

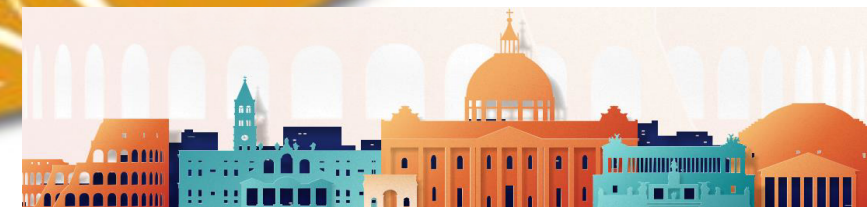
**Reimpianto di
pacemaker dopo
estrazione per
infezione:
pacemaker
tradizionale o
leadless?**

Francesco Perna, MD, PhD

UOSD Aritmologia

Fondazione Policlinico
Universitario Agostino Gemelli
IRCCS

Roma, 25/06/2026



Reimplantation after TLE



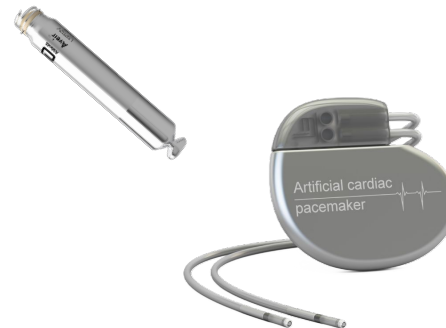
- Reimplant or not?



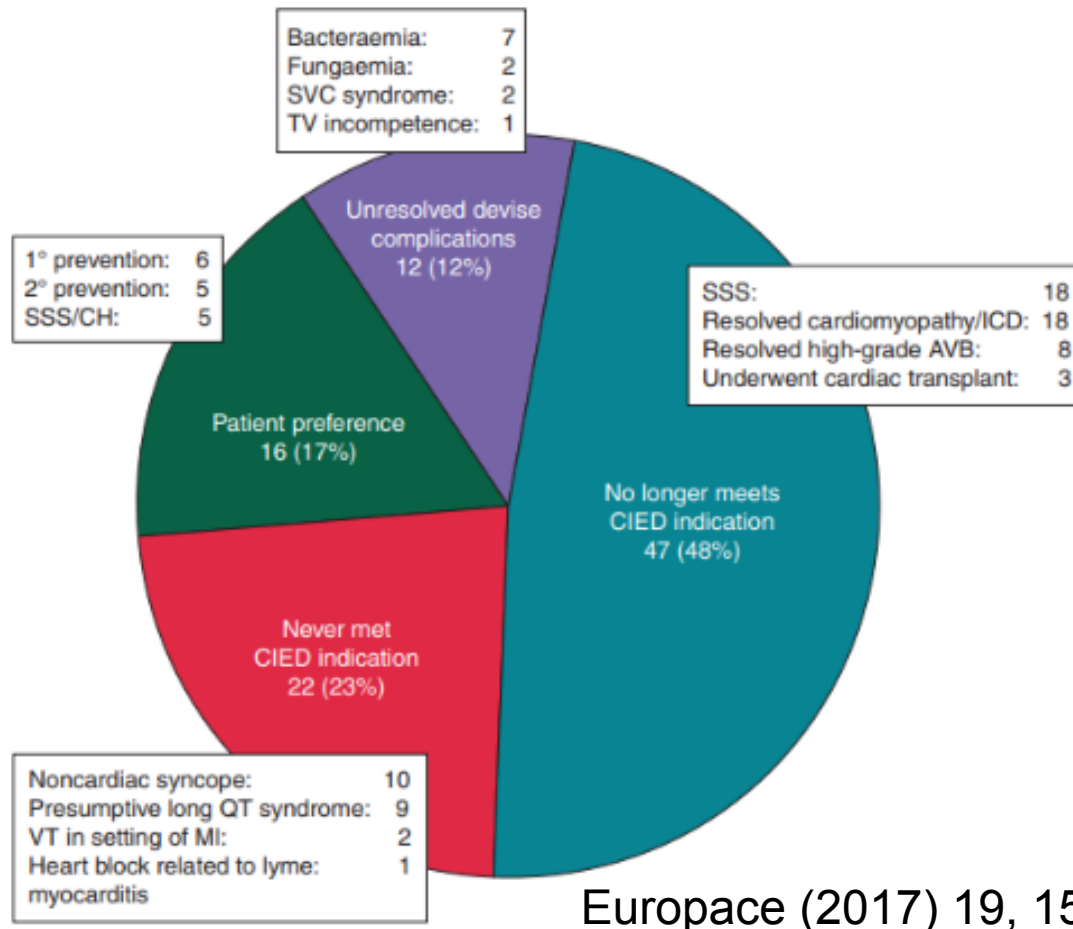
- When to reimplant?



- What to reimplant?

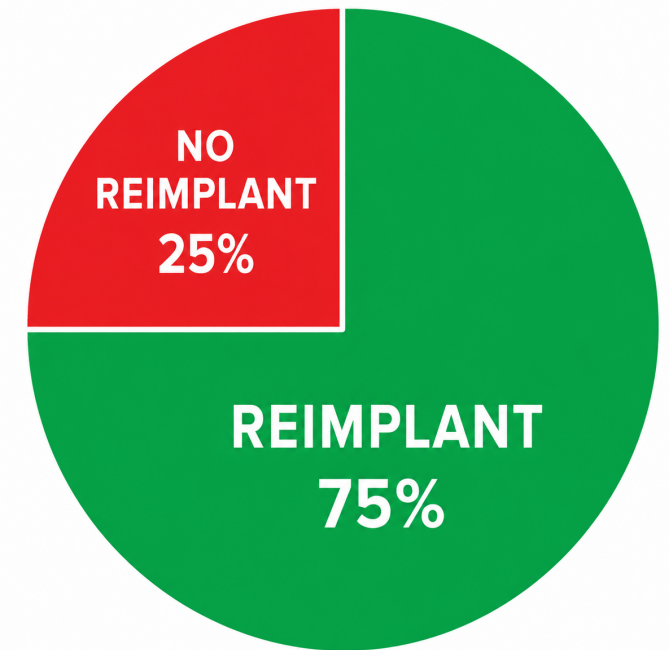


Reimplantation after TLE



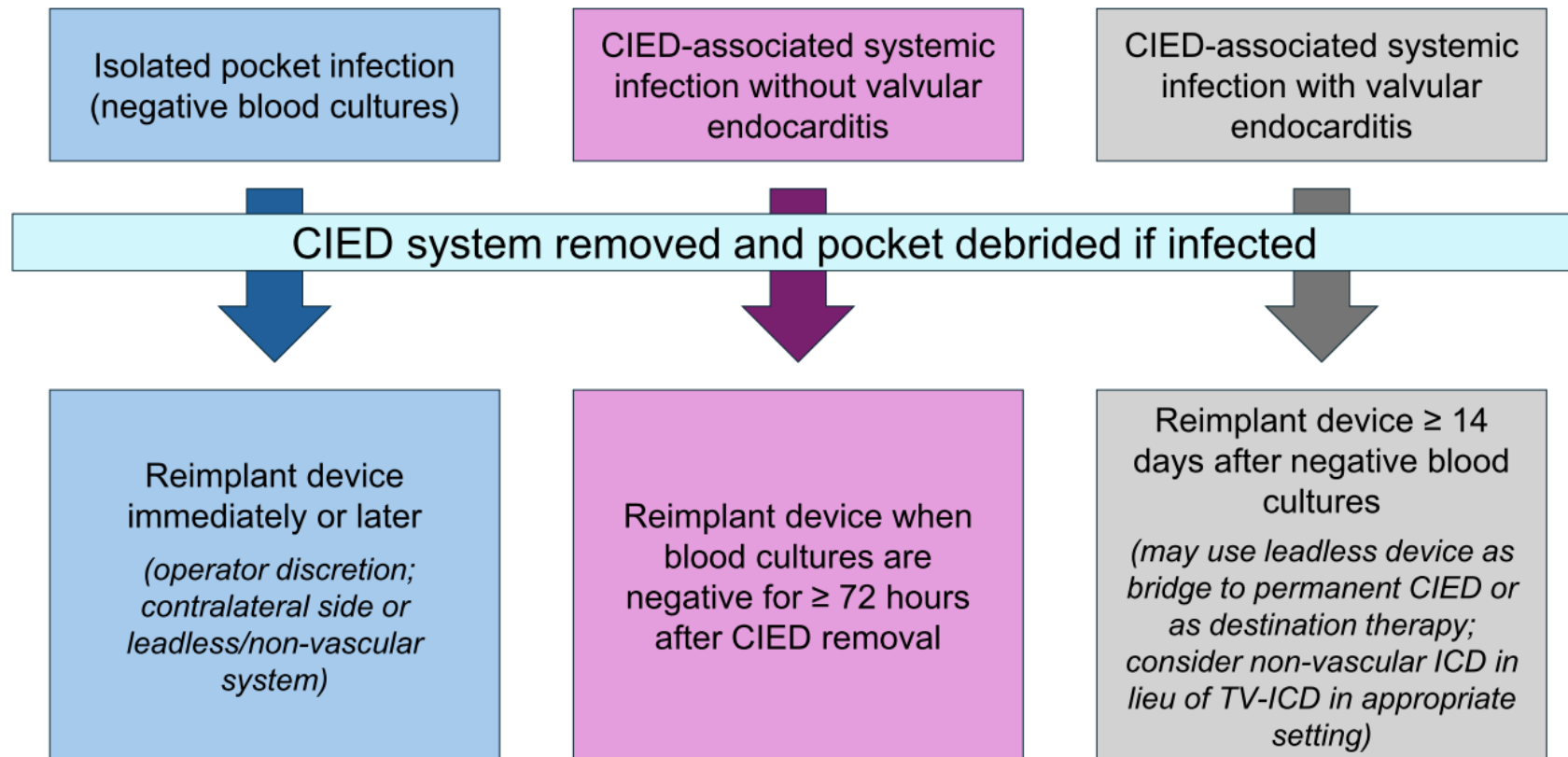
Europace (2017) 19, 1527–1534

Figure 3 Reasons for no CIED reimplantation in the no-reimplant group. Numbers in the boxes indicate the number of patients with the listed condition. AVB, atrioventricular block; CH, carotid sinus hypersensitivity; CIED, cardiovascular implantable electronic device; ICD, implantable cardioverter-defibrillator; MI, myocardial infarction; SSS, sick sinus syndrome; SVC, superior vena cava; TV, tricuspid valve.



Reimplantation rate at FPG

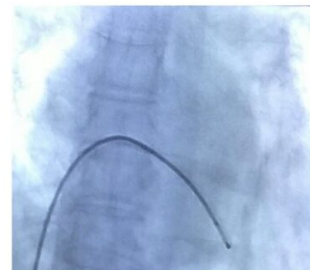
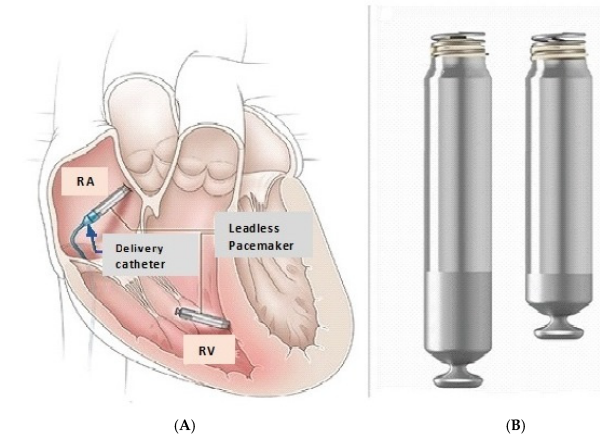
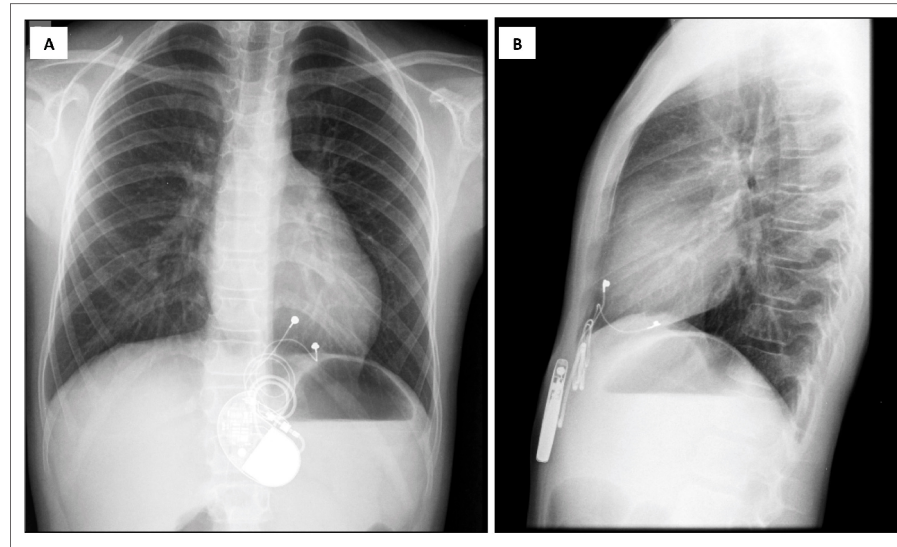
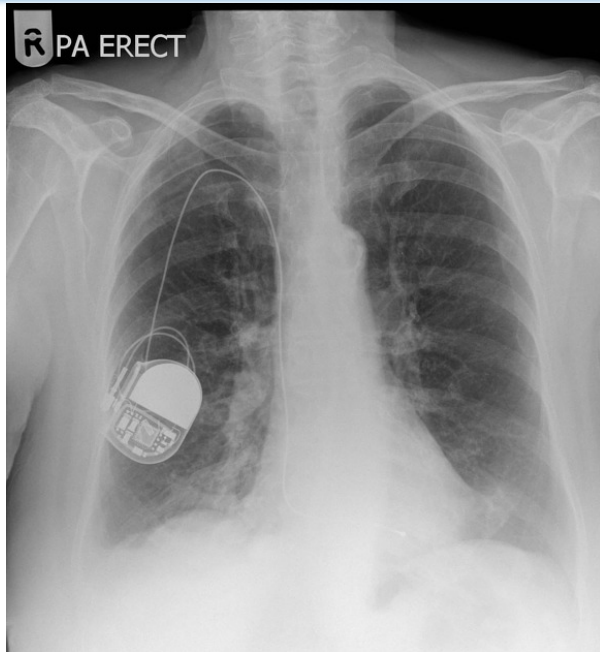
Reimplantation timing



Recommendations for reimplantation timing after CIED removal for infection

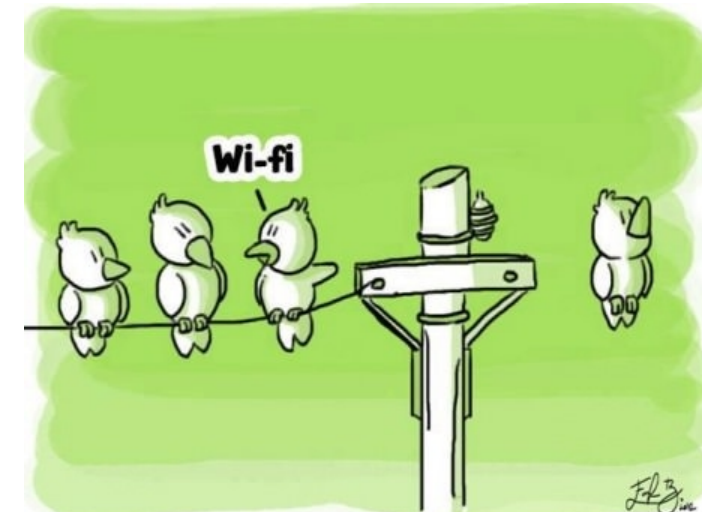
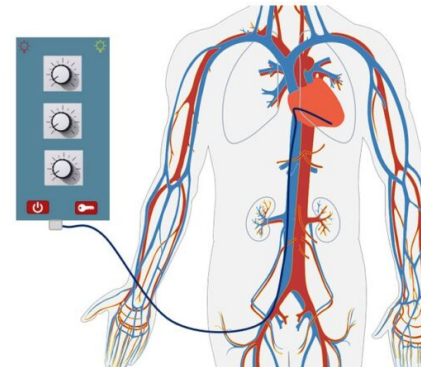
COR	LOE	Recommendations
1	C-LD	1. In patients who are pacemaker dependent and undergoing CIED removal for infection, the timing of reimplantation and device selection should be individualized based on clinical status and risk of reinfection. ^{262,267–269}

What to reimplant



Temporary pacing
lead on fluoroscopy

Temporary pacemaker and
lead schematic diagram



Recommendations for leadless pacing therapies

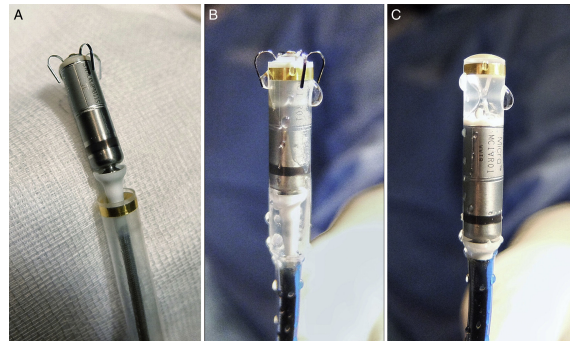
COR	LOE	Recommendations
1	C-EO	1. In patients who require bradycardia pacing support, shared decision making is recommended to choose the type of pacemaker based on a patient-centered approach.

Leadless pacemakers reduce risk of device-related infection: Review of the potential mechanisms

Mikhael F. El-Chami, MD, FHRS,^{*} Matt Bonner, PhD,[†] Reece Holbrook, BSEE,[†] Kurt Stromberg, MS,[†] Jane Mayotte, MS,[†] Amy Molan, PhD,[†] M. Rizwan Sohail, MD,[‡] Laurence M. Epstein, MD[§]



Pocket involvement in 60% of CIED infections

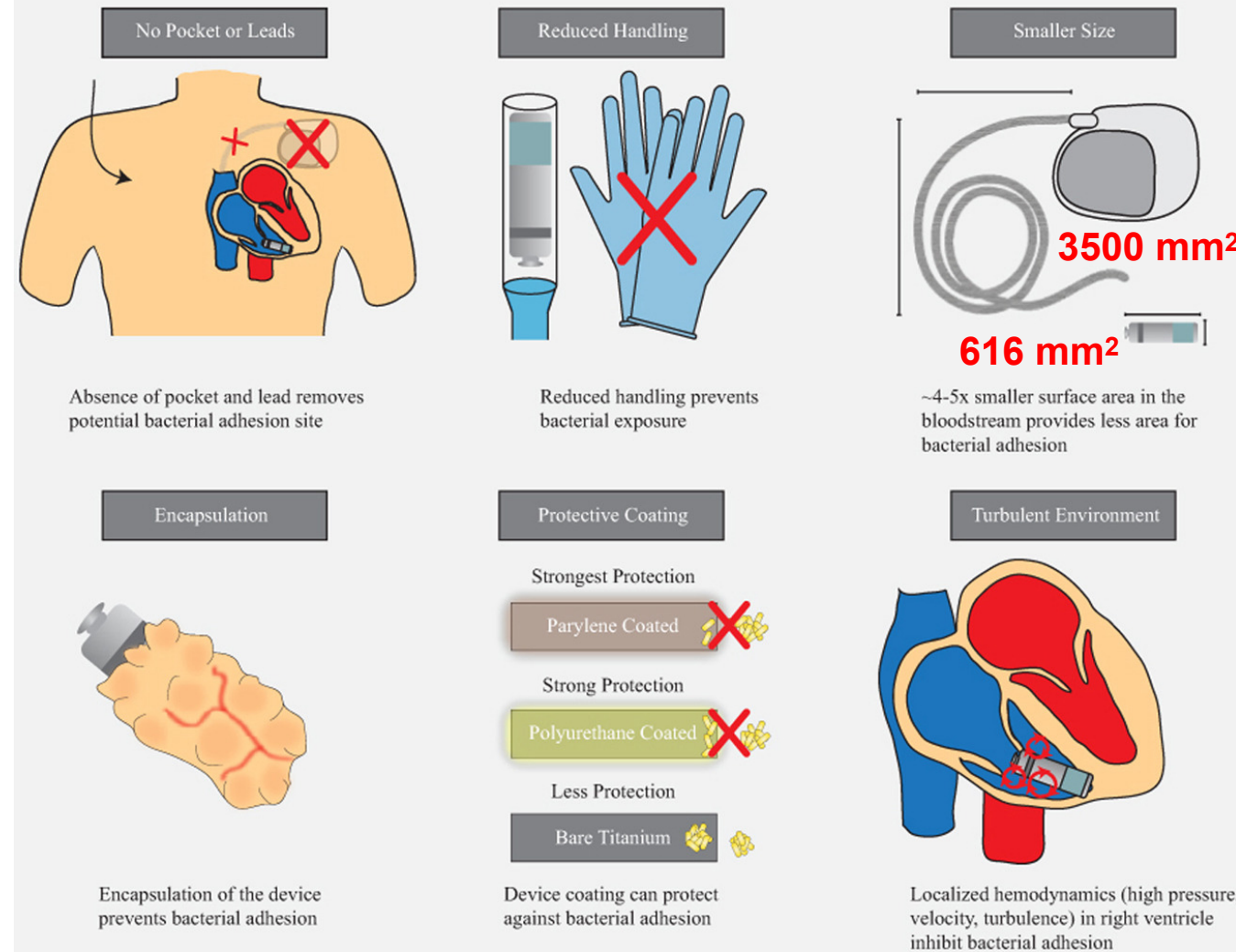


Parylene coating



Figure 1 Fully encapsulated Micra device.

Factors Impacting Leadless Pacemaker Infection Resistance





Leadless pacemakers at 5-year follow-up: the Micra transcatheter pacing system post-approval registry

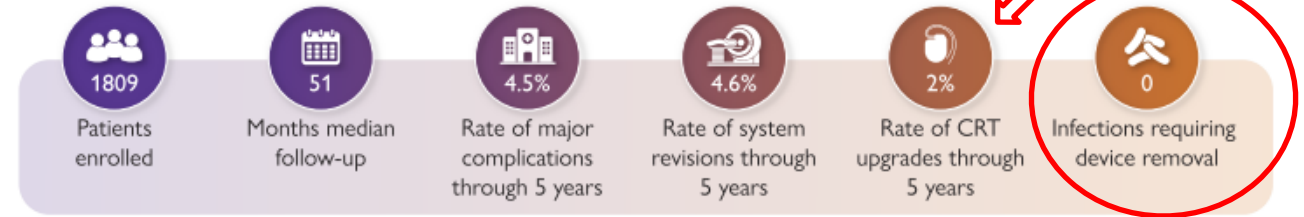
Mikhael F. El-Chami^{1*}, Christophe Garweg², Nicolas Clementy³,
Faisal Al-Samadi⁴, Saverio Iacopino⁵, Jose Luis Martinez-Sande⁶, Paul R. Roberts⁷,
Claudio Tondo⁸, Jens Brock Johansen⁹, Xavier Vinolas-Prat¹⁰,
Yong-Mei Cha¹¹, Eric Grubman¹², Pierre Bordachar¹³, Kurt Stromberg¹⁴,
Dedra H. Fagan¹⁴, and Jonathan P. Piccini¹⁵

Included a subset of high risk pts:

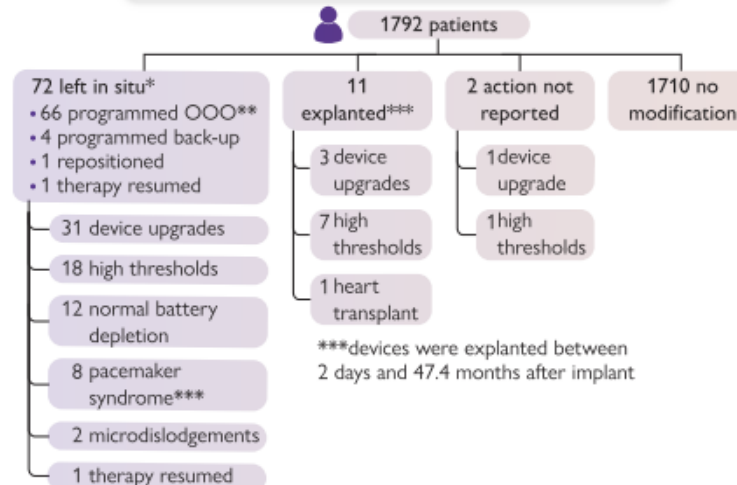
Diabetes (25.3%), renal dysfunction (20.8%), preclusion of a transvenous device because of previous infection, need for dialysis, or cancer (22.4%).

Only 12 PM syndrome or PICM cases → 11 upgrades

5-year follow-up of the Micra VR post-approval registry

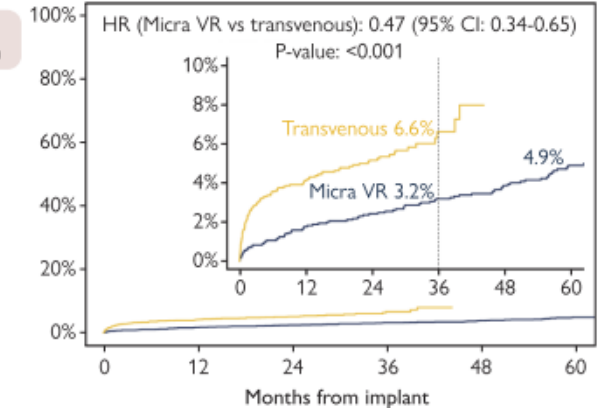


Disposition of system revisions among Micra VR patients



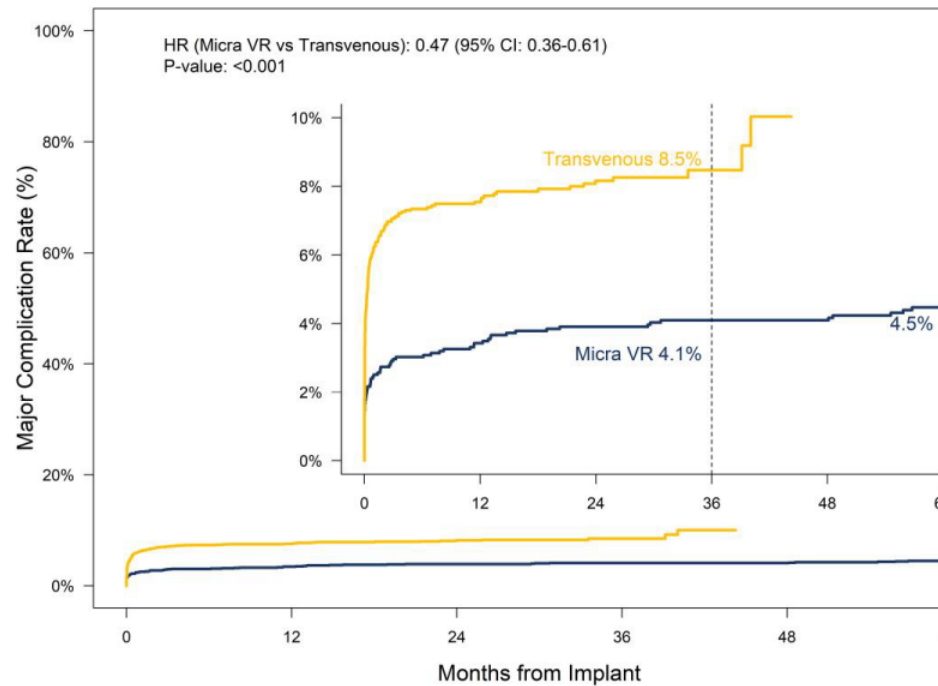
Significantly lower rate of system revisions compared to transvenous PPM

System revision rate (%)



Number at risk

	Micra VR	1792	1494	1300	1104	949	611
Transvenous	2667	1595	1053	238	0	0	0



	Micra VR	1809	1476	1284	1100	949	0
Transvenous	2667	1526	1002	221	0	0	0

*72 events in 70 patients; **66 events in 65 patients;
***7 associated with pacemaker syndrome major complications,
1 associated with pacing induced cardiomyopathy major complication



Leadless pacemakers at 5-year follow-up: the Micra transcatheter pacing system post-approval registry

Mikhael F. El-Chami^{1*}, Christophe Garweg², Nicolas Clementy³,
Faisal Al-Samadi⁴, Saverio Iacopino⁵, Jose Luis Martinez-Sande⁶, Paul R. Roberts⁷,
Claudio Tondo⁸, Jens Brock Johansen⁹, Xavier Vinolas-Prat¹⁰,
Yong-Mei Cha¹¹, Eric Grubman¹², Pierre Bordachar¹³, Kurt Stromberg¹⁴,
Dedra H. Fagan¹⁴, and Jonathan P. Piccini¹⁵

No devices removed
for infection

9 all-cause
infections

4 observations

5 major
complications
criteria

1 sepsis

Catheter site
groin infection

1 abdominal
wall infection

Haematoma
infection

1 possible
device
endocarditis

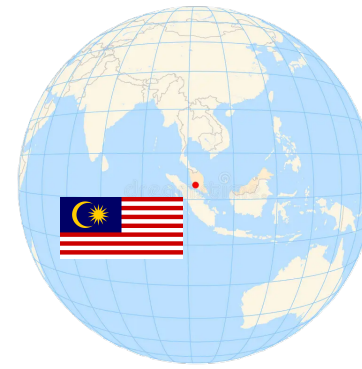
Resolved with
antibiotics

390 days post implant in haemodialysis pt

Treating an infected transcatheter pacemaker system via percutaneous extraction

Alan Koay, MD, MRCP, Surinder Khelae, MBBS, FHRs, Koh Kok Wei, MBBS, MRCP, Zulkeflee Muhammad, MBChB, MRCP, Rosli Mohd Ali, MD, FAPSIC, Razali Omar, MD, FHRs

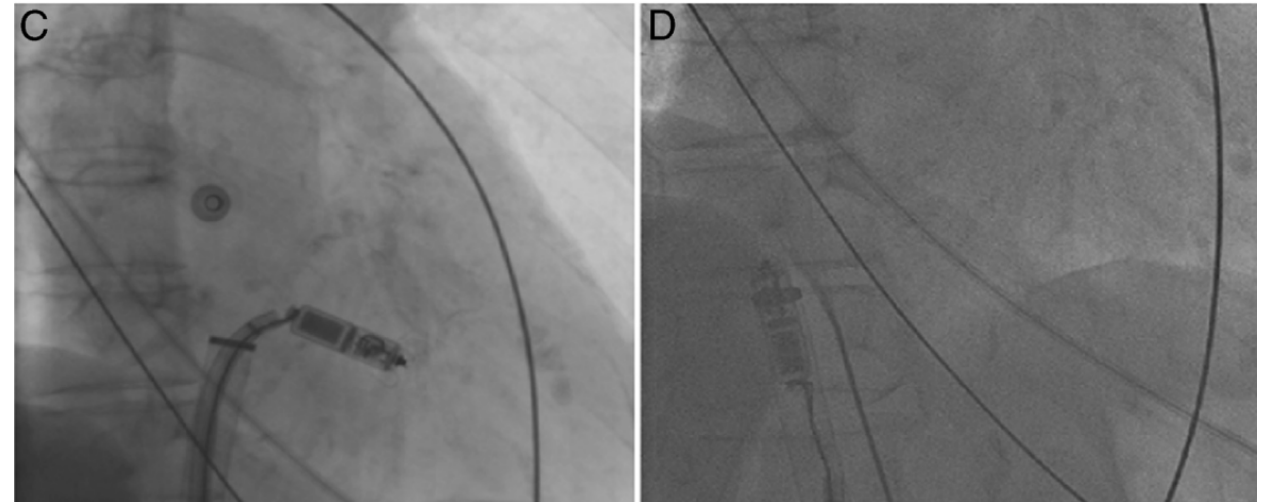
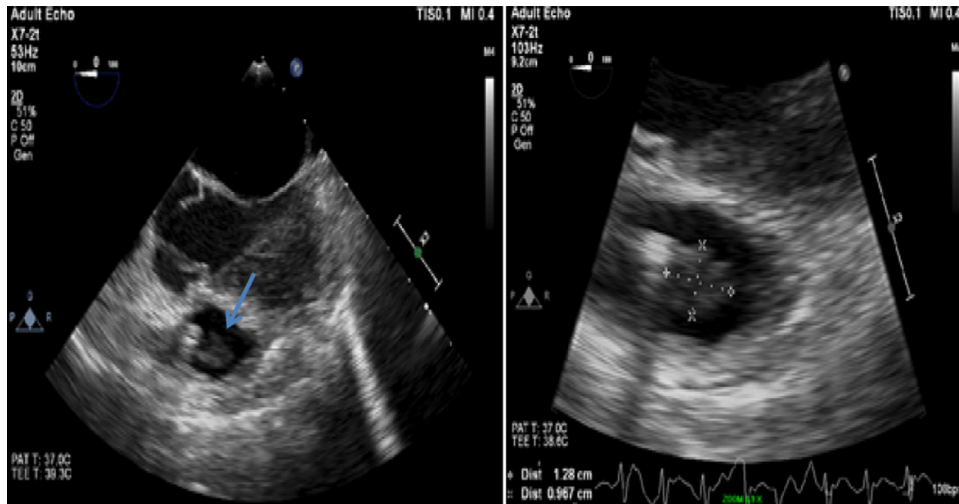
From the National Heart Institute, Kuala Lumpur, Malaysia.



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Gemelli



Fondazione Policlinico Universitario A. Gemelli
Università Cattolica del Sacro Cuore



80 yo woman
Fever and MRSA sepsis
1 month after Micra
implantation

Vegetation at TEE

Successfully explanted



> 50.000 LPs implanted worldwide

Single case reported of a LP removed
because of infection

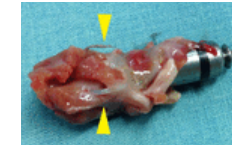
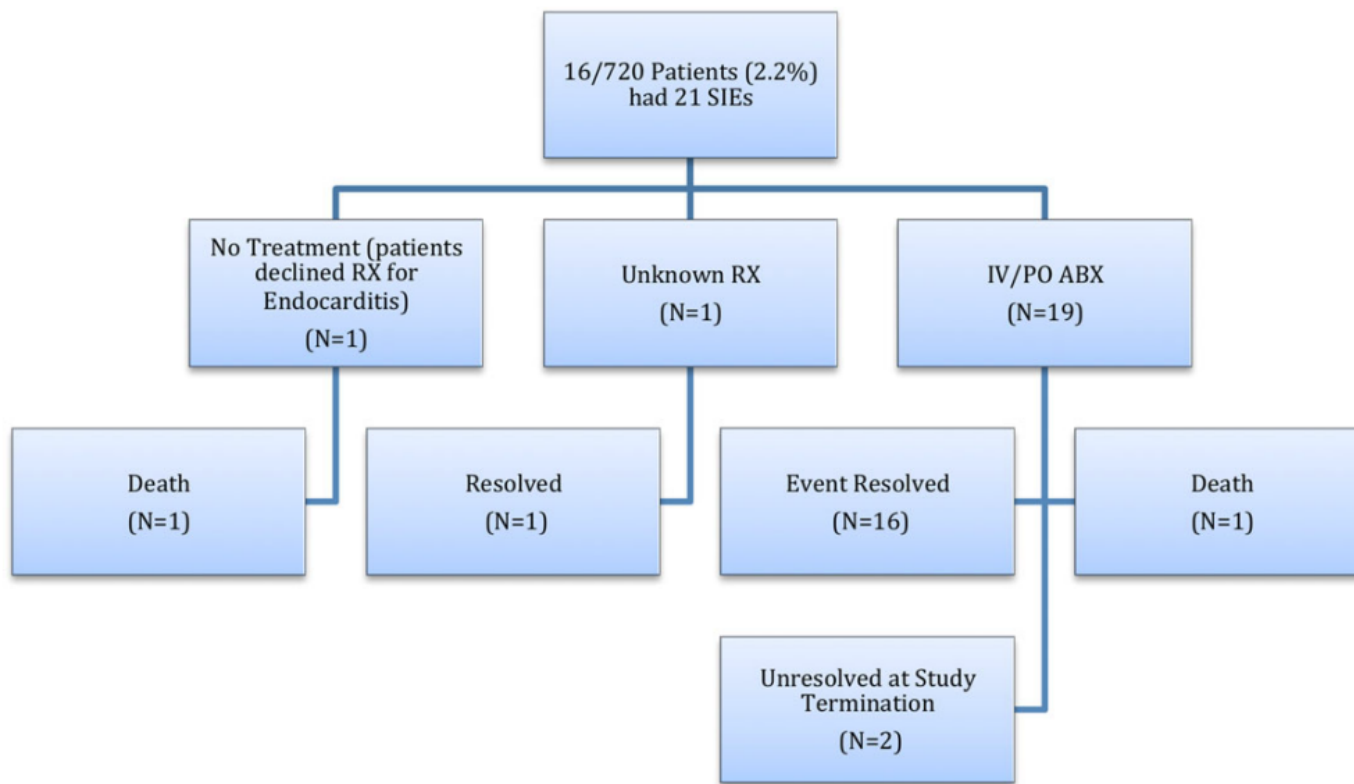
Infection rate = 0.002%

(transvenous PM: 0.77 - 2.08%)

Incidence and outcomes of systemic infections in patients with leadless pacemakers: Data from the Micra IDE study

Mikhael F. El-Chami MD¹  | Kyoko Soejima MD² | Jonathan P. Piccini MD, MHS³  |
Dwight Reynolds MD⁴ | Philippe Ritter MD⁵ | Toshimasa Okabe MD⁶  |
Paul A. Friedman MD⁷  | Yong-Mei Cha MD⁷  | Kurt Stromberg MS⁸ |
Reece Holbrook BS⁸ | Dedra H. Fagan PhD⁸  | Paul R. Roberts MD⁹

Background. Micra Trials: > 3000 patients, no device-related infections requiring removal (smaller surface area, greater tendency for encapsulation).



Outcome of Micra patients who developed bacteremia and/or endocarditis during follow-up.

16 patients out of 720 (2.2%)

Most Gram-positive, mainly *S. aureus* → seeds up to **68%** of transvenous leads in the setting of bacteremia.

In contrast, **no** Micra pacemakers in this study required **extraction** due to infection.

All cases responded to antibiotic therapy.

All events were adjudicated as unrelated to the Micra device or procedure.

No persistent bacteremia after antibiotic cessation

Leadless Cardiac Pacemaker Implantation After Lead Extraction in Patients With Severe Device Infection

ALEXANDER KYPTA, M.D.,* HERMANN BLESSBERGER, M.D.,* JUERGEN KAMMLER, M.D.,* THOMAS LAMBERT, M.D.,* MICHAEL LICHTENAUER, Ph.D.,† WALTER BRANDSTAETTER, M.D.,‡ MICHAEL GABRIEL, M.D.,‡ and CLEMENS STEINWENDER, M.D.*

From the *Department of Cardiology, Kepler University Hospital Linz, Medical Faculty of the Johannes Kepler University Linz, Linz; †Department of Cardiology, Clinic of Internal Medicine II, Paracelsus Medical University of Salzburg, Salzburg; and ‡Institute of Nuclear Medicine and Endocrinology, Kepler University Hospital Linz, Medical Faculty of the Johannes Kepler University Linz, Linz, Austria

Leadless Cardiac Pacemaker Implantation After Lead Extraction. *Background:* Conventional pacemaker therapy is limited by short- and long-term complications, most notably device infection. Transcatheter pacing systems (TPS) may be beneficial in this kind of patients as they eliminate the need for a device pocket and leads and thus may reduce the risk of re-infection.

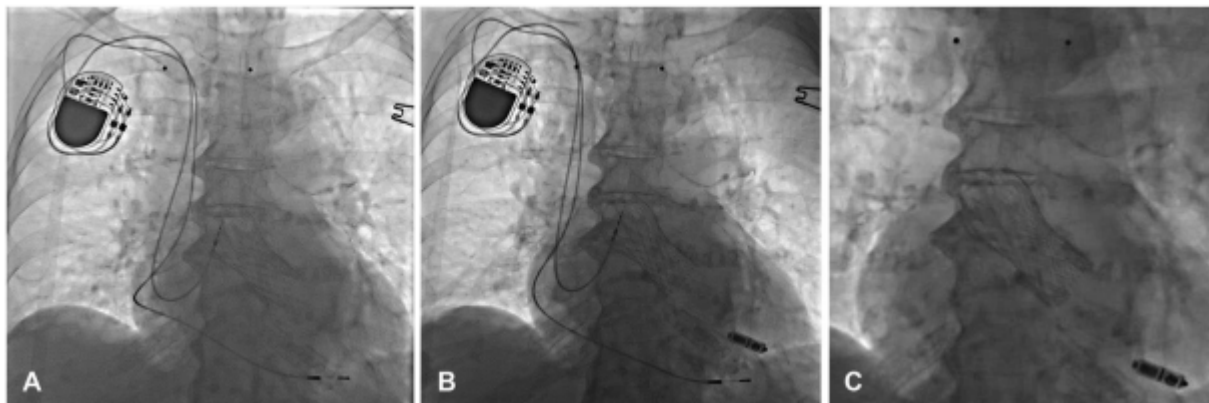
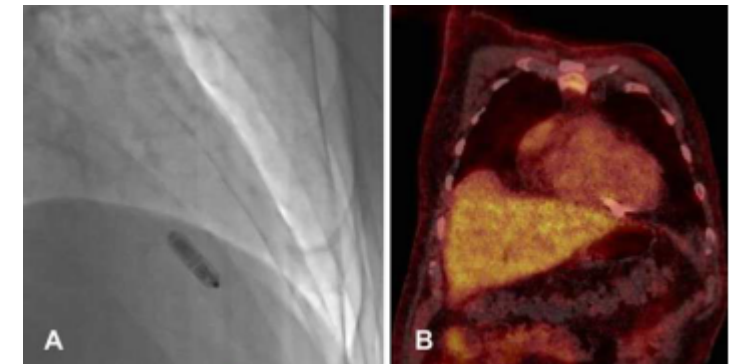
Methods: We assessed a novel procedure in 6 patients with severe device infection who were pacemaker dependent. After lead extraction a single chamber TPS was implanted into the right ventricle.

Results: Of the 6 patients who underwent lead extraction due to severe device infection at our institution, 3 were diagnosed with a pocket infection only, whereas the other 3 showed symptoms of both pocket and lead infection. Successful lead extraction and TPS implantation was accomplished in all patients. Four patients were bridged with a temporary pacemaker between 2 hours and 2 days after lead extraction, whereas 2 patients had the TPS implanted during the same procedure just before traditional pacemaker system removal. All patients stayed free of infection during the follow-up period of 12 weeks. An additional positron emission tomography scan was performed in each patient and indicated no signs of an infection around the TPS.

Conclusion: Transcatheter pacemaker implantation was safe and feasible in 6 patients and did not result in re-infection even if implanted before removal of the infected pacemaker system within the same procedure. Therefore, implantation of a TPS may be an option for patients with severe device infection, especially in those with blocked venous access or who are pacemaker dependent. (*J Cardiovasc Electrophysiol*, Vol. 27, pp. 1067-1071, September 2016)



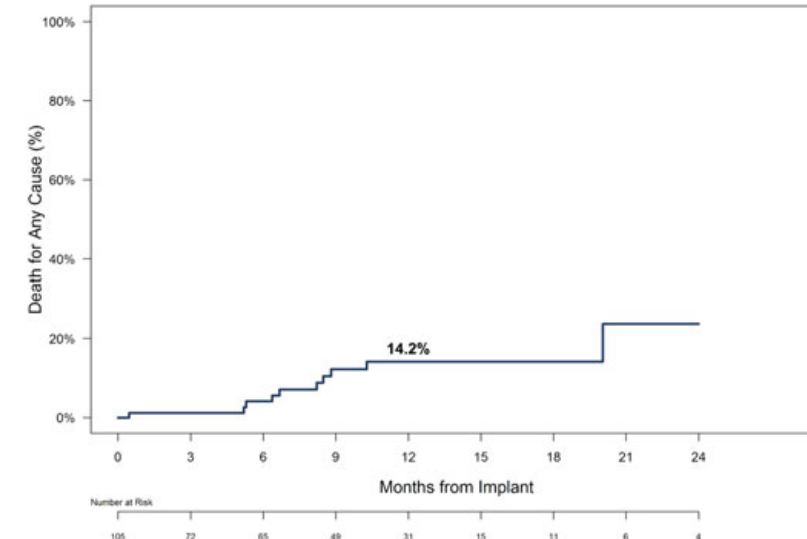
PET-TC scan a 3 mesi negative



6 pts
(3 infezioni tasca, 3 infezioni tasca e cateteri)
2 impianti micra contestuali, 4 con bridge cath temporaneo
No reinfezioni a 6 mesi

Leadless pacemaker implant in patients with pre-existing infections: Results from the Micra postapproval registry

Mikhael F. El-Chami MD, FHRS¹  | Jens Brock Johansen MD, PhD² | Amir Zaidi MD³ | Svein Faerestrland MD, PhD⁴ | Dwight Reynolds MD⁵ | Javier Garcia-Seara MD⁶ | Jacques Mansourati MD⁷ | Jean-Luc Pasquie MD, PhD⁸ | Hugh Thomas McElderry MD⁹ | Paul R. Roberts MD¹⁰ | Kyoko Soejima MD¹¹  | Kurt Stromberg MS¹² | Jonathan P. Piccini MD, MHS, FHRS¹³ 



105 pts with prior CIED extraction because of infection and Micra leadless pacemaker implant within 30 days. Pts with multiple comorbidities.

Explant a median of 6 days before Micra implant - **37% same day**

Mean follow-up 8.5 ± 7.1 months (range 0 - 28.5)

2 pts died for sepsis, unrelated to Micra (1 within 14 days, one at day 161 but multiple comorbidities and infection sources)

No leadless pacemaker explanted due to infection.

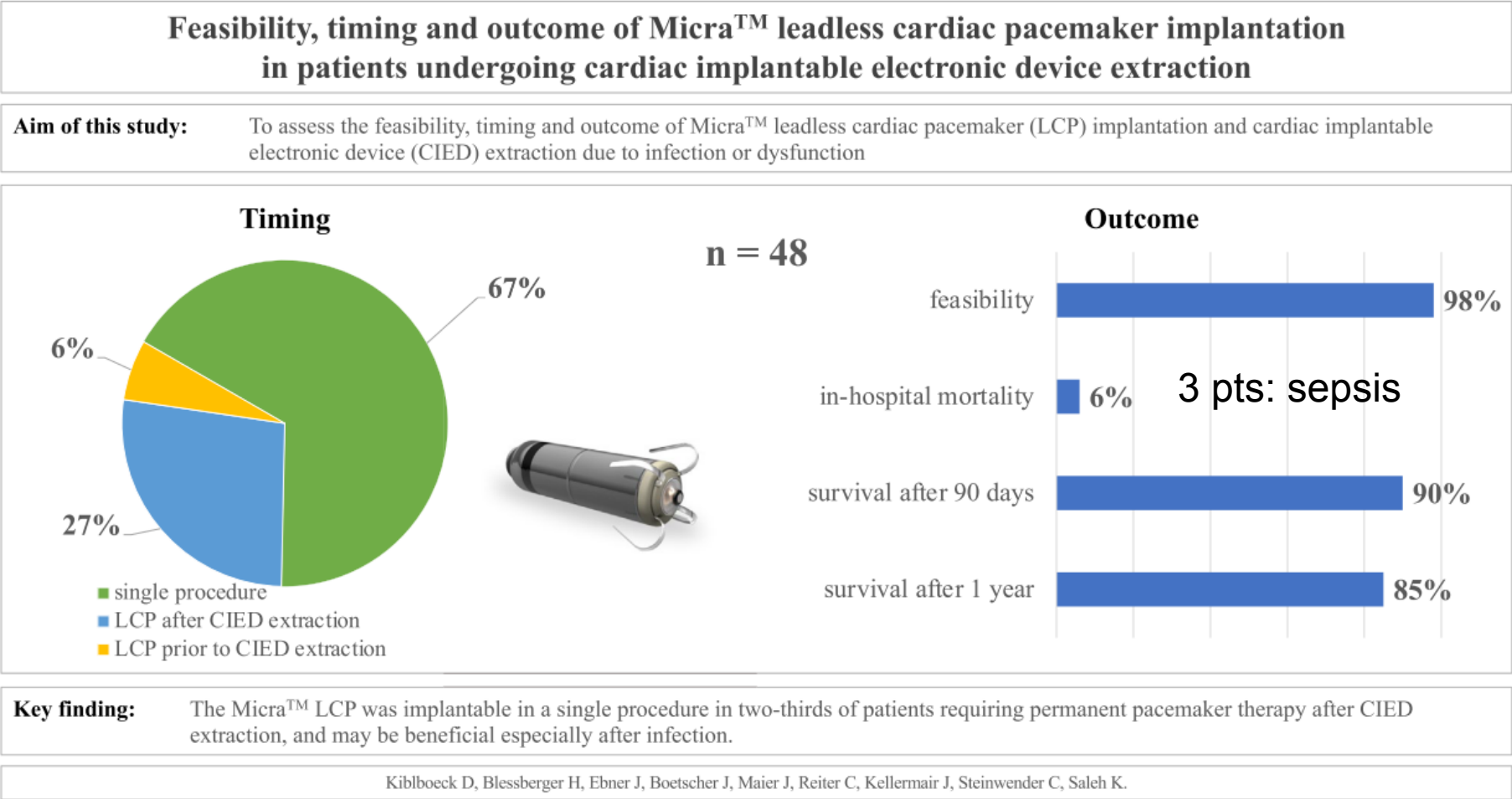
1 yr mortality 14.2% (vs average 20-35% after CDRIE)

Leadless pacemakers appear to be a safe pacing alternative for patients with CIED infection who undergo lead extraction



Feasibility, timing and outcome of leadless cardiac pacemaker implantation in patients undergoing cardiac implantable electronic device extraction

Daniel Kiblböck¹ · Hermann Blessberger¹ · Jakob Ebner¹ · Jakob Boetscher¹ · Julian Maier¹ · Christian Reiter¹ · Joerg Kellermair¹ · Clemens Steinwender^{1,2} · Karim Saleh¹



One AMI,
one cancer

No recurrent
infections at
15 months

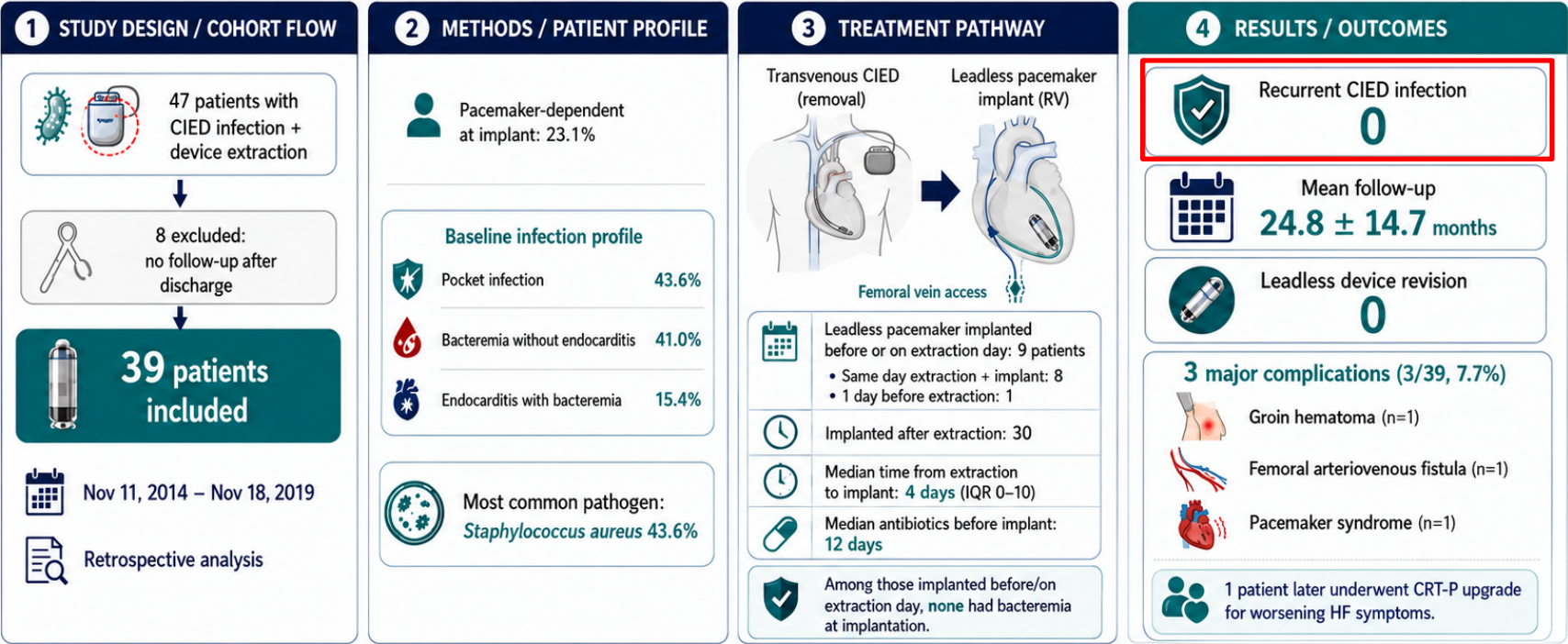
Leadless pacemaker implantation after lead extraction for cardiac implanted electronic device infection

Li Bicong MD¹ | John Carson Allen Jr, PhD⁴ | Kelly Arps MD¹ |
Sana M. Al-Khatib MD, MHS, FHRS^{1,2} | Tristram D. Bahnson MD, FHRS¹ |
James P. Daubert MD, FHRS¹ | Camille Frazier-Mills MD, MHS¹ |
Donald D. Hegland MD¹ | Kevin P. Jackson MD¹ |
Larry R. Jackson II MD, MHS^{1,3} | Robert K. Lewis MD, PhD^{1,3} |
Sean D. Pokorney MD, MBA^{1,2} | Albert Y. Sun MD^{1,3} |
Kevin L. Thomas MD, FHRS^{1,2} | Jonathan P. Piccini MD, MHS, FHRS^{1,2}

Leadless pacemaker implantation after lead extraction for CIED infection

Retrospective single-center cohort study • Duke University Hospital • Bicong et al. • J Cardiovasc Electrophysiol 2022

Despite previous CIED infection and an increased risk of future infection, during a mean follow-up of over 2 years, there was **no evidence of CIED infection** following LP implantation at or after the time of CIED removal.



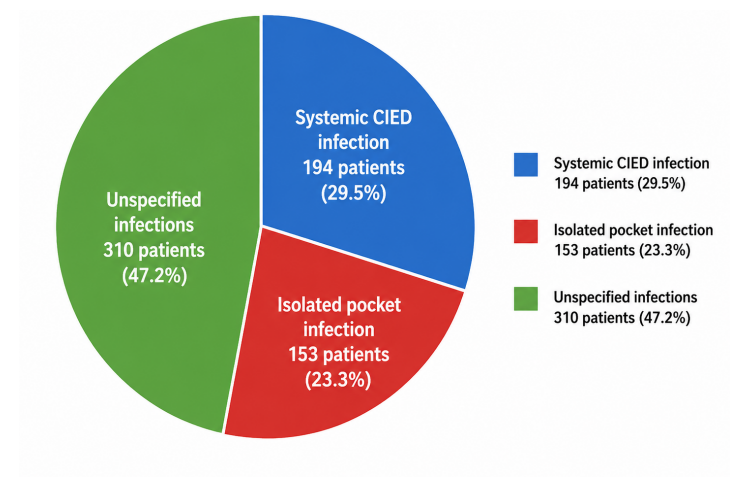
**Leadless pacing after extraction for CIED infection was feasible and associated with no recurrent infection over more than 2 years of follow-up.**

Complication burden was low, supporting leadless pacing as a potential alternative to transvenous reimplantation in selected patients.



Outcomes of concurrent and delayed leadless pacemaker implantation following extraction of infected cardiovascular implantable electronic device

Bilawal Nadeem^{1,2} · Surik Sedrakyan^{1,2} · Amel Fatima³ · Mirza Mehmood Ali Baig⁴ · Ali Ahmed⁴ · Mifrah Rahat Khan Sherwani⁵ · John Wylie^{6,7}



Total number of patients	N = 657
Concurrent LP implantation and LR procedure	295 (44.9%)
Overall timing of LP implantation from TLR (days)	4.32 ± 3.9
Follow-up length (months)	13.3 ± 9.4

Concurrent or delayed (1-7 days later)
None with bacteremia at the time of LP implantation

In conclusion, our systematic review indicates that both concurrent and delayed LP implantation following the extraction of infected CIEDs is a viable and safe approach, characterized by a low rate of reinfection and minimal complications. These findings support the adoption of LPs as a preferable alternative to traditional pacemakers for patients with a history of CIED infections and advocate for the use of LPs as a bridging strategy to eventual CRT device implantation,

Total number of patients	N = 657
Persistent or recurrent Infections	3 (0.5%)
Pacemaker syndrome	4 (0.6%)
Extraction pocket or groin hematomas	4 (0.6%)
Femoral arterio-venous fistula	2 (0.3%)
Pericardial effusion	2 (0.3%)

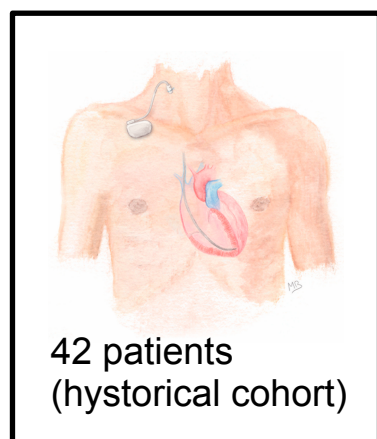
Article

Leadless Pacemaker Implantation During Extraction in Patients with Active Infection: A Comprehensive Analysis of Safety, Patient Benefits and Costs

Aviv Solomon ^{1,2,*} , Maor Tzuberi ^{1,2}, Anat Berkovitch ^{1,2} , Eran Hoch ¹, Roy Beinart ^{1,2} and Eyal Nof ^{1,2}

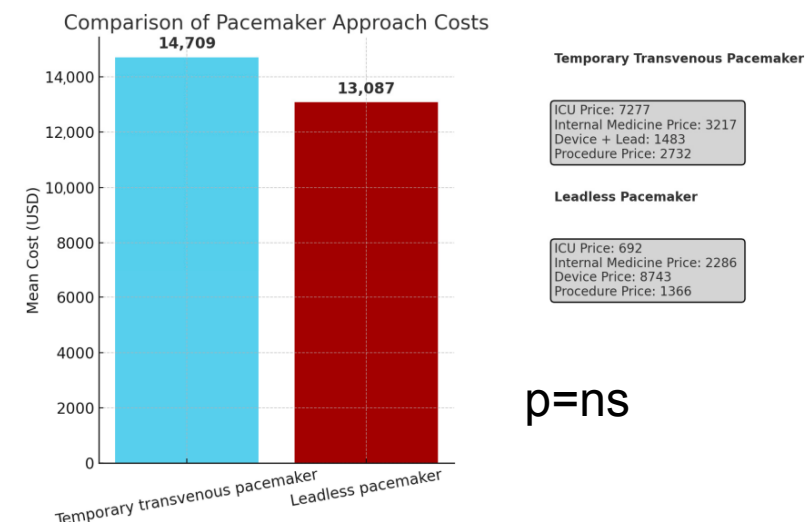
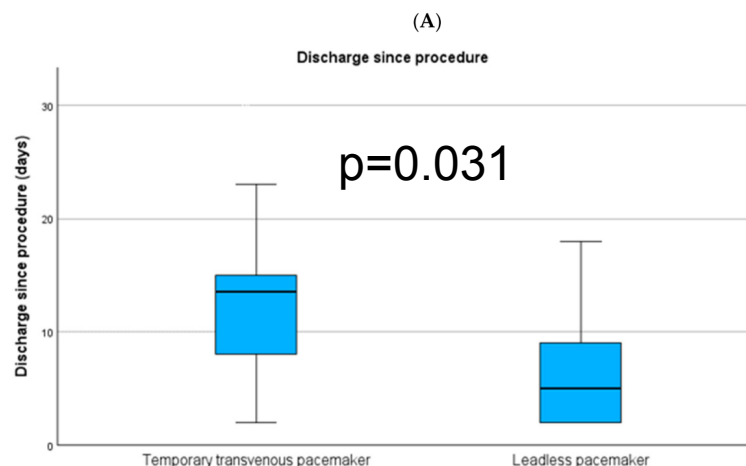
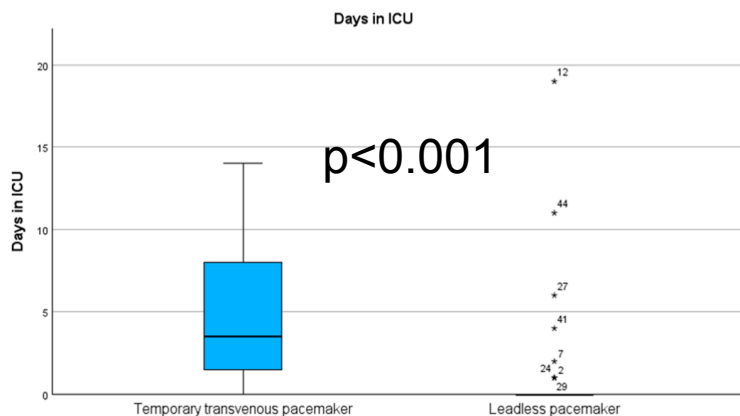
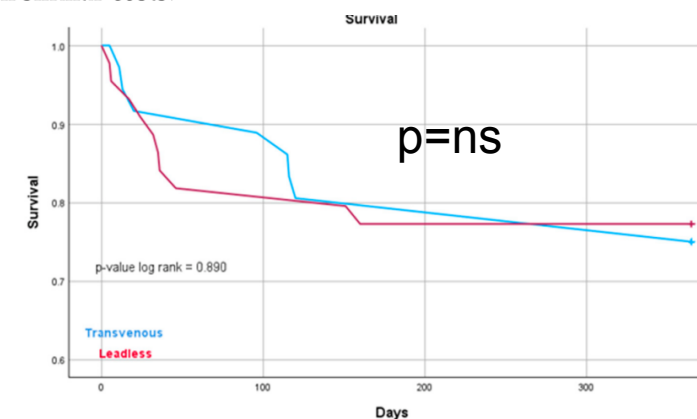


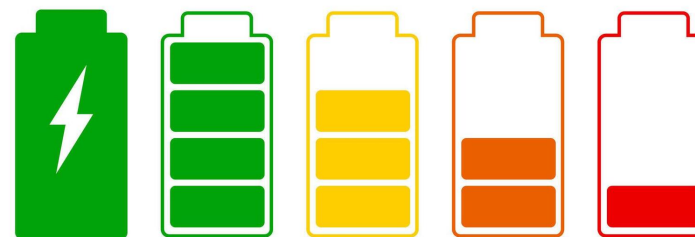
VS



Potential to optimize
resource utilization

The main finding of our study is that **LP implantation during extraction for CIED infection reduces the burden on health systems compared to SP implantation followed by PPM implantation**. Although LPs are significantly more expensive than traditional transvenous pacemakers, implantation of LPs in this specific setting shortened ICU and total hospitalization stay, resulting in overall similar costs.





Battery longevity of a helix-fixation dual-chamber leadless pacemaker: results from the AVEIR DR i2i Study

Vivek Y. Reddy^{1*}, Rahul Doshi², James E. Ip³, Pascal Defaye⁴, Derek V. Exner⁵, Robert Canby⁶, Morio Shoda⁷, Maria G. Bongiorno⁸, Gerhard Hindricks⁹, Petr Neuzil¹⁰, Thomas Callahan¹¹, Nima Badie¹², Matthew G. Fishler¹², and Reinoud E. Knops¹³

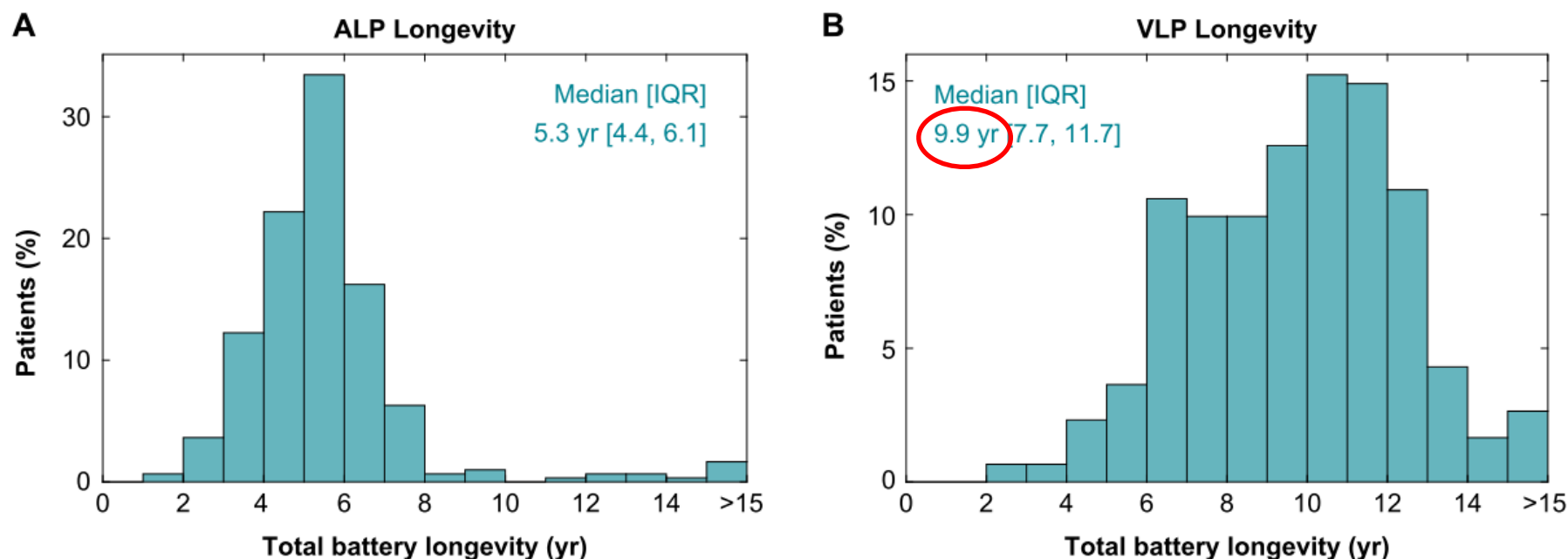


Figure 2 Leadless pacemaker device battery longevity. Total battery longevity observed for (A) ALP and (B) VLP devices, as projected from measurements at 12M.

This dual-chamber LP system demonstrated adequate battery longevity after 12 months of use. Patient-specific implant location and device programming considerations, unique to leadless devices, may extend longevity.

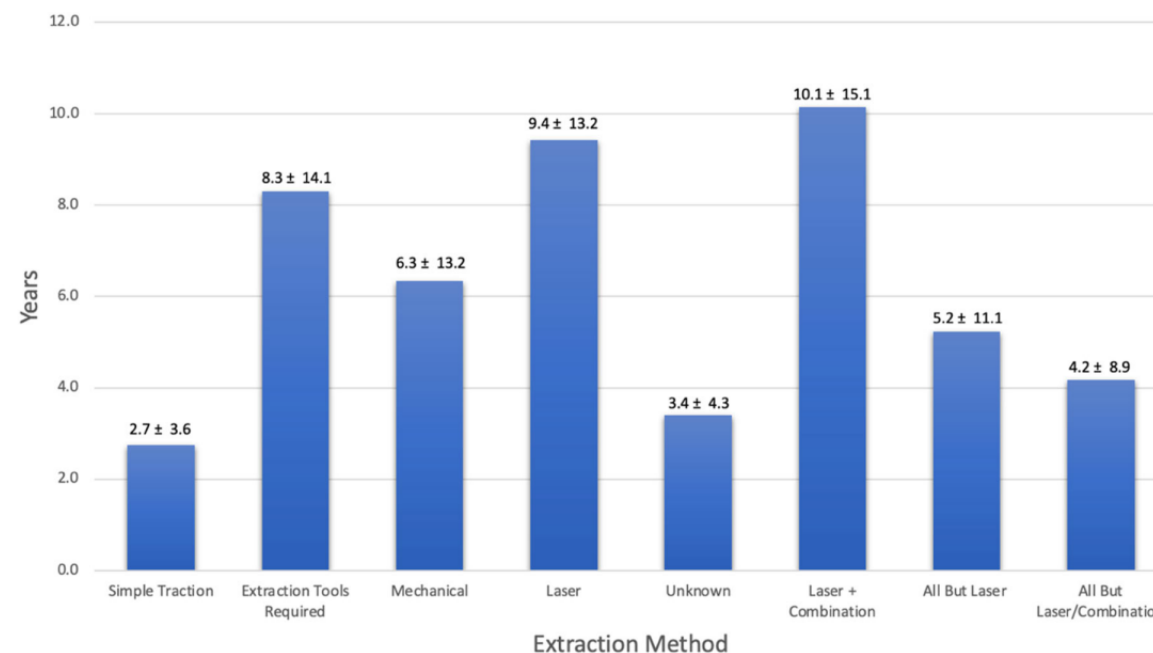
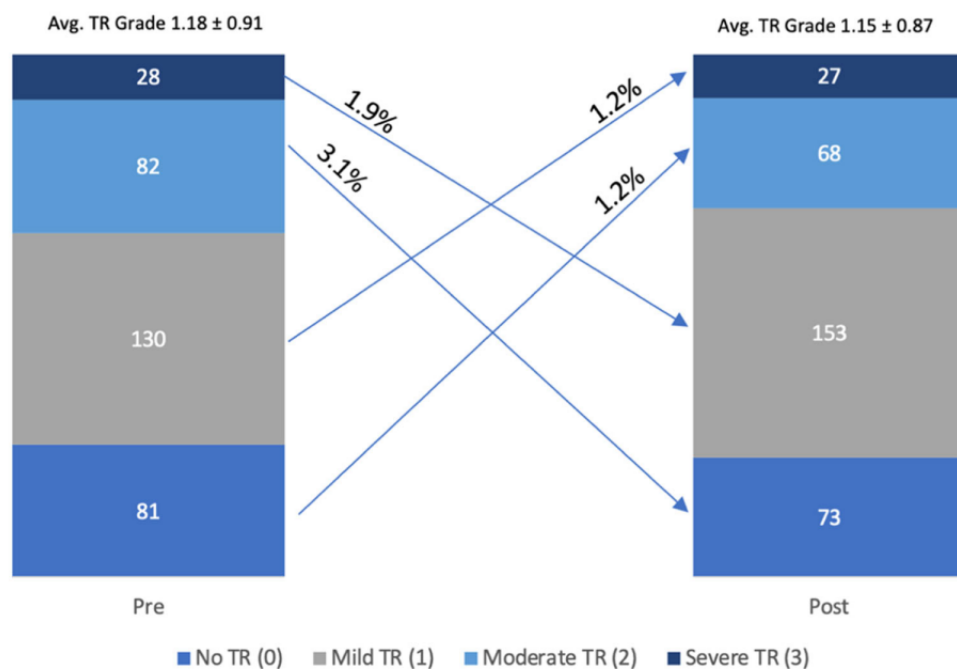
Special needs

- Tricuspid valve issues
- ACHD
- Need for both ICD and PPM
- Need for physiological pacing

Outcomes of tricuspid regurgitation after lead extraction

Colby Shanafelt MD | Thomas G. Middour MD | Rand Ibrahim MD | Miguel Leal MD | Michael S. Lloyd MD | Anand D. Shah MD | Stacy B. Westerman MD | Mikhael F. El-Chami MD | Faisal M. Merchant MD | Neal K. Bhatia MD | and other members of the Tricuspid Regurgitation after Lead Extraction Group

In our single-center analysis, extraction of leads across the TV **did not significantly alter the extent of TR**. **Laser lead extraction was associated with a higher rate of worsening TR** after extraction, although **this may be the result of a longer dwell time** for the leads requiring laser-powered sheaths. Further studies are needed to determine if certain TLE strategies predispose to worsening TR.



Evaluation of tricuspid valve regurgitation following transvenous rotational mechanical lead extraction

Federico Migliore ^{1*}†, Raimondo Pittorru ^{1†}, Manuel De Lazzari ¹, Pietro Bernardo Dall'Aglio ², Antonella Cecchetto ¹, Marco Previtero ¹, Valeria Pergola ¹, Gaetano Thiene ¹, Giulia Masiero ¹, Giuseppe Tarantini ¹, Vincenzo Tarzia^{1‡}, and Gino Gerosa ^{1‡}

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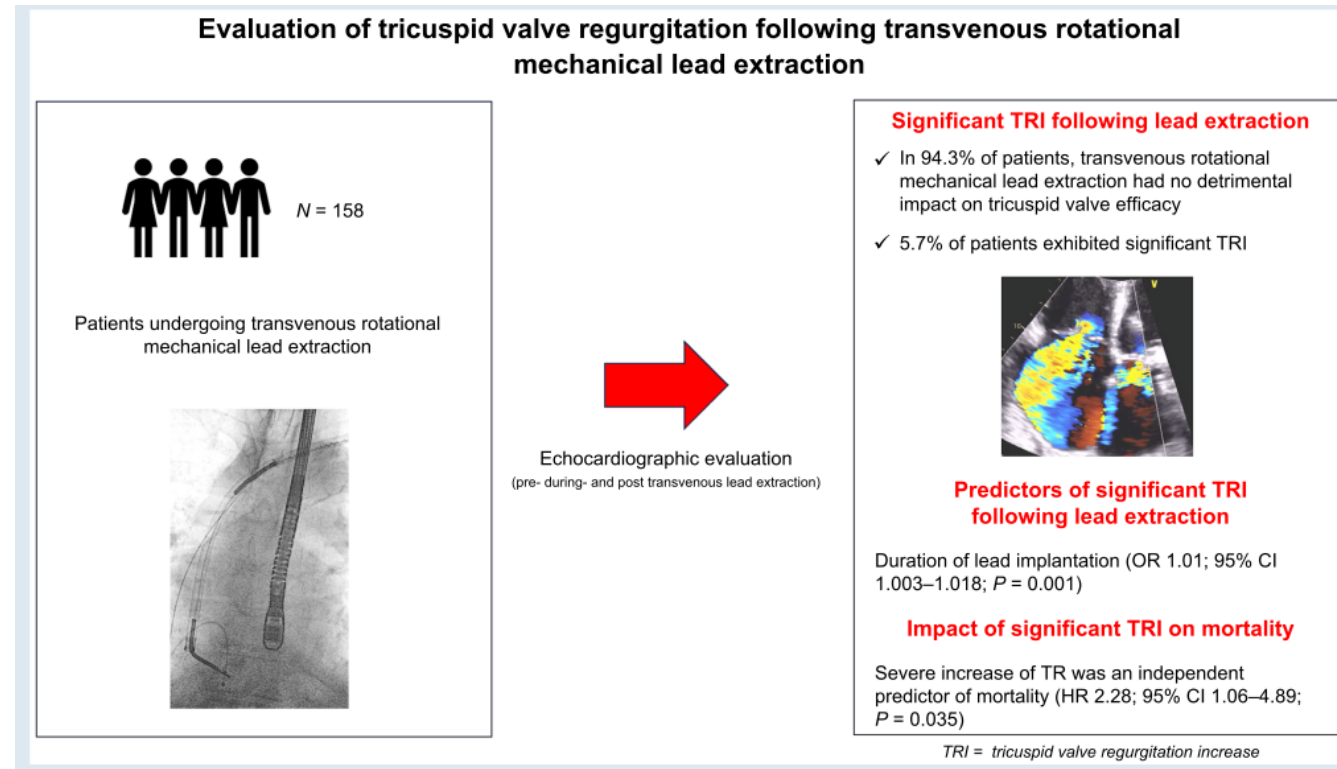
Received 29 April 2024; accepted after revision 3 July 2024; online publish-ahead-of-print 11 July 2024

5.7% significant TRI.

Non-urgent TV replacement in 1.9% of severe TR

Duration of lead implantation only predictor of significant TRI following TLE.

Severe increase of TR: independent predictor of mortality, along with severe systolic dysfunction and systemic infection.





ESC

European Heart Journal (2024) 45, 346–365
https://doi.org/10.1093/eurheartj/ehad783

STATE OF THE ART REVIEW

Valvular heart disease

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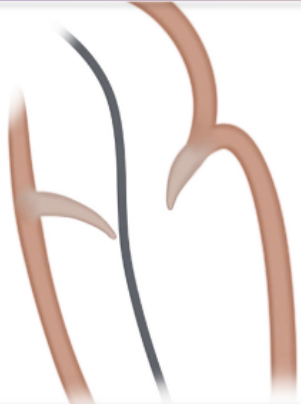


Fondazione Policlinico Universitario A. Gemelli
Università Cattolica del Sacro Cuore

Tricuspid valve disease and cardiac implantable electronic devices

Martin Andreas ^{1*}, Haran Burri ², Fabien Praz ³, Osama Soliman ⁴, Luigi Badano ^{5,6}, Manuel Barreiro ⁷, João L. Cavalcante ⁸, Tom de Potter ⁹, Torsten Doenst ¹⁰, Kai Friedrichs ¹¹, Jörg Hausleiter ^{12,13}, Nicole Karam ¹⁴, Susheel Kodali ¹⁵, Azeem Latib ¹⁶, Eloi Marijon ¹⁷, Suneet Mittal ¹⁸, Georg Nickenig ¹⁹, Aldo Rinaldi ²⁰, Piotr Nikodem Rudzinski ²¹, Marco Russo ²², Christoph Starck ²³, Ralph Stephan von Bardeleben ²⁴, Nina Wunderlich ²⁵, José Luis Zamorano ²⁶, Rebecca T. Hahn ¹⁵, Francesco Maisano ²⁷, and Christophe Leclercq ²⁸

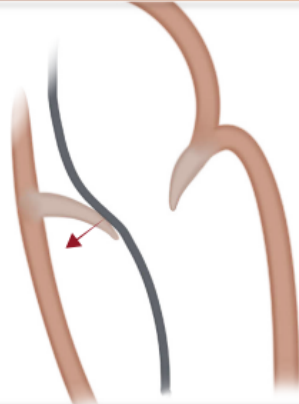
Lead-associated TR



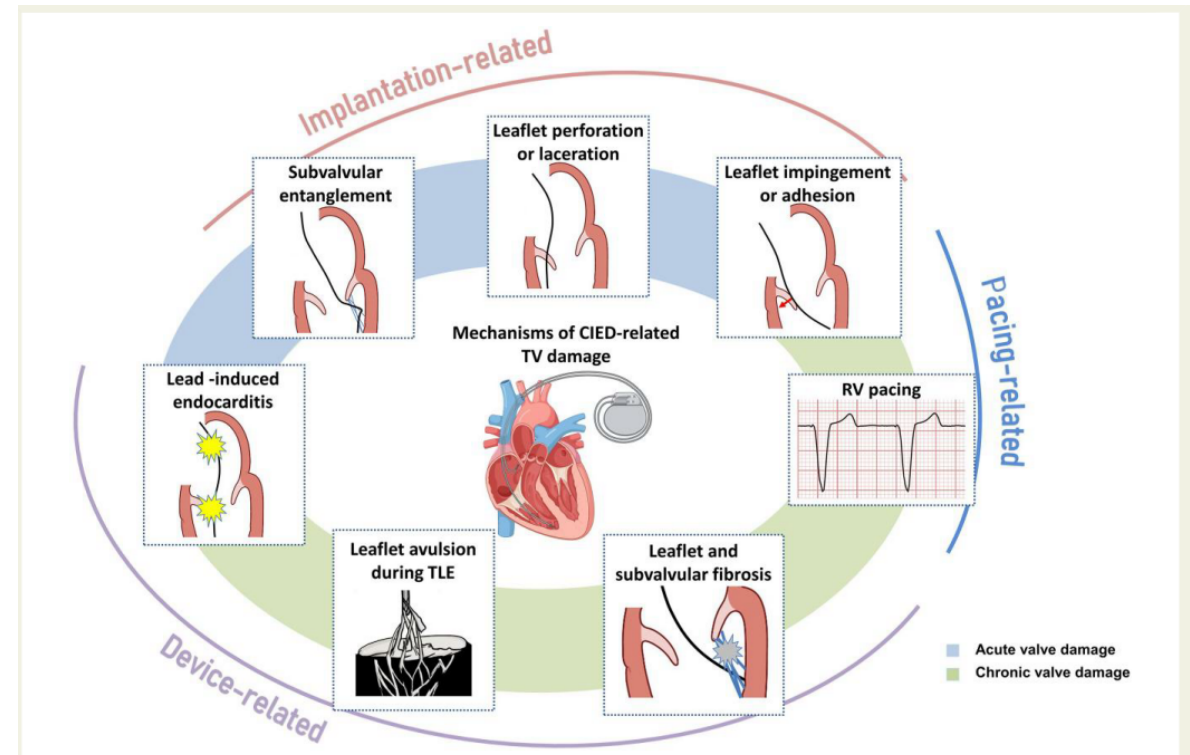
No clear causative relationship between CIED and TR
Prevalence of at least moderate TR after CIED implantation: **7–30%**

Evolution of TR dependent on the **usual risk factors**

Lead-related TR



Established causative relationship between CIED and TR
TR worsens by at least 1 grade in about **20%** of the patients after CIED implantation
Leaflet impingement occurs in **14%**
Severe lead-related TR in **4–7%**
Accelerated TR evolution



CASE REPORT

Transcatheter Extraction and Implantation of a Novel Leadless Pacemaker via Tricuspid Valve-in-Valve: A Case Report

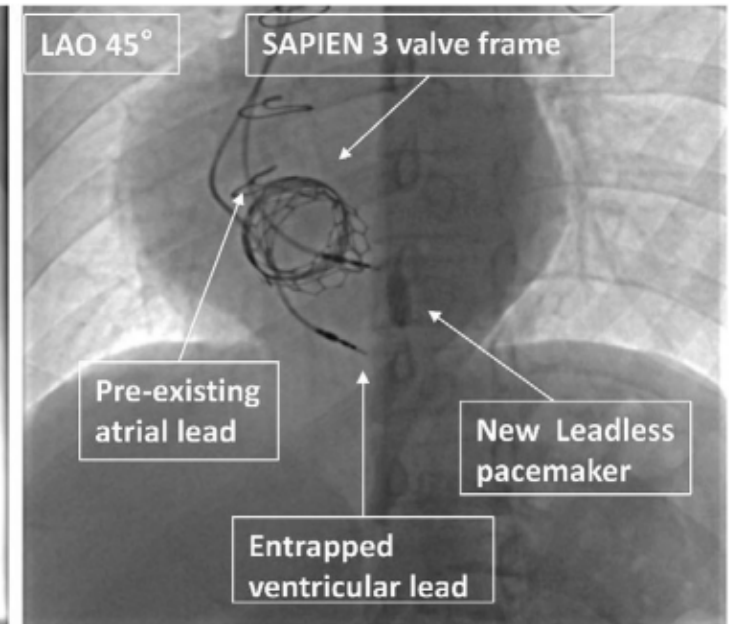
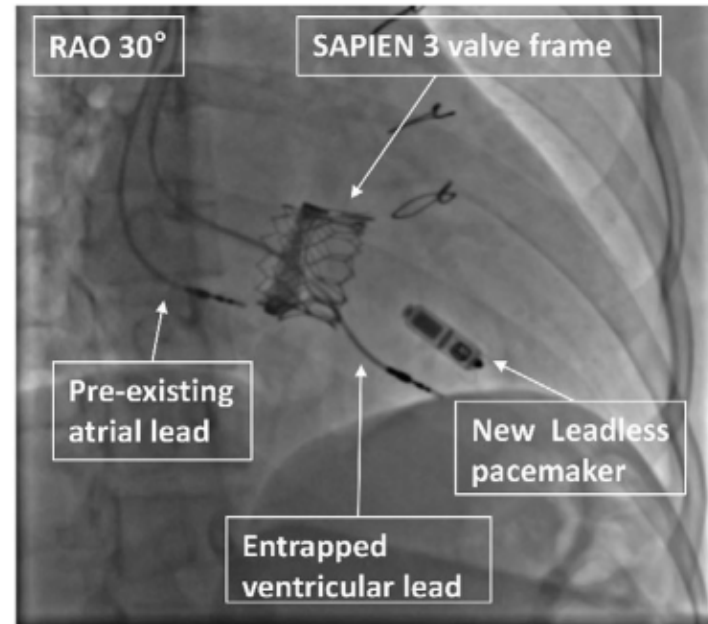
Zijia Wu | Shuyi Zeng | Zhihai Lin 

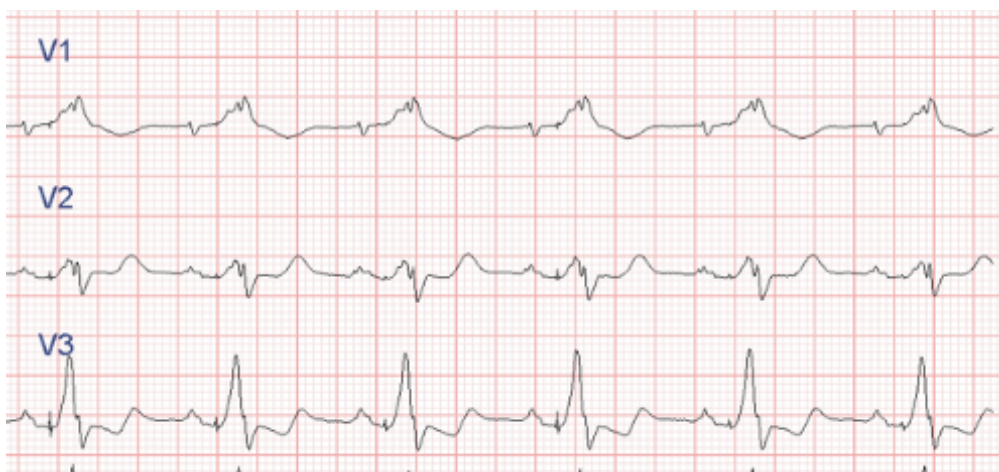
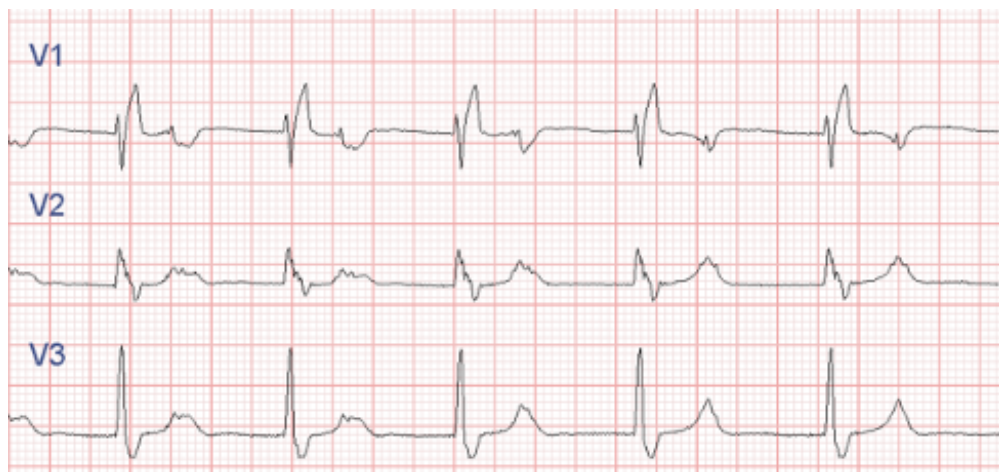
42 yo woman, rise in RV threshold after transcatheter tricuspid ViV

First LP implanted, dislodged after 1 week

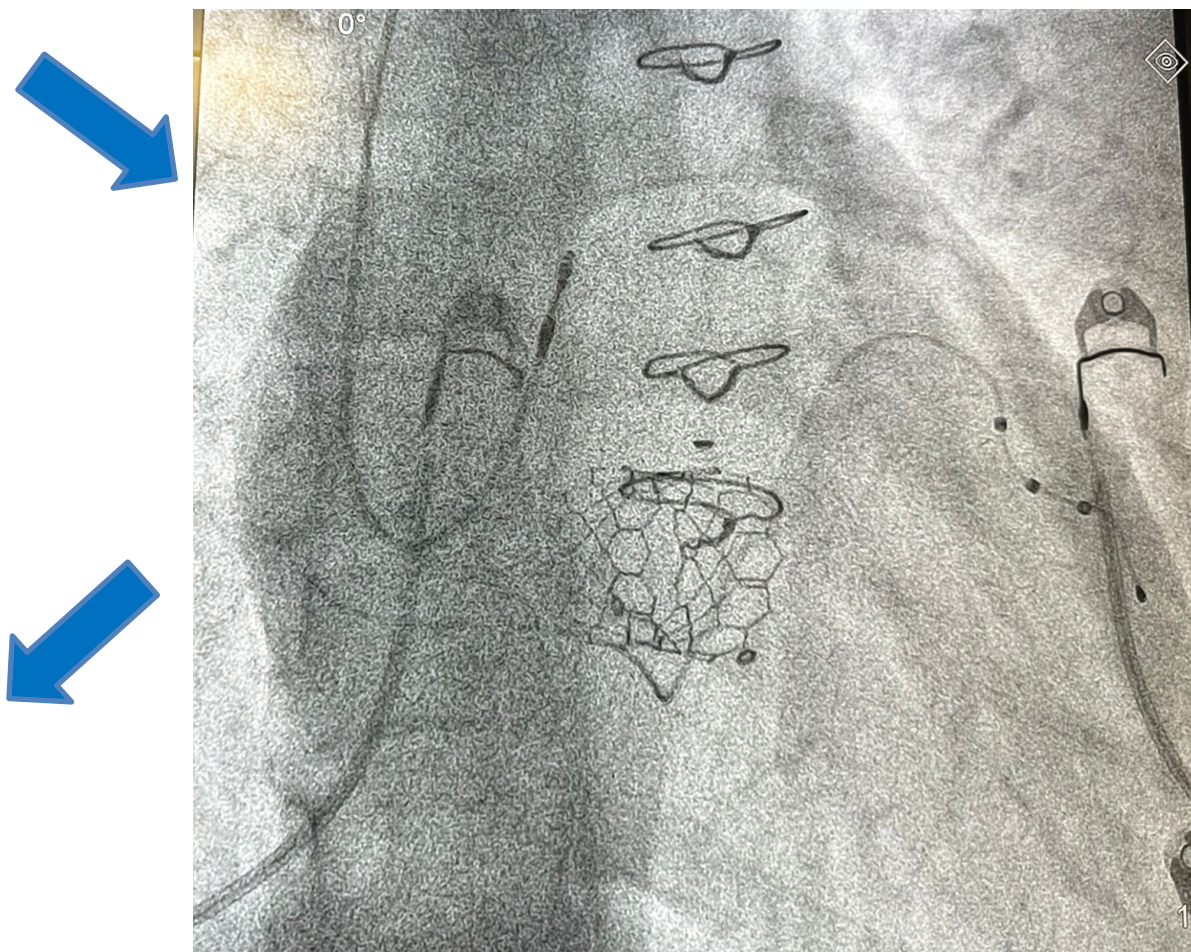
First LP retrieved, second one implanted.

Parameters stable at 12 months FU





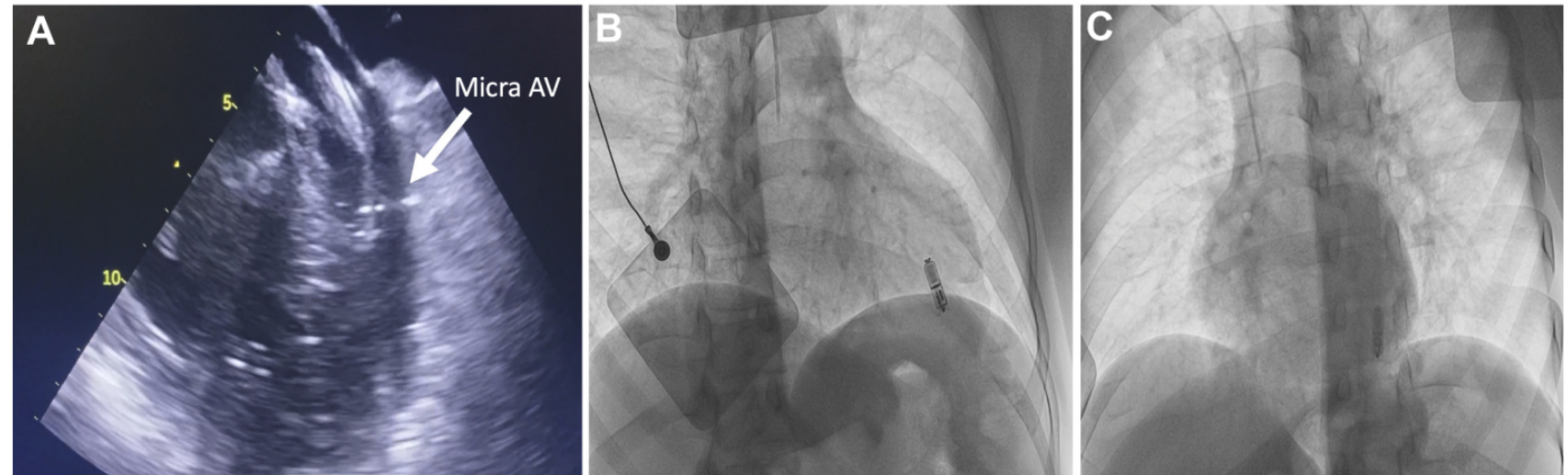
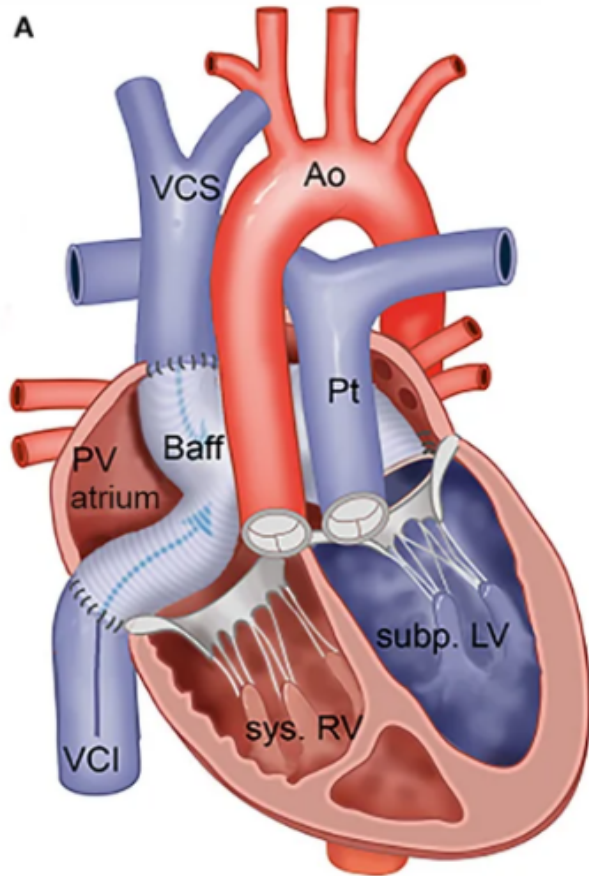
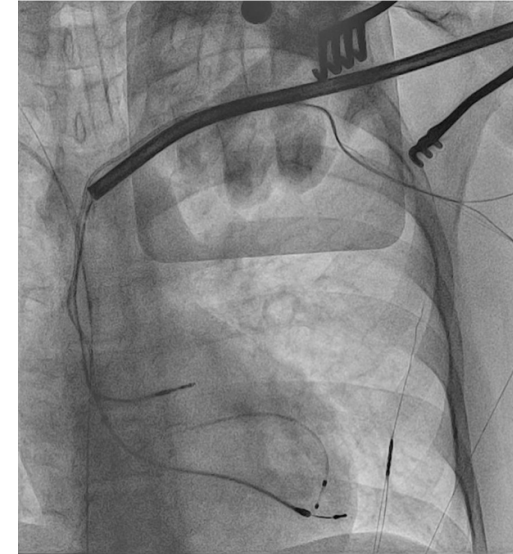
21 yo Ebstein anomaly
Tricuspid bioprosthesis
and subsequent ViV
Long 1° degree AVB and
2° AVB with 2:1 conduction



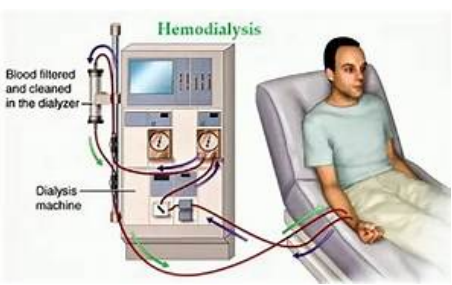
Doing good at 1y FUP despite some phrenic nerve capture issues

Combined Lead Extraction and Leadless VDD Pacemaker Implantation in d-TGA Patient After Senning Procedure

Hamza Hamayel, MD,^a Fateh Awwad, PhD,^a Mohammed Abutaqa, MD,^b Mohammed Abu Baker, MD,^c Arab Ramadan, MD,^d Yunis Daralammouri, MD,^{a,e} Ibraheem Marie, MD^a



(A) Transesophageal echocardiography showing the delivery system of the leadless pacemaker crossing the mitral valve. (B and C) Fluoroscopic RAO 33° and LAO 30° views showing the Micra AV2 in the apical septum. LAO = left anterior oblique; RAO = right anterior oblique.



Improved outcomes with leadless vs. single-chamber transvenous pacemaker in haemodialysis patients

Alexandre Panico ^{1,2}, **Adrien Flahault** ^{1,3*}, **Francis Guillemin** ^{2,3}, **Emilie Varlet**⁴, **Cécile Couchoud** ⁵, **Marc Bauwens**^{5,6}, **Eloi Marijon** ^{4,7,8}, **Stéphane Roueff**⁹, and **Hélène Lazareth** ^{7,9}

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High risk of systemic infection

High mortality rates (up to 75%) among HD pts with PM infections

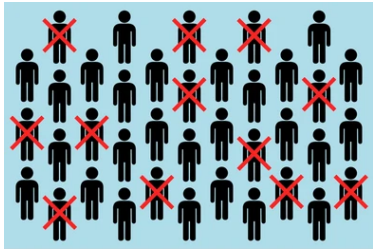
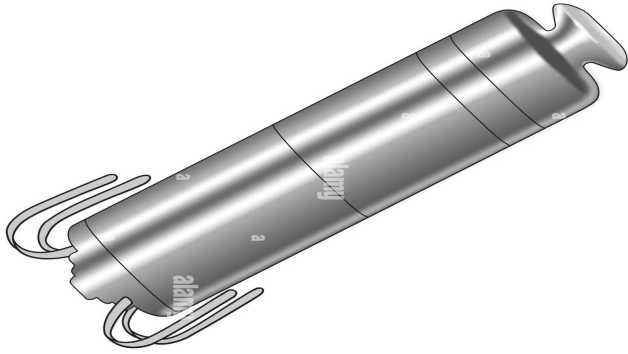
High risk of central venous stenosis/occlusion after PM implantation

Impact on fistula haemodynamics

Conduction disorders common in HD pts (5% PM implants)



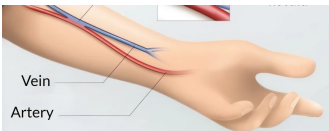
Scarcity of vascular access



Lower all-cause mortality

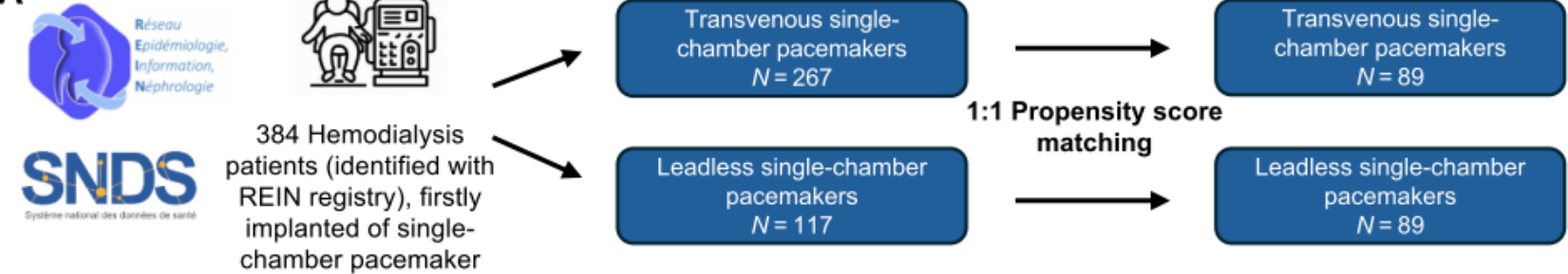


Less device infections



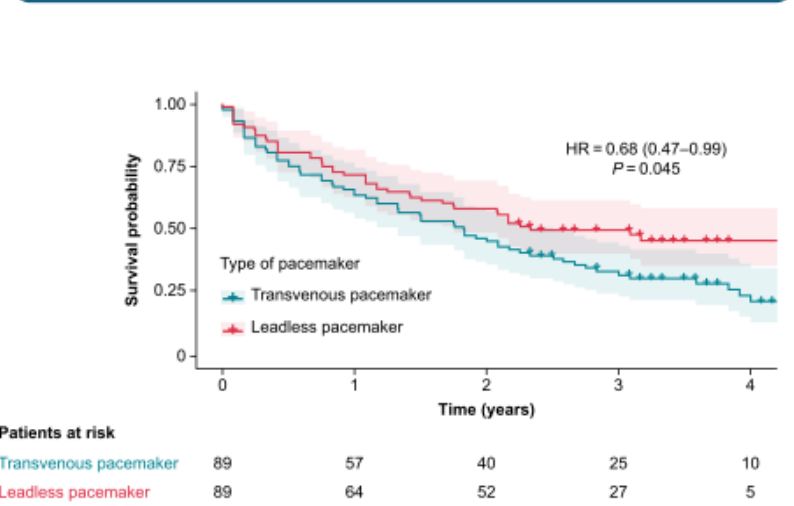
Less interventions on HD vascular access

A



B

Significantly higher survival associated with leadless pacemakers



C

Device infections and interventions on vascular access are reduced

Adverse events	Transvenous pacemaker N = 89	Leadless pacemaker N = 89	HR/RR	95% CI
Hemopericardium n (%)	0 (0)	1 (1.1)		
Complication at the site of access (pacemaker implantation) n (%)	2 (2.2)	8 (9)	4.25	(0.88–20.39)
Endocarditis/device related infection n(%)	8 (9)	0 (0)	0.43	(0.21–0.86)
DVT/PE n (%)	11 (13)	9 (7.9)	1.32	(0.30–5.86)
Interventions on hemodialysis vascular access				
Annual rate (n/10 py)	8.18	3.99	0.49	(0.31–0.75)

A Modular Communicative Leadless Pacing–Defibrillator System

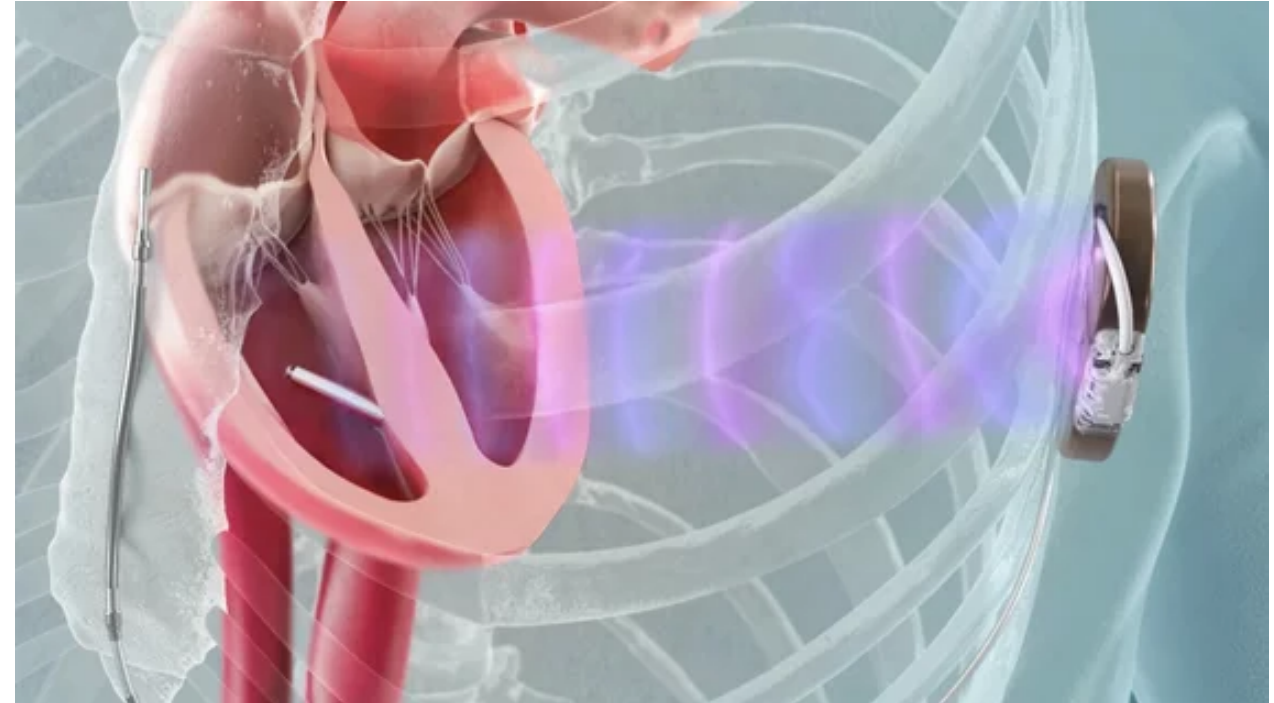
R.E. Knops, M.S. Lloyd, P.R. Roberts, D.J. Wright, L.V.A. Boersma, R. Doshi, P.A. Friedman, P. Neuzil, C. Blomström-Lundqvist, M.G. Bongiorno, M.C. Burke, D. Gras, S.P. Kutalek, A.K. Amin, E.Y. Fu, L.M. Epstein, J.M. Tolosana, T.D. Callahan, J.D. Aasbo, R. Augostini, H. Manyam, D.G. Nair, B. Mondésert, W.W. Su, C. Pepper, M.A. Miller, J. Grammes, K. Saleh, C. Marquie, F.M. Merchant, Y.-M. Cha, C. Cunningham, D.S. Frankel, J. West, E. Matznick, B. Swackhamer, A.J. Brisben, J. Weinstock, K.M. Stein, V.Y. Reddy, and L. Mont, for the MODULAR ATP Investigators*

RESULTS

We enrolled 293 patients, 162 of whom were in the 6-month end-point cohort and 151 of whom completed the 6-month follow-up period. The mean age of the patients was 60 years, 16.7% were women, and the mean ($\pm$ SD) left ventricular ejection fraction was $33.1\pm 12.6\%$. The percentage of patients who were free from leadless pacemaker-related major complications was 97.5%, which exceeded the prespecified performance goal. Wireless-device communication was successful in 98.8% of communication tests, which exceeded the prespecified goal. Of 151 patients, 147 (97.4%) had pacing thresholds of 2.0 V or less, which exceeded the prespecified goal. The percentage of episodes of arrhythmia that were successfully terminated by antitachycardia pacing was 61.3%, and there were no episodes for which antitachycardia pacing was not delivered owing to communication failure. Of 162 patients, 8 died (4.9%); none of the deaths were deemed to be related to arrhythmias or the implantation procedure.

CONCLUSIONS

The leadless pacemaker in wireless communication with a subcutaneous ICD exceeded performance goals for freedom from major complications related to the leadless pacemaker, for communication between the leadless pacemaker and subcutaneous ICD, and for the percentage of patients with a pacing threshold up to 2.0 V at a 0.4-msec pulse width at 6 months. (Funded by Boston Scientific; MODULAR ATP ClinicalTrials.gov NCT04798768.)



LEAP2: A First-in-Human Evaluation of a Chronically-Implanted Novel Leadless Pacemaker for Conduction System Pacing

Vivek Y. Reddy, MD, Devi G. Nair, MD, FHRS, Milan Chovanec, MD, Rahul N. Doshi, MD, FHRS, Shephal K. Doshi, MD, Chunlan Jiang, PhD, Leyla Sabet, PhD, Vishnu Charan, MSc, MBA, Kyungmoo Ryu, PhD, FHRS, Leonard I. Ganz, MD, FHRS, Petr Neuzil, MD PhD

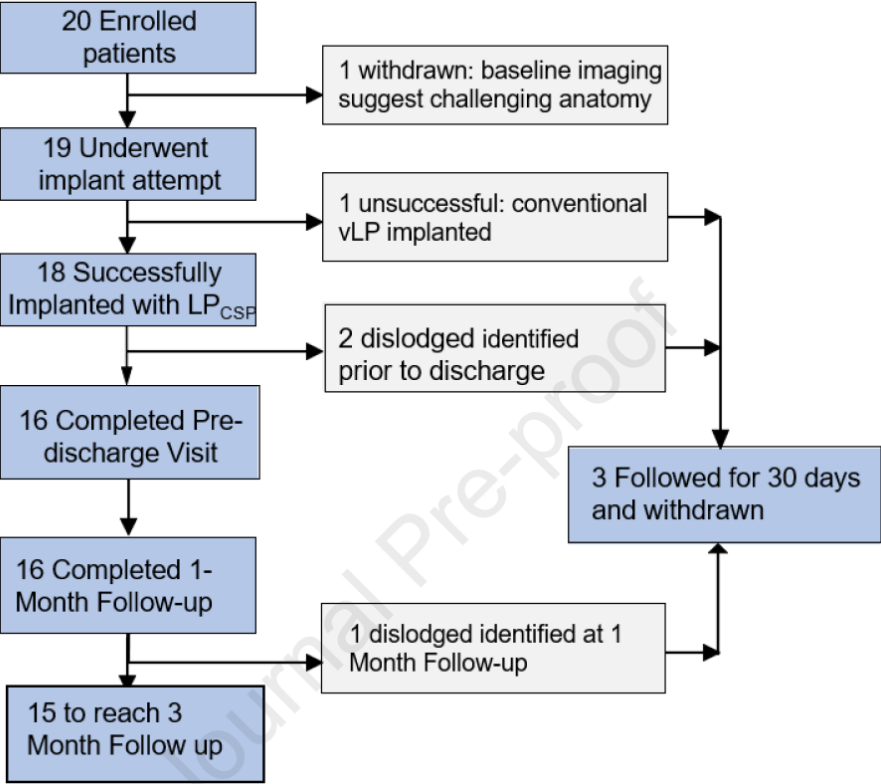
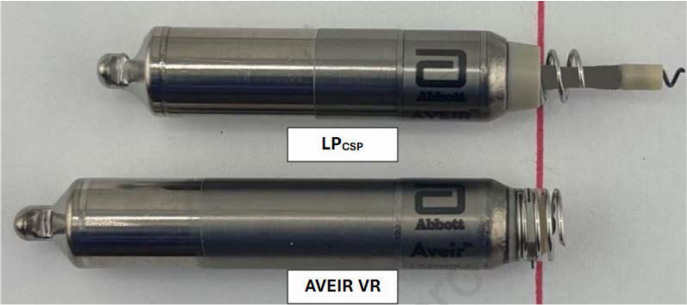
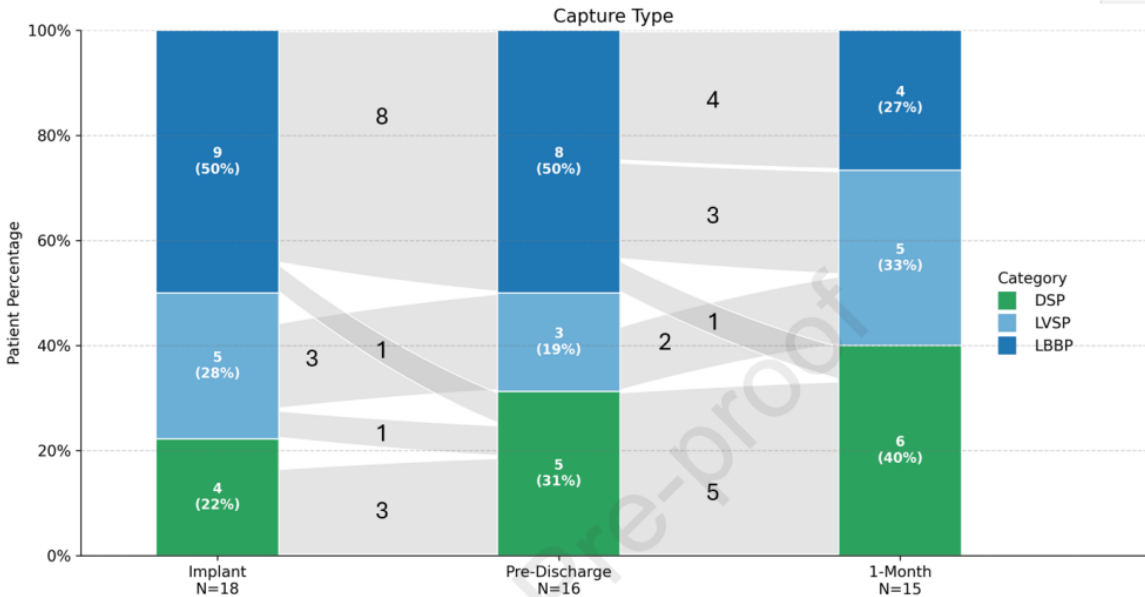
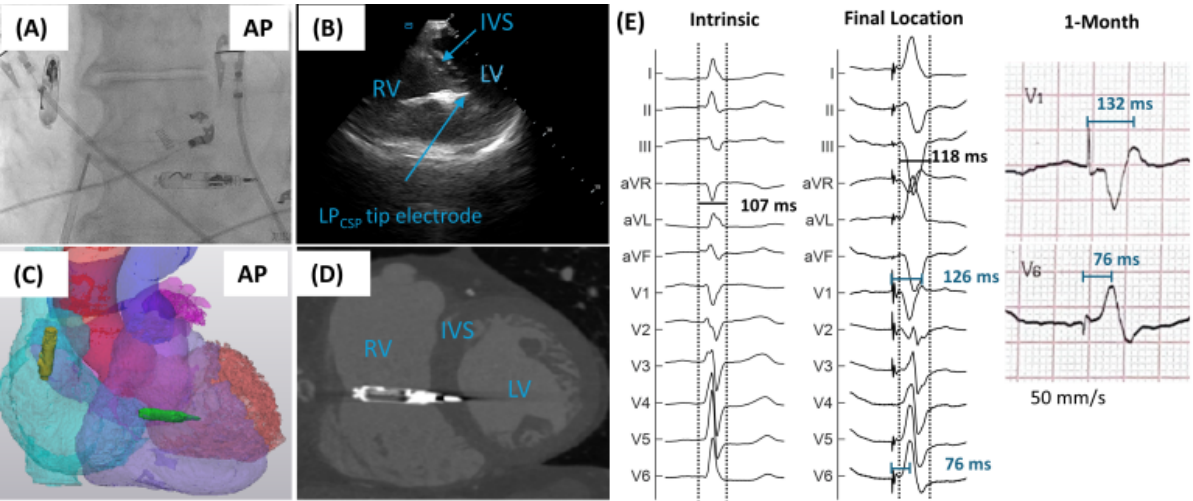


Figure 1: Comparison of the LP_{CSP} and the commercial Aveir VR device



1-month LPCSP complication-free-rate = 68.4%

Feasible, but but improvements in LPCSP stability fixation needed



Take home message

- After CIED extraction, the best implant is the one the patient really needs
- The second best one is the one with as less hardware as possible
- Leadless pacemaker have very low device-related infection, even when implanted in the setting of ongoing systemic infection
- Strongly consider in:
 - Most PM-dependent patients (shorter ICU and hospital stays)
 - Systemic infection with high risk of reinfection (e.g. haemodialysis)
 - Complex anatomy/difficult access
 - Tricuspid issues
 - Bridge to CRT/CSP

Thank you

