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S-ICD CLINICAL REPORT 10

S-ICD: REAL-WORLD SHOCK EFFECTIVENESS

This clinical report explores the latest real-world data on subcutaneous implantable cardioverter-defibrillator (S-ICD) performance that can be applied to clinical practice leading to improvements in patients' outcomes. First, clinical experiences from two retrospective analyses from the observational Rhythm Detect registry are described.[1,2] One analysis explores acute-shock efficacy according to S-ICD implantation technique;[1] the other evaluates the effect of S-ICD implantation technique on optimal position for effective defibrillation.[2] Second, this report presents recently released data from the EFFORTLESS registry – the first large multicentre registry to report 5-year outcomes of patients implanted with S-ICD.[3] Finally, we explore a retrospective analysis of S-ICD conversion rates until the end of device life and recommendations to improve defibrillation efficacy (DE).[4]

1. Impact of implantation technique on acute shock efficacy: A real-world experience

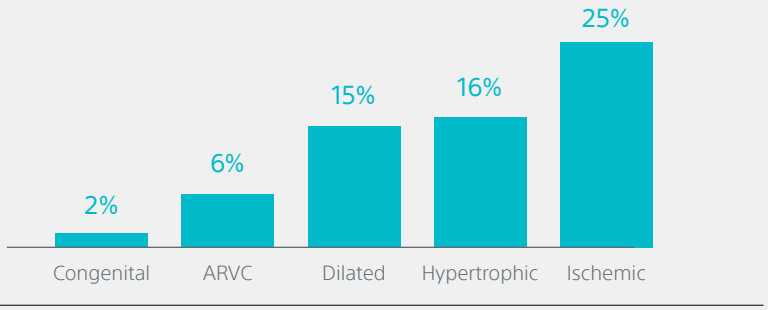
Acute shock efficacy of S-ICD according to implantation technique: The Rhythm Detect registry

The intermuscular (IM) 2-incision technique, which has been shown to prevent complications and have better cosmetic outcomes, shorter procedural times and low PRAETORIAN scores, is now widely adopted.[2,5-7] However, it is unclear whether the use of this technique affects DE.[1] In their retrospective study, Francia *et al.* assessed acute DE of S-ICD according to implantation technique.[1] The study evaluated 805 patients who had undergone *de-novo* S-ICD implantation in the Italian Rhythm Detect registry between January 2013 and July 2018 (Table 1).[1]

THE IM 2-INCISION TECHNIQUE REDUCES POCKET-ASSOCIATED COMPLICATIONS AND OFFERS BETTER COSMETIC OUTCOMES AND SHORTER PROCEDURAL TIMES[5,6]

Table 1. Key baseline characteristics of patients in the registry.[1]

Characteristic	N=805
Male, n (%)	660 (82)
Age, years (SD)	48 (15)
BMI (range), kg/m²	25.2 (23.1–27.6)
LVEF (range), %	55 (33–64)
LVEF ≤35%, n (%)	272 (34)
Beta blockers, n (%)	411 (51)
Antiarrhythmic drugs, n (%)	107 (13)



ARVC, arrhythmogenic right ventricular cardiomyopathy; BMI, body mass index; LVEF, left ventricular ejection fraction.

546 (67.8%) patients underwent IM 2-incision technique

Patients were grouped based on the technique used for implantation: IM with two (n=546) or three incisions (n=15), and subcutaneous (SC) with two (n=133) or three incisions (n=111).[1]

High acute shock success rate

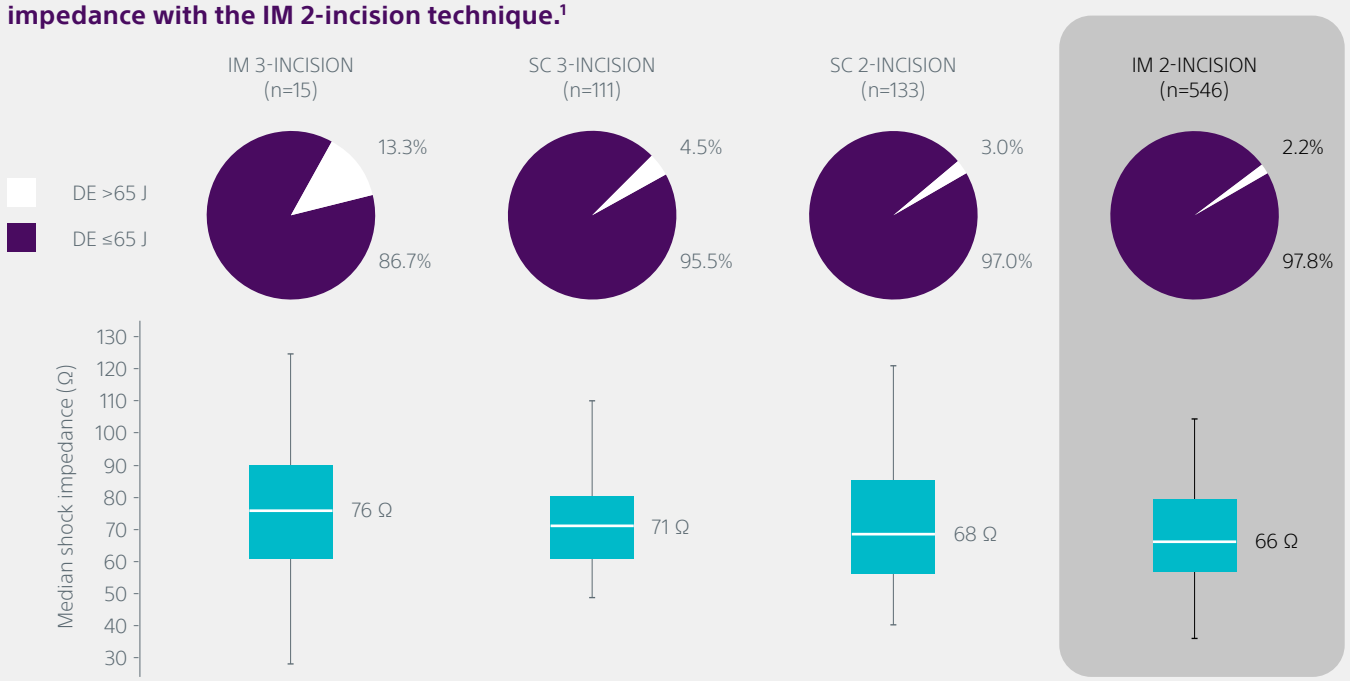
DE of ≤65 J was observed in 782 (97.1%) patients. Compared with patients with DE >65 J, these patients showed a trend towards lower BMI (25.1 *versus* 26.5; p=0.12), were not as likely to be receiving antiarrhythmic drugs (13% *versus* 26%; p=0.06) and were more frequently implanted using the 2-incision technique (85% *versus* 70%; p=0.04). On a multivariate analysis, the 2-incision technique was associated with a significantly lower incidence of shock failure (odds ratio [OR] 0.305; 95% CI 0.102–0.907; p=0.033) independent of BMI and the use of antiarrhythmic drugs.[1]

The overall rate of shock failure decreased over the years. However, patients implanted with a combination of surgical approaches that included either SC (2- or 3-incision) or IM 3-incision technique presented higher shock failure rates despite being implanted in recent years. In contrast, shock failure with the IM 2-incision technique was steadily low throughout the 7-year study period.[1]

Lowest conversion failure rate and shock impedance with IM 2-incision technique

The IM 2-incision technique showed the lowest defibrillation failure rate (2.2%) and median shock impedance (66 Ω, interquartile range [IQR] 57–77). Median shock impedance was significantly lower with IM than with the SC approach (66 Ω *versus* 70 Ω, p=0.002) and with the 2-incision rather than the 3-incision technique (67 Ω *versus* 72 Ω; p=0.006).[1]

Lowest defibrillation failure rate and median shock impedance with the IM 2-incision technique.[1]



DE, defibrillation efficacy.

Conclusions

- There was a clear association between implant technique and acute shock efficacy (DE ≤65 J observed in 97.1% of patients) in S-ICD patients.[1]
- The IM 2-incision technique resulted in the lowest acute shock failure rate (2.2%) and the lowest shock impedance (66 Ω).[1]

Implantation technique and optimal S-ICD position: A PRAETORIAN score-based study

Optimal implantation of the S-ICD can be achieved by minimising the amount of adipose tissue between the coil and the sternum and between the pulse generator (PG) and the thorax.[2,8,9] The PG must also be positioned appropriately along the anterior–posterior axis of the thorax.[10] The PRAETORIAN score effectively identifies patients whose device positioning may put them at high risk of unsuccessful defibrillation (higher PRAETORIAN score) and it can be used to determine the components of the implantation procedure that contribute to the risk of conversion failure.[10] The score has been retrospectively validated and prospective validation is ongoing in the PRAETORIAN-DFT trial.[10,11]

A HIGHER PRAETORIAN SCORE EFFECTIVELY IDENTIFIES PATIENTS WHOSE DEVICE POSITIONING CAN PUT THEM AT INCREASED RISK OF UNSUCCESSFUL DEFIBRILLATION[10]

The primary aim of this analysis was to evaluate whether implantation technique affected the optimal position of the S-ICD on chest radiographs, according to the PRAETORIAN score.[2]

The study analysed 213 patients who had undergone S-ICD implantation between 2013 and 2018 at 13 referral centres participating in the Rhythm Detect registry. All patients had anterior–posterior and lateral chest radiographs of sufficient quality to calculate the PRAETORIAN score. Most patients (86%) were male, with a mean age of 48 years and mean BMI of 25.5. The IM 2-incision approach was used in 171 patients (80%).[2]

The PRAETORIAN score was calculated using four steps, as described below.[10]

Determining the PRAETORIAN score.[10]

1

Assess the amount of adipose tissue between the coil and the sternum.

2

Assess the PG position to ensure the electric field is directed towards the critical mass of the heart (PG positioned on or posterior to the midline).

3

Measure the amount of adipose tissue between the PG and thorax.

4

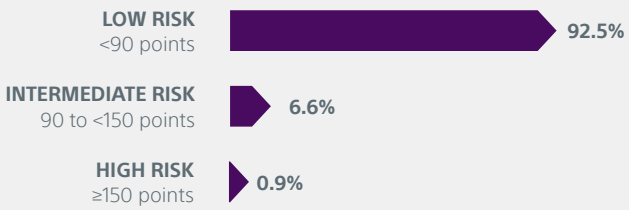
Patients with a BMI of ≤25 kg/m^2 are rewarded by subtracting 40 points in the case of a score of ≥90.

BMI, body mass index.

Low PRAETORIAN scores with IM 2-incision technique

According to the PRAETORIAN score, the risk of conversion failure was low (PRAETORIAN score <90) in 197 patients (92.5%); intermediate (PRAETORIAN score 90 <150) in 14 (6.6%) patients, and high (PRAETORIAN score ≥150) in two (0.9%) patients. Patients with intermediate or high PRAETORIAN scores had higher BMI than patients with low scores. All other baseline characteristics were comparable between groups.[2]

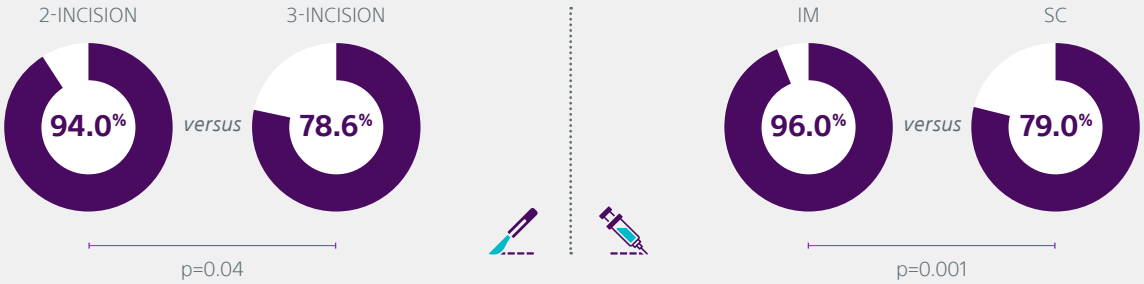
Risk of unsuccessful conversion using the PRAETORIAN score.[2]



Most patients (92.5%) were at low risk of conversion failure according to the PRAETORIAN score.[2]

Patients who underwent the IM 2-incision technique were more likely to have low PRAETORIAN scores (<90) than any other combination of implantation approaches (95.9% *versus* 78.6%; p <0.001). Patients who underwent IM implantation were significantly more likely to have a low PRAETORIAN score (<90) than those who had SC implantation (p=0.001). These differences were observed even after correction for BMI (HR 3.76 [95% CI 1.01–14.02]; p=0.04).[2]

Low PRAETORIAN score (<90) by implantation technique.[2]



PRAETORIAN score according to chest radiograph analysis.
IM, intermuscular; SC, subcutaneous.

Low shock impedance among PRAETORIAN low-risk patients

Shock impedance was lower among PRAETORIAN low-risk patients than among patients in the intermediate- or high-risk categories (66 Ω versus 96 Ω, respectively; p=0.001). Patients undergoing the IM technique were more likely to have the PG implanted on or posterior to the midline as compared to SC patients. The probability of effective defibrillation was high and comparable to that observed in previous studies.[2]

PATIENTS WHO UNDERWENT IM 2-INCISION TECHNIQUE WERE SIGNIFICANTLY MORE LIKELY TO HAVE LOW (<90) PRAETORIAN SCORES[2]

Conclusions

- S-ICD implantation technique affects optimal chest-radiograph position of the defibrillation system.[2]
- IM implantation combined with the 2-incision technique is associated with low PRAETORIAN scores (<90).[2]
- The IM 2-incision technique yields lower shock impedance than any other implantation approach.[2]

2. Long-term efficacy of S-ICD and its impact on clinical outcomes

Five-year efficacy and final outcomes of the EFFORTLESS S-ICD registry

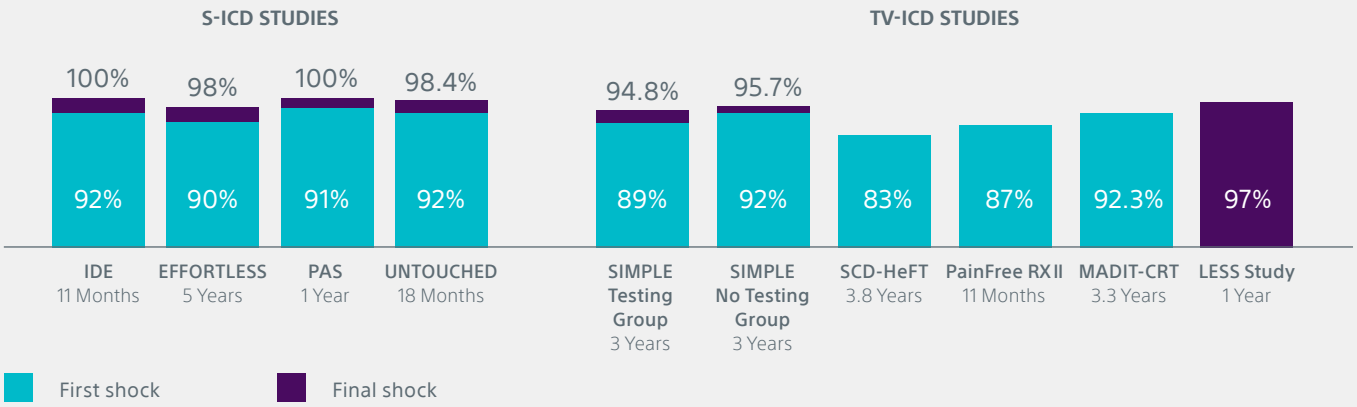
The EFFORTLESS S-ICD (Evaluation oF FactORs ImpacTing CLinical Outcome and Cost EffectiveneSS of the S-ICD) study is a non-randomised multicentre registry. It was designed to collect long-term, system-related, clinical and patient-reported outcome data from difficult-to-treat patients (N=984; 32.4% had ischaemic cardiomyopathy, 18% non-ischaemic or dilated cardiomyopathies, and 20% channelopathies) who had undergone S-ICD implantation in August 2009–December 2014 across 42 centres in 10 countries.[12-14]

The initial results of the EFFORTLESS registry demonstrated the safety and efficacy of S-ICD after 3.1 years of follow up.[12] Longer follow-up has confirmed a shock efficacy of 98% overall and a shock efficacy for discrete spontaneous episodes between 96% and 100% over a period of five years.[3]

The high efficacy demonstrated in the EFFORTLESS registry is consistent with that observed in other S-ICD clinical studies, across a diverse range of patients.[5,15-17]

THE CONVERSION RATE DURING SPONTANEOUS EPISODES REMAINS HIGH AND COMPARABLE TO THE CONVERSION RATE DURING INDUCED EPISODES[5,15-22]

The spontaneous conversion rates for S-ICD are comparable to transvenous ICD (TV-ICD).[5,15-22] Shock efficacy did not change over time.[17]



Results from different clinical studies are not directly comparable and information is provided for educational purposes only. Additionally, only first shock data were available for SCD-HeFT, PainFree RX II, and MADIT-CRT and only final shock data were available for the LESS study. S-ICD, subcutaneous implantable cardioverter defibrillator; TV-ICD, transvenous implantable cardioverter defibrillator.

Conclusion

- The EFFORTLESS registry provides valuable clinical evidence of the long-term efficacy of S-ICD, demonstrating consistently high DE conversion rates over five years.[17]

S-ICD replacement: Long-term S-ICD efficacy

In a retrospective analysis, Stuijt *et al.* aimed to describe the procedural characteristics of the replacement procedure and to provide an insight in the shock conversion rate during defibrillation testing at replacement. A total of 72 patients underwent elective generator replacement due to battery depletion, after an average of 5.9 ± 0.7 years. The patients in this cohort were young (mean age 46 ± 15 years) with a preserved LVEF (49.6 ± 11.6%), and limited comorbidities. The majority of patients were implanted using a 2-incision technique (65%) and 89% of them had a low PRAETORIAN score after initial implant. In all patients, the chest X-ray after implant was carefully reviewed to check for intermediate or high PRAETORIAN scores (≥90). The implanting physician could choose to reposition the pocket more posteriorly during the replacement procedure in order to minimise the defibrillation threshold.[4]

Table 2. Practical aspects of S-ICD replacement procedure[4]

	N=72
Battery longevity (years), mean (SD)	5.9 (0.7)
Procedural time (minutes), mean (SD)	38 (13)
Defibrillation testing, n (%)	
Successful first shock	53 (91.4) [n=58]
Unsuccessful first shock	5 (8.6) [n=58]
Unable to induce VF	5 (7.9) [n=63]
Shock impedance during implant (Ω), mean (SD)	77 (26) [n=48]
Shock impedance during replacement (Ω), mean (SD)	86 (28) [n=48]

SD, standard deviation; VF, ventricular fibrillation.

High conversion rate during defibrillation testing at replacement

VF was successfully induced in 58 out of 63 (92%) patients. Although there was an increase in shock impedance compared to during the implant procedure, the first S-ICD shock effectively terminated the arrhythmia in 53 out of 58 patients, resulting in a first conversion rate of 91.4% and up to 100% after multiple attempts.[4]

This is consistent with the first shock success rate after S-ICD implantation, as shown in both the EFFORTLESS registry and the Investigational Device Exemption (IDE) clinical study.[4,13,16]

Conversion rate during defibrillation testing at replacement.[4]

91.4%
first conversion rate

100%
conversion rate after multiple attempts

Mean shock impedance was significantly higher during replacement than during original implantation (86 ± 28 Ω *versus* 77 ± 26 Ω, p<0.001), possibly caused by device encapsulation or fibrotic tissue, but this did not impact the success rate of defibrillation.[4]

THE INCREASE IN IMPEDANCE WAS NOT SIGNIFICANTLY DIFFERENT BETWEEN PATIENTS WITH A SUCCESSFUL FIRST SHOCK AND THOSE WITH AN UNSUCCESSFUL FIRST SHOCK DURING DEFIBRILLATION TESTING (10 ± 15 Ω *versus* 12 ± 34 Ω, P= 0.85)[4]

Conclusions

- The first shock success rate was high (91.4%) during the defibrillation testing after replacement, in line with the first shock success rate observed after initial S-ICD implantation.[4]
- An increase in shock impedance between implantation and replacement procedure was observed, possibly caused by device encapsulation or fibrotic tissue.[4]
- The position of the implant better predicts defibrillation success than shock impedance.[4]
- Implanters should make every effort to ensure optimal S-ICD position during implantation, while consulting chest X-rays for possible repositioning of PG during the replacement procedure to increase S-ICD efficacy.[4]

Summary

Lower shock impedance and higher likelihood of successful defibrillation is observed in patients who undergo S-ICD implantation with the IM 2-incision technique.[1]

The IM 2-incision technique is associated with low risk of shock failure as assessed by the PRAETORIAN score.[2]

The EFFORTLESS registry demonstrated high spontaneous shock efficacy (≈98%) of S-ICD over five years.[17]

S-ICD replacement is associated with a high shock conversion rate consistent with the first shock after implantation.[4]

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