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09

Clinical EVIDENCE

Personalised Strategies in ICD Therapy

Contemporary Issues in Implantable Cardioverter-Defibrillators: Personalising Device Therapy (Monkhouse et al.)[1]

Longevity of Modern S-ICDs: Real-World Data

Estimated Longevity of Contemporary Subcutaneous Implantable Cardioverter-Defibrillators: Multicenter Real-World Data (Ziacchi et al.)[2]

Stylet-Driven Lead Performance in LBBAP Implantations

Implantation Success, Electrical Performance, and Safety of an Active Fixation Stylet-Driven Lead for LBBAP in Clinical Practice: A Multicenter Experience (Santoro et al.)[3]

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Summary

This edition of *Clinical Evidence* explores recent advances in cardiac implantable devices, focusing on two main topics: subcutaneous ICDs (S-ICDs) and left bundle branch area pacing (LBBAP) with the INGEVITY+ lead.

The first two publications explore the technological evolution of cardiac defibrillators. They review recent advances in ICD technologies, highlighting their strengths and limitations, and present emerging data – including the performance of current subcutaneous ICD batteries – to inform ongoing developments and future directions in personalised device therapy.

In the third article, LBBAP with the INGEVITY+ lead is shown to achieve high implantation success, stable electrical performance, and low complication rates, supporting its feasibility and safety in routine clinical practice.

Recent Evidence in ICD Therapy: Evolution and Perspective

Implantable Cardioverter Defibrillators (ICDs) have evolved significantly since the 1980s, aiming to reduce sudden cardiac death (SCD) while minimising device-related complications.

In this review Monkhouse *et al.*[1] highlight the current landscape of ICD technologies and their respective strengths and limitations, drawing on data available in 2025.

1980s	 First ICDs: (epicardial patch)	– Thoracotomy – High infection risk
1993	 Transvenous ICDs	– Implant via cephalic/subclavian vein – Decreased size – Pectoral location
2010	 Subcutaneous ICDs (S-ICD)	– Subcutaneous lead placement – Device on left lateral ribcage
2016	 2nd Generation S-ICD	– Thinner device – Algorithms to reduce shocks
2022	 Extravascular ICD	– Sub-sternal lead placement – Lateral device location
2025+	 Modular ICD	– S-ICD+ leadless pacemaker – Multiple devices communicating

Figure 1: A visual History of Defibrillator Technologies.

- **TV-ICD (Transvenous ICD):** A complete solution for both defibrillation and pacing. However, long-term lead complications remain a concern, including venous occlusion, tricuspid regurgitation, fibrosis, and infection. **Lead failure occurs in over 20% of patients at 10 years**, and extraction procedures carry significant risk.
- **S-ICD (Subcutaneous ICD):** Eliminates the need for intracardiac leads, resulting in more than a **90% reduction in lead-related complications**. This translates into lower risks of infection and device extraction. The introduction of the SMART Pass filter has reduced **inappropriate** shock rates to approximately **1 – 1.5% per year**, now comparable to TV-ICDs.
- **Modular CRM (S-ICD + leadless pacemaker):** Combines the **benefits of S-ICD with leadless pacing**, enabling painless ATP and bradycardia support without switching to a transvenous system. This approach offers flexible and tailored therapy for patients requiring combined defibrillation and pacing support.
- **EV-ICD (Extravascular ICD):** Provides antitachycardia pacing **(ATP) and short-term pacing**, though ATP may be painful and is associated with higher capture thresholds, with its clinical benefit still under debate. Inappropriate therapy rates are higher, reported at 9.8% at 1 year and 17.5% at 3 years.

Device Type	TV-ICD	S-ICD	EV-ICD
Screening	Not required	Yes (ECG screening, ~6% not eligible)	Yes (CT scan to assess retrosternal space)
Patients who have had prior Sternotomy	Yes	Yes	No (but 1 case report of feasibility)
Implant Failure	~ 0.1%	~ 0.5% (DFT failure)	5% fail to implant
Implant Ease	Local	GA / Local block + sedation	GA (Lateral screening in lab + Surgeon present for the first 5)
Implant Complication Rate	5.7% (mostly lead displacement)	1.9% (mostly hematoma)	3.1% (mostly lead displacement)
Brady Pacing	Yes (painless)	Post shock subcutaneous (unpleasant) Upgrade with leadless-VVI (painless)	Pause prevention & post-shock epicardial (unpleasant)
Anti-tachycardia Pacing	Yes (painless)	No. Upgrade with leadless (painless)	Yes (unpleasant) Only 81.2% had programmed on in PIVOTAL
Innapropriate Shocks	~ 1.8% at 1 year	1.1 – 2.4 at 1 year* (SMARTpass™ enabled devices)	Estimated ~ 7% at 1 year
Comfort	Baseline	Same as transvenous in randomised evidence	No comparative comfort data Initial evidence promising
Battery	7.1 – 14.7 years (vary on battery)	8 – 9 years (non-advisory, real-life data)	9.3 – 11.8 years (predicted)
Long-Term Complication Rate	> 1% per year	0.5% per year	2.3% per year (with only 4 years follow-up)
Lead Removal	1 – 5% major complications	0% complication rate and 100% success	Unknown. Successful case reports
Level Of Evidence	**1A**	**1B**	**2B**

Table 1: Comparative Summary of Transvenous, Subcutaneous, and Extravascular ICD Systems using current literature in 2025.

- Traditional transvenous ICDs (TV-ICDs) remain highly effective and comprehensive, but their reliance on intravascular leads exposes patients to potential long-term risks.
- By eliminating transvenous leads, Subcutaneous ICDs reduce the risk of intravascular complications and are particularly attractive in younger patients, those with limited venous access, or increased infection risk.
- Recent innovations in modular ICD therapy – combining an S-ICD with a leadless pacemaker that communicates to deliver painless antitachycardia pacing and antibradicardia pacing – could be a comprehensive solution.
- The extravascular ICD (EV-ICD) is a promising emerging technology within a fully extravascular approach, although long-term clinical data are still limited.

Key findings:

- The evolution of ICDs reflects a progression from intrapericardial to intravascular, subcutaneous, and intrathoracic approaches, aiming **to minimise complications and inappropriate shocks** while maintaining **effective therapy** for ventricular arrhythmias.
- Contemporary ICD therapy requires moving beyond implantation criteria toward individualised device selection, balancing arrhythmic protection, device-related risks, life expectancy, and patient preferences.

Modern S-ICDs Longevity in Real-World Practice

Device longevity is a critical aspect of ICD therapy, both clinically – due to the need for surgical replacement – and economically, given the cumulative costs of device exchanges. However, data on the performance of modern S-ICD systems remain limited.

As implantation volumes increase, real-world evidence from contemporary S-ICD models is beginning to emerge, with remote monitoring offering a unique opportunity to assess device performance over time.

In this context, Ziacchi *et al.*[2] evaluated the longevity of contemporary S-ICD generators and the factors influencing battery performance in a multicentre cohort followed through remote monitoring.

1.713* S-ICD

Data were collected from implanted S-ICD EMBLEM devices monitored via the LATITUDE system in 24 Italian centres (2015 – 2025)

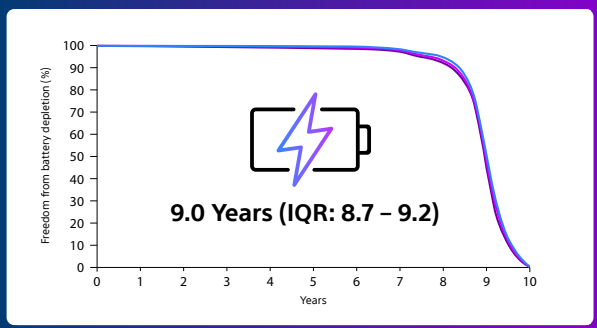
9 Years

The overall median estimated device longevity was **9.0 years** (25th – 75th percentile: **8.7 – 9.2**)

*Devices implanted for less than 3 months or subject to a safety advisory for possible premature depletion were excluded from the analysis.

1.713 S-ICD in LATITUDE™
24 centres
Median follow-up: 2.7 years

Estimated longevity



		Median estimated longevity (years)
In-office interrogations per year	< 2	9.0
	≥ 2	9.0
Remote monitoring transmissions per year	< 12	9.0
	≥ 12	8.9
Shocks per year	0	9.1
	< 1	8.6
	≥ 1 & < 2	8.1
	≥ 2 (median 6, from 2 to 40)	7.0

Figure 2: Graphical abstract.

Factors associated with device longevity are summarised in Table 1.

- Even among factors associated with longevity, the impact of in-office interrogations and remote transmissions was minimal (< 0.1 year).
- The observed decrease associated with frequent shocks is significant, yet it reflects a subgroup (n = 42) with a substantial and variable shock burden (median 6, range 2 – 40).

	Coefficient	Standard Error	p
Shocks per year	-0.31	0.01	< 0.001
Post-shock pacing ON	-0.10	0.05	0.078
In-office interrogations per year	-0.05	0.01	< 0.001
Remote monitoring transmissions per year	-0.01	0.01	0.018
Atrial fibrillation episodes per year	-0.01	0.00	0.245

Table 2: Graphical abstract.

Ziacchi's conclusions are consistent with the previously cited Monkhouse[1] review, which reported a real-world S-ICD longevity of 8.7 years – longer than the 7.3 years indicated in the device user manual – and further reinforce the importance of **standardised reporting criteria across manufacturers**, an issue addressed in the present work by generating longevity estimates with continuous EGM recording to avoid hidden sources of energy consumption.

Key findings:

- Contemporary **subcutaneous ICDs** show a median estimated **longevity** of **approximately 9 years** in real-world clinical practice, exceeding manufacturer projections and remaining **stable over time**.
- Energy consumption related to **remote monitoring and in-office device interrogations** has a **negligible effect** on overall device lifespan.

Stylet-Driven Lead Performance in LBBAP Implantations

Safety and Performance of INGEVITY™+ Lead for LBBAP in Clinical Practice

Left bundle branch area pacing (LBBAP) is emerging as a physiological alternative to traditional pacing. Stylet-driven leads have gained attention for their maneuverability and compatibility, despite concerns about long-term performance when used for LBBAP.

Building on evidence demonstrating favourable implantation success, short and long-term integrity and performance[4,5], this analysis by Dr Santoro *et al.*[3], evaluated the real-world implantation success rates, acute and chronic electrical performance, and the incidence of complications during follow-up of the INGEVITY+ lead for LBBAP.

200 patients RV implantations
207 patients LBBAP attempts

Mean follow-up **9 months**

The most frequent indication in LBBAP group is **AV BLOCK (55%)**

Procedural Outcome

The study included 200 patients in the control group, who received standard right ventricular (RV) pacing with the INGEVITY+ lead, and 207 patients who underwent LBBAP implantation attempts. LBBAP was successfully achieved in 201 patients (97%) (Fig. 3).

Only three lead-related complications occurred in the LBBAP arm – one helix fracture, one atrioventricular block, and one septal perforation – with no adverse sequelae. Electrical parameters were satisfactory in both arms, with a slightly higher capture threshold observed in the LBBAP group.

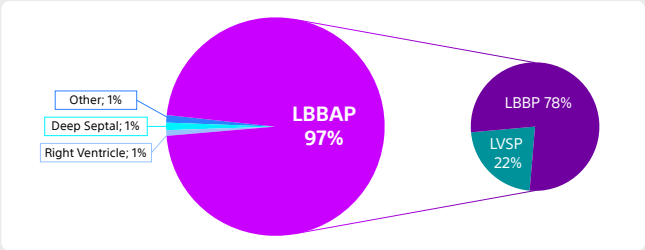


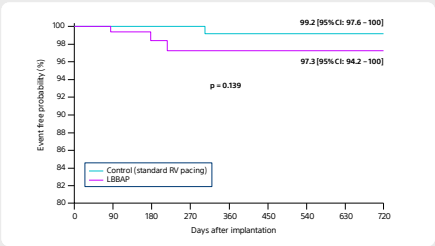
Figure 3: Procedural Outcome in LBBAP Group.

Follow-up Outcome

Lead-related Complication (LRC)

98.5% LBBAP patients were free from any LRC

LRC include only three dislodgements



No lead fractures or malfunctions were reported

Figure 4: Kaplan-Meier to first LRC.

Electrical parameters Performance

98% LBBAP patients with capture thresholds ≤ 2 V

92% LBBAP patients with sensed amplitudes ≥ 5 mV

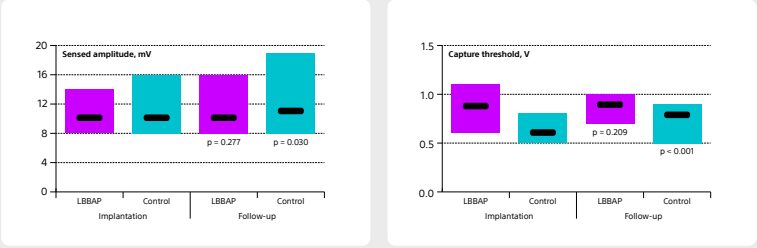


Figure 5: Comparison of medians pacing capture thresholds and sensed amplitudes of LBBAP and control patients.

Key findings:

- **LBBAP using the INGEVITY+ stylet-driven lead is feasible in routine clinical practice**, with high implantation success, low complication rates, and good electrical performance.
- **No lead fractures and a low dislodgement rate** were observed during follow-up, supporting the reliability of the INGEVITY+ lead.
- Consistent **electrical performance** observed during follow-up confirms that the INGEVITY+ lead is suitable for use in LBBAP implantations.

"Algorithm Improvements in an Insertable Cardiac Monitor Reduce False Positives and Episode Review Burden"[6]

Richards M. et al.

The adoption of insertable cardiac monitors (ICMs) continues to rise, along with the growing volume of data clinicians need to review, often including false positives and non-actionable alerts.

The latest generation of **LUX-Dx II+**™ incorporates three key enhancements to the ICM's atrial fibrillation, pause, and bradycardia algorithms, with the aim of improving detection accuracy and reducing non-actionable data.

This analysis[6] assessed the updated LUX-Dx II+ algorithms using adjudicated real-world ECGs and in-silico testing, comparing them with legacy performance and simulating nighttime programming to quantify their impact on overall event burden.

What are the key results?

Enhanced AF Algorithm

38%

Reduction in false positive AF events *while maintaining a relative sensitivity > 98%.*

Enhanced AF algorithm based on run-test theory to more accurately differentiate true atrial fibrillation from organised rhythms.

Enhanced Pause Algorithm

48.6%

Reduction in false positive PAUSE events *while maintaining a 100% relative sensitivity.*

Enhanced pause algorithm designed to detect true pauses while rejecting false episodes caused by low signal-to-noise ratio.

Nocturnal Programming for Bradycardia and Pauses

98%

Reduction in nocturnal bradycardia episodes

90%

Reduction in nocturnal pause episodes

Nocturnal programming (11 pm to 7 am) applies thresholds and duration (≤ 30 bpm, ≥ 5 s) to limit non-actionable bradycardia and pause alerts during night.

These enhancements are expected to significantly reduce the time clinics spend reviewing ICM transmissions, while maintaining the accuracy of the LUX-Dx II+ in detecting clinically meaningful events.

Key Messages

- **Personalised Strategies in ICD Therapy**

  Monkhouse *et al.*'s[1] 2025 review provides a clear snapshot of the current ICD technologies, highlighting both their strengths and limitations. It underscores a simple but crucial point: choosing the right therapy for each patient is more important than ever.

- **Longevity of Modern S-ICDs: Real-World Data**

  Real-world data on contemporary S-ICDs are emerging, showing that remote monitoring is key to tracking device performance. Ziacchi *et al.*[2] report new findings on battery longevity, with performance exceeding the estimates provided in device manuals.

- **Stylet-driven Lead Performance in LBBAP Implantations**

  The analysis by Santoro *et al.*[3] demonstrated that LBBAP with the INGEVITY™+ lead is a safe and high-performing strategy in routine clinical practice, achieving high implantation success, stable electrical performance, and reliable lead integrity, with no reported lead fractures and minimal dislodgement.

Drive Results with the CSP Toolkit

Boston Scientific's CSP solutions integrate seamlessly: from the INGEVITY+ lead to the Site Selective Pacing Catheters. Offering tools designed to improve procedural efficiency and long-term patient outcomes.

Now CE-approved for LBBAP, it's time to elevate your pacing strategy.

Explore our CSP portfolio

1. Monkhouse C, Ahsan S, Lambiase PD. Contemporary issues in implantable cardioverter-defibrillators: Personalising device therapy. Indian Heart J. 2025 Oct 17:S0019-4832(25)00181-6. doi: 10.1016/j.ihj.2025.10.003.
2. Ziacchi M, Viani S, Bambagioni G, *et al.* Estimated Longevity of Contemporary Subcutaneous Implantable Cardioverter-Defibrillators: Multicenter Real-World Data. Heart Rhythm O2. doi: 10.1016/j.hroo.2026.01.020.
3. Santoro A, Ziacchi M, Calvanese R, *et al.* Implantation Success, Electrical Performance, and Safety of an Active Fixation Stylet-Driven Lead for LBBAP in Clinical Practice: A Multicenter Experience. J Cardiovasc Electrophysiol. 2025 Dec 27. doi: 10.1111/jce.70237.
4. Friedman D. J, Shadrin I, Goldbarg S, *et al.*, "Performance of an Active Fixation Stylet-Driven Lead in Left Bundle Branch Area Pacing: Results From INSIGHT-LBBA," Heart Rhythm 22, no. 25 (2025): 2047–2054. doi: 10.1016/j.hrthm.2025.01.041.
5. De Pooter J, Breitenstein A, Özpak E, *et al.*, "Lead Integrity and Failure Evaluation in Left Bundle Branch Area Pacing," JACC: Clinical Electrophysiology 11 (2025): 158–170. doi: 10.1016/j.jacep.2024.09.020.
6. Richards M, Kupfer M, Herrmann K *et al.* Algorithm Improvements in an Insertable Cardiac Monitor Reduce False Positives and Episode Review Burden. Pacing Clin Electrophysiol. 2025 Dec;48(12):1337-1343. doi: 10.1111/pace.70043.

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