

Intermuscular technique for implantation of the subcutaneous implantable defibrillator: a propensity-matched case–control study

Giovanni Luca Botto ^{1*}, Matteo Ziacchi ², Gerardo Nigro ³, Antonio D’Onofrio ⁴, Antonio Dello Russo ⁵, Pietro Francia ⁶, Stefano Viani ⁷, Ennio Pisanò ⁸, Giovanni Bisignani⁹, Fabrizio Caravati ¹⁰, Federico Migliore ¹¹, Paolo De Filippo¹², Luca Ottaviano ¹³, Roberto Rordorf ¹⁴, Michele Manzo ¹⁵, Fabio Lorenzo Canevese ¹, Mariolina Lovecchio¹⁶, Sergio Valsecchi ¹⁶, and Luca Checchi ¹⁷ on behalf of ‘S-ICD Rhythm Detect’ Investigators

¹U.O. Electrophysiology, ASST Rhodense, Viale Carlo Forlanini 95, 20024 Garbagnate Milanese (MI), Italy; ²Institute of Cardiology, Department of Experimental, Diagnostic and Specialty Medicine, University of Bologna, Policlinico S.Orsola-Malpighi, Bologna, Italy; ³Department of Translational Medical Sciences, University of Campania ‘Luigi Vanvitelli’, Monaldi Hospital, Naples, Italy; ⁴Unità Operativa di Elettrofisiologia, Studio e Terapia delle Aritmie, Monaldi Hospital, Naples, Italy; ⁵Cardiology and Arrhythmology Clinic, Università Politecnica delle Marche, Ancona, Italy; ⁶Cardiology, Department of Clinical and Molecular Medicine, Sapienza University, St Andrea Hospital, Rome, Italy; ⁷Second Cardiology Division, Department of Cardio-Thoracic and Vascular, University Hospital of Pisa, Pisa, Italy; ⁸Cardiology Division, ‘Vito Fazzi’ Hospital, Lecce, Italy; ⁹Division of Cardiology, Castrovillari Hospital, Cosenza, Italy; ¹⁰Department of Heart and Vessels, Ospedale di Circolo e Fondazione Macchi, Varese, Italy; ¹¹Department of Cardiac, Thoracic Vascular Sciences and Public Health University of Padova, Padua, Italy; ¹²Cardiac Electrophysiology and Pacing Unit, Papa Giovanni XXIII Hospital, Bergamo, Italy; ¹³Arrhythmia and Electrophysiology Unit, Cardiothoracic Department, Istituto Clinico Sant’Ambrogio, Milan, Italy; ¹⁴Arrhythmia and Electrophysiology and Experimental Cardiology, IRCCS Fondazione Policlinico ‘S. Matteo’, Pavia, Italy; ¹⁵Ospedali Riuniti San Giovanni di Dio e Ruggi d’Aragona, Salerno, Italy; ¹⁶Boston Scientific, Milan, Italy; and ¹⁷University of Florence, Florence, Italy

Received 7 November 2022; accepted after revision 9 December 2023; online publish-ahead-of-print 16 February 2023

Aims

A previous randomized study demonstrated that the subcutaneous implantable cardioverter defibrillator (S-ICD) was non-inferior to transvenous ICD with respect to device-related complications and inappropriate shocks. However, that was performed prior to the widespread adoption of pulse generator implantation in the intermuscular (IM) space instead of the traditional subcutaneous (SC) pocket. The aim of this analysis was to compare survival from device-related complications and inappropriate shocks between patients who underwent S-ICD implantation with the generator positioned in an IM position in comparison with an SC pocket.

Methods and results

We analysed 1577 consecutive patients who had undergone S-ICD implantation from 2013 to 2021 and were followed up until December 2021. Subcutaneous patients ($n = 290$) were propensity matched with patients of the IM group ($n = 290$), and their outcomes were compared. During a median follow-up of 28 months, device-related complications were reported in 28 (4.8%) patients and inappropriate shocks were reported in 37 (6.4%) patients. The risk of complication was lower in the matched IM group than in the SC group [hazard ratio 0.41, 95% confidence interval (CI) 0.17–0.99, $P = 0.041$], as well as the composite of complications and inappropriate shocks (hazard ratio 0.50, 95% CI 0.30–0.86, $P = 0.013$). The risk of appropriate shocks was similar between groups (hazard ratio 0.90, 95% CI 0.50–1.61, $P = 0.721$). There was no significant interaction between generator positioning and variables such as gender, age, body mass index, and ejection fraction.

Conclusion

Our data showed the superiority of the IM S-ICD generator positioning in reducing device-related complications and inappropriate shocks.

Clinical trial registration

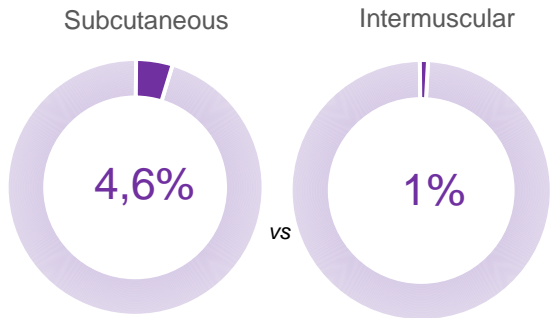
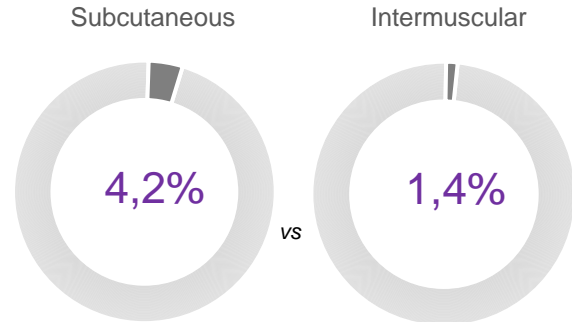
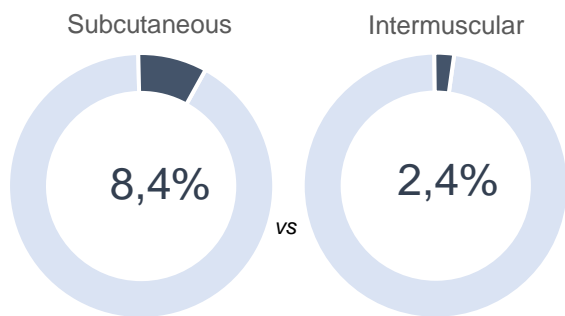
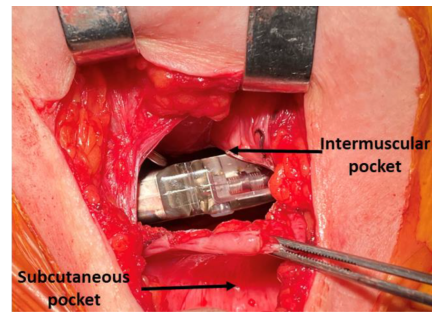
Clinical Trial Registration: ClinicalTrials.gov; NCT02275637.

* Corresponding author. Tel. +39 02 99430 3340, E-mail address: gbotto@asst-rhodense.it

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

This is an Open Access article distributed under the terms of the Creative Commons Attribution-NonCommercial License (<https://creativecommons.org/licenses/by-nc/4.0/>), which permits non-commercial re-use, distribution, and reproduction in any medium, provided the original work is properly cited. For commercial re-use, please contact journals.permissions@oup.com

Graphical Abstract

Improved safety profile of the S-ICD with intermuscular technique**Device-related complications at 1 year****Inappropriate shocks at 1 year****Composite endpoint at 1 year
(inappropriate shocks or complications)****Intermuscular vs Subcutaneous pocket**

Placing the S-ICD generator in the intermuscular space instead of the standard subcutaneous pocket resulted in fewer device-related complications and inappropriate shocks over a medium-term follow-up.

Keywords

Implantable defibrillator • Subcutaneous • Intermuscular technique • Complication • Inappropriate shock

What's new?

- Placing the S-ICD generator in the IM space instead of the standard subcutaneous pocket resulted in fewer device-related complications and composite endpoints of complication or inappropriate shock over a mid-term follow-up.
- The rate of complications decreased at 1 year from 4.6% in the subcutaneous group to 1.0% in the IM group.
- The components that seem to have determined this result are a lower need for reinterventions aimed at improving defibrillation efficacy and shock impedance and fewer revisions for pocket infections or patient discomfort.

Introduction

The subcutaneous implantable cardioverter defibrillator (S-ICD) was specifically designed to ensure prevention of sudden cardiac death, while overcoming lead-related complications of the traditional

transvenous ICD.¹ Observational studies have confirmed the overall efficacy and safety of S-ICD over medium- and long-term follow-up.²⁻⁴ Recently, the first randomized clinical trial comparing S-ICD and transvenous ICD has been published. The Prospective Randomized Comparison of Subcutaneous and Transvenous Implantable Cardioverter Defibrillator (PRAETORIAN) Trial has demonstrated that S-ICD was noninferior to transvenous ICD with respect to the composite endpoint of device-related complications and inappropriate shocks.⁵ However, the results of the trial cannot be fully extended to the S-ICD therapy in current clinical practice. Indeed, the traditional S-ICD implantation technique adopted in the trial, which involves the insertion of the pulse generator under the subcutaneous (SC) tissue, has significantly changed over time. A new technique that uses an intermuscular (IM) pocket for the pulse generator is now widely adopted^{6,7} and has been shown to result in low complication rates.⁸

The present study evaluated the mid-term outcome of patients who underwent S-ICD implantation with the generator positioned in an IM position in comparison with an SC pocket. For this purpose, we compared survival from device-related complications and inappropriate shocks.

Methods

Study design

From January 2013 to January 2021, consecutive patients undergoing *de novo* implantation of an S-ICD (Boston Scientific Inc., Natick, MA, USA) were enrolled at 66 Italian centres (see Appendix 1). Before implantation, adequate S-ICD sensing was verified by means of the surface electrocardiogram screening method, which is based on a dedicated electrocardiogram morphology tool.⁹ 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 December 2021.

Implantation procedure

According to physician preference, the pulse generator was positioned in an SC pocket (over the fifth intercostal space between the mid and the anterior axillary lines) or in an IM position (between the serratus anterior and the latissimus dorsi muscles; Figure 1).^{6,7} Initially, old-generation pulse generators, larger in volume and not equipped with the SMART Pass filter, were implanted. New-generation pulse generators became available in 2016, and are the ones included in the present analysis. The decision to perform the acute defibrillation test was left to the discretion of the implanting physician. When executed, defibrillation testing was performed at 65J or less. The implanting physicians were all experienced in S-ICD implantation, having performed more than 13 procedures before the cases included in both groups of this report.¹⁰ Data were collected at the study centres within the framework of a prospective registry. The Institutional Review Boards approved the study, and all patients provided written informed consent for data storage and analysis.

Definition of outcomes

The primary endpoint of the study consisted of device-related complications. Complications were defined as device- or procedure-related events that led to intervention or prolongation of hospitalization, and included device infection, pocket haematoma, lead repositioning or replacement and other complications related to the lead or generator. Secondary endpoints included inappropriate shocks, i.e. S-ICD shocks delivered for any rhythm other than ventricular fibrillation or ventricular tachycardia, and the composite of complications and inappropriate shocks.⁵ We also assessed death from any cause, appropriate shocks and ineffective S-ICD therapies. Therapy was classified as ineffective when the first shock failed to convert the ventricular arrhythmia to sinus rhythm.

Propensity score matching

We implemented 1:1 nearest neighbour propensity score matching without replacement, with a propensity score estimated using logistic regression of the treatment on the covariates. The variables considered for propensity score calculation are shown in Table 1. After matching, all standardized mean differences for the covariates were below 0.1, indicating adequate balance.

Statistical analysis

Descriptive statistics are reported as mean \pm standard deviation for normally distributed continuous variables, or medians and interquartile range (25th–75th percentile) in the case of skewed distribution. Normality of distribution was tested by means of the nonparametric Kolmogorov–Smirnov test. Categorical variables are reported as percentages. Differences between mean data were compared by means of a *t*-test for Gaussian variables, and by Mann–Whitney nonparametric test for non-Gaussian variables. Differences in proportions were compared by means of a χ^2 analysis. Cumulative survival rates were compared between groups within the propensity-matched cohort by using Kaplan–Meier curves and Cox proportional hazards model. Finally, we made a pre-specified subgroup analysis on primary endpoint based on gender, age (\leq or $>$ mean value), body mass index (\leq or $>$ mean value), and ejection fraction (\leq or $>$ 35%). 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

A total of 1577 consecutive S-ICD procedures were performed within the observation period. Eighty-four patients with old-generation pulse generators were excluded from the analysis. Among the remaining patients, the S-ICD generator was positioned in a standard SC pocket in 290 (19%) patients (SC group), while an intermuscular approach was adopted in 1203 (81%) patients (IM group). Table 1 shows the baseline clinical variables and pre-discharge device programming of the patients in analysis and the comparison between the SC and IM groups. Patients of the IM group more frequently had dilated cardiomyopathy with reduced ejection fraction. After propensity score matching, the analysis was restricted to 580 patients: 290 (50%) SC group vs. 290 (50%) IM group. Baseline clinical variables and device programming of the matched cohort were equally distributed between the two study groups, as reported in Table 1.

Implantation procedure

Cardioversion at a shock energy of ≤ 65 J was tested in 444 (77%) patients. Of the patients who underwent testing, successful was reported in 434 (98%) patients, 219 in the SC group (97% of 226) and 215 in the IM group (99% of 218, *P* = 0.339). Intraoperative complications were reported in 10 (1.7%) patients, 7 (2.4%) in the SC group and 3 (1.0%, *P* = 0.339) in the IM group.

Outcome analysis

In the overall matched cohort, over a median follow-up of 28 (25th–75th percentile: 17–49) months, 17 (2.9%) deaths occurred. Device-related complications were reported in 28 (4.8%) patients during follow-up. The risk of device-related complication was lower in the matched IM group than in the SC group [unadjusted hazard ratio 0.41, 95% confidence interval (CI) 0.17–0.99, *P* = 0.041]. The rate at 1 year was 1.0% (95% CI 0.0–2.2) in the IM group and 4.6% (95% CI 2.1–7.1) in the SC group. The Kaplan–Meier survival curves are shown in Figure 2. The incidence of all study endpoints and hazard ratios in the matched study groups are reported in Table 2. The Kaplan–Meier analysis of time to first inappropriate shock and the composite endpoint of complications and inappropriate shocks is reported in Figure 3. Inappropriate shocks were reported in 37 (6.4%) patients. The rate of inappropriate shocks at 1 year was 1.4% (95% CI 0.1–2.7) in the IM group and 4.2% (95% CI 1.8–6.7) in the SC group. The rate of the composite endpoint at 1 year was 2.4% (95% CI 0.6–4.2) in the IM group and 8.4% (95% CI 5.1–11.7) in the SC group. During follow-up, 46 patients (7.9%) received appropriate shocks. The first shock was effective in 41 (89%) patients, while a second shock (in four patients) and a third shock (in one patient) were required to terminate the arrhythmia. The final conversion rate was 100% for all events. The Kaplan–Meier analysis of time to first appropriate shock is reported in Figure 3. The association between generator positioning and the risk of device-related complication occurrence in the pre-specified subgroups is shown in Figure 4. There was no significant interaction between positioning and each of the variables that defined the subgroup of interest.

Discussion

In this study, placing the S-ICD generator in the IM space instead of the standard SC pocket resulted in fewer device-related complications and

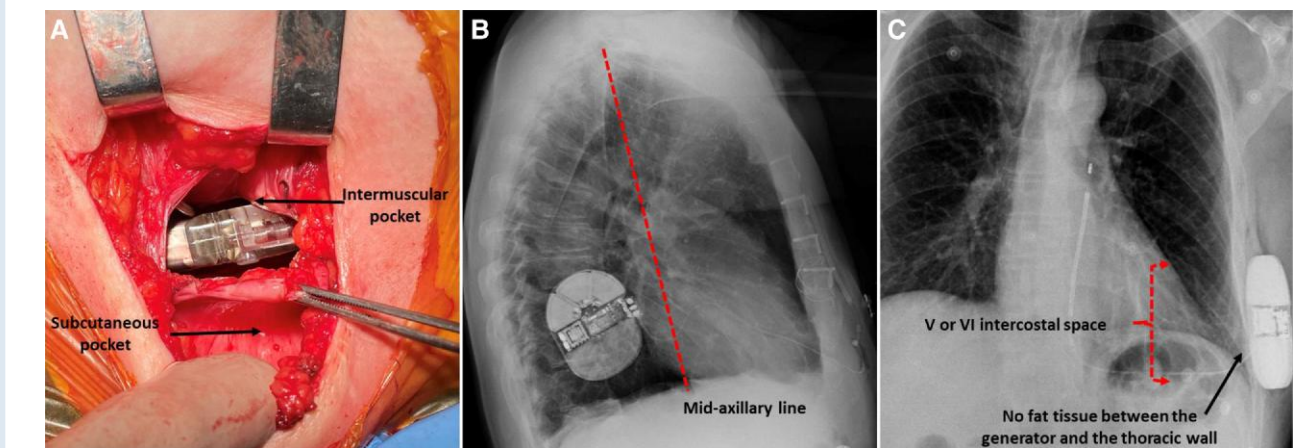


Figure 1 With the intermuscular technique, the generator is placed in a deeper position that ensures better device protection, patient's comfort, and aesthetic results. The resulting system position is also optimal for effective defibrillation. The pulse generator is positioned in an intermuscular pocket between the serratus anterior and the anterior margin of the latissimus dorsi muscle (A). The latissimus dorsi muscle runs posteriorly to the mid-axillary line, thus preventing anterior mispositioning of the S-ICD (B). The generator is optimally placed at the fifth or sixth intercostal space and in contact with the muscular fascia (C), thus preventing too inferior or superior placement, or the interposition of fat tissue. Adapted from Francia P, et al. *Europace* 2020; 22:1822–1829.

Table 1 Baseline characteristics and pre-discharge device programming of the unmatched and the propensity score-matched cohort

	All patients ^a (n = 1577)	IM group (n = 1203)	SC group (n = 290)	P-value ^b	Matched IM group (n = 290)	P-value ^c
Male gender, n (%) ^d	1250 (79)	959 (80)	226 (78)	0.500	236 (81)	0.302
Age, years ^d	49 ± 15	49 ± 15	49 ± 16	0.721	49 ± 14	0.963
Body mass index, kg/m ^{2d}	26 ± 4	26 ± 4	26 ± 4	0.080	27 ± 4	0.710
LV ejection fraction, % ^d	45 ± 16	45 ± 16	47 ± 15	0.043	46 ± 16	0.413
Dilated cardiomyopathy, n (%)	817 (52)	643 (53)	140 (48)	0.113	150 (52)	0.406
Hypertrophic cardiomyopathy, n (%)	254 (16)	185 (15)	52 (18)	0.286	42 (15)	0.260
Arrhythmic syndromes, n (%)	506 (32)	375 (31)	98 (34)	0.389	98 (34)	1.000
History of atrial fibrillation, n (%)	213 (13)	149 (12)	40 (13)	0.518	30 (10)	0.202
Chronic kidney disease, n (%)	173 (11)	120 (10)	28 (10)	0.870	17 (6)	0.088
Diabetes, n (%)	185 (12)	127 (11)	25 (9)	0.328	31 (11)	0.399
Conditional zone cut-off rate (beats/min)	200 (200–220)	200 (200–220)	200 (200–220)	0.461	200 (200–220)	0.408
Shock zone cut-off rate (beats/min)	230 (210–250)	230 (210–250)	220 (210–230)	0.033	230 (210–240)	0.074
Dual-zone programming, n (%)	1561 (99)	1191 (99)	286 (99)	0.531	288 (99)	0.686

LV: Left ventricular.

^aThe overall population included 84 patients with old-generation devices (excluded from the analysis).

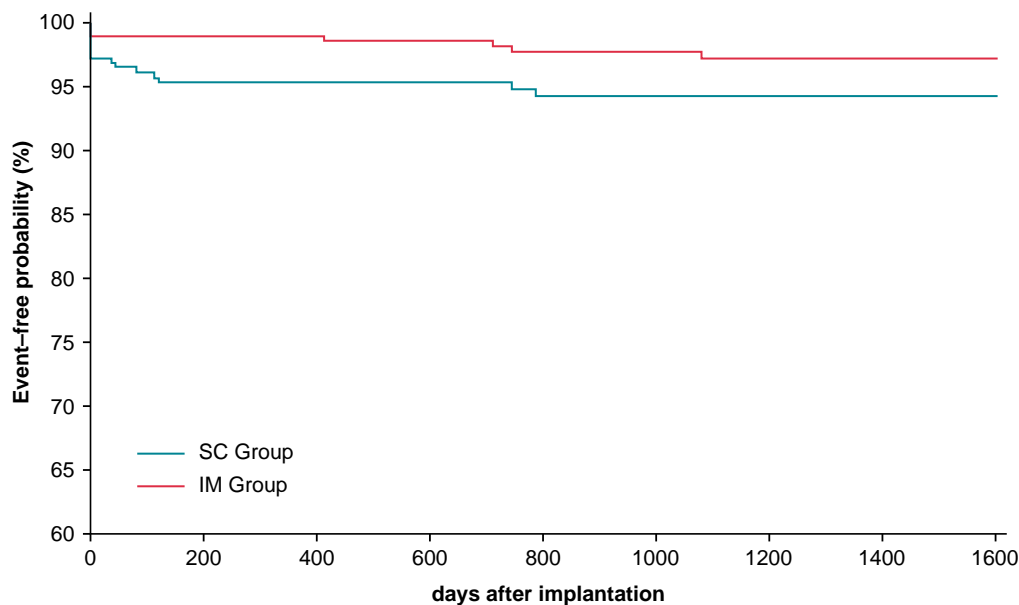
^bIM vs. SC group.

^cMatched IM vs. SC group.

^dVariables were used for the calculation of propensity scores.

composite endpoints of complication or inappropriate shock over a mid-term follow-up. This is a relevant finding in the light of the first and only randomized clinical trial comparing S-ICD and transvenous ICD, i.e. the PRAETORIAN study, that demonstrated the noninferiority of the S-ICD with respect to the same composite endpoint of device-related complications and inappropriate shocks.⁵ That study was initiated in 2011, when S-ICD therapy was in its early development

stages. Subsequently, the existence of a learning curve for S-ICD implanters with respect to implant-related complications has been demonstrated,¹⁰ new implantation techniques,^{6,7} and anaesthesia/analgesia approaches¹¹ have been proposed, improvements in S-ICD device technology have been shown to reduce the inappropriate shock rate.¹² All these considerations make the PRAETORIAN results not fully extendable to the S-ICD therapy in current clinical practice. In



Number at risk		days after implantation								
Group:		0	200	400	600	800	1000	1200	1400	1600
Group: SC Group	290	248	226	206	173	150	132	117	98	
Group: IM Group	290	286	270	248	231	203	162	81	23	

Figure 2 Kaplan–Meier estimates of time to first device-related complication (unadjusted hazard ratio 0.41, 95% CI 0.17–0.99, $P = 0.041$).

Table 2 Study endpoints in the matched study groups

	IM group (n = 290)	SC group (n = 290)	P-value	Hazard ratio (95% CI)
Device-related complication, ^a n (%)	7 (2.4)	21 (7.2)	0.041	0.41 (0.17–0.99)
Surgical reintervention for defibrillator test failure or high shock impedance during implantation, n (%)	3 (1.0)	7 (2.4)		
Infection, ^b n (%)	0 (0)	5 (1.7)		
Pain or discomfort, n (%)	1 (0.3)	5 (1.7)		
Lead replacement or repositioning, n (%)	1 (0.3)	2 (0.6)		
Surgical reintervention for high shock impedance during follow-up, n (%)	0 (0)	1 (0.3)		
Sensing issues, n (%)	2 (0.6)	1 (0.3)		
Inappropriate shock therapy, ^a n (%)	15 (5.2)	22 (7.6)	0.133	0.60 (0.31–1.16)
Atrial fibrillation or supraventricular tachycardia, n (%)	4 (1.4)	3 (1.0)		
T-wave oversensing, n (%)	4 (1.4)	9 (3.1)		
Other oversensing, n (%)	7 (2.4)	10 (3.4)		
Composite endpoint, n (%)	21 (7.2)	42 (14.5)	0.013	0.50 (0.30–0.86)
Death from any cause, n (%)	4 (1.4)	13 (4.5)	0.101	0.36 (0.12–1.10)
Appropriate shock therapy, n (%)	23 (7.9)	23 (7.9)	0.721	0.90 (0.50–1.61)
First ineffective shock, n (%)	3 (1.0)	2 (0.6)	0.461	2.26 (0.26–19.66)

^aComponent of the composite endpoint.

^bThis category included three pocket infections, one lead-related infection, and one pocket and lead-related infection.

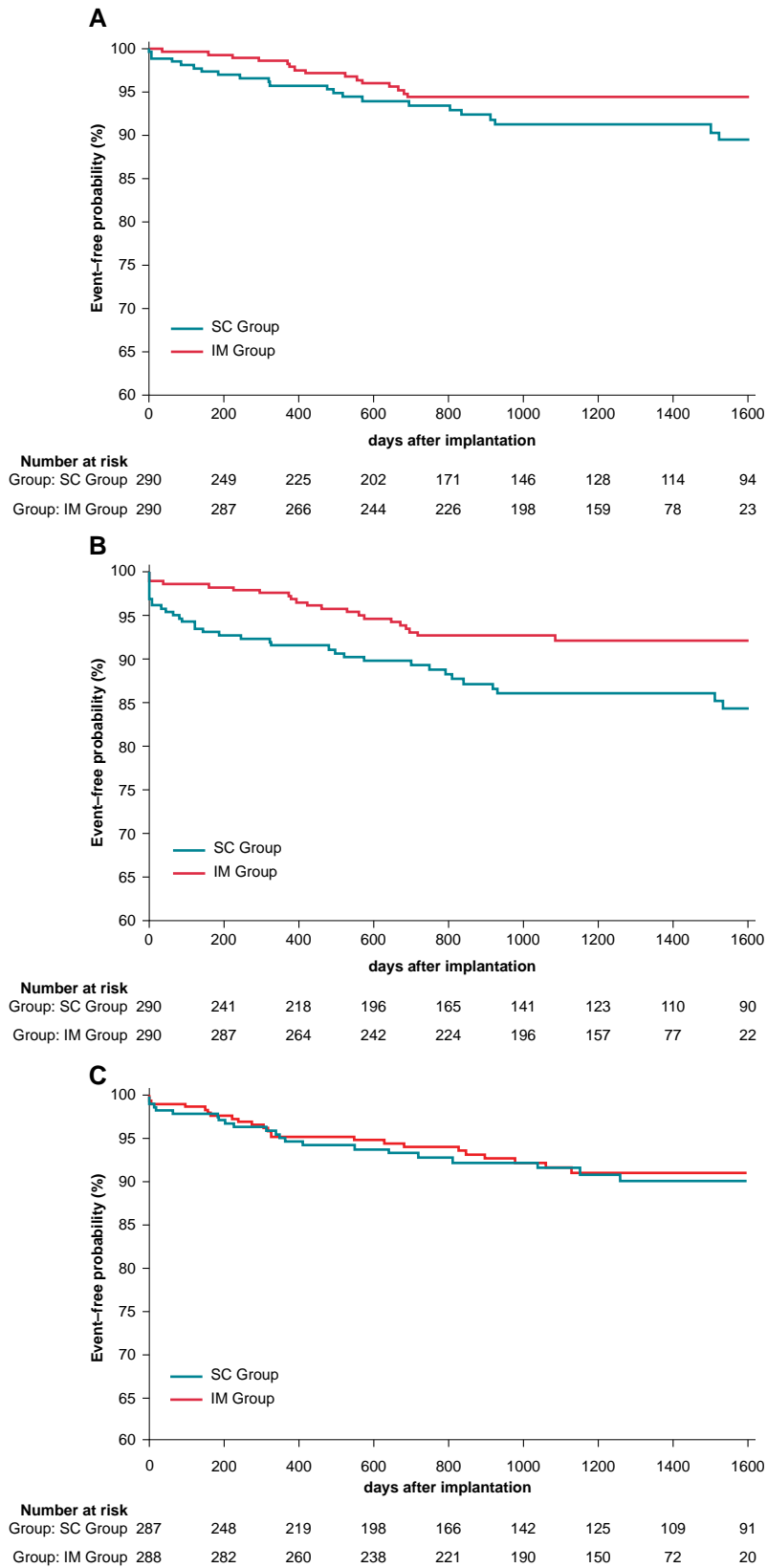
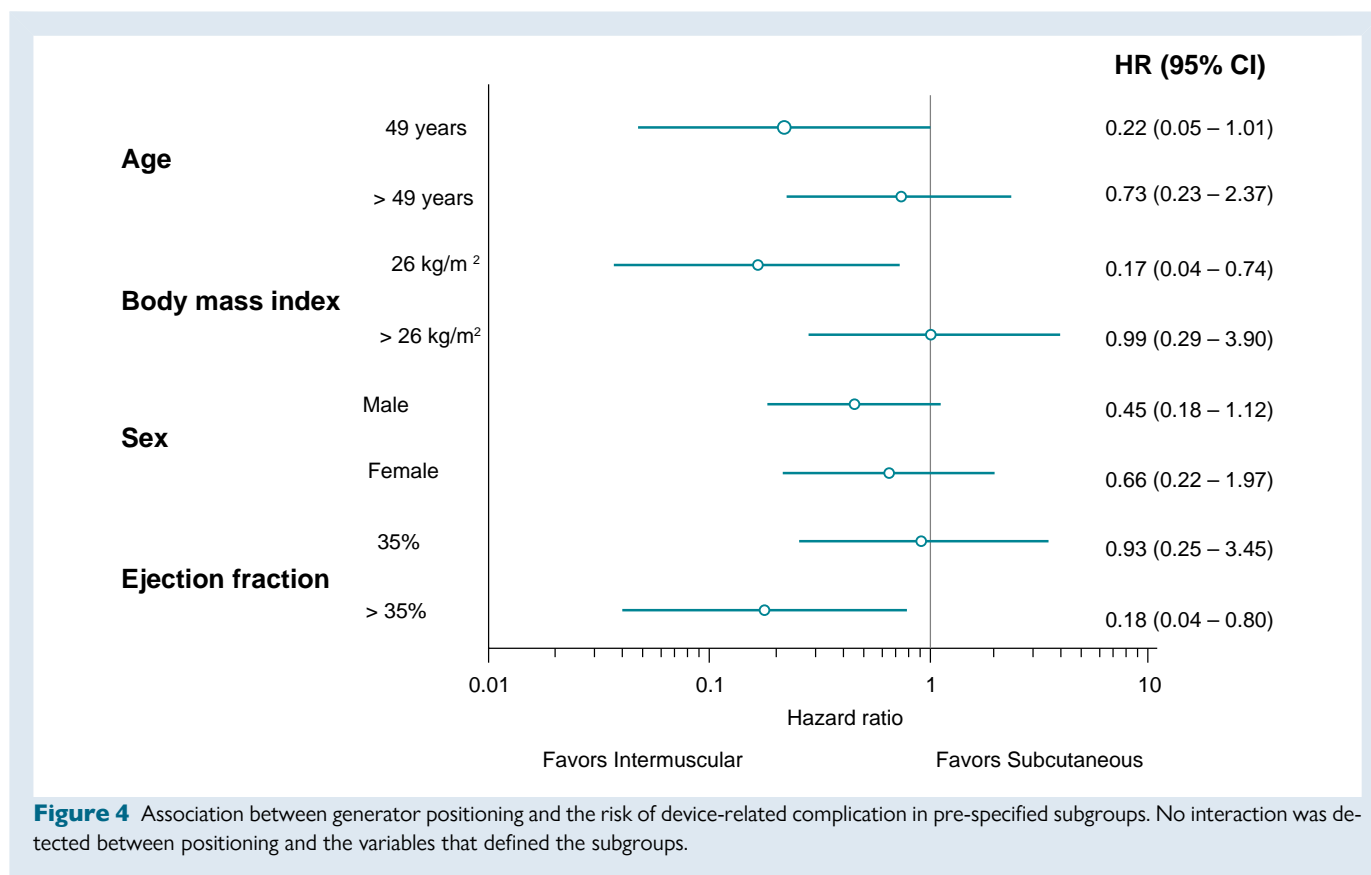


Figure 3 Kaplan–Meier estimates of time to first: inappropriate shock (unadjusted hazard ratio 0.60, 95% CI 0.31–1.16, $P = 0.133$) (A); the composite of complications and inappropriate shocks (unadjusted hazard ratio 0.50, 95% CI 0.30–0.86, $P = 0.013$) (B); appropriate shock (unadjusted hazard ratio 0.90, 95% CI 0.50–1.61, $P = 0.721$) (C).



particular, the IM technique, not tested in the PRAETORIAN study, is now the most frequently adopted in Europe.^{13,14} It has been shown to be safe and effective, to offer better cosmetic outcomes and shorter procedural times,^{6,15} to yield low PRAETORIAN scores and shock impedance values, indicating optimal defibrillation system position and a high probability of effective defibrillation.⁷ The results of the present analysis extend these findings, demonstrating a better safety profile of the S-ICD therapy in patients who received the generator in an IM position, thus confirming previous observations from one uncontrolled study.⁸ In the present study, we showed a reduction in the rate of the combined endpoint with the IM positioning of the generator, the rate at 1 year decreasing from 8.4 to 2.4%. This result well compares with the PRAETORIAN study⁵ that demonstrated a rate of 8% at 1 year in the S-ICD arm. In particular, the rate of device-related complications at 1 year was ~4% among the S-ICDs in the PRAETORIAN study.⁵ Although there was no significant difference between S-ICD and transvenous ICD in overall device-related complications in the PRAETORIAN trial,⁵ a recent secondary analysis showed that complications in the transvenous ICD group were more severe as they required significantly more often an invasive intervention.¹⁶ The present analysis revealed a decrease in the rate of complications from 4.6% in the SC group to 1.0% in the IM group, demonstrating an even better safety profile of the S-ICD when new implantation techniques are adopted. The components that seem to have determined this result are a lower need for reinterventions aimed at improving defibrillation efficacy and shock impedance and fewer revisions for pocket infections or patient discomfort, in agreement with preliminary findings on the benefits of the IM technique for implantation of the S-ICD.^{6,7,15} The rate of inappropriate shocks at 1 year was 1.4% in the IM group and 4.2% in the SC group, well comparing with the S-ICDs of the PRAETORIAN study whose rate was ~5%. Indeed, a novel sensing

methodology, the SMART Pass, was implemented in new-generation devices to reduce inappropriate shocks.¹² In the UNTOUCHED study, the rate of inappropriate shocks at 1 year was 3.1% in the overall population and as low as 2.4% when SMART Pass-enabled generators were considered.³ Our analysis did not show any interaction between baseline variables and the primary endpoint. This is particularly reassuring for the adoption of the S-ICD therapy in patients with heart failure and reduced ejection fraction, which has been shown to be increasing in recent years.¹³

Large trials have documented high rates (above 90%) of successful conversion on defibrillation testing with S-ICDs.^{2,13,17,18} In the present study, we confirmed this finding, as we recorded a conversion rate of 98% with 65J shock energy. This also yielded a high rate of conversion of clinical ventricular arrhythmias during follow-up, regardless of the generator positioning. In the present study, we reported successful cardioversion in 89% of episodes with the first shock, and 100% final success. Our results are in agreement with previous findings. Indeed, in the S-ICD System Post-Approval Study,¹⁹ first shock efficacy was 91% and final efficacy was 100% at 1 year. In the UNTOUCHED Trial, first shock efficacy was 94% and the final conversion efficacy was 98% at 18 months.³ The same efficacy rates were recently reported in the PRAETORIAN study.²⁰ In the Evaluation of Factors Impacting Clinical Outcome and Cost-effectiveness of the S-ICD (EFFORTLESS S-ICD) Registry, the first shock success rate over 5-year follow-up was 90% and the final efficacy was 98%.⁴

Limitations

The limitations of our study should be acknowledged. First, its observational design may have introduced an inherent bias. Minor events may have been underestimated to some extent. However, we exclude that this limitation may have introduced a bias in the comparison of the two

groups. The propensity score matching method was employed in order to minimize baseline differences between groups; however, residual and unmeasured confounding cannot be ruled out. Second, the limited sample size of our matched cohort might have prevented us from observing significant differences in the association between implantation technique and outcomes in the overall population and across subgroups. Third, the relatively short follow-up might have limited the statistical power of the analysis and concealed differences between the groups.

Conclusions

In this study, placing the S-ICD generator in the IM space instead of the standard SC pocket resulted in fewer device-related complications and the composite of complications and inappropriate shocks over a medium-term follow-up.

Conflict of interest: M.L. and S.V. are employees of Boston Scientific. G.L.B. received speaker's fee from Abbott, Biotronik, Boston Scientific, Medtronic, and Microport; P.F. received speaker's fees and educational grants from Boston Scientific and research grants from Abbott. R.R. received speaker's fees from Abbot and Boston Scientific. The other authors report no conflicts of interest.

Data availability

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

Appendix 1

List of participating centres

- ASST Rhodense, Rho-Garbagnate Milanese, Milan: G.L. Botto, F.L. Canevese, 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, A. Setzu;
- Azienda Ospedaliera Mater Domini, Catanzaro: A. Curcio;
- Azienda Ospedaliera Universitaria Senese, Siena: A. Santoro, C. Baiocchi, R. Gentilini, S. Lungchetti;
- Clinica Montevergine, Mercogliano, Avellino: F. Solimene, G. Shopova, V. Schillaci, A. Arestia, A. Agresta;
- Fatebenefratelli Hospital, Rome: S. Bianchi, P. Rossi, F. M. Cauti;
- Fondazione Poliambulanza, Brescia: C. La Greca, D. Pecora;
- 'Giovanni Battista Grassi' Hospital, Ostia, Rome; F. Ammirati, L. Santini, K. Mahfouz, C. Colaico;
- IRCCS Fondazione Policlinico 'S. Matteo', Pavia: R. Rordorf, A. Vicentini, S. Savastano, B. Petracchi, A. Sanzo, E. Baldi, M. Casula;
- Istituto Auxologico Italiano—IRCCS, Milan: G.B. Perego, V. Rella;
- Istituto Clinico Sant'Ambrogio, Milan: L. Ottaviano;
- Monaldi Hospital, Naples: A. D'Onofrio, V. Bianchi, V. Tavoletta, S. De Vivo;
- Ospedale 'G. Panico', Tricase, Lecce: P. Palmisano; M. Accogli;

- Ospedale 'Vito Fazzi', Lecce: E. Pisanò, G. Milanese;
- Ospedale Carlo Poma, Mantova: P. Pepi, D. Nicolis;
- Ospedale di Legnano, Milan: M. Mariani, M. Pagani;
- Ospedale Di Venere, Carbonara di Bari, Bari: Massimo Vincenzo Bonfantino;
- Ospedale F. Miulli, Acquaviva delle Fonti, Bari: V. Caccavo, M. Grimaldi, G. Katsouras;
- Ospedale Luigi Sacco, Milan: G.B. Forleo;
- Ospedale Maggiore, Crema: E. Chieffo, E. Tavarèlli;
- Ospedale Manzoni, Lecco: R. Brambilla, A. Pani;
- Ospedale Maria Vittoria, Turin: M. Giammaria, M.T. Lucciola, 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; C. Leidi;
- Ospedale Pediatrico 'Bambino Gesù', Palidoro, Fiumicino: F. Drago, M.S. Silveti, V. Pazzano, S. Russo, R. Remoli, I. Battipaglia, I. Cazzoli, 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, A. Mattera;
- Ospedale S. Anna, Como: S. Pedretti;
- Ospedale S. Biagio, Domodossola: A. Lupi, S. Tommasi;
- Ospedale S. Camillo de Lellis, Rieti: A. Kol, M. C. Gatto, A. Persi;
- Ospedale S. Croce e Carle, Cuneo: A. Gonella, G. Rossetti, E. Menardi, R. Rossini;
- Ospedale S. Donato, Arezzo: P. Notarstefano, M. Nesti, A. Fraticelli;
- Ospedale S. Maria, Terni: G. Carreras, S. Donzelli, C. Marini, A. Tordini, L. Lazzari;
- Ospedale S. Martino, Genova: P. Sartori, P. Rossi, P. Di Donna, G. Mascia;
- Ospedale San Giovanni Bosco, Naples: P. Capogrosso, P. Magliano, M. Colimodio;
- Ospedale San Raffaele, Milan: S. Sala, P. Mazzone, P. Della Bella;
- Ospedale SS. Annunziata, Savigliano, Cuneo: A. Coppolino;
- Ospedale SS. Giacomo e Cristoforo, Massa: G. Arena, V. Borrello, M. Ratti, C. Bartoli;
- Ospedale S. Andrea, Rome: P. Francia, F. Palano, C. Adduci;
- Ospedale Villa Scassi, Genova: A. Torriglia, M. Laffi;
- Ospedali Riuniti San Giovanni di Dio e Ruggi d'Aragona, Salerno: M. Manzo; C. Esposito, A. Giano. F. Franculli;
- Ospedali Riuniti, Reggio Calabria: A. Pangallo;
- P.O. Ferrari, Castrovillari, Cosenza: G. Bisignani, S. De Bonis;
- Paediatric Cardiology Unit, Second University of Naples, Napoli: B. Sarubbi, D. Colonna, A. Correrà, E. Romeo;
- Policlinico Federico II, Naples: A. Rapaciuolo, V. Liguori, A. Viggiano, T. Strisciullo;
- Policlinico S.Orsola-Malpighi, Bologna: M. Biffi, I. Diemberger, M. Ziacchi, C. Martignani;
- Policlinico Umberto I, Rome: A. Piro; C. Lavallo, M. Magnocavallo, M. V. Mariani;

- Policlinico Universitario Campus Bio-Medico, Rome: D. Ricciardi; V. Calabrese, F. Gioia, F. Picarelli;
- Presidio Ospedaliero Muscatello, Augusta (SR): G. Licciardello, G. Busacca;
- Presidio Ospedaliero Rodolico, Catania: V.I. Calvi;
- 'San Eugenio' Hospital, Rome: F. Lamberti, G. Lumia, C. Bellini, C. Bianchi;
- 'San Giovanni Battista' Hospital, Foligno: G. Savarese, C. Andreoli, L. Pimpinichio, D. Pellegrini;
- 'San Luca' Hospital, Lucca: D. Giorgi, Bovenzi, F. Busoni;
- Santa Maria della Misericordia, Udine: E. Daleffe, D. Facchin, L. Rebellato;
- Università di Tor Vergata, Rome: G. Stifano, G. Magliano, D. Sergi, L. Barone, R. Morgagni;
- Università Politecnica delle Marche, Ancona: A. Dello Russo, M. Casella, F. Guerra, L. Cipolletta; S. Molini;
- University Hospital of Pisa, Pisa: R. De Lucia, A. Di Cori, G. Grifoni, L. Paperini, L. Segreti, E. Soldati, S. Viani, G. Zucchelli;
- University of Campania 'Luigi Vanvitelli', Naples: G. Nigro, V. Russo, A. Rago, E. Ammendola, A. Papa;
- University of Florence, Florence: P. Pieragnoli, G. Ricciardi, L. Checchi, L. Perrotta;
- University of Padua: F. Migliore.

References

1. Weiss R, Knight BP, Gold MR, Leon AR, Herre JM, Hood M et al. Safety and efficacy of a totally subcutaneous implantable-cardioverter defibrillator. *Circulation* 2013;**128**: 944–53.
2. 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.
3. 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.
4. 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.
5. 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.
6. Migliore F, Allocca G, Calzolari V, Crosato M, Facchin D, Daleffe E et al. Intermuscular two-incision technique for subcutaneous implantable cardioverter defibrillator implantation: results from a multicenter registry. *Pacing Clin Electrophysiol* 2017;**40**: 278–85.
7. 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 score-based study. *Europace* 2020;**22**:1822–9.
8. Winter J, Siekiera M, Shin DI, Meyer C, Kröpl 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.
9. Francia P, Ziacchi M, De Filippo P, Viani S, D'Onofrio A, Russo V 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**:61–7.
10. 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.
11. Ziacchi M, Bisignani G, Palmisano P, Scalone A, Martignani C, Elvira Mocavero P et al. Serratus anterior plane block in subcutaneous implantable cardioverter defibrillator implantation: a case-control analysis. *J Cardiovasc Electrophysiol* 2020;**31**:144–9.
12. Theuns DAMJ, Brouwer TF, Jones PW, Allavatam V, Donnelley S, Auricchio A et al. Prospective blinded evaluation of a novel sensing methodology designed to reduce inappropriate shocks by the subcutaneous implantable cardioverter-defibrillator. *Heart Rhythm* 2018;**15**:1515–22.
13. D'Onofrio A, Pieragnoli P, Biffi M, Nigro G, Migliore F, Francia P et al. Subcutaneous implantable cardioverter defibrillator implantation: an analysis of Italian clinical practice and its evolution. *Int J Cardiol* 2018;**272**:162–7.
14. Lenarczyk R, Boveda S, Haugaa KH, Potpara TS, Syska P, Jedrzejczyk-Patej E et al. Peri-procedural routines, implantation techniques, and procedure-related complications in patients undergoing implantation of subcutaneous or transvenous automatic cardioverter-defibrillators: results of the European Snapshot Survey on S-ICD implantation (ESSS-SICDI). *Europace* 2018;**20**:1218–24.
15. Brouwer TF, Miller MA, Quast AB, Palaniswamy C, Dukkipati SR, Reddy V et al. Implantation of the subcutaneous implantable cardioverter-defibrillator: an evaluation of implantation techniques. *Circ Arrhythm Electrophysiol* 2017;**10**:e004663.
16. Knops RE, Peplinkhuizen S, Delnoy PPHM, Boersma LVA, Kuschyk J, El-Chami MF et al. Device-related complications in the subcutaneous and transvenous ICD: a secondary analysis of the PRAETORIAN trial. *Eur Heart J* 2022;**43**:4872–83.
17. Gold MR, Aasbo JD, El-Chami MF, Niebauer M, Herre J, Prutkin JM et al. Subcutaneous implantable cardioverter-defibrillator post-approval study: clinical characteristics and perioperative results. *Heart Rhythm* 2017;**14**:1456–63.
18. Friedman DJ, Parzynski CS, Varosy PD, Prutkin JM, Patton KK, Mithani A et al. Trends and in-hospital outcomes associated with adoption of the subcutaneous implantable cardioverter defibrillator in the United States. *JAMA Cardiol* 2016;**1**:900–11.
19. 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.
20. Knops RE, van der Stuijt W, Delnoy PPHM, Boersma LVA, Kuschyk J, El-Chami MF et al. Efficacy and safety of appropriate shocks and antitachycardia pacing in transvenous and subcutaneous implantable defibrillators: analysis of all appropriate therapy in the PRAETORIAN trial. *Circulation* 2022;**145**:321–9.