



LBBAP: NEW INSIGHTS

Affidabilità degli attuali elettrocateri nel pacing del sistema di conduzione: a che punto siamo?

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Leads designs used for CSP

Lead designs used for CSP

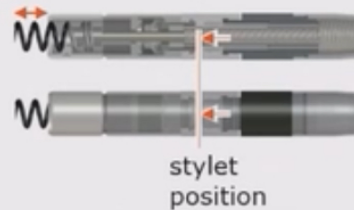
➔ Lumenless leads/ **Fixed helix**



SelectSecure 3830, Medtronic

➔ Stylet-driven leads with **extendable/retractable helix**

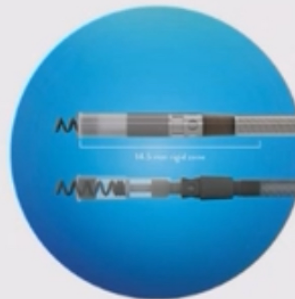
SoliaS,
Biotronik



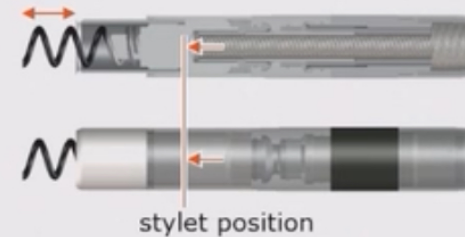
Ingevity (Plus),
Boston Scientific



Tendril / Ultipace
Abbott



➔ Stylet-driven leads **with fixed helix**

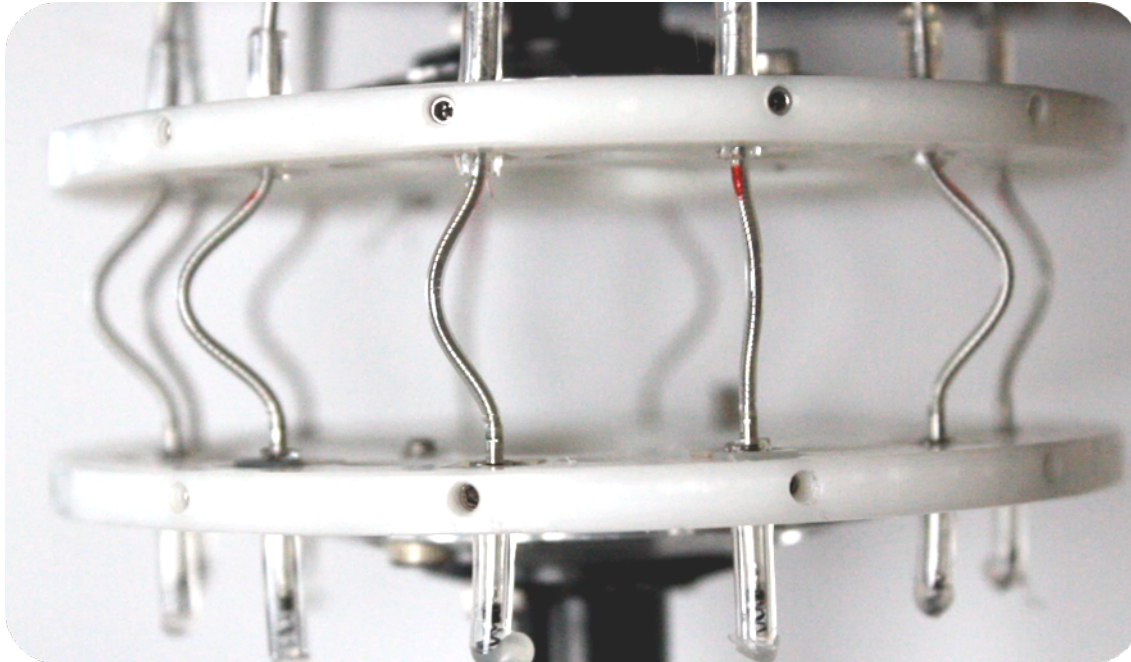


Solia CSP S, Biotronik



Validazione 3830 LBBAP con dati real-world

- Test di resistenza a fatica simulando 10anni di stimolazione in LBBAP (>400M cicli)¹



Conclusione

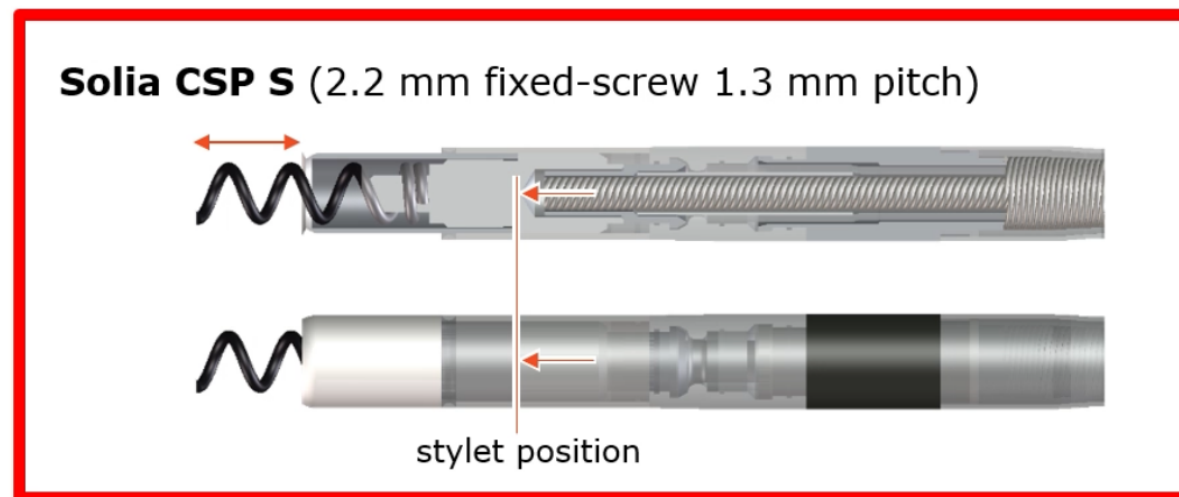
Le prestazioni di resistenza alla fatica del 3830 in LBBAP sono paragonabili a quelle in RVP (98% di affidabilità, IC al 95%)¹

Dimostrata sicurezza ed efficacia co dati real-world dell'elettrocatteter 3830 posizionato nell'area della braca sinistra.

¹ Zou et al. Clinical use conditions of lead deployment and simulated lead fracture rate in LBBAP. JCE 2023 1-8



Solia CSP S: **stylet-driven, fixed helix** lead design



➤ Modifications in helix design

- **Fixed helix!**
- Longer helix (2,2 mm instead of 1,8 mm, +22%)
- Wider pitch of helix (1,3 mm vs 0,9 mm)
- Sharper helix (two sided grinded)

➤ Modifications in lead design

- Deeper insertion of stylet (+3,6 mm)
- Optimized distal part for high resilience

BIO|MASTER.CSP

Pivotal study of the Amvia pacemaker and Solia CSP
on conduction system pacing

BIOTRONIK SE & Co. KG // Center for Clinical Research

- International multicentric (14 centers), 152 patients
- Prospective, nonrandomized study
- Acute (1 month) implantation and safety success

Participating sites		Patients
BEL026	UZ Gent - Universitair Ziekenhuis, Gent	23 (+7) ¹
AUS064	Integral Healthcare, Adelaide	20 (+5) ¹
AUS035	Lyell McEwin Hospital, Elizabeth Vale	14 (+2) ¹
BEL039	AZ Sint-Jan, Brugge	12 (+1) ¹
NZL002	Auckland City Hospital, Grafton	11 (+1) ¹
AUS041	Victorian Heart Hospital, Clayton	11 (+3) ¹
FRA100	Hôpital Haut Lévéque (CHU), Pessac Cedex	9 (+9) ¹
NLD035	Noordwest Ziekenhuisgroep, Alkmaar	9 (+8) ¹
BEL067	Clinique Saint-Pierre, Ottignies	8 (+1) ¹
FRA267	Hopital de la Timone (CHU La Timone), Marseille	8 (+3) ¹
FRA305	Hôpital privé du Confluent, Nantes Cedex	8 (+0) ¹
NLD014	Catharina Ziekenhuis, Eindhoven	8 (+7) ¹
BEL068	Grand Hôpital de Charleroi, Charleroi	7 (+1) ¹
FRA078	Centre Hospitalier Metz-Thionville, Metz	4 (+2) ¹
Total number out of 152		152

¹ Enrollment in August and September

Results BIOMASTER CSP: safety

➔ **0% SADE** (Serious adverse device-related events)

➔ Procedural Complications

Septal perforations: **2%** (3 pts, no sequela)

➔ Lead Dislodgements

Macro-dislodgement: **0,7%** (1 pt, Day 1)

Micro-dislodgement: **5,7%**



Micro-dislodgements with contemporary
pacing leads: up to 13,5%



Two-year follow-up of the safety and clinical outcomes of stylet-driven leads for left bundle branch area pacing compared with right ventricular pacing in the Medicare population ^e

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ABSTRACT

BACKGROUND Stylet-driven leads have been increasingly used for left bundle branch area pacing (LBBAP). The long-term outcomes associated with LBBAP by stylet-driven leads have not been reported in a large cohort.

OBJECTIVE The purpose of this study was to compare the safety and clinical outcomes of stylet-driven leads placed at LBBAP vs right ventricular pacing (RVP) locations in dual-chamber (DC) pacemaker patients using large real-world data.

METHODS Medicare Fee-for-Service claims and Abbott device registration databases were linked to identify patients who had de novo DC pacemaker implants with the Tendril STS or UltiPace leads (Abbott, Abbott Park, IL) from January 1, 2020, to June 30, 2024, at LBBAP or RVP locations. The unadjusted and propensity score overlap weight-adjusted rates of complications, reinterventions, heart failure hospitalizations (HFHs), incident HFHs, and all-cause mortality at 2 years post-implantation were compared between the 2 groups.

RESULTS A total of 2341 patients with LBBAP and 68,241 patients with RVP were identified. There was no difference in the rates of 30-day acute complications (hazard ratio [HR] 1.01; $P = .95$), chronic complications (HR 0.92; $P = .51$), or reinterventions (HR 0.76; $P = .06$) at 2 years between patients with LBBAP and RVP. The LBBAP group experienced significantly lower rates of HFHs (HR 0.72; $P = .015$), incident HFHs (HR 0.54; $P = .04$), and all-cause mortality (HR 0.64; $P < .0001$) at 2 years than did the RVP group.

CONCLUSION DC pacemaker patients with LBBAP using Tendril STS or UltiPace stylet-driven leads experienced significantly lower rates of HFH and all-cause mortality, with similarly low complication rates compared with RVP over 2 years of follow-up in this large Medicare population.

KEYWORDS Left bundle branch area pacing; Stylet-driven lead; Right ventricular pacing; Outcomes; Hospitalizations; Complications

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Introduction

Right ventricular pacing (RVP) has been the main pacing strategy for patients with bradycardia indications because of its high procedural success rate and relatively low acute complication rate.¹ However, RVP has been shown to accelerate the

progression of left ventricular dysfunction and increase the risk of atrial fibrillation and heart failure hospitalization (HFH).^{2–6} Left bundle branch area pacing (LBBAP) has emerged as a safe alternative to RVP for patients with bradycardia.^{7–9} LBBAP has demonstrated improved clinical outcomes, including improved cardiac function, reduced

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Medicare Registry – Tendril STS & UltiPace

Study population

- 70,582 dual-chamber pacemaker recipients
- 2,341 LBBAP
- 68,241 RVP
- 24-month follow-up

Safety

- Acute complications:
 - LBBAP 7.8%
 - RVP 7.7%
- Chronic complications:
 - LBBAP 7.4%
 - RVP 8.0%
- No significant differences

Reinterventions

- Similar overall reintervention rates
- Fewer CRT upgrades with LBBAP:

- 0.96% vs 2.46%

Clinical outcomes

- HF hospitalization ↓ 28%
- Incident HF ↓ 46%
- All-cause mortality ↓ 36%

Take-home message

LBBAP using Abbott stylet-driven leads (Tendril STS/UltiPace) demonstrated comparable safety to RVP, with lower HF hospitalizations and lower mortality at 2 years

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

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ABSTRACT

BACKGROUND Left bundle branch area pacing (LBBAP) has been rapidly adopted despite a lack of leads with approved indications for LBBAP.

OBJECTIVE This study aims to analyze the performance of a 6Fr active fixation, stylet-driven lead in LBBAP.

METHODS The multicenter INSIGHT-LBBA registry analyzed consecutive LBBAP implant attempts with INGEVITY+ leads. Data were retrospectively collected with standardized entry via REDCap. Prespecified safety (lead-related complication [LRC]-free rate with performance goal >90% at 3 months) and effectiveness (pacing capture threshold [PCT] ≤2 V@ 0.4 ms and R-waves ≥5 mV; 3-month performance goal = 80%) endpoints were analyzed. External validation of lead effectiveness was performed on a separate cohort of LBBAP patients from the LATITUDE remote monitoring database.

RESULTS The study enrolled 1122 single- or dual-chamber pacemaker patients from 8 US sites (mean age 76 ±10 years, 43% female, 48% atrioventricular [AV] block, 40% sinus node dysfunction). Those successfully implanted had a median follow-up of 302 days. Left bundle or left septal capture was achieved in 95.6% of patients (1073 of 1122) and 89.6% of leads (1073 of 1197, 1.07 leads per patient). The 3-month LRC-free rate was 97.7% (lower confidence limit [LCL] 96.6%) with an LRC-free rate of 97.2% at 24 months. At 3 months, 98.8% (LCL 97.7%) of PCTs were ≤2 V, and 94.8% (LCL 92.7%) of sensed amplitudes were ≥5 mV. Results were stable through 24 months; 864 LBBAP implants were analyzed in the external validation cohort, and lead effectiveness was clinically indistinguishable across datasets.

CONCLUSION In this study of an active fixation, stylet-driven lead, all prespecified performance goals for pacing, sensing, and LRC rates were met when used for LBBAP. External validation demonstrated concordant results.

CLINICAL TRIAL REGISTRATION NCT06014866

KEYWORDS Complications; Conduction system pacing; Electrical performance; Left bundle branch area pacing; Stylet-driven lead

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Introduction

Left bundle branch area pacing (LBBAP) has demonstrated rapid growth because of its ability to achieve physiological activation of the left ventricle with more stable thresholds and reduced procedural time compared with His bundle pacing.¹ For years, the majority of clinical data supporting this growth

have come from a 4.1Fr lumenless lead with a fixed extended electrically active helix.² Compared with stylet-driven leads, this lumenless lead is less stiff, with lower torqueability, and its smaller diameter delivery sheath may be more prone to kinking, potentially providing less support during challenging LBBAP implants.³ Recent publications have supported the

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<https://doi.org/10.1016/j.hrthm.2025.01.041>

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INSIGHT-LBBAP – Key Points



Study population:

- 1122 patients, multicenter
- (8 US sites)
- LBBAP using Ingevity +
- (6Fr, stylet-driven lead)
- Real-world retrospective registry



Electrical performance

- Pacing threshold ≤2V: **98.8% at 3 months**
- R-wave ≥5 mV: **94.8%**
- Parameters stable up to 24 months



Safety (Lead reliability)

- LRC-free rate:
 - **97.7% at 3 months**
 - **97.2% at 24 months**
- Overall complications: **2.8%**



Lead fracture (key point)

- **0 distal conductor fractures observed**
- 1 proximal (clavicular) fracture
- Follow-up up to ~24 months



Procedural success

- LBBAP success: **95.6%**
- First-attempt success: **90.6%**
- Lead-level success: **89.6%**



Main complications

- Lead dislodgement: **2.3% (most common)**
- Elevated threshold/loss of capture: **0.4%**
- Oversensing: **0.1%**
- Perforation: **0.1%**



ORIGINAL ARTICLE

Implantation Success, Electrical Performance, and Safety of an Active Fixation Stylet-Driven Lead for LBBAP in Clinical Practice: A Multicenter Experience

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Received: 23 July 2025 | Revised: 15 November 2025 | Accepted: 20 December 2025

Keywords: conduction system pacing | left bundle branch area pacing | pacemaker implantation | stylet-driven lead

ABSTRACT

Background: Left bundle branch area pacing (LBBAP) has emerged as a promising physiological pacing strategy. However, its feasibility and safety using conventional stylet-driven leads (SDL) such as INGEVITY+ remain under investigation.

Objective: To evaluate the clinical performance, safety, and follow-up outcomes of LBBAP using the INGEVITY+ lead in a real-world electrophysiology setting.

Methods: From 2021 to 2024, 207 consecutive patients underwent LBBAP implant attempts using the INGEVITY+ lead across 19 centers. Of these, 146 had bradycardia indications, and 61 had heart failure indications. A control group of 200 patients received standard right ventricular (RV) pacing with the same lead. Procedural outcomes, electrical parameters, complications, and mid-term lead performance were assessed.

Results: LBBAP was successfully achieved in 201 (97%) cases. Procedural and fluoroscopy times were slightly longer for LBBAP than for RV pacing. Acute complications included one helix fracture, one atrioventricular block, and one septal perforation. During a median follow-up of 9 months, no lead fractures were reported; lead dislodgment occurred in three cases. Kaplan–Meier analysis showed no significant difference in time to first lead-related complication between the LBBAP and RV pacing groups (hazard ratio: 4.69, 95%CI: 0.63–34.90, $p = 0.139$). Electrical performance remained stable, with 98% of retained leads maintaining capture thresholds ≤ 2 V and 92% with sensed amplitudes ≥ 5 mV.

Conclusions: LBBAP using the INGEVITY+ SDL is feasible and safe in clinical practice, with excellent implant success and stable mid-term electrical performance. These findings support its use as a viable conduction system pacing strategy.



Study population

- 207 patients (LBBAP group)
- 200 control (RV pacing)
- Multicenter (19 Italian centers)
- LBBAP using Ingevity+
- 6Fr, stylet-driven lead
- Real-world retrospective study



Safety (Lead reliability)

- No lead fractures during follow-up (~9 months)
- Lead dislodgement: ~1.5% (3 cases)
- Overall low complication rate
- Similar safety vs RV pacing



Electrical performance

- Pacing threshold ≤ 2 V: 98% at follow-up
- R-wave ≥ 5 mV: 92%
- Parameters stable over time
- Comparable to RV pacing



Procedural success

- LBBAP success: 97%
- LBB capture: 78%
- LV septal pacing: 22%
- Longer procedure and fluoroscopy time vs RV pacing



Main complications

- Lead dislodgement: 3 cases
- Helix fracture (acute): 1 case
- AV block: 1 case
- Septal perforation: 1 case



No long-term adverse sequelae



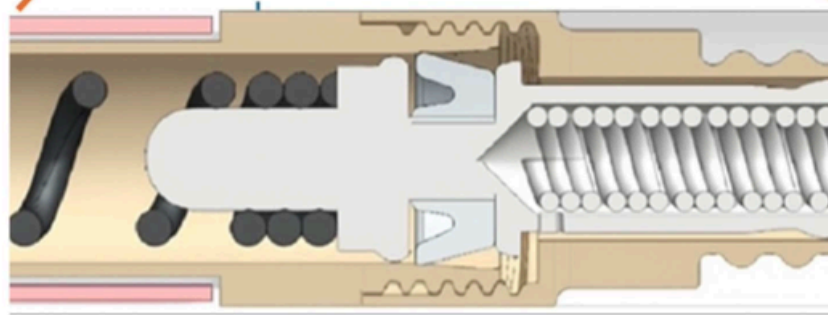
Lead fracture (key point)

- 0 lead fractures at follow-up
- Despite:
 - deep septal implantation
 - multiple screw attempts
- Preserved lead integrity

A long, thin, flexible cable with a white connector at one end and a small, cylindrical component at the other. The cable is coiled in a loose loop. The white connector has some text on it, including "PCE" and "1000". The cylindrical component is white with a black band and a small gold-colored ring.



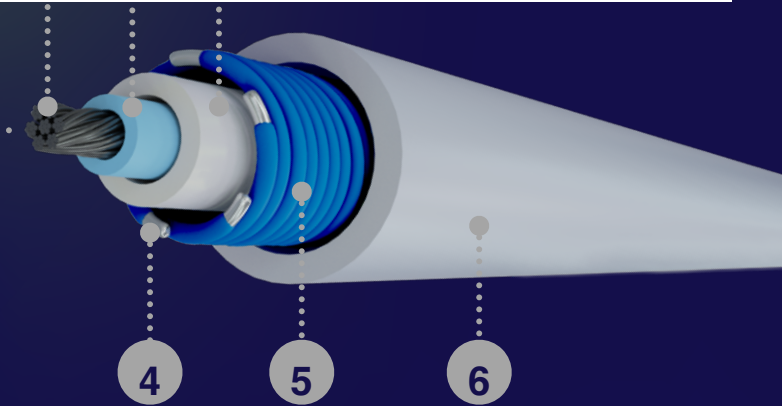
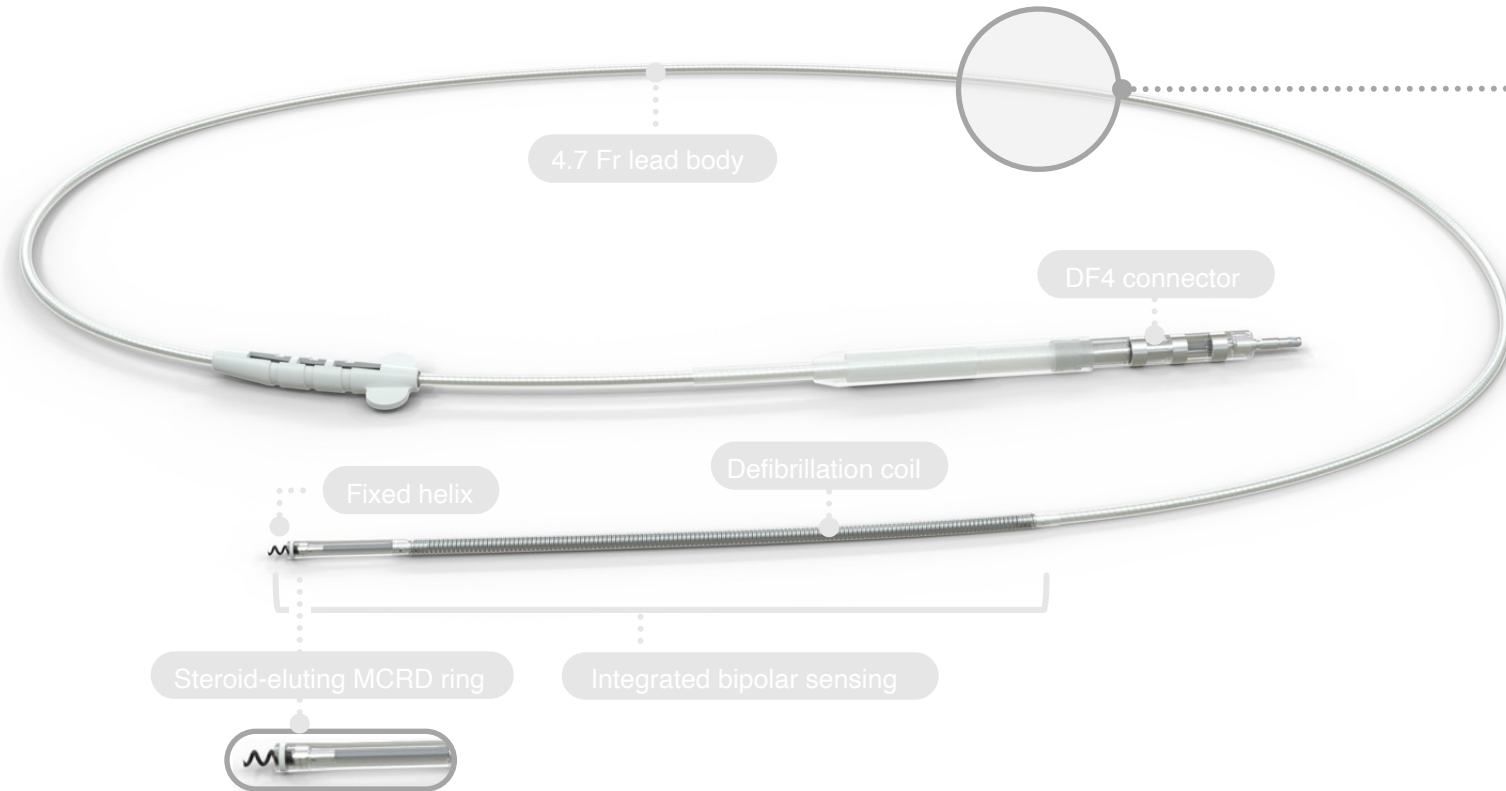
A close-up photograph of a cable assembly. On the left, a black spring is attached to a black plastic component. An orange line points from the text 'Spring' to this component. The cable itself is black and braided, extending to the right where it connects to a black plastic connector. Another orange line points from the text 'Cable' to the braided section of the cable.



This study demonstrates that LBBAP using the INGEVITY+ SDL—a lead originally designed for conventional pacing—is feasible, safe, and effective in routine clinical practice. Implant success rates were high and complication rates remained low. Electrical performance and lead stability were comparable to standard RV pacing, with excellent mid-term follow-up outcomes. These findings support the use of INGEVITY+ as a viable option for LBBAP.

FIGURE 1 | (A) The INGEVITY+ pacing lead is a 6Fr steroid-eluting, endocardial pace/sense lead designed for permanent implantation for either atrial or ventricular applications including Left Bundle Branch Area pacing as an alternative to right ventricular pacing. (B) The site-selective pacing catheter sheaths family includes four fixed curve sheaths. (C) Distal tip fluoroscopic view and coupler joint design.

OmniaSecure™ defibrillation lead construction

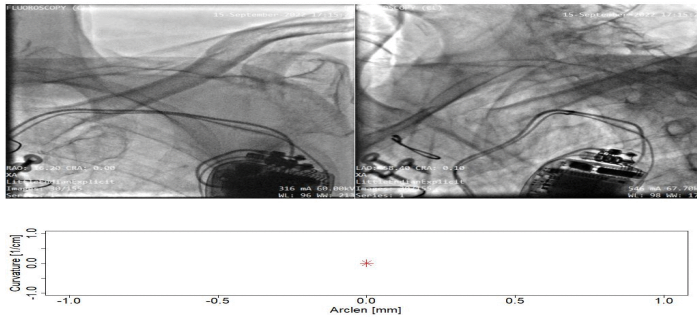


- 1 Conductor cable: MP35N
- 2 Inner insulation: ETFE
- 3 Inner insulation: silicone
- 4 Conductor coil: silver-cored MP35N
- 5 Conductor coil insulation: SI polyimide
- 6 Outer insulation: 55D polyurethane

OmniaSecure™ defibrillation lead predicted to be highly durable with an overall 98.2% fracture-free rate at 10 years

Understand in-vivo use conditions

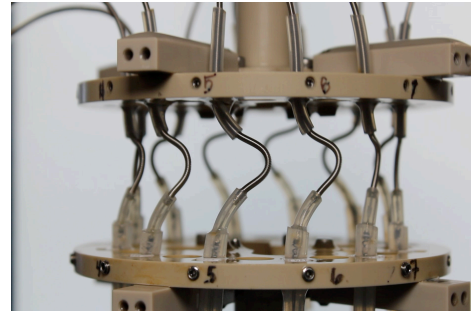
- OmniaSecure LEADR substudy imaged patients during full range of arm motion to assess and quantify in-vivo bending
- Inclusion of cyclic use conditions based on patient activity



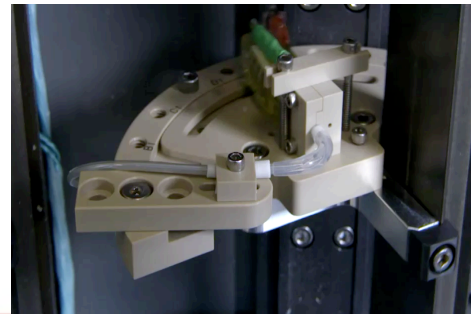
Clinically relevant bench testing and test to failure¹

Benchtop fatigue tests designed to mimic in-vivo use conditions and reflect extreme levels of stress, taking into consideration:

- Patient anatomy and lead interaction in different zones of the body
- Implant techniques



Distal fatigue test



Proximal connector fatigue test

Massive tests to look at the lead durability at 10 years:

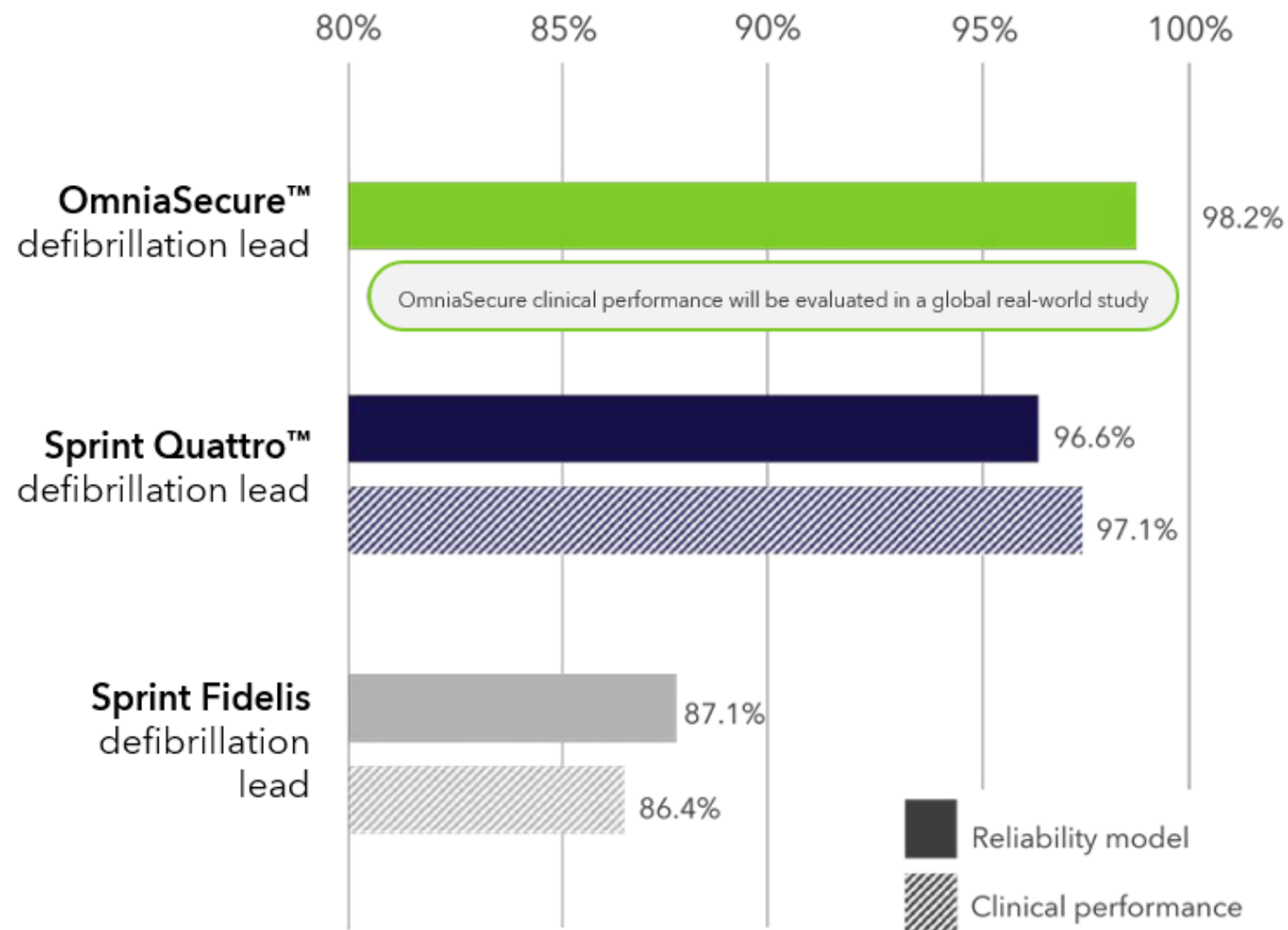
- 400 million cycles for cardiac motion
- 5 million cycles of arm motions.
- 50.000.000 patients
- 5.000 cohorts

1. Crossley GH, et al. *Heart Rhythm*. 2025;22:302–310.
2. Wilkoff BL, et al. *Heart Rhythm*. 2021;18:1605–1612.

OmniaSecure™ defibrillation lead predicted to be highly durable with an overall 98.2% fracture-free rate at 10 years

Validated fatigue survival model²

The reliability model accurately predicted 10-year real-world performance of Medtronic commercialized leads²



1. Crossley GH, et al. *Heart Rhythm*. 2025;22:302–310.

2. Wilkoff BL, et al. *Heart Rhythm*. 2021;18:1605–1612.

Conduction System vs Biventricular Pacing in Heart Failure
The PhysioSync-HF Randomized Clinical Trial

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Visual Abstract

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Supplemental content

IMPORTANCE

Conduction system pacing (CSP) is a promising and potentially cost-effective alternative to biventricular pacing (BiVP) in patients with heart failure with reduced ejection fraction (HFrEF) and left bundle-branch block (LBBB), but its impact on heart failure (HF) outcomes remains uncertain.

OBJECTIVE

To compare CSP vs BiVP on an HF-related outcome in patients with HFrEF and LBBB.

DESIGN, SETTING, AND PARTICIPANTS

PhysioSync-HF (Conduction System Pacing Versus Biventricular Resynchronization in Patients With Chronic Heart Failure) was an investigator-initiated, multicenter, noninferiority randomized clinical trial enrolling participants from November 2022 to December 2023 with 12 months of follow-up at 14 hospitals across all regions of Brazil. Adults with symptomatic HFrEF (New York Heart Association NYHA) classes II through III), left ventricular ejection fraction (LVEF) of 35% or less, and LBBB (QRS duration ≥130 milliseconds) were eligible for inclusion. Data were analyzed from May to August 2025.

INTERVENTION

Patients were randomized 1:1 to either CSP (preferentially left bundle-branch area pacing) or BiVP.

MAIN OUTCOMES AND MEASURES

The primary outcome was a hierarchical composite of death, HF hospitalizations, urgent HF visits, and change in LVEF at 12 months. The prespecified noninferiority margin for the odds ratio (OR) was 1.2.

RESULTS

A total of 173 patients (median [IQR] age, 62 years [56-68]; 86 female patients [49.7%]; 115 (66.5%) with dilated cardiomyopathy; median [IQR] LVEF, 26% [22%-31%]; median [IQR] QRS, 180 milliseconds [170-200]) were included. At 12 months, CSP failed to meet noninferiority and was inferior to BiVP for the primary end point (OR, 2.36; 95% CI, 1.37-4.06; *P* = .99 for noninferiority; *P* = .002 for between-group difference). The time-to-event composite of death, HF hospitalizations, or urgent HF visits was higher in CSP (hazard ratio, 2.35; 95% CI, 0.99-5.61). Mean (SD) LVEF increased to 35% (12%) with CSP and 39% (12%) with BiVP (mean difference, 3.8%; 95% CI, 0.3%-7.3%). Relative to baseline, both groups had comparable improvements in QRS duration, Kansas City Cardiomyopathy Questionnaire Overall Summary Score, NYHA class, and natriuretic peptide levels. Total direct medical cost related to the procedure and heart failure care was the equivalent of \$7090 (95% CI, \$5779-\$8648) lower in patients randomized to CSP at 12 months.

CONCLUSIONS AND RELEVANCE

In patients with HFrEF and LBBB, CSP was inferior to BiVP for a composite of death, HF hospitalizations, urgent HF visits, and change in LVEF at 12 months. These findings do not support the routine use of CSP as the first-line resynchronization strategy in this population.

TRIAL REGISTRATION

ClinicalTrials.gov Identifier: [NCT05572736](#)

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The apparent discrepancy between PhysioSync-HF and HeartSync-LBBP likely reflects differences in patient selection, operator experience, procedural success, and the distinction between true LBBP and broader CSP/LBBAP strategies.

Long-Term Outcomes of Left Bundle-Branch Pacing vs Biventricular Pacing in Heart Failure
The HeartSync-LBBP Randomized Clinical Trial

Xueying Chen, MD; Xi Liu, MD; Ruogu Li, MD; Zhongkai Wang, MD; Yixiu Liang, MD; Lei Zhang, MD; Wei Wang, MD; Jin Bai, MD; Jingfeng Wang, MD; Shengmei Qin, MD; Weiwei Zhang, MD; Tianbao Yao, MD; Dong Huang, MD; Ting Chen, MD; Xianxian Zhao, MD, PHD; Dening Liao, MD, PHD; Jingbo Li, MD, PHD; Jialiang Mao, MD, PHD; Mihail G. Chelu, MD, PHD; Yangang Su, MD, PHD; Kenneth A. Ellenbogen, MD; Junbo Ge, MD, PHD

IMPORTANCE

Left bundle-branch pacing (LBBP) has been proposed as an alternative to biventricular pacing (BiVP) for patients with heart failure with left bundle-branch block (LBBB). However, robust clinical evidence from randomized clinical trials is lacking.

OBJECTIVE

To evaluate the long-term clinical outcomes of LBBP and BiVP.

DESIGN, SETTING, AND PARTICIPANTS

This multicenter, prospective, randomized clinical trial enrolled 200 patients at 6 centers in China with a left ventricular ejection fraction (LVEF) of 35% or less and LBBB from October 2020 to March 2022. This study was took place from October 2020 to September 2024. These data were analyzed September 2024 to December 2024.

INTERVENTIONS

Patients were randomly assigned in a 1:1 ratio to receive either LBBP or BiVP.

MAIN OUTCOMES AND MEASURES

The primary end point was the time to death from any cause or heart failure hospitalization (HFH). The secondary end points included all-cause death, HFH, echocardiographic response (absolute increase in LVEF ≥5%), and super response (absolute increase in LVEF ≥15% or improvement of LVEF to ≥50%) rates.

RESULTS

Of the 200 included patients, 136 were male and 64 were female. The success rate was 98% in the LBBP group and 94% in the BiVP group (*P* = .28). The median follow-up duration was 36 (range, 33-39) months. The primary end point of time to death or HFH was significantly lower in the LBBP group compared with BiVP (8% vs 28%; hazard ratio [HR], 0.26; 95% CI, 0.12-0.57; *P* < .001). There was no significant difference in all-cause mortality between the groups (2.0% vs 5.0%; HR, 0.40; 95% CI, 0.08-2.04; *P* = .25). However, LBBP significantly reduced the risk of HFH (7.0% vs 28.0%; HR, 0.23; 95% CI, 0.10-0.52; *P* < .001). The echocardiographic response rates were similar in both groups (86.0% vs 81.0%; *P* = .34) but the super-response rate was higher in the LBBP group (55.0% vs 36.0%; *P* < .007).

CONCLUSIONS AND RELEVANCE

In this study, LBBP was superior to BiVP in reducing the risk of death or HFH in patients with LBBB and severely reduced LVEF. Further trials are warranted in this patient population.

TRIAL REGISTRATION

Chinese Clinical Trial Registry identifier: [ChiCTR2000036554](#)

Conduction System vs Biventricular Pacing in Heart Failure
The PhysioSync-HF Randomized Clinical Trial

André Zimmerman, MD, PhD; Alexander dal Forno, MD; Luis E. Rohde, MD, PhD; Caique M. Ternes, MD, PhD; Fernanda D. Alves, PhD; Lucas P. Damiani, PhD; Martino Martinelli-Filho, MD, PhD; Roberto Costa, MD, PhD; Alexandro A. Fagundes, MD; Rodrigo M. Barbosa, MD; Eduardo B. Gadelha, MD; Carlos Eduardo Lima, MD, PhD; Márcio A. Silva, MD; Jaime A. Maldonado, MD; Julio César de Oliveira, MD, PhD; Fabricio Mallmann, MD; José M. Baggio Júnior, MD; Carlos E. Duarte, MD; Liliane A. de Souza, PhD; Juliana S. Santos, BSc; Anderson D. Silveira, MD, PhD; Sérgio R. R. Decker, MD, PhD; Leandro I. Zimmerman, MD, PhD; Carisi A. Polanczyk, MD, PhD; André d'Ávila, MD, PhD

IMPORTANCE Conduction system pacing (CSP) is a promising and potentially cost-effective alternative to biventricular pacing (BiV) in patients with heart failure with reduced ejection fraction (HFrEF) and left bundle-branch block (LBBB), but its impact on heart failure (HF) outcomes remains uncertain.

OBJECTIVE To compare CSP vs BiV on an HF-related outcome in patients with HFrEF and LBBB.

DESIGN, SETTING, AND PARTICIPANTS PhysioSync-HF (Conduction System Pacing Versus Biventricular Resynchronization in Patients With Chronic Heart Failure) was an investigator-initiated, multicenter, noninferiority randomized clinical trial enrolling participants from November 2022 to December 2023 with 12 months of follow-up at 14 hospitals across all regions of Brazil. Adults with symptomatic HFrEF (New York Heart Association NYHA) classes II through III), left ventricular ejection fraction (LVEF) of 35% or less, and LBBB (QRS duration ≥130 milliseconds) were eligible for inclusion. Data were analyzed from May to August 2025.

INTERVENTION Patients were randomized 1:1 to either CSP (preferentially left bundle-branch area pacing) or BiV.

MAIN OUTCOMES AND MEASURES The primary outcome was a hierarchical composite of death, HF hospitalizations, urgent HF visits, and change in LVEF at 12 months. The prespecified noninferiority margin for the odds ratio (OR) was 1.2.

RESULTS A total of 173 patients (median [IQR] age, 62 years [56-68]; 86 female patients [49.7%]; 115 (66.5%) with dilated cardiomyopathy; median [IQR] LVEF, 26% [22%-31%]; median [IQR] QRS, 180 milliseconds [170-200]) were included. At 12 months, CSP failed to meet noninferiority and was inferior to BiV for the primary end point (OR, 2.36; 95% CI, 1.37-4.06; $P = .99$ for noninferiority; $P = .002$ for between-group difference). The time-to-event composite of death, HF hospitalizations, or urgent HF visits was higher in CSP (hazard ratio, 2.35; 95% CI, 0.99-5.61). Mean (SD) LVEF increased to 35% (12%) with CSP and 39% (12%) with BiV (mean difference, 3.8%; 95% CI, 0.3%-7.3%). Relative to baseline, both groups had comparable improvements in QRS duration, Kansas City Cardiomyopathy Questionnaire Overall Summary Score, NYHA class, and natriuretic peptide levels. Total direct medical cost related to the procedure and heart failure care was the equivalent of \$7090 (95% CI, \$5779-\$8648) lower in patients randomized to CSP at 12 months.

CONCLUSIONS AND RELEVANCE In patients with HFrEF and LBBB, CSP was inferior to BiV for a composite of death, HF hospitalizations, urgent HF visits, and change in LVEF at 12 months. These findings do not support the routine use of CSP as the first-line resynchronization strategy in this population.

TRIAL REGISTRATION ClinicalTrials.gov Identifier: NCT05572736

PhysioSync-HF – Summary



Study design

- Randomized clinical trial
- 173 patients with HFrEF and LBBB
- CSP vs BiV pacing
- Multicenter (14 centers)



Intervention

- CSP strategy including:
 - LBBP
 - LBBAP
 - Deep septal pacing
 - His bundle pacing



Heterogeneous approach



Primary endpoint

- Hierarchical composite:
 - Death
 - HF hospitalization
 - Urgent HF visits
 - LVEF change

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Chronic-HF – Key Limitations



Main results

- CSP failed to demonstrate non-inferiority
- CSP associated with worse overall outcome vs BiV
- More events in CSP group



Key observations

- Major impact on composite endpoint
- 3 procedural deaths in CSP vs 0 in BiV
- endpoint complexity
- Small number of events (~15–20 per group)
- Includes hard and soft outcomes (e.g., LVEF)
- ~20% of CSP = deep septal pacing (not true LBBP)



Interpretation

- Outcome influenced by non-clinical components
- Reflects real-world CSP practice
- Heterogeneous CSP strategy
- Outcomes influenced by:
 - Choice of LBBP, LBBAP, deep septal pacing, HBP
 - Lack of a uniform or optimized technique
 - Operator experience
 - Technique variability
 - Non-standardized approach
- Multicenter (14 centers) with variable experience



Standardization

- Different leads and delivery systems
- Variable implantation techniques
- Inconsistent LBB capture confirmation



HeartSync-LBBP

Study design

- Prospective
- 200 patients
 - HFr
 - True LBBB
- LBBP vs BiV
- 6 centers (4 in China, 2 in USA)
- Median follow-up: 36 months
- more effective in reducing HF events
- especially in:
 - true LBBB
 - non-ischemic cardiomyopathy

Procedural results

- LBBP success: **98%**
- BiV success: **94%**
- Crossovers allowed
- very high implantation success

Primary endpoint

- Composite:
 - All-cause death
 - HF hospitalization

Main results

- Primary endpoint:
 - **8% (LBBP) vs 28% (BiV)**
- **Key limitations**
 - Highly selected population
 - true LBBB
 - high NICM prevalence
 - Very high operator expertise
 - Not generalizable to all centers

Echocardiographic outcomes

- Similar responder rate:
 - 86% vs 81%
- Higher **super-response** with LBBP:
 - **55% vs 36%**
- better reverse remodeling

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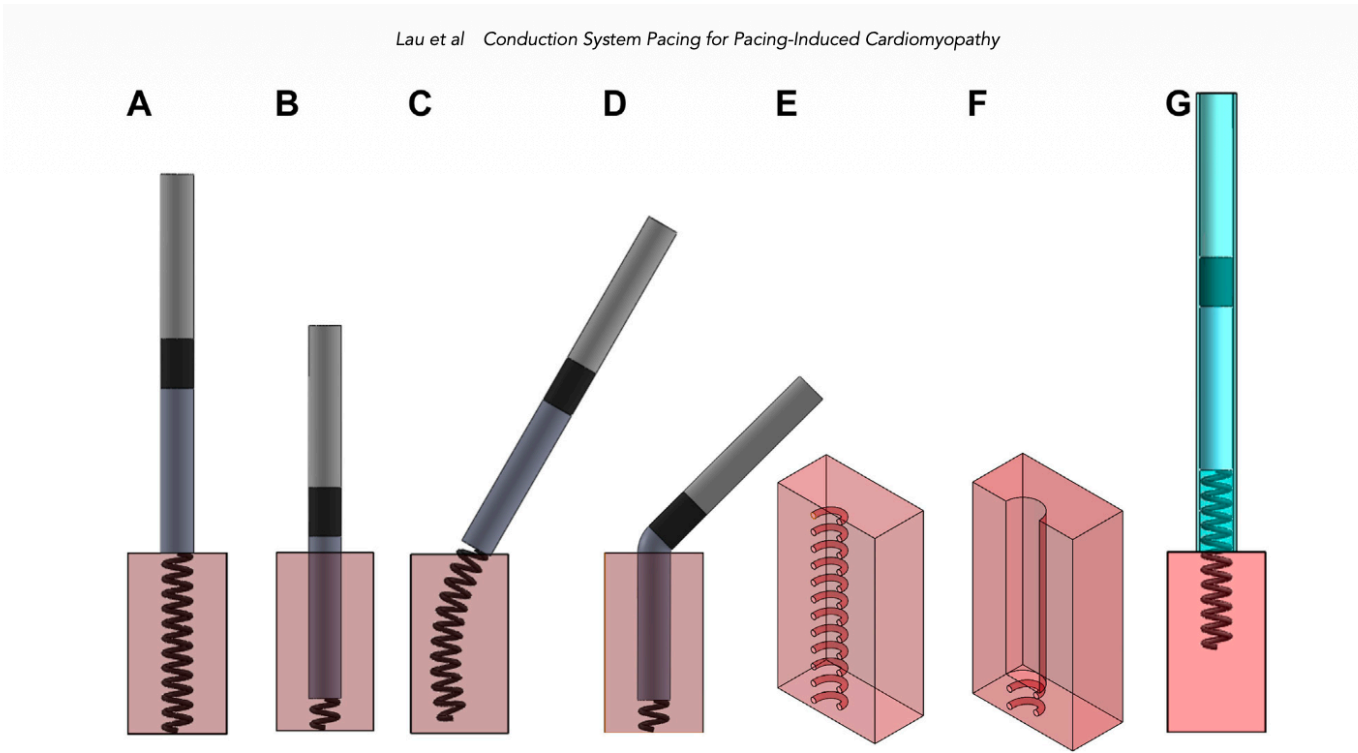
INTERVENTIONS Patients were randomly assigned in a 1:1 ratio to receive either LBBP or BiVP.

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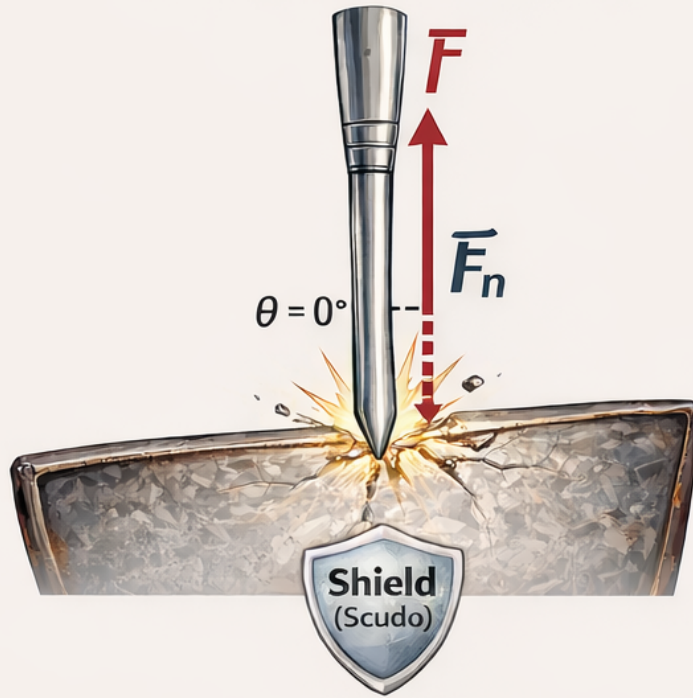
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TRIAL REGISTRATION Chinese Clinical Trial Registry identifier: [ChiCTR2000036554](https://www.clinicaltrials.gov/ct2/show/study?term=ChiCTR2000036554)



Rigid Lance Impact: Perpendicular vs Inclined

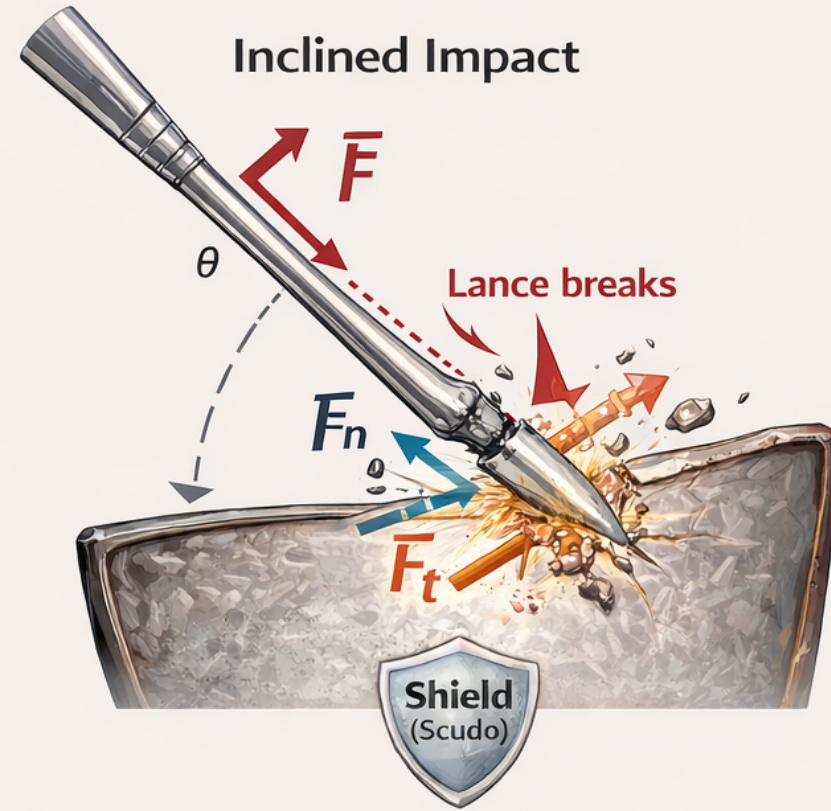
Perpendicular Impact



- Force is fully in line with the lance
- Efficient penetration

$$\vec{F}_n = F \cdot \cos \theta$$

Inclined Impact

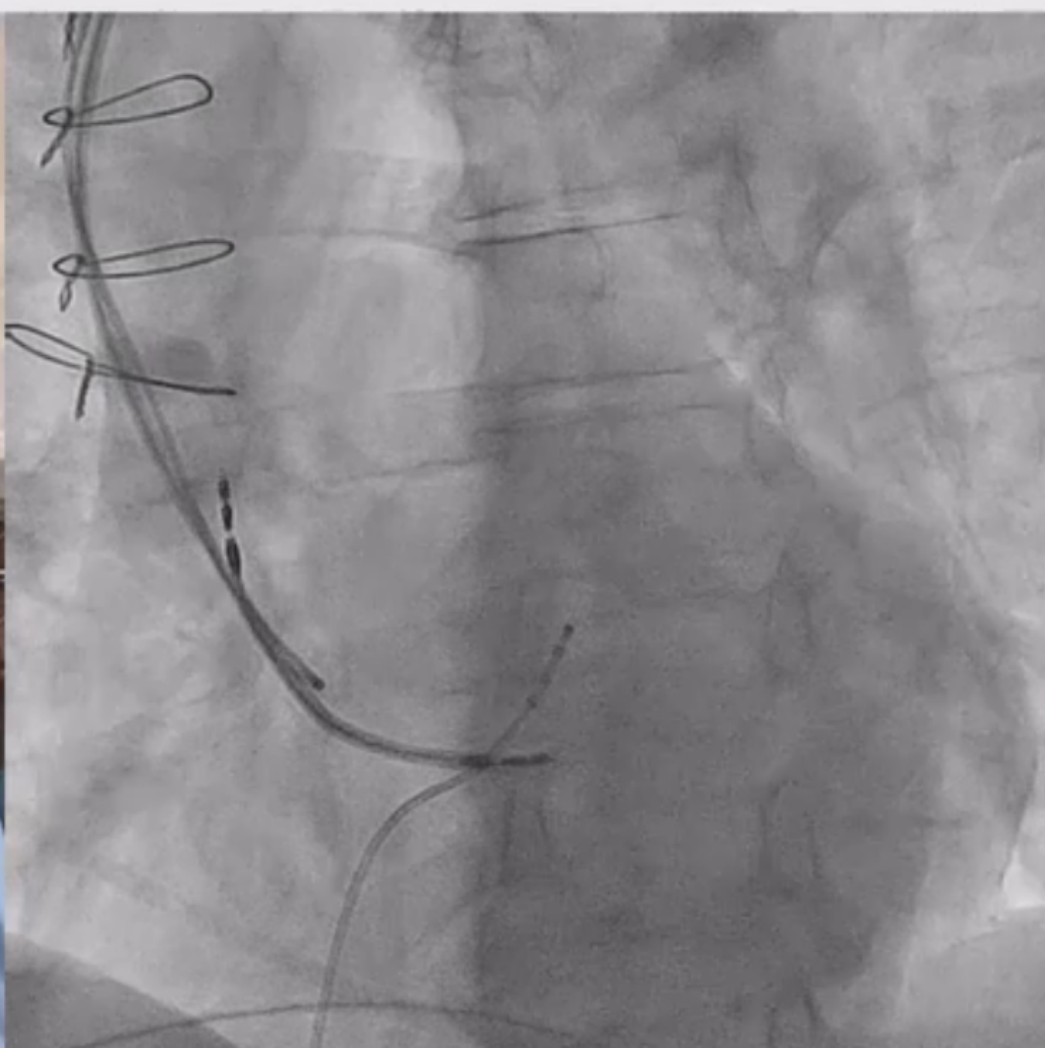


- Force is split into normal and tangential components
- Bending stress on lance
- Penetration difficult / Lance fracture risk

$$\vec{F}_n = F \cdot \sin \theta \rightarrow \vec{F}_t = F \cdot \cos \theta$$







◈ **SDL and LLL:**

- ◈ Support of lead against septum
- ◈ Coaxial outline of sheath and lead
- ◈ Initial fast rotations for easy advancement in septum (LBBAP)

◈ **For SDL:**

- ◈ Stylet advanced to tip of lead

◈ **For SDL with extendable helix:**

- ◈ Keep locking tool connected during implant

Lead designs used for CSP

- **Similarities** between SDL and LLL
 - Electrical active helix
 - Steroid coated helix or collar
 - Use of dedicated delivery sheaths
- **Differences** between SDL and LLL
 - Stylet versus no stylet
 - Lead body diameter (6,0 versus 4,1Fr)
 - Helix design:
 - Fixed versus retractable
 - Helix optimized for LBBAP
 - Helix length: 1,8 – 2,2 mm



From stylet-driven to lumenless leads: what changes in my conduction system pacing technique?



CSP lead designs in practice

- Obtaining successful CSP
- Maintaining stable CSP capture on long term
- Avoiding lead damage



Jan De Pooter
Belgium

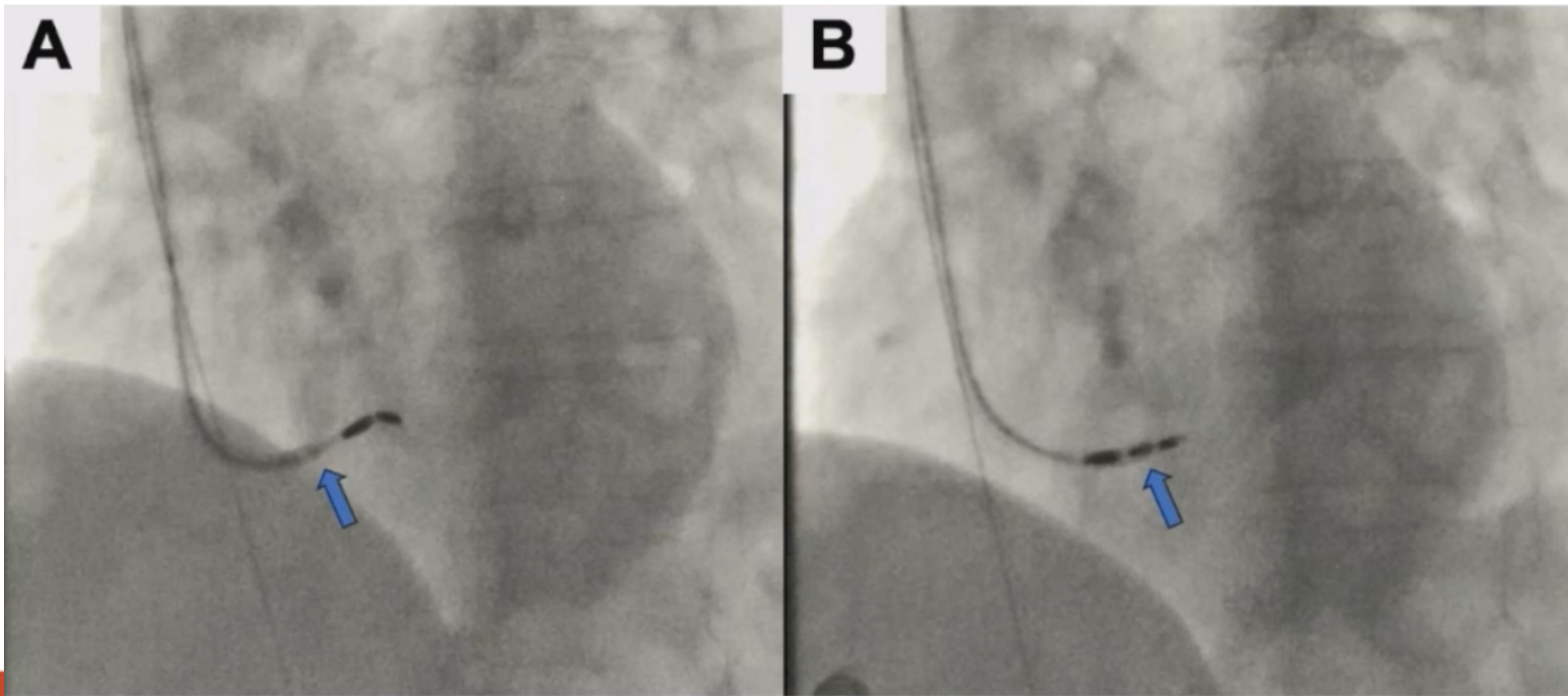


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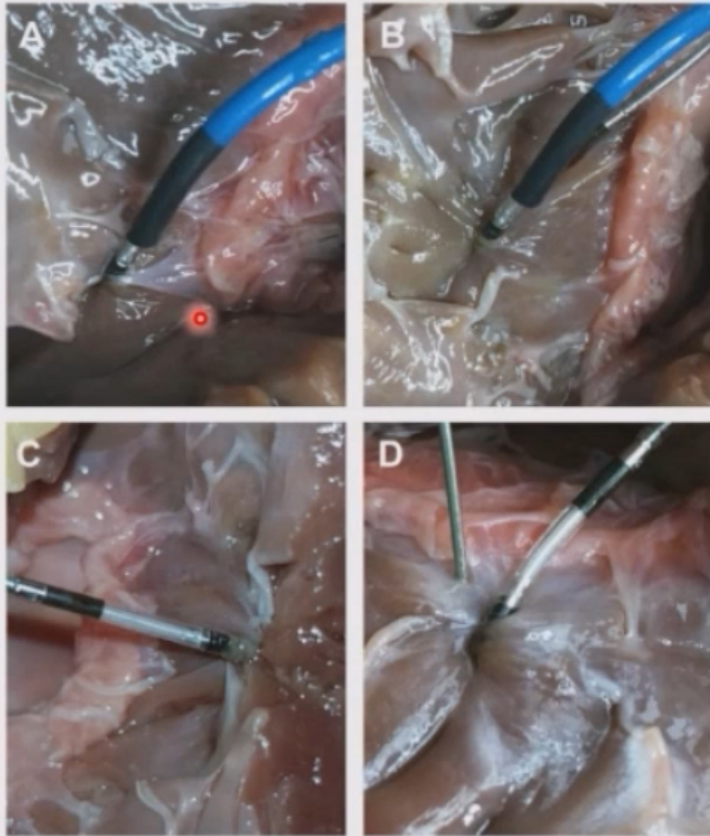
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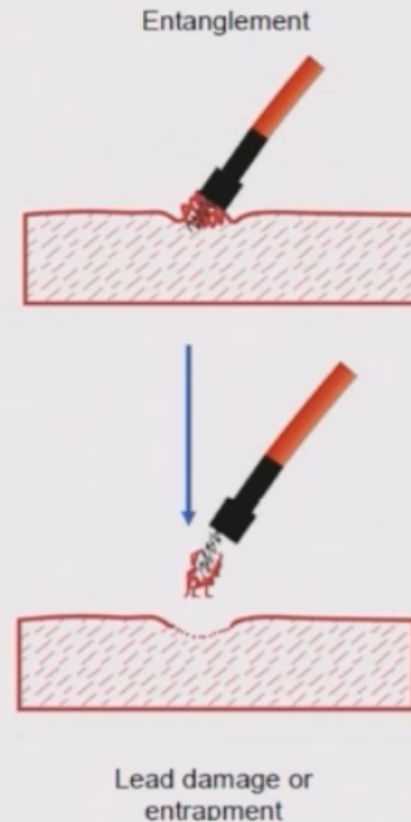
AVOIDING LEAD DAMAGE



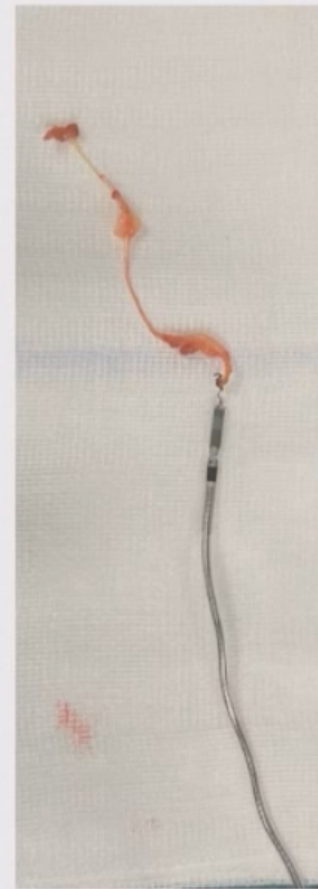
Avoiding lead damage: helix entanglement



Jastrzebski et al, Europace 2020



EHRA consensus paper on CSP Burri et al, 2023

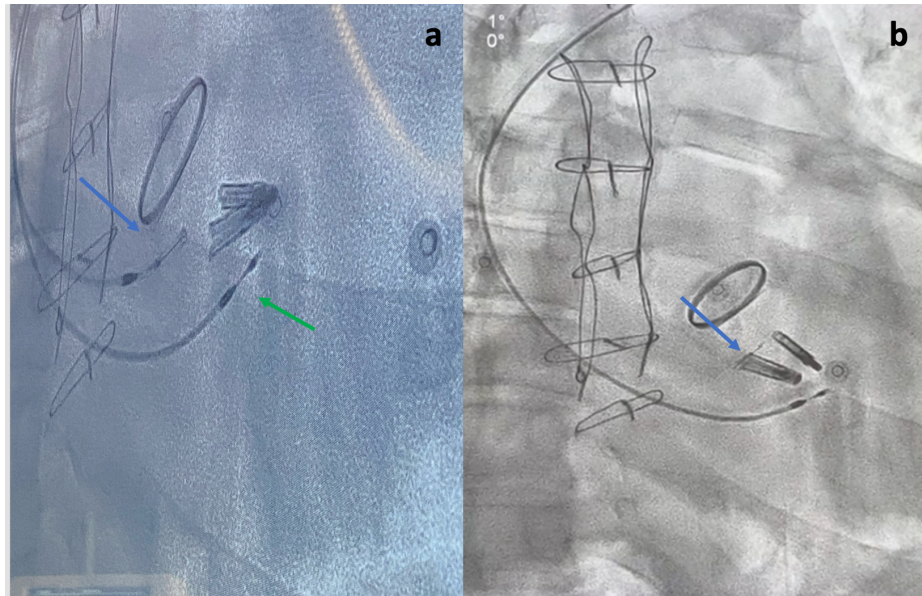


➤ How to avoid?

- Lead positioning with retracted helix or protected within sheath
- Fast rotations at initial screwing (LBBAP)
- Stop rotations if no septal penetration or significant torque build up (LBBAP), with HBP torque build up indicates proper fixation
- If entanglement, CCW (and CW) rotations with gentle traction usually untangles the lead (sometimes pulling needed)

Helix breakage during left bundle pacing area implantation

Amato Santoro MD¹ | Simone Taddeucci MD²



SANTORO and TADDEUCCI

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separated by an insulator. These leads are thicker and more non-isodiametric than lumenless leads (LLL) for LBBPa. The SDL allow a continuous monitoring of the pacing impedance in a unipolar mode without connecting and disconnecting the crocodiles as performed using LLL. This approach avoids repetitive connections and disconnections of the clamps, limits lead body rotation, and offers continuous unipolar pacing and reliable impedance monitoring during screwing. The impedance usually increases as it penetrates the right septum but reduces by 50–100 Ohm as it reaches the left septal border. The initial impedance parameter is essential to verify individual and sudden changes in impedance.¹ Screw incarceration is a potential pitfall when SDL are used.² Typically, when this occurs, counterclockwise rotations while holding the lead under tension can release the lead. In the presented case, a non-perpendicular deep septal penetration may be a major determinant in lead incarceration and subsequent helix damage in SDLs, but other factors, such as increased septal thickness (e.g., due to fibrosis), may have favored helix despiralization. Therefore, locking the screw system is essential. However, when rotating the outer lead body of the SDL, helix retraction may occur due to tissue fixation, causing the outer coil to turn over the inner coil. However, a custom-made fixation tool can be created by using an IS-1 lead-end cap.¹ The locking of the screw system was required. The absence of a locking system in the screwing system combined with inadequate perpendicular position of delivery probably caused a misalignment of the helix which was then damaged and subsequently broken.¹

Hence a schematic approach to perform a LBBPa using SDL is shown:

LLL.⁴ Currently, in our EP lab, we perform 4–5 conduction system pacing (CSP) implantation every week. This described helix fracture was obtained after 20 CSP implantation using SDL. This complication occurred after 15 implants of Ingevity+ lead; after this event, other 25 Ingevity+ lead was used to obtain a CSP without any complications. The complications are part of a learning curve, but their analysis and description allow technical modifications to reduce the incidence of further similar complications.

In conclusion, the use of SDL for LBBPa is safe and feasible. Rarely some potential acute complications such as septal perforation, micro or macroscopic lead dislodgment and lead damage could occur; it is also related to EP lab experience.⁴ In this paper, we reported a rare case of helix despiralization and subsequent rupture of the helix, that was abandoned into the septum.

A rigorous lead placement approach and careful repositioning maneuvers during LBBPa procedures, could reduce the risk of intraprocedural complications during challenging lead placements.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

Research data are not shared.

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Helix retraction with SDL

Avoiding helix retraction with SDL

➤ Locking tools to avoid helix retraction

➤ Stylet insertion tool (Biotronik)

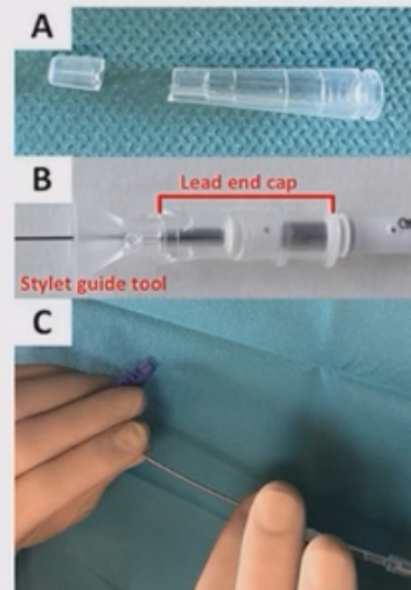
- Fixation on silicon sealing prevents helix retraction
- Often combined with pretensioning of inner coil (more grip between inner and outer coil)



© BIOTRONIK

- Stylet guides can be sterilized and reused interchangeably among manufactures

➤ Cut lead end cap



De Pooter et al: Front in CV med, 2022

➤ Dedicated helix locking tools

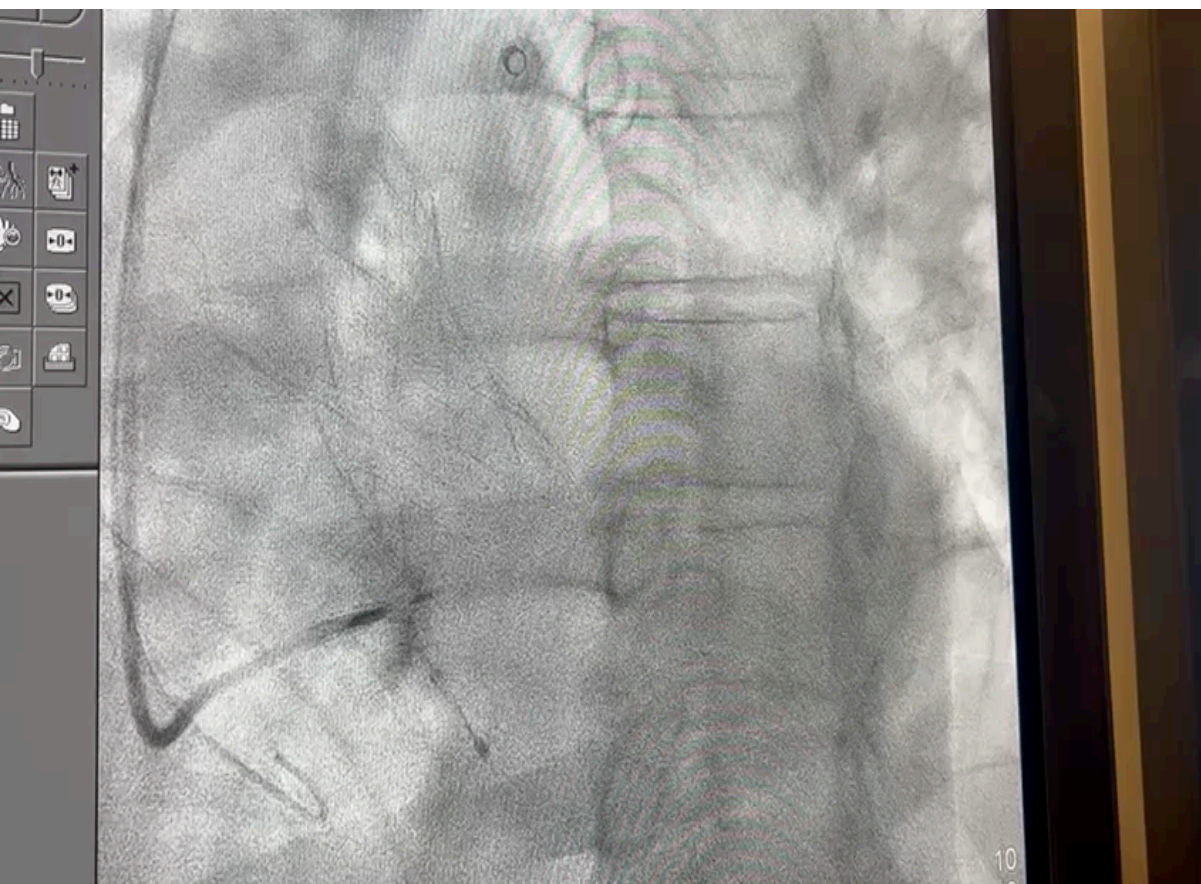


Abbott

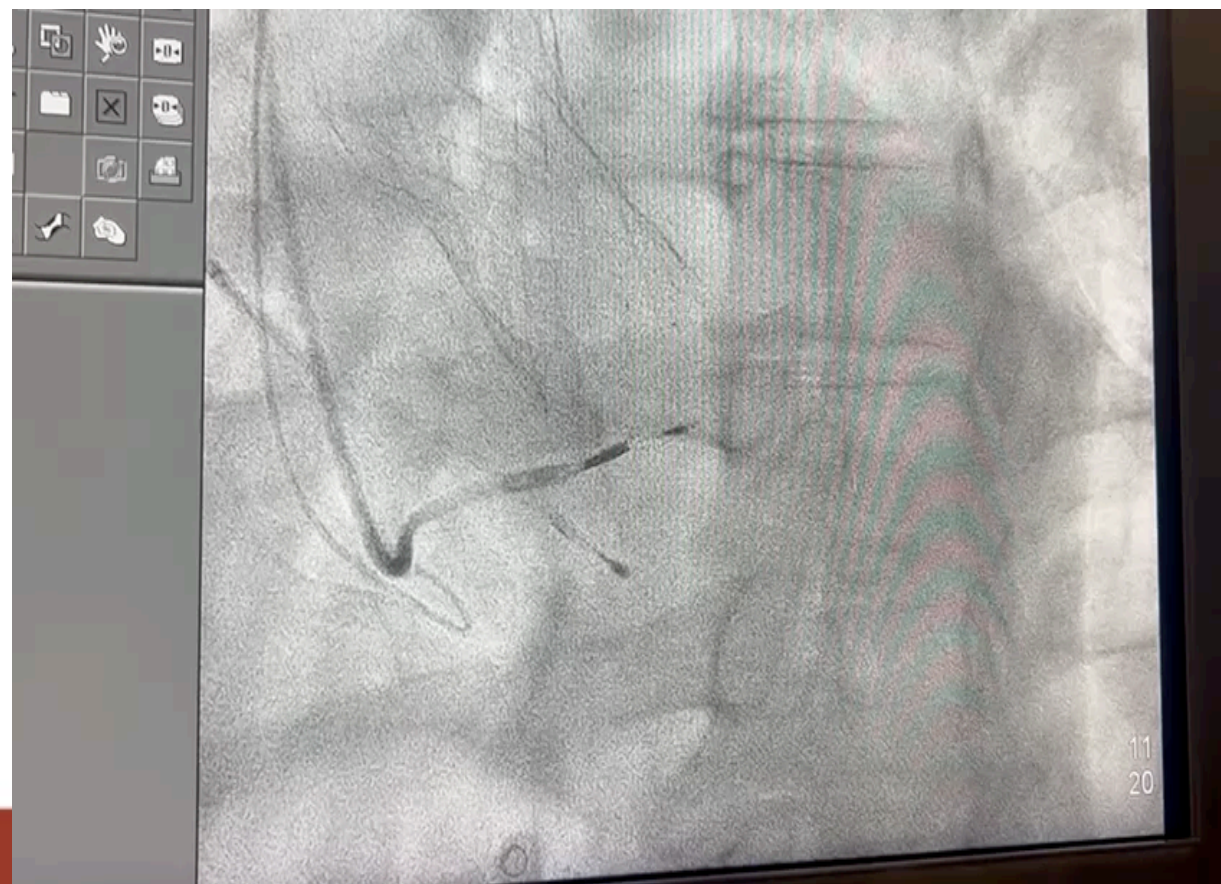


Boston Scientific

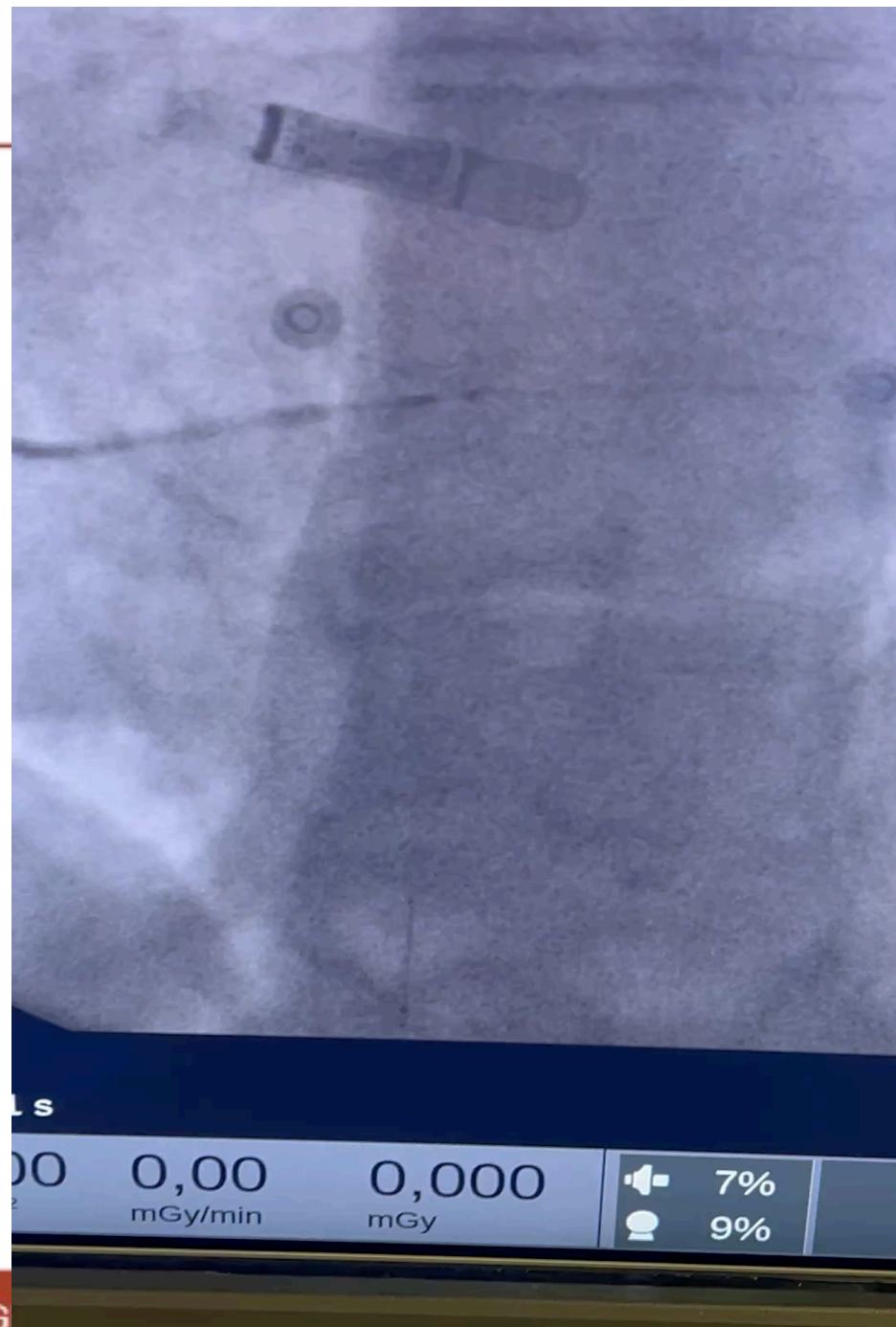
Lumenless non allineato



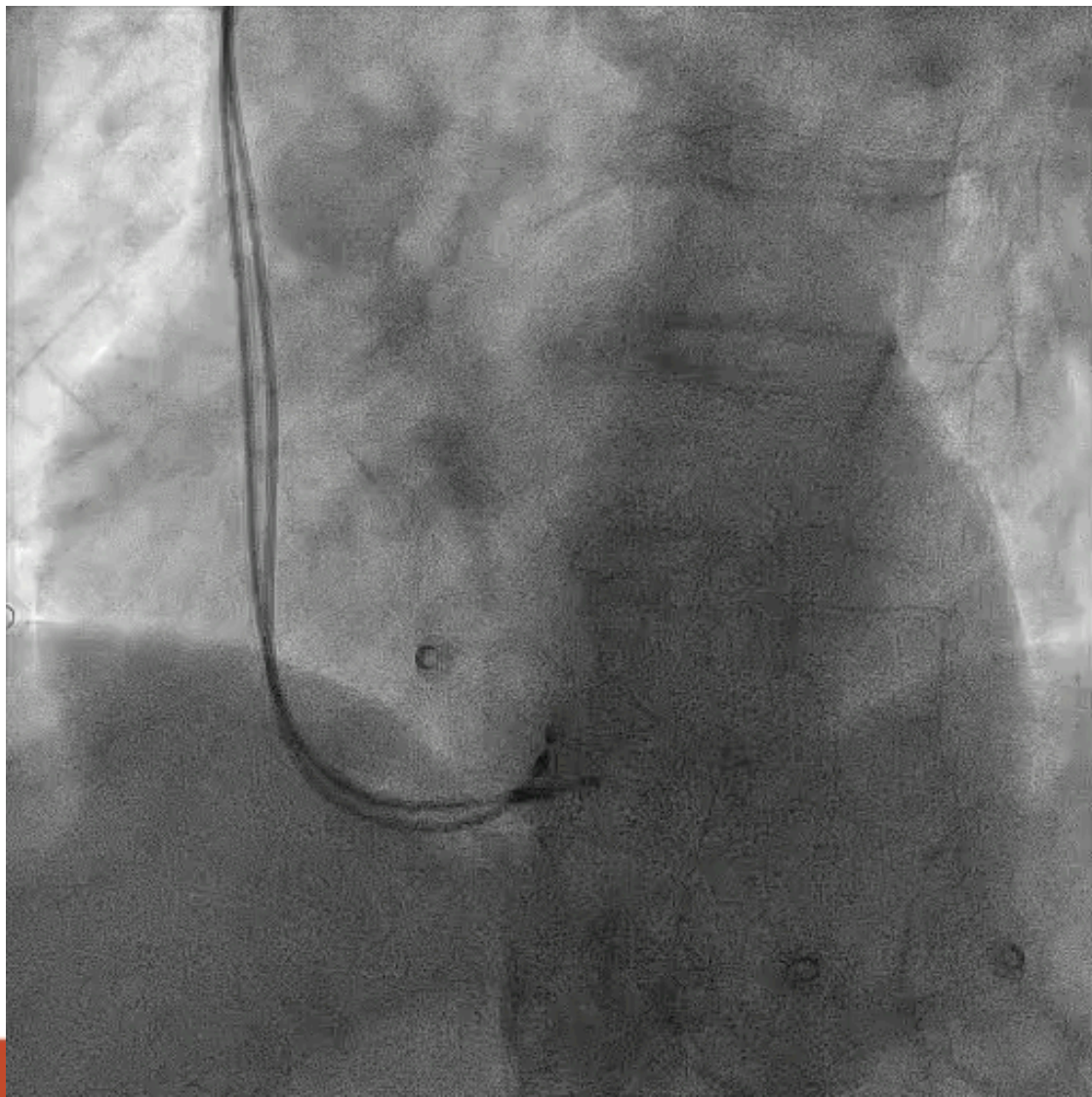
Lumenless a contatto e perpendicolare stesso caso

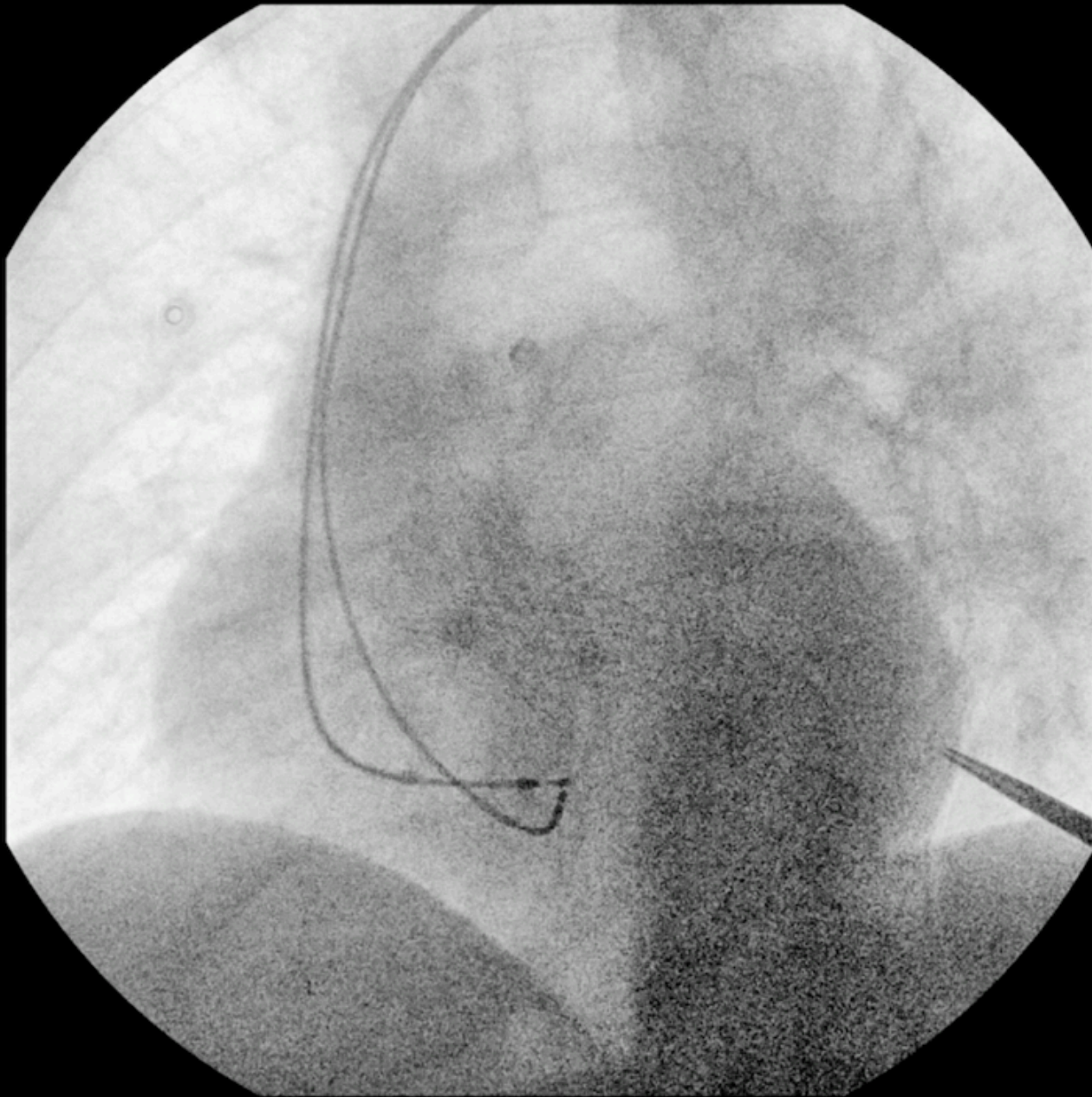


C320LBB (round wire)



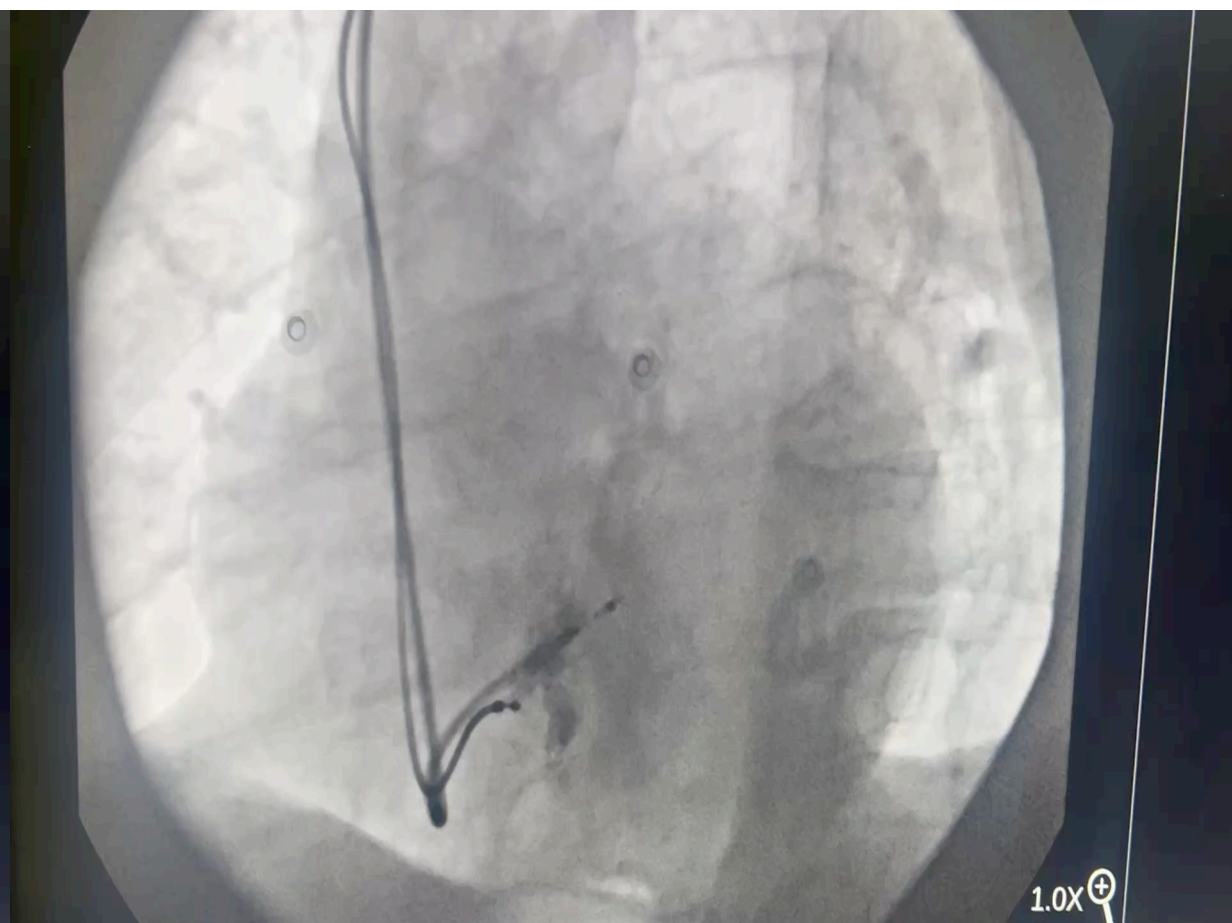
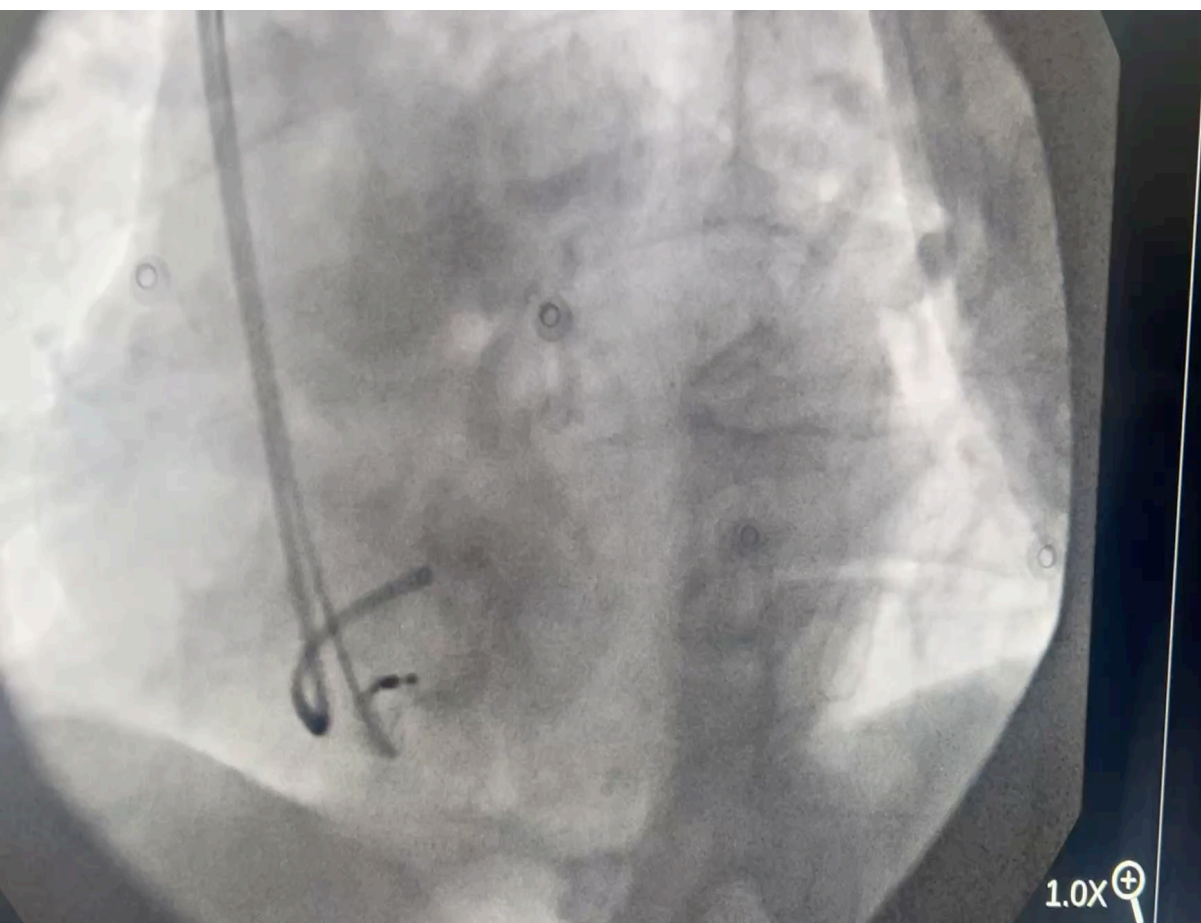
Perpendicolarità atrio normale





Ricerca della perpendicolarità





Avoiding lead damage: lead fracture

Study design (LIFE-LBBAP)

Multicenter registry: 17 centers

 8255 patients with successful LBBAP

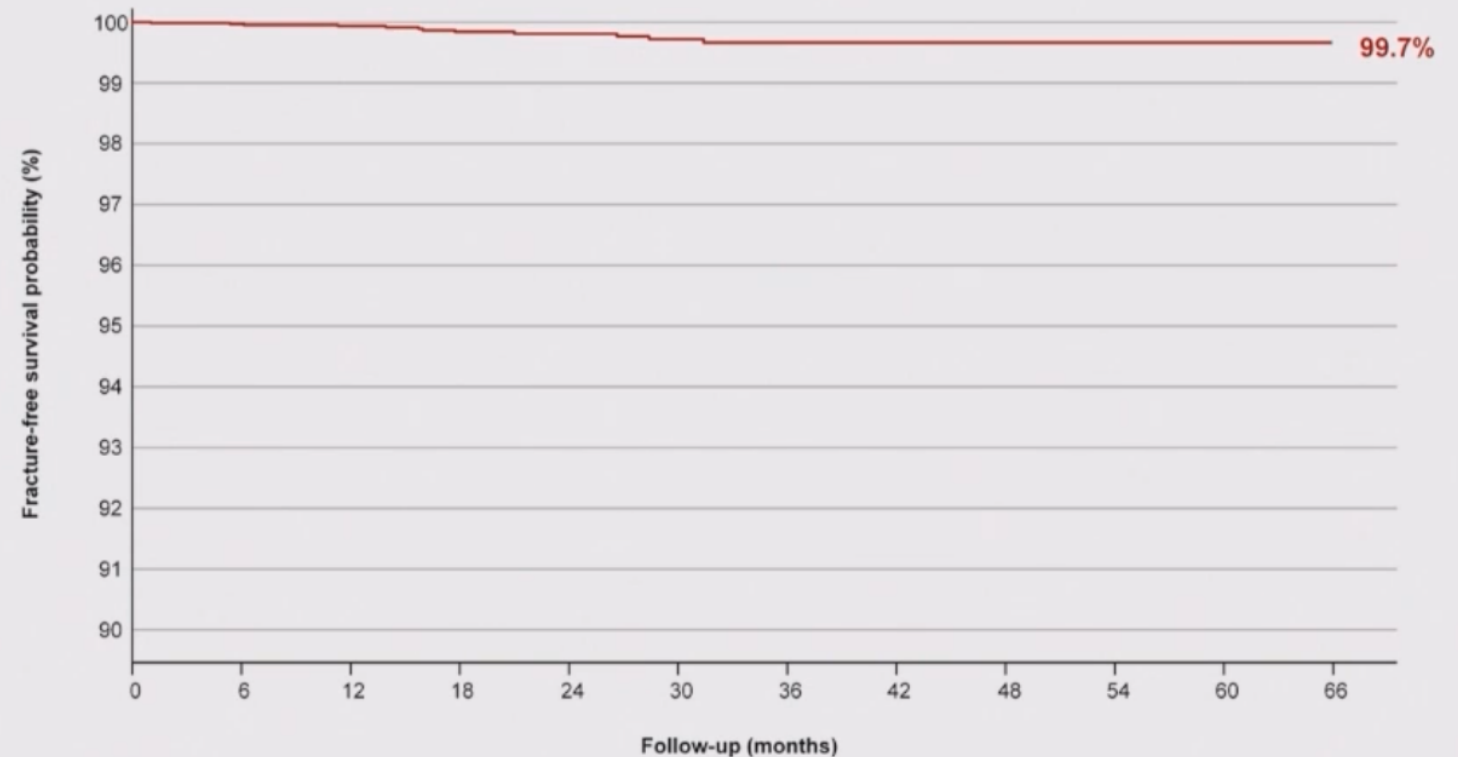
Median follow up: 16.4 [6.4:28.8] months

Endpoint

LBBAP lead failure (lead fracture or insulation defects)

Results

OVERALL LEAD SURVIVAL PROBABILITY



No. at risk	8255	6278	5151	3786	2746	1928	1152	672	362	155	40	1
-------------	------	------	------	------	------	------	------	-----	-----	-----	----	---

➔ 8255 leads in LBBAP position

➔ Type of leads:

➔ LLL: 5609

➔ SDL: 2646

➔ Solia S: 2342

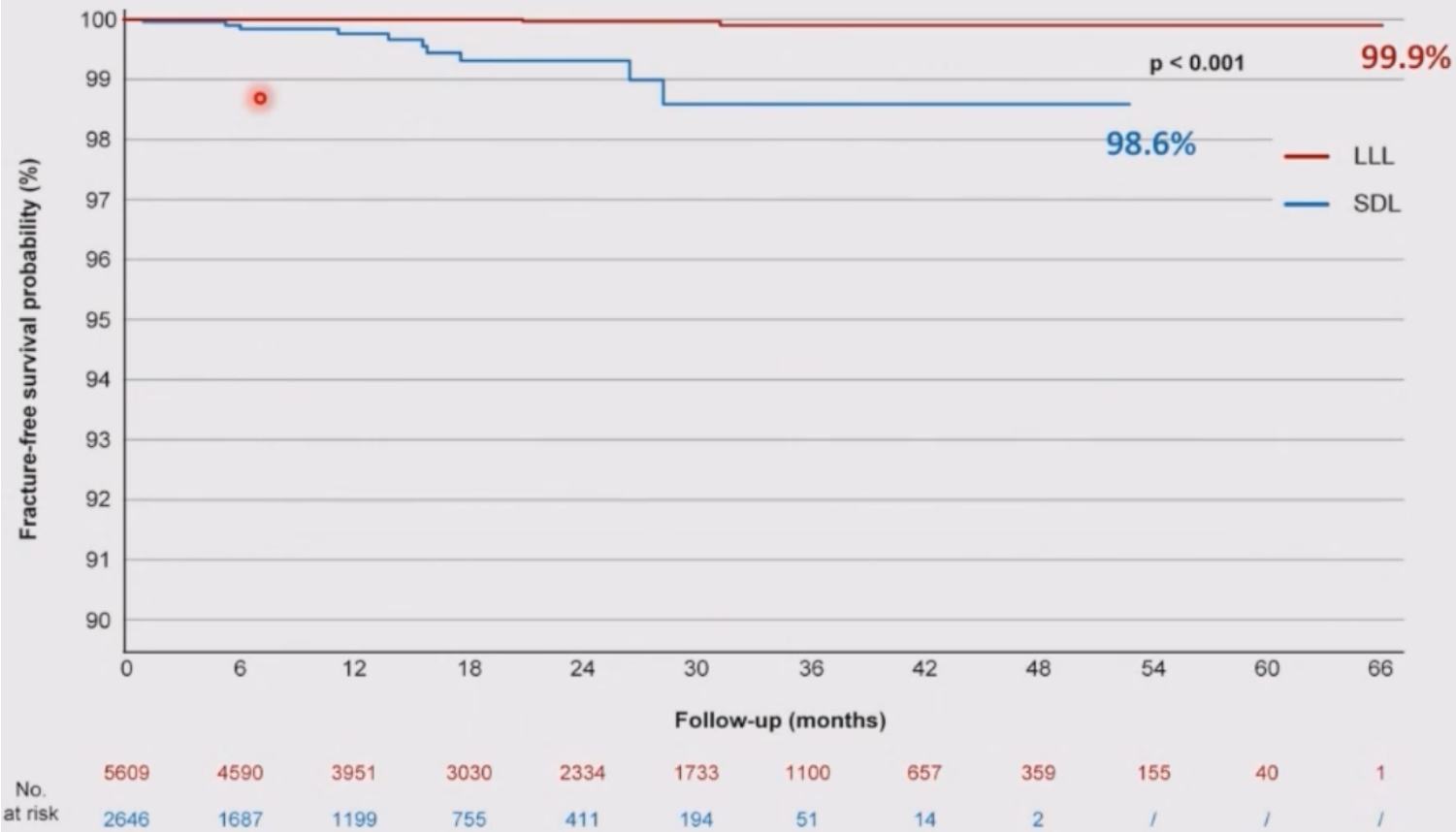
➔ Tendril: 184

➔ Ingevity: 185

➔ Vega: 8

LIFE-LBBAP: Lead Integrity and Failure Evaluation in LBBAP

➡ SDL versus LLL lead performance



Lead Integrity and Failure in Left Bundle Branch A
The LIFE-LBBAP Study

Jan De Pooter, MD, PhD,^a Alexander Breitenstein, MD, PhD,^b
Daniel Hofer, MD,^c Jean-Benoit Le Polain de Waroux, MD, F
So-Ryoung Lee, MD, PhD,^d Young Jun Park, MD,^e Michael C
Dipen Zalavadia, MD,^f Heli Tolppanen, MD, PhD,^g David Ziz
Lina Marcantoni, MD,^h Shunmuga Sundaram Ponnusamy, M
Marek Jastrzebski, MD, PhD,ⁱ Pugazhendhi Vijayaraman, MD

TABLE 1 Baseline Patient Demo
Lead Type (N = 8,255)

Baseline patient characteristics

Age, y
Female

Pacing indication

Sick sinus
Atrioventricular block
Heart failure
Other

Lead type

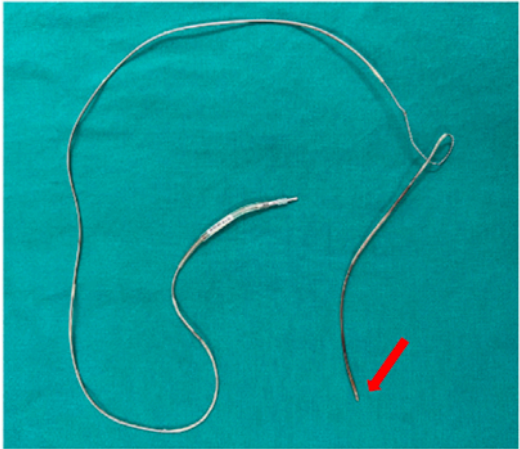
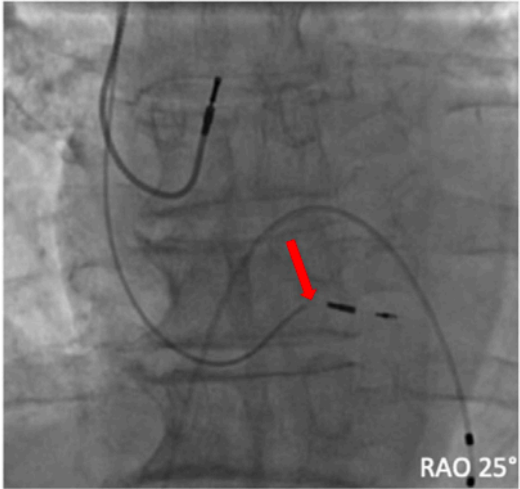
Lumenless pacing lead
SelectSecure 3830 (Medtronic)
Stylet-driven pacing lead
Solia S (Biotronik)
Tendril (Abbott)
Ingevity (Boston Scientific)
Vega (MicroPort)

Implant characteristics

LBBAP capture response
(EHRA definition) (n = 2,584, 3
LBBP
LVSP
Screw attempts (n = 2,456, 29.8
Implant depth mm (n = 1,172, 14

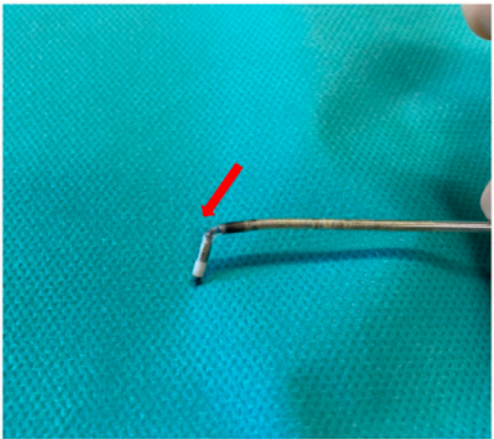
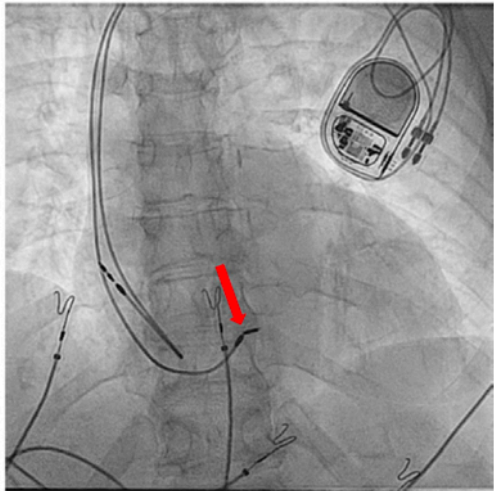
Values are mean ± SD or n (%). EHRA =
consensus document on conduction syst
EHRA = European Heart Rhythm Associ
pacing; LBBP = left bundle branch pacin

Location of Lead fractures with LLL LBBAP



SelectSecure 3830, Medtronic

Location of Lead fractures with SDL LBBAP



Solia S60, Biotronik

Examples of LBBAP lead fractures. (Left) LLLs presented with fractures proximal of the ring electrode. On extraction, the distal lead end broke proximal of the ring electrode and the distal lead fragment was retained in the septum. (Right) Fractures with SDLs originated in the interelectrode segment. Figures reproduced with permission from Rangaswamy et al.¹⁴ RAO = right anterior oblique; other abbreviations as in Figures 1 and 2.

New LBBAP Attempt	New LBBAP Successful
1	1
1	1
1	1
1	1
0	NA
0	NA
1	1
0	NA
0	NA
0	NA
1	0

Mechanical Principles of Lead Behavior

TABLE 3 Lead Fracture Characteristics

Fracture Case	Lead Type	Center	Implant (n/n)	Sex	Age (y)	Pacing Indication	Screw Attempts (n)	Implant Depth (mm)	Time to Fracture (mo)
1	SDL	9	136/513	F	75	AVB	1	11	6
2	LLL	10	164/1833	M	70	HF	/	/	21
3	SDL	9	153/513	M	70	AVB	/	/	18
4	SDL	11	72/295	M	66	HF	4	7	16
5	SDL	6	10/104	M	71	AVB	/	/	16
6	LLL	15	191/608	M	75	AVB	5	9	31
7	SDL	8	272/415	F	54	AVB	1	/	1
8	SDL	3	8/207	M	78	AVB	1	/	27
9	SDL	6	52/104	M	/	SS	/	/	11
10	SDL	5	80/99	F	79	AVB	4	11	5
11	SDL	7	55/133	M	53	AVB	/	/	14
12	SDL	9	176/513	M	79	AVB	2	14	28

/ = unknown; LOC = loss of capture; AVB = atrioventricular block; HF = heart failure; HVR = high ventricular rates; HVR = high ventricular rates; SS = sick sinus; other abbreviations as in Tables 1 and 2.

In the LIFE-LBBAP study, mean implantation depth was approximately 12 mm (range ~7–14 mm), but no relationship between depth and lead fracture was demonstrated.

◆ If too shallow

- The lead is poorly anchored
- The septal entry point becomes highly mobile
- ↑ cyclic bending
- ↑ fatigue at the segment proximal to the ring

◆ If adequately deep (≈ 12–14 mm range)

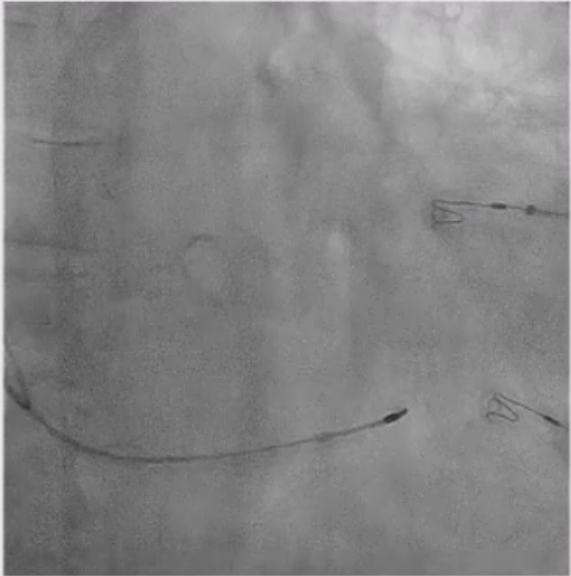
- More of the lead is “embedded” within the septum
- Reduced relative motion above the entry point
- ↓ cyclic stress

◆ If too deep

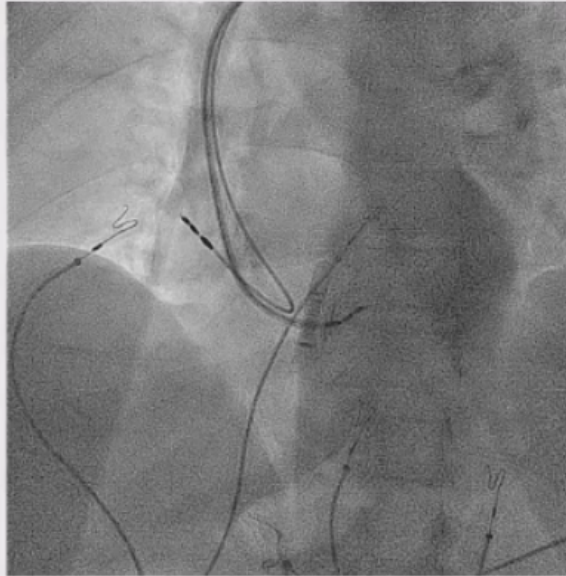
- Increased implantation-related stress
- Higher risk of structural damage
- Potential increase in local mechanical stress

Not all leads are the same, but all of them can kink against the septum

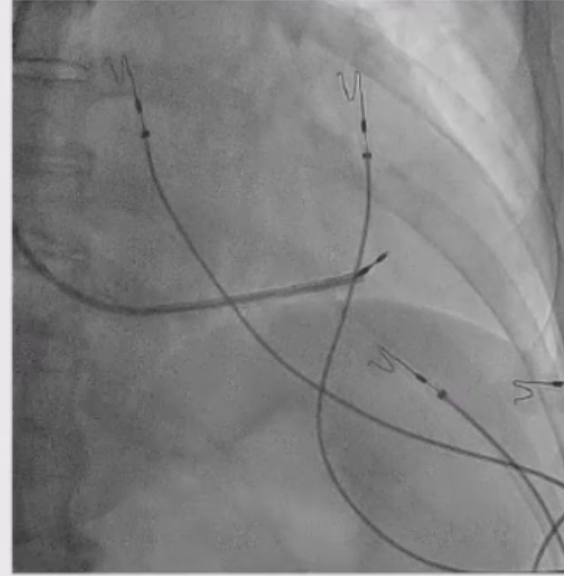
Ingevity, Boston



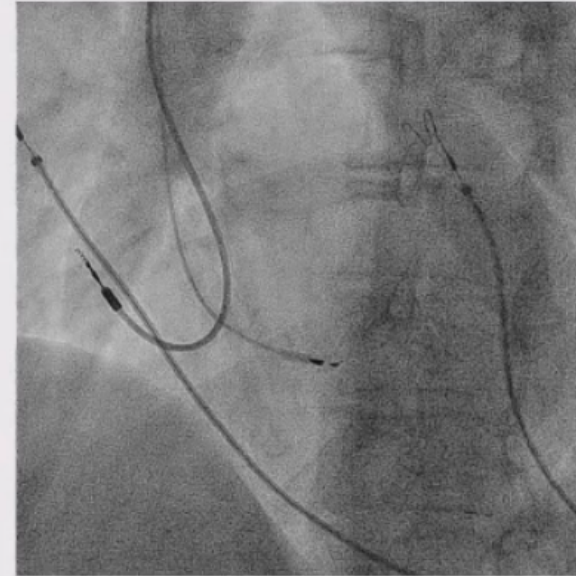
SoliaS, Biotronik



Tendril, Abbott



SelectSecure, Medtronic



• Kinked interelectrode segment

• Kinked interelectrode segment

• Kinked lead segment proximal of ring electrode

• Kinked lead segment proximal of ring electrode

Avoid lead kinking during LBBAP



Lead performance of stylet-driven leads in left bundle branch area pacing: Results from a large single-center cohort and insights from *in vitro* bench testing

Ermine Özpak, MD, Frederic Van Heuverswyn, MD, Frank Timmermans, MD, PhD,
Jan De Pooter, MD, PhD

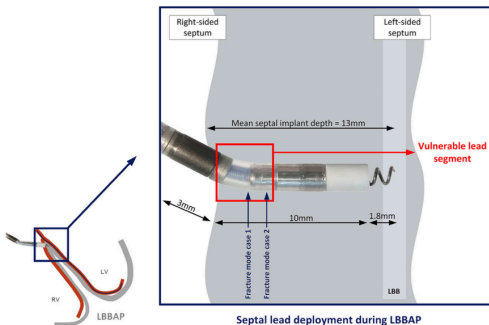


Figure 2
Septal lead deployment during left bundle branch area pacing (LBBAP) and areas of early conductor fracture. LV = left ventricle; RV = right ventricle.

Lead bending angulation

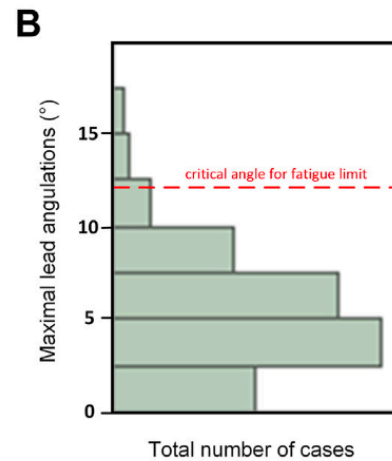
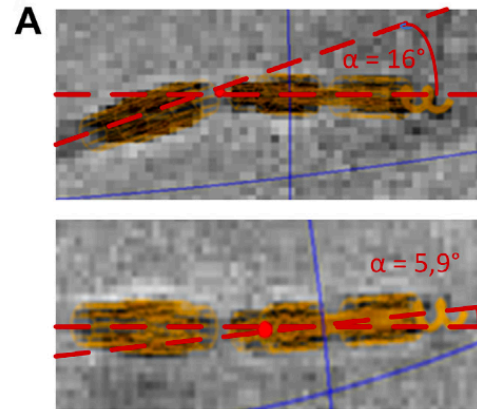
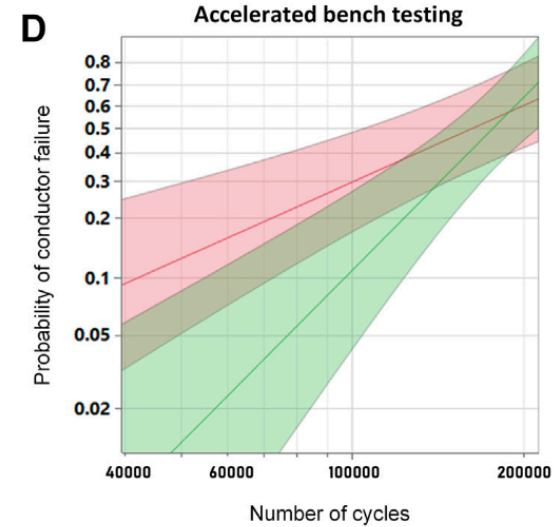
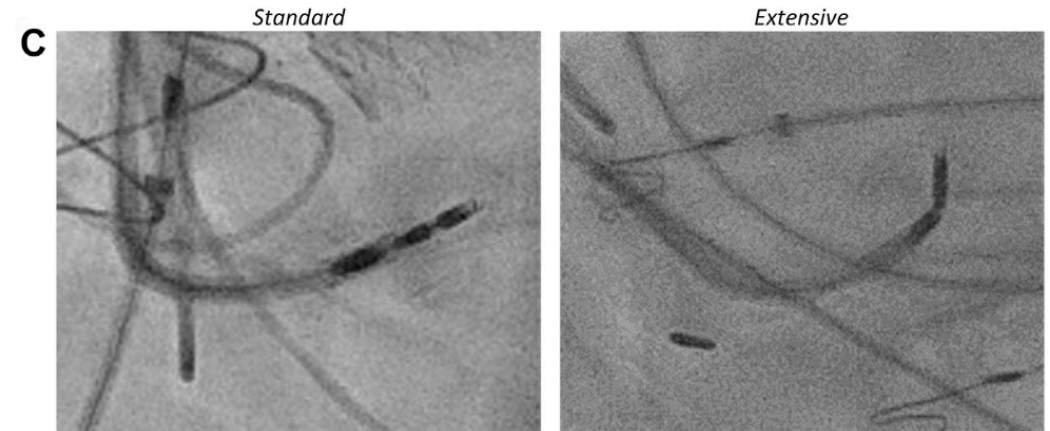


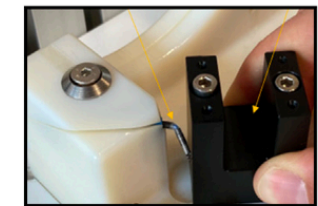
Figure 3

In vitro analysis of stylet-driven leads for left bundle branch area pacing (LBBAP). **A:** Two examples of measuring maximum lead angulation (α) in fluoroscopic views. **B:** Bar chart of the maximum angles of the analyzed patient pool. Dotted red line indicates the critical angle of 12° for fatigue failure limit. **C:** Fluoroscopic images of standard preconditioning during implantation (left) vs extensive preconditioning by rotating the lead while the lead tip is kinked against the septum (right). **D:** Weibull curve of accelerated fatigue fracture testing of standard (green) vs extensive (red) preconditioned leads.

Lead preconditioning modes during LBBAP



Standard preconditioning
Extensive preconditioning





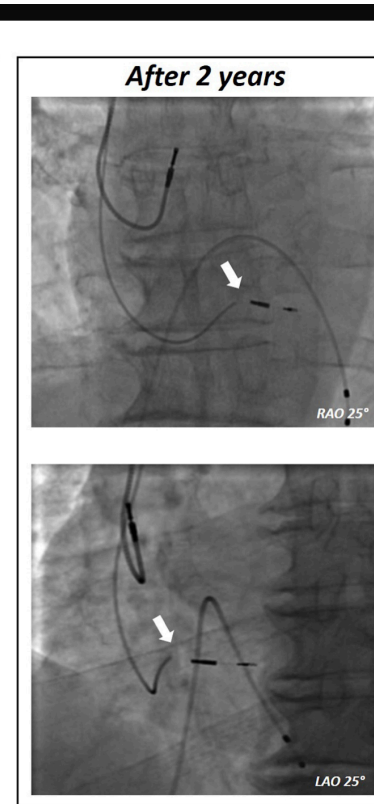
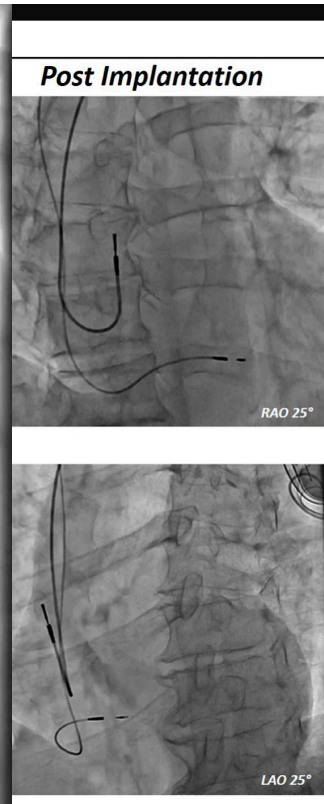
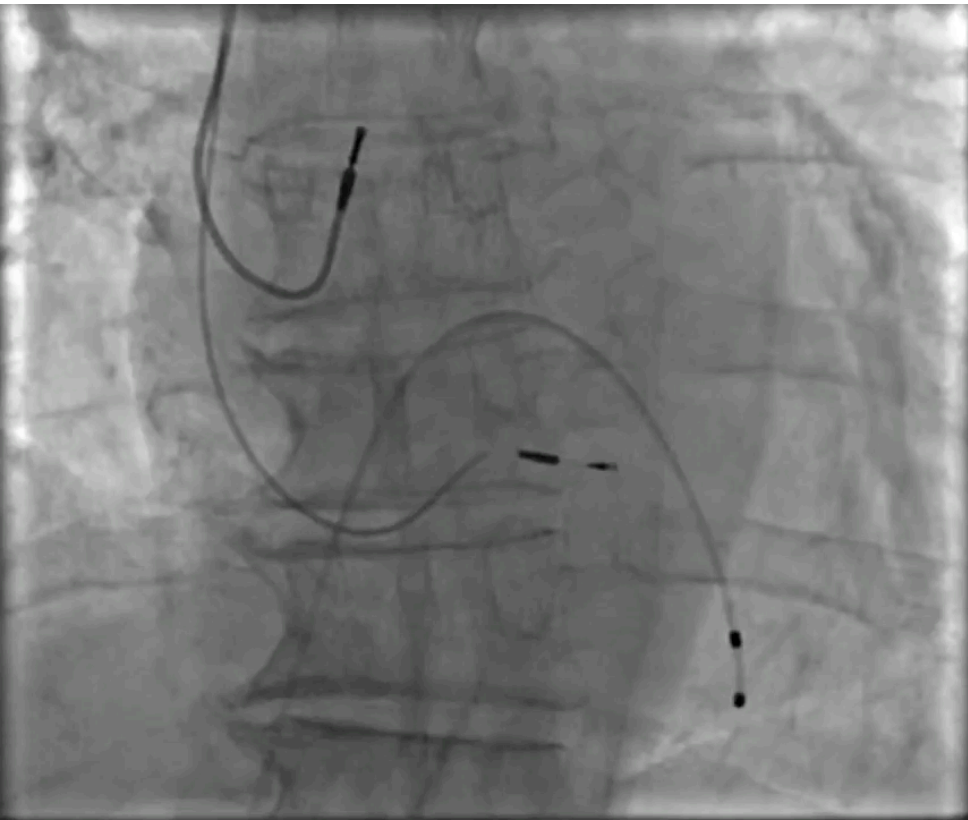
Image

Late distal conductor fracture of the lumenless pacing lead after left bundle branch area pacing

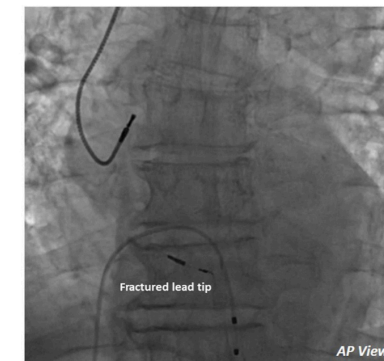
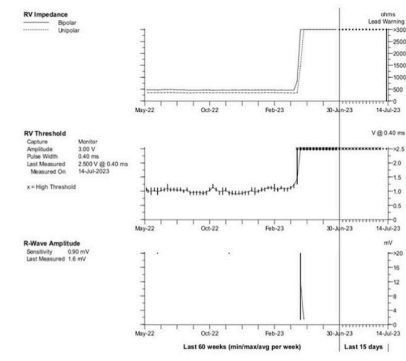
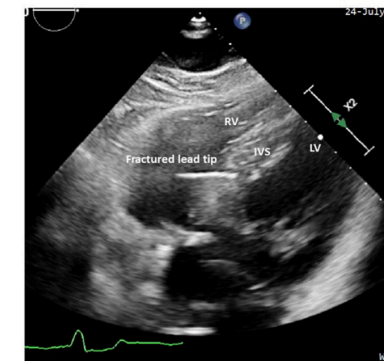
Vickram Vignesh Rangaswamy, MD, DM,¹ Shunmuga Sundaram Ponnusamy, MD, DM, CEPS²

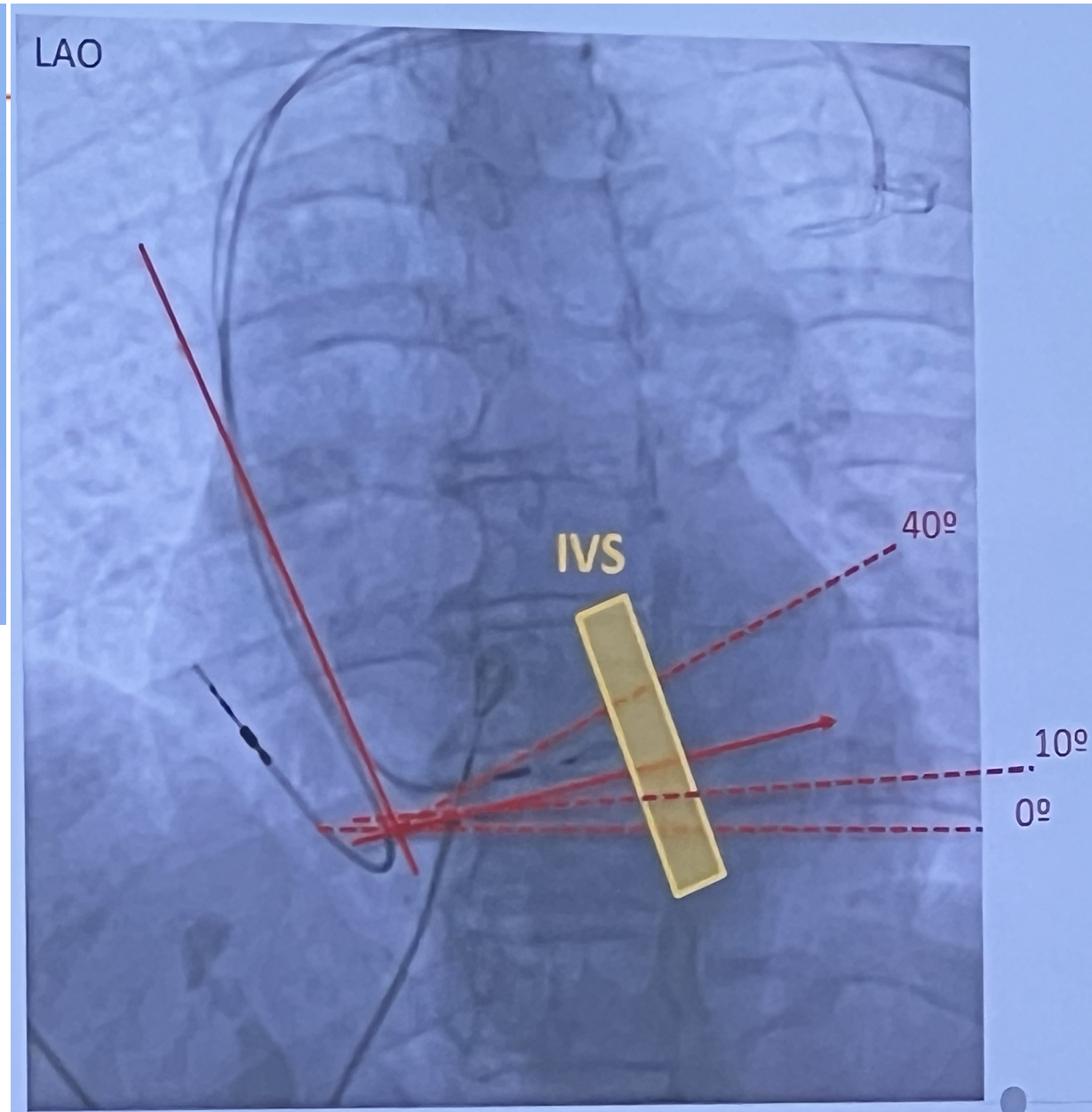
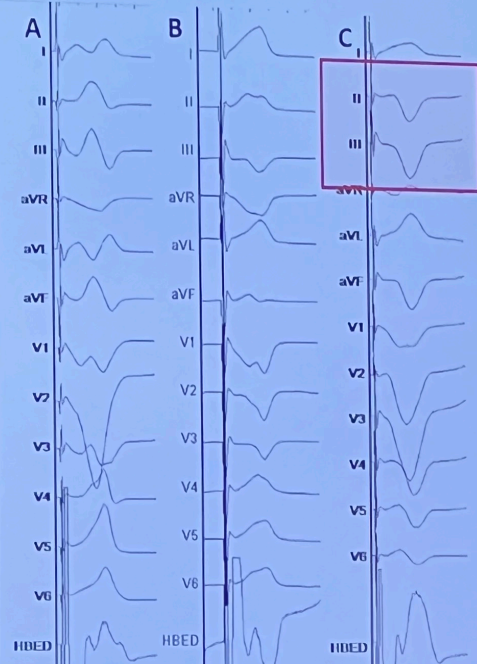
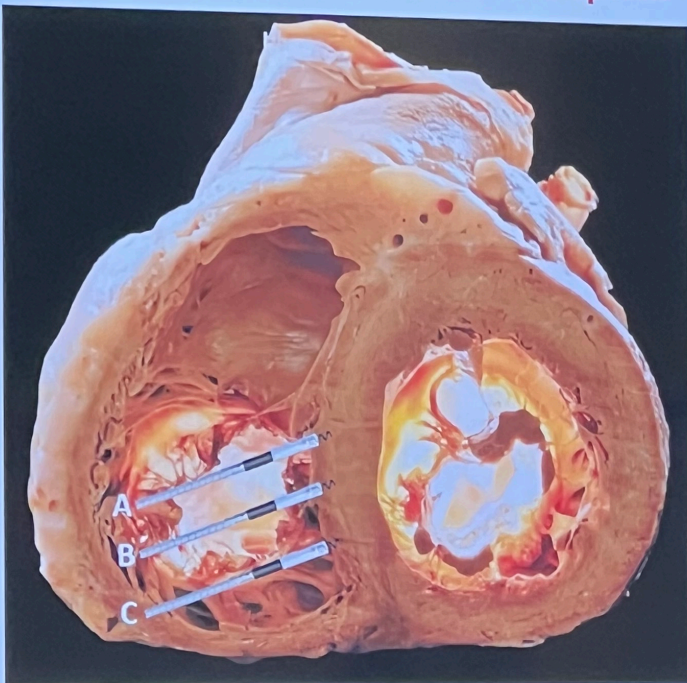
KEYWORDS Left bundle branch area pacing; Lumenless pacing lead; Distal conductor fracture

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B





- ✓ MOVE TO LAO 20-35°
- ✓ SHEATH PERPENDICULAR TO IVS
- ✓ CONTRAST INJECTION MAY HELP

Point/Counterpoint

Conduction system pacing for pacing-induced cardiomyopathy: Could the cure be worse than the ill?

Ernest W. Lau, MD,¹ Hendrik Bonnemeier, MD, PhD,^{2,3,4} Benito Baldauf, MD^{3,4}

See related article on page 458

KEYWORDS Pacing-induced cardiomyopathy; Conduction system pacing; His bundle pacing; Left bundle area pacing; Lead-related tricuspid valve dysfunction; Accelerated conduction fracture; Fixation helix deformation/damage; Left bundle branch origin pacing; Multiorthogonal-planar deflectable catheters; Long fixation helix

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Introduction

Primum non nocere (First do no harm)

Conduction system pacing (CSP) aims to replicate physiological activation of the ventricles by artificial stimulation, so as to mitigate, if not obviate, the harm of pacing-induced cardiomyopathy (PICM),^{1–4} which could affect both the left ventricle (LV) and right ventricle (RV).⁵ Cardiac resynchronization therapy (CRT) ameliorates but does not eliminate the deleterious effects of conventional (apical or septal) RV pacing.^{6,7} Thus, components of the atrioventricular (AV) conduction axis were explored for CSP. Early attempts at His bundle pacing (HBP) were met with procedural difficulty and suboptimal outcomes.^{8–15} Left bundle branch (LBB) area pacing (LBBAP) soon overtook HBP as the dominant mode of CSP by virtue of its procedural ease and acceptable short- to medium-term outcomes.^{16–18} However, LBBAP can be technically challenging and unsuccessful owing to difficulty in advancing the fixation helix and its housing through almost the entire thickness of the interventricular (IV) septum (IVS) and may result in significant complications.^{19–22} Although LBBAP is poised to become the default for ventricular pacing^{18,23} because of the prevalence, severity, and unpredictability of PICM,^{1–4,24–26} any headlong embrace of LBBAP might be premature at this stage and store up major problems in years to come. Apart from the known acute and short-term complications, LBBAP might generate other severe but less well-characterized delayed harms such as lead-related tricuspid valve (TV) dysfunction^{27–29} and accelerated conduction fracture near the lead

tip.^{30,31} This article reviews the clinical burden of PICM, specific risks of LBBAP, limitations in the tools currently available for CSP, and an alternative paradigm of pacing the LBB origin through the membranous septum (MS) from the right atrium (RA) and the specific tools required.

PICM

Prevalence

The prevalence of PICM depends on definitions and surveillance. PICM is generally defined in terms of low (eg, <50%) or reduced (eg, by ≥10%) LV ejection fraction (LVEF), and different threshold values yield different estimates (5.9%–39%; ≈20%).^{32–35} PICM might be underdetected owing to inadequate surveillance, subthreshold LVEF deterioration, and exclusion of other modes of LV dysfunction^{36–38} from the diagnostic criteria. The RV could also develop PICM (22% new RV dysfunction within 29 months of RV pacing).⁵

Clinical severity

The harm of PICM extends beyond mere deterioration in LVEF or imaging parameters.³⁹ Conventional RV pacing is associated with increased risks of heart failure (HF) (10.6% with vs 6.7% without RV pacing within 2 years⁴⁰; 26% with >90% RV pacing after a median follow-up of 7.8 years⁴¹), atrial fibrillation (17.5% and 23.3% in dual-chamber pacing with long and short AV delays vs 7.4% in single-chamber RA pacing over 2.9 ± 1.1 years⁴²; 12.7% vs 7.9% in dual-chamber pacing without and with ventricular pacing minimization over 1.7 ±

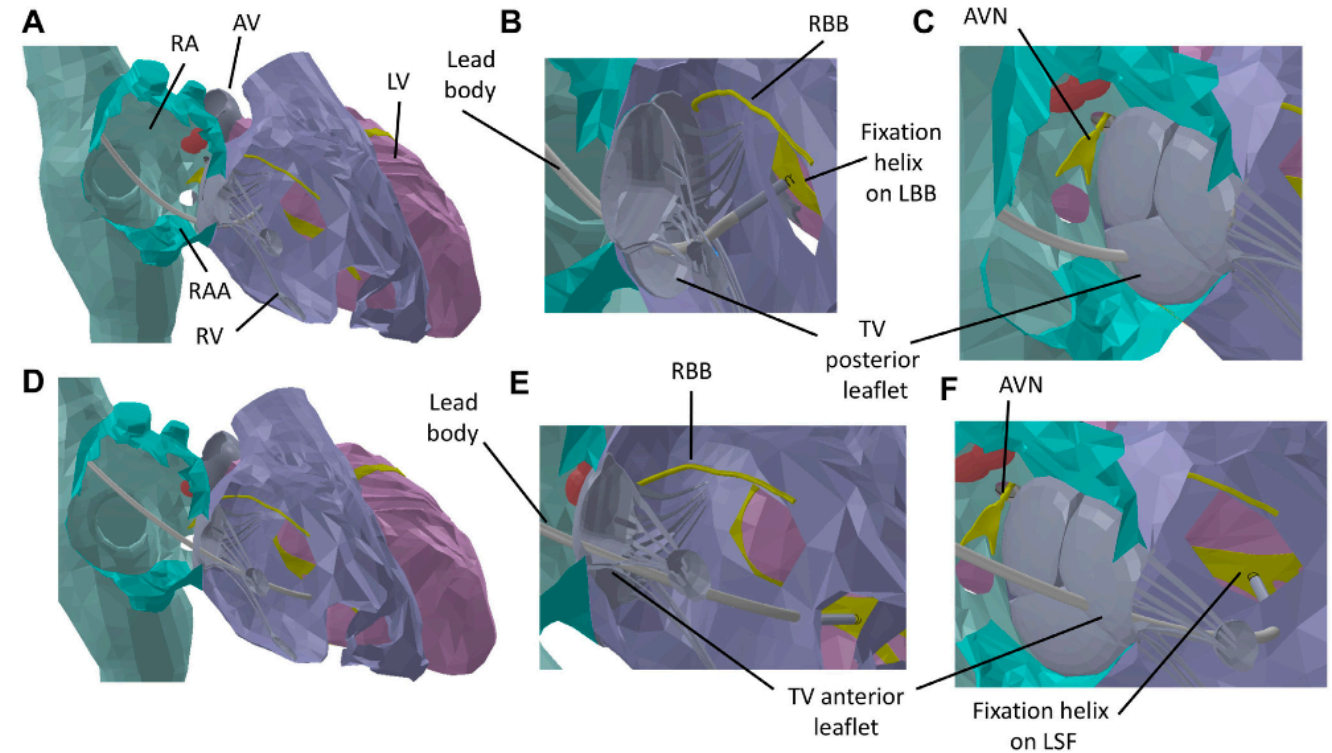


Figure 1

Simulated LBB area pacing on reconstructed 3D anatomic model of the human heart. The 3D heart model was modified from a commercially available version intended for 3D printing. The AV conduction axis comprising the AVN, RBB, LBB, LSF, etc, were added by the authors based on dimensions and positions of the structures described in the medical literature (Table 2).^{73–76} Only the endocardial surfaces of the RA, RAA, RV, LV, papillary muscles, and TV are shown. The heart has been opened up in a modified coronal section to illustrate the key points. A: A lead implanted in the LBB close to the TV annulus approaches the RV endocardial surface almost perpendicularly. The TV septal leaflet and its chordae could be interfered with or damaged by the lead. B and C: A magnified view shows the fixation helix on the LBB in the LV subendocardium with the rigid segment of the lead spanning the rest of the interventricular septal thickness. The lead body is forced to take a near right-angle bend (the “fulcrum” sign) to reach the RA, impinging on the TV posterior leaflet. The TV posterior leaflet abrades against the lead body and might damage its insulation. Alternatively, the lead could cut into the TV posterior leaflet through abrasion (especially if it is covered by a metal shock coil and not polymer insulation) and subsequently become sealed over by fibrous tissues, giving the false impression of leaflet perforation by the lead. The lead effectively becomes embedded in the TV, causing severe TV dysfunction. Removing the embedded lead will likely “destroy” the TV. The sharp bend at the lead-endocardium interface provides a high baseline stress that would accelerate fatigue fracture for any amplitude of cyclic stress. D: A lead implanted into the LSF further away from the TV annulus but still approaches the RV endocardial surface almost perpendicularly. Whether any of the LBB fascicles would be hit by the fixation helix deploying from the RV endocardial surface could only be haphazard without electrophysiological and anatomic mapping of the fascicular potentials. E and F: As for panels B and C, but the anterior rather than the posterior leaflet of the TV is affected by the lead. AV = atrioventricular; AVN = atrioventricular node; LBB = left bundle branch; LSF = left septal fascicle; LV = left ventricle; RA = right atrium; RAA = right atrial appendage; RBB = right bundle branch; RV = right ventricle; TV = tricuspid valve.

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<https://doi.org/10.1016/j.hrthm.2025.06.017>

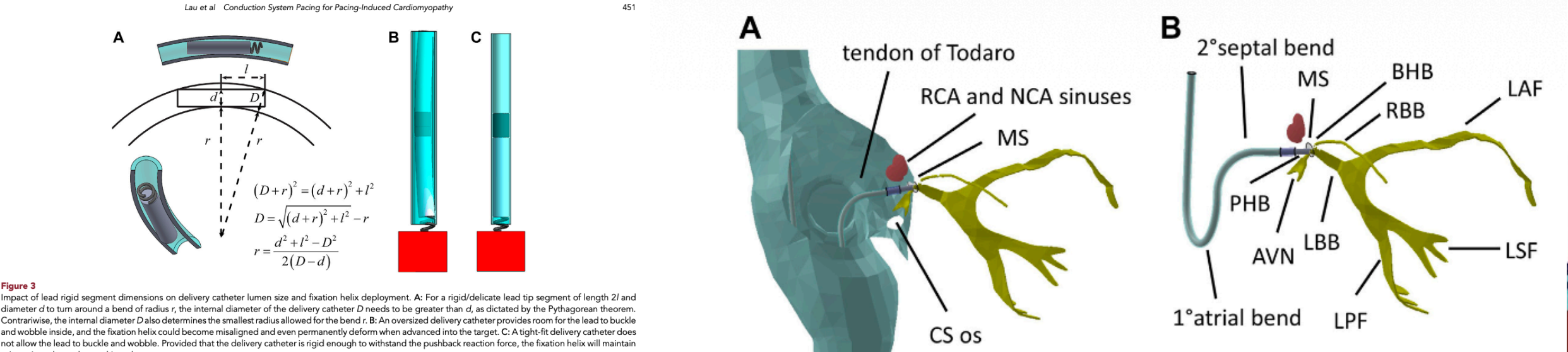
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Table 1 Relevant dimensions of leads and delivery catheters currently available for conduction system pacing

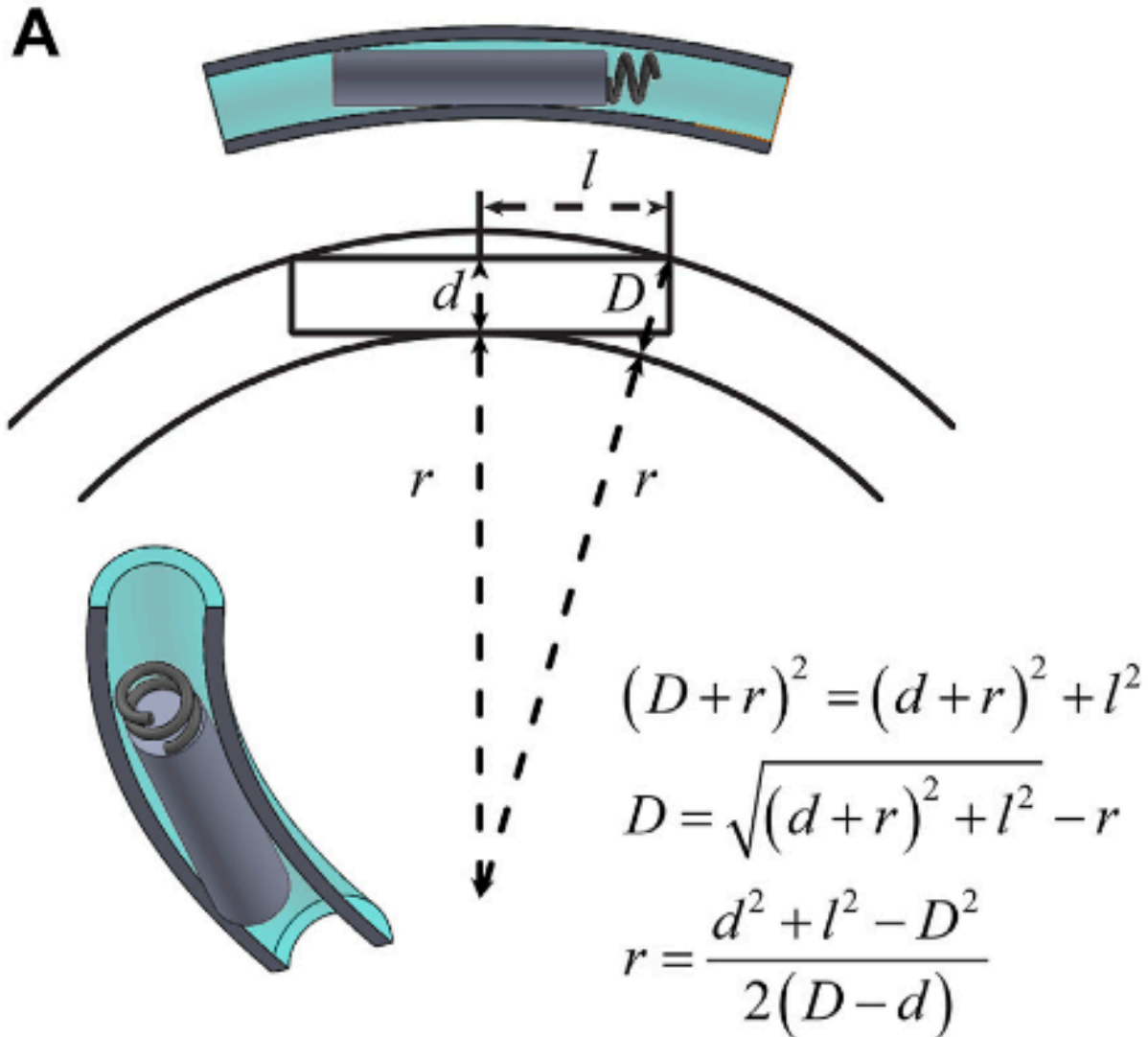
Leads	Helix length (mm)	Tip-ring distance (mm)	Rigid segment length 2l (mm)	Lead diameter d (mm/F)	Delivery catheter	Internal diameter D (mm/F)	External diameter (mm/F)	Catheter minimum bending radius r (mm)
SelectSecure 3830	1.8	9	10.8	1.4 (4.1)	SelectSite C315-HIS	1.8 (5.4)	2.4 (7)	34.9
SelectSecure 3830	1.8	9	10.8	1.4 (4.1)	SelectSite C304-HIS	1.9 (5.7)	2.8 (8.4)	27.5
Solia S (extended helix)	1.8	10	11.8	1.8 (5.6)	Selectra 3D	2.44 (7.3)	2.91 (8.7)	25.1
Solia S (retracted helix)	1.8	10	10	1.8 (5.6)	Selectra 3D	2.44 (7.3)	2.91 (8.7)	17.4
Ingevity+ (extended helix)	1.8	10.7	12.5	1.9 (5.7)	Site Selective Pacing (SSP)	2.17 (6.5)	2.67 (8)	70.3
Ingevity+ (retracted helix)	1.8	10.7	10.7	1.9 (5.7)	Site Selective Pacing (SSP)	2.17 (6.5)	2.67 (8)	51.0
Tendril STS/UtiPace (extended helix)	2	10	16.5*	1.9 (5.8)	Agilis HisPro/CPS Locator 3D	2.44 (7)	3.5/3 (10.5/9)	63.3
Tendril STS/UtiPace (retracted helix)	2	10	14.5*	1.9 (5.8)	Agilis HisPro/CPS Locator 3D	2.44 (7)	3.5/3 (10.5/9)	46.5

The minimal bending radius r for the delivery catheter is estimated using the formula $r = (d^2 + l^2 - D^2) / 2 (D - d)$ (Figure 3A). The rigid/delicate lead tip segment $2l$ is generally taken as the tip-ring distance $\pm$ length of the fixation helix. The rigid segment of the Tendril STS and UtiPace leads extends to include the ring electrode and hence is longer by 4.5 mm. Stylet-driven leads might have the fixation helix extended or retracted during insertion into delivery catheters.¹²⁸ The data were compiled from scientific publications and the leads' technical manuals. 3D = 3-dimensional.

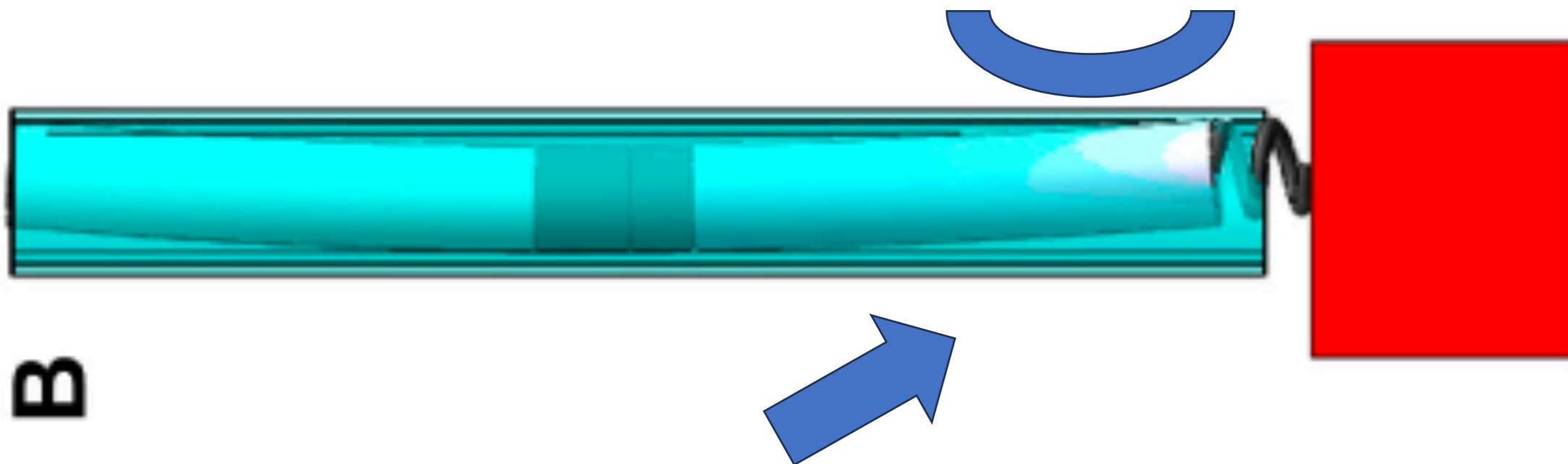
*The Tendril STS/UtiPace leads are atypical in having a rigid segment that extends proximal to the ring electrode and hence is longer than the tip-ring distance.



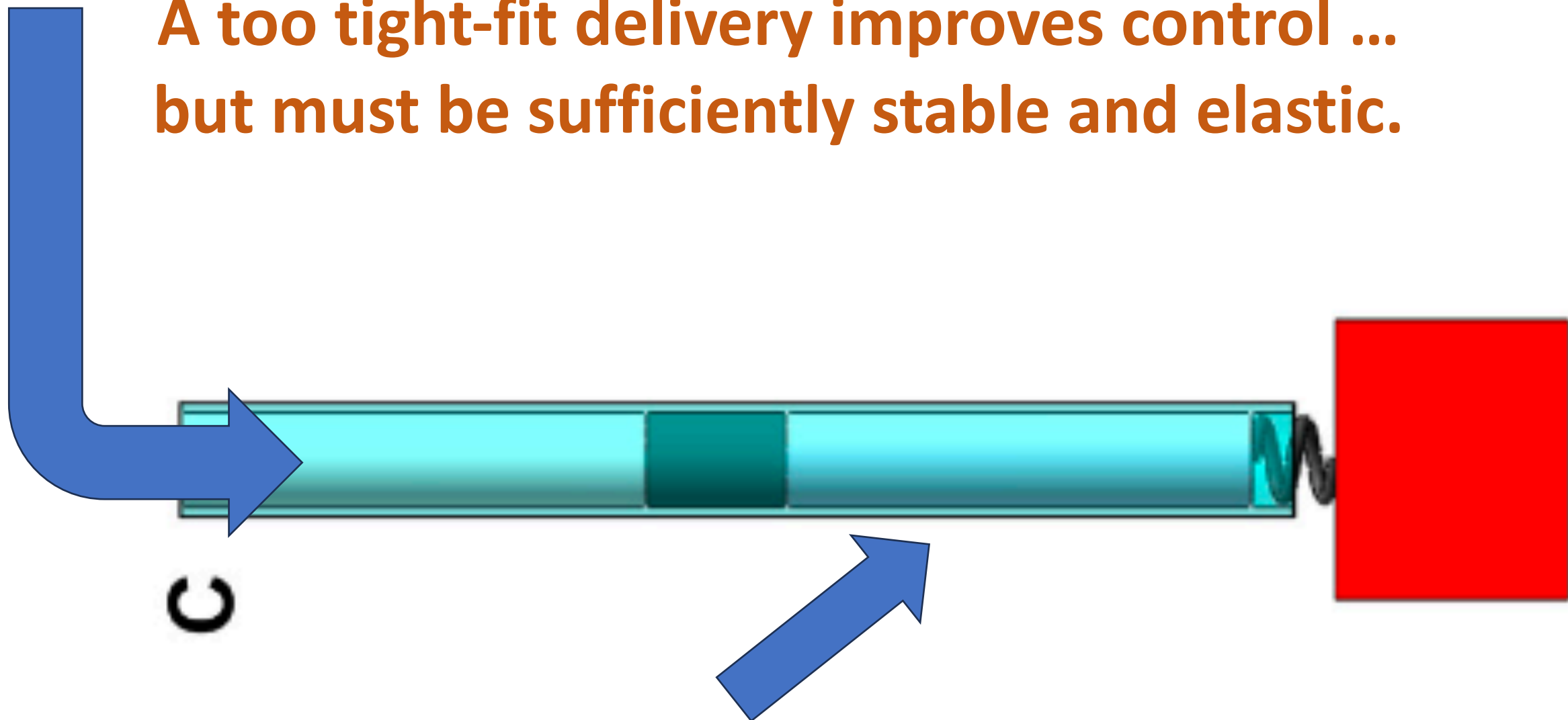
The relationship between delivery diameter and lead rigidity determines system curvature and control.



A too oversized delivery could cause wobble, loss of alignment, and helix damage.



**A too tight-fit delivery improves control ...
but must be sufficiently stable and elastic.**



Stylet-driven Leads or Lumenless Leads for Conduction System Pacing

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Abstract

Stylet-driven leads have been recently introduced for conduction system pacing, while most of the previous experience has been obtained with lumenless leads. Design and structural characteristics of both lead types are significantly different, resulting in different implant techniques and independent learning curves. Lead performance appears to be comparable, whereas data on direct comparison of clinical outcomes are scarce. Currently, there are no specific clinical scenarios favouring the use of one lead type over another and the decision should rely on the individual experience of the implantor.

Keywords

Conduction system pacing, stylet-driven lead, lumenless lead, left bundle branch area pacing, His bundle pacing

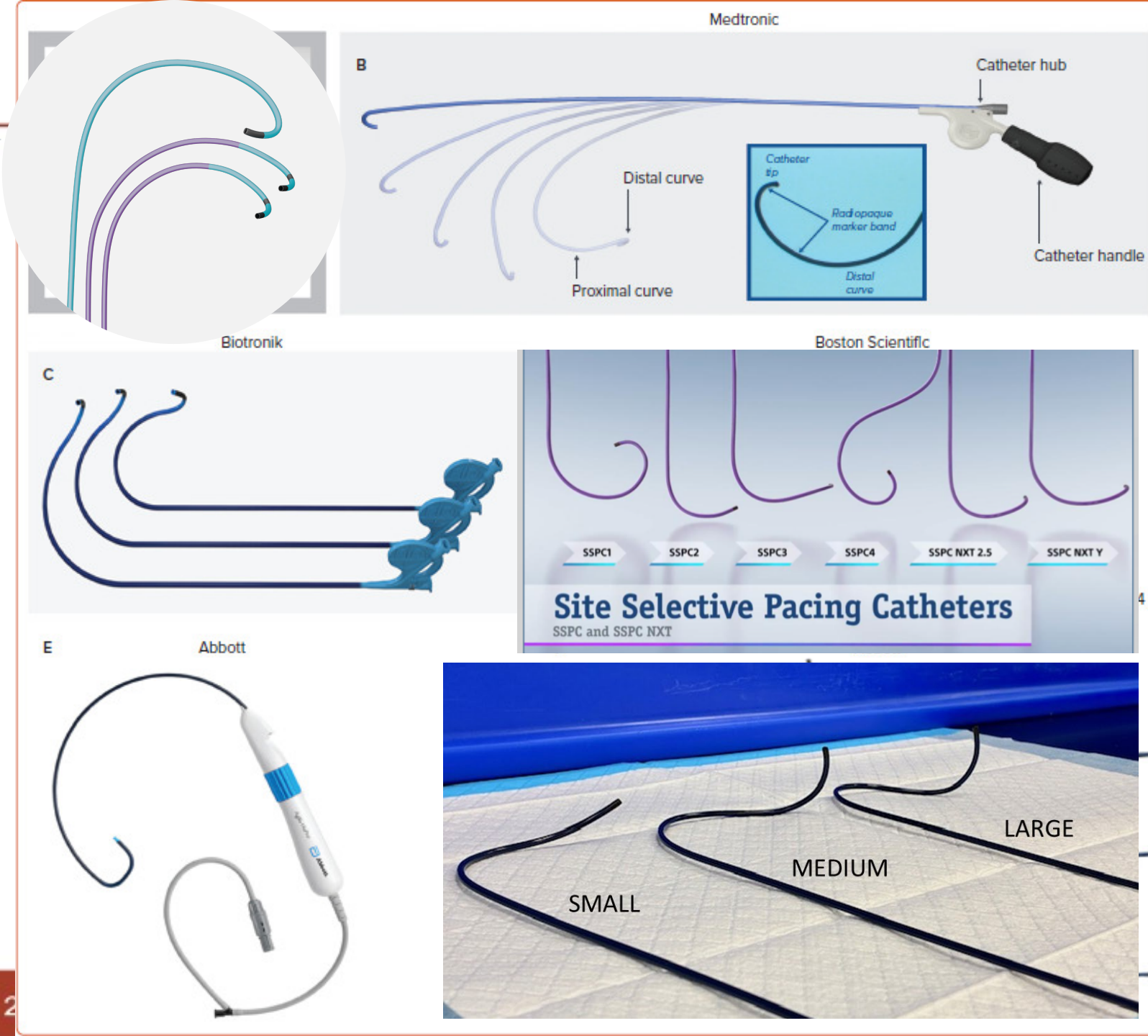
Received: 15 April 2024 Accepted: 30 May 2024 Citation: Anthymia & Electrophysiology Review 2024;13:e14. DOI: <https://doi.org/10.15420/aer.2024.13.e14>

Disclosure: OC has received speaker honoraria and consulting fees from Abbott, Biotronik, Boston Scientific, Medtronic and MicroPort. JDP has received speaker honoraria and consultancy fees from Abbott, Biotronik, Boston Scientific and Medtronic. FZ has received honoraria from Abbott, Biotronik, Boston Scientific, Medtronic and MicroPort.

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Delivery systems for CSP are generally double-curved: a primary curve to reach the septum and a secondary out-of-plane curve to achieve a more perpendicular orientation against the septum.



Take Home Message

Conduction System Pacing is not a lead or a device
It is a system

- Heart anatomy
- Alignment determines penetration
- Geometry determines control
- Technique determines outcome
- Delivery evolution determines system performance
- Experience, data, and iteration drive progress

