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11

Clinical EVIDENCE

In this issue:

ICDs Still Matter in Contemporary HFrEF Era

Implantable Cardioverter-Defibrillator Therapy in Contemporary Heart Failure Patients - An Analysis From the EMPEROR-Reduced Trial (Aktas et al.)[1]

S-ICD Implant Workflow: From PRAETORIAN DFT to Simplified Score Assessment

Intraprocedural PRAETORIAN score for early assessment of S-ICD implantation: A proof-of-concept study (Gasperetti et al.)[2]

Ultrasound-guided S-ICD implantation: A proof-of-concept study (Lüker et al.)[3]

ILRs Performance in Arrhythmia Detection

Accuracy of Implantable Loop Recorders - Multicenter, Multidevice Comparison (Kamsani et al.)[4]

ISSUE 11 September 2026

Contents

SEPTEMBER 2026

Summary

This edition of Clinical Evidence explores recent advances in cardiac implantable devices, focusing on ICD role in HFrEF patients, innovation in PRAETORIAN score assessment during S-ICD implantation, and the accuracy of implantable loop recorder.

The publication from EMPEROR-Reduced trial confirms the continued value of ICD therapy for sudden cardiac death prevention in contemporary HFrEF patients receiving optimised medical therapy.

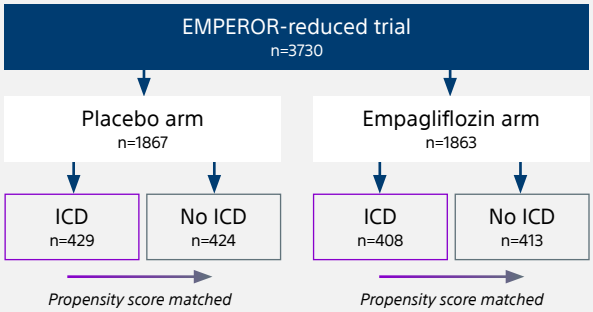
Recent proof-of-concept studies explore practical approaches to simplify PRAETORIAN score calculation during S-ICD implantation. In particular, Gasperetti *et al.* demonstrates the feasibility of intraprocedural score calculation using fluoroscopy, while Lüker *et al.* investigated ultrasound-guided system positioning as potential tools for real-time implant quality evaluation

Finally, Kamsani *et al.* provide valuable real-world evidence on ILR performance, highlighting meaningful differences in diagnostic accuracy and false-positive burden across currently available devices.

Can ICDs still reduce sudden cardiac death despite advances in guideline-directed medical therapy?

Contemporary HFrEF management has evolved with the introduction of ARNI and SGLT2 inhibitors. In EMPEROR-Reduced (Empagliflozin Outcome Trial in Patients with Chronic Heart Failure and a Reduced Ejection Fraction) trial[5], empagliflozin reduced the risk of cardiovascular death or heart failure hospitalisation by 25%, raising the question about the incremental benefit of ICD therapy in patients receiving contemporary guideline-directed medical therapy (GDMT).

To address this issue, Aktas *et al.*[1] performed a propensity score-matched analysis of 1,674 patients enrolled in EMPEROR-Reduced, evaluating the association of ICD/CRT-D therapy with sudden cardiac death and all-cause mortality (Figure 1).



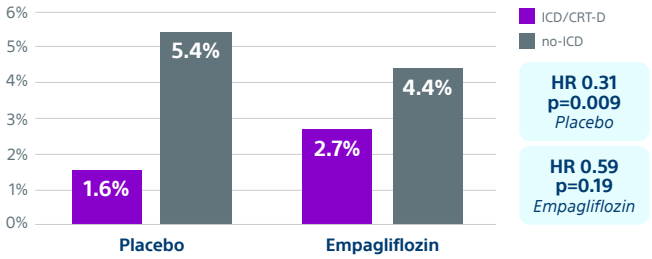
EMPAGLIFLOZIN arm: standard HF therapy plus empagliflozin

PLACEBO arm: standard HF therapy plus placebo.

Figure 1: Flowchart of patients included in the analysis.

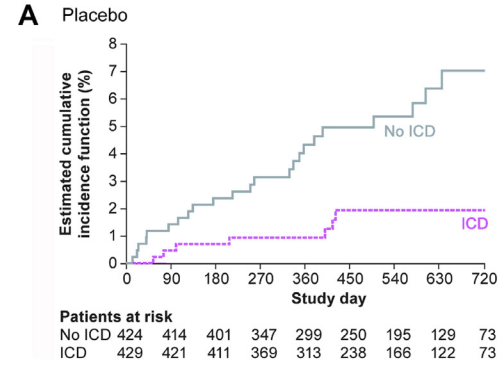
Sudden Cardiac Death

Rate of Sudden Cardiac Death (SCD)

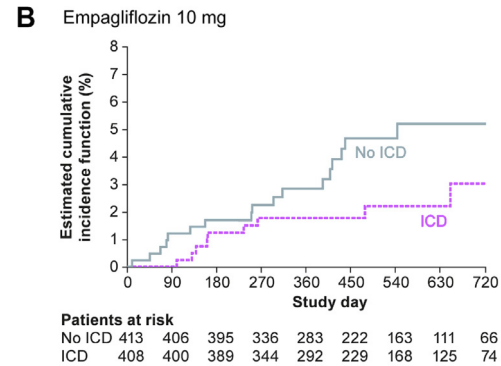


Despite contemporary GDMT, ICD/CRT-D therapy was associated with lower rates of sudden cardiac death. The greatest reduction was observed in the placebo arm (1.6% vs. 5.4%; HR 0.31).

2-years cumulative incidence of SCD



3.5-fold higher SCD incidence without ICD



Numerically lower SCD incidence with ICD

Figure 2: Cumulative incidence function curve for Sudden Cardiac Death in patients with or without ICD at baseline, considering other causes as competing risks.

All-cause mortality

Despite a trend toward lower 2-year mortality among ICD recipients (19% vs. 24% in the placebo arm; 14% vs. 19% in the empagliflozin arm), **ICD therapy was not associated with a significant reduction in all-cause mortality**, suggesting an increasing contribution of competing non-arrhythmic causes of death in contemporary HFrEF patients.

Key findings:

- **ICD therapy remained associated with a lower risk of sudden cardiac death** regardless of empagliflozin treatment, with no significant treatment interaction.
- Despite reducing SCD, ICD therapy was not associated with a significant improvement in all-cause mortality, highlighting the **need for improved risk stratification** to identify patients most likely to derive a survival benefit.

Feasibility of intraprocedural PRAETORIAN score for S-ICD implant

Recent PRAETORIAN DFT[6] results have highlighted the importance of accurate implant positioning assessment, reinforcing the role of the PRAETORIAN score in guiding VF conversion testing decisions.

Consequently, attention is shifting toward **practical methods for assessing implant quality during the procedure and simplifying PRAETORIAN score calculation in clinical practice.**

From evidence, to everyday practice

Intraprocedural PRAETORIAN score for early assessment of S-ICD implantation: a proof-of-concept study

In this proof-of-concept study including 40 consecutive S-ICD implants, Gasperetti *et al.*[2] evaluated whether the PRAETORIAN score (PS), traditionally calculated post-procedure using chest X-ray (PP-PS), could be reliably assessed during S-ICD implantation using fluoroscopy before pocket closure (intraprocedural PRAETORIAN score, i.e., IP-PS).

Complete agreement

Observed between IP-PS (with fluroscopy) and PP-PS (with chest X-ray). **100% agreement; κ = 1.00; p<0.001**

No workflow burden

In comparison with an historical cohort, procedural time in the IP-PS cohort did not increase. **45 [41–52] vs. 45 [39–49] min; p=0.351**

Key findings:

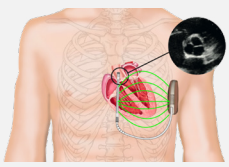
- Routine PRAETORIAN score assessment using fluoroscopy during S-ICD placement is **feasible and effective** in identifying patients at high risk of conversion failure.
- **Immediate feedback** before pocket closure, potentially avoiding early repositioning.

Ultrasound-guided S-ICD implantation: a proof-of-concept study

As interest grows in translating the PRAETORIAN score into a practical tool for routine clinical use, Lüker *et al.*[3] investigated whether ultrasound (US) could support both S-ICD positioning and intraoperative lead-depth assessment, potentially enabling a simplified and radiation-free evaluation of implant quality.

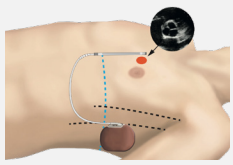
US-guided positioning

Aortic valve identification through ultrasound was **feasible in 100% of patients, with optimal system positioning confirmed in 95%** of cases (19/20).



Electrode assessment

Lead depth assessment by ultrasound was **feasible in 100% of patients, showing good agreement** with post-procedural X-ray measurement.



Key findings:

- **Ultrasound-based S-ICD positioning was feasible** in a proof-of-concept cohort.
- **Lead-to-sternum** distance could be assessed intraoperatively.
- This approach may support future radiation-free, **real-time risk assessment** for selective DFT omission.

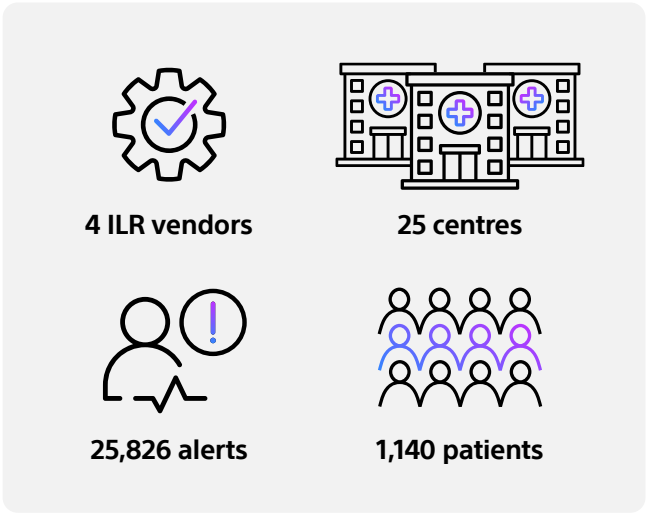
These studies suggest that PRAETORIAN score assessment may evolve from a post-procedural assessment tool to a practical intraprocedural guide. Fluoroscopy-based intraprocedural scoring and ultrasound-guided lead assessment both move in this direction, offering practical strategies to simplify score calculation.

Positive Predictive Value of ILRs across Different Arrhythmias and Device Types

Implantable loop recorders (ILRs) are increasingly used for long-term rhythm monitoring. However, the growing use of remote monitoring has also increased the volume of transmitted alerts, making diagnostic accuracy and false-positive burden increasingly important considerations for both clinicians and device clinics.

To address this challenge, Kamsani *et al.*[4] conducted the largest multidevice comparison of currently available ILR platforms:

1. LINQ II with AccuRhythm AI (MDT)
2. Confirm Rx with SharpSense Technology (ABT)
3. Biomonitor III with RhythmCheck (BIO)
4. LUX-Dx™ with Dual-Stage Algorithm (BSX)



Positive predictive value

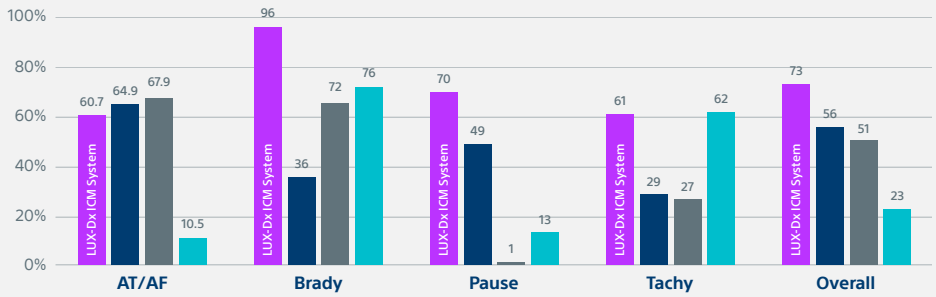


Figure 1: Positive Predictive Value across different arrhythmias episodes and device type.

LUX-Dx achieved the highest overall diagnostic accuracy, with the best aggregate positive predictive value among all evaluated ILR platforms.

False positive burden

LUX-Dx was associated with the lowest overall false-positive rate among all evaluated ILRs.

This lower false-positive burden has the potential to improve diagnostic efficiency, reduce unnecessary alert reviews, and streamline workflow within device clinics.

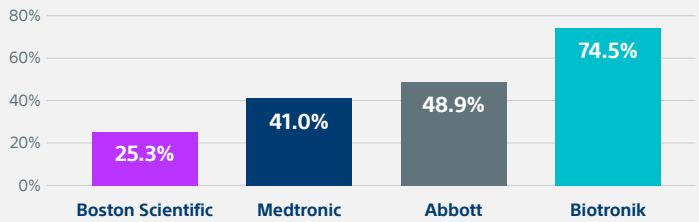


Figure 2: False positive burden. p<0.001

Key findings:

- **LUX-Dx demonstrated the highest overall diagnostic accuracy** among evaluated ILRs, with consistently high positive predictive values across multiple arrhythmia categories.
- **LUX-Dx was associated with a lower false-positive alert burden,** supporting diagnostic confidence and potentially reducing device clinic workload.

"Variability in implantable cardioverter-defibrillator battery longevity"[7]

Freeman J.V. et al.

Device longevity has become an increasingly important topic in the management of cardiac implantable electronic devices, as longer battery life can significantly reduce the need for generator replacement and the associated risks, including infection, lead damage, and healthcare costs.

As the population of CRT-D recipients continues to grow, maximising **device longevity has become a key clinical and economic objective**.

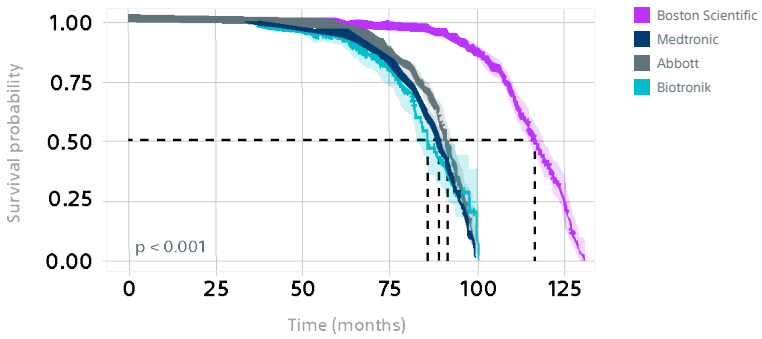
A total of 17,247 CRT-Ds implanted between 2003 and 2023 were analysed. Battery longevity was compared across manufacturers and related to device programming parameters, including pacing burden, output amplitude, and pulse width.

Breaking News

"...significantly longer battery life among Boston Scientific transvenous generators compared with other manufacturers"

What are the key results?

Longevity across manufacturer



Boston Scientific had consistently longer battery longevity than other manufacturers by approximately 2–3 years.

Determinants of battery longevity

Substantial predictors of biventricular ICD battery longevity were:

- *Device manufacturer: HR* 10.7 (ABT) – 19.0 (MDT)*
- *Programmed pulse width: HR* 2.55 (RA) – 8.63 (RV)*
- *Programmed output amplitude: HR* 1.13 (RA) – 2.28 (LV)*

*Adjusted HR.

Download the economic analysis performed by EP Edge

The same analysis was also performed in 15,029 single-chamber and 10,822 dual-chamber ICDs. The results confirmed that **Boston Scientific transvenous devices demonstrated the longest estimated battery longevity** across manufacturers - median longevities of 151 months for ICD VR and 134 months for ICD DR, compared with approximately 84–130 months and 92–109 months, respectively, for other manufacturers ($P < 0.001$).

Key Messages

- **ICDs Still Matter in Contemporary HFrEF Era**

  The EMPEROR-Reduced propensity-matched analysis[1] reinforces the continued value of ICD/CRT-D therapy for sudden cardiac death prevention, demonstrating meaningful protection even in contemporary HFrEF patients receiving optimised medical therapy.

- **S-ICD Implant Workflow: From PRAETORIAN DFT to Simplified Score Assessment**

  Recent proof-of-concept studies[2,3] have explored practical approaches to simplify PRAETORIAN score assessment during S-ICD implantation paving the way toward simplified, real-time implant quality evaluation and more informed procedural decision-making.

- **ILRs Performance in Arrhythmia Detection**

  Kamsani *et al.*[4] demonstrated that diagnostic accuracy varies considerably across currently available ILRs, with LUX-Dx™ delivering the strongest overall performance and the lowest false-positive burden in a real-world clinical setting.

1. Aktaş MK, Talha KM, Goldenberg I, *et al.* Implantable Cardioverter-Defibrillator Therapy in Contemporary Heart Failure Patients: An Analysis From the EMPEROR-Reduced Trial. JACC Heart Fail. 2026 Jul 1:103166. doi: 10.1016/j.jchf.2026.103166.
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5. Packer M, Anker SD, Butler J, *et al.* EMPEROR-Reduced Trial Investigators. Cardiovascular and Renal Outcomes with Empagliflozin in Heart Failure. N Engl J Med. 2020 Oct 8;383(15):1413-1424. doi: 10.1056/NEJMoa2022190.
6. Knops RE, Marquie C, Nordbeck P, *et al.* Subcutaneous Defibrillator Implantation With or Without Defibrillation Test: The Primary Results of the Randomized PRAETORIAN-DFT Trial. Circulation. 2026 Apr 25. doi: 10.1161/CIRCULATIONAHA.126.080638.
7. Freeman JV, Torre M, Sanders P, *et al.* Variability in implantable cardioverter-defibrillator battery longevity. Heart Rhythm. 2026 May;23(5):1162-1171. doi: 10.1016/j.hrthm.2025.05.031.

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CRM-2548601-AA

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