

LBBAP: NEW INSIGHTS

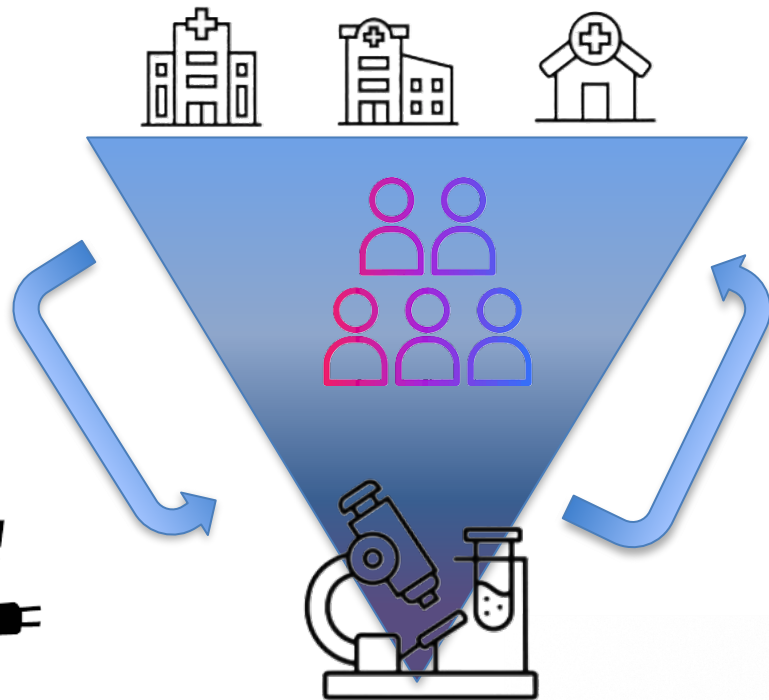
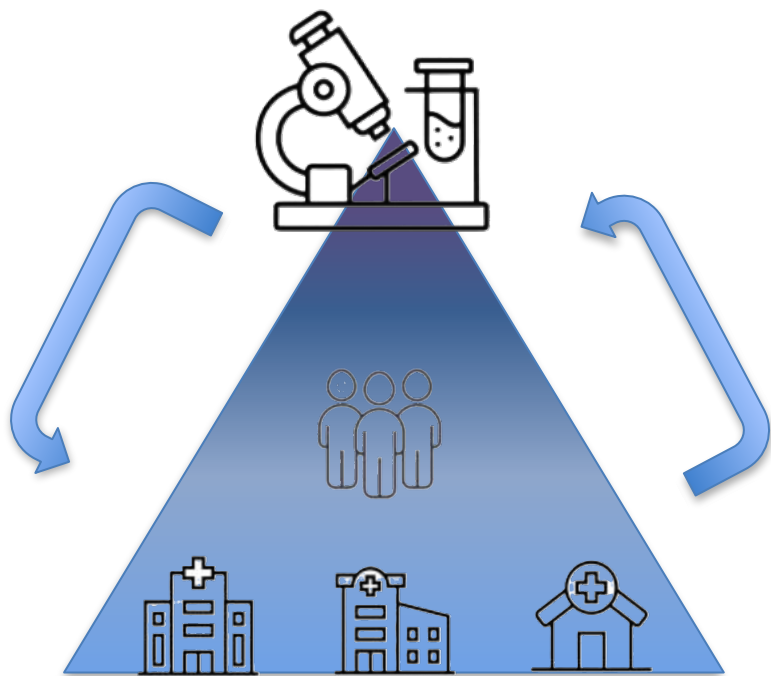
Electrode Selection in Left Bundle Branch Stimulation: Technical and Physiological Implications

Lorente Ros, Alvaro

Cardiac electrophysiology and pacing unit.

Hospital Universitario Central de Asturias. Oviedo, Spain

Power to the people



~~Where are we now?~~

Where were we?



Delivery catheter

Fixed Curve

C315 His (Medtronic)
Selectra 3D (Biotronik)
SSP (Boston Scientific)

Deflectable

C304 SelectSite (Medtronic)
Agilis HisPro (Abbott)



Pacing lead

Lumenless lead

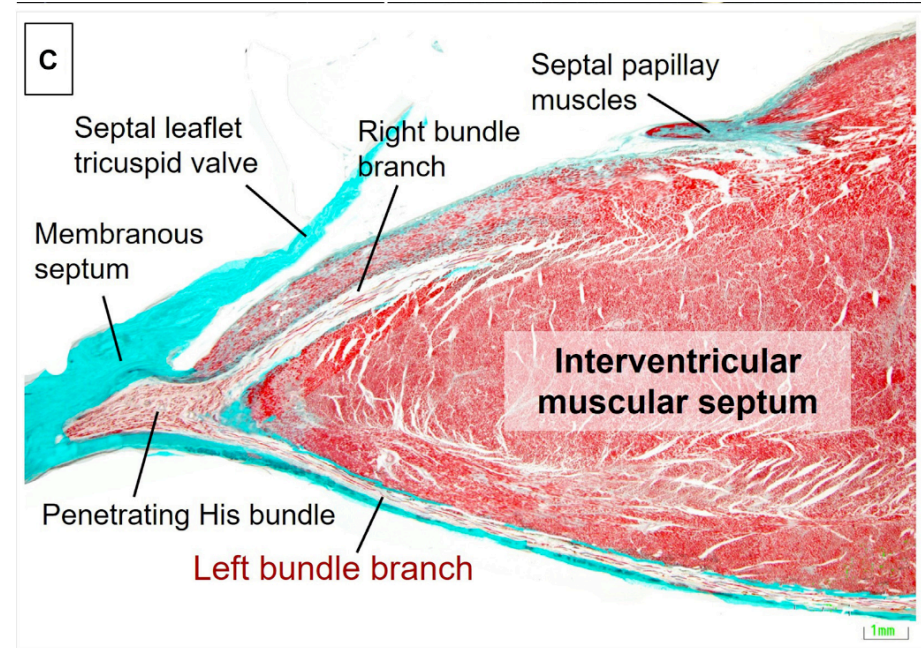
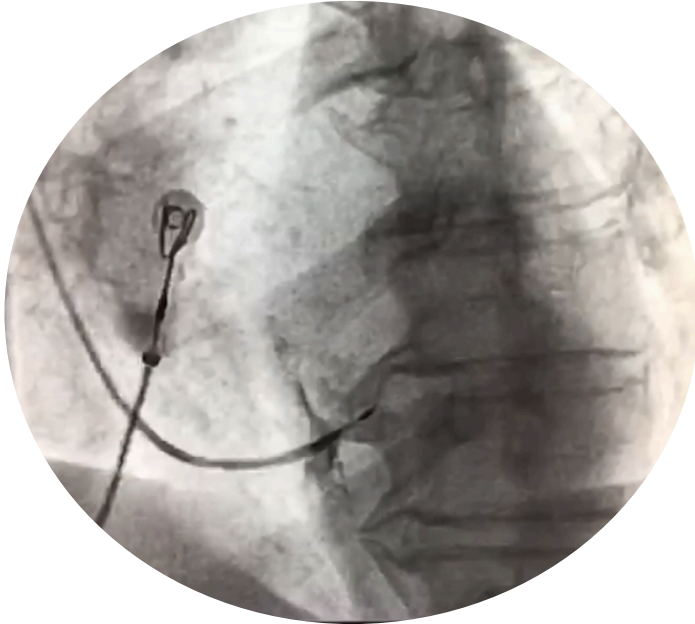
3830 SelectSecure

Stylet-driven leads

Solia S (Biotronik)
Ingevity (Boston Scientific)
Fineline II Sterox EZ (Boston Scientific)
Tendril 2088TC (Abbott)



What are we aiming for?

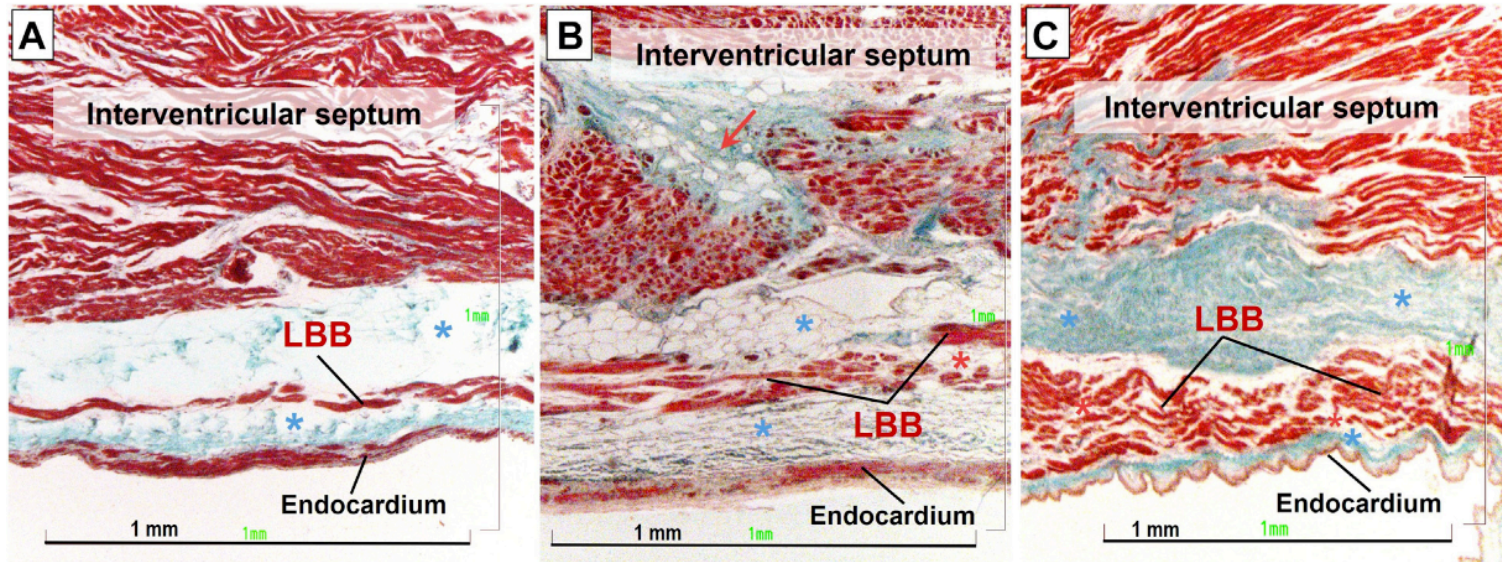


Cabrera JA, et al. Left bundle branch pacing: histology is the key. JACC Clin Electrophysiol. 2025;11:1659–1666.



What are we aiming for?

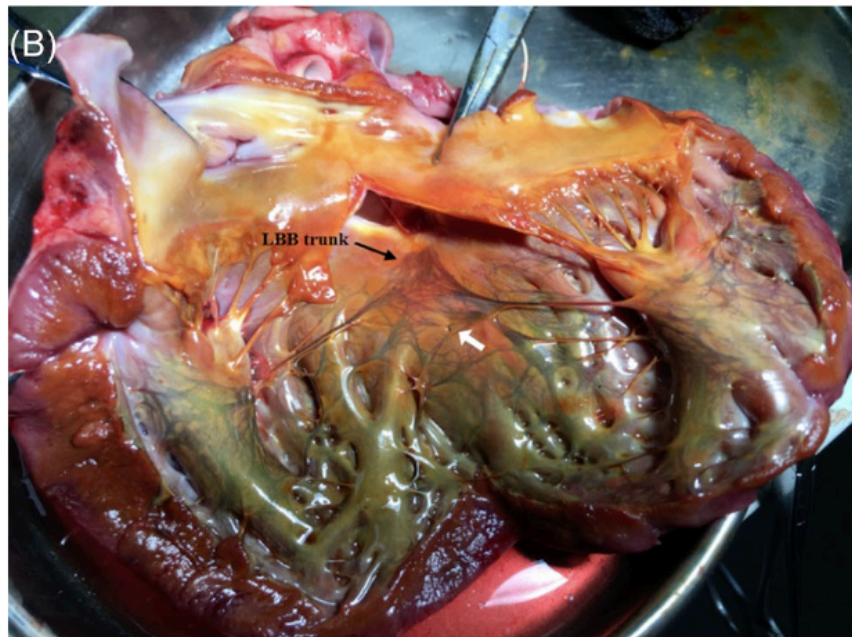
FIGURE 4 LBB: Comparison of the 3 Different Types



Cabrera JA, et al. Left bundle branch pacing: histology is the key. JACC Clin Electrophysiol. 2025;11:1659–1666.



What are we aiming for?



MELOS — MULTICENTER EUROPEAN LEFT BUNDLE BRANCH AREA PACING OUTCOMES STUDY



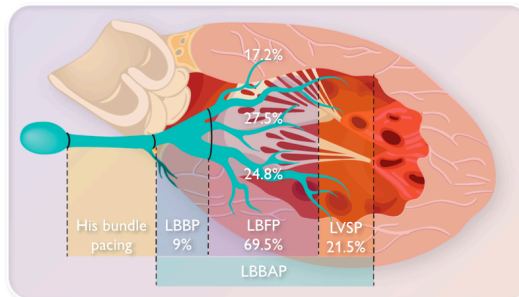
Prospective, multicenter,
registry-based observational study



2533
Participants



14
European centres



LBBAP implantation success
 Bradycardia indication success **92.4%**
 Heart failure indication success **82.2%**

LBBAP lead complications **8.3%**

- Acute perforation to LV 3.7%
- Lead dislodgement 1.5%
- Acute chest pain 1.0%
- Capture threshold rise 0.7%
- Acute coronary syndrome 0.4%
- Trapped/damaged helix 0.4%
- Delayed perforation to LV 0.1%
- Other 0.7%

Independent predictors of LBBAP lead implantation failure

Heart failure indication	OR 1.49, 95% CI 1.01–2.21
Baseline QRS duration, per 10 ms	OR 1.08, 95% CI 1.03–1.14
LVEDD, per 10 mm increase	OR 1.53, 95% CI 1.26–1.86

Chen X, et al J Cardiovasc Electrophysiol. 2020;31:214–219.
 European Heart Journal (2022) 43, 4161–4173



Lead selection

Stylet-driven

Lumenless

5.6 F – 5.8 F (Greater diam)

4.1 F

Non isodiametric

Isodiametric (uniform design)

Lumen for stylet

More rigid,
better torque transmission?

High tensile strenght

Retractable helix

Fixed Helix

Monitoring during perforationg possible

Cannot monitor during perforation *
Specific tool

Smaller distal end

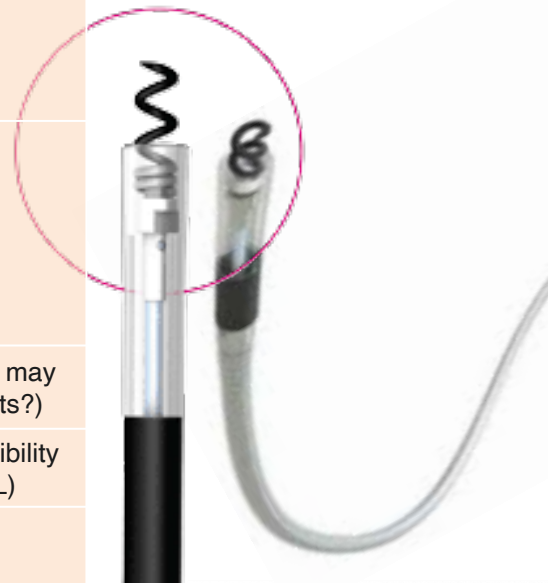


Lead selection

Stylet-driven

Lumenless

Using different stylets-> Varyin stiffness and additional support X-stiff (fibrotic septum)	4.1 F
Larger lead and sheath: easier torque transmission Interchangeability of SDLs and sheaths	Less myocardial injury
Use of locking stylets for extraction	Supposedly high tensile strenght may enable manual extraction (doubts?)
Possibility of unipolar continuous pacing Transition zone prone to rupture	Continuous pacing now is a possibility (Rotatable Connector 5944RL)
Helix retraction Myocardial damage/edema	
Drilling	Smaller distal end



PERSPECTIVES IN CONTRAST

Table 2 Comparison of lumenless and stylet-driven bundle branch pacing **My preferred approach to left bundle branch pacing: Lumenless leads**

Parameter	Lumenless lead	Sty
Lead size, F	4.1	5.6
Lead length, cm	59/69/74	53-
Helix length, mm	1.8	1.8
Interelectrode distance, mm	9	- - - - -
Isodiametric tip	Y	
Steroid at lead tip	B	
Potential for helix damage	L	
Long-term studies	A	
Potential for myocardial injury	L	
Lead repositioning	P	
Risk of LBB capture loss	L	
Lead extraction	F	
Septal coronary-cameral fistula	R	

LBB = left bundle branch.

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*From the *Division of Cardiology, Velammal Medical College, Madurai, India, and [†]Geisinger Heart Institute, Wilkes-Barre, Pennsylvania.*

Acute performance of stylet driven leads for left bundle branch area pacing: A comparison with lumenless leads

Óscar Cano, MD, PhD,*^{†‡} Javier Navarrete-Navarro, MD,*[†] Dipen Zalavadia, MD,[§]
Pablo Jover, MD,*[†] Joaquín Osca, MD, PhD,*^{†‡} Radhika Bahadur, MD,[¶]
Maite Izquierdo, MD, PhD,*^{†‡} Josep Navarro, MD,* Faiz A. Subzposh, MD,[¶]
Hebert D. Ayala, MD,*[†] Luis Martínez-Dolz, MD, PhD,*^{†‡}
Pugazhendhi Vijayaraman, MD, FHRS,[¶] Syeda Atiqah Batul, MD^{||}

 Check for updates

 Check for updates



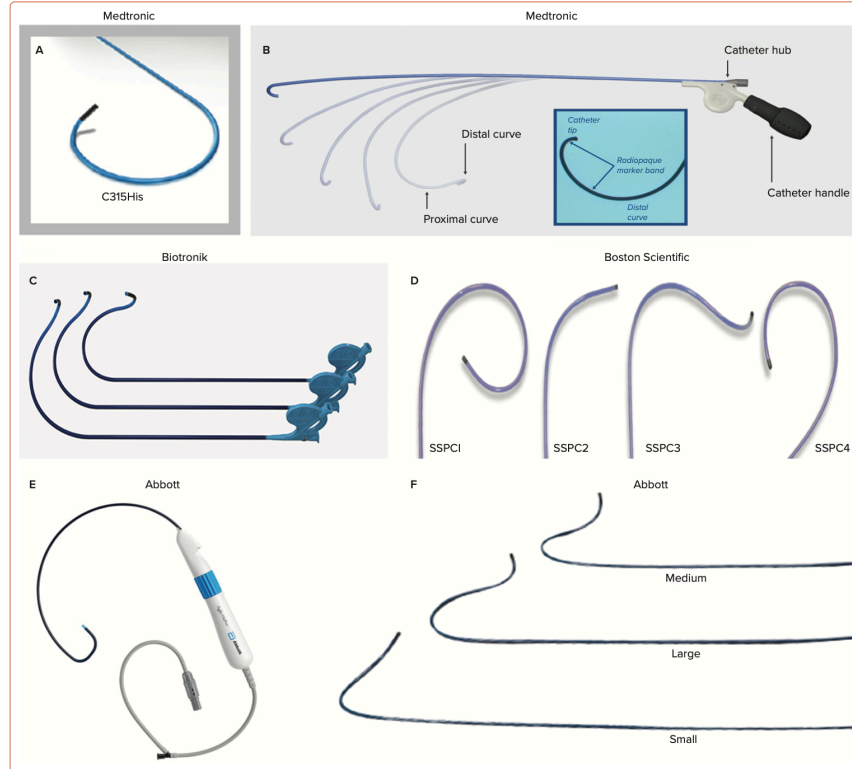
- J Cardiovasc Electrophysiol. 2021;32:439–448.
- European Heart Journal (2022) 43, 4161–4173
- J Cardiovasc Electrophysiol. 2023;34:710–717
- Cardiovasc Electrophysiol 2023;34:718–725.
- Heart Rhythm O2 2023;4:147–153)
- Heart Rhythm O2 2023;4:765–776
- J. Clin. Med. 2024, 13, 4758
- Arrhythmia & Electrophysiology Review 2024;13:e14.
- Heart Rhythm 2024;21:2242–2249
- Circ Arrhythm Electrophysiol. 2024;17:e013385.
- JACC Clin Electrophysiol. 2025;11:158–170)
- PacingandClinicalElectrophysiology,2025;48:682–690 (MTA)

Scarce (1 single-operator) randomized evidence

Now we are starting to have growing observational/prospective evidence that allow us to make some considerations when choosing an LBBAP strategy



Figure 1: Commercially Available Sheaths for Conduction System Pacing



Each system comes with its own sheath (CF)

Cano et al. Arrhythmia & Electrophysiology Review 2024;13:e14.



MELOS

J Cardiovasc Electrophysiol. 2023;34:710–717

Registry

N= 2553 (84% with LLL)

Higher success with SDL (93% SDL vs 89% LLL)

Higher complication rate (16 vs 9%)

-Lead displacement (4 vs 1 %)

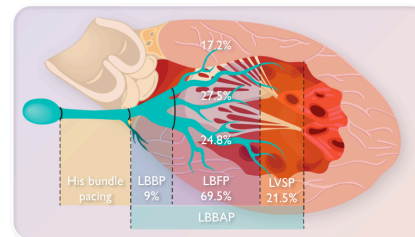
-Higher perforation rates (4,8 vs 3,5%)

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• Other	0.7%



Cano 2023

Heart Rhythm O2 2023;4:765–776

Observational

N= 925 (270 SDLs)

Higher success LLL (95 vs 85%)

Higher complications SDLs
(15.9 vs 6.1%)

Shorter procedure and
fluoscopy times (SDL)

Sritharan 2023

Europace (2023) 25, 1–9

Observational

N= 306 consecutive
(153 SDLs)

No differences
(96% SDL vs 94%
LLL)

Dislodgment 6.1 vs
3% (SDL vs LLL) (p 0.26)

Braunstein 2022

J Cardiovasc Electrophysiol.
2023;34:710–717

Observational

N= 83 consecutive

No differences (76%
SDL vs 80% LLL)

Solia S60...



ORIGINAL ARTICLE

Comparison of Procedural Outcomes of
Lumenless Fixed-Helix Versus Stylet-Driven
Extendable-Helix Lead Systems in Left Bundle
Branch Pacing: COMPARE LBBP

COMPARE-LBBP(Circ Arrhythm Electrophysiol. 2024;17:e013385.)

Randomized single-operator (n= 100)

No differences success (90 vs 92% SDL vs LLL)

No differences in dislodgment (micro or macro)

1 entrapment in SDLs (vs 0 LLL) -> other studies have described it as more frequent with SDLs

2 helix retraction events on SDLs



2 MTAs

Pacing and Clinical Electrophysiology

WILEY
PACE 

Clinical Research in Cardiology
<https://doi.org/10.1007/s00392-025-02673-w>

ORIGINAL PAPER



DEVICES

Stylet-Driven Lead Vs. Lumenless Lead for Left Bundle Branch Area Pacing: Systematic Literature Review and Meta-Analysis

Ga-In Yu¹ | Tae-Hoon Kim²  | Yun-Ho Cho¹ | Jae-Seok Bae¹ | Jong-Hwa Ahn¹ | Jeong Yoon Jang¹ | Choong Hwan Kwak¹

Outcomes of stylet-driven leads compared to lumenless leads for left bundle branch are pacing: systematic review and meta-analysis

Amr Abdin¹  · Haran Burri² · Guram Imnadze³ · Khaled Turkmani⁴ · Hussam Al Ghorani¹ · Alhasan Almasri¹ · Christian Werner¹ · Saarraaken Kulenthiran¹

Received: 4 December 2024 / Accepted: 2 May 2025
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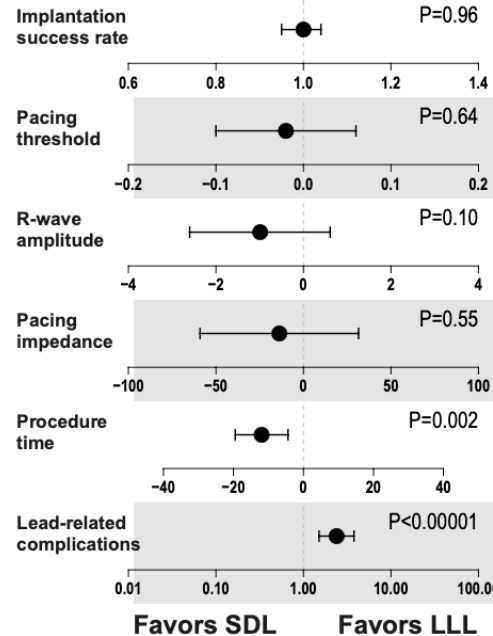
Pacing and Clinical Electrophysiology, 2025; 48: 682–690



Different lead performance?

Methods and results: Systematic review and meta-analysis of 11 studies with 12,916 patients (SDL: 3,920 vs. LLL: 8,996) with follow-up durations up to 28 months

Stylet-driven Lead (SDL)



Lumeless Lead (LLL)



Different lead performance?

Electrical parameters

R wave sensing

Similar

Greater in LLL (tissue damage?)

Similar threshold

Impedance

- Lower in SDL
- Consistently reported
- Inversely related to lead-to-tissue interface

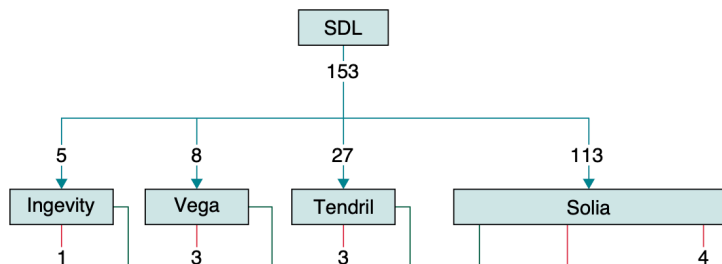


Procedural outcome and follow-up of stylet-driven leads compared with lumenless leads for left bundle branch area pacing

Aarthiga Sritharan , Nikola Kozuharov , Nicolas Masson, Elise Bakelants 
Valérien Valiton , and Haran Burri *

Cardiac Pacing Unit, Department of Cardiology, University Hospital of Geneva, Rue Gabrielle-Perret-Gentil 4, CH-1211 Genève, Switzerland

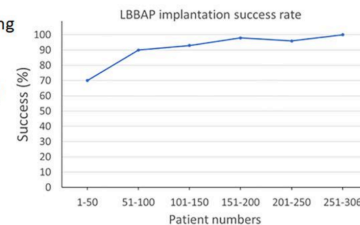
Received 28 May 2023; accepted after revision 21 September 2023; online publish-ahead-of-print 28 September 2023



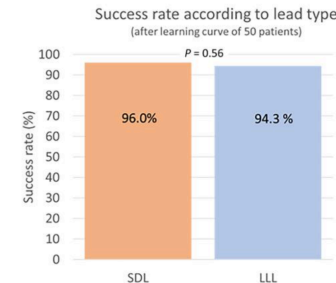
Graphical Abstract

Left bundle branch area pacing with stylet-driven leads (SDL) as compared to lumenless leads (LLL)

- Prospective single-centre study on left bundle branch area pacing
- 153 patients with initial LLL (3830 lead)
153 patients with initial SDL (Solia, Tendril, Vega, Ingevity leads)
- 4 crossovers in each group after initial failure (and successful implantation in half of the patients with the other lead type)
- No differences in electrical parameters at implantation and follow-up of 7.7±5.8 months



	SDL	LLL	P
<i>Per-operative complications</i>			
Perforation	11.6%	10.2%	0.59
Micro/macro dislodgements	6.1%	4.5%	0.62
Helix damage	6.1%	0%	0.007
<i>Post-operative complications</i>			
Macro dislodgement	5.4%	3.0%	0.39
Loss conduction system capture	6.1%	3.0%	0.26



Keywords

Conduction system pacing • Left bundle branch area pacing • Lumenless lead • Stylet-driven lead • Success • Failure • Complications





ESC

European Society
of Cardiology

Europace (2023) 25, 1–9

<https://doi.org/10.1093/europace/euad295>

CLINICAL RESEARCH

Procedural outcome and follow-up of stylet-driven leads compared with lumenless leads for left bundle branch area pacing

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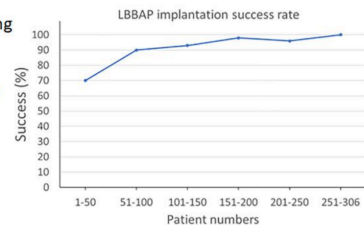
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- LOCSC without fluoroscopic evidence of displacement **6,1% SDLs vs 3% in LLL.**
- **Helix damage only seen in SDLs**
- Macro-dislodgement probably due to drilling.
- **Time of implantation was lower w/ SDLs** so there must be something about SDLs that make it easier or faster.

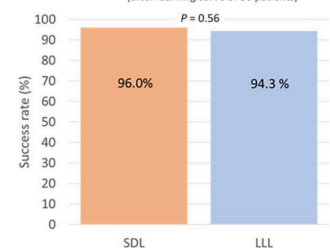
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Success rate according to lead type (after learning curve of 50 patients)



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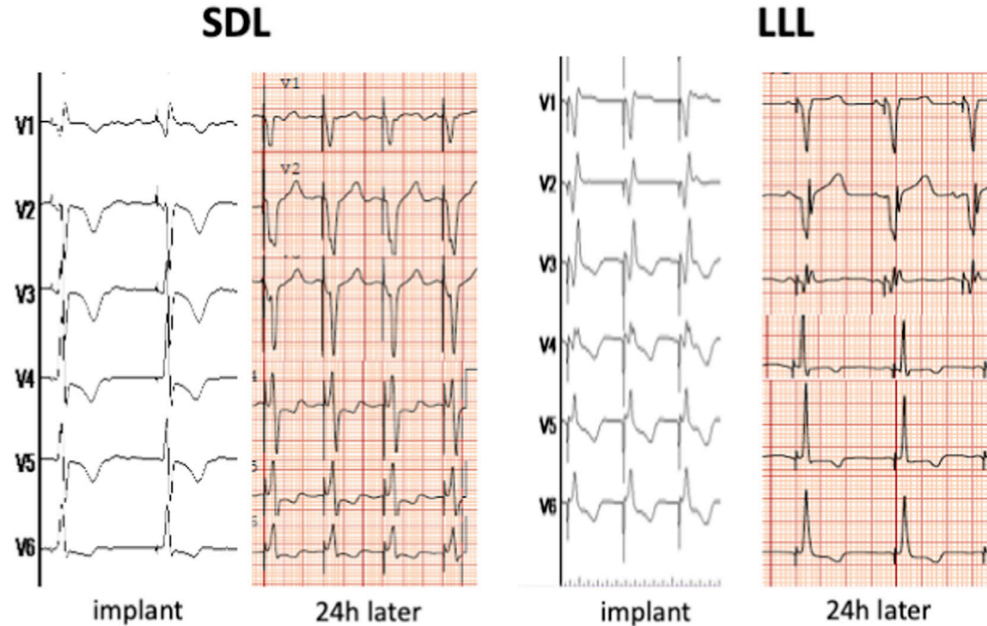


Figure 3 Examples of left bundle branch area pacing lead microdislodgment after implant (24 hours later) before discharge in a patient with stylet-driven lead (SDL) (**left**) and a patient with lumenless lead (LLL) (**right**). In both cases, significant paced QRS changes can be observed with loss of the “r” prime wave in lead V1 and QRS duration prolongation. Paper speed = 25 mm/s.



Loss of capture

RESEARCH LETTER

Predictors of loss of capture in left bundle branch pacing: A multicenter experience

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Rodney Soh, MBBS,^{*} Swee-Chong Seow, MBBS, FHRS,^{*†} Lisa J.T. Teo, BSc,[§]
Colin Yeo, MBBS,[§] Vern Hsen Tan, MBBS,[§] Pipin Kojodjojo, MBBS, PhD, FHRS^{*†‡}

From the ^{}Department of Cardiology, National University Heart Centre, Singapore, [†]Yong Loo Lin School of Medicine, National University Singapore, Singapore, [‡]Department of Cardiology, Ng Teng Fong General Hospital, Singapore, and [§]Department of Cardiology, Changi General Hospital, Singapore.*

Up to 12% of patients (too much)

**Most happen a short time after
implantation: 55% on day 1 and 82% first 30
days**

SDL >>> LLL. (4.7 vs 1.1%) Cano et al (Heart Rhythm
O2, Vol 4, No 12, December 2023)

Newer studies tend to report lower dislodgment (3.8% MELOS SDL,
2.3% INSIGHT LBBAP, 1.7% BIO-CONDUCT, 1.1% MELOS LLL)



Different lead performance?

Learning curve

MELOS: fluoroscopy + LVAT
decreased over 110 cases and
stabilized afterward

Wang et al: 50 cases (LLL)

Yu et al: 25 cases (SDL)



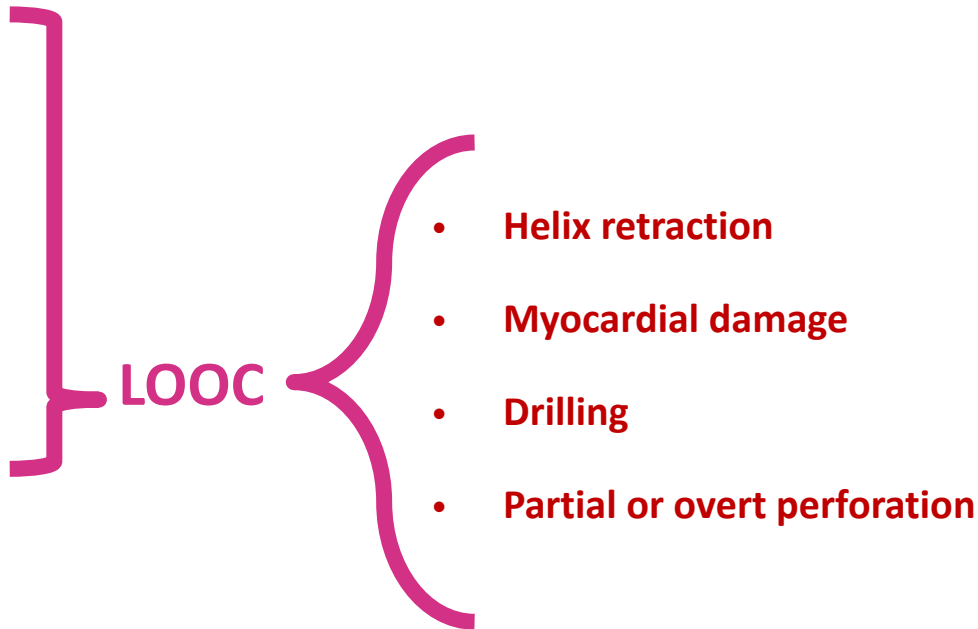
Lead instability

- **Macrodislodgment**

- **Macroscopic dislocation (1-5%)**
- Almost all <24h post-procedure

- **Microdislodgment**

- **Loss of CS capture without apparent changes in position (1-4%)**
- **Tends to be 24h after implantation**
- **Not always warrants reintervention**
- 1.5% vs 0.9% after discharge (Cano et al 2023)



Europace (2023) 25, 1–9
Heart Rhythm O2 2023;4:765–776



How to prevent these issues?



Lead instability

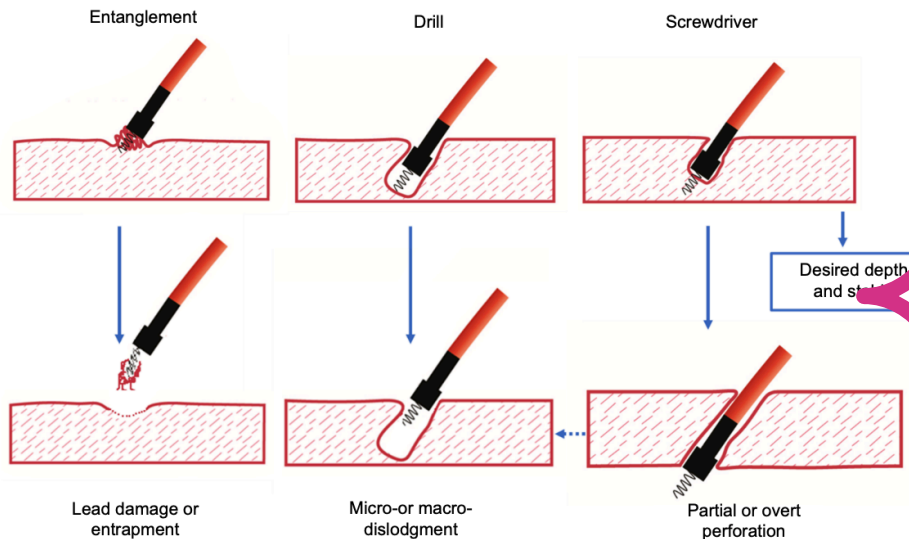


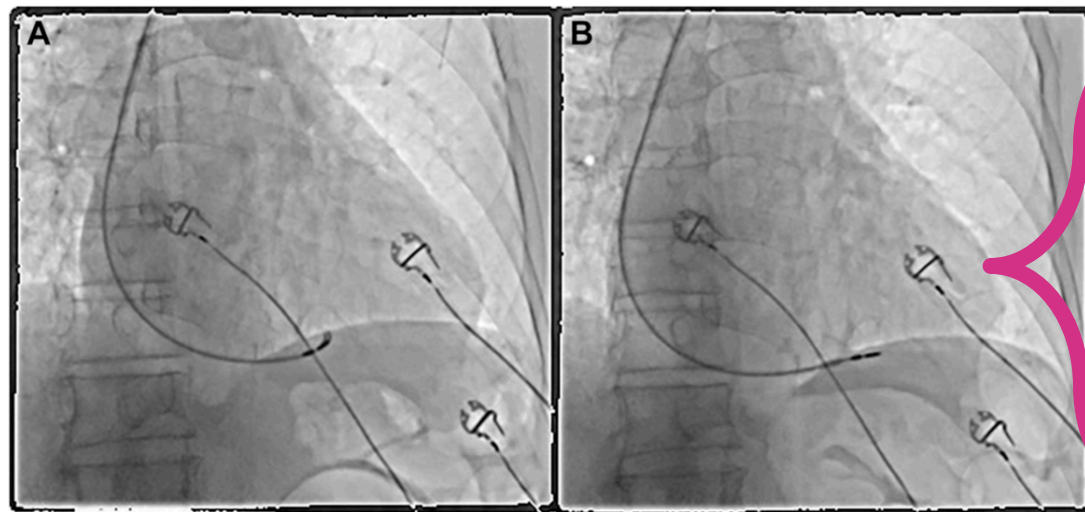
Figure 16 Lead behaviour during penetration of the septum during LBBAP. Both drill and screwdriver effects can result in perforation.

• Helix retraction

- **RELEASE LEAD PRETENSIONING AS SOME BACKSPIN MAY OCCUR** (before testing and sitting)
- **STOP PUSHING IF BENDING OBSERVED**
- **Specific locking mechanism (or other)**
- Fluoroscopic landmarks
- Keep an eye on unipolar pacing (increases over 800 Ohm)



Lead instability



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Heart Rhythm 2026 May 14:S1547-5271(26)02367-2.



Lead instability

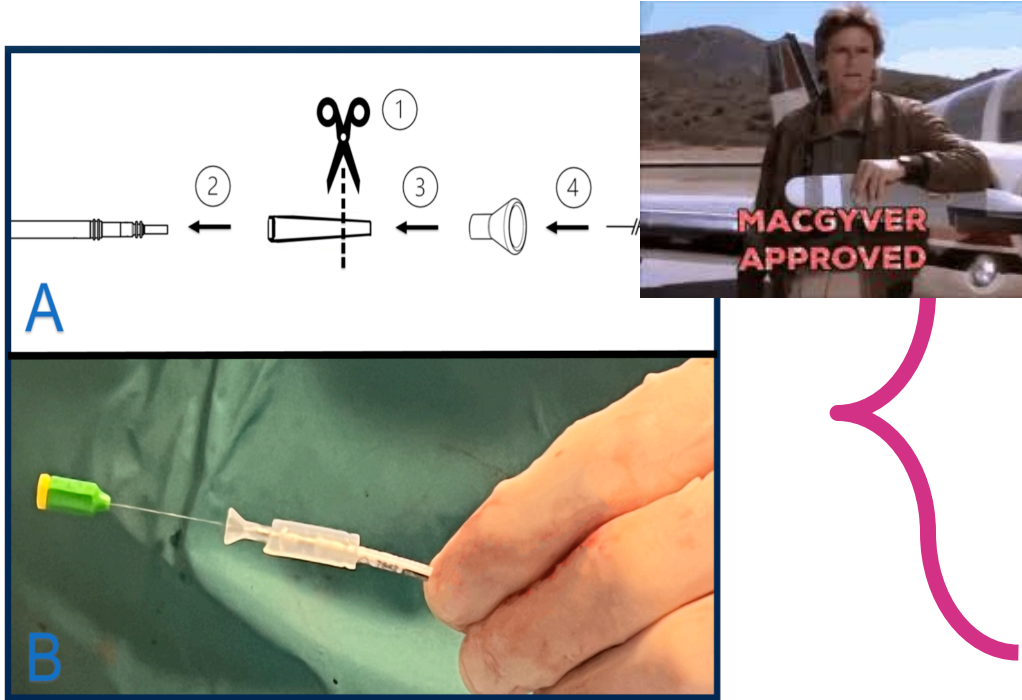


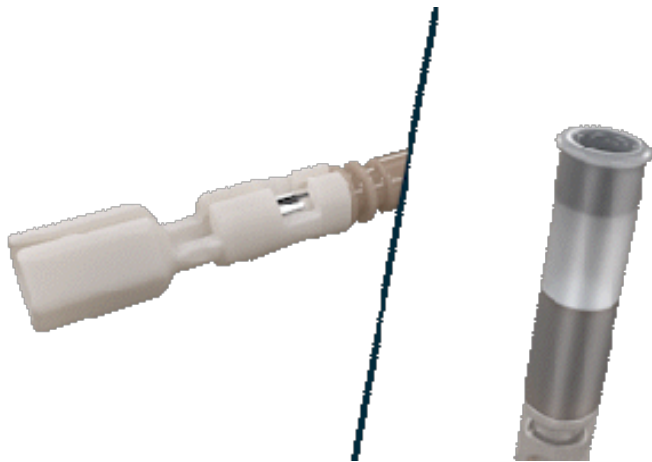
Figure 6. Panel (A) shows a customized locking tool for the Ingevity + catheter lead. Step 1: Cut the

Helix retraction

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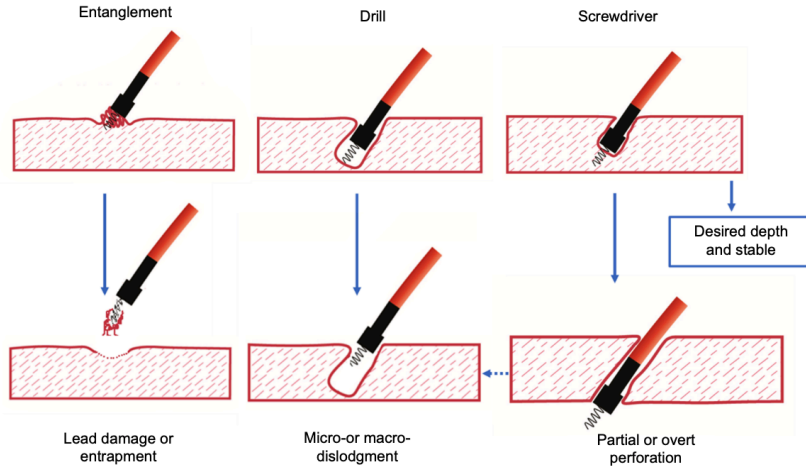


Figure 16 Lead behaviour during penetration of the septum during LBBAP. Both drill and screwdriver effects can result in perforation.

- **Myocardial damage**
 - x3 elevation troponin ULN
 - Not clinically significant.
- **Drilling**
 - LLLs more rapid rotations rather than pushing
 - **Coaxial disposition of sheath required!**
 - Reposition if turning but not advancing



Lead instability



Heart Rhythm 2026 May 14:S1547-5271(26)02367-2.

- **Partial or overt perforation**

- Some older series suggest higher incidence of septal perforation with SDLs... but appears to have relation to learning curve
- It appears to be easier to perforate with SDLs but **COMPLICACIONES ARE PREVENTABLE**
- **CONTINUOUS IMPEDANCE AND COI MONITORING**



COI monitoring

- filtered (30–500 Hz)
→ conduction system signals
- unfiltered (0.5–500 Hz) signals → COI analysis
- Expect 20-25mv →
10mV → 5mv (do NOT progress)

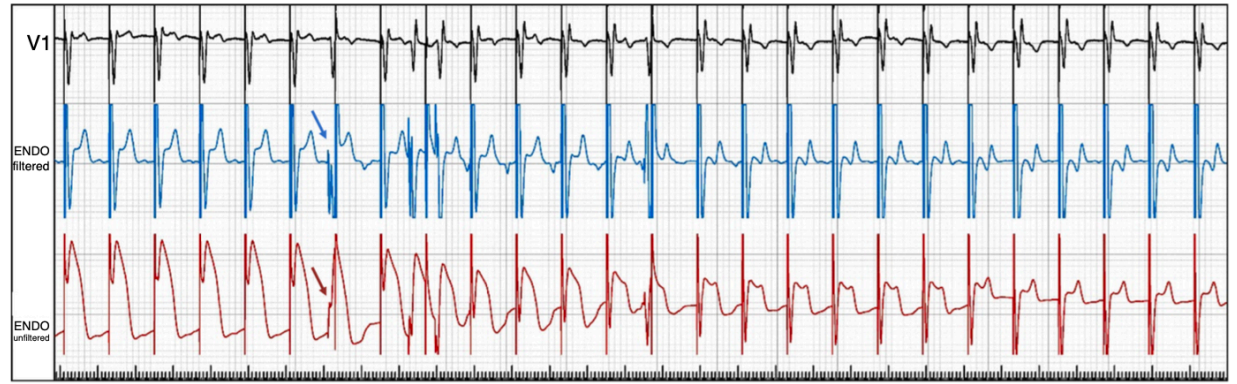
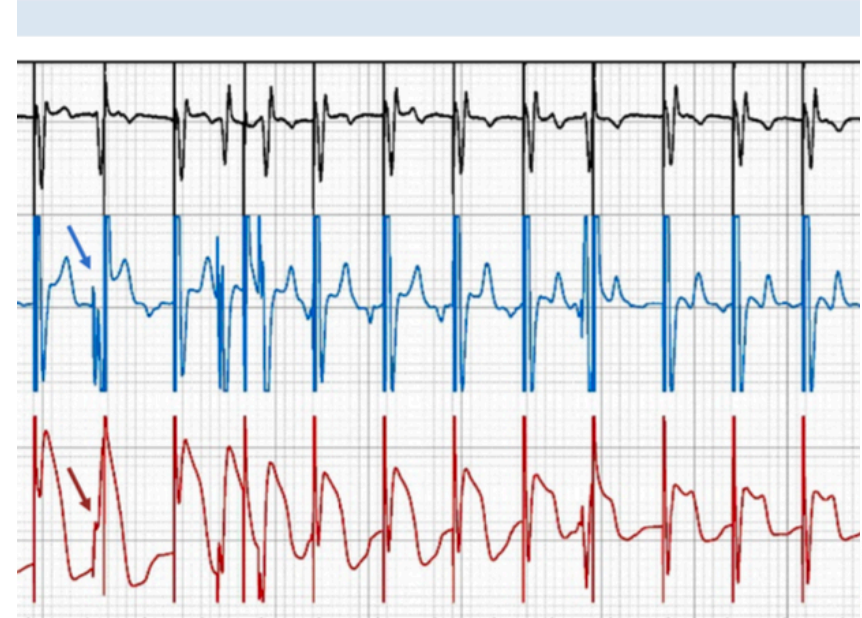
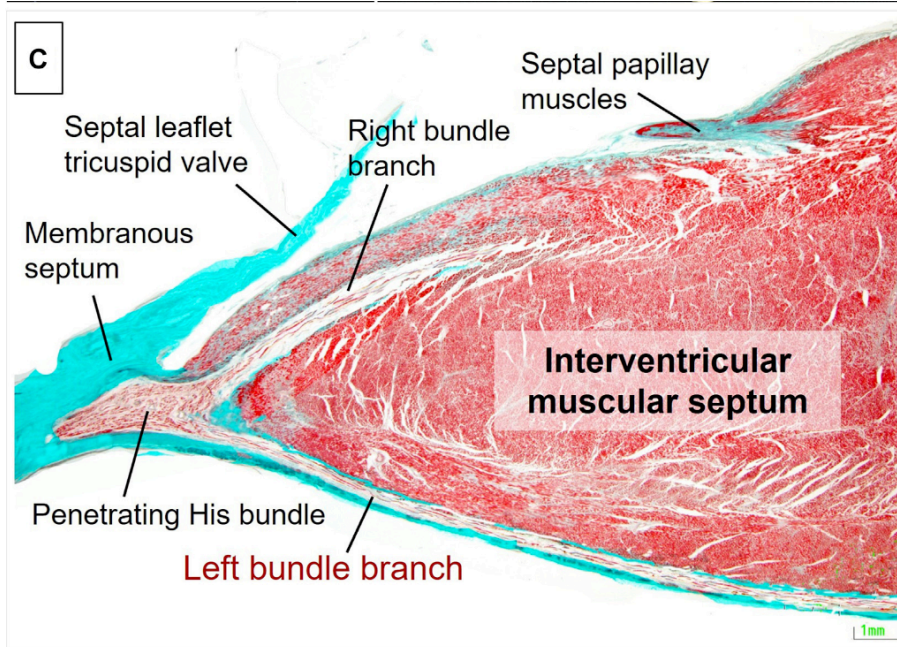


Figure 19 Myocardial COI during lead progression. A 15 s strip of the endocardial signals from the lead tip recorded during LBBAP implantation with continuous pacing at 100 bpm. Immediately after the premature fixation beat, preceded by a Purkinje potential (arrow), there is an obvious drop of the paced myocardial COI. Both COI drop and Purkinje potential are valuable markers indicating that the subendocardial area of the interventricular septum was reached by the pacing lead tip and that the lead rotations should be immediately stopped. In the present case, the lead rotations were continued and a further decrease in COI was observed (<4 mV and <25% of V wave), indicating imminent perforation. The endocardial signals (ENDO) from the pacing lead are acquired in unipolar mode and presented as filtered (30–100 Hz) and unfiltered (0.1–500 Hz). Sweep speed 12.5 mm/s. Reproduced, with permission from Jastrzebski et al.⁷⁵



COI monitoring



Europace (2023) 25, 1208–1236



Lead instability

Rotatable Connector 5944RL



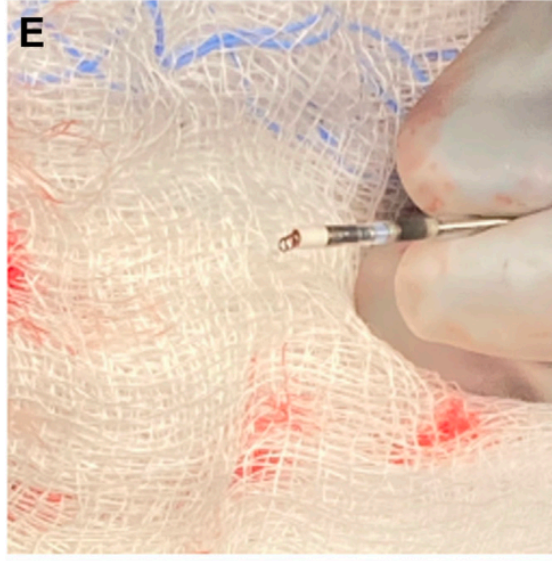
Different lead performance?

Tissue entrapment



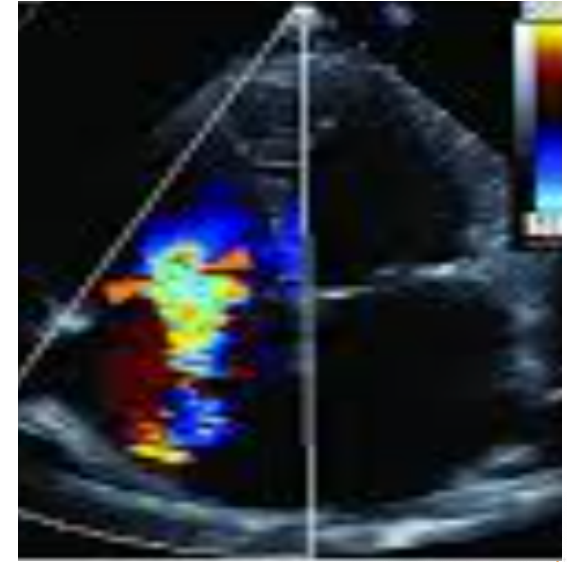
Heart Rhythm O2 2023;4:147–153)

Helix elongation



Heart Rhythm O2 2023;4:147–153)

Valve apparatus entrapment
Risk of severe TR

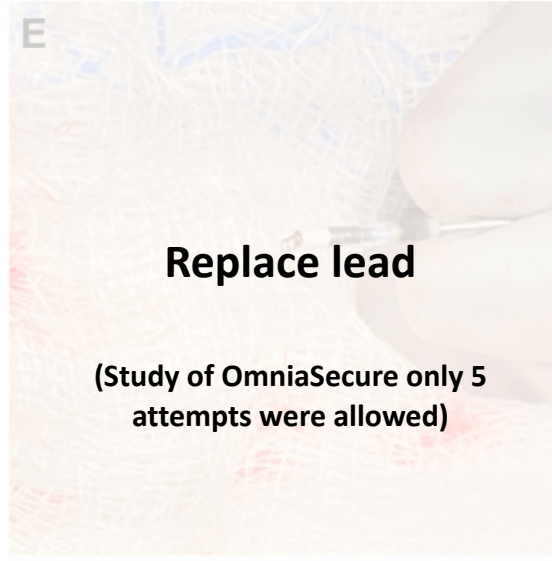


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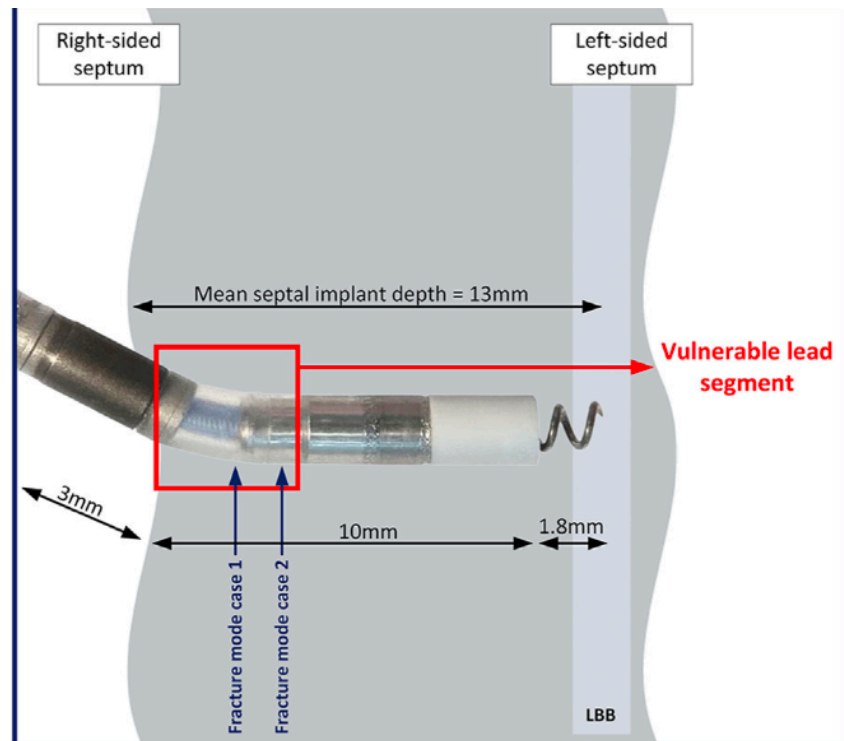


Heart Rhythm O2 2023;4:147–153)



¿Do SDLs break more?

- Studies with SDLs (almost all Solia S60) show a discrete but consistently higher number of lead failures
- Newer leads come reinforced at those points.
- It is of paramount importance:
 - Stylet be fully advanced and sheath perpendicular to the septum: pushing otherwise might lead to kinking of the lead tip and future breaking.
 - Maintain coaxial forces.



ORIGINAL RESEARCH

Lead Integrity and Failure Evaluation in Left Bundle Branch Area Pacing (LIFE-LBBAP) Study



Jan De Pooter, MD, PhD,^a Alexander Breitenstein, MD, PhD,^b Emine Özpak, MD,^a Andreas Haeberlin, MD, PhD,^c
Daniel Hofer, MD,^d Jean-Benoit Le Polain de Waroux, MD, PhD,^e Aurélien Wauters, MD, PhD,^f Tae-Hoon Kim, MD,^g
So-Ryoung Lee, MD, PhD,^{h,i} Young Jun Park, MD,^j Michael Gobitz, MD,^b Grzegorz Kielbasa, MD, PhD,^k
Dipen Zalavadia, MD,^l Heli Tolppanen, MD, PhD,^m David Žižek, MD, PhD,ⁿ Francesco Zanon, MD,^o
Lina Marcantoni, MD,^o Shunmuga Sundaram Ponnusamy, MD,^p Jarkko Karvonen, MD, PhD,^m Oscar Cano, MD, PhD,^q
Marek Jastrzebski, MD, PhD,^k Pugazhendhi Vijayaraman, MD, PhD,^l Haran Burri, MD^r

N= 8255 patients (OBS)

12 fractures (0.04% LLLs, 0.4% SDLs)

2 LLL (both extracted with manual traction)

**10 SDLs : 5 manual traction, 5 locking stylet, 2 lead tip broke off
requiring femoral extraction tools.**



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Lead Integrity and Failure Evaluation in Left Bundle Branch Area Pacing (LIFE-LBBAP) Study



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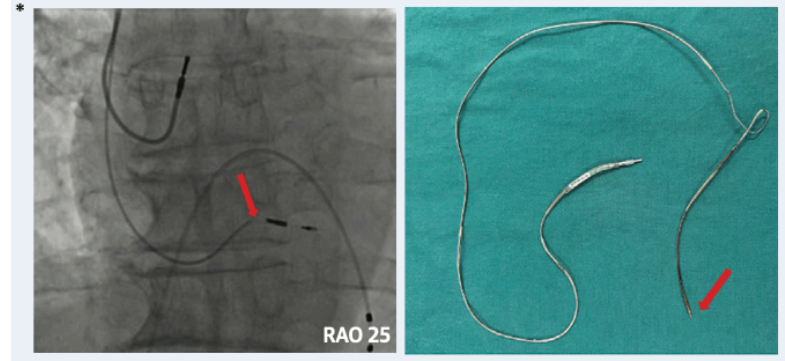
N= 8255 patients

12 fractures (0.04% LLLs, 0.4% SDLs)

2 LLL (both extracted with manual traction)

10 SDLs : 5 manual traction, 5 locking stylet, 2 lead tip broke off requiring femoral extraction tools.

LBBAP LLL Fracture Location (n = 2/5,609, 0.04%):



Fracture Occurs Proximal of Ring Electrode



ORIGINAL RESEARCH

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N= 8255 patients

Lead type

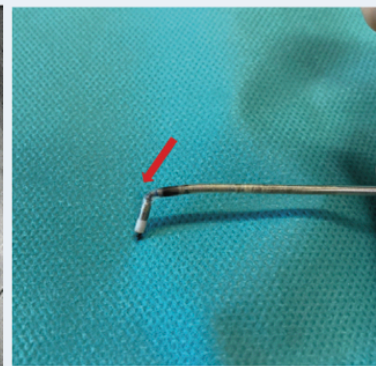
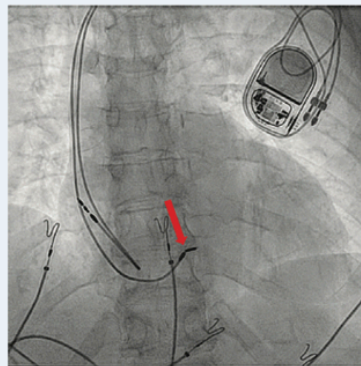
Lumenless pacing lead	5,609 (67.9)
SelectSecure 3830 (Medtronic)	5,609 (67.9)
Stylet-driven pacing lead	2,646 (32.1)
Solia S (Biotronik)	2,269 (27.5)
Tendril (Abbott)	184 (2.2)
Ingevity (Boston Scientific)	185 (2.2)
Vega (MicroPort)	8 (0.1)

12 fractures (0.04% LLLs, 0.4% SDLs)

2 LLL (both extracted with manual traction)

10 SDLs : 5 manual traction, 5 locking stylet, 2 lead tip broke off requiring femoral extraction tools.

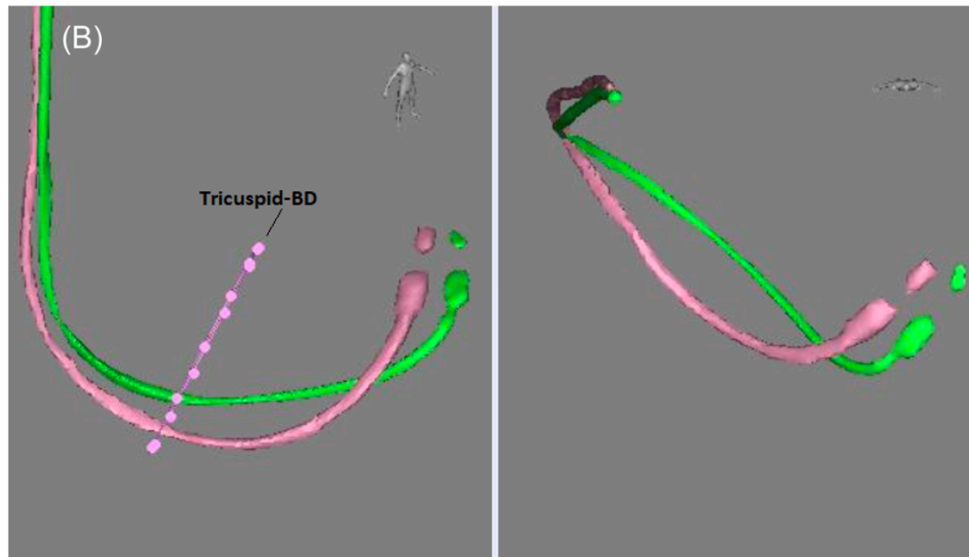
LBBAP SDL Fracture Location (n = 10/2,646, 0.4%):



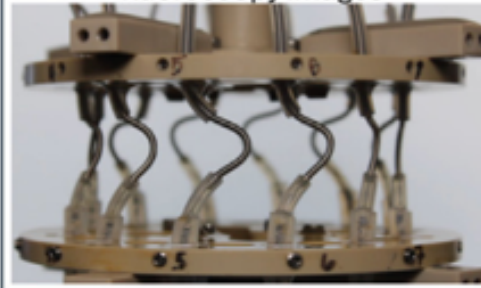
Fracture Occurs at Interelectrode Segment



Longevity in vitro testing



OmniaSecure leads were tested under extreme use conditions representing greater bending curvatures than observed in the LEADR patient biplane fluoroscopy images



2017

Case Report
A Novel Pacing Strategy With Low and Stable Output: Pacing the Left Bundle Branch Immediately Beyond the Conduction Block
Weijian Huang, MD, FHRS,¹ Lan Su, MD,² Shengjie Wu, MD,³ Lei Xu, MD,⁴ Fangqi Xiao, MD,⁵ Xiaohong Zhou, MD,⁶ and Kenneth A. Ellenbogen, MD, FHRS⁷

2023

CLINICAL RESEARCH
Procedural outcome and follow-up of stylet-driven leads compared with lumenless leads for left bundle branch area pacing

2024

ORIGINAL ARTICLE
Comparison of Procedural Outcomes of Lumenless Fixed-Helix Versus Stylet-Driven Extendable-Helix Lead Systems in Left Bundle Branch Pacing: COMPARE LBBP

2025: Lead integrity

ORIGINAL RESEARCH
Lead Integrity and Failure Evaluation in Left Bundle Branch Area Pacing
The LIFE-LBBAP Study



2020: SDLs

Received: 20 August 2020 | Revised: 20 November 2020 | Accepted: 12 December 2020
DOI: 10.1111/pace.14551

ORIGINAL ARTICLES

WILEY

Left bundle branch area pacing using stylet-driven pacing leads with a new delivery sheath: A comparison with lumen-less leads

Jan De Pooter MD, PhD¹ | Simon Calle MD² | Frank Timmermans MD, PhD³ | Frederic Van Haverbeem MD⁴

2023

Acute performance of stylet driven leads for left bundle branch area pacing: A comparison with lumenless leads

Óscar Cano, MD, PhD,^{1,2} Javier Navarrete-Navarro, MD,^{1,3} Dipen Zalavadiya, MD,⁴ Pablo Jover, MD,^{1,5} Joaquín Osca, MD, PhD,^{1,6} Radhika Bahadur, MD,⁷ Maite Izquierdo, MD, PhD,^{1,8} Josep Navarro, MD,⁹ Faiz A. Subzposh, MD,¹ Hebert D. Ayala, MD,^{1,10} Luis Martínez-Solís, MD, PhD,^{1,11} Pugazhendhi Vijayarajan, MD, FHRS,¹ Syeda Atiqia Batul, MD¹

2024

HeartRhythm
The Official Journal of the Heart Rhythm Society
Left bundle branch area pacing using a stylet-driven, retractable-helix lead: Short-term results from a prospective multicenter IDE trial (the BIO-CONDUCT study)

Left bundle branch area pacing using a stylet-driven, retractable-helix lead: Short-term results from a prospective multicenter IDE trial (the BIO-CONDUCT study)

2025

Pacing and Clinical Electrophysiology

DEVICES

Stylet-Driven Lead Vs. Lumenless Lead for Left Bundle Branch Area Pacing: Systematic Literature Review and Meta-Analysis

2026: DF leads

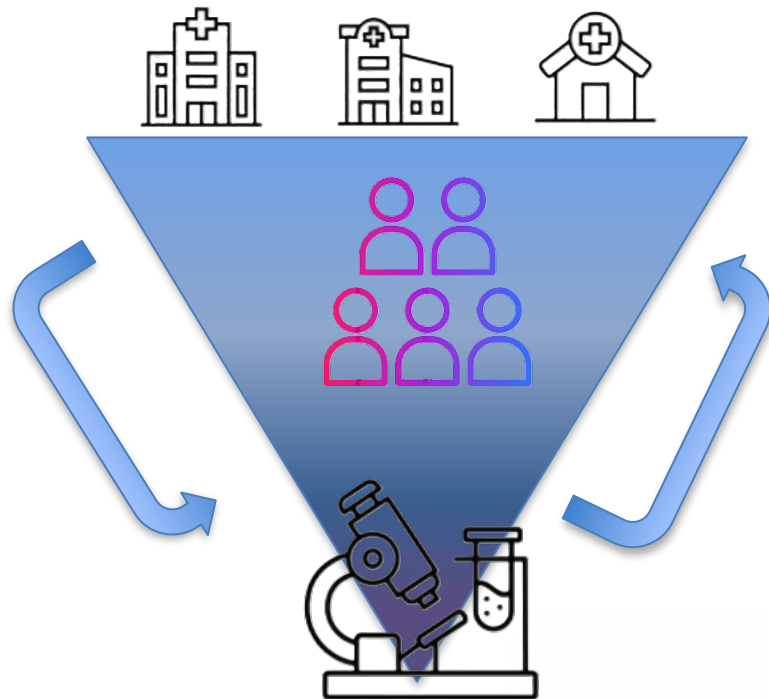
HeartRhythm
The Official Journal of the Heart Rhythm Society
High predicted durability for the novel small-diameter OmniaSecure defibrillation lead

High predicted durability for the novel small-diameter OmniaSecure defibrillation lead

WILEY
PACE



Where are we really now?



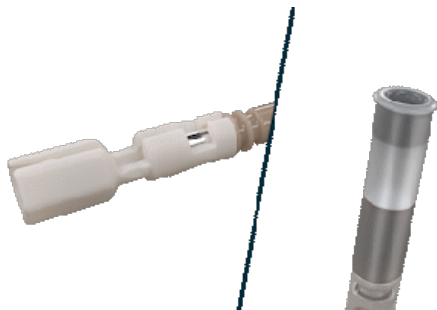
Where are we really now?

New design trends:

Intro on the new material:

- Abbot
- Biotronik
- Boston
- Microport





ROBUST DISTAL END DESIGN²

UltiPace Pacing Leads have a robust distal end design without a flexible zone seen in other pacing leads that helps reduce stress on the conductors.



SUPERIOR OUTCOMES

Significantly lower rates of heart failure hospitalization and all-cause mortality when used in LBBAP compared to traditional apical pacing.¹



DEMONSTRATED SAFETY

Freedom from adverse effects in left bundle branch area pacing.^{1,4}

RESISTANCE TO DISTAL FATIGUE FAILURE³

TESTED TO
**400
MILLION**
CYCLES

SIMULATING
**10
YEARS**
OF SERVICE

AND MULTIPLE STUDIES ALL WITH
**ZERO
CONDUCTOR FRACTURES**
IN LEFT BUNDLE BRANCH AREA PLACEMENT.^{4,5}



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 ^②

Pugazhendhi Vijayaraman, MD, FHRS,¹ Parikshit S. Sharma, MD, MPH, FHRS,²
Brett D. Atwater, MD, FHRS,³ Devi Nair, MD, FHRS,⁴ Jacqueline Joza, MD, MSc,⁵
Francesco Zanon, MD,⁶ Wenwen Li, PhD,⁷ Jeeyun A. Kim, MS,⁷ Yelena Nabutovsky, MS,⁷
Kwangdeok Lee, PhD,⁷ Robert D. Schaller, DO, FHRS⁸

1.28% device malfunction (LBBAP)

1.37% dislodgment

Table 2 Unadjusted and adjusted acute (30-d) complication rates of patients treated with LBBAP vs RVP

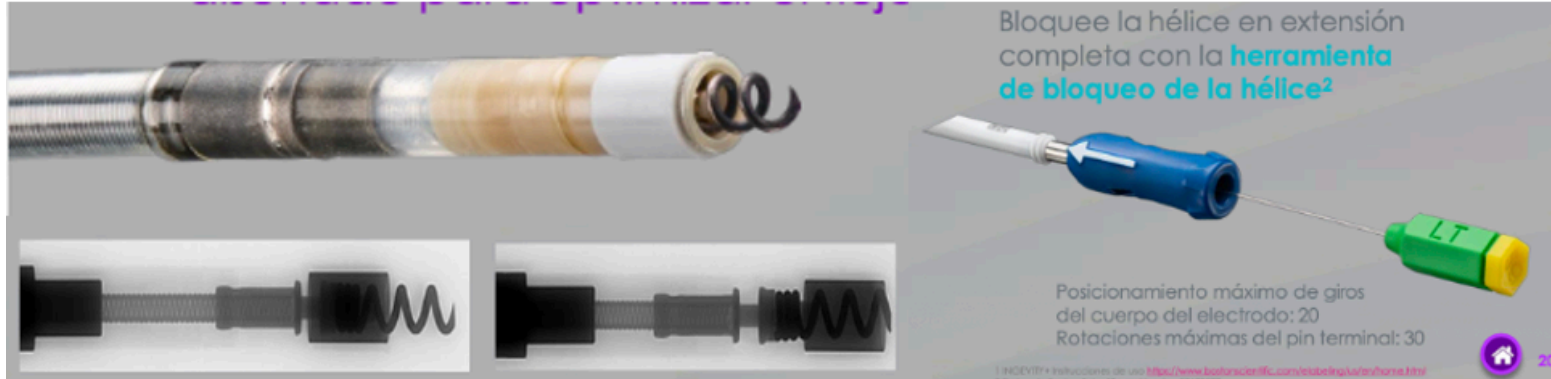
Complications	Unadjusted rates			Adjusted rates		
	LBBAP (n = 2341), n (%)	RVP (n = 68,241), n (%)	P	LBBAP (n = 2341), %	RVP (n = 68,241), %	P
Overall complications	182 (7.79)	5098 (7.47)	.55	7.76	7.71	.95
Embolism and thrombosis	44 (1.88)	1,504 (2.20)	.29	1.88	2.23	<.01
Deep vein thrombosis	21 (0.90)	723 (1.06)	.45	0.90	1.07	.02
Pulmonary embolism	24 (1.03)	842 (1.23)	.37	1.02	1.25	<.01
Thrombosis due to cardiac device	0	19 (0.03)	N/A	0	0.03	N/A
Embolism due to cardiac device	0	*	N/A	0	*	N/A
Events at the puncture site	*	159 (0.23)	.14	*	0.26	<.01
Cardiac effusion/perforation	12 (0.51)	267 (0.39)	.36	0.51	0.45	.3
Device-related complication	84 (3.59)	2165 (3.17)	.26	3.58	3.23	<.01
Device dislodgment	32 (1.37)	820 (1.20)	.47	1.37	1.22	.08
Infection	*	263 (0.39)	.32	*	0.37	<.01
Hemorrhage	13 (0.56)	211 (0.31)	.04	0.56	0.32	<.01
Device malfunction	30 (1.28)	798 (1.17)	.62	1.28	1.15	.13
Pain	*	109 (0.16)	.26	*	0.16	<.01
Stenosis	*	85 (0.12)	.24	*	0.19	.6
Pocket complications	13 (0.56)	388 (0.57)	.93	0.55	0.57	.83
Other complications	57 (2.43)	1538 (2.25)	.56	2.43	2.36	.56
Postprocedural hematoma	*	145 (0.21)	.65	*	0.24	.69
Postprocedural hemorrhage	*	63 (0.09)	.91	*	0.11	.34
Pericarditis	14 (0.60)	330 (0.48)	.43	0.6	0.52	.16
Acute myocardial infarction	*	66 (0.10)	.02	*	0.13	<.01
Intraoperative cardiac arrest	*	87 (0.13)	.1	*	0.18	.02
Bleeding or failure of the vascular closure device requiring intervention	*	81 (0.12)	.9	*	0.14	.53
Hemothorax	0	*	N/A	0	*	N/A
Pneumothorax	22 (0.94)	878 (1.29)	.14	0.94	1.24	<.01

N/A = not applicable; other abbreviations as in Table 1.

*Centers for Medicare and Medicaid Services requires cell suppression for values between 1 and 10 to protect patient privacy.

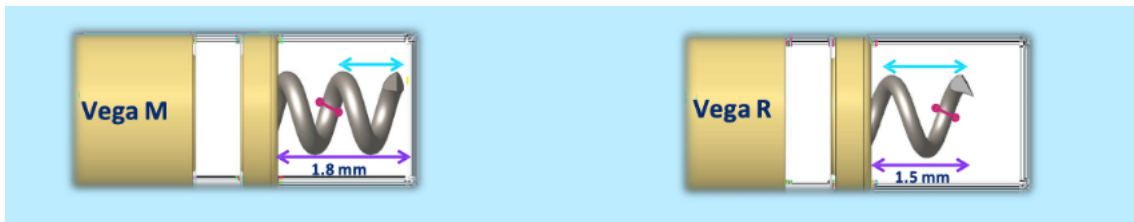
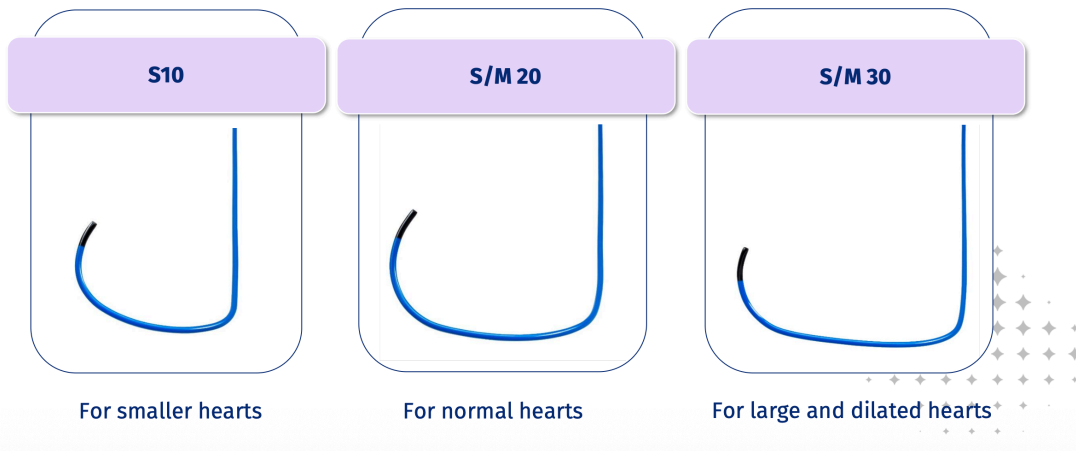


- Report preconditioning and in vitro durability studies >99% expected durability
- Real life registry (INSIGHT) no lead fractures (median fu 302 days)



Microport

3 shapes for every patients' needs





Solia CSP S



Selectra



¹ BIOTRONIK Solia CSP S technical manual; Medtronic SelectSecure 3830 technical manual; Boston Scientific INGEVITY+ physician's lead manual; Abbott UltiPace user's manual.

² BIOIMASTER.CSP Interim Clinical Analysis Report. Data on file.

³ BIOTRONIK Internal Test. Data on file.

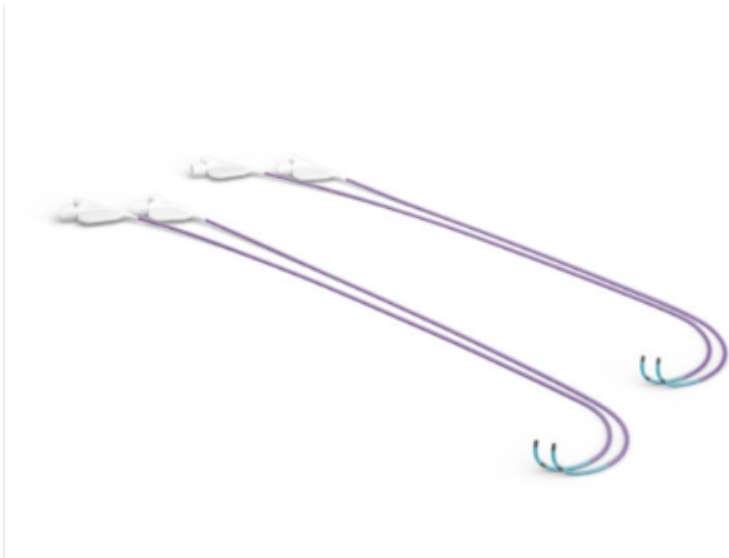
⁴ BIOTRONIK Internal Investigation Report. Data on file.

⁵ BIOTRONIK Internal Test. Data on file.

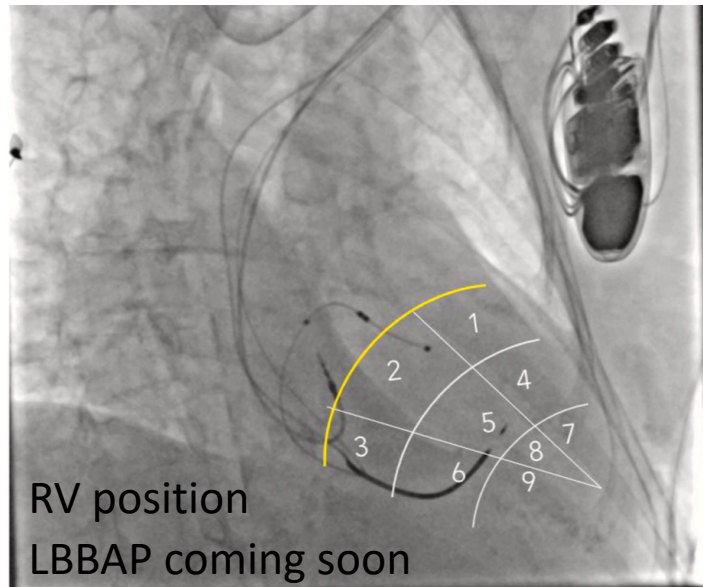
⁶ BIOTRONIK Solia CSP S, Instructions for use



C320LBB



OmniaSecure™ defibrillation lead



Conclusion

- Both electrodes have **similar success rates (LBBAP)**
- SDLs have technical differences that have to be taken care of during the implant procedure in order to minimize complications and helix retraction: **there is a specific learning curve for each technique!**
- Long term performance is important, although **current data supports safety of both types of leads**
- **Newer materials** have been developed, and probably (due to the variability and variety) we won't see a head to head comparison between them, but will have to build up new evidence to support their use.





THANK YOU

Electrode Selection in Left Bundle Branch Stimulation