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Acute shock efficacy of the subcutaneous implantable cardioverter-defibrillator according to the implantation technique

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Abstract

Background: The traditional technique for subcutaneous implantable cardioverter defibrillator (S-ICD) implantation involves three incisions and a subcutaneous (SC) pocket. An intermuscular (IM) 2-incision technique has been recently adopted.

Aims: We assessed acute defibrillation efficacy (DE) of S-ICD (DE ≤65 J) according to the implantation technique.

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Methods: We analyzed consecutive patients who underwent S-ICD implantation and DE testing at 53 Italian centers. Regression analysis was used to determine the association between DFT and implantation technique.

Results: A total of 805 patients were enrolled. Four groups were assessed: IM + 2 incisions ($n = 546$), SC + 2 incisions ($n = 133$), SC + 3 incisions ($n = 111$), and IM + 3 incisions ($n = 15$). DE was ≤65 J in 782 (97.1%) patients. Patients with DE ≤65 J showed a trend towards lower body mass index (25.1 vs. 26.5; $p = .12$), were less frequently on antiarrhythmic drugs (13% vs. 26%; $p = .06$) and more commonly underwent implantation with the 2-incision technique (85% vs. 70%; $p = .04$). The IM + 2-incision technique showed the lowest defibrillation failure rate (2.2%) and shock impedance (66 Ohm, interquartile range: 57–77). On multivariate analysis, the 2-incision technique was associated with a lower incidence of shock failure (hazard ratio: 0.305; 95% confidence interval: 0.102–0.907; $p = .033$). Shock impedance was lower with the IM than with the SC approach (66 vs. 70 Ohm $p = .002$) and with the 2-incision than the 3-incision technique (67 vs. 72 Ohm; $p = .006$).

Conclusions: In a large population of S-ICD patients, we observed a high defibrillation success rate. The IM + 2-incision technique provides lower shock impedance and a higher likelihood of successful defibrillation.

KEYWORDS

conversion, defibrillation test, ICD, safety, subcutaneous

1 | INTRODUCTION

The subcutaneous implantable cardioverter-defibrillator (S-ICD) is an effective alternative to the traditional ICD and protects from complications associated with the insertion and long-term presence of transvenous leads in the heart and the vascular system.[1] The initial worldwide experience with the S-ICD has been described in two studies, the S-ICD System IDE Clinical Investigation (IDE) study[2] and the Evaluation oF FactORs ImpacTing CLinical Outcome and Cost EffectiveneSS of the S-ICD (EFFORTLESS S-ICD) Registry.[3] More recently, the PRAETORIAN randomized trial[4] and the UNTOUCHED prospective registry[5] confirmed the safety and efficacy of the S-ICD.

In patients with S-ICD, defibrillation testing on implantation is recommended[6] and independent studies have confirmed high rates of successful conversion in clinical practice.[7–10] The traditional S-ICD implantation technique, involving 3 incisions and insertion of the pulse generator under the subcutaneous (SC) tissue, has significantly changed over time, and a 2-incision technique has been introduced; this avoids the superior parasternal incision, and uses an intermuscular (IM) pocket for the pulse generator between the anterior surface of the serratus anterior and the posterior surface of the latissimus dorsi muscles.[11–14] The 2-incision IM technique offers better cosmetic outcomes, is faster, and has been recently reported to yield lower PRAETORIAN score than conventional implantation approaches.[15] In this study, we aimed to assess whether newer S-ICD implantation techniques (i.e., 2-incision and IM) affects defibrillation efficacy (DE) on induced ventricular fibrillation (VF).

2 | METHODS

2.1 | Study population

From January 2013 to July 2018, consecutive patients undergoing de-novo implantation of an S-ICD (Boston Scientific Inc.) were enrolled at 53 Italian centers (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 (ECG), estimation of NYHA functional class and echocardiographic evaluation.

2.2 | S-ICD implantation

Before implantation, S-ICD eligibility was assessed through surface ECG screening by means of a dedicated ECG morphology tool or an automatic screening tool.[16] The S-ICD implantation technique has changed significantly over the years. According to the first technique described, implantation is performed through three incisions: one on the left-lateral chest for the pulse generator pocket, and two parasternal for lead tunneling. The pulse generator is positioned in a SC pocket created over the fifth intercostal space between the mid and the anterior axillary lines. The electrode is tunneled from the lateral pocket through the parasternal incision, just below the level of the xiphoid process, and lies parallel to the left side of the sternum, with its upper pole anchored at the level of the sternal notch. A new implantation technique (the “2-incision technique”) has been developed that avoids the third superior parasternal incision by tunneling the defibrillation lead through a peel-away sheath introducer.[11–13] With the IM approach, the S-ICD is placed in a virtual space between the anterior surface of the serratus anterior and the posterior surface of the latissimus dorsi muscles. Physician preference and patient characteristics determined the implant technique used.

2.3 | Defibrillation testing

DE testing was performed according to the local clinical practice. Briefly, at the end of the procedure, VF was induced by means of a 50 Hz current delivered by the device itself and ≤65 J DE was assessed. Success was defined as termination of VF by the first shock at 65 J. Dichotomization of DE (≤65 vs. >65 J) was based on S-ICD manufacturer recommendation of having at least 15 J safety margin over the maximal S-ICD shock output (80 J). After implantation, the S-ICD was programmed to deliver only shocks at 80 J.

2.4 | Study aims

The primary aim of this study was to assess the acute effectiveness of S-ICD (defined as DE ≤65 J) according to the implantation technique.

2.5 | Statistical analysis

Descriptive statistics are reported as mean ± *SD* for normally distributed continuous variables, or medians with corresponding interquartile range (IQR) in the case of skewed distribution. Categorical variables are reported as percentages. Differences were compared by means of *t* test for normally distributed variables and Wilcoxon's or Kruskal–Wallis nonparametric tests for non-Gaussian variables, as appropriate. The χ^2 or Fisher's exact test were used to compare proportions, as appropriate. Multivariate logistic regression analysis was used to determine the association between the acute effectiveness of the system and clinical characteristics or implantation variables. The multivariate model was performed using the block model and fitted with baseline covariates associated with DE ≤65 by means of univariate analysis at the 0.1 significance level. The assumptions underlying the model (absence of outliers in the data, lack of multicollinearity among predictors, linear relationship between the logit of the outcome and predictor variables) were tested. Odd ratios (ORs) and 95% confidence intervals (CIs) were estimated and the p value was set at 0.05. Pearson or Spearman tests were used to assess correlations between variables, as appropriate. All tests were two-sided and a *p* value of less than .05 was considered significant. All statistical analyses were performed by means of SPSS, version 21.

3 | RESULTS

3.1 | Study population

A total of 1053 consecutive S-ICD implantation procedures were performed during the study period. In 212 (20%) patients, either DE testing was not performed, or VF was not inducible. In 36 (3%) patients, data on the DE test were missing. The remaining 805 patients were included in the present analysis. Table 1 shows the baseline clinical variables of the study population. Patients were predominantly male (82%), relatively young (48 ± 15 years), and mainly implanted for primary prevention (81%). A total of 40% had

TABLE 1 Clinical characteristics of the study population

	***n* = 805**
Male gender, *n* (%)	660 (82)
Age, years	48 ± 15
Body mass index	25.2 (23.1–27.6)
Body weight, Kg	75 (68–86)
LV ejection fraction, %	55 (33–64)
LV ejection fraction ≤35%, *n* (%)	272 (34)
Cardiomyopathy	
Ischemic, *n* (%)	203 (25)
Dilated, *n* (%)	122 (15)
Hypertrophic, *n* (%)	128 (16)
ARVC, *n* (%)	44 (6)
Congenital, *n* (%)	15 (2)
Myocarditis, *n* (%)	11 (1)
Valvular disease, *n* (%)	14 (2)
Idiopathic ventricular fibrillation	59 (7)
Channelopathies	
Brugada syndrome, *n* (%)	147 (18)
Long QT syndrome, *n* (%)	7 (1)
Other ion channel diseases, *n* (%)	5 (1)
Other, *n* (%)	50 (6)
Chronic kidney disease, *n* (%)	63 (8)
Diabetes, *n* (%)	68 (8)
Beta Blockers, *n* (%)	411 (51)
Antiarrhythmic drugs, *n* (%)	107 (13)
Amiodarone, *n* (%)	86 (80)
Sotalol, *n* (%)	17 (16)
Quinidine, *n* (%)	3 (3)
Mexiletine, *n* (%)	1 (1)

Abbreviations: ARVC, arrhythmogenic right ventricular cardiomyopathy; LV, left ventricular; VF, ventricular fibrillation.

either ischemic or dilated cardiomyopathy. Median ejection fraction (EF) was 55 (IQR: 33–64) and 34% of patients had EF ≤35%. Patients who did not undergo DE testing, or in whom VF was not inducible, or DE testing data were missing ($n = 248$) were older (52 ± 16 years; $p < .01$) and had lower EF (median: 35%; IQR: 25–54; $p < .01$) than the study patients.

3.2 | S-ICD implantation

In 206 (26%) patients, general anesthesia was used during device implantation. In the remaining 599 patients, implantation was carried out under local anesthesia or moderate-to-deep sedation. The S-ICD generator was positioned in an IM pocket in 561 patients (70%). The 2-incision technique was adopted in the majority of patients ($n = 679$; 84%). By combining the two surgical approaches, four groups were assessed: IM with 2 incisions (IM + 2; $n = 546$; 67.8%), SC with 2 incisions (SC + 2; $n = 133$; 16.5%), SC with 3 incisions (SC + 3; $n = 111$; 13.8%), and IM with 3 incisions (IM + 3; $n = 15$; 1.9%). This last group had significantly higher body mass index (BMI) (28; IQR: 25–38; $p < .03$). The other clinical characteristics were comparable among the groups. Sensing was programmed on the primary vector in 481 (59.8%) patients, secondary in 258 (32%) and alternate in 66 (8.2%), without significant differences between groups ($p = .11$).

3.3 | Acute defibrillation success according to the implantation technique

The DE was ≤65 J in 782 (97.1%) patients (12 with reverse polarity). In 17 of the 23 patients in whom the 65 J shock failed, a second, higher energy, shock was effective (mean effective energy: 75 ± 5 J). In the remaining five patients, a second shock was effective after either pulse generator or coil repositioning (4 out of 5 shocks at 65 J). In one patient with Brugada syndrome, who had undergone implantation by means of the SC + 3 approach, the S-ICD shock was ineffective at 65 and 80 J, with both standard and reverse polarity. This patient received an ineffective external 200 J biphasic shock and VF terminated spontaneously. The test was repeated after positioning the pulse generator in the IM space with DE still more than 80 J. The patient subsequently underwent implantation of a transvenous ICD and tested successfully with an internal 41 J shock.

Median shock impedance was 66 (57–77) Ohm in patients with DE ≤65 J and 71 (58–98) Ohm in patients with DE >65 J ($p = .153$).

Patients with DE ≤65 J showed a nonsignificantly lower BMI (25.1 vs. 26.5; $p = .12$) and more commonly underwent implantation by means of the 2-incision approach (85% vs. 70%; $p = .04$) (Table 2).

In further detail, Figure 1 shows the impact of the implantation technique on the rate of acute defibrillation failure (2.2%–13.3%; $p = .04$) and shock impedance (66–76 Ohm; $p = .005$). Indeed, patients who underwent implantation with the IM + 2 approach had the

TABLE 2 Acute S-ICD conversion efficacy according to clinical characteristics and implantation technique

Parameter	Patients with successful test (782)	Patients with failed test (23)	p
Age, years	48 ± 15	52 ± 14	.264
Body mass index	25.1 (22.9–27.4)	26.5 (23.7–29.0)	.129
LV ejection fraction, %	55 (33–65)	62 (33–69)	.781
LV ejection fraction ≤35%, n (%)	261 (33)	11 (48)	.179
Hypertrophic cardiomyopathy, n (%)	128 (16)	0 (0)	.037
ARVC, n (%)	43 (5)	1 (4)	1.000
Channelopathies, n (%)	153 (20)	6 (26)	.439
Chronic kidney disease, n (%)	61 (8)	2 (9)	.699
Diabetes, n (%)	68 (9)	0 (0)	.249
Beta blockers, n (%)	403 (51)	8 (35)	.113
Antiarrhythmic drugs, n (%)	101 (13)	6 (26)	.067
Shock impedance, Ohm	66 (57–77)	71 (58–98)	.153
General anesthesia	201 (26)	5 (22)	.811
Subcutaneous generator	235 (30)	9 (39)	.362
2-incision technique	663 (85)	16 (70)	.048
Emblem device (A209-A219)	730 (93)	21 (91)	.663

Abbreviations: ARVC, arrhythmogenic right ventricular cardiomyopathy; LV, left ventricular; S-ICD, subcutaneous implantable cardioverter defibrillator.

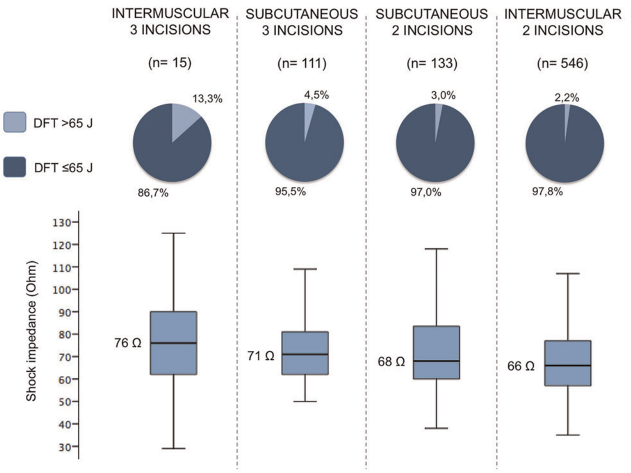


FIGURE 1 DE testing and Shock Impedance. Conversion testing outcome and median shock impedance according to the implantation technique. DE, defibrillation efficacy

lowest conversion failure rate (2.2%) and shock impedance (66 Ohm, IQR: 57–77).

On univariate analysis, BMI and the use of antiarrhythmic drugs were associated with shock failure at the less than 0.1 significance level, while the 2-incision technique predicted ≤65 J shock efficacy (Table 3). On multivariate analysis, the 2-incision technique was associated with a significantly lower incidence of shock failure (hazard ratio [HR]: 0.305; 95% CI: 0.102–0.907; $p = .033$) independently from BMI and use of antiarrhythmic drugs (Table 3).

Regarding the temporal distribution of the use of the IM and 2-incision implantation techniques, the rate of acute shock failure was similar across quartiles of enrollment in the registry (2.0%–3.5%; $p = .81$). While the overall rate of shock failure decreased through years, patients implanted with a combination of surgical approaches that included the SC or 3-incision techniques presented higher shock failure rates despite being implanted in recent years. On the contrary, shock failure with the IM + 2 technique was steadily low across years (Figure 2).

3.4 | Shock impedance

High voltage impedance predicted shock failure on univariate analysis (HR: 1.025; 95% CI: 1.001–1.049; $p = .04$) and was lower with the IM than the SC approach (66 vs. 70 Ohm; $p = .002$) and with the 2- than the 3-incision technique (67 vs. 72 Ohm; $p = .006$). Moreover, shock impedance was correlated with BMI ($r = .392$; 95% CI: 0.32–0.46; $p < .001$) and showed a significant stepwise increase according to BMI (Figure 3).

4 | DISCUSSION

The S-ICD implantation technique affects the proper system position on chest radiographs. Indeed, patients undergoing a combination of the IM and 2-incision techniques have lower PRAETORIAN score as compared to those implanted with conventional approaches.[15] However, it has never been reported whether this translates into a lower rate of shock failure during post-implant conversion testing. In this study we systematically evaluated the impact of IM and 2-incision techniques on post-implant DE in a large cohort of S-ICD recipients. We recorded a very high DFT success rate and found an association between successfully induced VF termination and S-ICD implantation technique. Specifically, the combination of IM generator implantation and the 2-incision technique resulted in the smallest shock impedance and lowest rate of shock failure.

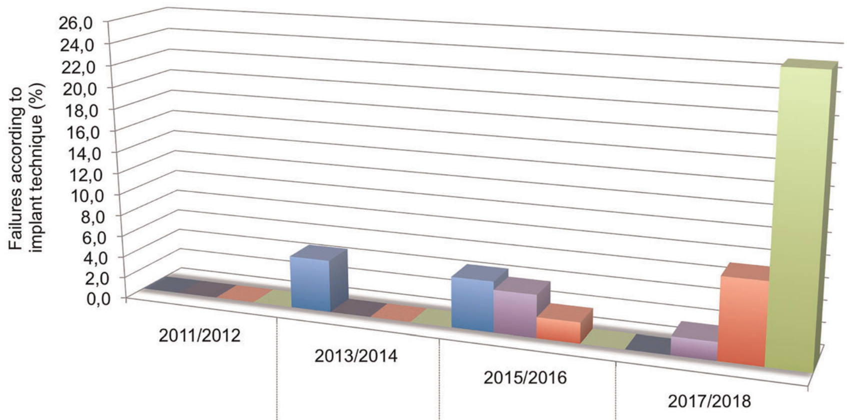
The S-ICD implantation technique has changed significantly over time, with the introduction of different anatomical and surgical approaches for pulse generator and defibrillation lead positioning.[11,12] The IM pulse generator implantation and the 2-incision technique have been shown to be safe and effective approaches that reduce complications, offer better cosmetic outcomes and shorter procedural times.[11–13,17] Unexpectedly, in the UNTOUCHED study[5] the 2-incision technique was associated with a higher rate of inappropriate shocks, possibly due to higher risk of lead migration. However, chest radiographs were not included in the UNTOUCHED data collection and it is therefore difficult at present to explain this finding. Moreover, in other studies with intermediate-to-long follow-up[18,19] the 2-incision technique did not result in an excess of inappropriate shocks or the need for surgical implant revision.

In our cohort, patients who underwent the **IM + 2** incision approach had the lowest acute shock failure rate. Interestingly, in a recent single center study[19] the 2-incision technique yielded significant lower shock impedance during DE testing than the 3-incision approach but resulted in similar rate of shock failure. Likely, the size of the study population may explain why the lower shock impedance did not translate into higher shock success rate.

TABLE 3 Logistic regression analysis of clinical and implantation variables associated with failed ≤65 J conversion testing

	Univariate analysis			Multivariate analysis		
	OR	95% CI	*p*	OR	95% CI	*p*
Body mass index	1.096	0.990–1.214	.078	1.071	0.967–1.186	.186
Ejection fraction ≤35%	1.830	0.797–4.203	.154	–	–	–
Antiarrhythmic drugs	2.380	0.917–6.177	.075	1.837	0.561–6.016	.315
2-incision technique	0.410	0.165–1.019	.055	0.305	0.102–0.907	.033
Subcutaneous generator	1.496	0.639–3.505	.353	–	–	–

Abbreviations: CI, confidenc interval; OR, odds ratio.



	2011/2012 Tested	Failure	Rate	2013/2014 Tested	Failure	Rate	2015/2016 Tested	Failure	Rate	2017/2018 Tested	Failure	Rate
SC + 3-incision	4	0	0	41	2	4.9	64	3	4.7	3	0	0
IM + 2-incision	0	0	0	2	0	0	127	5	3.9	417	7	1.7
SC + 2-incision	0	0	0	1	0	0	105	2	1.9	27	2	7.4
IM + 3 incision	0	0	0	0	0	0	7	0	0	8	2	25
Overall failure rate	0%			4.5%			3.3%			2.4%		

FIGURE 2 DFT failure rate according to the implantation technique across years. Temporal distribution of conversion testing failure according to the implantation technique. The overall rate of shock failure decreased through years. However, specific implant techniques were associated with shock failure in a time-independent manner. IM, intermuscular; SC, subcutaneous

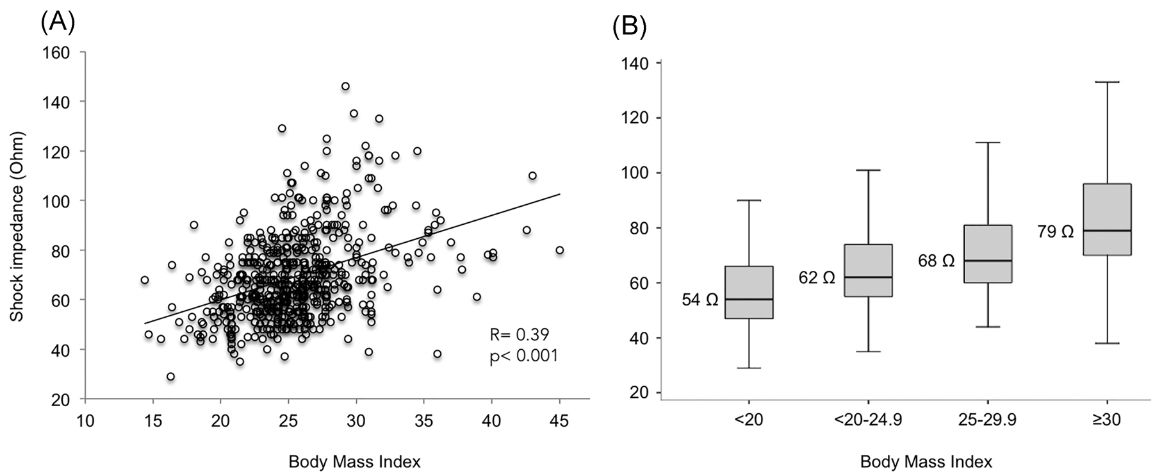


FIGURE 3 Shock Impedance and Body Mass Index. (A) Median shock impedance measured at the time of DE testing was correlated with body mass index ($r = .392$; $p < .001$). (B) Shows a significant stepwise increase according to BMI ranges. BMI, body mass index; DE, defibrillation efficacy

Brouwer et al.[17] investigated the impact on periprocedural and short-term outcomes of four different S-ICD implantation techniques and showed that the 2-incision, submuscular and subfascial approaches had similar clinical outcomes to the 3-incision SC technique. The discrepancy between this and our study may be due to several factors. First, the study population of DE-tested patients in the present analysis is more than fourfold larger and may, therefore, be more powered to detect small but important differences in outcomes. Second, in Brouwer's study, none of the patients underwent implantation with the IM approach. Third, unlike the present study, Brouwer et al. did not explore the impact on peri-procedural outcomes of combining pocket site with the 2- or 3-incision technique.

Previous studies have suggested that conversion success and defibrillation safety margin are associated with BMI.[8,20–24] A putative explanation for this phenomenon is offered by computer modeling simulations, which have shown that sub-coil adipose tissue and anterior positioning of the ICD increase DFT.[23] Recently, Amin et al.[25] confirmed that S-ICD shock efficacy depends on system position and high-voltage impedance. According to their data, high impedance is associated with inferior placement of the generator and electrode system, inadequate coil depth, and a lower rate of defibrillator success. Moreover, patients with high BMI had a greater likelihood of inferiorly positioned electrodes/generator and superficially positioned coil, resulting in higher shock impedance. Of note, when an appropriate system position was achieved in patients with high BMI, conversion efficacy was comparable to that obtained in lower-BMI patients.[25] In agreement with these findings, we confirmed that shock impedance increased according to BMI. Moreover, lower impedance was observed with the IM approach than with the SC approach, and with the 2- than the 3-incision technique. Indeed, the IM approach reduces the risk of inappropriate generator positioning in the

SC adipose tissue and prevents system placement that is too inferior or anterior. Likewise, the higher defibrillation success with the 2-incision technique may be explained by the fact that the coil is implanted more deeply when the dedicated sheath introducer is used.

Although the current S-ICD delivers only 80 J shocks, optimal implantation strategies that reliably reduce DFT could enable maximum energy output to be reduced, thereby increasing device longevity, or prompting to manufacture smaller devices. Warranting a wide safety margin with currently adopted S-ICD is also reassuring in clinical scenarios in which DE testing is not performed owing to safety reasons or physician preference.[20] The ongoing randomized Trial of S-ICD implantation with and without defibrillation testing (PRAETORIAN-DFT)[26] will prove the safety of withholding DFT testing when implantation is optimized according to the PRAETORIAN score.

4.1 | Limitations

Our study is retrospective and nonrandomized. As the implant technique was based on physician preference and patient characteristics, these factors might have impacted defibrillation success despite the multivariable analysis performed.

While shock failures occurred more frequently with the SC and 3-incision techniques, it is difficult to separate the time-dependent effects of general improvements in knowledge of optimal S-ICD implantation from changes in implant technique.

The large study population allowed us to assess patients according to the implantation technique. However, the group of patients who underwent implantation with the IM + 3 technique was too small to support definite conclusions.

High voltage impedances and BMI were not available in all patients.

Patients in this study were younger and had higher EF as compared to common ICD patients or those enrolled in the recent PRAETORIAN and UNTOUCHED trials. This may reflect a gap between randomized trials and real-world clinical practice, as S-ICD is currently the preferred option especially in young patients with longer life expectancy and preserved EF.[10] Moreover, we cannot exclude a selection bias, as physicians may have adopted a tailored approach to conversion testing, with testing omitted in patients who were either at risk for conversion testing complications or unlikely to experience shock failure for spontaneous VT/VF. This bias has already been described in previous reports.[8] Indeed, our results cannot be readily extrapolated to general ICD patient's population.

5 | CONCLUSIONS

In a large cohort of S-ICD patients, we observed a high DE success rate and demonstrated an association between acute shock efficacy and implantation technique. The IM plus 2-incision technique yields lower shock impedance and higher rate of successful defibrillation.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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REFERENCES

1. Bardy GH, Smith WM, Hood MA, et al. An entirely subcutaneous implantable cardioverter-defibrillator. *N Engl J Med*. 2010;363:36-44.
2. Weiss R, Knight BP, Gold MR, et al. Safety and efficacy of a totally subcutaneous implantable-cardioverter defibrillator. *Circulation*. 2013;128:944-953.
3. Lambiase PD, Barr C, Theuns DA, et al. EFFORTLESS Investigators. Worldwide experience with a totally subcutaneous implantable defibrillator: early results from the EFFORTLESS S-ICD Registry. *Eur Heart J*. 2014;35:1657-1665.
4. Knops RE, Olde Nordkamp LRA, Delnoy PHM, et al. PRAETORIAN Investigators. Subcutaneous or transvenous defibrillator therapy. *N Engl J Med*. 2020;383:526-536.
5. Gold MR, Lambiase PD, El-Chami MF, et al, UNTOUCHED Investigators. Primary results from the understanding outcomes with the S-ICD in primary prevention patients with low ejection fraction (UNTOUCHED) Trial. *Circulation*. 2020;143:7-17. https://doi.org/10.1161/CIRCULATIONAHA.120.048728
6. Wilkoff BL, Fauchier L, Stiles MK, et al. Document reviewers. 2015 HRS/EHRA/APHRS/SOLAECE expert consensus statement on optimal implantable cardioverter-defibrillator programming and testing. *Europace*. 2016;18:159-183.
7. Gold MR, Aasbo JD, El-Chami MF, et al. Subcutaneous implantable cardioverter-defibrillator post-approval study: clinical characteristics and perioperative results. *Heart Rhythm*. 2017;14:1456-1463.
8. Friedman DJ, Parzynski CS, Varosy PD, et al. Trends and in-hospital outcomes associated with adoption of the subcutaneous implantable cardioverter defibrillator in the United States. *JAMA Cardiol*. 2016;1:900-911.
9. Boersma L, Barr C, Knops R, et al, EFFORTLESS Investigator Group. Implant and midterm outcomes of the subcutaneous implantable cardioverter-defibrillator registry: the EFFORTLESS study. *J Am Coll Cardiol*. 2017;70:830-841.
10. D'Onofrio A, Pieragnoli P, Biffi M, et al. "S-ICD Rhythm Detect" Investigators. Subcutaneous implantable cardioverter defibrillator implantation: an analysis of Italian clinical practice and its evolution. *Int J Cardiol*. 2018;272:162-167.
11. Knops RE, Olde Nordkamp LR, De Groot JR, Wilde AA. Two-incision technique for implantation of the subcutaneous implantable cardioverter-defibrillator. *Heart Rhythm*. 2013;10:1240-1243.
12. Migliore F, Allocca G, Calzolari V, et al. Intermuscular two-incision technique for subcutaneous implantable cardioverter defibrillator implantation: results from a multicenter registry. *Pacing Clin Electrophysiol*. 2017;40:278-285.
13. Droghetti A, Basso Ricci E, Scimia P, Harizai F, Marini M. Ultrasound-guided serratus anterior plane block combined with the two-incision technique for subcutaneous ICD implantation. *Pacing Clin Electrophysiol*. 2018;41:517-523.
14. Winter J, Siekiera M, Shin DI, et al. Intermuscular technique for implantation of the subcutaneous implantable cardioverter defibrillator: long-term performance and complications. *Europace*. 2017;19:2036-2041.

15. Francia P, Biffi M, Adduci C, et al. Implantation technique and optimal subcutaneous defibrillator chest position: a PRAETORIAN score-based study. *Europace*. 2020;22:1822-1829. https://doi.org/10.1093/europace/euaa231
16. Francia P, Ziacchi M, De Filippo P, et al. Subcutaneous implantable cardioverter defibrillator eligibility according to a novel automated screening tool and agreement with the standard manual electrocardiographic morphology tool. *J Interv Card Electrophysiol*. 2018;52:61-67.
17. Brouwer TF, Miller MA, Quast AB, et al. Implantation of the subcutaneous implantable cardioverter-defibrillator: an evaluation of 4 implantation techniques. *Circ Arrhythm Electrophysiol*. 2017;10:e004663. https://doi.org/10.1161/CIRCEP.116.004663
18. Migliore F, Mattesi G, De Franceschi P, et al. Multicentre experience with the second-generation subcutaneous implantable cardioverter defibrillator and the intermuscular two-incision implantation technique. *J Cardiovasc Electrophysiol*. 2019;30:854-864.
19. Van der Stuijt W, Baalman SWE, Brouwer TF, Quast ABE, de Groot JR, Knops RE. Long-term follow-up of the two-incision implantation technique for the subcutaneous implantable cardioverter-defibrillator. *Pacing Clin Electrophysiol*. 2020;43:1476-1480. https://doi.org/10.1111/pace.14022
20. Friedman DJ, Parzynski CS, Heist EK, et al. Ventricular fibrillation conversion testing after implantation of a subcutaneous implantable cardioverter defibrillator: report from the national cardiovascular data registry. *Circulation*. 2018;137:2463-2477.
21. Do K, Chang P, Konecny T, et al. Predictors of elevated defibrillation threshold with the subcutaneous implantable cardioverter-defibrillator. *J Innov Card Rhythm Manag*. 2017;8:2920-2929.
22. Biffi M, Ziacchi M, Angeletti A, et al. Successful defibrillation verification in subcutaneous implantable cardioverter-defibrillator recipients by low-energy shocks. *Clin Cardiol*. 2019;42:612-617.
23. Heist EK, Belalcazar A, Stahl W, Brouwer TF, Knops RE. Determinants of subcutaneous implantable cardioverter-defibrillator efficacy: a computer modeling study. *JACC Clin Electrophysiol*. 2017;3:405-414.
24. Frankel DS, Burke MC, Callans DJ, Stivland TM, Duffy E, Epstein AE. Impact of body mass index on safety and efficacy of the subcutaneous implantable cardioverter-defibrillator. *JACC Clin Electrophysiol*. 2018;4:652-659.
25. Amin AK, Gold MR, Burke MC, et al. Factors associated with high-voltage impedance and subcutaneous implantable defibrillator ventricular fibrillation conversion success. *Circ Arrhythm Electrophysiol*. 2019;12:e006665. https://doi.org/10.1161/CIRCEP.118.006665
26. Quast ABE, Baalman SWE, Brouwer TF, et al. A novel tool to evaluate the implant position and predict defibrillation success of the subcutaneous implantable cardioverter-defibrillator: the PRAETORIAN score. *Heart Rhythm*. 2019;16:403-410.

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APPENDIX

List of participating centers

- Monaldi Hospital, Naples: A. D'Onofrio, V. Bianchi; V. Tavoletta, S. De Vivo;
- University of Florence, Florence: P. Pieragnoli, G. Ricciardi, L. Checchi, L. Perrotta;
- Istituto Clinico Sant'Ambrogio, Milan: L. Ottaviano;
- Policlinico S.Orsola-Malpighi, Bologna: M. Biffi, I. Diemberger, M. Ziacchi, C. Martignani;
- Second University of Naples, Naples: G. Nigro, V. Russo, A. Rago, E. Ammendola;
- University Hospital of Pisa, Pisa: M.G. Bongiorni, S. Viani;
- University of Padua: F. Migliore;
- Ospedale St. Andrea, Rome: P. Francia, F. Palano, C. Adduci;
- Ospedale Papa Giovanni XXIII, Bergamo: P. De Filippo; P. Ferrari; C. Leidi;
- Università Politecnica delle Marche, Ancona: A. Capucci, M. Luzi, L. Cipolletta; S. Molini;
- Ospedale S. Anna, Como: S. Pedretti;
- Ospedale Maria Vittoria, Turin: M. Giammaria, M.T. Lucciola, C. Amellone;
- Ospedale "G. Panico", Tricase, Lecce: P. Palmisano; M. Accogli;
- Azienda ospedaliera "G. Brotzu", Cagliari: B. Schintu, A. Scalone, G. Tola, A. Setzu;
- Ospedale "Vito Fazzi", Lecce: E. Pisanò, G. Milanese;
- P.O. Ferrari, Castrovillari, Cosenza: G. Bisignani, S. De Bonis;
- Fondazione Poliambulanza, Brescia: C. La Greca, D. Pecora;
- Pediatric Cardiology Unit, Second University of Naples, Naples: B. Sarubbi, D. Colonna, E. Romeo;
- Ospedale San Raffaele, Milan: S. Sala, P. Mazzone, P. Della Bella;
- Ospedale S. Anna e S. Sebastiano, Caserta: M. Viscusi, D. Di Maggio, M. Brignoli;
- Ospedale Pediatrico "Bambino Gesù", Palidoro, Fiumicino: F. Drago, M.S. Silvetti;
- Ospedale Manzoni, Lecco: R. Brambilla, A. Pani;
- Ospedale S. Biagio, Domodossola: A Lupi, A. Mazzuero;
- Ospedale S. Maria, Terni: S. Donzelli, C. Marini;
- Circolo e Fondazione Macchi, Varese: F. Caravati;
- Ospedale S. Croce e Carle, Cuneo: E. Racca, A. Gonella, G. Musumeci, G. Rossetti, E, Menardi, G. P. Ballari;
- Ospedale G. B. Grassi, Ostia, Rome: F. Ammirati, L. Santini, N. Danisi, V. Schirripa;
- Istituto Auxologico Italiano—IRCCS, Milan: GB. Perego, V. Rella;
- Ospedale S. Martino, Genova: G. Bertero, P. Sartori, P. Rossi;
- Policlinico Federico II, Naples: A. Rapacciuolo, V. Liguori, A. Viggiano;
- Presidio Ospedaliero Muscatello, Augusta (SR): G. Licciardello, G. Busacca;
- Ospedale S. Giovanni Battista, Foligno: G.Savarese, C.Andreoli;
- Ospedale S. Camillo de Lellis, Rieti: G. Stifano;
- Università di Tor Vergata, Rome: F. Romeo, D. Sergi;
- Ospedale S. Andrea, La Spezia: S. Badolati;
- Ospedale Carlo Poma, Mantova: P. Pepi, D. Nicolis;
- Policlinico San Matteo, Pavia: R. Rordorf, A. Vicentini;
- Clinica Montevergine, Mercogliano (AV): F. Solimene, G. Shopova, V. Schillaci;
- Policlinico Umberto I, Rome: A. Piro; C. Lavalle;

- Ospedale Luigi Sacco, Milan: GB. Forleo;
- Ospedali Riuniti, Reggio Calabria:
- Ospedali Riuniti San Giovanni di Dio e Ruggi d'Aragona, Salerno: M. Manzo; C. Esposito, F. Esposito;
- Azienda Ospedaliera Mater Domini, Catanzaro:
- Policlinico Universitario Campus Bio-Medico, Rome: D. Ricciardi; V. Calabrese;
- Ospedale Campo di Marte, Lucca: D. Giorgi;
- Ospedale Villa Scassi, Genova: A. Torriglia, M. Laffi, G. Gaggioli;
- Ospedale SS. Giacomo e Cristoforo, Massa: G. Arena, V. Molendi, Borrello V, Ratti M, Bartoli C;
- Ospedale San Giovanni Bosco, Naples: P. Capogrosso, M. Volpicelli, G. Covino;
- Ospedale di Legnano, Milan: M. Mariani, M. Pagani;
- Ospedale S. Donato, Arezzo: P. Notarstefano, M. Nesti;
- Ospedale Careggi, Florence: E. Dovellini; L. Giurlani;
- Policlinico D. Casula, Monserrato: V. Nissardi;
- Ospedale Maggiore, Crema: M. Landolina, E. Tavarelli.