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CLINICAL RESEARCH

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

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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.

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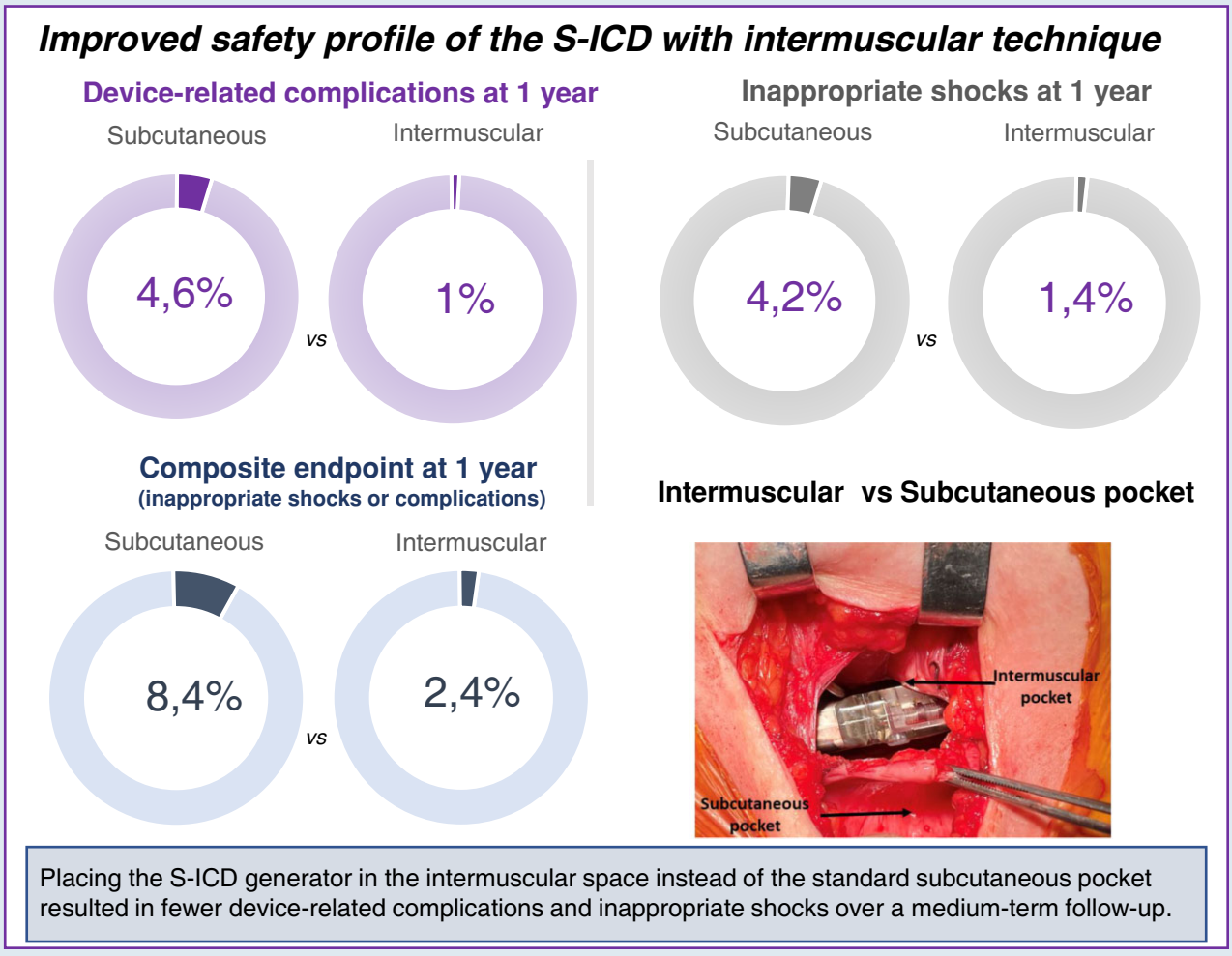
Graphical Abstract



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 ± 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 (≤ or > mean value), body mass index (≤ or > mean value), and ejection fraction (≤ 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 ≤65J 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, $P = 0.339$). Intraprocedural 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

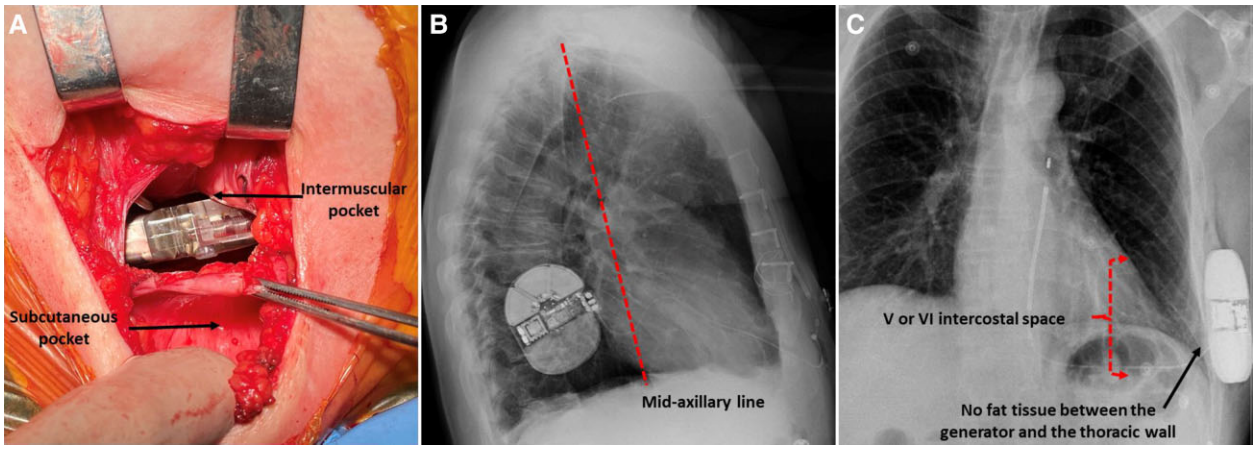


Figure 1 With the intermuscular technique, the generator is placed in a deeper position that ensures better device protection, patient's comfort, and aesthetic results. The resulting system position is also optimal for effective defibrillation. The pulse generator is positioned in an intermuscular pocket 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^2[d]	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.
[a]The overall population included 84 patients with old-generation devices (excluded from the analysis).
[b]IM vs. SC group.
[c]Matched IM vs. SC group.
[d]Variables 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 approaches[11] 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

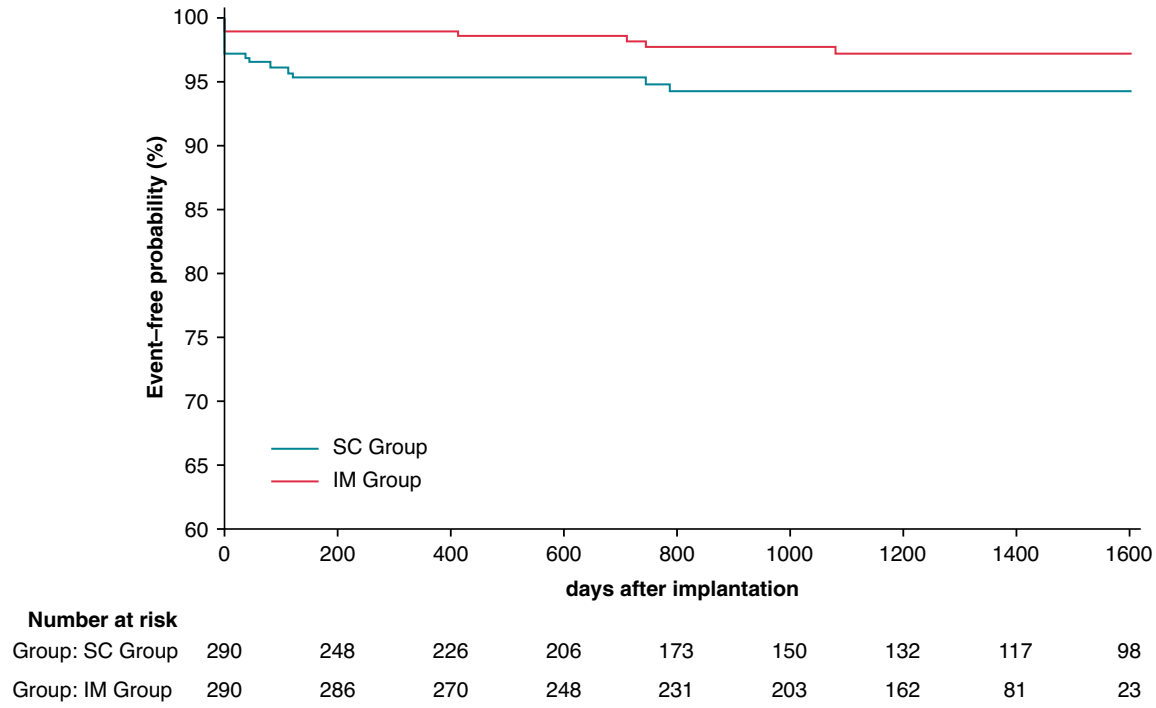


Figure 2 Kaplan–Meier estimates of time to first device-related complication (unadjusted hazard ratio 0.41, 95% CI 0.17–0.99, $P = 0.041$).

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)

[a]Component of the composite endpoint.
[b]This category included three pocket infections, one lead-related infection, and one pocket and lead-related infection.

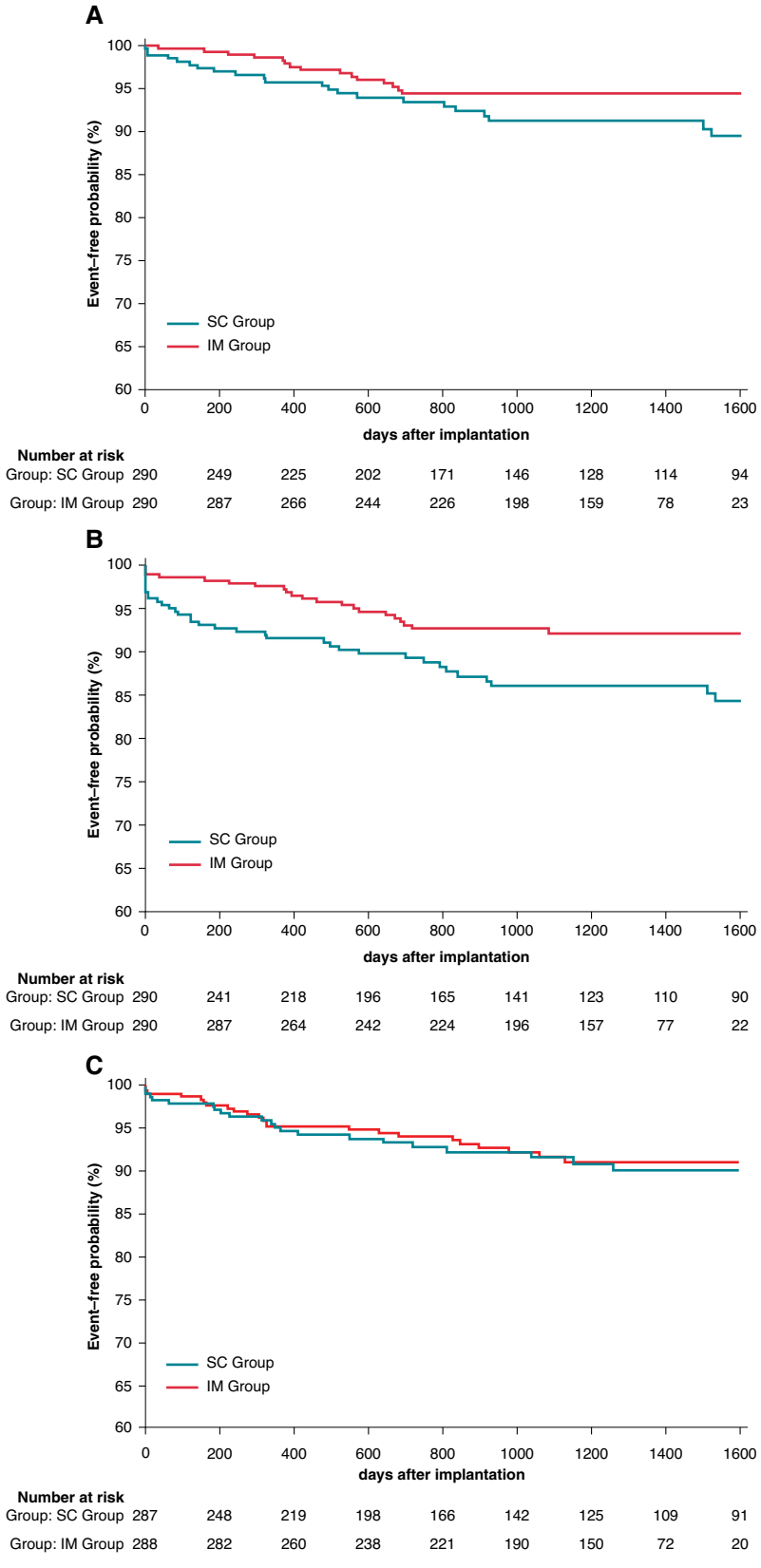


Figure 3 Kaplan–Meier estimates of time to first: inappropriate shock (unadjusted hazard ratio 0.60, 95% CI 0.31–1.16, $P = 0.133$) (*A*); the composite of complications and inappropriate shocks (unadjusted hazard ratio 0.50, 95% CI 0.30–0.86, $P = 0.013$) (*B*); appropriate shock (unadjusted hazard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

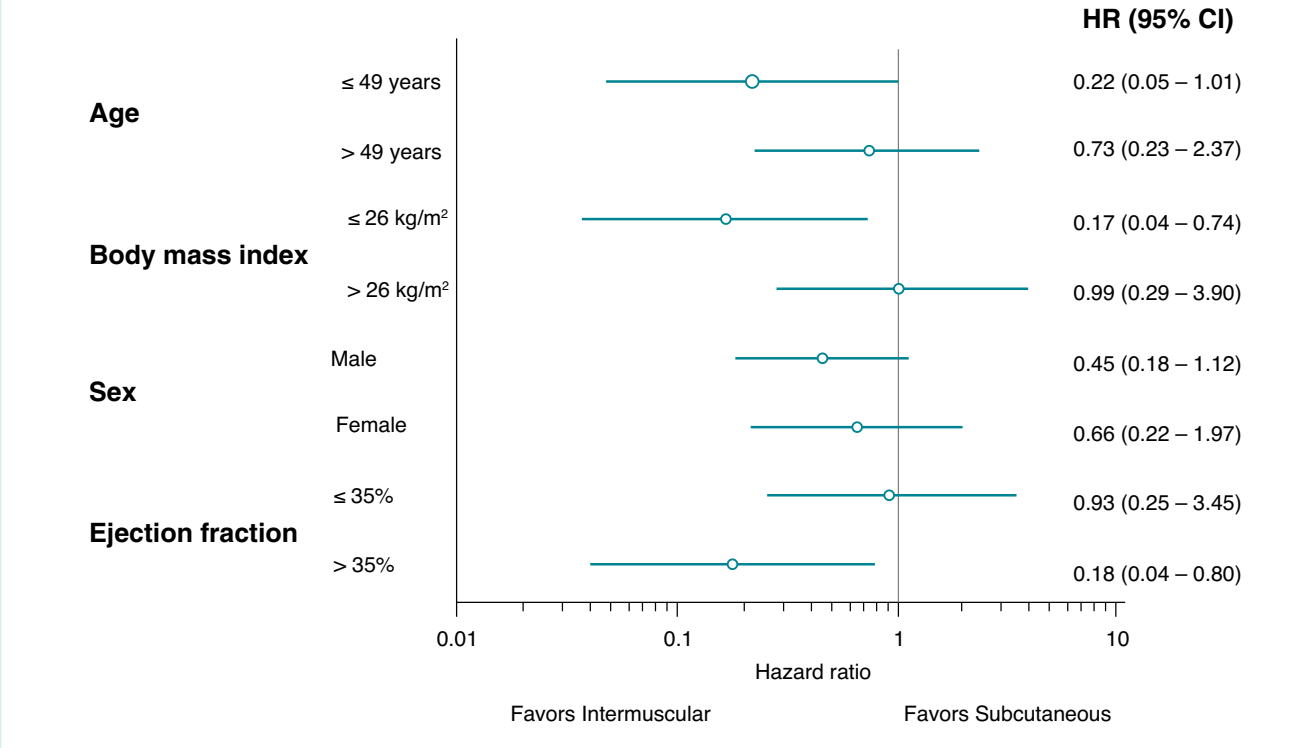


Figure 4 Association between generator positioning and the risk of device-related complication in pre-specified subgroups. No interaction was detected between positioning and the variables that defined the subgroups.

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 study[5] 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 Lunghetti;
- 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;
- 'Giovan Battista Grassi' Hospital, Ostia, Rome; F. Ammirati, L. Santini, K. Mahfouz, C. Colaiaco;
- IRCCS Fondazione Policlinico 'S. Matteo', Pavia: R. Rordorf, A. Vicentini, S. Savastano, B. Petracci, A. Sanzo, E. Baldi, M. Casula;
- Istituto Auxologico Italiano—IRCCS, Milan: GB. 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: GB. Forleo;
- Ospedale Maggiore, Crema: E. Chieffo, E.Tavarelli;
- 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. Silvetti, 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;
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