## Procedure, management, and outcome of subcutaneous implantable cardioverter-defibrillator extraction in clinical practice

Paolo De Filippo (1) 1\*, Federico Migliore (1) 2, Pietro Palmisano (1) 3, Gerardo Nigro (1) 4, Matteo Ziacchi (1) 5, Roberto Rordorf (1) 6, Paolo Pieragnoli (1) 7, Angelo Di Grazia (1) 8, Luca Ottaviano (1) 9, Pietro Francia (1) 10, Ennio Pisanò (1) 11, Gianfranco Tola (1) 12, Massimo Giammaria (1) 13, Antonio D'Onofrio (1) 14, Giovanni Luca Botto (1) 15, Giulio Zucchelli (1) 16, Paola Ferrari 1, Mariolina Lovecchio 17, Sergio Valsecchi (1) 17, and Stefano Viani (1) 16 on behalf of 'S-ICD Rhythm Detect' Investigators

<sup>1</sup>Cardiac Electrophysiology and Pacing Unit, ASST Papa Giovanni XXIII, Piazza OMS 1, Bergamo 24127, Italy; <sup>2</sup>Department of Cardiac, Thoracic Vascular Sciences and Public Health University of Padova, Padova, Italy; <sup>3</sup>Cardiology Unit, 'Card. G. Panico' Hospital, Tricase (Le), Italy; <sup>4</sup>Department of Translational Medical Sciences, University of Campania 'Luigi Vanvitelli,' Monaldi Hospital, Naples, Italy; <sup>5</sup>Institute of Cardiology, Department of Experimental, Diagnostic and Specialty Medicine, University of Bologna, Policlinico S. Orsola-Malpighi, Bologna, Italy; <sup>6</sup>Arrhythmia and Electrophysiology Unit, IRCCS Fondazione Policlinico S. Matteo, Pavia, Italy; <sup>7</sup>Institute of Internal Medicine and Cardiology, University Hospital of Florence, Florence, Italy; <sup>8</sup>Cardiology Department, Policlinico 'G. Rodolico—San Marco', Catania, Italy; <sup>9</sup>Arrhythmia and Electrophysiology unit, Arrhythmia and Electrophysiology Unit, Cardiothoracic Department, IRCCS Galeazzi-S. Ambrogio, Milan, Italy; <sup>10</sup>Cardiology, Department of Clinical and Medicine, Sant'Andrea Hospital, University Sapienza, Rome, Italy; <sup>11</sup>Cardiology Division, U.O.S.V.D. Cardiac Electrophysiology, 'Vito Fazzi' Hospital, Lecce, Italy; <sup>12</sup>Cardiology Division, A.O. Brotzu, Cagliari, Italy; <sup>13</sup>M. Vittoria' Hospital, Torino, Italy; <sup>14</sup>Unità Operativa di Elettrofisiologia, Studio e Terapia delle Aritmie', Monaldi Hospital, Naples, Italy; <sup>15</sup>Department of Clinical cardiology and Electrophysiology, ASST Rhodense, Rho-Garbagnate Milanese (MI), Italy; <sup>16</sup>Second Cardiology Division, Cardio-Thoracic and Vascular Department, University Hospital of Pisa, Pisa, Italy; and <sup>17</sup>Rhythm Management Division, Boston Scientific, Milan, Italy

Received 7 April 2023; accepted after revision 31 May 2023

### Aims

Subcutaneous implantable cardioverter—defibrillator (S-ICD) therapy is expanding rapidly. However, there are few data on the S-ICD extraction procedure and subsequent patient management. The aim of this analysis was to describe the procedure, management, and outcome of S-ICD extractions in clinical practice.

## Methods and results

We enrolled consecutive patients who required complete S-ICD extraction at 66 Italian centres. From 2013 to 2022, 2718 patients undergoing *de novo* implantation of an S-ICD were enrolled. Of these, 71 required complete S-ICD system extraction (17 owing to infection). The S-ICD system was successfully extracted in all patients, and no complications were reported; the median procedure duration was 40 (25th–75th percentile: 20–55) min. Simple manual traction was sufficient to remove the lead in 59 (84%) patients, in whom lead-dwelling time was shorter [20 (9–32) months vs. 30 (22–41) months; P = 0.032]. Hospitalization time was short in the case of both non-infectious [2 (1–2) days] and infectious indications [3 (1–6) days]. In the case of infection, no patients required post-extraction intravenous antibiotics, the median duration of any antibiotic therapy was 10 (10–14) days, and the re-implantation was performed during the same procedure in 29% of cases. No complications arose over a median of 21 months.

### Conclusion

The S-ICD extraction was safe and easy to perform, with no complications. Simple traction of the lead was successful in most patients, but specific tools could be needed for systems implanted for a longer time. The peri- and post-procedural management of S-ICD extraction was free from complications and not burdensome for patients and healthcare system.

### Clinical Trial Registration

URL: http://clinicaltrials.gov/Identifier: NCT02275637.

<sup>\*</sup> Corresponding author: Tel: +39 0352673557, E-mail address: pdefilippo@asst-pg23.it

<sup>©</sup> The Author(s) 2023. Published by Oxford University Press on behalf of the European Society of Cardiology.

### **Graphical Abstract**

# S-ICD extraction procedure Simple Manual Traction in 85% Median dwell time: 20 months Non-powered mechanical sheats in 15% Median dwell time: 30 months Sicentific Corporation or its affiliates. All rights reserved. Median dwell time: 30 months

- S-ICD extraction is safe and easy to perform, with no intra-procedural complications.
- Simple manual traction of the lead is successful in most patients, but specific tools could be needed for systems implanted for a longer time.
- S-ICD extraction, even in the case of infection, is associated with short hospital stay, early re-implantation and no complications over follow-up.

### **Keywords**

Implantable defibrillator • Subcutaneous • Extraction • Infection

### What's new?

- Subcutaneous implantable cardioverter-defibrillator (S-ICD) extraction is safe and easy to perform, with no intra-procedural complications.
- Simple manual traction of the lead is successful in most patients, but specific tools could be needed for systems implanted for a longer time.
- The S-ICD extraction, even in the case of infection, is associated with short hospital stay, early re-implantation and no complications over follow-up.
- Peri- and post-procedural management of S-ICD extraction, even in the case of infection, is not very burdensome for patient and healthcare system.

### Introduction

Many studies have confirmed the overall efficacy and safety of the subcutaneous implantable cardioverter—defibrillator (S-ICD) over medium- and long-term follow-up, 1-3 and randomized clinical trials comparing S-ICDs and transvenous ICDs (T-ICDs) have been published. The Prospective Randomized Comparison of Subcutaneous and Transvenous Implantable Cardioverter Defibrillator (PRAETORIAN) Trial found that the S-ICD was non-inferior to the T-ICD with respect to device-related complications and inappropriate shocks and superior with respect to lead-related complications. This finding was confirmed both by the recent Avoid Transvenous Leads in Appropriate Subjects (ATLAS S-ICD) trial. However, although the use of the S-ICD is associated with fewer complications, data on their management and outcome are few.

The aim of the present study was to report on the experience of S-ICD system extraction for infectious and non-infectious indications within a large multicentre registry by describing current intraprocedural, peri- and post-operative practice, and measuring acute and mid-term outcomes.

### **Methods**

### Study design

From January 2013 to April 2022, consecutive patients undergoing *de novo* implantation of an S-ICD (Boston Scientific Inc., Natick, MA, USA) were enrolled at the 66 Italian centres that participate in the Rhythm Detect registry (NCT02275637) (see Appendix). The Institutional Review Boards approved the study, and all patients provided written informed consent for data storage and analysis. Baseline assessment comprised the collection of demographic data and medical history, clinical examination, 12-lead electrocardiogram, and echocardiographic evaluation. After implantation, patients were followed up in accordance with the standard practice of the participating centres until October 2022.

For the aims of the present analysis, we retrospectively identified all adult patients who required complete S-ICD extraction during the observation period. The extraction and implantation procedures, and peri-operative and post-operative clinical management, were performed in accordance with the clinical practice of each centre. Information on clinical outcomes was collected during hospital visits or, if patients missed scheduled visits, via telephone calls. Events resulting in prolonged hospitalization or surgical intervention for system revision were considered to be complications.

### Statistical analysis

Descriptive statistics are reported as means  $\pm$  standard deviation (SD) for normally distributed continuous variables, or as medians and interquartile range (25th–75th percentile) in the case of skewed distribution. Categorical variables are reported as percentages. Differences between mean data were compared by means of a t-test for Gaussian variables and the Mann–Whitney non-parametric test for non-Gaussian variables. Differences in proportions were compared by means of chi-square analysis or Fisher's exact test, as appropriate. A P value < 0.05 was considered significant for all tests. All statistical analyses were performed by means of R: a language and environment for statistical computing (R) Foundation for Statistical Computing, Vienna, Austria).

### **Results**

### Study population

From 2013 to 2022, a total of 2718 consecutive S-ICD procedures were performed at the study centres (Baseline variables are reported

**Table 1** Baseline clinical and implantation variables

Parameter	S-ICD overall N = 71	Extracted for infection $(n = 17)$	Extracted for any other reasons $(n = 54)$
Age at S-ICD extraction procedure, years	49 ± 15	47 ± 17	50 ± 14
Male gender, n (%)	61 (87)	13 (76)	48 (89)
Body mass index, kg/m <sup>2</sup>	27 ± 5	$27 \pm 6$	$27 \pm 4$
Left ventricular ejection fraction, %	45 ± 16	51 ± 16	$43 \pm 16$
Cardiomyopathy			
Ischaemic, n (%)	21 (30)	5 (29)	16 (30)
Dilated, n (%)	18 (25)	3 (18)	15 (28)
Hypertrophic, n (%)	7 (10)	2 (12)	5 (9)
Arrhythmogenic, n (%)	6 (8)	1 (6)	5 (9)
Congenital, n (%)	1 (1)	0 (0)	1 (2)
Channelopathies/other			
Idiopathic ventricular fibrillation, $n$ (%)	5 (7)	1 (6)	4 (8)
Brugada, n (%)	10 (14)	5 (29)	5 (9)
Long-QT syndrome, $n$ (%)	2 (3)	0 (0)	2 (4)
Other, n (%)	1 (1)	0 (0)	1 (2)
History of median sternotomy, n (%)	9 (13)	2 (12)	7 (13)
Implanted generator			
Cameron SQRX, n (%)	7 (10)	3 (18)	4 (7)
Emblem A209/A219, n (%)	64 (90)	14 (82)	50 (93)
Implanted lead			
3010/3 <del>4</del> 01, n (%)	27 (38)	7 (41)	20 (37)
3501, n (%)	44 (62)	10 (59)	34 (63)
S-ICD generator in intermuscular pocket, n (%)	57 (80)	11 (65)	46 (85)
Two-incision lead-implantation technique, n (%)	68 (96)	15 (88)	53 (98)
Time from implantation, months	22 (11–33)	7 (5–16)	24 (15–37)

S-ICD, subcutaneous implantable cardioverter-defibrillator.

in Supplementary material online, *Table S1*). During the observation period, 71 patients required complete S-ICD system extraction. The median time from S-ICD implantation to extraction was 22 (25th–75th percentile: 11–33) months. Baseline clinical and implantation variables are reported in *Table 1*. The indications for S-ICD extraction are reported in *Table 2*. Overall, 17 (24%) patients underwent extraction for system infection, 25 (35%) patients for device-related complications, and the remaining patients for clinical needs or patient discomfort. Among device-related complications, sensing issues were reported in 10 (14%) cases. T-wave oversensing was reported in three cases and was managed by replacing the device with a SMART Pass enabled S-ICD or with a T-ICD. Non-cardiac oversensing was reported in five cases, and undersensing of low-amplitude R-waves was described in the remaining two cases.

### Subcutaneous implantable cardioverterdefibrillator extraction procedure

All the procedures were performed under local anaesthesia and conscious sedation. In no case was general anaesthesia required. The S-ICD system was successfully extracted in all patients, and no complications were reported. The median procedure duration was 40 (25th–75th percentile: 20–55) min. First, the sub-axillary pocket was opened.

In the case of the original intermuscular pocket or in the case of generator to be shifted from subcutaneous to intermuscular pocket, the adipose tissue was dissected gradually until the muscle fascia was reached. the intermuscular connective tissue was dissected, and the two muscle fasciae were separated. The pocket was intermuscular in 57 (80%) patients, and the pulse generator was easily removed in all the cases. Then, the lead was released from the can, and the xiphoid wound was opened to remove the sleeve suture. In the case of a three-incision implantation technique (three patients), a third incision was made in order to release the distal lead suture. In all patients, simple manual traction of the lead at the xiphoid wound was sufficient to remove the lead from the generator pocket through the horizontal tunnel. The parasternal tunnel was then approached: simple manual traction of the S-ICD lead through the xiphoid incision was sufficient to remove the lead in 59 (84%) patients, whereas one patient required an additional parasternal incision, and 11 (15%) required the use of a sheath to remove lead adhesions around the coil. In this latter group, extraction was obtained by dilatation with non-powered mechanical sheaths used for transvenous lead extraction (standard Byrd dilator sheath from Cook Intravascular, Leechburg, PA, USA). First, the S-ICD lead connector was cut, and a standard ligature was placed around the distal portion of the lumenless S-ICD lead. Gentle traction was then maintained, while the sheath was advanced by means of clockwise and

**Table 2** Indication for S-ICD extraction and re-implantation

Parameter	All S-ICD extractions N = 71	Re-implantation of an S-ICD $n=24$	Implantation of a T-ICD $n = 26$	No device re-implanted $n = 21$
Indication for S-ICD extraction				
Infection, n (%)	17 (24)			
Pocket/pulse generator	8	2	2	4
Lead	2	1	0	1
Pulse generator and lead	7	4	1	2
Device-related complication, n (%)	25 (35)			
Sensing issues	10	4	5	1
Lead dysfunction	8	7	1	0
Lead dislocation	4	4	0	0
Ineffective therapy	3	0	3	0
Clinical need	25 (35)			
Need for pacing				
Sinus node dysfunction	4	0	4	0
Cardiac resynchronization	10	0	10	0
Ventricular tachycardia requiring ATP	1	0	1	0
Heart transplantation	8	0	0	8
Ejection fraction improvement/re-evaluation of	2	0	0	2
indication				
Patient discomfort	4 (6)	1	0	3

ATP, antitachycardia pacing; S-ICD, subcutaneous implantable cardioverter-defibrillator; T-ICD, transvenous ICD.

**Table 3** Baseline and implantation characteristics according to the success of simple traction for lead extraction

Parameter	Simple traction (n = 59)	Unsuccessful simple traction (n = 12)	P value
Age at S-ICD extraction procedure, years	49 ± 15	52 ± 13	0.439
Male gender, n (%)	51 (86)	10 (83)	0.673
Body mass index, kg/m <sup>2</sup>	$27 \pm 5$	27 ± 3	0.567
History of median sternotomy, n (%)	9 (15)	0 (0)	0.340
S-ICD extraction for infection, <i>n</i> (%)	15 (25)	2 (2)	0.718
Two-incision lead-implantation technique	56 (95)	12 (100)	1.000
Time from implantation, months	20 (9–32)	30 (22–41)	0.032

counterclockwise rotation in order to overcome the adhesions in the parasternal tunnel. An 11.6 F outer yellow sheath was used in most cases. Rarely, inner 10 F and outer 13.1 F green sheaths were necessary in a telescopic modality. Most of the adherences were located at the

**Table 4** Peri- and post-procedural management of patients with device extracted for infection

Parameter	S-ICD extracted for infection (n = 17)
Hospitalization time, days	3 (1–6)
Pre-extraction antibiotics	8 (47)
Post-extraction antibiotics	
Oral antibiotic only	17 (100)
Intravenous post-extraction	0 (0)
antibiotics	
Duration of antibiotic therapy	10 (10–14)
Patient discharged with wearable	3 (17)
ICD	
Time to re-implantation, days	5 (0–58)
Concomitant re-implantation	5 <sup>a</sup> (29)

 $^{\rm a}\text{Two T-ICDs}$  and three S-ICDs; new system components shifted to non-contaminated locations (e.g. from subcutaneous to intermuscular pocket).

transition point between the proximal electrode and the coil, and a minority at the distal portion of the lead. The dwell time was significantly shorter in patients who required only simple traction [20 (9–32) vs. 30 (22–41) months, P=0.032, Table 3]. No complications occurred during the extraction procedure. Details of re-implantation after extraction are reported in Table 2.

5

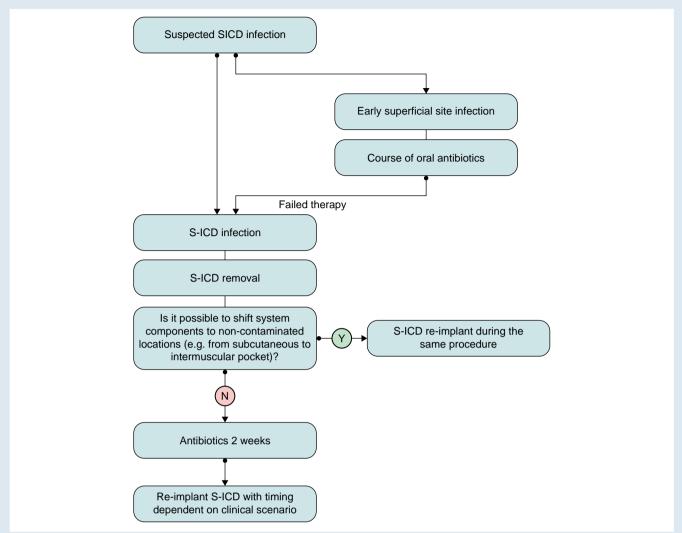


Figure 1 Application in practice of the algorithm of management and re-implantation for suspected S-ICD infection. S-ICD, subcutaneous implantable cardioverter—defibrillator.

### Peri- and post-procedural management

In patients undergoing extraction for non-infectious indications, the median hospitalization time was 2 days (25th–75th percentile: 1–2). In non-infected S-ICD patients (54), the device was re-implanted during the same procedure in 49 patients (91%); two patients underwent re-implantation after 3 days, and three underwent implantation of a T-ICD before S-ICD extraction.

In patients who underwent extraction for infection, the median hospitalization time was 3 days.  $^{1-6}$  No patients required post-extraction intravenous antibiotics, and the median duration of any antibiotic therapy was 10 days  $^{10-14}$ . The re-implantation was performed during the same procedure in 29% of cases. In particular, in three patients, a new system was ipsilaterally re-implanted, just after the extraction, shifting the new S-ICD generator from a subcutaneous to an intermuscular position. Details are reported in  $Table\ 4$ .

No patients exhibited signs of systemic infection, such as fever, high white blood cell count, or high C-reactive protein or procalcitonin levels. Over a median of 21 months, no complications were reported.

### **Discussion**

In the present analysis, S-ICD extraction proved safe and easy to perform, with no peri-procedural complications. In all cases, the procedure was performed under local anaesthesia and conscious sedation. Simple traction of the lead was successful in the vast majority of patients, but non-powered mechanical sheaths were needed for systems implanted for a longer time. The peri- and post-procedural management of S-ICD extraction was straightforward, also in the case of infectious indication. Despite short antibiotic treatments and early re-implantation performed in some cases, the outcome was positive with no complications or recurring infections over mid-term follow-up. This analysis of the data obtained from the large database of a national registry revealed that conditions requiring S-ICD extraction were quite rare. These included device-related complications, such as lead malfunction or inappropriate shocks not manageable by reprogramming, new-onset clinical needs, such as pacing or cardiac resynchronization therapy, and, more rarely, infections. By contrast, infections were responsible for about 50% of T-ICD lead extractions in published studies.<sup>6</sup> According to current recommendations, the key to successful

treatment of T-ICD infections is complete removal of all parts of the system and transvenous hardware. This treatment concept applies to systemic as well as localized pocket infections. Indeed, about half of the infections in T-ICD patients result in endovascular infections, which are associated with a high mortality risk.<sup>8,9</sup>

An infection rate of up to 3.2% has also been reported among S-ICD-related complications requiring surgical intervention in large studies.<sup>3,10</sup> However, the S-ICD involves no exposure of hardware to the intravascular system, and no case of systemic infection was identified in the Evaluation oF FactORs ImpacTing Clinical Outcome and Cost EffectiveneSS of the S-ICD (EFFORTLESS S-ICD) Registry. Moreover, a recent secondary analysis of the PRAETORIAN trial<sup>11</sup> found significantly more systemic infections in T-ICD patients than in S-ICD patients. Similarly, a prospective multicentre observational registry showed that all infections in T-ICD patients were systemic, vs. none in S-ICD patients. 12 These findings may have encouraged more conservative approaches to complications, with the preservation of system components in the clinical practice of the centres involved, thus explaining the small number of complete system extractions due to infection. The results obtained in previous studies may not be applicable to populations with different characteristics. Indeed, the patients enrolled in our registry differ from those enrolled in studies such as the PRAETORIAN<sup>4</sup> or the UNTOUCHED<sup>2</sup> (fewer co-morbidities and better cardiac function) but do not appear to significantly differ from the S-ICD Post Approval Study<sup>10</sup> and other studies. <sup>1,12</sup>

The widespread adoption of the intermuscular technique of implantation, which results in a deeper position of the generator and allows improved placement of the device, <sup>13,14</sup> may also have offered greater protection from erosion and reduced the number of cases of patient discomfort requiring extraction. Indeed, a recent propensity-matched case-control study demonstrated that placing the S-ICD generator in the intermuscular space, instead of in the standard subcutaneous pocket, resulted in fewer device-related complications, mainly pocket infections or patient discomfort, over a medium-term follow-up. <sup>15</sup>

Our procedural data showed that S-ICD extraction performed under local anaesthesia was safe, associated with a short procedure duration and free from complications. In our experience, the pulse generator was easily removed from both subcutaneous and intermuscular pockets. In all patients, simple manual traction of the lead at the xiphoid wound was sufficient to remove the lead from the generator pocket through the horizontal tunnel. Simple traction of the lead was also sufficient to remove the lead from the parasternal tunnel in 84% of patients. The remaining patients required additional tools or manoeuvres in order to dissect adhesions around the lead coil. In particular, standard polypropylene non-powered sheaths (from 10 to 13.1 F), usually employed for transvenous lead extraction, were successfully used. Since this occurred more frequently in patients who had systems implanted for a longer time, operators could benefit from having these tools available in case of extraction of an S-ICD system implanted for more than 2 years. This result is in line with, or even better than, that reported by Behar et al., 16 who described a series of 32 S-ICD extractions, all performed under general anaesthesia. Indeed, they reported a success rate of 60% with simple traction in patients in whom the time from S-ICD lead implantation to extraction was shorter (9 vs. 22 months). In our experience, no complications or recurring infections were reported in the post-operative phase and over a median of 21 months, in line with previous findings obtained in patients undergoing elective S-ICD generator replacement at a tertiary centre, <sup>17</sup> and in patients with device infection in the S-ICD Post Approval Study, who did not experience recurring infections, bacteraemia or a higher mortality rate.

Replacement of the S-ICD with a T-ICD was rare, except in the case of very few patients who developed indications for bradycardia pacing, cardiac resynchronization therapy, or anti-tachycardia pacing (25 out of 2718 patients enrolled in the registry), confirming recent findings from

large studies.<sup>2,3</sup> By contrast, in a previous study,<sup>19</sup> an S-ICD was frequently implanted after T-ICD removal, mostly in the case of infection. In the case of non-infectious indications, hospitalization time was very short, and re-implantation of the device was almost always performed during the same procedure and sometimes even before S-ICD extraction. In S-ICD patients who underwent extraction for infection, hospitalization time was also short, as was the duration of antibiotic therapy, and only oral antibiotics were used after extraction. Moreover, the device was re-implanted early or even during the same S-ICD extraction procedure, while current recommendations regarding T-ICDs suggest that re-implantation should be delayed until symptoms and signs of infection have resolved and more specifically indicate 2–6 weeks of antibiotics before re-implantation (Figure 1). Although the S-ICD does not permit the contralateral side to be used for the replacement device. complications were effectively managed by implanting new S-ICD components ipsilaterally but moving them from their original position to alternative locations (e.g. the generator from a subcutaneous to an intermuscular pocket, the electrode being covered by the fascia of the pectoral muscle), as previously described. 20 These results, in addition to having positive consequences in terms of ease of management and organization, certainly have implications in terms of therapy cost. Indeed, a propensity-matched case-control study<sup>21</sup> comparing the costs of the S-ICD and T-ICD demonstrated that the initial higher cost of the S-ICD was mitigated over a 5-year follow-up period and might be reversed over 10 years, thanks to the lower incidence rate of device-related complications. The present analysis suggests a further advantage, due to the probably lower cost of managing each complication.

On trying to interpret how the recommended algorithm of diagnosis, management, and re-implantation for suspected device infection has been applied in the clinical practice of the registry centres, we noticed an important simplification in the case of suspected S-ICD infection (Figure 1). In brief, reassured by the very low risk of systemic infections, operators appear to have managed complications such as pocket infections by administering shorter antibiotic treatments and performing early re-implantation. While larger studies are certainly needed in order to draw up clear management guidelines, the outcome observed in our analysis of clinical practice was positive. The present findings extend the picture of possible advantages of S-ICD therapy. Indeed, the superiority of S-ICD over T-ICD with respect to the rate of complications had been demonstrated in previous studies. 4,5,11 Here, we have shown that S-ICD complications can be safely and easily managed. Compared with T-ICD extraction, the management of S-ICD extraction seemed less burdensome for patients and the healthcare system, especially in the case of infectious indication. This supports the preference for the S-ICD option in indicated patients at high risk of infection.<sup>22–2</sup>

### Limitations

The limitations of our study should be acknowledged. The main limitations are the observational design and the small sample size. However, although the number of complications in analysis was limited, they derived from a large population managed in clinical practice. Indeed, consecutive patients were enrolled in the registry at 66 Italian centres, i.e. a representative sample (56%) of the 117 Italian centres (according to manufacturer's data) experienced in S-ICD implantation, having performed more than 13 procedures since 2013. Moreover, our results may not be applicable to other populations with different underlying demographics or to other healthcare systems.

### **Conclusions**

The S-ICD extraction procedure was safe and easy to perform, with no peri-procedural complications. Simple traction of the lead was

successful in the vast majority of patients, but specific tools could be needed for systems implanted for a longer time. The peri- and post-procedural management of S-ICD extraction was not very burdensome for patients and the healthcare system, also in the case of infectious indication. This could constitute an additional reason for preferring the S-ICD in indicated patients, especially when they are at high risk of infection.

### Supplementary material

Supplementary material is available at Europace online.

### **Funding**

This was an independent study. No external funding was received for this project.

**Conflict of interest:** R.R. received speaker fees from Abbot and Boston Scientific. L.O. is a consultant for Boston Scientific. P.F. received speaker fees from Boston Scientific and research or educational grants from Abbott and Boston Scientific. G.L.B. reports speaker fees (small amount) from Boston Scientific, Medtronic, Biotronik, Abbot, Microport, and Zoll. M.L. and S.V. are employees of Boston Scientific. The other authors report no conflicts.

### Data availability

The experimental data used to support the findings of this study are available from the corresponding author upon request.

### **Appendix**

List of participating centres

- ASST Rhodense, Rho-Garbagnate Milanese, Milan: G.L. Botto, F.L. Canevese, and M.C. Casale;
- ASST Sette Laghi, Ospedale di Circolo e Fondazione Macchi, Varese: F. Caravati;
- Azienda Ospedaliera 'G. Brotzu', Cagliari: B. Schintu, A. Scalone, G. Tola, and A. Setzu:
- Azienda Ospedaliera Mater Domini, Catanzaro: A. Curcio;
- Azienda Ospedaliera Universitaria Senese, Siena: A. Santoro, C. Baiocchi, R. Gentilini, and S Lunghetti;
- Clinica Montevergine, Mercogliano, Avellino: F. Solimene, G. Shopova, V. Schillaci, A. Arestia, and A. Agresta;
- Fatebenefratelli Hospital, Rome: S. Bianchi, P. Rossi, and F.M. Cauti;
- Fondazione Poliambulanza, Brescia: C. La Greca and D. Pecora;
- 'Giovan Battista Grassi' Hospital, Ostia, Rome: F. Ammirati, L. Santini, K. Mahfouz, and C. Colaiaco;
- IRCCS Fondazione Policlinico 'S. Matteo', Pavia: R. Rordorf, A. Vicentini, S. Savastano, B. Petracci, A. Sanzo, E. Baldi, and M. Casula;
- Istituto Auxologico Italiano—IRCCS, Milan: G.B. Perego and V. Rella;
- Istituto Clinico Sant'Ambrogio, Milan: L. Ottaviano;
- Monaldi Hospital, Naples: A. D'Onofrio, V. Bianchi, V. Tavoletta, and S. De Vivo;
- Ospedale 'G. Panico', Tricase, Lecce: P. Palmisano and M. Accogli;
- Ospedale 'Vito Fazzi', Lecce: E. Pisanò and G. Milanese;
- Ospedale Carlo Poma, Mantova: P. Pepi and D. Nicolis;
- Ospedale di Legnano, Milan: M. Mariani and M. Pagani;
- Ospedale Di Venere, Carbonara di Bari, Bari: Massimo Vincenzo Bonfantino;
- Ospedale F. Miulli, Acquaviva delle Fonti, Bari: V. Caccavo, M. Grimaldi, and G. Katsouras;
- Ospedale Luigi Sacco, Milan: G.B. Forleo;
- Ospedale Maggiore, Crema: E. Chieffo and E. Tavarelli;
- Ospedale Manzoni, Lecco: R. Brambilla and A. Pani;
- Ospedale Maria Vittoria, Turin: M. Giammaria, M.T. Lucciola, and C. Amellone;
- Ospedale Melorio, Santa Maria Capua Vetere, Caserta: C. Uran;
- Ospedale Niguarda Cà Granda, Milano: M. Baroni;

 Ospedale Papa Giovanni XXIII, Bergamo: P. De Filippo, P. Ferrari, and C. Leidi;

7

- Ospedale Pediatrico 'Bambino Gesù', Palidoro, Fiumicino: F. Drago, M.S. Silvetti, V. Pazzano, S. Russo, R. Remoli, I. Battipaglia, I. Cazzoli, and F. Saputo:
- Ospedale S. Andrea, La Spezia: C. Devecchi;
- Ospedale S. Andrea, Vercelli: L. Barbonaglia;
- Ospedale S. Anna e S. Sebastiano, Caserta: M. Viscusi, M. Brignoli, and A. Mattera;
- Ospedale S. Anna, Como: S. Pedretti;
- Ospedale S. Biagio, Domodossola: A Lupi and S. Tommasi;
- Ospedale S. Camillo de Lellis, Rieti: A. Kol, M.C. Gatto, and A. Persi;
- Ospedale S. Croce e Carle, Cuneo: A. Gonella, G. Rossetti, E. Menardi, and R. Rossini:
- Ospedale S. Donato, Arezzo: P. Notarstefano, M. Nesti, and A. Fraticelli;
- Ospedale S. Maria, Terni: G. Carreras, S. Donzelli, C. Marini, A. Tordini, and L. Lazzari:
- Ospedale S. Martino, Genova: P. Sartori, P. Rossi, P. Di Donna, and G. Mascia;
- Ospedale San Giovanni Bosco, Naples: P. Capogrosso, P. Magliano, and M. Colimodio;
- Ospedale San Raffaele, Milan: S. Sala, P. Mazzone, and P. Della Bella;
- Ospedale SS. Annunziata, Savigliano, Cuneo: A. Coppolino;
- Ospedale SS. Giacomo e Cristoforo, Massa: G. Arena, V. Borrello, M. Ratti, and C. Bartoli;
- Ospedale S. Andrea, Rome: P. Francia, F. Palano, and C. Adduci;
- Ospedale Villa Scassi, Genova: A. Torriglia and M. Laffi;
- Ospedali Riuniti San Giovanni di Dio e Ruggi d'Aragona, Salerno: M. Manzo, C. Esposito, A. Giano, and F. Franculli;
- Ospedali Riuniti, Reggio Calabria: A. Pangallo;
- P.O. Ferrari, Castrovillari, Cosenza: G. Bisignani and S. De Bonis;
- Paediatric Cardiology Unit, Second University of Naples, Napoli: B. Sarubbi, D. Colonna, A. Correra, and E. Romeo;
- Policlinico Federico II, Naples: A. Rapacciuolo, V. Liguori, A. Viggiano, and T. Strisciullo;
- Policlinico S. Orsola-Malpighi, Bologna: M. Biffi, I. Diemberger, M. Ziacchi, and C. Martignani;
- Policlinico Umberto I, Rome: A. Piro; C. Lavalle, M. Magnocavallo, and M.V. Mariani:
- Policlinico Universitario Campus Bio-Medico, Rome: D. Ricciardi, V. Calabrese, F. Gioia, and F. Picarelli;
- Presidio Ospedaliero Muscatello, Augusta (SR): G. Licciardello and G. Busacca:
- Presidio Ospedaliero Rodolico, Catania: V.I. Calvi;
- 'San Eugenio' Hospital, Rome: F. Lamberti, G. Lumia, C. Bellini, and C. Bianchi:
- 'San Giovanni Battista' Hospital, Foligno: G. Savarese, C. Andreoli, L. Pimpinicchio, and D. Pellegrini;
- 'San Luca' Hospital, Lucca: D. Giorgi, Bovenzi, and F. Busoni;
- Santa Maria della Misericordia, Udine: E. Daleffe, D. Facchin, and L. Rebellato:
- Università di Tor Vergata, Rome: G. Stifano, G. Magliano, D. Sergi, L. Barone, and R. Morgagni;
- Università Politecnica delle Marche, Ancona: A. Dello Russo, M. Casella, F. Guerra, L. Cipolletta, and S. Molini;
- University Hospital of Pisa, Pisa: R. De Lucia, A. Di Cori, G. Grifoni, L. Paperini, L. Segreti, E. Soldati, S. Viani, and G. Zucchelli;
- University of Campania 'Luigi Vanvitelli', Naples: G. Nigro, V. Russo, A. Rago, E. Ammendola, and A. Papa;
- University of Florence, Florence: P. Pieragnoli, G. Ricciardi, L. Checchi, and L. Perrotta;

University of Padua: F. Migliore.

### References

- Boersma L, Barr C, Knops R, Theuns D, Eckardt L, Neuzil P et al. Implant and midterm outcomes of the subcutaneous implantable cardioverter-defibrillator registry: the EFFORTLESS study. J Am Coll Cardiol 2017;70:830–41.
- Gold MR, Lambiase PD, El-Chami MF, Knops RE, Aasbo JD, Bongiorni MG et al. Primary results from the understanding outcomes with the S-ICD in primary prevention patients with low ejection fraction (UNTOUCHED) trial. Circulation 2021;143:7–17.

 Lambiase PD, Theuns DA, Murgatroyd F, Barr C, Eckardt L, Neuzil P et al. Subcutaneous implantable cardioverter-defibrillators: long-term results of the EFFORTLESS study. Eur Heart J 2022;43:2037–50.

8

- Knops RE, Olde Nordkamp LRA, Delnoy PHM, Boersma LVA, Kuschyk J, El-Chami MF et al. Subcutaneous or transvenous defibrillator therapy. N Engl J Med 2020;383: 526–36.
- Healey JS, Krahn AD, Bashir J, Amit G, Philippon F, McIntyre WF et al. Perioperative safety and early patient and device outcomes among subcutaneous versus transvenous implantable cardioverter defibrillator implantations: a randomized, multicenter trial. Ann Intern Med. 2022;175:1658–65.
- Bongiorni MG, Kennergren C, Butter C, Deharo JC, Kutarski A, Rinaldi CA et al. The European Lead Extraction ConTRolled (ELECTRa) study: a European Heart Rhythm Association (EHRA) registry of transvenous lead extraction outcomes. Eur Heart J 2017;38:2995–3005.
- Kusumoto FM, Schoenfeld MH, Wilkoff BL, Berul CI, Birgersdotter-Green UM, Carrillo R et al. HRS Expert consensus statement on cardiovascular implantable electronic device lead management and extraction. Heart Rhythm 2017;14:e503–51.
- Le KY, Sohail MR, Friedman PA, Uslan DZ, Cha SS, Hayes DL et al. Mayo Cardiovascular Infections Study Group. Impact of timing of device removal on mortality in patients with cardiovascular implantable electronic device infections. Heart Rhythm 2011;8:1678–85.
- Tarakji KG, Wazni OM, Harb S, Hsu A, Saliba W, Wilkoff BL. Risk factors for 1-year mortality among patients with cardiac implantable electronic device infection undergoing transvenous lead extraction: the impact of the infection type and the presence of vegetation on survival. Europace 2014;16:1490–5.
- Burke MC, Aasbo JD, El-Chami MF, Weiss R, Dinerman J, Hanon S et al. 1-year prospective evaluation of clinical outcomes and shocks: the subcutaneous ICD post approval study. JACC Clin Electrophysiol 2020;6:1537–50.
- Knops RE, Pepplinkhuizen S, Delnoy PPHM, Boersma LVA, Kuschyk J, El-Chami MF et al. Device-related complications in subcutaneous versus transvenous ICD: a secondary analysis of the PRAETORIAN trial. Eur Heart J 2022;43:4872–83.
- Palmisano P, Ziacchi M, Ammendola E, D'Onofrio A, Dell'Era G, Laffi M et al. Italian Association of Arrhythmology and Cardiac Pacing (AIAC). rate and impact on patient outcome and healthcare utilization of complications requiring surgical revision: subcutaneous versus transvenous implantable defibrillator therapy. J Cardiovasc Electrophysiol 2021;32:1712–23.
- Francia P, Biffi M, Adduci C, Ottaviano L, Migliore F, De Bonis S et al. Implantation technique and optimal subcutaneous defibrillator chest position: a PRAETORIAN scorebased study. Europace 2020;22:1822–9.
- Winter J, Siekiera M, Shin DI, Meyer C, Kröpil P, Clahsen H et al. Intermuscular technique for implantation of the subcutaneous implantable cardioverter defibrillator: long-term performance and complications. Europace 2017;19:2036–41.

 Botto GL, Ziacchi M, Nigro G, D'Onofrio A, Dello Russo A, Francia P et al. Intermuscular technique for implantation of the subcutaneous implantable defibrillator: a propensity-matched case—control study. Europace 2023;25:1423–1431.

- Behar N, Galand V, Martins RP, Jacon P, Badenco N, Blangy H et al. Subcutaneous implantable cardioverter-defibrillator lead extraction: first multicenter French experience. *JACC Clin Electrophysiol* 2020; 6:863–70.
- van der Stuijt W, Quast ABE, Baalman SWE, de Wilde KC, Brouwer TF, Wilde AAM et al. Complications related to elective generator replacement of the subcutaneous implantable defibrillator. Europace 2021:23:395–9.
- Gold MR, Aasbo JD, Weiss R, Burke MC, Gleva MJ, Knight BP et al. Infection in patients with subcutaneous implantable cardioverter-defibrillator: results of the S-ICD post approval study. Heart Rhythm 2022;19:1993–2001.
- Viani S, Migliore F, Tola G, Pisanò ECL, Russo AD, Luzzi G et al. Use and outcomes of subcutaneous implantable cardioverter-defibrillator (ICD) after transvenous ICD extraction: an analysis of current clinical practice and a comparison with transvenous ICD reimplantation. Heart Rhythm 2019;16:564–71.
- Droghetti A, Pecora D, Maffè S, Badolati S, Pepi P, Nicolis D et al. Shift and cover technique: conservative management of complications for the rescue of S-ICD subcutaneous implantable defibrillator systems. J Interv Card Electrophysiol 2022. Online ahead print.
- Honarbakhsh S, Providencia R, Srinivasan N, Ahsan S, Lowe M, Rowland E et al. A propensity matched case-control study comparing efficacy, safety and costs of the subcutaneous vs. transvenous implantable cardioverter defibrillator. Int J Cardiol 2017;228: 280–5.
- 22. Al-Khatib SM, Stevenson WG, Ackerman MJ, Bryant WJ, Callans DJ, Curtis AB et al. 2017 AHA/ACC/HRS guideline for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: A report of the American College of Cardiology/American Heart Association task force on clinical practice guidelines and the Heart Rhythm Society. Heart Rhythm 2018;15:e73–e189.
- Botto GL, Forleo GB, Capucci A, Solimene F, Vado A, Bertero G et al. The Italian subcutaneous implantable cardioverter-defibrillator survey: S-ICD, why not? Europace 2017;19:1826–32.
- Boveda S, Lenarczyk R, Fumagalli S, Tilz R, Gościńska-Bis K, Kempa M et al. Factors influencing the use of subcutaneous or transvenous implantable cardioverterdefibrillators: results of the European Heart Rhythm Association prospective survey. Europace 2018;20:887–92.
- Boveda S, Lenarczyk R, Haugaa K, Fumagalli S, Madrid AH, Defaye P et al. Implantation of subcutaneous implantable cardioverter defibrillators in Europe: results of the European Heart Rhythm Association survey. Europace 2016;18:1434–9.
- Knops RE, Brouwer TF, Barr CS, Theuns DA, Boersma L, Weiss R et al. The learning curve associated with the introduction of the subcutaneous implantable defibrillator. Europace 2016;18:1010–5.