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S-ICD CLINICAL REPORT 12

Performance excellence: S-ICD safety, efficacy and beyond

This clinical report focuses on the long-term safety, efficacy and longevity of the subcutaneous implantable cardioverter-defibrillator (S-ICD), drawing together insights gleaned from two studies and one abstract showcased at the 2023 European Society of Cardiology congress. A US Food and Drug Administration (FDA)-mandated post-approval study focuses on the long-term safety and efficacy of S-ICDs through extended follow-up in a patient cohort exhibiting a greater prevalence of comorbidities than observed in most previous trials.[1] The S-ICD extraction procedure, along with associated management strategies and their resulting outcomes, was explored in an in-depth study of real-world clinical practice in Italy.[2] Finally, we present results from an abstract dedicated to estimating the longevity of S-ICDs based on real-world data, while also evaluating factors that influence device longevity.[3]

Long-term efficacy and safety: Real-world evidence from a diverse patient cohort

The post-approval study was an FDA-mandated post-market study, designed to evaluate the long-term safety and efficacy of the S-ICD. It involved 86 US centres and enrolled 1,643 patients with a median follow-up of 4.2 years, with 665 patients completing 5 years of follow-up.[1] While the patient age was 'typical' for S-ICD studies,[1] enrolled patients exhibited more comorbidities compared with cohorts in the EFFORTLESS[4] and IDE[5] studies.

The primary efficacy endpoint was the overall shock efficacy in converting spontaneous, discrete episodes of ventricular tachycardia (VT) or ventricular fibrillation (VF) through 60 months. The primary safety endpoint was the type I (directly caused by the S-ICD) complication-free rate at 60 months.[1]

S-ICD performance is maintained over the long-term

The high rate of defibrillation success was maintained through the 5-year follow-up: the overall shock efficacy rate for spontaneous discrete ventricular arrythmia episodes was 98.4%, which exceeded the performance goal of 94% (Figure 1A). Importantly, both the first and overall shock efficacies were similar for monomorphic/polymorphic VT/VF and maintained over time.

Despite enrolling a more diverse patient population, complication-free rates were 93.4% for the S-ICD device (type 1 complications) and 99.3% for the S-ICD lead; both of which exceeded the performance goals of 85% and 92.5%, respectively (Figure 1B). The electrode-related complication rate at 5 years was only 0.7%, emphasising the S-ICD's superiority in minimising lead-related issues compared with traditional transvenous ICDs (TV-ICDs).[1]

Infections necessitating device explantation affected 2.8% of patients, and 0.4% experienced explantation due to erosion – both well within the range of previous S-ICD studies. Importantly, none of these infections led to bacteraemia. A transition from S-ICDs to transvenous systems for pacing occurred in 1.6% of cases (most commonly for cardiac resynchronisation therapy implantation), which is similar to upgrade rates for TV-ICD implants and is attributed to the natural progression of heart disease.[1] In their editorial comment featuring the post-approval study, Steinberg and Kutyifa state, 'The S-ICD represents a significant tool within the modern electrophysiologist's arsenal, offering a valuable solution for a specific group of patients with indications for ICD therapy. It effectively mitigates the risk of lead-related complications, ensuring consistent and dependable treatment for life-threatening ventricular tachyarrhythmias'.[6]

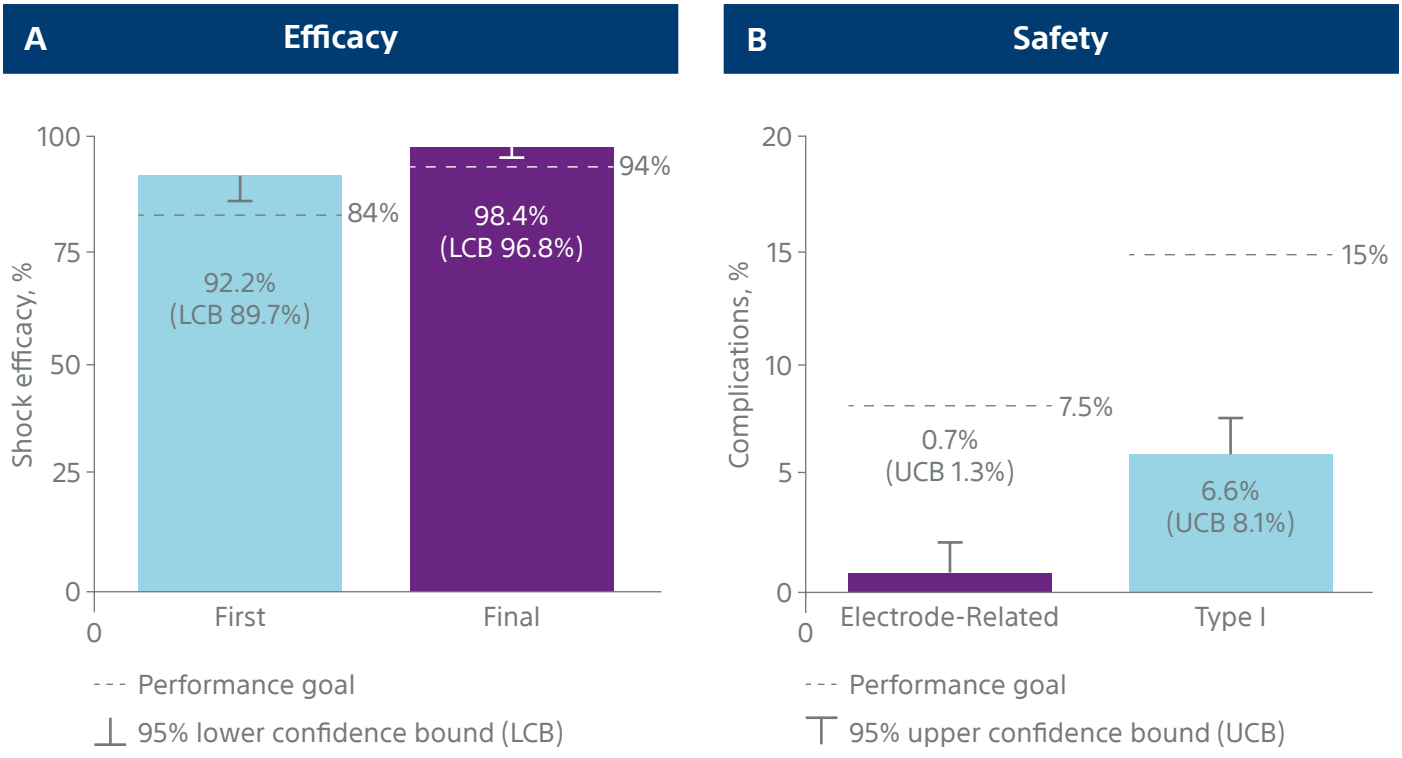


Figure 1. Subcutaneous implantable cardioverter-defibrillator post-approval study primary safety and efficacy endpoints.[1]

S-ICD extractions: Insights from mid-term follow-up

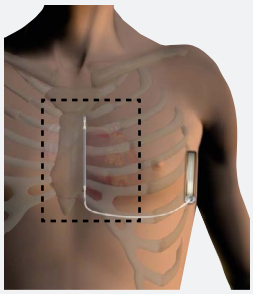
Large studies have reported infection rates of up to 3.2% in S-ICD-related complications requiring surgical intervention.[2,4,7] Furthermore, a recent secondary analysis of the PRAETORIAN trial revealed a significantly higher rate of systemic infections among TV-ICD patients compared with S-ICD patients.[2,8] S-ICD therapy is experiencing rapid growth. However, while extraction rates are low, as demonstrated by the very low rates observed in the post-approval study, there is a dearth of data on their management and outcome. Therefore, De Filippo *et al.* analysed data from the Rhythm Detect registry to provide insights into the procedure, management and outcomes of S-ICD extractions in real-world clinical practice.[2]

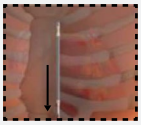
S-ICD extractions are easy to perform, with no intraprocedural complications and positive outcomes over mid-term follow-up

Between 2013 and 2022, 2,718 patients underwent initial S-ICD implantation and were included in the Italian Rhythm Detect registry. Among these, 71 required complete S-ICD system extraction (due to infection in 17 patients).[2]

In this analysis, the extraction of S-ICDs was both safe and uncomplicated. The S-ICD system was successfully extracted in all patients with no intraprocedural complications and a median procedure duration of 40 min. All procedures were conducted under local anaesthesia and conscious sedation. 85% of patients required only simple lead traction, while non-powered mechanical sheaths were occasionally necessary for longer-implanted systems (Figure 2). Hospitalisation time was short in the case of both non-infectious (2 days) and infectious indications (3 days). The management of peri- and post-procedural aspects of S-ICD extraction was straightforward, even in cases involving infections (Figure 2). Despite short courses of antibiotics (no patients required post-extraction intravenous antibiotics) and, in some instances, early re-implantation (concomitant with extraction in 29% of cases), the outcomes were consistently positive, with no complications or recurrent infections observed during mid-term follow-up (median 21 months).[2]

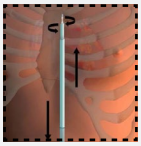
S-ICD extraction procedure





Simple manual traction in 85%

Median dwell time: 20 months



Non-powered mechanical sheaths in 15%

Median dwell time: 30 months

Management	
Non-infectious indications	
Hopitalisation time	2 days
Concomitant re-implantation	91%
Infectious indications	
Hopitalisation time	3 days
Concomitant re-implantation	29%
Post-extraction IV antibiotics	0 patients
Median duration of antibiotic therapy	10 (10–14) days

Figure 2. S-ICD extraction procedure and management.[2] IV, intravenous; S-ICD, subcutaneous implantable cardioverter-defibrillator.

While attempting to assess the application of the currently recommended algorithm for diagnosing, managing, and re-implanting suspected device infections within the clinical practices of the registry centres, the authors observed a notable simplification in cases of suspected S-ICD infections (Figure 3). The very low risk of infections appears to reassure operators to the extent that complications such as pocket infections are managed with shorter antibiotic treatments and early re-implantation.[2]

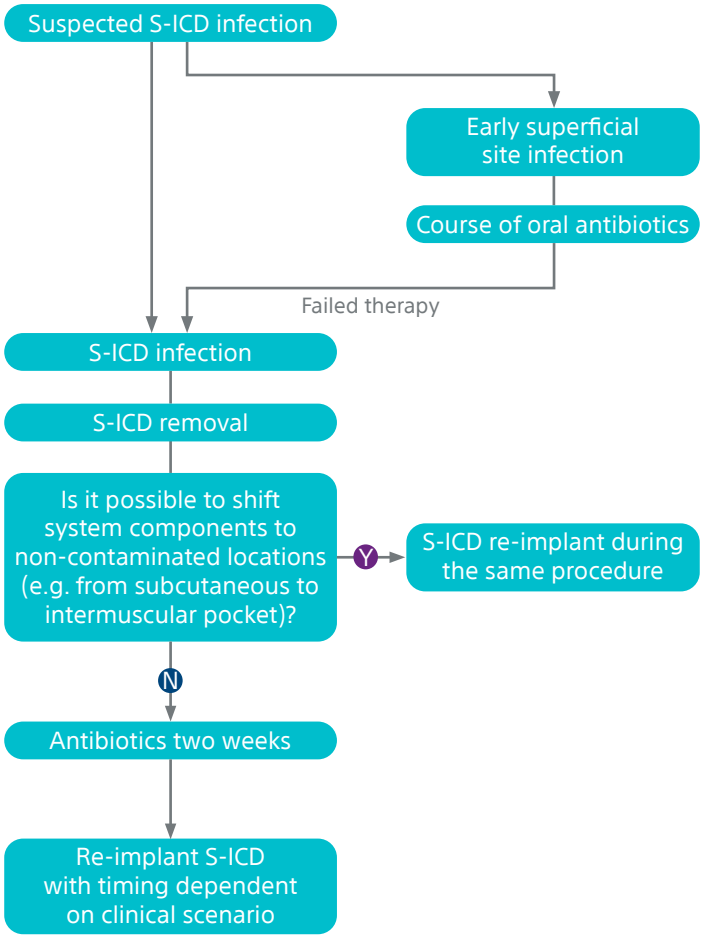


Figure 3. The practical implementation of the management and re-implantation algorithm for suspected S-ICD infection.[2] S-ICD, subcutaneous implantable cardioverter-defibrillator.

Real-world longevity of S-ICD devices

S-ICD device longevity is officially labelled at 7.3 years, under normal usage, including features like remote monitoring and pre-arrhythmia electrogram storage, for second- and third-generation devices (EMBLEM™ and EMBLEM MRI™).[9] Van Der Stuijt *et al.* conducted an analysis to investigate the real-world longevity of S-ICD devices.[3]

The longevity of S-ICD is exceeding expectations

In November 2022, de-identified data from 32,678 S-ICD devices implanted for a minimum of 3 months, with approximately 42.5% of them subject to the Premature Battery Depletion advisory, were obtained. These data were sourced from recent uploads from patient devices to the US LATITUDE system.[3]

Using the Monte Carlo simulation model, based on real-world data, S-ICD EMBLEM and EMBLEM MRI longevity was predicted to be 8.7 years, surpassing the labelled duration of 7.3 years.[3,9] Only number of shocks delivered impacted device longevity, with a reduction of 0.8 years for patients who experience two or more shocks per year and 0.4 years for patients with less frequent shocks (Figure 4). Observations from this analysis align with results published in the Boston Scientific Product Performance Report that longevity for devices under the advisory is projected to be 6.6 years.[10] Furthermore, when accounting for devices affected by shocks and premature battery depletion, no other factor (such as defibrillation threshold testing, atrial fibrillation trend monitoring and LATITUDE transmission use) impacted device longevity by more than 0.09 years.[3]

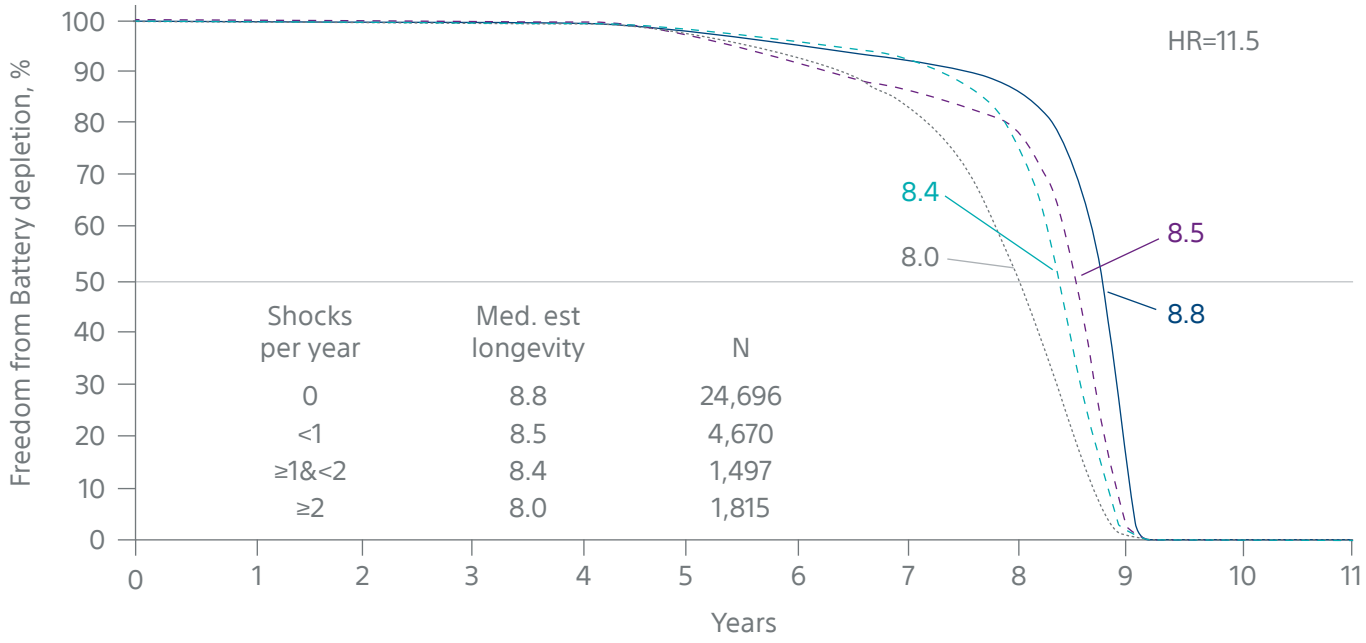


Figure 4. Impact of shocks on battery longevity.[3] HR, hazard ratio.

Summary

- The long-term safety and efficacy of the S-ICD were established in a large prospective study of a patient cohort with more comorbidities than previous trials.[1,4,5] Complication rates were low, and shock efficacy was high and consistent throughout the 5-year follow-up.[1]
- When necessary, S-ICD extraction in clinical practice is simple to perform and is associated with positive outcomes, such as short hospital stays and early re-implantation.[2]
- S-ICD longevity exceeded labelling expectations in the real world, with a median estimated longevity of 8.7 years.[3]

References

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