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Clinical EVIDENCE

New data from EHRA Congress

In this issue:

New RCT evidence for LBBAP vs. BiV

LECART (Left Bundle Branch Area Pacing Using Conventional Stylet-driven Pacemaker Leads for Cardiac Resynchronization Therapy): LBBAP vs BiVP trial (Le Polain de Waroux et al.)[1]

Left bundle branch area vs biventricular pacing for cardiac resynchronization therapy: the LEFT-BUNDLE-CRT trial (Cano et al.)[2]

Real-world validation of LUX-Dx™

Real-World Evaluation of the Positive Predictive Value and Transmission Burden of a Novel Implantable Cardiac Monitor: Insights from a Single-Center Experience (Fareh et al.)[3]

Patient Experience and Hospital Workload Associated with Insertable Cardiac Monitor Management: Italian Multicenter Evaluation (Nardi et al.)[4]

New Insights on S-ICD in Real Clinical Practice

Subcutaneous ICD After Sternotomy: Feasibility and Long-term Outcomes in a Propensity-Matched Analysis from a National Registry (Checchi et al.)[5]

Subcutaneous ICD Therapy in Patients with Monomorphic Ventricular Tachycardia: Arrhythmia Recurrence, Shock Burden, and Management Strategies (Botto et al.)[6]

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Summary

This issue of *Clinical Evidence* covers a broad range of topics presented at the recent EHRA Congress (Paris, April 12 – 14).

Within the current debate on LBBAP versus CRT, the first Clinical Evidence topic focus on two randomised studies presented as Late-Breaking Clinical Trials (LBCTs), which reported contrasting results on the role of LBBAP in heart failure patients and especially the comparison with conventional CRT therapy.

Subsequently, two posters presented at the congress are reviewed, focusing on the diagnostic accuracy of the LUX-Dx ICM and the evaluation of the patient App for remote monitoring.

The final two abstracts present new real-world S-ICD analyses, further strengthening the clinical evidence supporting extrathoracic therapy. One evaluated feasibility and long-term outcomes in post-sternotomy patients, while the other assessed arrhythmia recurrence, system efficacy, and management in patients with prior monomorphic ventricular tachycardia.

Is Conduction System Pacing Ready to Challenge Conventional CRT?

Conduction system pacing (CSP), particularly left bundle branch area pacing (LBBAP), has become one of the most debated topics in contemporary cardiac electrophysiology. During EHRA Congress 2026, two randomised clinical trials have been presented in the Late-Breaking Clinical Trial (LBCT) sessions further strengthened interest in CSP as an alternative to conventional biventricular (BiV) pacing for cardiac resynchronisation therapy (CRT).

The LECART trial (1), presented by Dr Le Polain de Waroux, and the **LEFT-BUNDLE-CRT trial**, presented by Dr Cano Pérez and simultaneously published on European Heart Journal **(2)**, provided new but not fully concordant evidence on the comparative performance of LBBAP versus BiV pacing, which is not yet consistent enough to support a definitive shift away from standard BiV pacing.

LECART Trial

Population: 168 patients with CRT indication per ESC Guidelines in 11 centres in Belgium

Design: 1:1 randomisation to LBBAP vs. biventricular pacing

Study Rational: to demonstrate that LBBAP is more EFFICIENT than BiV for CRT

Composite Primary Endpoint (at 1 year): composite of *all-cause death, heart failure hospitalisation, device-related complications requiring surgical reintervention, or failure to deliver effective CRT*

Key findings:

- CRT patients undergone to **LBBAP** implantation showed a **lower rate of the composite endpoint** compared with BiV pacing.
- **LBBBAP** provided **similar clinical outcome** as BiV pacing and is associated with a **lower rate of device-related complications.**

	BiV	LBBAP	
Primary Outcome 1 year	25%	12%	HR 2.14 (p = 0.039)
Device-related Complication 1 year	15%	2%	OR 6.76 (p = 0.006)
Procedure Time	98 min	76 min	p = 0.007

No significant differences were observed for death, heart failure hospitalisation and implant failure.

LEFT-BUNDLE-CRT trial

Population: 176 patients with CRT indication per ESC Guidelines in 11 centres in Spain

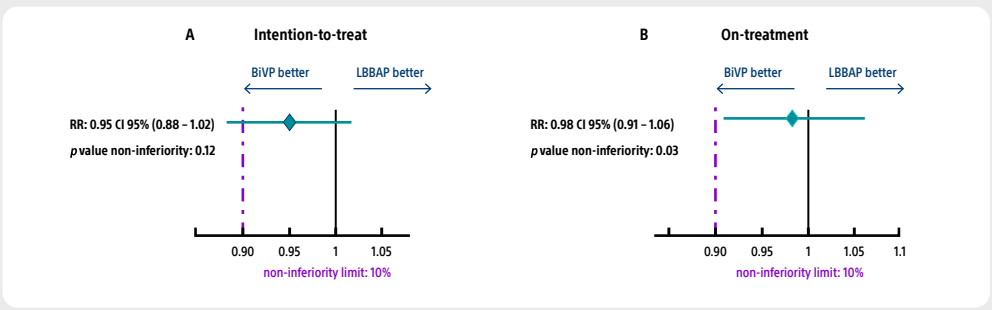
Design: 1:1 randomisation to LBBAP vs. biventricular pacing

Study Rational: to demonstrate that LBBAP is non-inferior (10%) to BiV in CRT responder rate

Composite Primary Endpoint (at 6 months): *improved Clinical Composite Score (CCS) or ≥ 15% reduction in left ventricular end-systolic volume (LVESV)*

Key findings:

- **LBBAP** did **not demonstrate non-inferiority** versus BiV pacing in the intention-to-treat analysis.
- On-treatment analysis suggested similar efficacy between LBBAP and BiV.



Exploratory analyses showed that patients with confirmed LBB capture had improved response compared with LVSP.

Figure 2: Primary endpoint in the intention-to-treat (A) and on-treatment (B) analysis.

"LBBAP represents a feasible alternative CRT delivery strategy [...] but further adequately powered randomised studies are needed to define its role and optimal implementation"[2]

What's next: The SYNCHRONICITY Trial

Building on this evolving evidence and the need for powered randomised data, Boston Scientific is sponsoring the **SYNCHRONICITY** Clinical Study[7] (https://clinicaltrials.gov/study/NCT07069738), a **large-scale randomised global** study designed to evaluate the **safety** and **effectiveness** of LBBAP compared with CRT in HF patients.

Minimum of
850 randomised patients

6 and 12 months
follow-up and annually up to 60 months

Conventional CRT-D
(CS Lead + RA Lead + RV (tachy) Lead)

LBBAP CRT-D
(LBBAP Lead + RA Lead + RV (tachy) Lead)

Diagnostic Accuracy and Transmission Burden with LUX-Dx

Dr Fareh[3] presented data from a single-centre analysis evaluating the real-world diagnostic accuracy and clinical efficiency of the LUX-Dx ICM, with a particular focus on Positive Predictive Value (PPV).

The analysis included 133 patients followed for a median duration of 13 months, during which a total of 55,064 transmitted episodes were reviewed.

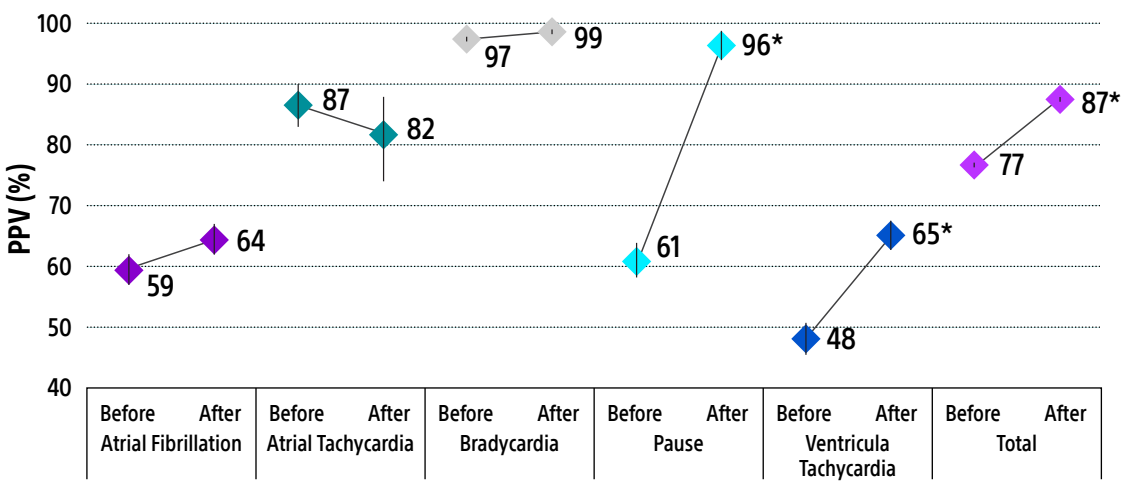
PPV at patient-level

71% for pause episodes →	100% for bradycardia episodes	**87% overall**

PPV at episode-level

55% for Ventricular Tachycardia →	98% for bradycardia episodes	**82% overall**

PPV at episode-level Before and After Remote Reprogramming



77% overall apex # after reprogramming → **87% overall apex # after reprogramming**

Figure 3: Comparison of positive predictive value between before and after reprogramming.
** p<0.001*
#In 34% of patients that underwent reprogramming

Key findings:

- The LUX-Dx ICM demonstrates **high diagnostic accuracy** in real-world clinical practice.
- Remote reprogramming contributes to a **meaningful reduction in the false-positive transmission** burden.
- By minimising unnecessary transmissions and reducing the need for in-person visits, LUX-Dx may help **streamline clinical workflow and decrease overall workload.**

Patient Experience and Connectivity Performance in ICM Remote Monitoring

The LUX-Dx ICM is supported by the myLUX™ Patient App (preloaded on a dedicated smartphone or installed directly on the patient's personal device) enabling remote data transmission.

Dr Nardi[4] presented the first real-world multicentre evaluation of patient experience, connectivity performance, and the operational impact associated with use of the Patient App.

A total of 587 patients were included in the analysis and followed for a median duration of 10 months.

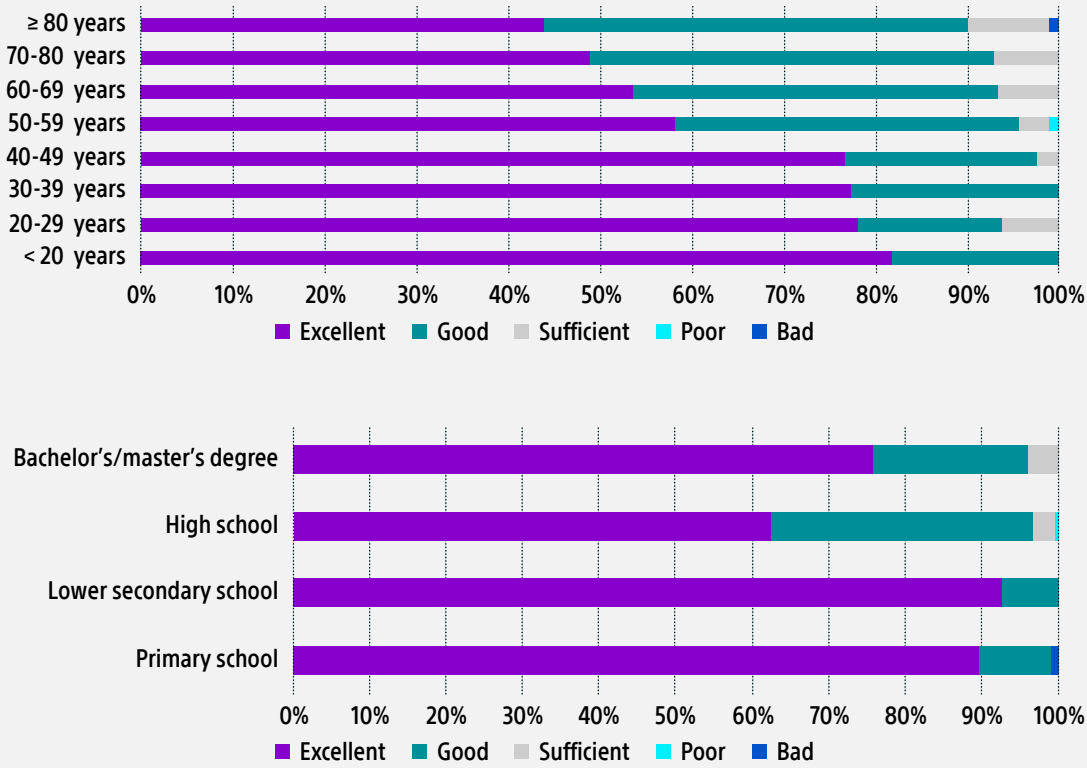


Figure 4: Survey questions on the ease of use stratified according to the patient age and school qualification.

Patients reported increased reassurance with remote monitoring, expressed no concerns regarding system use, and showed a low prevalence of anxiety or depression on psychological assessment.

	Dedicated phone	Personal phone	p
Connection loss notifications (pt-month)	0.55	0.42	0.044
Ease of use rated not good or excellent	89%	95%	0.071
Phone ran out of battery	50%	32%	0.007
Phone forgotten at home	64%	18%	<0.001

Key findings:

- The **myLUX Patient App** for remote monitoring of LUX-Dx showed high patient acceptance and usability.
- These findings confirm the **accessibility** and **feasibility** of **smartphone-based remote monitoring** across different patient populations.
- Smartphone-based remote monitoring of ICMs requires **limited hospital workload**, while providing **patient reassurance** without increasing psychological burden.

S-ICD After Sternotomy: Insights From a National Registry

In patients with prior sternotomy, sternal wires may create mechanical and electrical challenges that can potentially impact device safety and performance.

Data from the *RHYTHM DETECT registry* were presented at EHRA Congress 2026 and recently published in *Heart Rhythm Journal*[5].

In this propensity-matched national analysis, S-ICD implantation in patients with prior sternotomy (259 patients, 1:1 propensity matched with non-sternotomy patients, 43 months follow-up) was associated with:

High procedural success, in terms of optimal lead positioning — as reflected by favorable PRAETORIAN scores (<90 in 99% vs. 96%) and low shock impedance values (64 vs. 67 Ohm) — and acute defibrillation conversion efficacy (98% vs. 95% at 65J).

Favourable long-term outcomes, with rates of inappropriate shocks and device-related complications comparable to matched patients without previous sternotomy while maintaining an overall conversion success rate of 100% during spontaneous ventricular arrhythmia episodes.

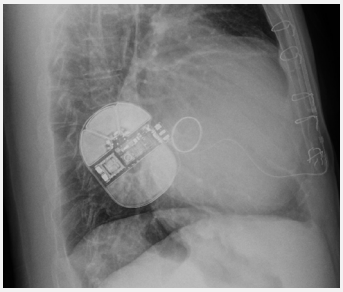
33 centres

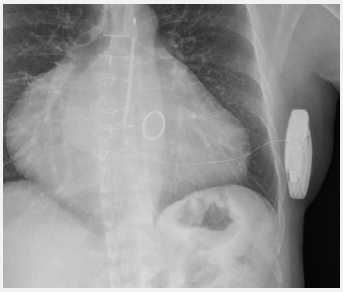
2,123 patients

259 patients
with prior sternotomy 1:1 propensity matched to 259 without sternotomy

Median follow-up:
43 months

Endpoint	Sternotomy group	Non-sternotomy group
Acute Success (≤65J)	98%	95%
Shock Impedance	64 Ω	67 Ω
PRAETORIAN Score<90	99%	96%
Complications	1.4%/y	1.1%/y
IAS	2.2%/y	1.8%/y
Conversion rate	100%	100%
AS	2.2%/y	2.2%/y





No electrical noise or interference related to sternal wires.

Figure 5: Graphical abstract.

Key findings:

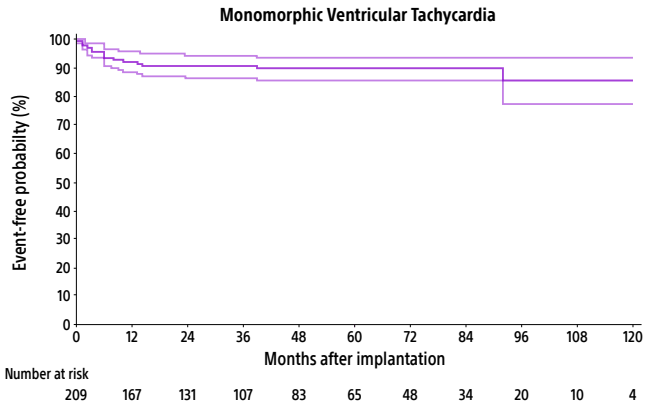
- In this large propensity-matched analysis, **prior sternotomy did not adversely affect S-ICD** implantation or performance.
- These findings support the **feasibility and safety of S-ICD** in this complex population, highlighting how it represents **the most viable non-transvenous option** for this patient group.

S-ICD in Patients With Monomorphic VT: Is It a Suitable Strategy?

The S-ICD is recommended for patients at risk of sudden cardiac death who do not require pacing or antitachycardia pacing (ATP)[8]. However, patients with a history of monomorphic ventricular tachycardia (MVT), which is often amenable with ATP, are underrepresented in clinical studies dealing with S-ICD.

Botto *et al*[6] recently analysed 210 patients with a history of sustained MVT, identified among 2,164 consecutive de novo S-ICD implantations enrolled in the RHYTHM DETECT registry.

The aim was to better investigate, in this specific clinical setting, long-term arrhythmia recurrence, device effectiveness, and real-world management strategies for these patients.



37 centres

2,164 patients

210 patients
with history of sustained monomorphic VT

Median follow-up:
43 months

Low recurrence – High efficacy

10% with MVT recurrence **(2.8%/yr)**

93% first-shock success for all VA

100% overall success

Safe and reliable therapy

Appropriate shocks: **4.9%/yr**

Inappropriate shocks: **2.8%/yr**

Complications: **2.3%/yr**

Effective management – No upgrade

~50% of MVTs successfully ablated

No TV-ICD conversion for ATP need

The S-ICD can be considered a viable strategy for patients with prior monomorphic VT, offering reliable protection against sudden cardiac death while avoiding the risks of transvenous leads and leaving future treatment options open.

Key findings:

- In patients with prior MVT, the **S-ICD provided safe and effective protection** from ventricular arrhythmias, with catheter ablation emerging as the preferred management strategy and **no need for conversion to a transvenous device.**
- These findings support the use of the S-ICD as a viable option in this patient population, **avoiding the risks of transvenous leads** and leaving future treatment options open.

"Subcutaneous Defibrillator Implantation With or Without Defibrillation Test: The Primary Results of the Randomized PRAETORIAN-DFT Trial"[9]

Knops RE et al.

The **PRAETORIAN-DFT** trial[9] is a global, prospective, randomised study designed to assess whether omitting ventricular fibrillation conversion testing during de novo S-ICD implantation, when guided by the PRAETORIAN score[10], is non-inferior to standard VF conversion testing.

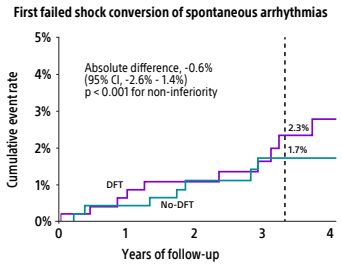
Results, presented by Knops at the latest HRS congress and simultaneously published in Circulation, showed that **the study met its primary endpoint**, demonstrating non-inferiority ($p < 0.001$) for omission of VF conversion testing in patients undergoing de novo S-ICD implantation guided by the PRAETORIAN score.

Breaking News

Optimising S-ICD Implant Strategy: With or Without Defibrillation Testing?

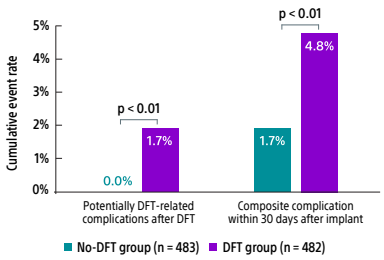
What are the key results?

Primary Endpoint



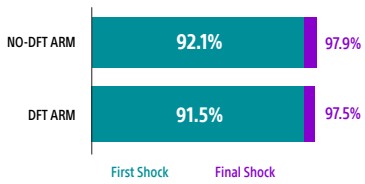
Both arms experienced **very low first failed shock conversion** of spontaneous arrhythmias.

Overall Complications



Complication rates were **lower in the no-DFT arm** compared to the DFT arm.

Conversion Efficacy



First and final shock efficacies in the PRAETORIAN DFT trial are **similar** to previous large S-ICD trials.[11-14]

These findings support a simplified and potentially safer S-ICD implantation strategy while avoiding the risks associated with induced ventricular arrhythmias and deep sedation.

A dedicated deep dive into the PRAETORIAN-DFT results and their potential impact on clinical practice will be included in the next issue.

Key Messages

- **Late Breaking Clinical Trials: Ongoing evidence for LBBAP vs. BiV**

  Two randomised trials presented as LBCT showed conflicting results regarding the option of LBBAP as an alternative to conventional CRT in HF patients. While the LECART trial[1] suggested procedural and clinical advantages with LBBAP, the LEFT-BUNDLE-CRT study[2] did not demonstrate non-inferiority in the intention-to-treat analysis, despite similar overall clinical outcomes.

- **New Insights on LUX-Dx™ in Real Clinical Practice**

  In current clinical practice, LUX-Dx ICM showed high diagnostic accuracy in arrhythmias detection and remote reprogramming reduced false-positive transmission burden, helping to optimise clinical workflow.[3]

  The myLUX™ Patient App for LUX-Dx remote monitoring showed high usability and strong patient acceptance suggesting that smartphone-based monitoring is feasible and scalable, with low clinical workload and good patient reassurance without added psychological burden.[4]

- **New Insights on S-ICD in Real Clinical Practice**

  Prior sternotomy does not adversely affect S-ICD implantation or device performance. Recent data further support the feasibility and safety of S-ICD, reinforcing its role as the most viable non-transvenous ICD option for this patient population.[5]

  In patients with prior MVT, the S-ICD was shown to provide safe and effective protection from ventricular arrhythmias, with a relatively low rate of arrhythmia recurrence, catheter ablation as the preferred management strategy, and no need for conversion to a transvenous device.[6]

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3. Fareh S. *et al.* Real-World Evaluation of the Positive Predictive Value and Transmission Burden of a Novel Implantable Cardiac Monitor: Insights from a Single-Center Experience. Presented at EHRA Congress 2026 and available on ESC 365 platform
4. Nardi S. *et al.* Patient Experience and Hospital Workload Associated with Insertable Cardiac Monitor Management: Italian Multicenter Evaluation Presented at EHRA Congress 2026 and available on ESC 365 platform
5. Checchi L, Perrotta L, Ziacchi M, *et al.* Subcutaneous ICD Therapy in Patients with Prior Sternotomy: Feasibility and Long-Term Outcomes in a Propensity-Matched Analysis from a National Registry. Heart Rhythm. 2026 Apr 29:S1547-5271(26)02308-8. doi: 10.1016/j.hrthm.2026.04.041.
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7. Safety and Effectiveness of Left Bundle Branch Area Pacing Versus Conventional Cardiac Resynchronization Therapy in Heart Failure (SYNCHRONICITY Clinical Study) NCT 07069738 https://clinicaltrials.gov/study/NCT07069738.
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14. Gold MR, El-Chami MF, Burke MC, *et al.* J Am Coll Cardiol. Aug 1 2023;82(5):383-397. doi:10.1016/j.jacc.2023.05.034.

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