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06

Clinical EVIDENCE

New data from EHRA Congress

New Insights on S-ICD and Modular System

Subcutaneous Implantable Defibrillator Therapy in Patients with Brugada syndrome: data from a large multicentre registry (Migliore et al.)[1]

Spontaneous arrhythmic episodes in the study of a modular, communicative, leadless defibrillator system (MODULAR ATP Trial) (Lloyd et al.)[2]

From PRAETORIAN Score to Clinical Practice

The PRAETORIAN score to estimate the risk of failure of subcutaneous implantable cardioverter defibrillator therapy: characterisation, associated variables and calculation in clinical practice (Ziacchi et al.)[3]

Long-term Low-voltage Impedance Measurements in Subcutaneous Implantable Cardioverter-defibrillators (Mugnai et al.)[4]

New Insights on LUX-Dx™ and HeartLogic™

Real-world Use of Insertable Cardiac Monitor Remote Programming (Fareh et al.)[5]

Dynamic Evaluation of Atrial Fibrillation Risk Factors Using Multiple Sensors of Implantable Cardioverter Defibrillators (Dell'Aquila 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 (Vienna, March 30 – April 1). It begins with the impressive results from the largest cohort of patients with Brugada syndrome implanted with an S-ICD, described to date and presented as a LBCT. The issue also delves into the arrhythmic episodes treated with ATP in the Modular ATP study. Additionally, it highlights intriguing findings on how the Praetorian score could be simplified in current clinical practice through the adoption of the intermuscular technique.

Lastly, two posters provide new insights into diagnostic tools: the first moderated poster explores the use of LUX-Dx ICM remote programming in clinical practice, while the second investigates the potential of a combined score using multiple ICD sensors for atrial fibrillation (AF) risk assessment.

S-ICD Therapy in Brugada Syndrome Patients: Insights from a Large Multicentre Registry

At EHRA, Prof. Migliore[1] presented – during a **Late-breaking Science session** – data from the largest study to date (n = 450) on the long-term outcomes of subcutaneous implantable defibrillator (S-ICD) therapy in patients with Brugada syndrome.

Key findings:

- Over a median follow-up period of 52 months, 3% of patients received **appropriate and effective shocks** (1.2% at 12 months), confirming the efficacy of the S-ICD.
- **Inappropriate shocks** (ISs) were observed in 7% of patients during follow up **(1.4% at 12 months)**. Events were managed in most cases through device reprogramming.
- **Device-related complications** requiring surgical revision occurred in 4% of patients **(2.5% at 12 months)**, with no associated sequelae.

100% Overall Efficacy

High efficacy:
95% at 65J, **100%** at 80J at implant.
90% at 1st shock, **100%** at 2nd during spontaneous episodes.

1.4% Inappropriate Shocks

Low rate of inappropriate shocks:
1.4% (95% CI, 0.3–2.5) at 1 year. Events were managed in most cases through device reprogramming.

0.7% BY Pacing Need

Low need for antibradycardia pacing:
0.7% at > 4 years.

The EMBLEM™ S-ICD is a viable alternative to transvenous implantable defibrillators (TV-ICDs) for preventing sudden cardiac death in patients with Brugada syndrome.

The study was simultaneously published in the Journal of the American College of Cardiology: Clinical Electrophysiology.[1]

Spontaneous Arrhythmic Episodes in the MODULAR ATP Trial

The MODULAR ATP trial[7] is a multicentre, international study evaluating a subcutaneous implantable cardioverter-defibrillator (S-ICD) that wirelessly communicates with a leadless pacemaker (LP).

Aim of this sub-analysis, presented by Dr. Llyod[2], was to describe the specific details of ventricular episodes and the behaviour of this novel system.

At the time of data cutoff, 286 patients were successfully implanted and observed for a median follow-up of 15 months.

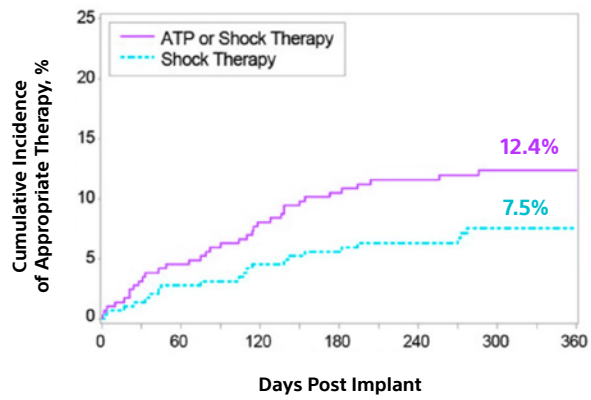


Figure 1: Incidence of appropriate therapy (ATP or shock) and appropriate shock (rates at 1 year: 12.4% and 7.5% respectively).

Key findings:

- **68%** of S-ICD detected episodes were **successfully terminated with ATP** delivered from the LP.
- **No patient** experienced lack of ATP therapy due to **communication failure**.
- **No patient** requested ATP or pacing therapy to be **inactivated** for any reason.

Can we simplify the calculation of the Praetorian score in current clinical practice?

The PRAETORIAN score, based on chest radiographs, has been validated to predict the probability of successful S-ICD defibrillation testing* by assessing factors like fat thickness between the coil and sternum and generator placement.[8]

This analysis, presented at EHRA by Dr. Ziacchi[3] and recently published in *Europace journal*, examined more than 1,200 S-ICD recipients with chest X-rays suitable for PRAETORIAN score assessment.

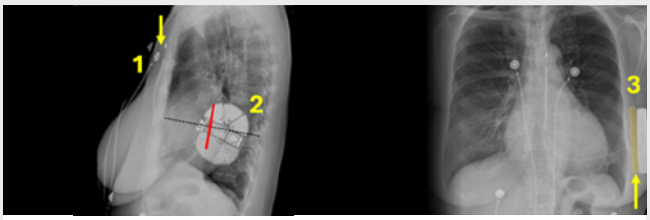
At the time of the study all patients were implanted using the intermuscular technique.

***Final PRAETORIAN score:**
- <90: Low risk of conversion failure
- 90-150: Intermediate risk of conversion failure
- ≥150: High risk of conversion failure

Key findings:

- With the optimised intermuscular technique, the **PRAETORIAN score is <90 in over 95% of patients** and consistently favourable (100%) in normal-weight patients.
- **Two of the 3 steps of the score** – evaluating the adequate posterior positioning of the generator via posterior-anterior chest radiograph (Step 2) and measuring the sub-generator fat (Step 3) – **become unnecessary**.
- **Shock impedance** was confirmed as the **only independent predictor of >1 coil width of sub-coil fat** (Step 1). A value >88 Ohm enabled to detect a PRAETORIAN score ≥90 with 98% (95% CI 97%-99%) NPV.

In contemporary practice, the PRAETORIAN score can be simplified. By adopting an intermuscular approach, two of the three steps of the score become superfluous, and shock impedance may serve as a reliable surrogate of sub-coil fat thickness.



Step 1: Fat tissue between the S-ICD coil and sternum or ribs.

Step 2: Position of S-ICD in relation to mid-line.

Step 3: Fat tissue between the generator and thoracic wall.

Figure 2: PRAETORIAN Score.

In case of PRAETORIAN score ≥ 90 and BMI ≤25, 40 points are subtracted from the partial score (**Step 4**).

95.7%
<90
The **PRAETORIAN score is <90** in over **95%** of patients and in 100% of non-obese.

100%x1
97%x1
Two steps of the score – Step 2 and Step 3 – become unnecessary.

Z>88 Ω
The sub-coil fat thickness can be identified through impedance (Z) measurement.

A challenge in adopting high voltage impedance (HVI) as a predictor of **Step 1** is the need to deliver a dedicated 10J shock, which, like defibrillation testing, typically requires sedation or general anaesthesia. However, the S-ICD has recently been upgraded to allow low voltage impedance (LVI) measurements. As demonstrated by Dr. Mugnai[4] at EHRA, these LVI show a strong correlation with HVI, potentially eliminating the risks and logistical issues associated with delivering a shock.

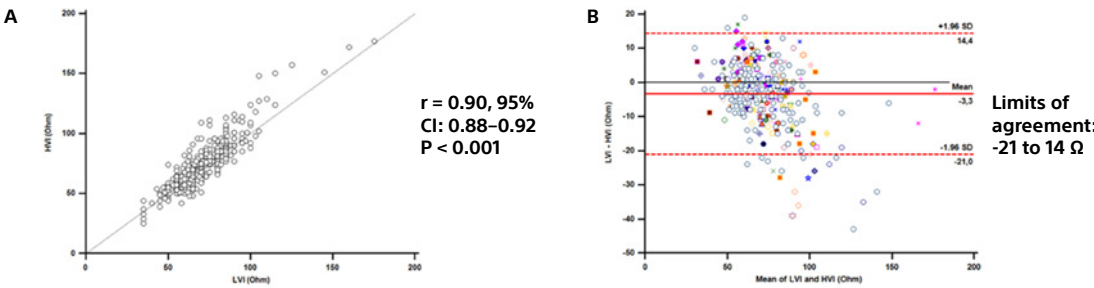


Figure 3: Diagram showing LVI and HVI average values measured during the same week (n=373) (Panel A). Bland-Altman plot: difference between LVI and HVI measures versus their mean. The solid red line indicates the bias and the dashed lines the limits of agreement between measures (Panel B).

LVI measurements obtained through the S-ICD showed strong agreement with HVI values measured during shock delivery, indicating that LVI could serve as a reliable surrogate marker for HVI at implantation, eliminating the need for shock delivery.

LUX-Dx remote reprogramming feature: real-world use

Insertable cardiac monitors (ICMs) generate high transmission volumes and increase clinic workload. The LUX-Dx ICM enables remote reprogramming of detection setting, potentially reducing the centre workload and in-office visits. Dr. Fareh[5] reported the initial experience in 23 European centres.

Data from **697 patients** followed for a median of 9 months were analysed.

18,668 device transmissions were recorded (3.0 transmissions per patient-month), with **scheduled transmissions** accounting for **31%** of the total.

A total of 401 reprogramming events were performed in 230 ICMs (0.8 events per patient-year), of which 156 (39%) were conducted remotely.

Reprogramming most commonly aimed **to lower detection sensitivity**, thereby increasing the stringency of alert criteria.

A paired analysis demonstrated a **median 57% reduction in transmission rate** after reprogramming (P<0.001) (Figure 4).

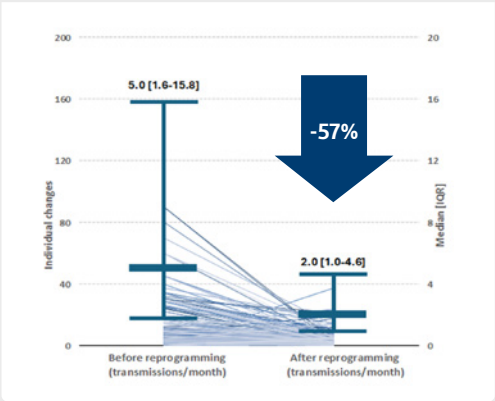


Figure 4. Rates of transmissions before and after reprogramming for patients who underwent reprogramming.

Key findings:

- ICM reprogramming **reduces the burden of remote monitoring and minimise unnecessary transmissions** by eliminating scheduled transmissions.
- Remote ICM reprogramming allows centres to adjust device settings without in-office visits, **optimising device management and reducing the need for in-office visits**.

Dynamic atrial fibrillation risk evaluation using multiple ICD sensors

Dr. Dell'Aquila[6] presented an analysis about the relationship between atrial high-rate episodes (AHREs) and ICD-detected surrogates for risk factors, based the HEAD2TOES schema (Figure 5).

Data were collected from **411 HF patients** with ICDs or CRT-Ds devices.

The HeartLogic Index measured HF status, the Respiratory Disturbance Index (RDI) identified severe Sleep Apnea (SA) (≥30 episodes/hour), and the accelerometer detected reduced physical activity (≥1 hour/day).

A score predicting AHRE burden ≥5 minutes and a score predicting AHRE burden ≥23 hours were defined (Figure 5).

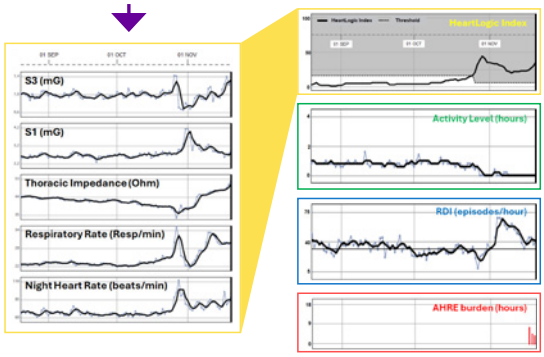
Key findings:

- The occurrence of **AHRE is independently associated** with three indexes automatically measured by ICD algorithms: **HF status** (HeartLogic index), an indicator of **SA severity** (RDI), and accelerometer-detected **physical activity**.
- **A combined multiparametric monitoring scores**, integrating these indexes, significantly enhances the ability to predict the risk of AHRE.
- This approach could support **more personalised** and **timely interventions** that could reduce the burden of AF, improve clinical outcomes, and optimise the long-term management of patients.

HEAD2TOES schema

- (H)eart Failure
- (E)xercise
- (A)rterial hypertension
- (D)iabetes type (2)
- (T)obacco
- (O)besity
- (E)thanol
- (S)leep apnea

Multivariate analysis of variables associated with AHRE occurrence



OR = 1.25

Combined AHRE – 5 min SCORE

2*HeartLogic IN-alert + 1*RDI ≥30episodes/h + 4*Reduction in activity ≥1h

Combined AHRE – 5 min SCORE ≥ 4

- **Higher risk of AHRE occurrence**
- **6.75 incidence rate ratio**

OR = 2.20

Combined AHRE – 23 hours SCORE

1*HeartLogic IN-alert + 2*Reduction in activity ≥1h

Combined AHRE – 23 hours SCORE ≥ 2

- **Higher risk of AHRE occurrence**
- **11.46 incidence rate ratio**

Figure 5: HEAD2TOES schema and scores definition.

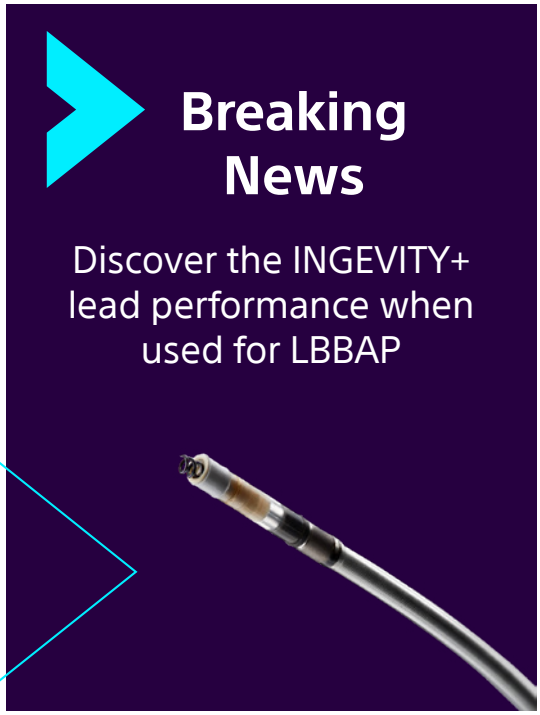
"Performance of an active fixation stylet-driven lead in left bundle branch area pacing: Results from INSIGHT-LBBA"[9]

Friedman D.J. et al.

INSIGHT-LBBA was an investigator-initiated retrospective, multicentre, nonrandomised single-arm registry (NCT 06014866). The study analysed all left bundle branch area pacing (LBBAP) implant attempts using INGEVITY+™ leads for a bradycardia indication – de novo single or dual chamber pacemaker generator.

In total, **1,122 patients** from 8 centres were included in the analysis.

Three primary endpoints were evaluated at **3-months post-implantation**: one for safety (lead-related complication 90%) and two for effectiveness (*pacing capture threshold ≤ 2 V and sensed amplitude ≥ 5 mV*).



What are the key results?

Procedural Success Rate

LBBAP was achieved in 95.6% of cases, 90.6% on the first lead attempt.

*All implants were performed using Site Selective Pacing Catheters **(SSPC)**.*

Lead-related Complication (LRC) Free Rate

97.7% of LBBAP INGEVITY+ lead were complication-free at 3 months.

97.2% LRC-free rate at 24 months.

No distal tip intercardiac conductor fractures were reported during a median follow-up time of 9.9 months.

Capture and Sensing Effectiveness

Patients with Pacing Capture Thresholds ≤ 2 V at 3 months.

Patients with Sensed Amplitudes ≥ 5 mV at 3 months.

Results were stable through 24 months of follow-up.

The implantation procedure for LBBAP using the INGEVITY+ lead demonstrated a high success rate. The analysis of the INSIGHT-LBBA registry was the largest report on stylet-driven leads for LBBAP and showed that the INGEVITY+ lead met all prespecified safety and efficacy goals.

Key Messages

- **New Insights on S-ICD and Modular System:**

  Real-world findings support the S-ICD as a safe and effective alternative to transvenous ICDs, providing a viable option for Brugada syndrome patients in need of sudden cardiac death prevention.[1]

  The modular system – S-ICD wirelessly communicating with the EMPOWER™ leadless pacemaker – effectively detects and treats ventricular arrhythmias with ATP success similar to that of a transvenous ICDs.[2]

- **From PRAETORIAN Score to Clinical Practice:**

  In current clinical practice, the PRAETORIAN score can be simplified. With the adoption of the intermuscular implantation technique, two of the three scoring steps may no longer be necessary, and shock impedance may serve as a reliable indicator of sub-coil fat thickness.[3]

  The S-ICD has recently been upgraded to measure low-voltage impedance (LVI), which strongly correlates with high-voltage impedance (HVI), potentially eliminating the risks and logistical challenges of shock delivery.[4]

- **New Insights on LUX-Dx™ and HeartLogic™:**

  ICM remote programming optimizes device management by reducing the need for in-office visits. Additional efficiency can be gained by adopting an alert-based monitoring approach and eliminating scheduled transmissions.[5]

  A combined risk score including HeartLogic, RDI (sleep apnea index), and physical activity can serve as a surrogate for HEAD2TOES risk factors and facilitate dynamic risk assessment of AHRE burden in HF patients.[6]

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3. Ziacchi M, Ottaviano L, Checchi L, *et al.* The risk of failure of subcutaneous implantable cardioverter defibrillator therapy: from PRAETORIAN score to clinical practice. Europace. 2025 Feb 5;27(2):euaf011. doi: 10.1093/europace/euaf011.
4. Mugnai G. *et al.* Long-term Low-Voltage Impedance Measurements in Subcutaneous Implantable Cardioverter-Defibrillators. Presented at EHRA Congress 2025 and available on ESC 365 platform.
5. Fareh *et al.* Real-world Use of Insertable Cardiac Monitor Remote Programming, Presented at EHRA Congress 2025 and available on ESC 365 platform.
6. Dell'Aquila *et al.* Dynamic Evaluation of Atrial Fibrillation Risk Factors Using Multiple Sensors of Implantable Cardioverter Defibrillators, Presented at EHRA Congress 2025 and available on ESC 365 platform.
7. Knops RE, Lloyd MS, Roberts PR, *et al.* A Modular Communicative Leadless Pacing-Defibrillator System. N Engl J Med. 2024 Oct 17;391(15):1402-1412. doi: 10.1056/NEJMoa2401807. Epub 2024 May 18. PMID: 38767244.
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9. Friedman DJ, 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. 2025 Feb 4:S1547-5271(25)00111-0. doi: 10.1016/j.hrthm.2025.01.041.

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