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RAPID COMMUNICATION

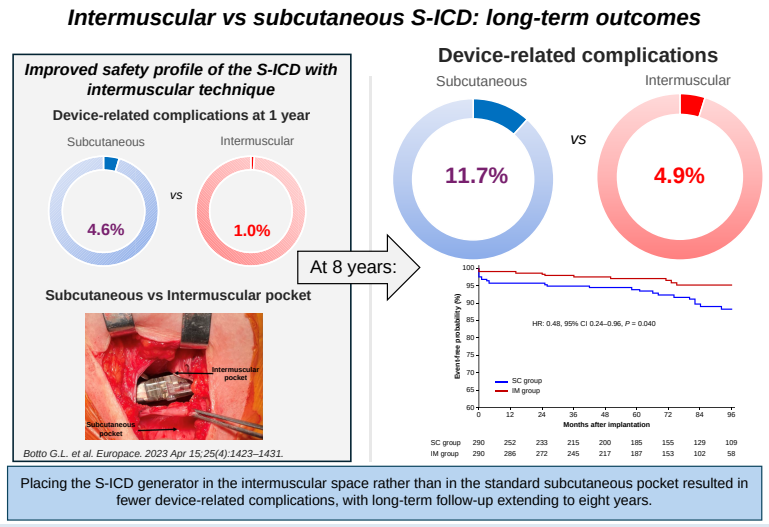
Long-term outcomes of intermuscular versus subcutaneous S-ICD implantation: extended follow-up of a propensity-matched multicentre analysis

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Graphical Abstract



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

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Introduction

The subcutaneous implantable cardioverter-defibrillator (S-ICD) was developed to prevent sudden cardiac death while avoiding the lead-related complications associated with transvenous implantable cardioverter-defibrillators (T-ICDs). Over the last decade, observational studies have confirmed its safety and efficacy,[1–3] while the randomized PRAETORIAN Trial demonstrated non-inferiority to T-ICD for the composite endpoint of device-related complications and inappropriate shocks.[4] However, PRAETORIAN was initiated during an early phase of S-ICD adoption, before substantial advances in implantation technique and device technology. In particular, positioning the generator in an intermuscular pocket between the serratus anterior and latissimus dorsi muscles has become widely adopted and is associated with improved system positioning and lower complication rates.[5,6]

In a previous propensity-matched analysis from a large multicentre Italian registry, we demonstrated that intermuscular positioning significantly reduced device-related complications and inappropriate shocks compared with the traditional subcutaneous (SC) technique over mid-term follow-up.[7] More recently, PRAETORIAN XL evaluated device-related complications at 8 years, without demonstrating superiority of S-ICD over T-ICD in the intention-to-treat analysis, although major complications were less frequent with S-ICD.[8]

We therefore extended the follow-up of our propensity-matched cohort to assess long-term device-related complications with intermuscular vs S-ICD implantation.

Methods

This study extends our previously published multicentre propensity-matched analysis of patients undergoing *de novo* S-ICD implantation at 66 Italian centres.[7] Study design, inclusion criteria, implantation techniques, and matching methodology have been previously described.

Consecutive patients receiving a new-generation S-ICD generator were enrolled from 2016 to 2021 in a prospective registry. Institutional Review Boards approved the study and all patients provided written informed consent.

According to physician preference, the pulse generator was positioned either in a traditional subcutaneous pocket or intermuscularly between the serratus anterior and latissimus dorsi muscles. One-to-one propensity score matching yielded two balanced groups.

For the present analysis, all patients included in the matched cohort were re-evaluated through extended follow-up. The primary endpoint was device-related complications requiring intervention or prolongation of hospitalization, including infection, pocket complications, generator revision/replacement due to malfunction, and lead-related interventions.

Time-to-event analysis was performed using Kaplan–Meier methods, and hazard ratios were estimated using Cox proportional hazards models. Analyses were performed using R (R Foundation for Statistical Computing, Vienna, Austria).

Results

The propensity-matched cohort consisted of 580 patients (49 ± 15 years, 80% male, left ventricular ejection fraction 46 ± 16, 50% dilated cardiomyopathy), with 290 patients in each group. Baseline clinical variables and device programming were balanced between groups.

During extended follow-up of 77 (25th–75th percentile: 47–101) months, 40 (7%) deaths occurred and device-related complications were reported in 37 (6%) patients.

Complication risk was lower with intermuscular positioning (hazard ratio 0.48, 95% CI 0.24–0.96, $P = 0.040$), with 8-year cumulative rates of 4.9% (95% CI 2.0–7.8) vs. 11.7% (95% CI 7.2–16.2) with subcutaneous positioning *(Figure 1)*. The incidence of all study endpoints is reported in the Table shown in *Figure 1*.

During follow-up, battery depletion occurred in 197 (34%) patients, 83 (29%) in the intermuscular, and 114 (39%) in the subcutaneous group, with no difference in time to replacement (hazard ratio 0.86, 95% CI 0.64–1.14, $P = 0.283$). Moreover, 59 (10%) patients experienced at least one appropriate shock. The first shock was ineffective in nine (15%) patients, five in the intermuscular, and four in the subcutaneous group, with no apparent difference between techniques.

Discussion

This extended follow-up confirms a sustained reduction in device-related complications with intermuscular S-ICD implantation up to 8 years. The persistent separation of the Kaplan–Meier curves resulted in an 8-year cumulative complication rate of 4.9% with intermuscular vs. 11.7% with subcutaneous positioning, with fewer pocket-related events and system revisions.

These findings are particularly relevant in the context of PRAETORIAN XL,[8] which did not demonstrate superiority of S-ICD over T-ICD for device-related complications in the intention-to-treat analysis, although S-ICD reduced major complications. PRAETORIAN, however, largely reflected early S-ICD practice. Since then, intermuscular implantation has become widely adopted and has been associated with improved generator positioning, lower defibrillation impedance, and fewer pocket-related complications.[5–7] Our findings suggest that contemporary S-ICD therapy using optimized implantation techniques may achieve a better long-term safety profile than that observed in earlier trials.

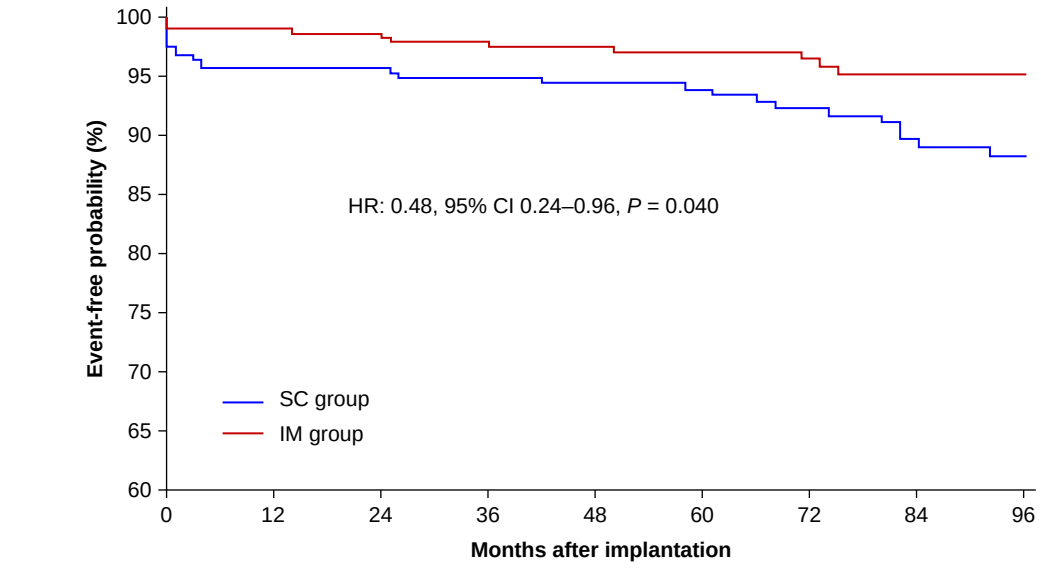
Generator replacement is particularly relevant to long-term safety, as additional procedures expose patients to new procedure-related complications and potential system revisions. In PRAETORIAN XL, S-ICD generators required replacement more frequently than T-ICDs, contributing to the increase in cumulative complications beyond 5 years.

In our cohort, however, fewer complications occurred beyond Year 5 with intermuscular positioning, with progressive divergence of the Kaplan–Meier curves and fewer revisions for optimization of device performance or patient comfort. This supports the long-term stability of intermuscular positioning, including at generator replacement, consistent with previous observations.[9] Importantly, although 34% of patients underwent replacement for battery depletion, time to replacement did not differ between groups, suggesting that differential exposure to generator replacement does not explain the lower complication risk with intermuscular positioning. Contemporary S-ICD systems also have an estimated battery longevity of ~9 years,[10] potentially further reducing replacement-related complications.

Taken together, these findings provide an updated estimate of the long-term safety profile of S-ICD therapy in contemporary clinical practice and reinforce the importance of optimized implantation strategies.

Conclusions

In this extended follow-up of a multicentre propensity-matched cohort, positioning a modern S-ICD generator in an intermuscular



SC group	290	252	233	215	200	185	155	129	109
IM group	290	286	272	245	217	187	153	102	58

	IM group (*n* = 290)	SC group (*n* = 290)
Device-related complications, *n* (%)	12 (4.1)	25 (8.6)
• System revisions for defibrillation test failure or high shock impedance during implantation, *n* (%)	3 (1.0)	7 (2.4)
• Infections Pocket, *n* (%) Lead-related, *n* (%)	2 (0.7) 0 (0)	8 (2.8) 1 (0.3)
• Lead Issues managed by Lead replacement, *n* (%) Lead repositioning, *n* (%)	2 (0.7) 0 (0)	0 (0) 2 (0.7)
• System revisions for High shock impedance, *n* (%) Shock failure, *n* (%) Patient discomfort, *n* (%)	0 (0) 0 (0) 1 (0.3)	2 (0.7) 1 (0.3) 2 (0.7)
• Sensing issues T-wave oversensing, *n* (%) Non-cardiac oversensing, *n* (%) Myopotential oversensing, *n* (%)	2 (0.7) 1 (0.3) 1 (0.3)	1 (0.3) 1 (0.3) 0 (0)

Figure 1 Kaplan–Meier curves for freedom from device-related complications in the matched cohorts. Event distribution for device-related complications comparing intermuscular and subcutaneous generator positioning.

pocket was associated with a sustained reduction in device-related complications over long-term follow-up approaching 8 years. These findings support the use of modern implantation techniques and provide contemporary evidence on the long-term safety profile of S-ICD therapy.

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Conflict of interest: G.L.B. received speaker's fee from Abbott, Biotronik, Boston Scientific, Medtronic, and Microport. M.Z.

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Data availability

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

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