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Clinical EVIDENCE

Physical Activity in S-ICD Recipients

Subcutaneous Implantable Defibrillators in Young Patients: Arrhythmias, Complications, and Physical Activity (Francia et al.)[1]

Living with S-ICD: New Insights on Patient Experience

Device-specific quality of life: results from the ATLAS trial — avoid transvenous leads in appropriate subjects (Carrol et al.)[2]

Quality of Life in Subcutaneous or Transvenous Implantable Cardioverter-Defibrillator Patients: A Secondary Analysis of the PRAETORIAN Trial (Knops et al.)[3]

HeartLogic™: New Insights in Readmissions and HF Management

Results of the Precision Event Monitoring for Patients With Heart Failure Using HeartLogic Study (PREEMPT-HF) (Sauer et al.)[4]

Evaluation of real-world application of cardiac implantable electronic device-based multi-sensor algorithm for heart failure management (Llewellyn et al.)[5]

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Summary

This issue of Clinical Evidence focuses on evaluating the patient experience and clinical considerations associated with living with a subcutaneous implantable cardioverter-defibrillator (S-ICD). Recent evidence has shown that subcutaneous ICDs support a safe return to physical activity without increasing the risk of device-related complications — an important consideration for maintaining a healthy and active lifestyle. Subgroup analyses from major randomised trials, such as ATLAS and PRAETORIAN, have further demonstrated that patient acceptance of subcutaneous and transvenous ICDs is comparable across different clinical profiles, reinforcing the importance of a shared decision-making process that takes into account patient quality of life.

This issue of the newsletter also includes two recent publications on HeartLogic: one highlights its usefulness for evaluating and managing patients after an initial hospitalisation, while the other confirms its strong effectiveness and efficiency in proactive patient management and the optimisation of resource utilisation in real-world clinical practice.

Active lifestyle and recreational sports in young patients with S-ICD

An active lifestyle and recreational sports are important for overall health and cardiovascular well-being.

Younger ICD candidates often face higher risks of complications from traditional transvenous leads, making the subcutaneous ICD (S-ICD) a preferred option. However, the impact of physical activity on arrhythmias, shocks, and device safety in S-ICD patients had not been systematically studied until the recent research by Dr. Francia[1], published in Circulation: Arrhythmia and Electrophysiology.

In this project, conducted within the Rhythm Detect registry, a cohort of 602 young adult S-ICD patients (aged 15–65 years) is assessed for physical activity using the International Physical Activity Questionnaire (IPAQ), and the association between lifestyle, recreational sports, and S-ICD safety — including shock incidence — is evaluated.

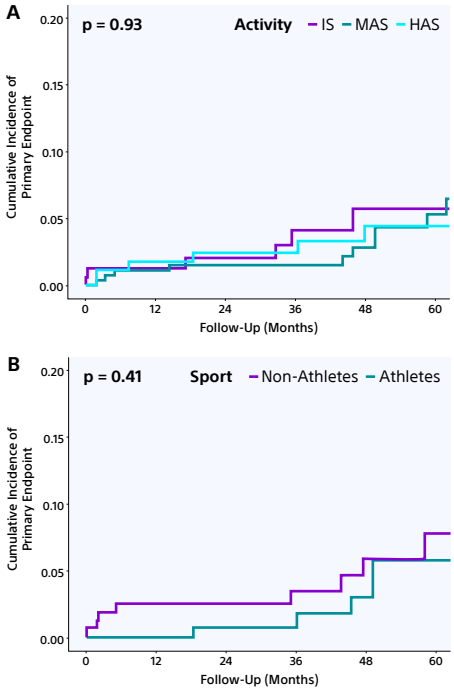


Figure 1. (to right) Kaplan-Meier curves showing time to arrhythmia- or device-related primary end point event in (A) inactive subjects (IS), moderately active subjects (MAS), and highly active subjects (HAS), and (B) recreational athletes vs. non-athletes.

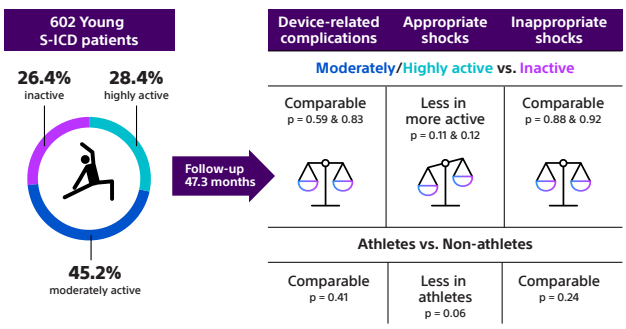
Over a median follow-up of 47.3 months (IQR 27.0–67.6):

3.8% of patients experienced **arrhythmia, or device-related complications.** Multivariate analysis showed no significant difference in the incidence of these events between moderately or highly active individuals and inactive patients (p = 0.59 and p = 0.83, respectively).

7.3% of patients experienced **appropriate therapies.** Although moderately and highly active patients had a lower incidence of appropriate shocks compared to inactive individuals, the difference was not statistically significant (p = 0.12 and p = 0.11, respectively). Similarly, athletes showed a trend toward fewer appropriate shocks than non-athletes (p = 0.06).

6.3% of patients experienced **inappropriate shocks.** No significant differences were observed in inappropriate shocks across activity levels (p = 0.92 and p = 0.88 for moderately and highly active versus inactive individuals, respectively).

After S-ICD implantation, **physical activity levels** varied, with many patients maintaining or increasing activity. For those who reduced their activity (14%), the main reason was the underlying heart disease rather than the device itself. Most recreational athletes (69%) continued their usual sports and exercise routines, stating that having the S-ICD increased their confidence to remain active.



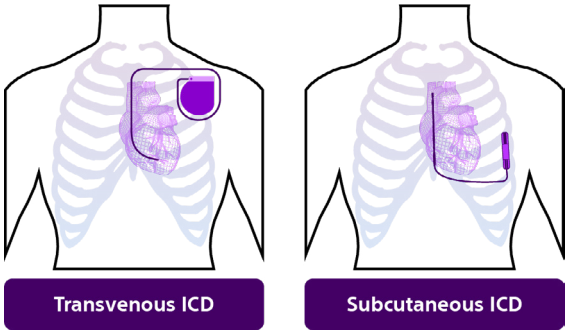
Key findings:

- Most young individuals with S-ICD are at least **moderately active**, and about 25% regularly engage in recreational sports.
- Higher physical activity levels in young S-ICD recipients **are not linked to a greater risk of arrhythmias or device-related complications.**
- Moderately and highly active individuals, including recreational athletes, **show a lower rate of appropriate shocks and no increase in inappropriate shocks.**

The findings align with recent guidelines[6] favouring more permissive sports participation for ICD patients, including those with S-ICD, and indicate that an active lifestyle does not increase the risk of complications or arrhythmias.

Patient-reported outcomes in subcutaneous versus transvenous ICD recipients

Patient-reported outcomes (PROs) are essential in ICD care, offering key insights into quality of life and device acceptance. Recent randomised sub-analyses — one from the ATLAS study[2] and another from the PRAETORIAN study[3] — have examined these outcomes by comparing the two gold-standard devices for sudden cardiac death prevention: transvenous (TV-ICD) versus subcutaneous (S-ICD).



Results from the ATLAS trial

To investigate device-specific quality of life measured by the Florida Patient Acceptance Survey (FPAS) generic quality of life measured by the SF-36 and implantation site pain in patients who were randomised to receive single-chamber T-ICD (n=197) *versus* S-ICD (n=207).

Good device specific quality of life (FPAS) reported by both S-ICD and TV-ICD patients up to six months.

No difference in pre-implant and 6 month generic quality of life (SF-36) between groups.

Implant site pain scores initially higher for S-ICD patients but declined with no differences between groups at 6 months.

ATLAS Key findings:

- Patients who received either an S-ICD or a TV-ICD reported good **early device-related quality of life, which improved over time.**
- There was no significant difference in FPAS total scores between the S-ICD and the TV-ICD groups and **no group differences in a priori–selected subgroups** (based on sex, age, and BMI).

Results from the PRAETORIAN trial

To compare the quality of life in patients receiving a subcutaneous S-ICD (n=426) versus a TV-ICD (n=423), using validated tools (SF-36 and Duke Activity Status Index) within a randomised population.

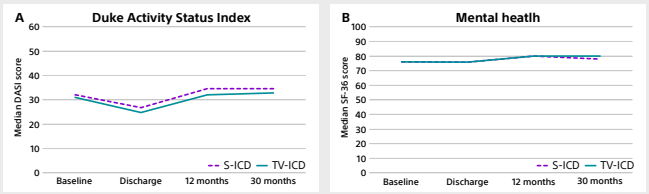


Figure 2: Outcomes between S-ICD and TV-ICD over time. A, Duke Activity Status Index (DASI). B, Mental health subscale of 36-Item Short Form Health Survey (SF-36).

PRAETORIAN Key findings:

- This study, the largest to date assessing QoL in patients with subcutaneous and transvenous ICDs, shows that both device types have a similar impact on quality of life.
- The findings confirm that ICD shocks — regardless of device type — negatively affect short-term quality of life, highlighting the need for strategies to minimise inappropriate shocks.

- No significant differences in QoL scores (physical functioning, pain, mental health) between S-ICD and TV-ICD groups at baseline, discharge, 12, or 30 months.
- Patients who received ICD shocks (appropriate or inappropriate) in the 90 days prior to assessment reported significantly lower scores in social and emotional role functioning — regardless of device type.

From a clinical perspective, these results can play a key role in supporting the **shared decision-making process** between physicians and patients, providing evidence-based insights into the comparable impact of subcutaneous and transvenous ICDs on quality of life. By incorporating these findings into clinical discussions, **healthcare providers can better align device selection with patient preferences, values, and lifestyle considerations.**

Association between HeartLogic trend and readmissions (PREEMPT-HF study)

The results of the **PREEMPT-HF** (PREcision Event Monitoring of Patients with Heart Failure using HeartLogic) study has been recently published on JACC: Heart Failure Journal by Dr. Sauer *et al.*[4]

The study included patients with HeartLogic-capable ICD or CRT devices, with the algorithm disabled to keep patients and clinicians blinded.

The **primary objective** was to assess the correlation between HeartLogic sensor data and the likelihood of readmission after hospitalisation for heart failure.

2.155 patients were enrolled at 103 sites and followed for 12 months. A total of 243 hospitalisations for HF were recorded, of which 156 (64%) were HF index hospitalisations (first hospitalisations).

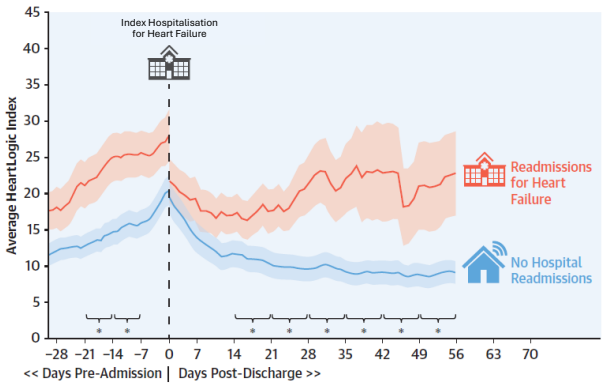


Figure 3. HeartLogic Index before admission and after discharge for patients readmitted for HF compared with those who were not readmitted.

*Weeks with value of P < 0.05, pairwise comparisons from generalised linear mixed model.

The overall performance of HeartLogic was similar to other publications: the alert sensitivity for HF events was 78.3%, and the false-positive rate (FPR) was 1.18 event/per year.

The results in terms of readmission risk highlighted that:

- The **HeartLogic** index was **significantly higher before (2-3 weeks) and after (2 weeks) HF hospitalisations** that were followed by a 30 and 90-days readmission for HF (Figure 3). **The same was true for 90 day all-cause readmissions.**
- The **change in HeartLogic index** from admission to discharge was not associated with readmission risk.
- Patients in a **HeartLogic alert state** either 1–2 weeks before hospitalisation or 14 days after discharge had a significantly higher risk of 90-day HF readmission — **HR ≈ 2.7 before admission and HR = 3.08 after discharge** — compared to those not in alert.

Key findings:

- **Higher HeartLogic index** values before admission and after discharge are linked to 90-day HF and all-cause readmissions.
- HeartLogic **adds prognostic value after discharge** by reflecting current HF status and helping identify high-risk patients post-hospitalisation.
- These findings suggest that patients at risk for readmission had **prolonged worsening** and/or inadequate treatment during initial HF hospitalisation.

Clinical evaluation of the HeartLogic algorithm in real-world practice

A single-centre experience to evaluate the HeartLogic performance and resources implication in real-world were described by Dr Llewellyn.[5]

Data were collected from **212 CRT-D patients** monitored for 12-months. During follow-up period a total of 197 HeartLogic alerts occurred and each alert was reviewed and actioned as reported in alert management protocol described in Figure 4.

Diagnostic Performance	• Sensitivity 100%. • Negative Predictive Value: 100%. • Unexplained alert rate: 0.46 alerts/ patient-year.
Clinical Management	• 74% of actionable alerts led to timely adjustments in drug therapy. • The majority of adjustments (59%) involved non-diuretic drug.
Resources Allocation	• The total time required for HF management of the cohort was 257 hours per year, corresponding to 0.57 full-time equivalents (FTEs) per 1,000 patients.

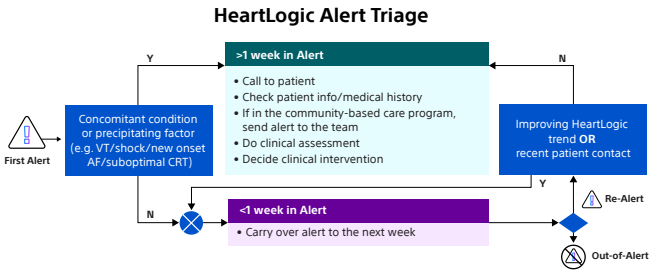


Figure 4: HeartLogic alert management protocol.

Key findings:

- HeartLogic performance in **predicting heart failure** events was confirmed, effectively identifying patients during **high-risk periods.**
- The integration of HeartLogic into a routine HF management workflow supported **efficient healthcare resource allocation,** enabling **timely interventions and reducing unnecessary clinical workload.**

"Device-related complications in transvenous versus subcutaneous defibrillator therapy during long-term follow-up: the PRAETORIAN-XL Trial"[7]

Olde Nordkamp L.R.A. et al.

The PRAETORIAN XL Trial is a BSC-funded, investigator sponsored study led by the Amsterdam University Medical Centre and is a 4-year extension of the PRAETORIAN Trial[8].

The PRAETORIAN XL Trial reconsented patients from the original PRAETORIAN enrolment (n = 849), including **263 with S-ICD and 265 with TV-ICD,** to extend follow-up to a total of 8 years.

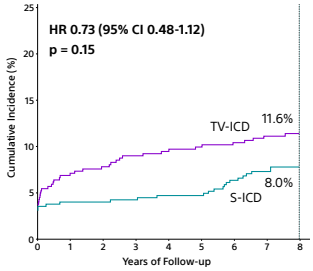
The study aimed to evaluate the superiority of the S-ICD over the TV-ICD regarding the composite primary endpoint of major and minor device-related complications.

Breaking News

Discover the Longest-Term Randomised Trial Results on ICDs: PRAETORIAN XL

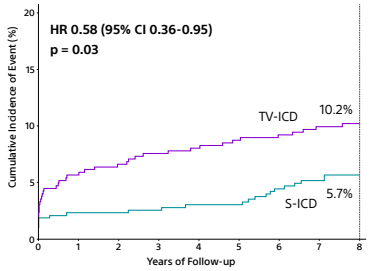
What are the key results?

Device-related complications: **11.6% (TV-ICD) vs. 8.0% (S-ICD)**



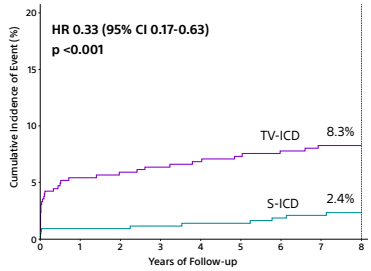
Major and minor device-related complication rates were not **statistically different** *between the S-ICD and TV-ICD.*

Major complications: **10.2% (TV-ICD) vs. 5.7% (S-ICD)**



Patients randomised to the S-ICD arm experienced a **42% lower risk of major complications** *compared to patients in the TV-ICD arm.*

Lead-related complications: **8.3% (TV-ICD) vs. 2.4% (S-ICD)**



Patients randomised to the S-ICD arm experienced a **67% lower risk of lead-related complications** *compared to patients in the TV-ICD arm.*

Investigators concluded that: "TV-ICD carries a significantly higher risk of major and lead-related complications compared with S-ICD therapy. The S-ICD should therefore be considered in all patients without a pacing indication who are evaluated for ICD".

Key Messages

- **Physical Activity in S-ICD Recipients:**
  Real-world findings[1] demonstrate the safety and efficacy of the S-ICD in young and physically active patients, without increasing the risk of device-related complications or inappropriate shocks.
- **Living with S-ICD: New Insights on Patient Experience**
  Recent findings from the ATLAS[2] and PRAETORIAN[3] trials highlight the comparable patient acceptance of both T-ICD and S-ICD devices across different subgroups, reinforcing the importance of a shared decision-making process that incorporates patient preferences and quality of life.
- **HeartLogic: New Insights in Readmissions and HF Management:**
  Higher HeartLogic index values before admission and after discharge indicate sustained worsening or inadequate treatment during initial HF hospitalisation and help identify patients at high risk of HF and all-cause readmissions in 90-days[4].
  HeartLogic confirmed its predictive performance for heart failure events, enabling timely interventions during high-risk periods and supporting efficient healthcare resource allocation[5].

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