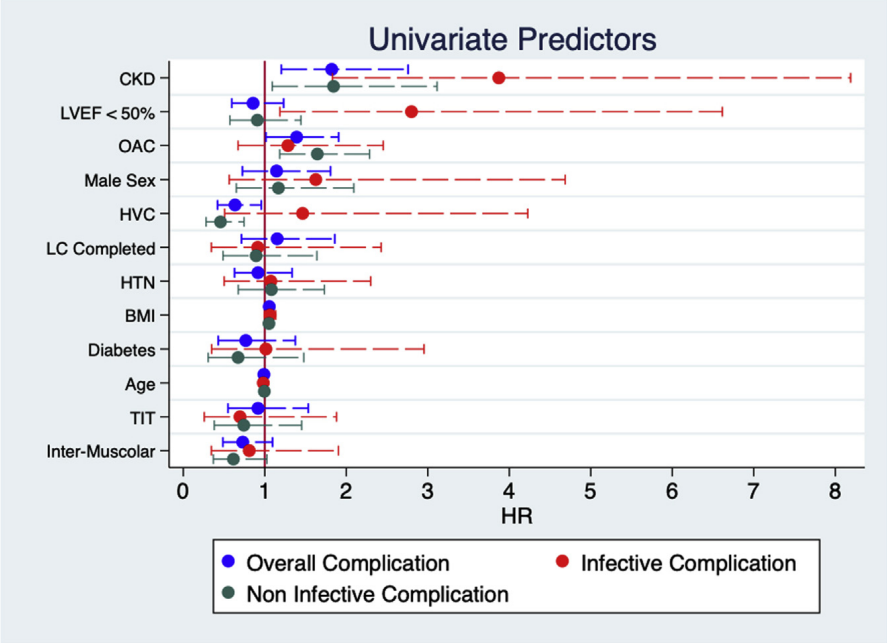

Figure 3 Univariate predictors of overall (*red*), noninfective (*teal*), and infective (*blue*) complications. BMI = body mass index; CKD = chronic kidney disease; HR = hazard ratio; HTN = hypertension; HVC = high-volume center; LC = learning curve; LVEF = left ventricular ejection fraction; OAC = oral anticoagulation; TIT = 2-incision technique.

Our results also confirmed the rate of premature battery depletion predicted by the medical device advisory,[12] with 2.2% of EMBLEM S-ICD devices requiring unanticipated replacement. In a single-center cohort, Ip[18] reported a prevalence of 3.4% of premature battery failure in his cohort, occurring at an average of 1095 days, in a cohort extending

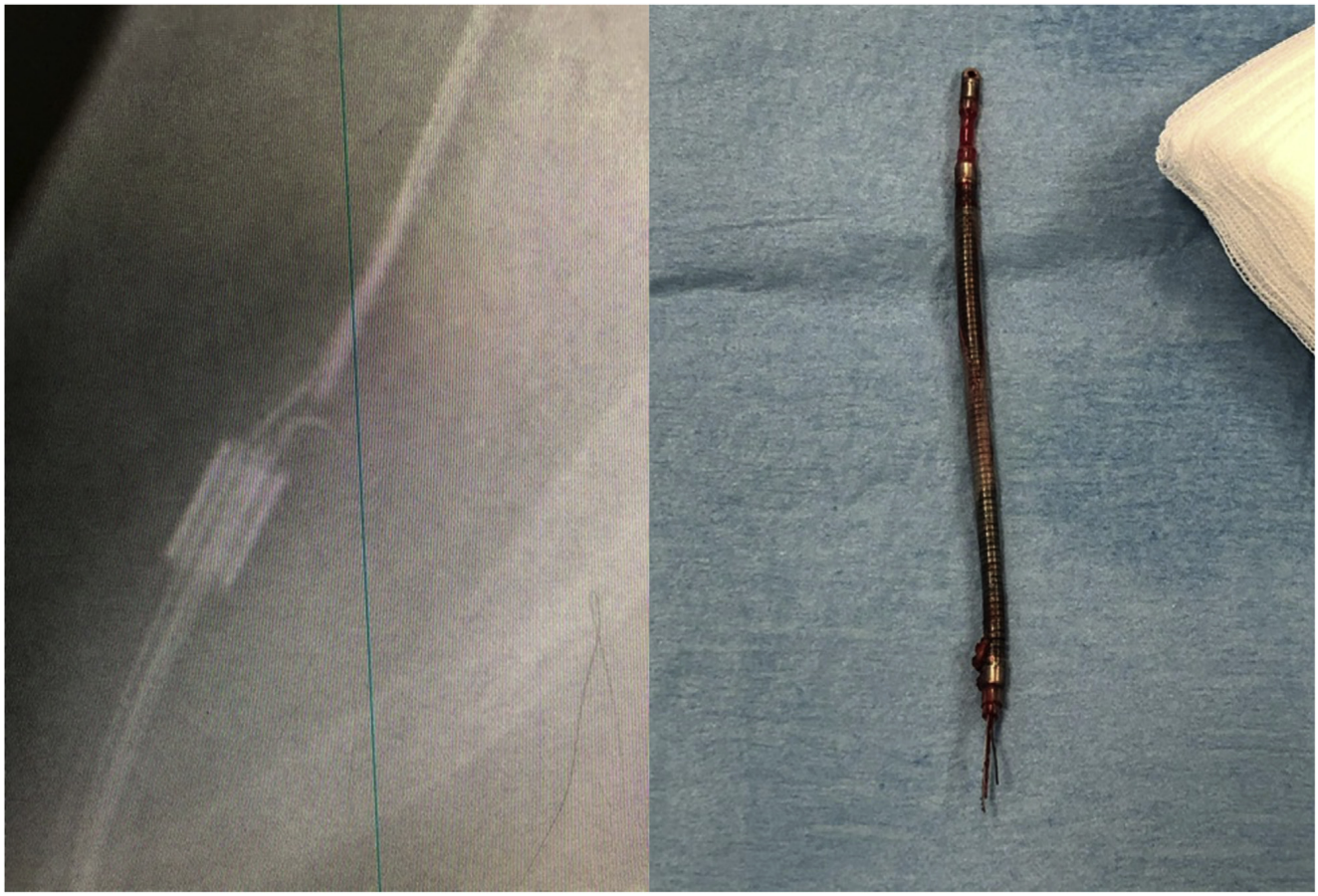

Figure 4 Lead extraction after lead fracture in a patient with subcutaneous implantable cardioverter-defibrillator.

beyond the initial advisory subset. We report slightly lower battery depletion rates at follow-up in a larger data set of patients.

Inappropriate shocks

The number of patients experiencing inappropriate shocks in our study was 9.4% at almost 2 years of follow-up. The leading cause was T-wave oversensing, and an important age dependency was observed (Online Supplemental Figure 2). This high rate of inappropriate shocks was unexpected, considering the device setting of VT/VF cutoff and the availability of the SMART Pass algorithm in 85% patients. Our results were similar to the first S-ICD release reported in the EFFORTLESS study, but higher when compared to the inappropriate shocks reported in the PRAETORIAN trial.[16,19] Despite the efforts made in trying to better set the devices and improve the discrimination algorithms, inappropriate shocks remain a relevant S-ICD complication, different from a TV-ICD complication, where programming optimization led to a clear reduction in oversensing-related inappropriate shocks over the years.[20] Nevertheless, it should be underlined that supraventricular tachycardia is still the leading cause of inappropriate shocks in the TV-ICD while it seems to have a lower weight in the S-ICD system.[1]

Complication predictors

The strongest overall predictor of any device-related complication at follow-up in our cohort was CKD. As expected, CKD was mostly associated with infective complications (Table 3). Our findings may appear partially in contrast with the report of El-Chami et al,[21] which showed that patients on hemodialysis may actually be safely treated with S-ICDs, since the complication rate was similar to that of the general population of S-ICD recipients (7.9%). Nevertheless, both experiences reported overall complication rates within comparable ranges, far lower than those reported in TV-ICDs recipients with CKD and on hemodialysis.[22,23] This underlines the importance of using a completely extravascular system for these patients (especially if on hemodialysis), with S-ICD being the best option for these patients in the absence of the need for pacing.

A higher BMI was also associated with a higher complication rate, affecting both infective and noninfective complications. This finding is not unexpected: an excess of subcutaneous adipose tissue may interfere with the correct placement of both the lead and the generator of the S-ICD, potentially leading to higher rates of lead/generator displacements. Additionally, the creation of an adequate pocket in patients with a higher BMI may be challenging, potentially exposing to a higher risk of pocket hematomas and/or infections. An elevated BMI has also been associated with more ineffective shocks and a lower effectiveness of the S-ICD device, and it is an important correction factor of the PRAETORIAN score.[13,24,25] Given all these findings, the use of S-ICD devices in morbidly obese patients should be carefully evaluated and TV-ICDs may be beneficial in some cases.

Finally, it should be noted that pocket hematomas were strong predictors of more severe infective complications in an S-ICD recipient, regardless of their conservative management or reintervention. This finding is in line with what has been observed in TV-ICDs, which presents significantly increased risks of infection requiring hospitalization due to pocket infection, bacteremia, or endocarditis after developing clinically relevant pocket hematoma. Our data did highlight a strong *liaison* between significant pocket hematomas and subsequent infections for S-ICD, similarly to the 7-fold increased for TV-ICD observed in the BRUISE registry.[26]

Limitations

The first limitation is inherently associated with the nonrandomized observational nature of this European, real-world, multicenter registry of unselected patients undergoing S-ICD implantation. Moreover, because of the retrospective nature of our registry, all complications could not be centrally adjudicated by a central committee, and no audit committee that might sample a statistically meaningful number of randomly selected charts to confirm (or deny) that underreporting complication was not a significant issue was present. Indeed, also because proceduralists sometimes may underreport their complications, a certain rate of underreported (or not) complications might have occurred. Nevertheless, most complications are self-evident, easy to define, and uncontroversial, such as infective events or lead displacement, while others always require engineering evaluation from the company, with subsequent official report of the issue, thereby providing consistency throughout the entire follow-up.

Conclusion

In this European multicenter study assessing long-term complications in patients undergoing S-ICD implantation, the overall complication rate was 9.3% during the first 2 years after implantation. Younger age, higher BMI, CKD, and the use of oral anticoagulants were main predictors of any complication during follow-up. Procedural performance in high-volume centers was associated with a significant reduction in overall complications. In our population, early unanticipated battery depletion occurred in 2.2% of patients while lead fracture was observed rarely (0.3%).

Appendix

Supplementary data

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.hrthm.2021.07.008.

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