Elettrofisiologia
le nozioni di base
fornite dallo specialista
Ecm: 4 crediti

15 ottobre 2022 - ore 8.30/13.00

Innovazioni nell'ambito dell'elettrostimolazione cardiaca: pacemaker leadless e ICD sottocutanei

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Technological evolution

1958 | 1981 | 1981 | 1995 | 2009 | 2013

2021 *PACES* Expert Consensus Statement:

Pediatric and Congenital Electrophysiology Society

- The high technology and development of the devices has necessitated classification according to the age of the patient.
- Pacemaker: PM implant indications should be based on symptom-bradycardia correlation and not absolutely based on heart rate alone
- Indications for ICD implantations are mainly based on data from adult patients, revised in certain respects for pediatric pcs.

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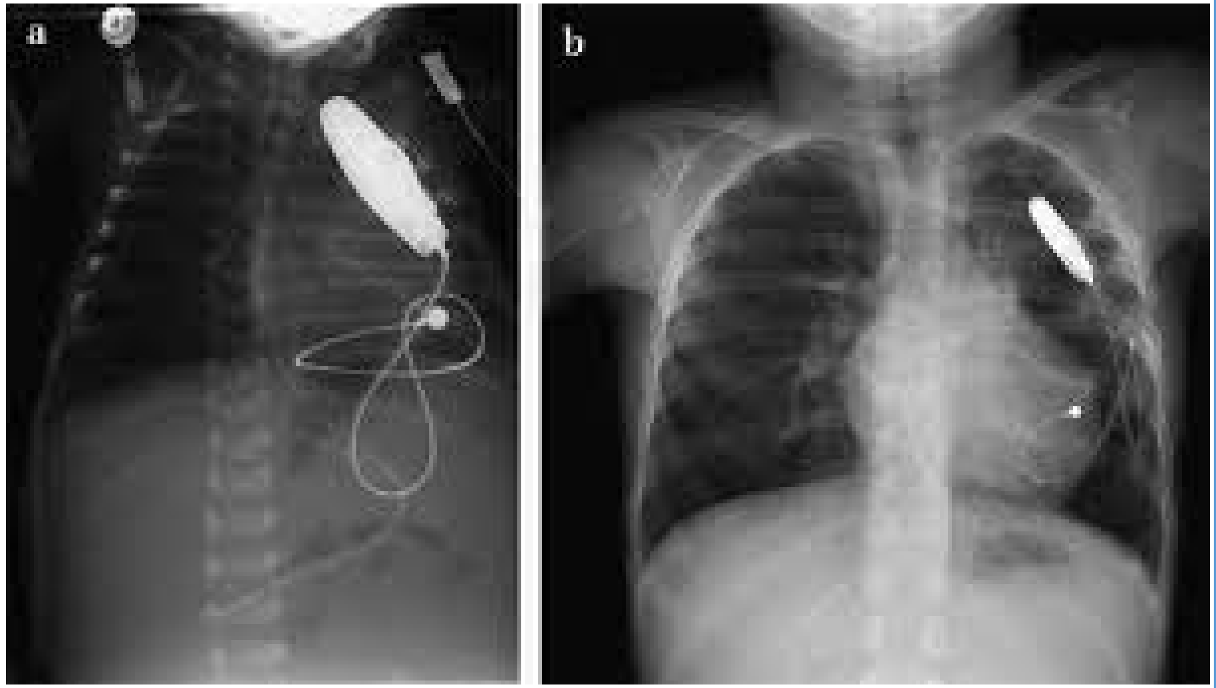
Pediatric pacemaker

- implants currently make up less than 1% of all implants
- The desire to avoid lead-related complications associated with transvenous systems influences the decision-making process.
- Infants and small children typically undergo epicardial pacemaker implantation to allow for growth and eventual transition to a transvenous system, although infant transvenous pacemakers are implanted at some centers.

Indication of pace maker implantation in pediatrics

- Complete A-V block following cardiac surgery
- Symptomatic congenital complete heart block
- Asymptomatic congenital complete heart block in association with:
  - Low mean heart rate <50–55 bpm in neonates
  - Nocturnal pauses
  - Bradycardia related arrhythmias
- Acquired heart block in myopathies
- Symptomatic bradycardias in:
  - Sick sinus syndromes
  - Long QT syndromes
- Reflex anoxic seizures with secondary anoxic epileptic seizures



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PM: Transvenous or Epicardial?

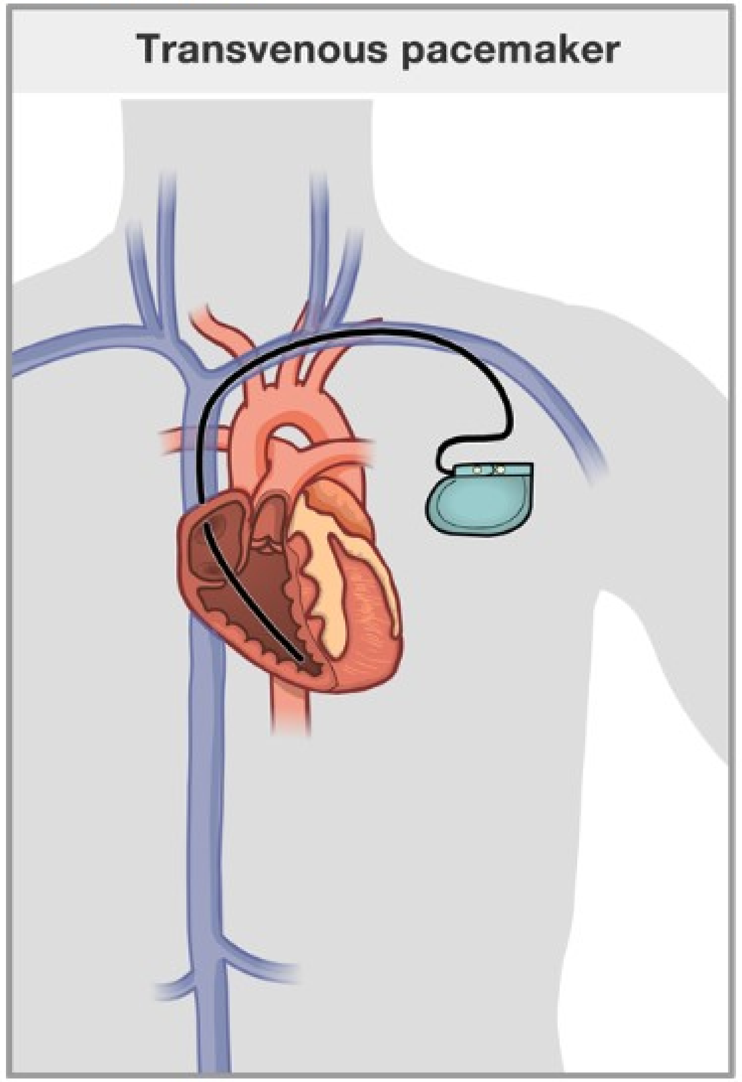
The choice depends mainly on **the patient's anatomy, size**, previous clinical interventions that may inlfuence access to certain cardiac structures

TV PM in infants **(<10 kg)** is associated with a high incidence of vascular occlusion, thrombosis, severe valve regurgitation IN long-term FU. We advocate an epicardial approach for PM implantation in small children[1].

✓ Chirurgia mininvasiva

✗ Rischio di occlusione vascolare

Pacemaker types



A transvenous pacemaker lead is passed through a ve
pacemaker lead is stitched to the outside of the heart

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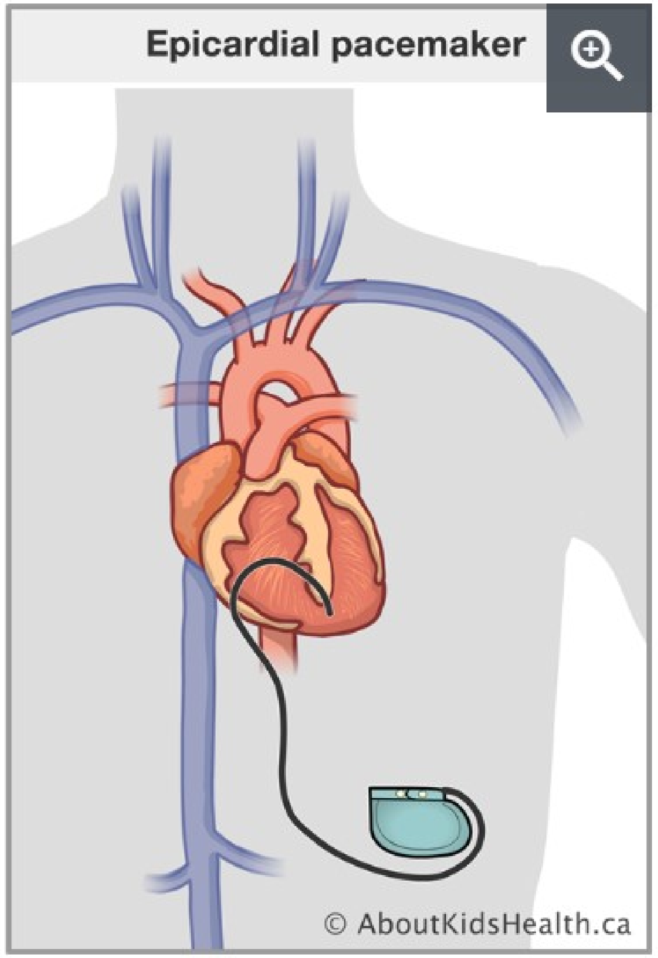
1) Long-term outcome of transvenous pacemaker implantation in infants: a retrospective cohort study-Laura M Vos, Janneke A E Kammeraad, Matthias W Freund
2) Permanent epicardial pacing in children: long-term results and factors modifying outcome-EP Europace, Volume 14, Issue 4, April 2012

PM: Transvenous or Epicardial?

The probability of continued epicardial pacing in children was 76% at 10 years after implantation, increased for implantation in recent years, and allowed transvenous pacing to be deferred to a significantly greater age. The use of *bipolar steroid-eluting* leads and of *a beat-to-beat capture tracking* feature significantly increased pacing system longevity and decreased the need for surgical reinterventions[2]



vein to the correct location inside the heart. An epicardial
rt muscle.

✓ Non dipendente dalla crescita fisiologica del pz

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1) Long-term outcome of transvenous pacemaker implantation in infants: a retrospective cohort study-Laura M Vos, Janneke A E Kammeraad, Matthias W Freund
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When to choose an epicardial PM?

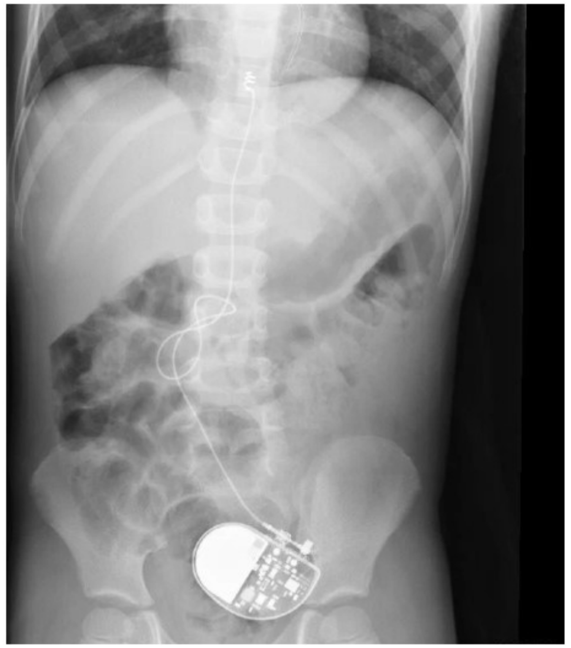
- **<15 kg**
- In the presence of intracardiac shunts
- With limited access to ventricular chambers
- In the presence of prosthetic tricuspid valves

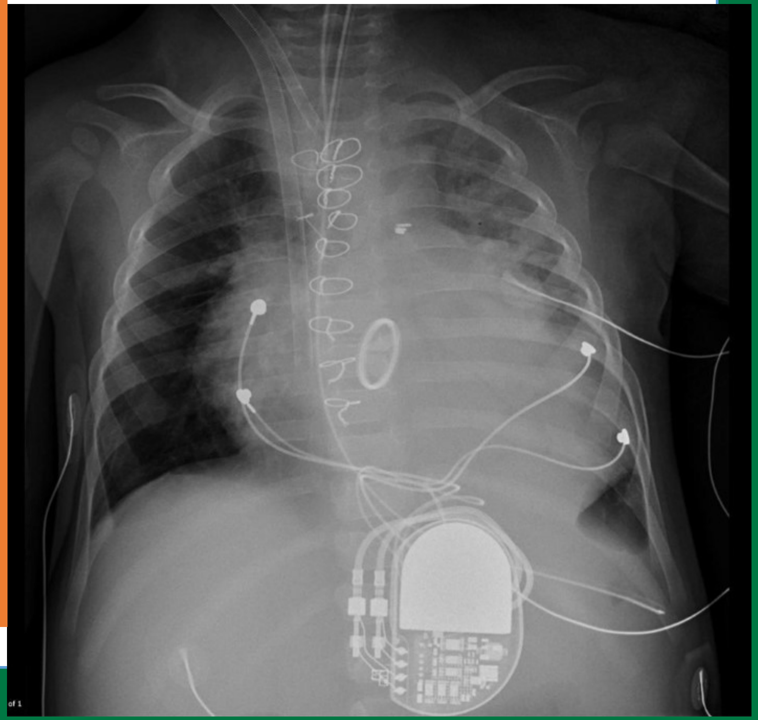
Implantation requires:

- Sternotomy/thoracotomy orSubxiphoid access
- Steroid-eluting catheters To preserve Threshold over time
- Epicardial catheters placed Preferably on LV

When to choose an epicardial PM?

Example of epicardial implantation, 6-month-old infant, mitral porthesis





Some limitations...

High risk of catheter rupture

Early battery discharge due even to high stimulation thresholds

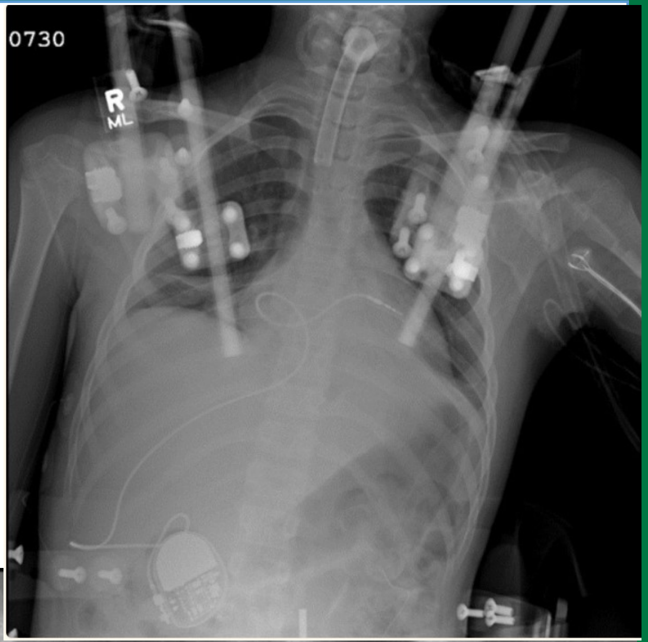
Risk of device migration!

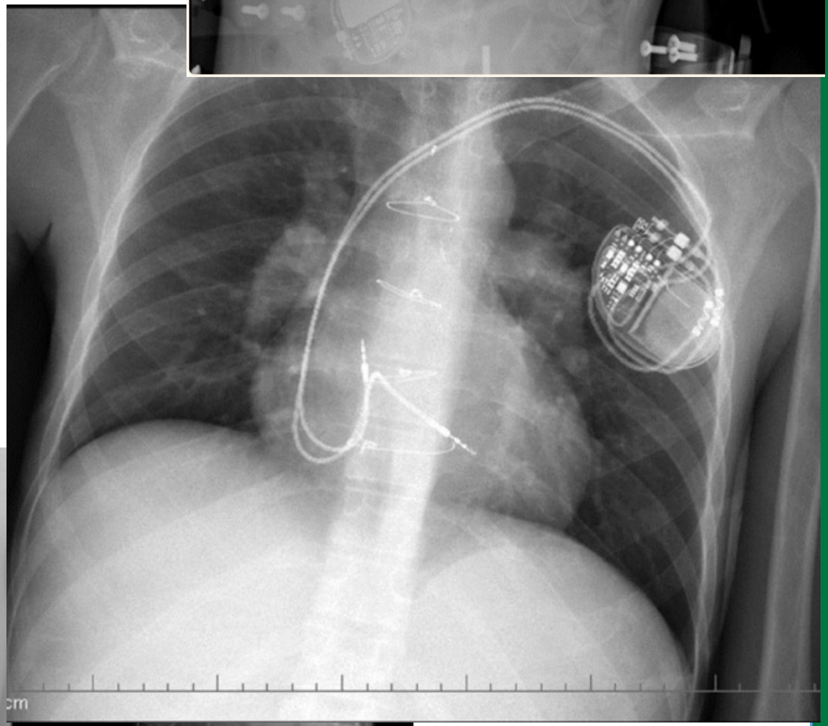
When to choose a PM via transvenous route?

- It is preferable excluding cases for which PM EPI is chosen
- Advantages: NO surgery
- Disadvantages:
  - Risk of catheter migration
  - Endocarditis
  - venous occlusion
  - embolic events
- Bicameral above >25kg

Implantation Technique

- Subcutaneous or submuscular pocket creation for very thin pcs
- Subclavian or axillary vein access to reduce risk of pnx
- pts with cardiac malformation, other veins such as cephalic, transhepatic etc. can be opted for.
- Venogram
- Catheter placement on septumRV





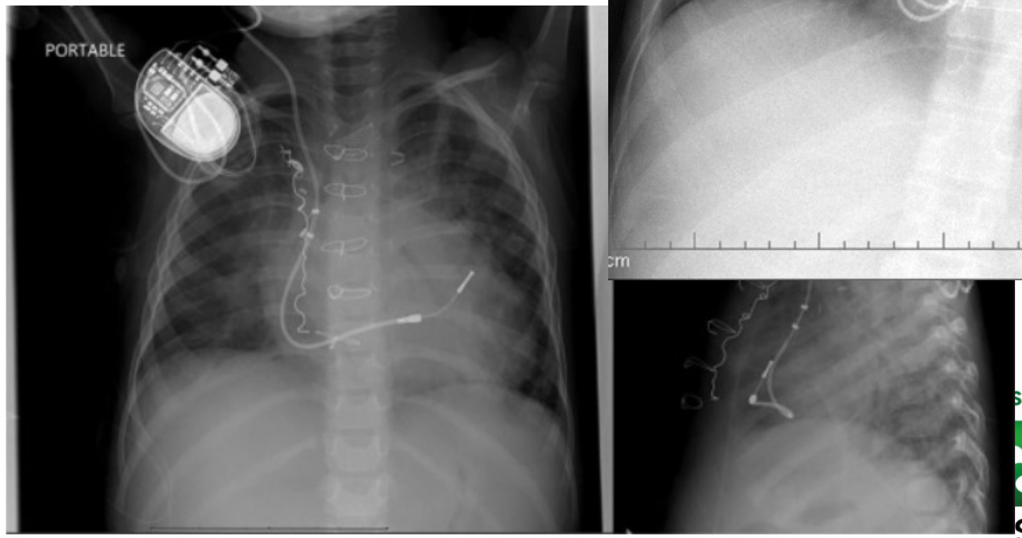
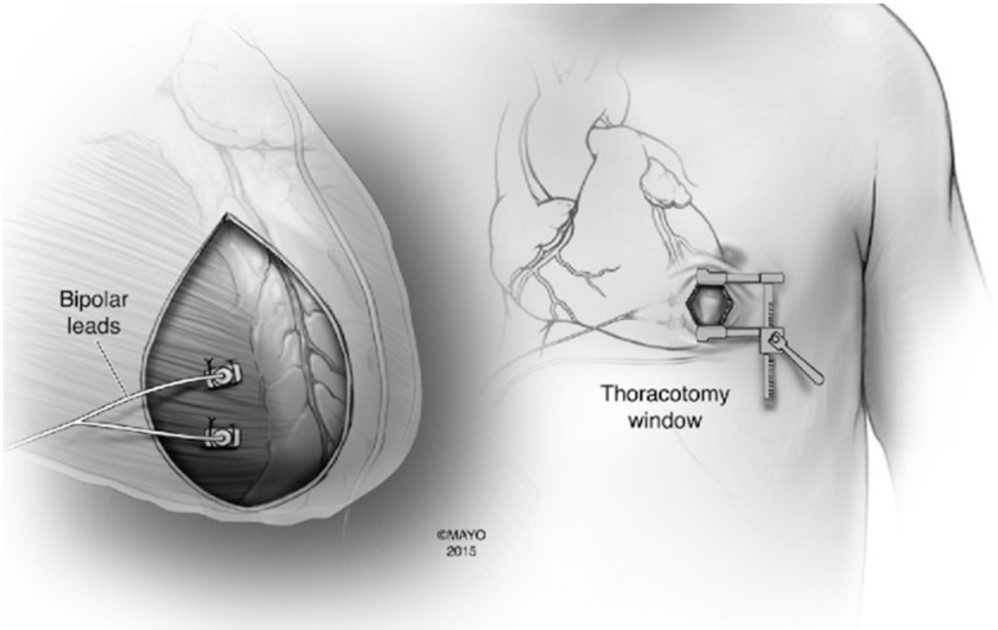


Figure 2 Chest radiograph of VDD lead.

ICD in pediatric PTS

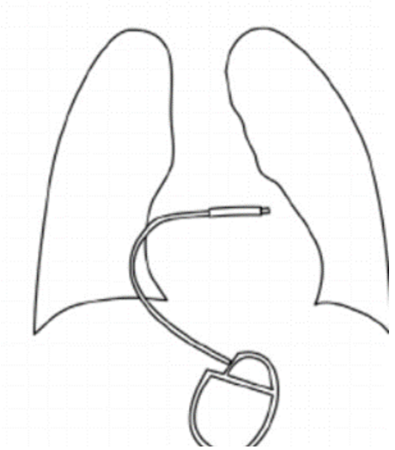
Transvenous

lead implantation with the lead looped or curved in the right ventricle to allow for a sufficient length of the lead to account for the growth of the child.



Epicardial lead implantation

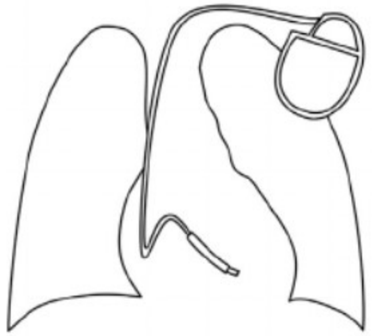
C



Lead implantation posteriorly

behind the heart and superiorly toward the transverse sinus by a subxiphoid incision through a pericardial window

A



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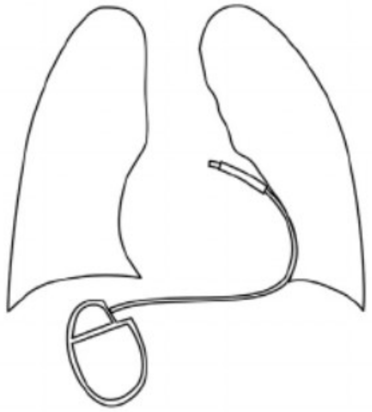

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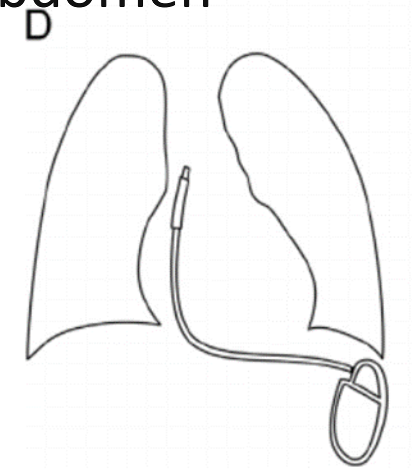
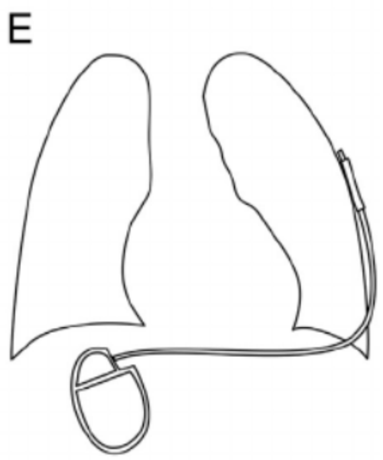
ICD in pediatric PTS

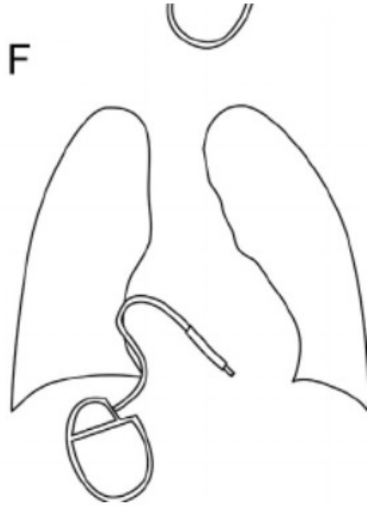
Lead implantation in a substernal position with the ICD placed in the left abdomen



Lead implantation in a left subcutaneous position with the ICD placed in the right abdomen.



Endocardial lead implantation through the right atrial appendage



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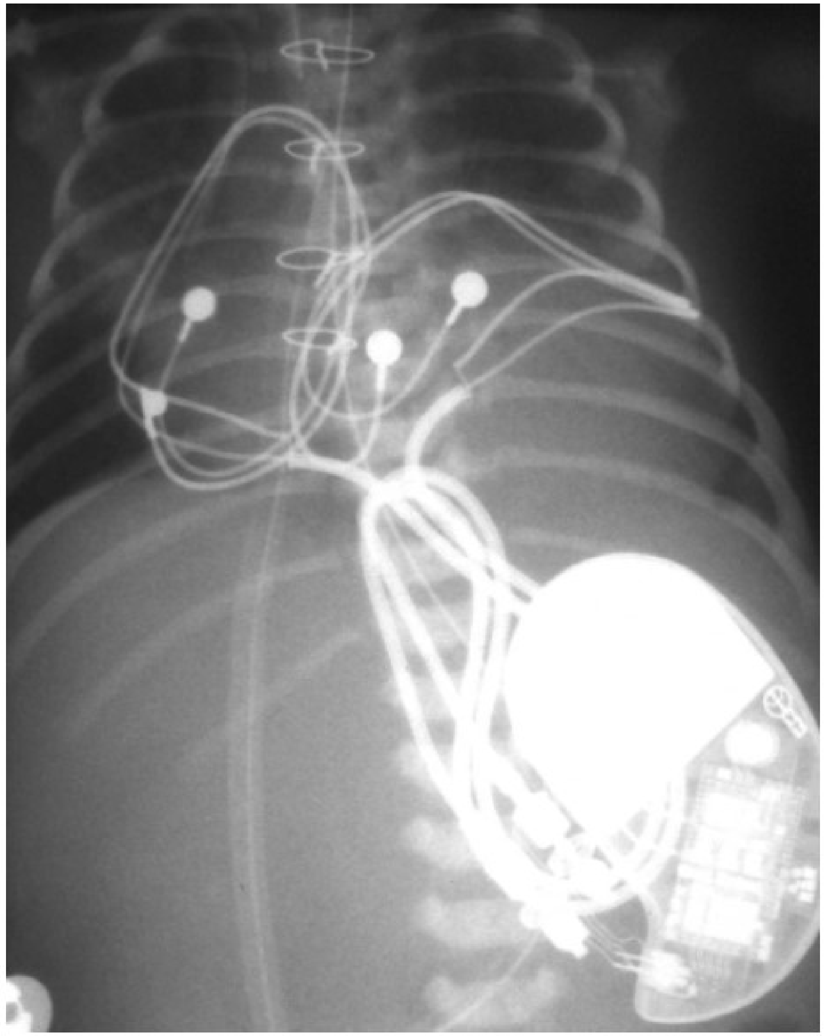
Decades of pacing
Cumulating hardware in a small body



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Hemodynamics

Do we need a specific ventricular pacing site?

- Incidence of RV pacing-associated LV dysfunction in the young
  - CCAVB: 4/63 pts. (6 %)[1]
  - Any AVB: 6/81 pts. (7.4 %)[2]
  - Any AVB: 11/82 pts. (13.4 %)[3]

[1] *Kim JJ et al. J Cardiovasc Electrophysiol 2007;18:373-7*
[2] *Moak JP et al. Cardiovasc Electrophysiol 2006;17:1068-71*
[3] *Gebauer RA et al. Eur Heart J 2009; 30:1097-104*

Hemodynamics

What is the appropriate maximum ventricular pacing rate?

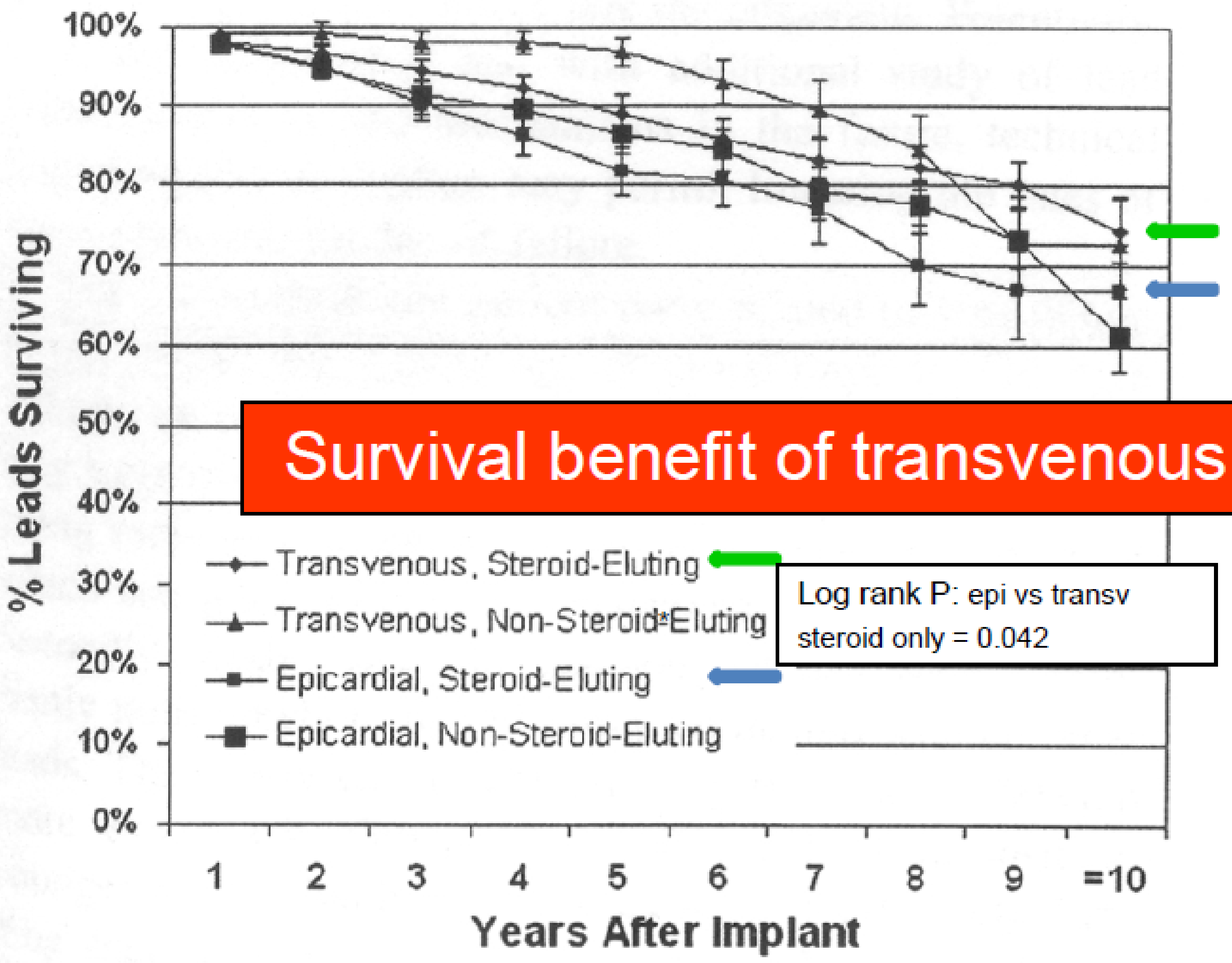
- Be careful with structural heart disease limiting diastolic filling and leading to ventricular underloading
  - d-TGA after atrial switch (Mustard, Senning)[1]
  - Fontan physiology[2,3]
- High ventricular pacing rates are counterproductive

[1] Reich O et al. Heart 1997; 78:376-81
[2] Karpawich PP et al. PACE 1991 ;14:2058-61
[3] Paridon SM et al. PACE 1993;16:1256-62

Lead survival

Is there a difference in epi vs transvenous lead survival?

N = 1007 leads / 5175 lead-years



Survival benefit of transvenous leads marginal

Log rank P: epi vs transv
steroid only = 0.042

Fortescue EB et al. HeartRhythm 2004;1:150-159

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COSTS INCREASE
QOL IMPACT

Traditional Pacemakers

Complication	Occurrence
Lead dislodgement	2.2% to 3.7%[1]
Pneumothorax	1.6% to 2.6%[1,2,3,4,5]
Lead perforation	< 1%[1,2]
Venous thrombosis	1%-3%[2,3,4,5]
Chronic Lead failure	2%-4% at 5 ys[2,3,]
Hematoma	<0.5%[2]
Skin erosion	0.8-0.9%[2,6]
Infection	1% - 2%

Traditional Pacemakers

What are the lead goals?

- Preserve sensing e pacing functions for a long time
- Preserve High Voltage circuit
- Endure 31 MLN of heart beats / year
- Keep intact in an aggressive background

What are the lead goals?

In patients ever more longer life expectancy

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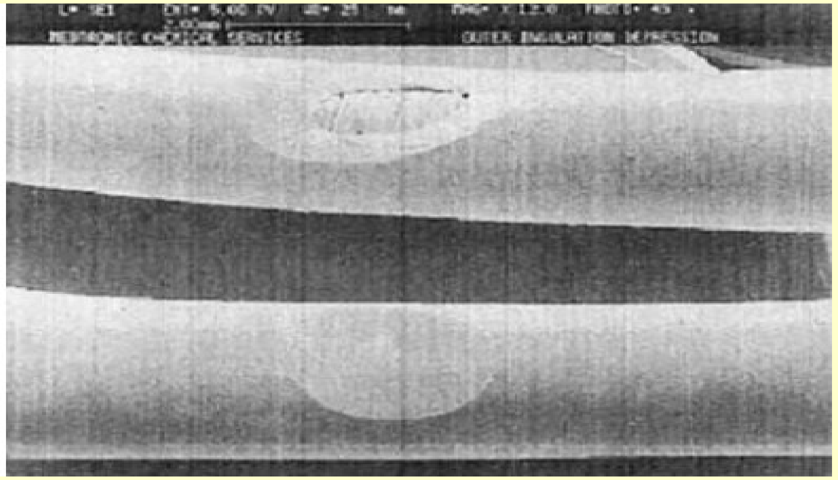
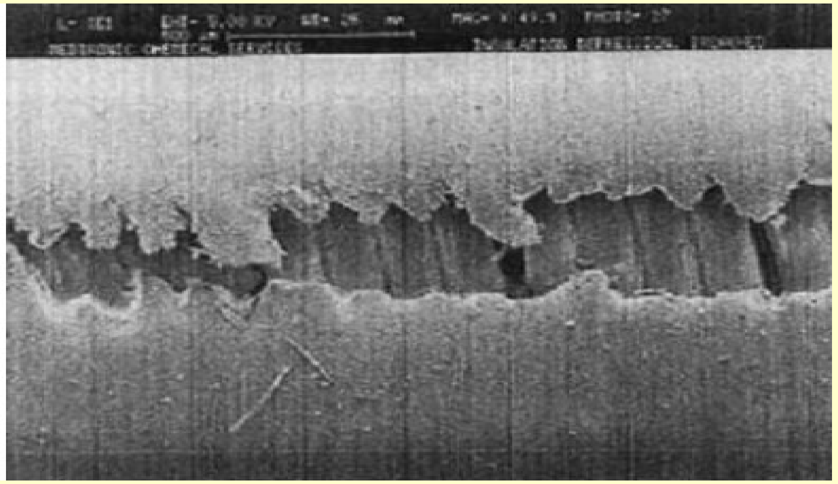
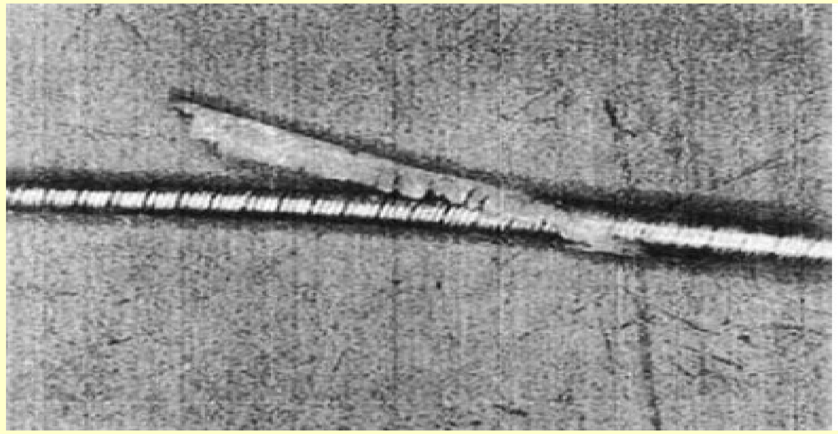
Agressive Background



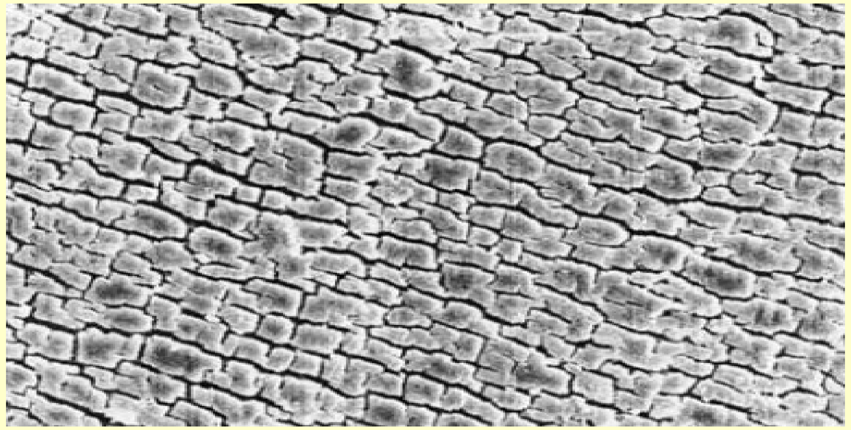
Insulation defect due to **abrasion**



insulation defect due to **traction** from lead migration

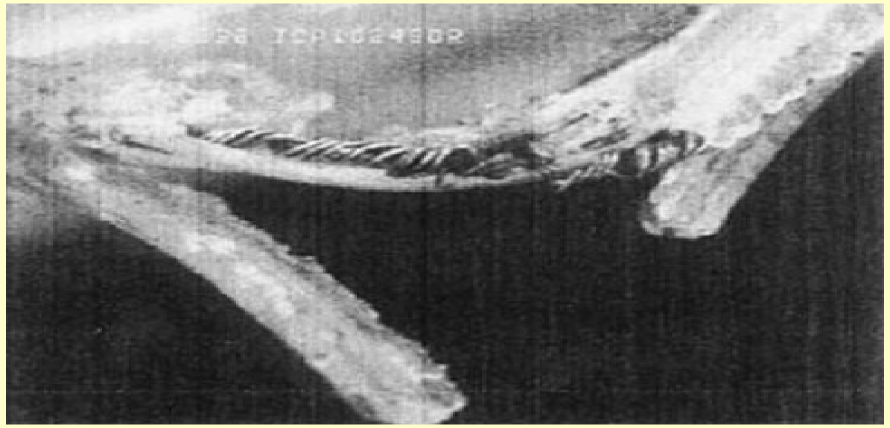


PU insulation with sign of metal **ion oxidation**



PU insulation with environmental **stress cracking**

Conductor fracture secondary to **compression**



Conductor fracture and insulation **defect due to pinching**

Agressive Background

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Complications, both acute and chronic, are more prevalent than generally acknowledged

CIED COMPLICATIONS

Infection

Lead failure

Risk of complication* at 6 years:

* Complication either: implant related, system/ lead related or infection (Infection, Device malfunction, Lead malfunction, Lead dislodgment, Pericardial effusion, Thrombotic event, Reintervention for pocket complication, Hematoma, Pneumothorax. Based on 4890 patients)

CIED COMPLICATIONS

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Leadless Pacemaker

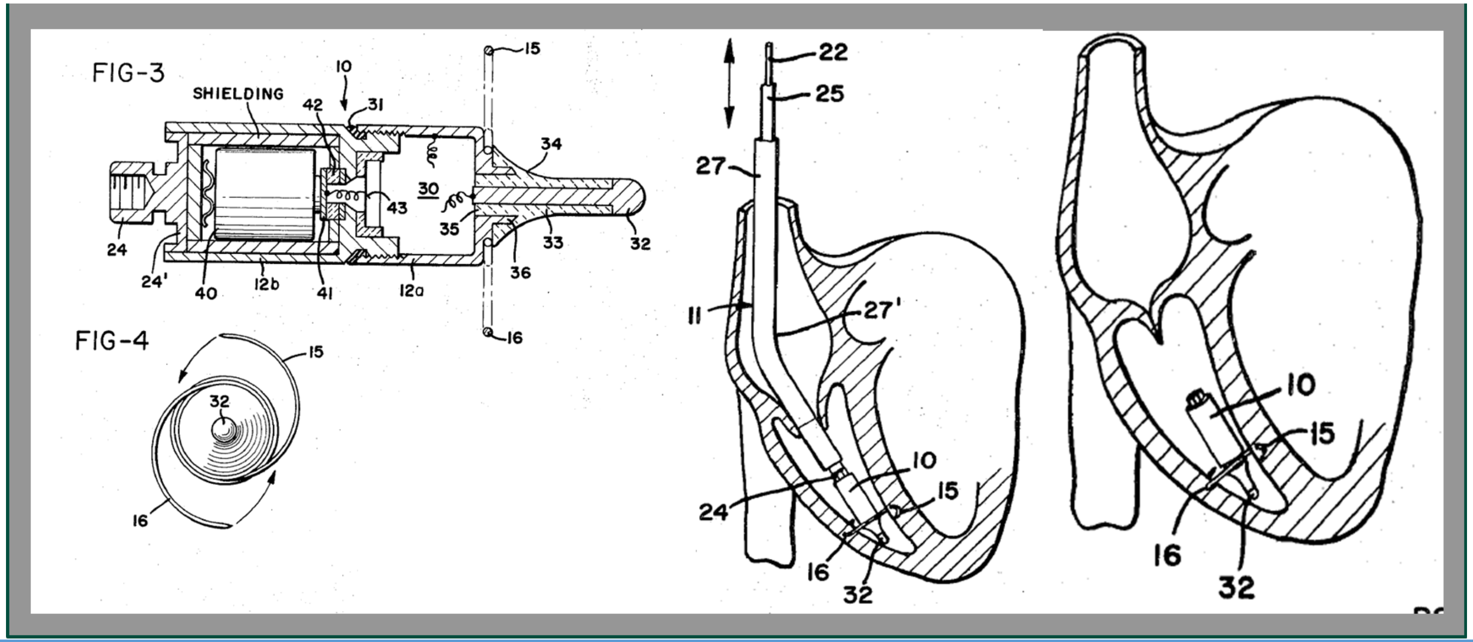
- The idea of a pacemaker that could be implanted directly in the heart is something that physicians have long considered.
- This kind of super-small pacemaker would eliminate the need for transvenous leads.
- It could be implanted without the need for a pulse generator pocket.

United States Patent [19]
Rasor et al.

[54] INTRA-CARDIAC STIMULATOR
[75] Inventors: Ned S. Rasor; Joseph William Spickler, both of Dayton, Ohio
[73] Assignee: Rasor Associates, Inc., Dayton, Ohio
[22] Filed: Sept. 21, 1970
[21] Appl. No.: 73,809

[11] 3,835,864
[45] Sept. 17, 1974

INVENTORS
NED S. RASOR &
JOSEPH WILLIAM SPICKLER
BY Marechal, Biebel, French & Bugg
ATTORNEYS



Leadless Pacemaker

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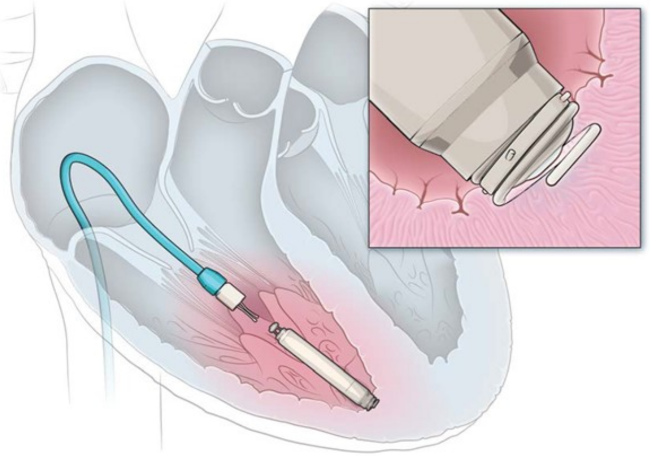
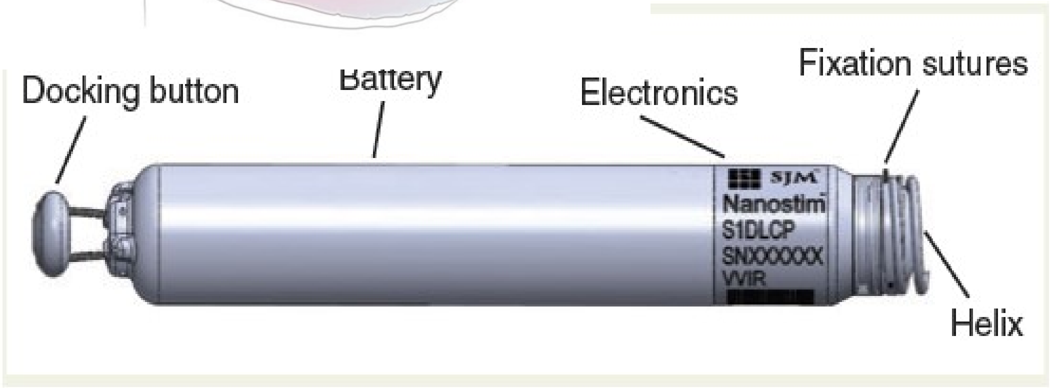
Leadless System for RV pacing

St. Jude Medical Nanostim™ leadless pacemaker (LCP)

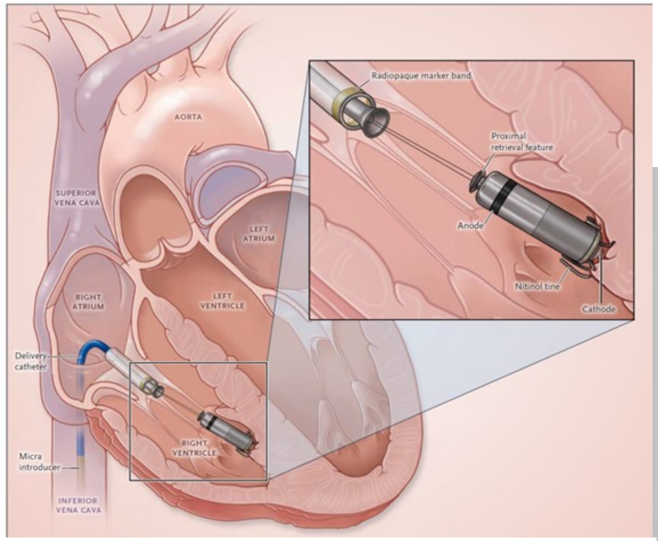
- Available in 2012
- VVI(R)
- Screw-in helix





Medtronic Micra™ Transcatheter Pacing System (TPS)

- Available in 2013
- VVI(R)
- Self-expanding nitinol tines



Leadless System for RV pacing

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ADVANTAGE leadless pacing

Redefined Pts Experience

- No chest scar
- No bump
- No visible or physical reminder of a PM
- Fewer post-implant activity restrictions

No Pocket-related Complications

- Infection
- Hematoma
- Erosion

No Lead-related Complications

- Fractures
- Insulation breaches
- Venous thrombosis and obstruction
- Tricuspid regurgitation

SAVE & SAFETY

- Lead- and pocket-related complications can be costly to the hospital and patient.[10, 68-70]
- ~1 in 8 patients treated with a traditional PM a complication attributed to the pocket or leads.[11, 68-]

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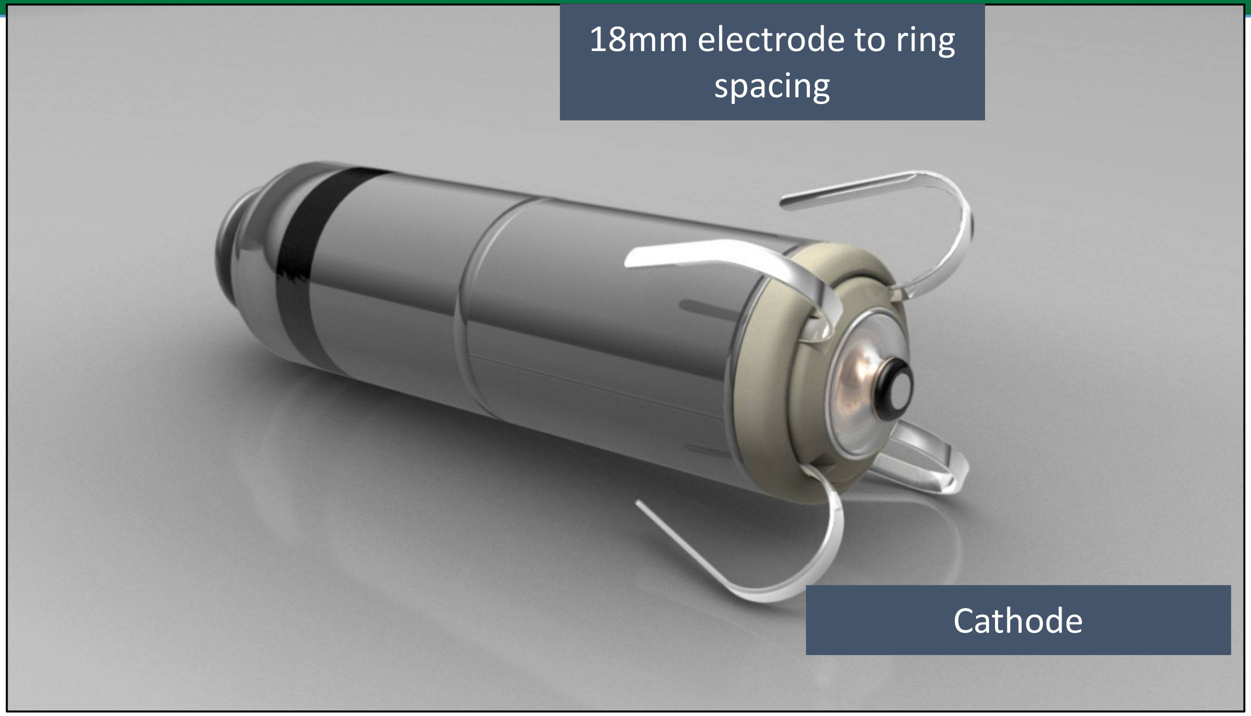
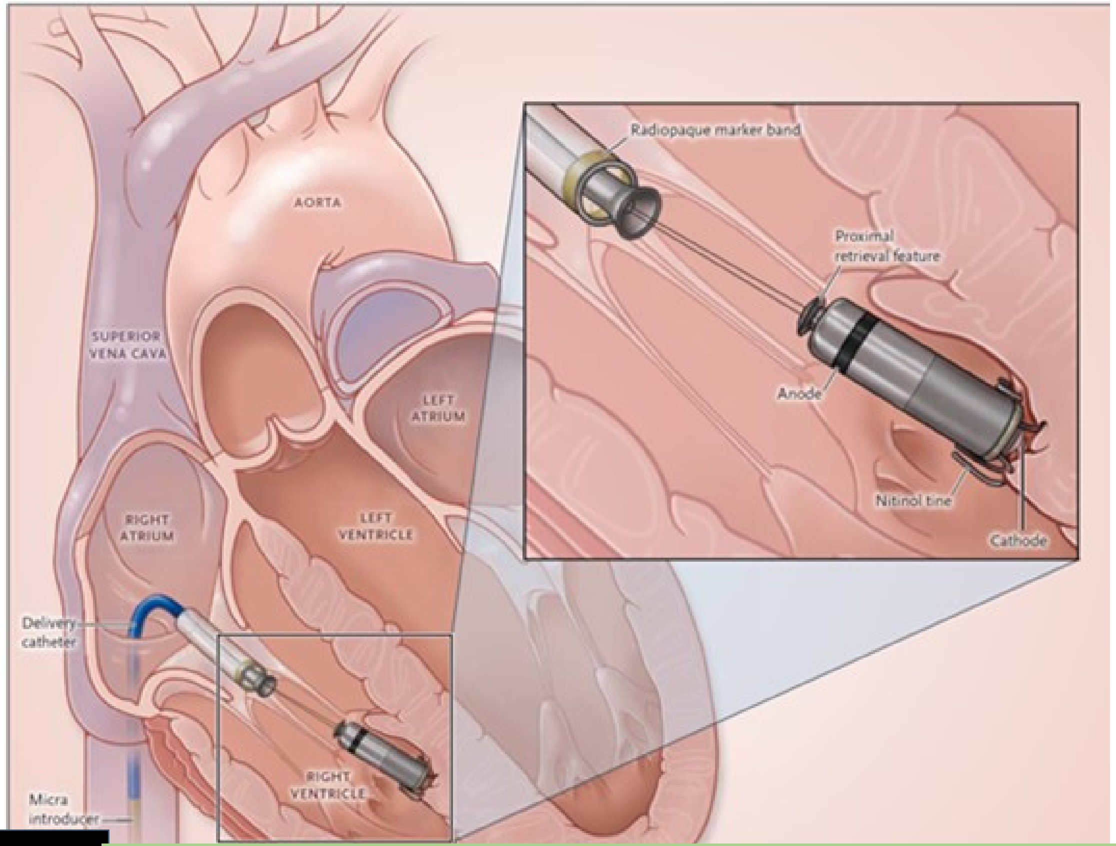
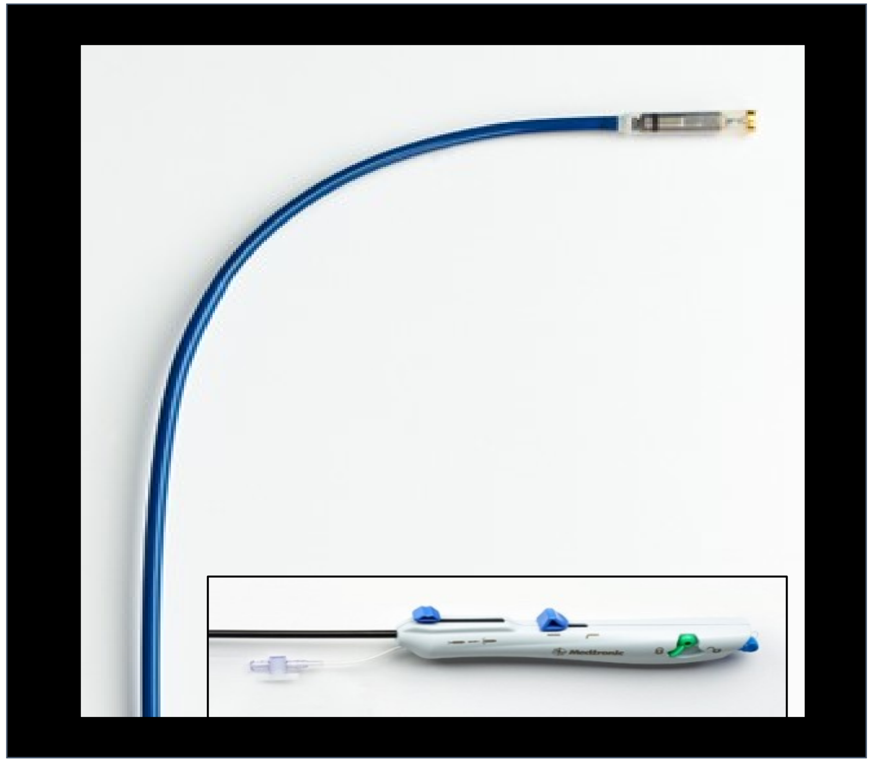




Micra™ Pacing Capsule



- World's smallest pacemaker[2]
  - 93% smaller than conventional pacemakers[3]
  - 63% fewer major complications than traditional pacemakers[4]
- 4,000+ Micra VR* patients studied in global clinical trials[4-6]

[2] Medtronic Micra MC1VR01 Clinician Manual, November 2014

leadless pacing experience

- Multidimensional redundancy: Two tines have 15x the holding force necessary to hold the device in place[20]
- Designed to minimize tissue trauma during deployment, repositioning, and retrieval[21]
- Optimal electrode-tissue interface allows for low and stable chronic thresholds[22]
- Low dislodgement rate (0.00-0.06%)[4,5]

Micra™ AV and Micra™ VR Transcatheter Pacing Systems

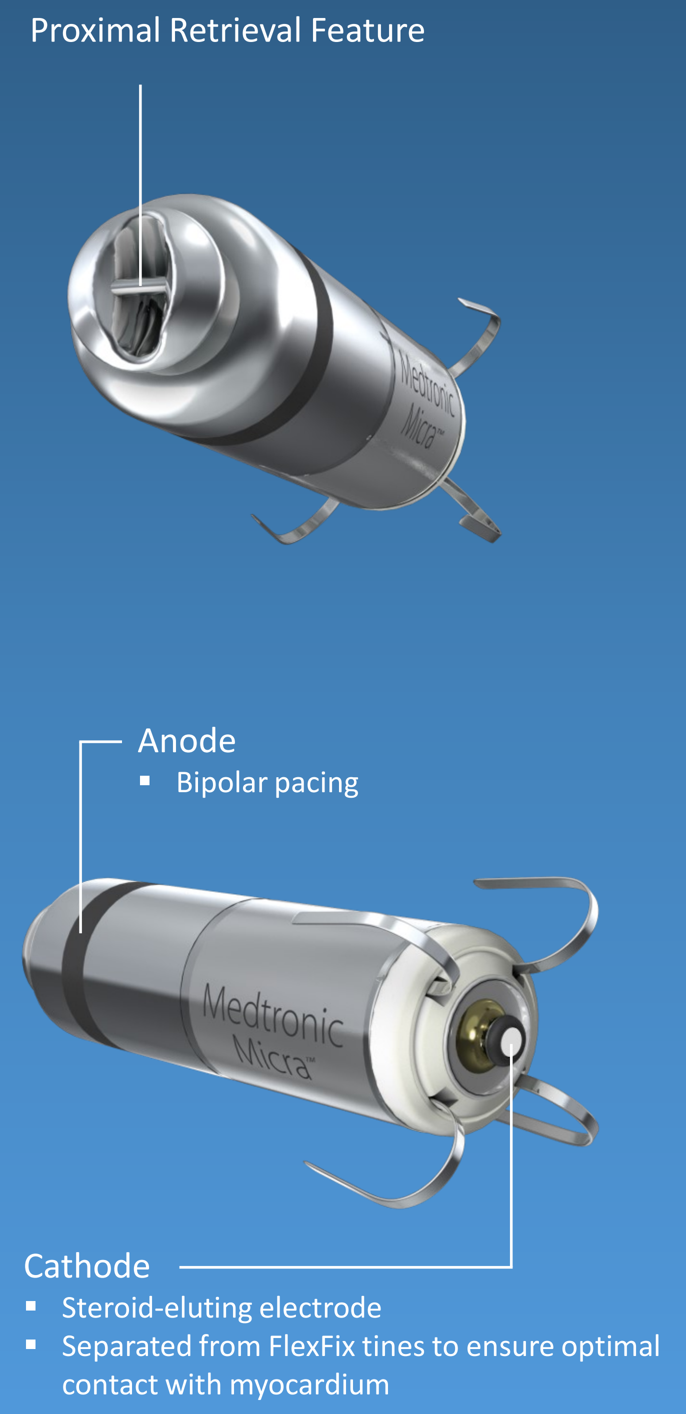
- Flexfix™ nitinol tines

Leadless Pacing Experience

Parameter	Micra™ AV[9]	Micra™ VR[16]

SAME PROCEDURE

- > 99% implant success[4,5]
- Low dislodgement & infection rates[4,5]
- Same implant tools for delivery and deployment



13 years = 15% VDD pacing, 70 bpm, pacing threshold 1.5 V, impedance 600 Ω, pulse width 0.24 ms.
†Use conditions included: median pacing 53.5%, median pacing threshold 0.50 V, median impedance 543 Ω; 89% of patients with > 10-year projected longevity; 99% of patients with > 5-year longevity.[18]

REDUCTION IN COMPLICATIONS

Leadless pacing provides the potential to reduce pacemaker complication rates and the associated healthcare utilization costs.[4,10, 68-70]

REDUCTION IN INFECTIONS

Leadless pacing provides the potential to avoid the healthcare utilization costs related to infections.[10,12-15, 68-70]

IMPROVED PATIENT ACCESS

24% of patients with a Micra VR implant had a condition that the implanting physician felt precluded them from receiving a transvenous device.[4]

MICRA™ ECONOMIC IMPACT

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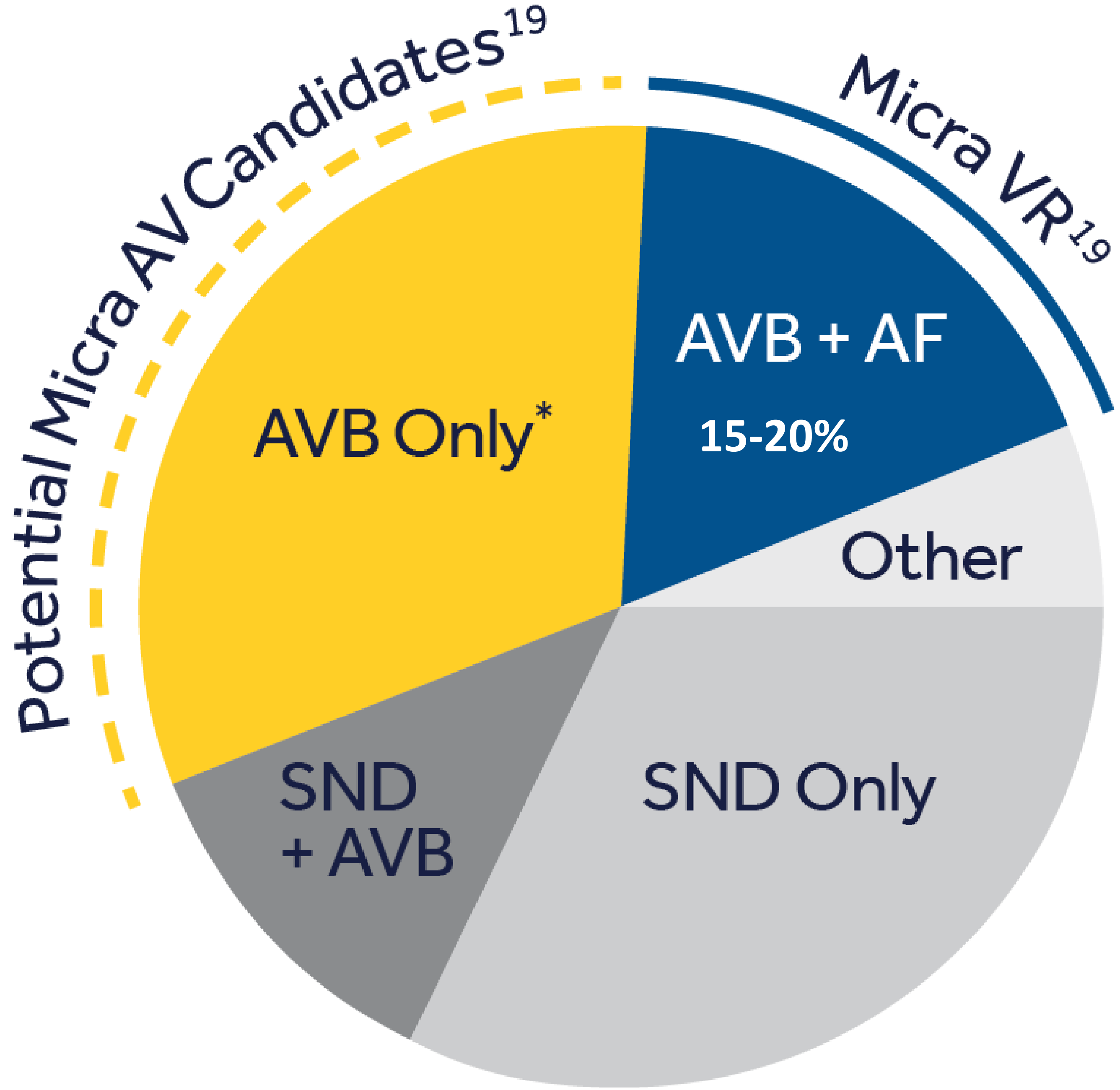
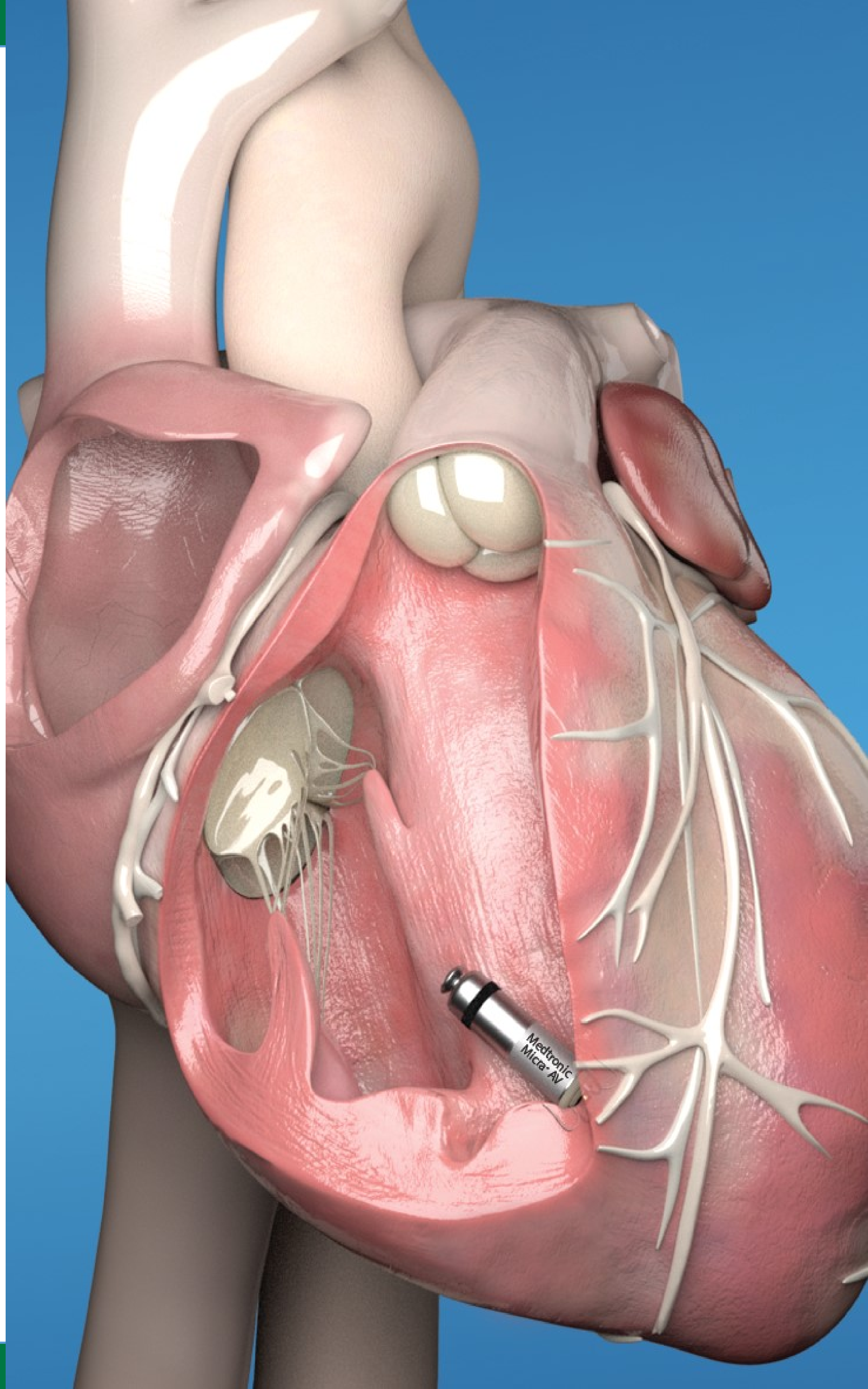
Micra™ AV and Micra™ VR Transcatheter Pacing Systems

Micra AV expands the potential pool of patients to AV block-only patients, who could benefit from AV synchrony.





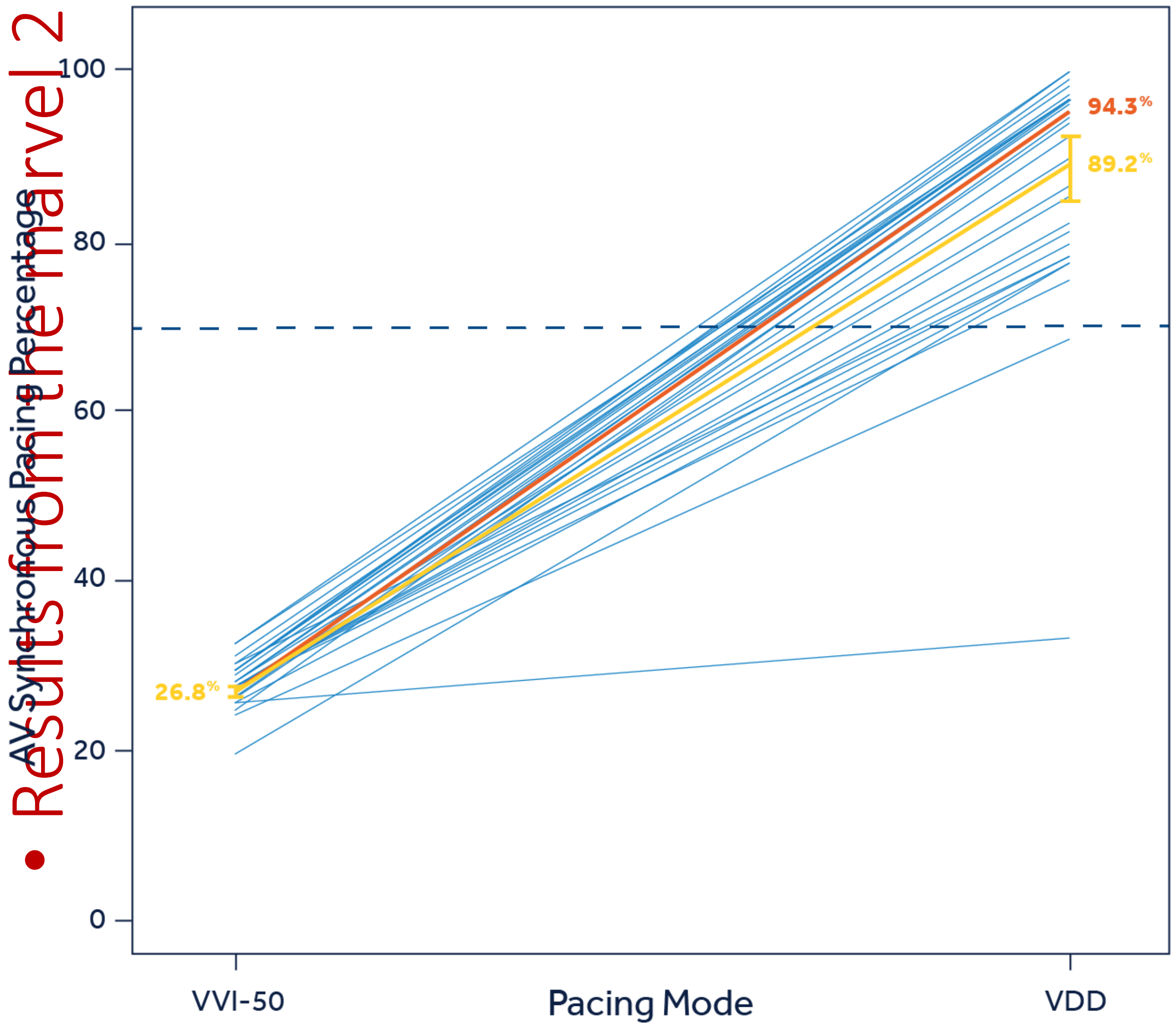
*AVB-only patients who would benefit from leadless pacing per the indications for use.

Micra™ AV and Micra™ VR Transcatheter Pacing Systems

AV SYNCHRONY REIMAGINED

• Results from the marvel 2 study[7]

Primary Efficacy Analysis Cohort (n = 40)



Micra™ AV and Micra™ VR Transcatheter Pacing Systems

94.3%

Median AV synchrony at rest in complete AV block patients with normal sinus rhythm (n = 40).

89.2%

Mean AV synchrony increased from 26.8% during VVI pacing to 89.2%.

Atrioventricular synchronous pacing using a leadless pacemaker: Results from the MARVEL 2 study[7]

Objective

To demonstrate AV synchronous pacing in existing Micra™ VR devices.

Analysis Design

Multicenter, pivotal IDE study, the MARVEL 2 algorithm was downloaded into 75 patients who had AV block and an existing Micra VR. The primary efficacy objective was to characterize the rate of AV synchrony at rest for 20 minutes in patients with complete heart block and normal sinus rhythm (N = 40). The primary safety objective was to demonstrate freedom from pauses and inappropriate tracking > 100 bpm among all 75 patients.

Results

- 94.3% median AV synchrony at rest in complete AV block patients with normal sinus rhythm (n = 40).
- Mean AV synchrony increased from 26.8% during VVI pacing to 89.2%.
- 95% of patients (38 of 40) with complete heart block and normal sinus rhythm had ≥ 70% AV synchrony.
- 8.8% improvement in stroke volume as measured by LVOT VTI (n = 39).

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intermediate-term results across a large pts population in the real-world

Updated performance of the Micra transcatheter pacemaker in the real-world setting: A comparison to the investigational study and a transvenous historical control

Check for updates

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CONCLUSION Performance of the Micra transcatheter pacemaker in international clinical practice remains consistent with previously reported data. Major complications were infrequent and occurred 63% less often compared to transvenous systems.

BACKGROUND Early results of the Micra Investigational Device Exemption (IDE) study and Micra Post-Approval Registry (PAR) demonstrated excellent safety and efficacy performance; however, intermediate-term results across a large patient population in the real-world setting have not been evaluated.

OBJECTIVES We report updated performance of the Micra transcatheter pacemaker from a worldwide PAR and compare it with the IDE study as well as a transvenous historical control.

METHODS The safety objective of the analysis was system- or procedure-related major complications through 12 months postimplantation. We compared the major complication rate with that of the 726 patients from the IDE and with a reference data set of 2667 patients with transvenous pacemakers by using a Fine-Gray competing risk model.

RESULTS The Micra device was successfully implanted in 1801 of 1817 patients (99.1%). The mean follow-up period was 6.8 ± 6.9 months. Through 12 months, the major complication rate was 2.7% (95% confidence interval [CI] 2.0%–3.7%). The risk of major complications for Micra PAR patients was 63% lower than that for patients with transvenous pacemakers through 12 months postimplantation (hazard ratio 0.37; 95% CI 0.27–0.52; $P < .001$). The

The Micra Post-Approval Registry and Micra Transcatheter Pacing Study are funded by Medtronic, plc, USA. Dr El-Chami has received compensation for services from Boston Scientific and Medtronic. Dr Clementy, Dr Martinez-Sande, Dr Ritter have received compensation for services from Medtronic. Dr Garweg has received proctoring fees from Medtronic. Dr Piccini has received compensation for services from Medtronic and research grant from Abbott and Boston Scientific. Dr Lloyd has received compensation for services from Boston Scientific and Medtronic; speakers' bureau from Medtronic; and research grant from Abbott, Boston Scientific, and Medtronic. Dr Johansen has received compensation for services from Cook Medical and speakers' bureau from Medtronic and MeritMedical. Dr. Liu, Dr Fagan, and Ms Eakley are employees/shareholders of Medtronic. Dr Roberts has received compensation for services from Medtronic; speakers' bureau from Medtronic; and research grant from Medtronic. The rest of the authors report no conflicts of interest. Address reprint requests and correspondence: Dr Mikhael F. El-Chami, Division of Cardiology, Section of Electrophysiology, Emory University Hospital, 550 Peachtree St NE, Atlanta, GA 3308. E-mail address: melcham@emory.edu.

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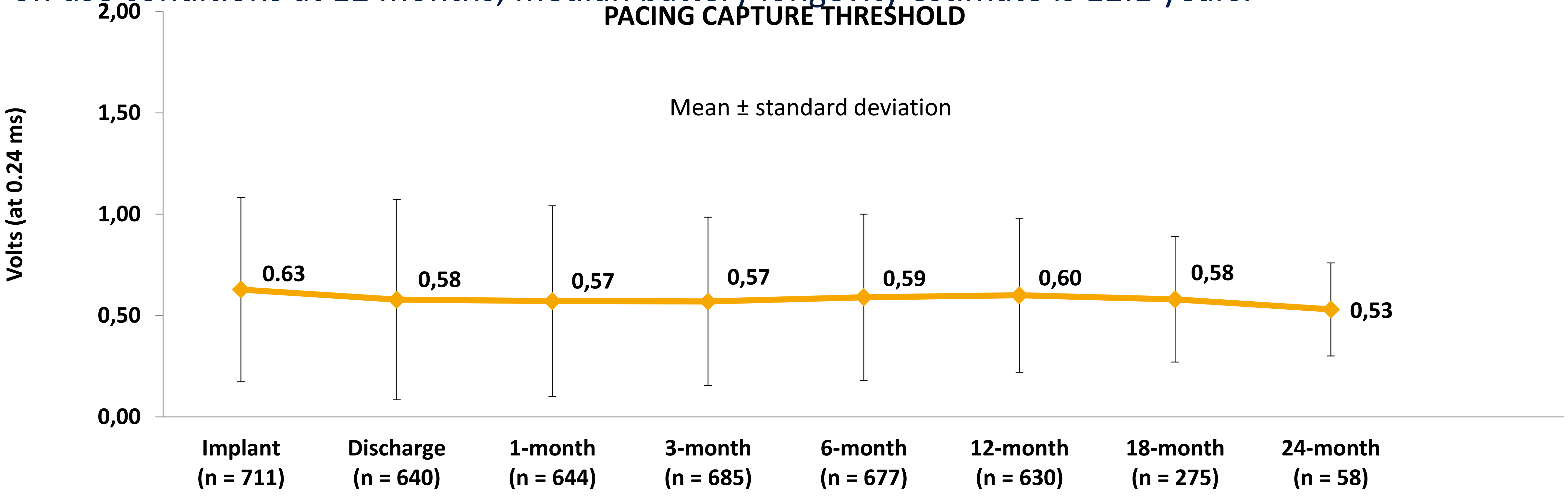
Low and stable pacing thresholds[17]

Battery Longevity Estimate

Based on use conditions at 12 months, median battery longevity estimate is 12.1 years.*



*Use conditions included: median pacing 53.5%, median pacing threshold 0.50 V, median impedance 543 Ω; 89% of patients with > 10-year projected longevity; 99% of patients with > 5-year longevity.[18]

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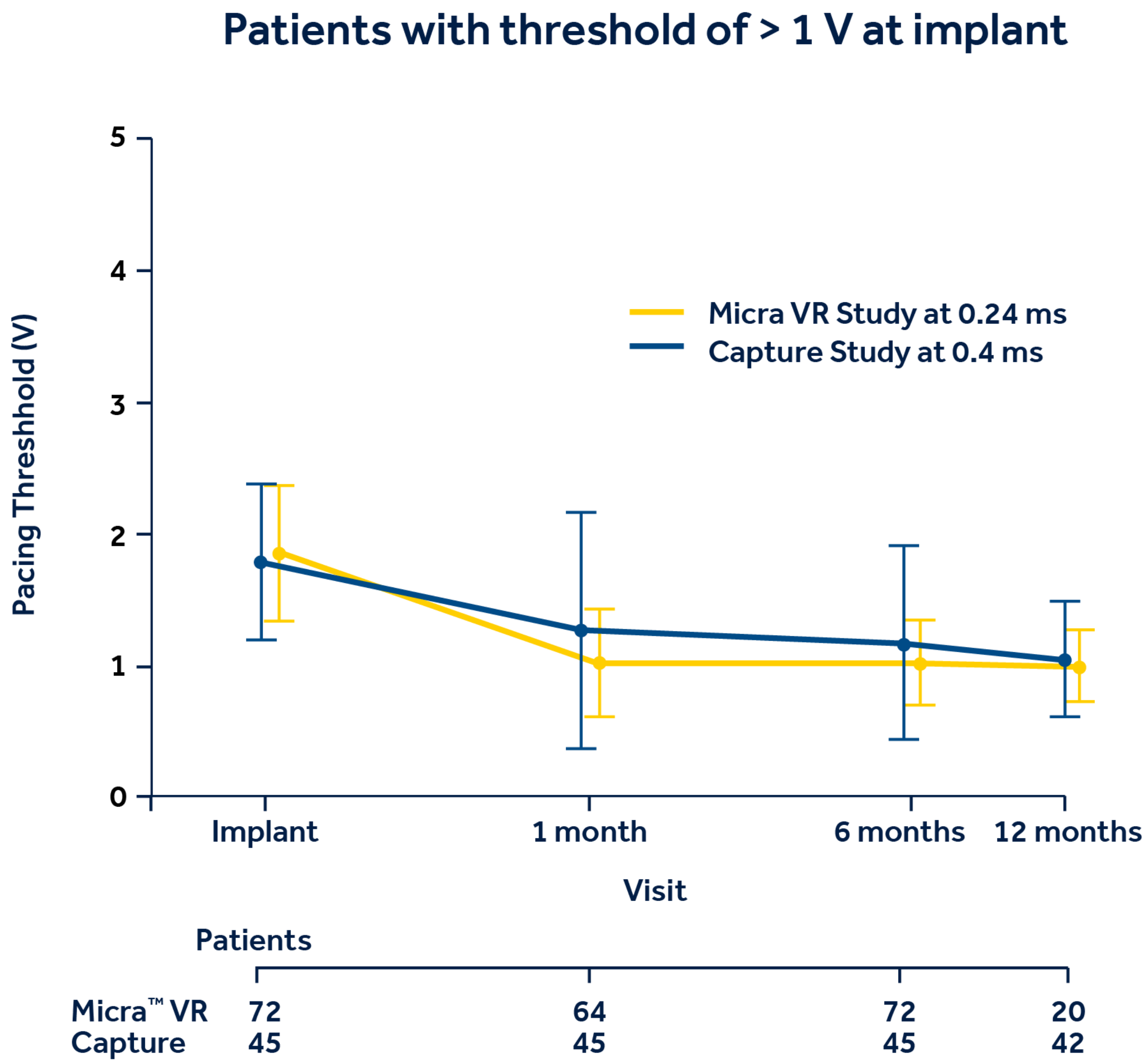
Heart Rhythm, Vol 15, No 12, December 2018

High thresholds at implant tend to decrease



*Significantly different from implant value (p < 0.05).

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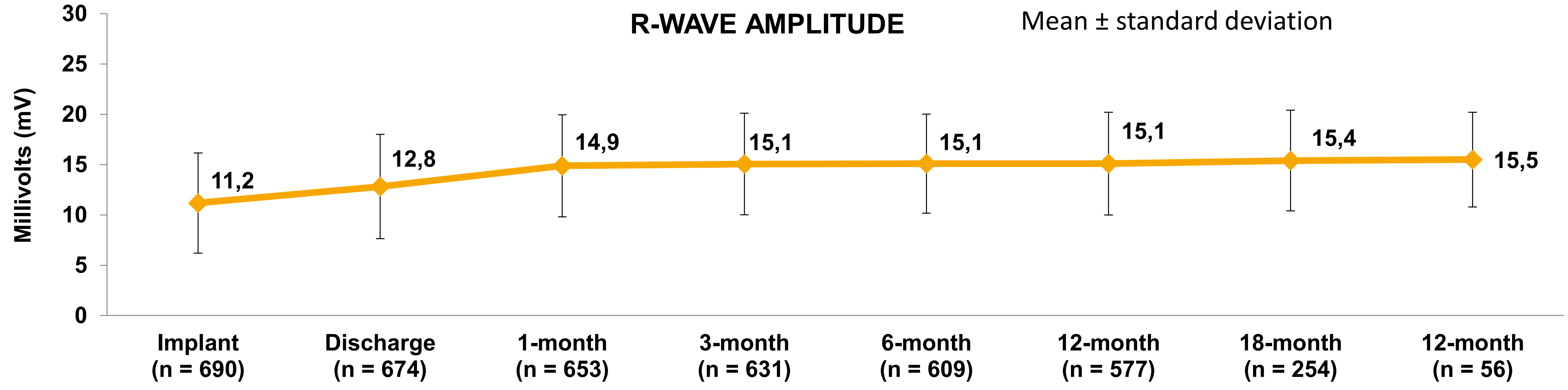
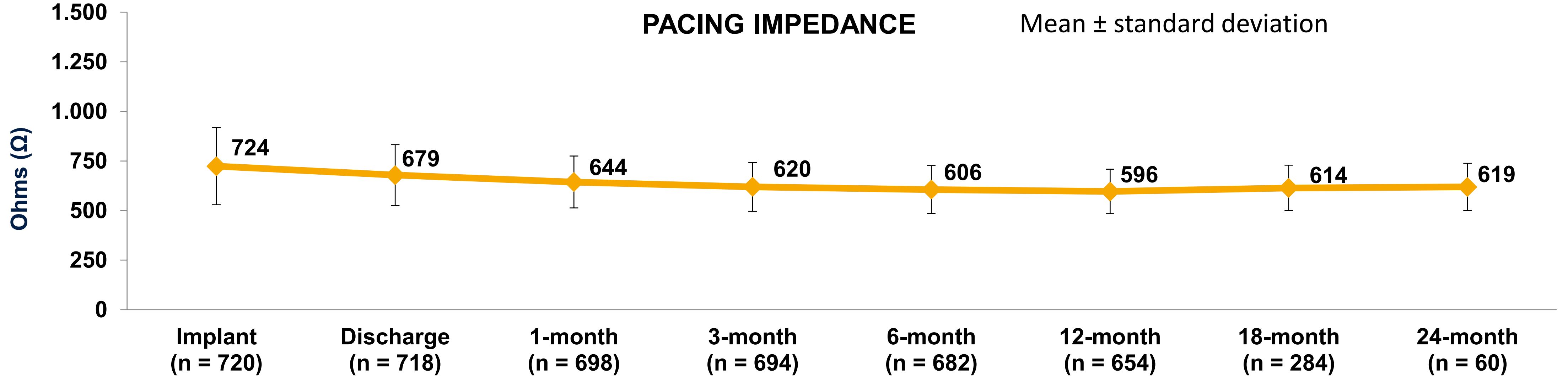
Micra™ VR electrical performance[17]





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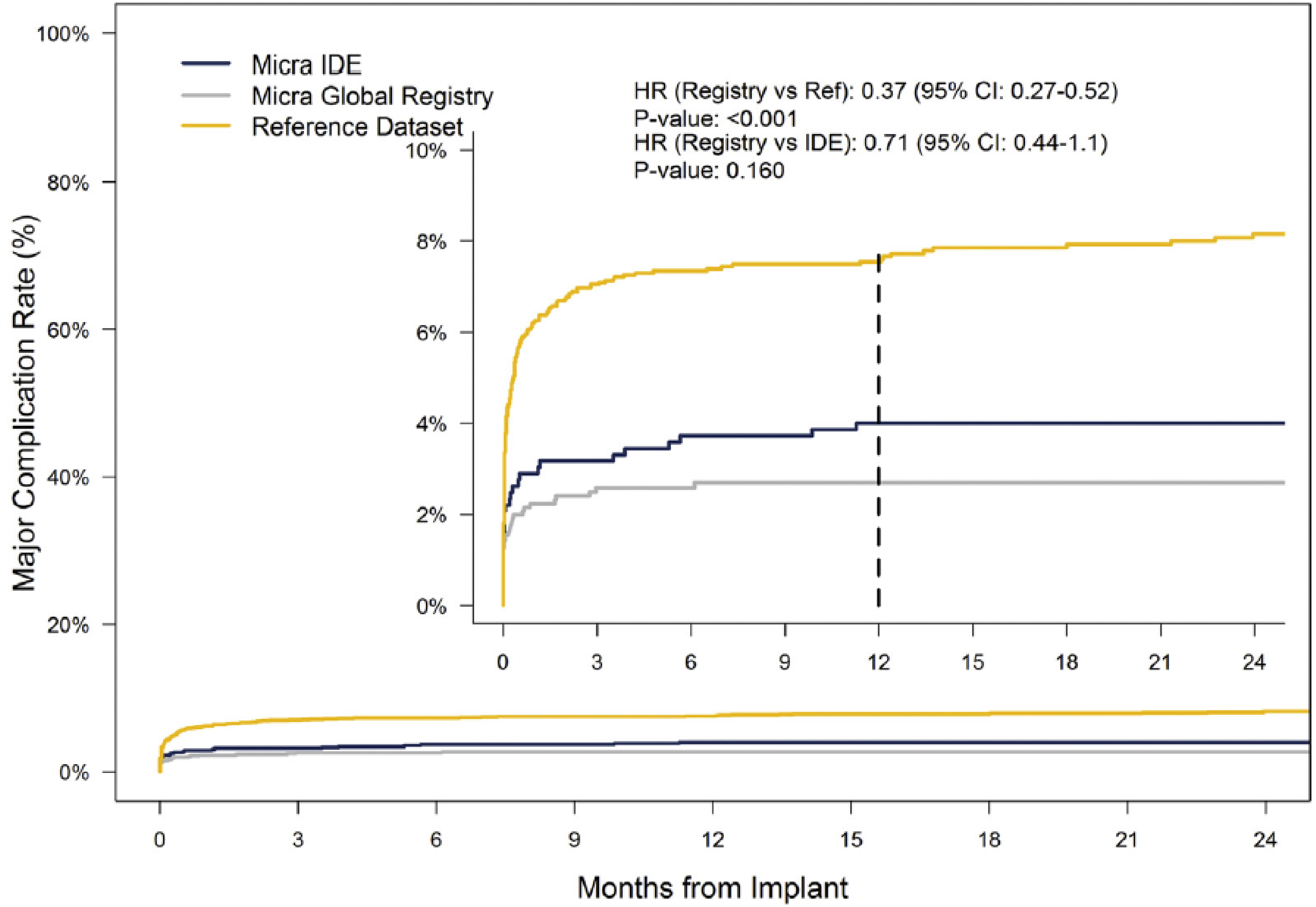
Heart Rhythm, Vol 15, No 12, December 2018

Major complication rates through 24 mths post-implantation



Number at Risk

	0	3	6	9	12	15	18	21	24
IDE	726	684	671	658	639	432	251	106	42
Global	1817	1008	846	630	458	222	144	64	28
Ref	2667	2260	1965	1698	1526	1319	1212	1137	1002

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Heart Rhythm, Vol 15, No 12, December 2018

• Implant tools

SAME, STREAMLINED procedure

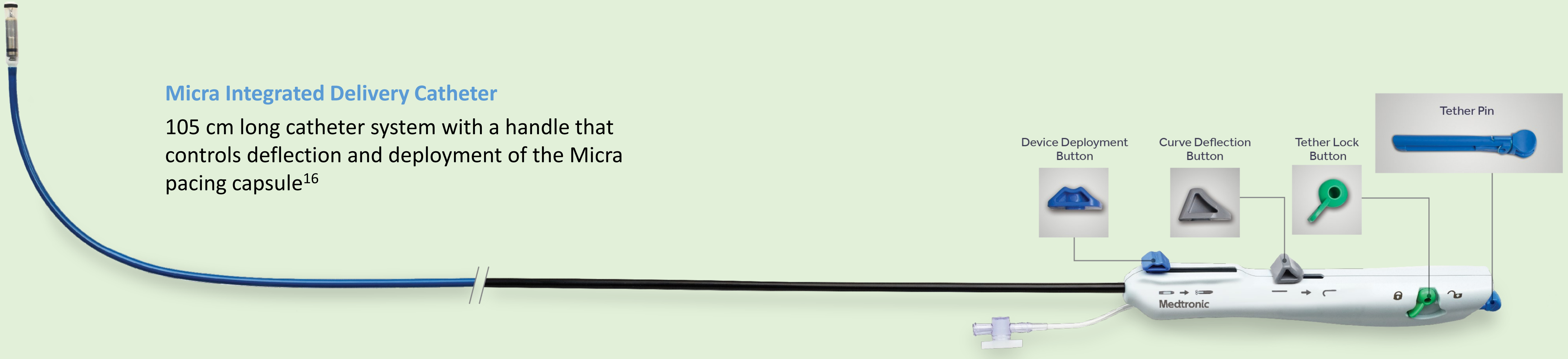
Smooth Vessel Navigation with the Micra™ Introducer

- Lubricious hydrophilic coating
- 23 Fr inner diameter (27 Fr outer diameter)
- Silicone oil-coated dilator tip

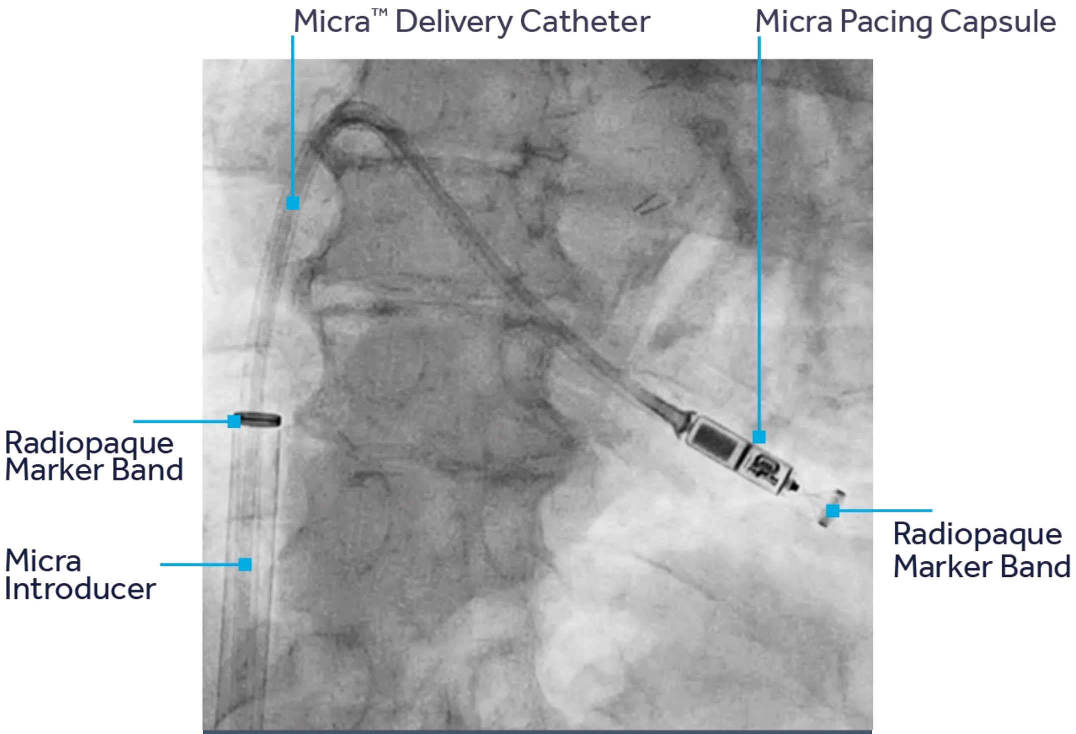
> 99%
Implant success in Micra VR clinical studies[4,5]

Micra Integrated Delivery Catheter

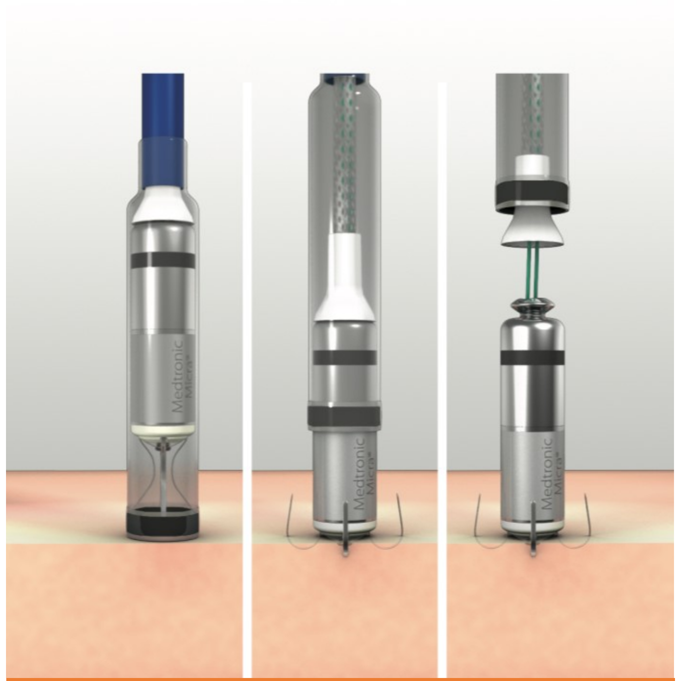
105 cm long catheter system with a handle that controls deflection and deployment of the Micra pacing capsule[16]



• PROCEDURE



Delivery catheter provides visual feedback when adequate tip pressure has been achieved, and retracts during deployment.[16]



Linear, one-step deployment facilitates consistent capsule placement; no torque required.[20]

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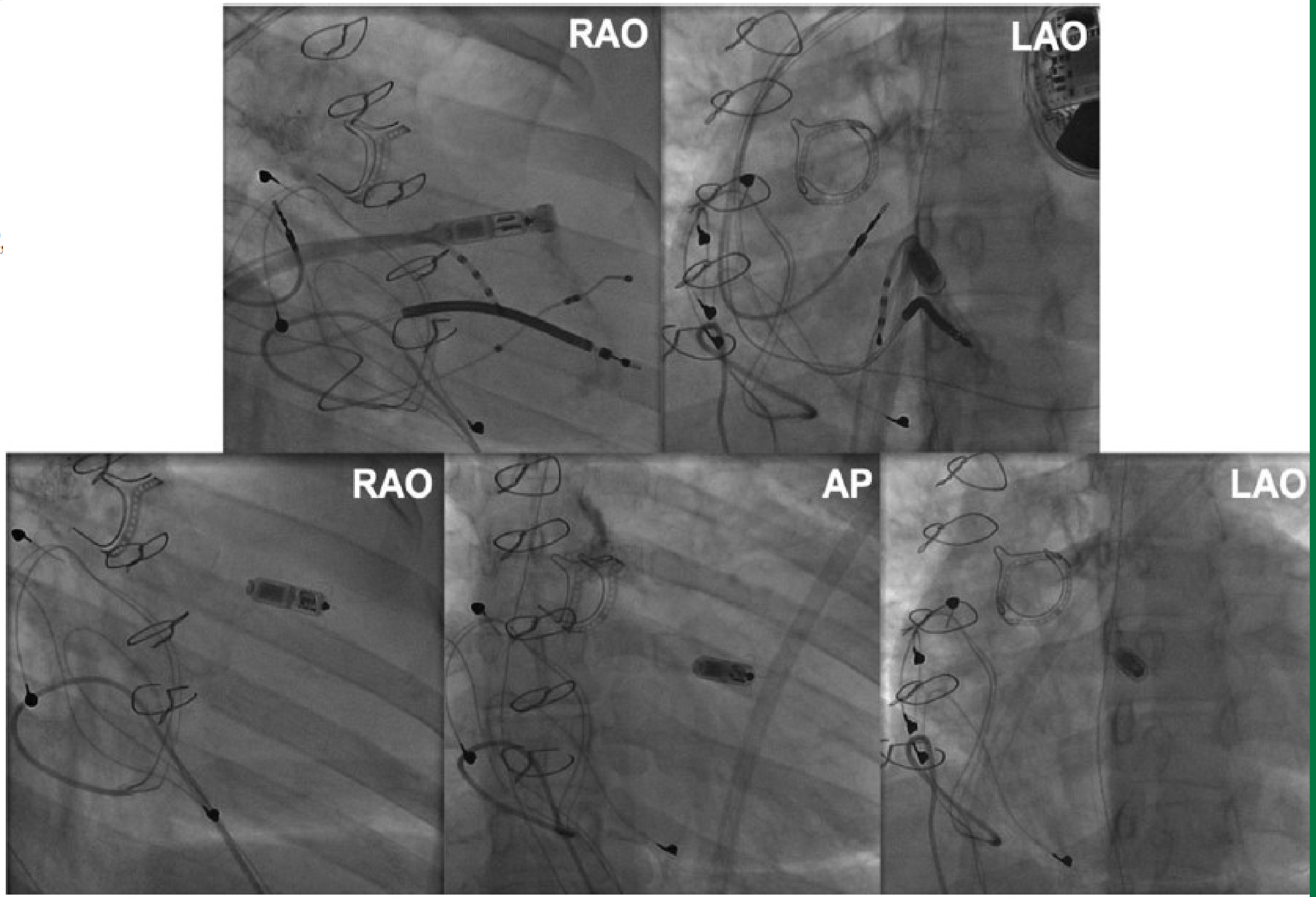
MICRA in pediatric patients

- Literature regarding the use of leadless pacemakers in pediatric patients is scarce.
- Breatnach et al. reported on the successful implantation of the Micra™ TPS in nine pediatric patients ranging in weight from 31 to 50 kg via the right femoral vein.
- A limitation to the use of the Micra™ TPS in the pediatric population is the large size of the delivery sheath.
- Limited case reports have described the placement of the Micra™ TPS via the right internal jugular vein in a patient as small as 18 kg.
- However, procedures reported in the literature using the right internal jugular vein due to small patient size have been limited to in patients with concurrent medical conditions that render the use of traditional systems unfavorable or contraindicated.6,7

Leadless ventricular pacemaker implant with atrial sensing in levo-transposition of the great arteries

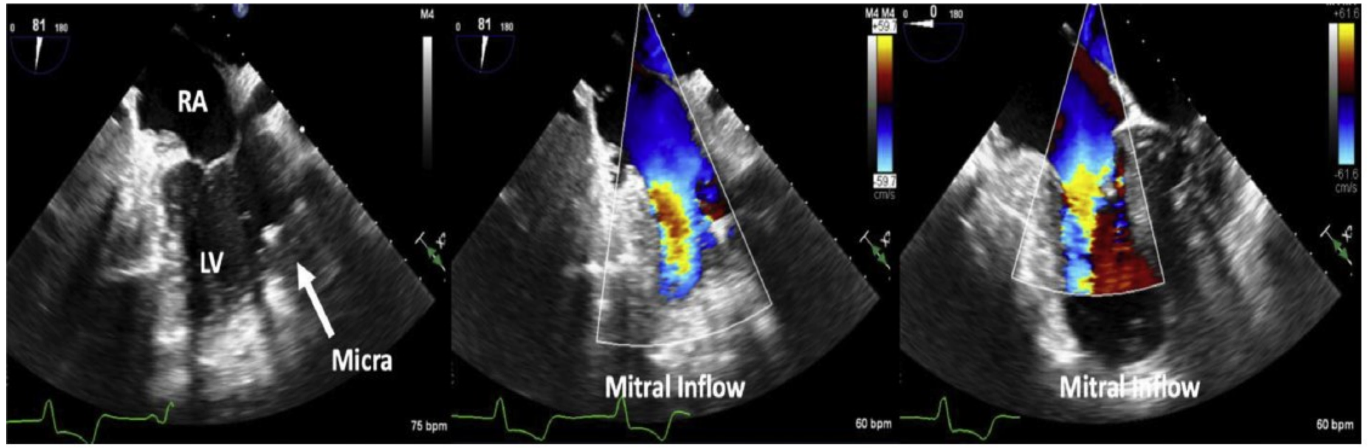
Joshua Rutland, MD, MS,* Kristen M. Tecson, PhD,†‡ Manish D. Assar, MD, FHRS*‡

*From the *Baylor Heart & Vascular Hospital, Dallas, Texas, †Baylor Heart and Vascular Institute, Dallas, Texas, and ‡Texas A&M College of Medicine Health Science Center, Dallas, Texas.*



KEY TEACHING POINTS

- Micra AV (Medtronic, Dublin, Ireland) implantation is feasible and safe in patients with levo-transposition of the great arteries.
- Anatomic differences of mitral valve anatomy and mitral inflow could potentially affect atrial sensing by the device accelerometer.
- Periprocedural imaging is safe and beneficial during device implantation.



- pt is a 27-year-old
- obesity, pre-diabetes, and L-TGA
- epicardial PM DDD placement within the 1 yr of life, ventricular septal defect requiring patchclosure

at 5 years of age, and severe valvular and subvalvular pulmonic stenosis requiring valvuloplasty and subseque

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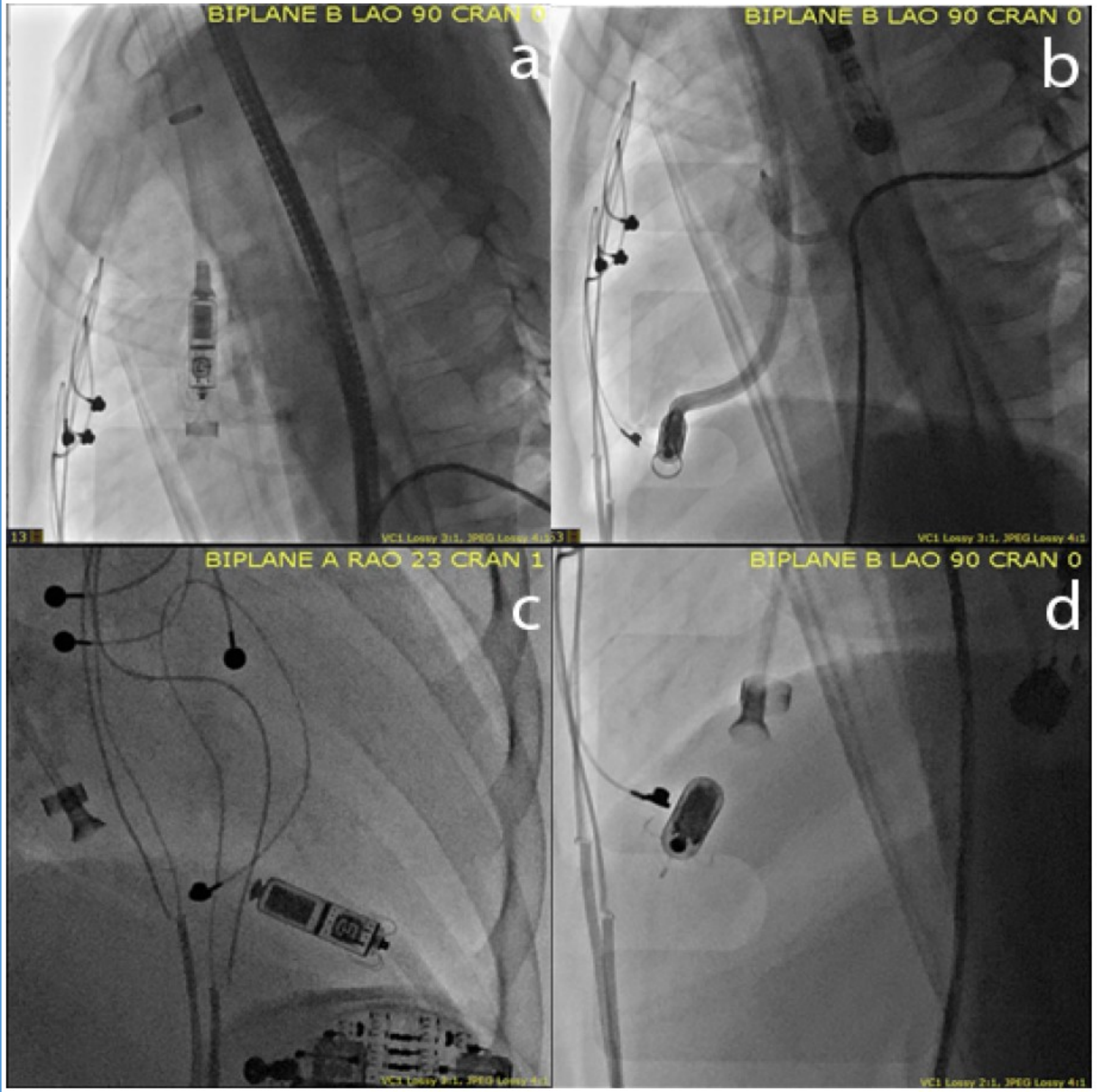
CASE REPORT

Percutaneous jugular leadless pacemaker implantation in a pediatric patient

Rohan N. Kumthekar MD, Ralph S. Augostini MD, Anna N. Kamp MD, Naomi J. Kertesz MD

First published: 16 July 2022 https://doi.org/10.1111/jce.15620



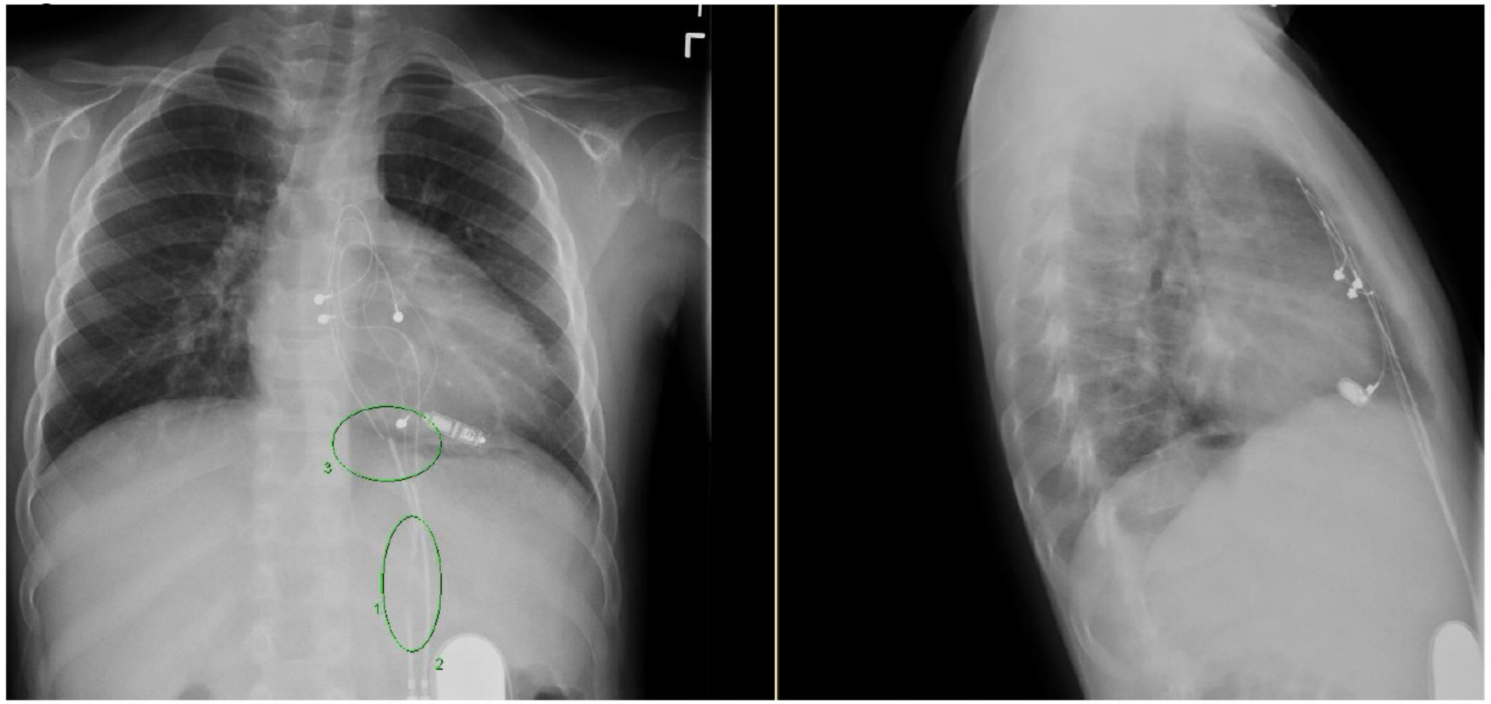


Figure 2: AP and lateral chest X-ray at 3 month follow up showing the Micra™ in stable position. Circles labelled #1 and #3 show epicardial lead fractures. #2 indicates previous epicardial pacemaker generator.

Conclusion

Micra™ AV implantation could be considered in a pediatric patient with complex congenital heart disease via a percutaneous transjugular approach without requiring a surgical cutdown. This helps minimize the risk of vascular injury from a femoral approach while providing the patient with a lower risk solution to pacing than a repeat epicardial system and avoiding a transvenous system at a small size. The ability for the AV synchrony algorithm to track higher atrial rates and greater clarity on device end of life solutions would significantly improve this device as a novel solution for pediatric patients.

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ESC
European Society
of Cardiology

European Heart Journal - Case Reports (2020) **4**, 1–6
doi:10.1093/ehjcr/ytaa064

CASE SERIES
Arrhythmias/electrophysiology

Successful implantation of leadless pacemakers in children: a case series

Ewa Jędrzejczyk-Patej [1]*, Aleksandra Woźniak [1], Linda Litwin [2,3], Alina Skiba-Zdrzałek[3], Michał Mazurek[1], Radosław Lenarczyk [1], Zbigniew Kalarus[2,4], and Oskar Kowalski [1,5]

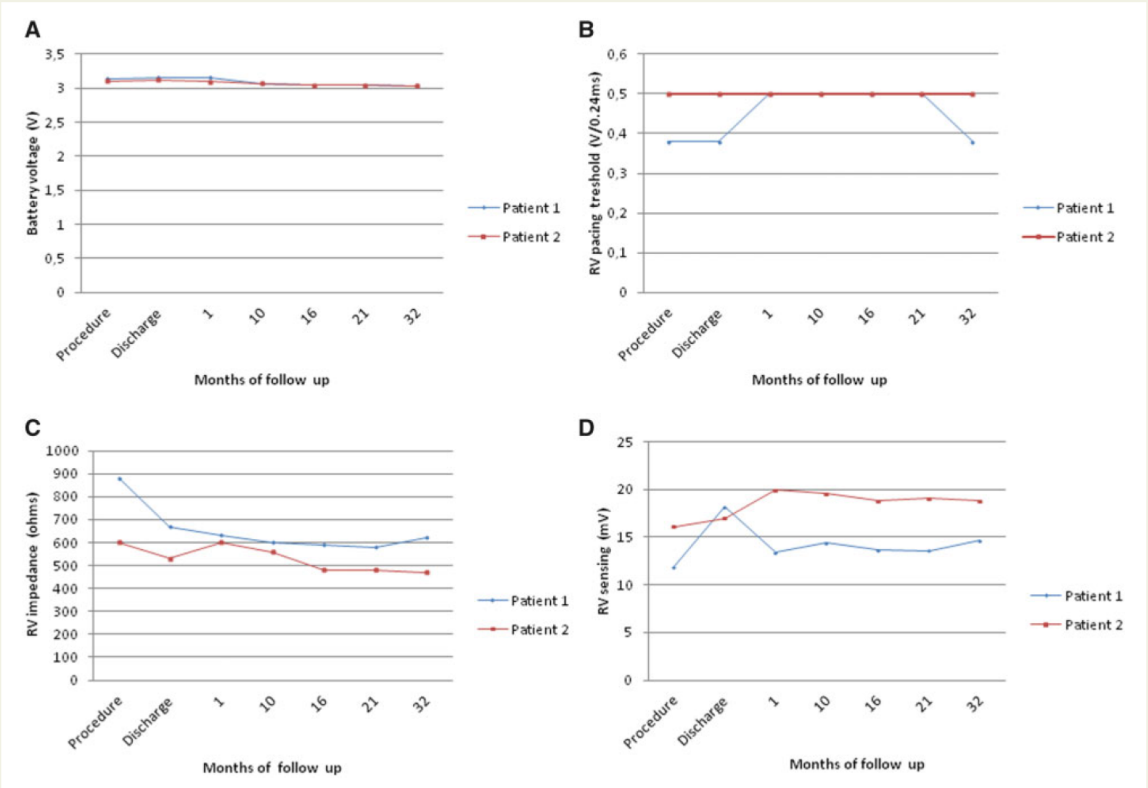

Figure 2 The electrical parameters of the device: battery voltage (*A*), right ventricular pacing threshold (*B*), right ventricular impedance (*C*), and right ventricular sensing (*D*). RV, right ventricle.

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EP CASE REPORT

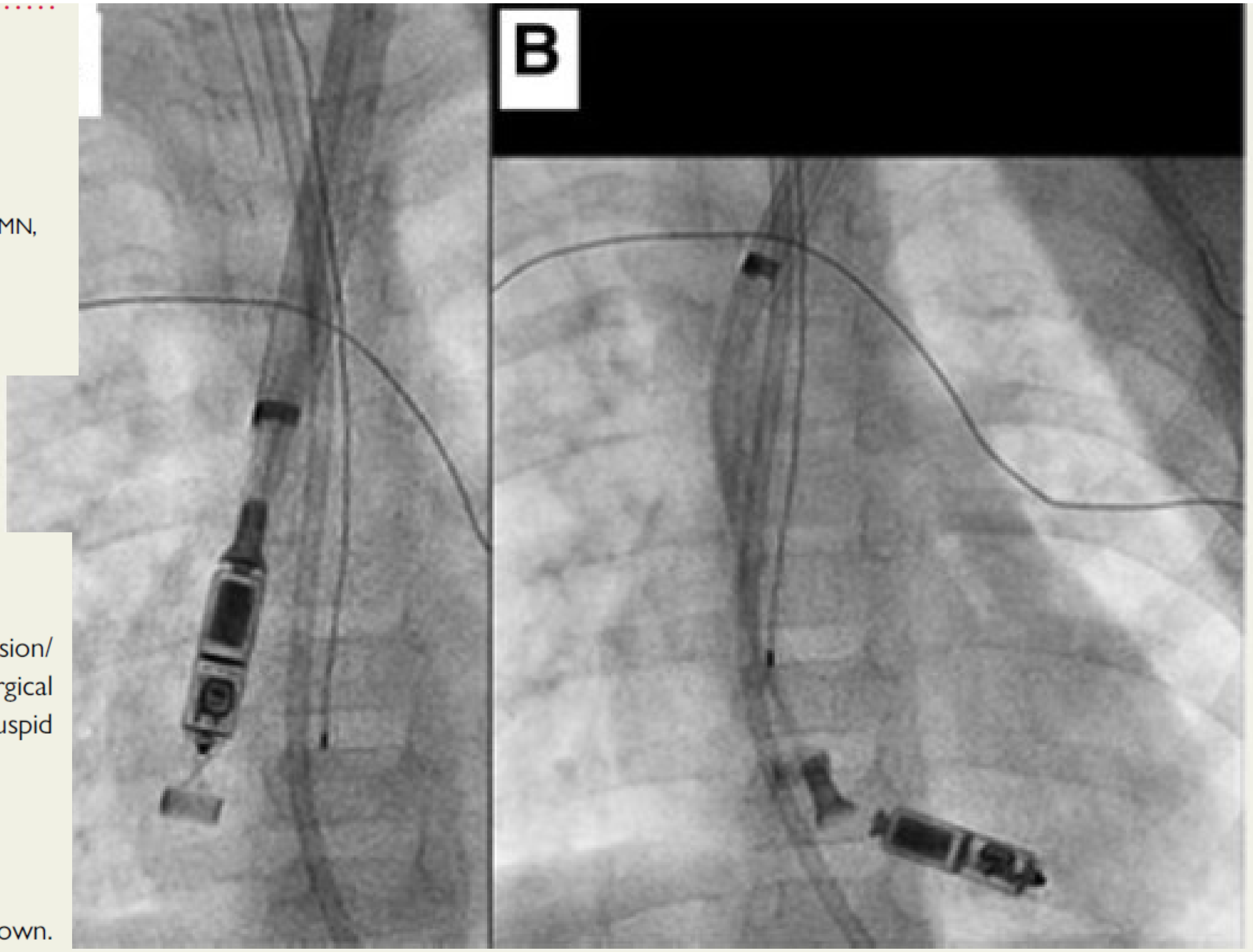
https://doi.org/10.1093/europace/euac093

An eSheath, left IJ approach to implantation of a Micra leadless pacemaker in a 2-year-old, 10.9 kg burn victim

Daniel Cortez[1]*, **Amr El-Bokl**[2], **Jonathan Dayan**[1], **Jay Yeh**[1], **Gary Raff**[1], and **Frank Ing**[1]

[1]Department of Pediatric Cardiology, Director of Pediatric Electrophysiology, UC Davis Medical Center, Sacramento, CA, USA; and [2]University of Minnesota, Minneapolis, MN, USA

*Corresponding author. *E-mail address*: dancortez@ucdavis.edu



Discussion

We demonstrate feasibility of Micra placement in a 10.9 kg patient through a 16 Fr eSheath, which helped decrease consistent tension/stretch of the small patient's veins once the Micra passed through it. Right or left IJ placement with the Micra sheath, without a surgical cut-down, has been demonstrated to be safe in larger patients.[1,3] Echocardiographic guidance was helpful to ensure unhindered tricuspid valve function and right ventricular device position.

Conclusion

A modified technique using the 16 Fr eSheath permitted safe/effective leadless pacing in a 10.9 kg patient via left IJ access without cut-down.

Leadless Micra Pacemaker Use in the Pediatric Population: Device Implantation and Short-Term Outcomes

C. R. Breatnach[1] · L. Dunne[1] · K. Al-Alawi[1] · P. Oslizlok[1] · D. Kenny[1] · K. P. Walsh[1]

Review data on Micra pacemaker insertion in a pediatric population

Table 1 Demographic details

	Patient number [9]
Age (years)	13 (12–14)
Weight (kg)	37 (31–50)
Gender	
Female	6
Male	3
Indication for pacing	
Post-operative AC block	3
Congenital AV block	5
Sinus pauses	1

Data are presented as median (IQR) or absolute count

Conclusion

This case series highlights the feasibility of implanting this device in a younger patient group. Long-term follow-up studies with larger patient numbers are required to establish data on efficacy and complication rates in children.

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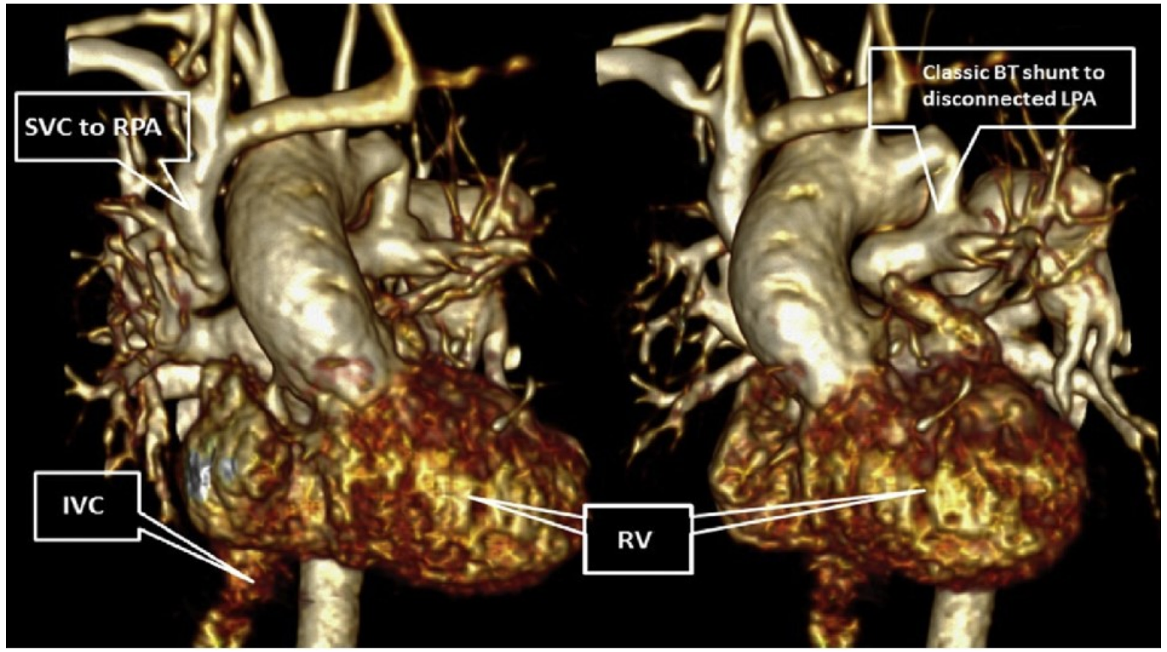
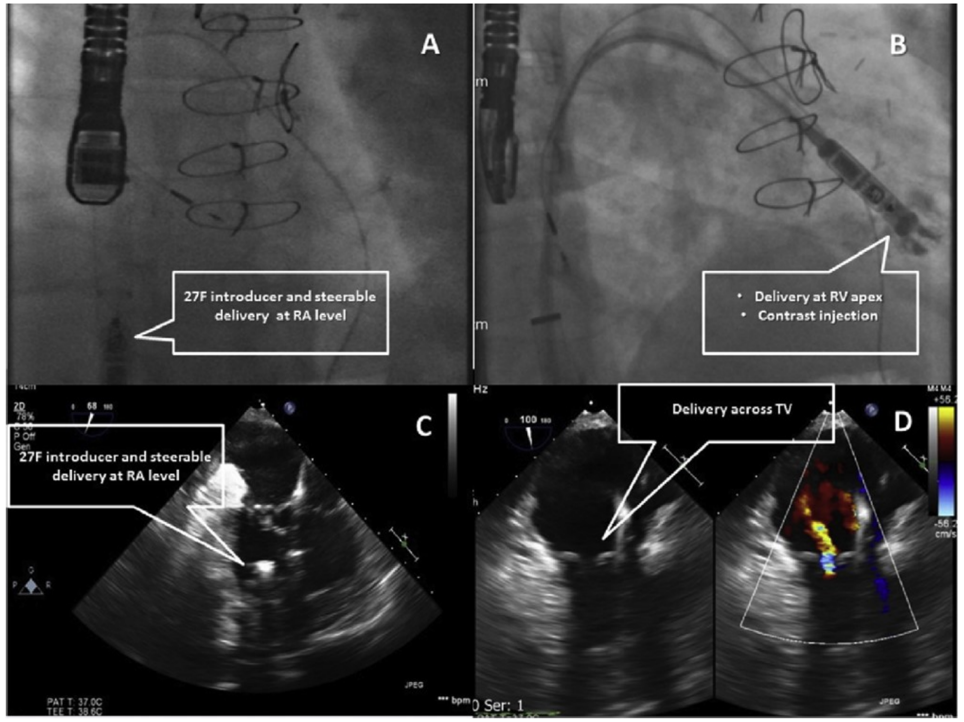
Leadless pacemaker implantation in a patient with complex congenital heart disease and limited vascular access

Paolo Ferrero [a, b, *], Michael Yeong [a], Emilia D'Elia [b], Edward Duncan [a], Alan Graham Stuart [a]

[a] *Bristol Heart Institute, Adult Congenital Heart Disease Department, University Hospital of Bristol, Bristol, United Kingdom*
[b] *Hospital Papa Giovanni XXIII, Cardiovascular Department, Bergamo, Italy*





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Indian Pacing and Electrophysiology Journal 16 (2016) 201e204

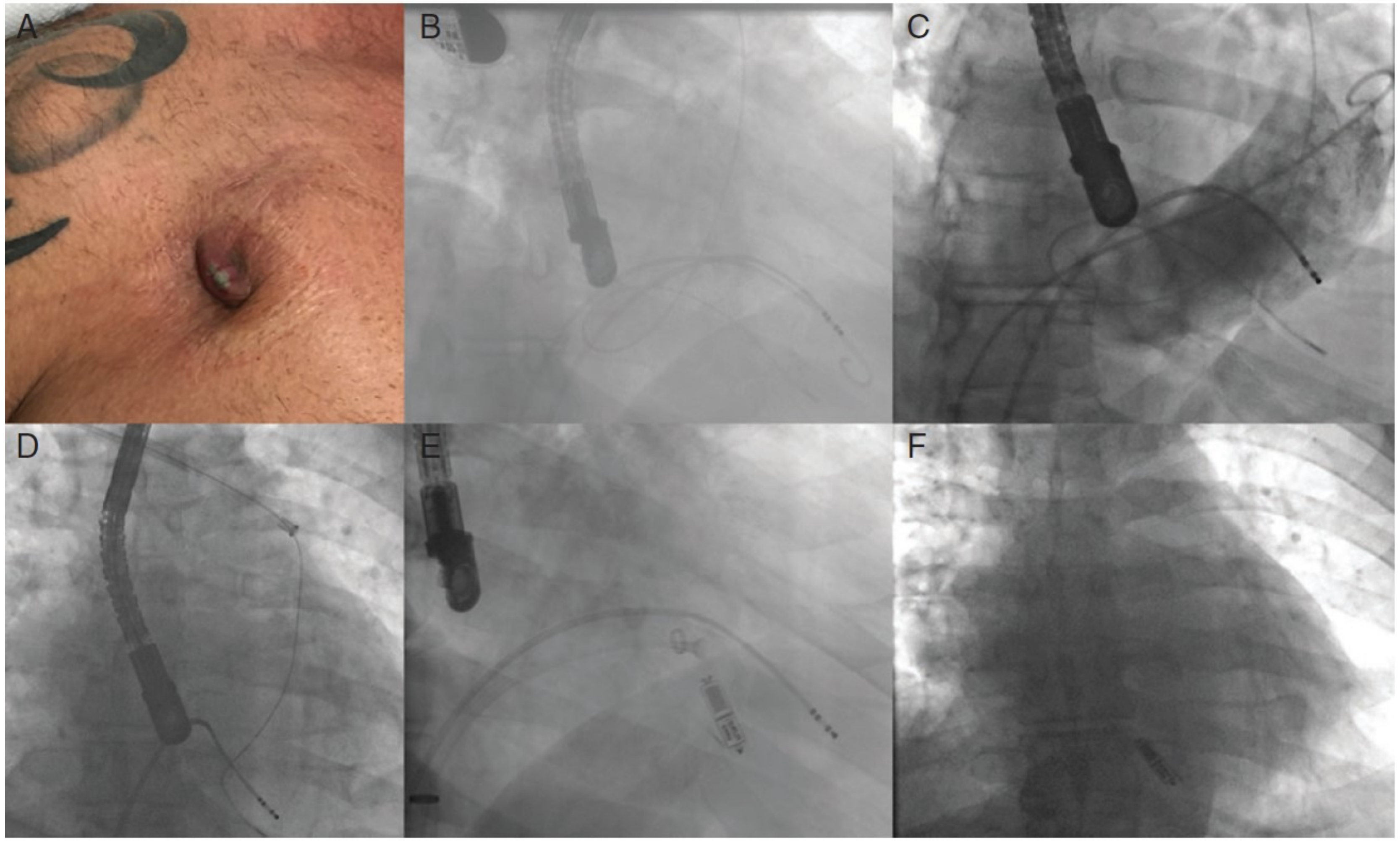
EP CASE REPORT

Leadless cardiac pacemaker as alternative in case of congenital vascular abnormality and pocket infection

Christophe Garweg*, Joris Ector, and Rik Willems

Department of Cardiovascular Sciences, KU Leuven, Leuven, Belgium

* Corresponding author. *E-mail address*: christophe.garweg@uzleuven.be



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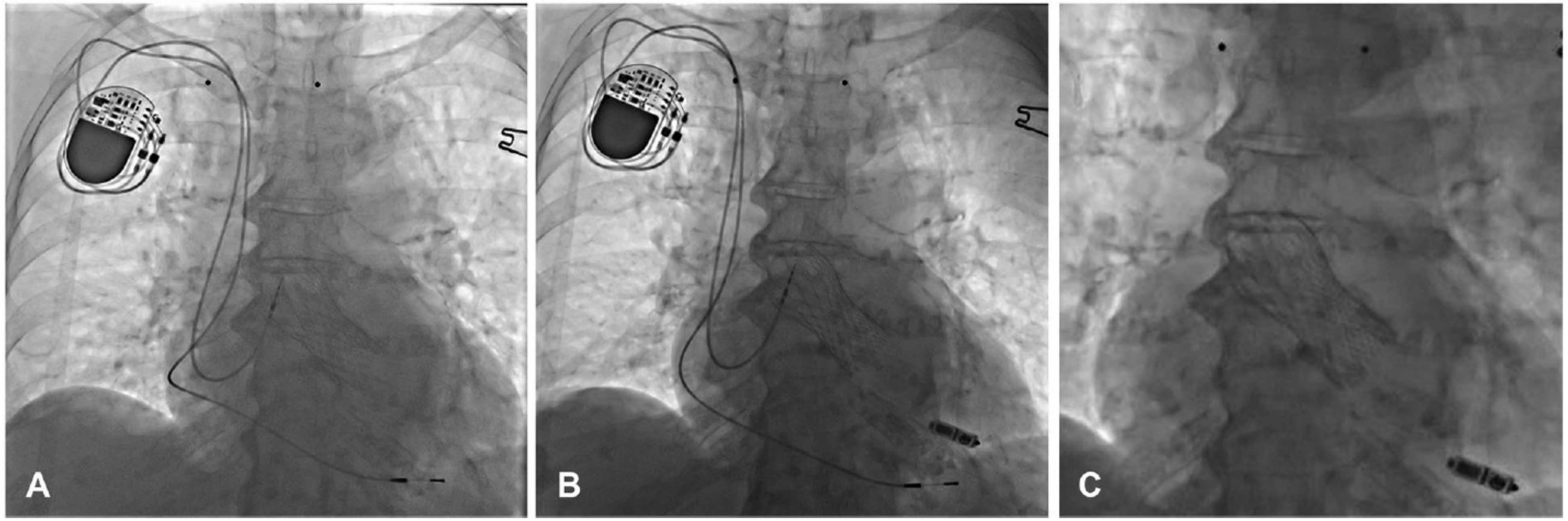
Leadless Cardiac Pacemaker Implantation After Lead Extraction in Patients With Severe Device Infection

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.*

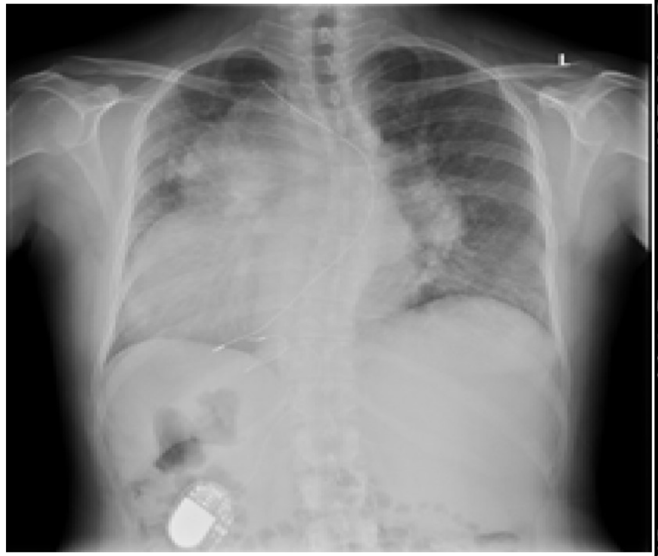
From the *Department of Cardiology, Kepler University Hospital Linz, Medical Faculty of the Johannes Kepler University Linz, Linz; †Department of Cardiology, Clinic of Internal Medicine II, Paracelsus Medical University of Salzburg, Salzburg; and ‡Institute of Nuclear Medicine and Endocrinology, Kepler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



Rescue Leadless Pacemaker Implantation in a Pacemaker-Dependent Patient with Congenital Heart Disease and no Alternative Routes for Pacing

Mohamed Sanhoury, Gaetano Fassini, Fabrizio Tundo, Massimo Moltrasio, Valentina Ribatti, Giuseppe Lumia, Flavia Nicoli, Elisabetta Mancini, Annalisa Filtz, Claudio Tondo

Cardiac Arrhythmia Research Centre, Department of Cardiovascular Sciences, University of Milan, Centro Cardiologico Monzino, IRCCS, Via Parea 4, Milan 20138, Italy.



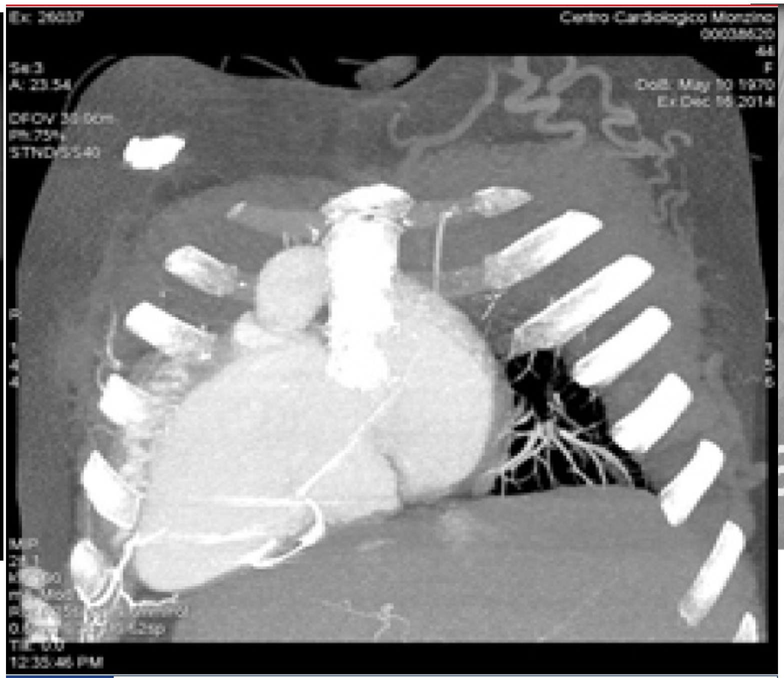
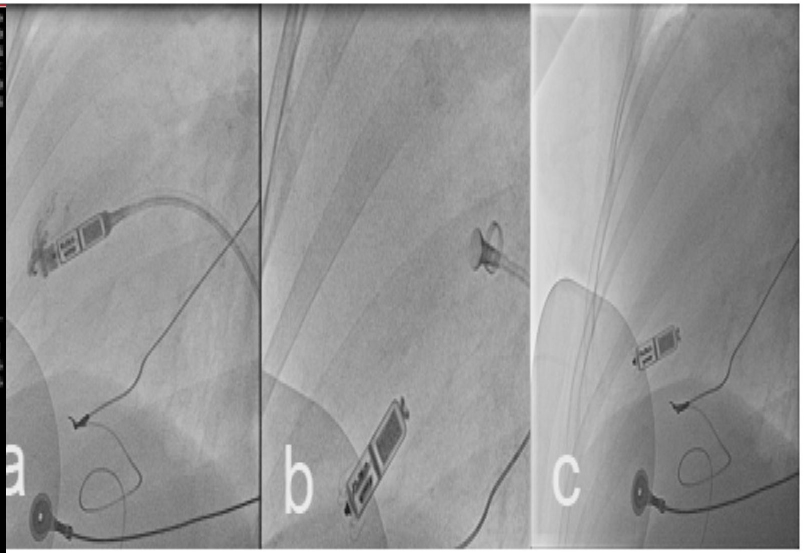


Figure 1: MDCT chest reveals extensive collateral formation (arrow) form the venous occlusion.



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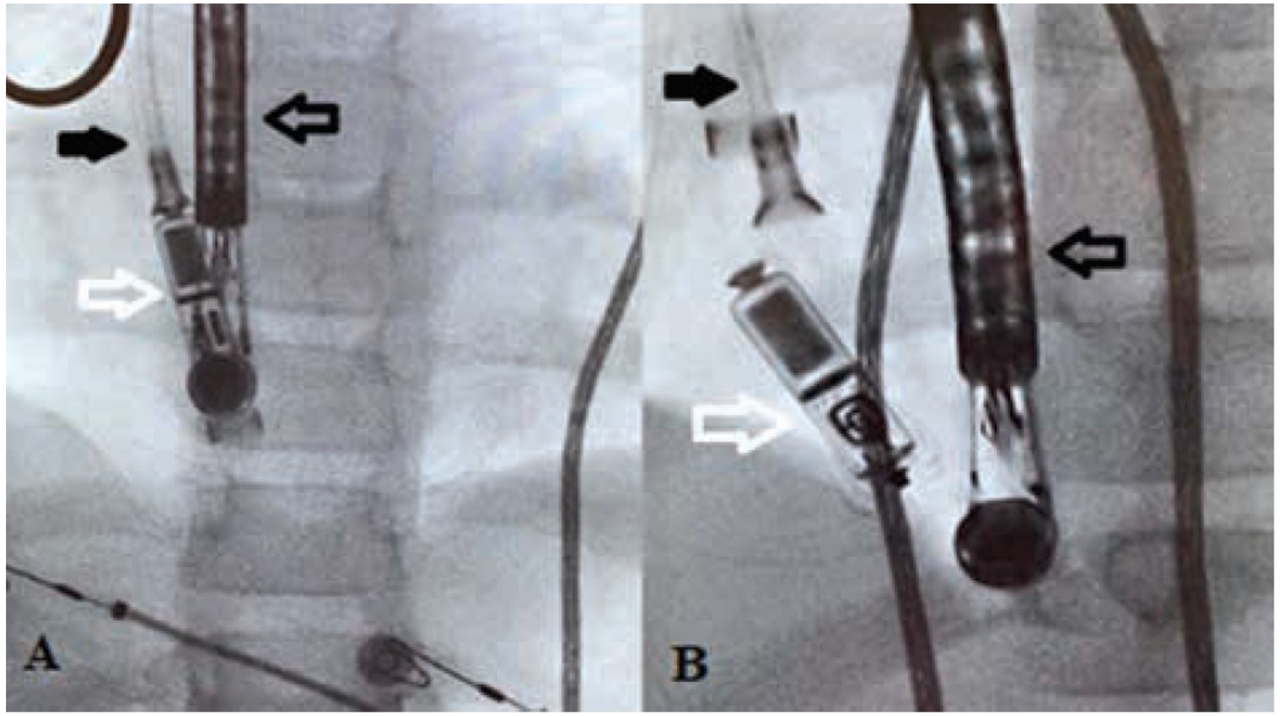
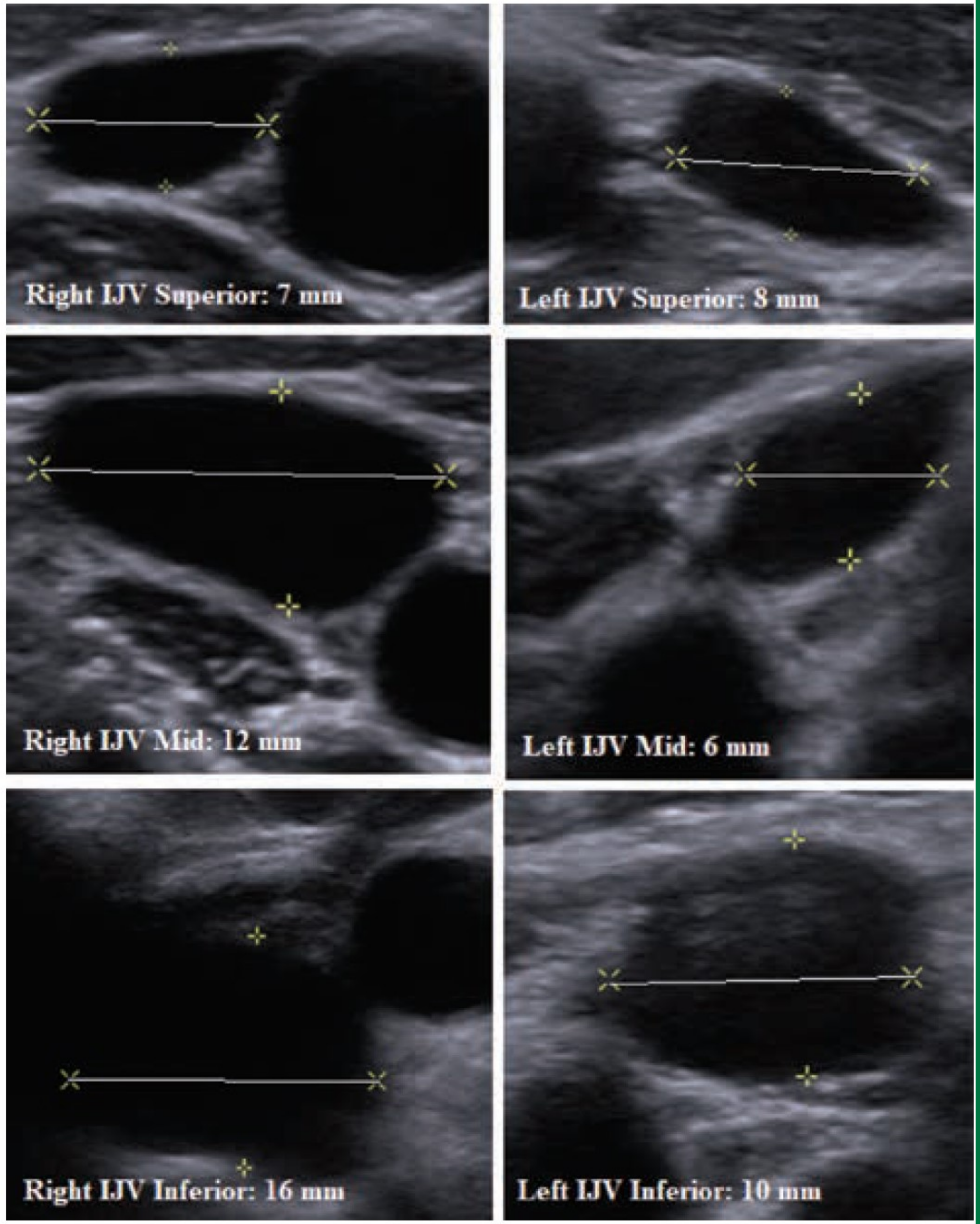
CASE UNICORNS

CASE REPORT

Delivery of a Leadless Transcatheter Pacing System as First-line Therapy in a 28-kg Pediatric Patient Through Proximal Right Internal Jugular Surgical Cutdown





Navigation to target location

DEVICE DEPLOYMENT

Minimally invasive, integrated delivery system facilitates a streamlined implant procedure.

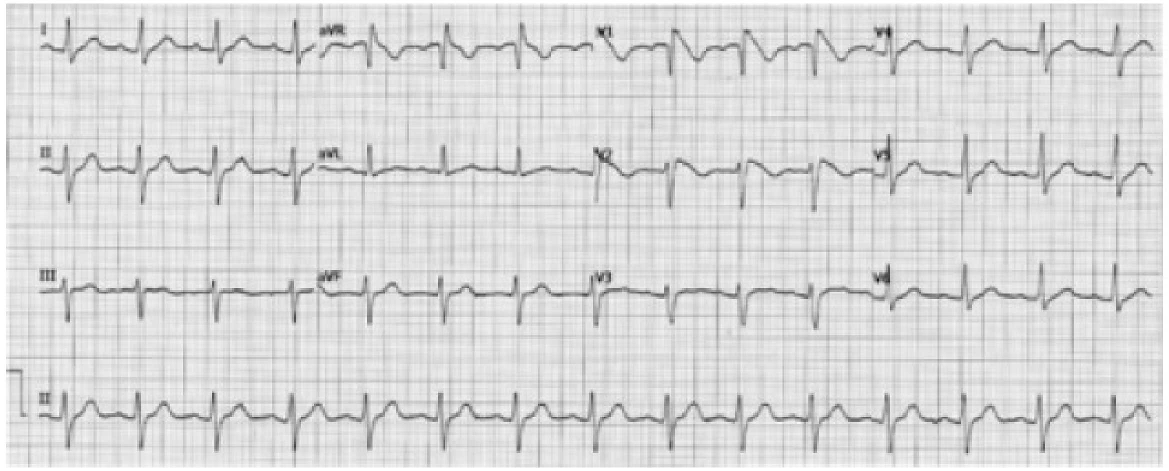
Special Considerations for Specific ICD Patient Populations

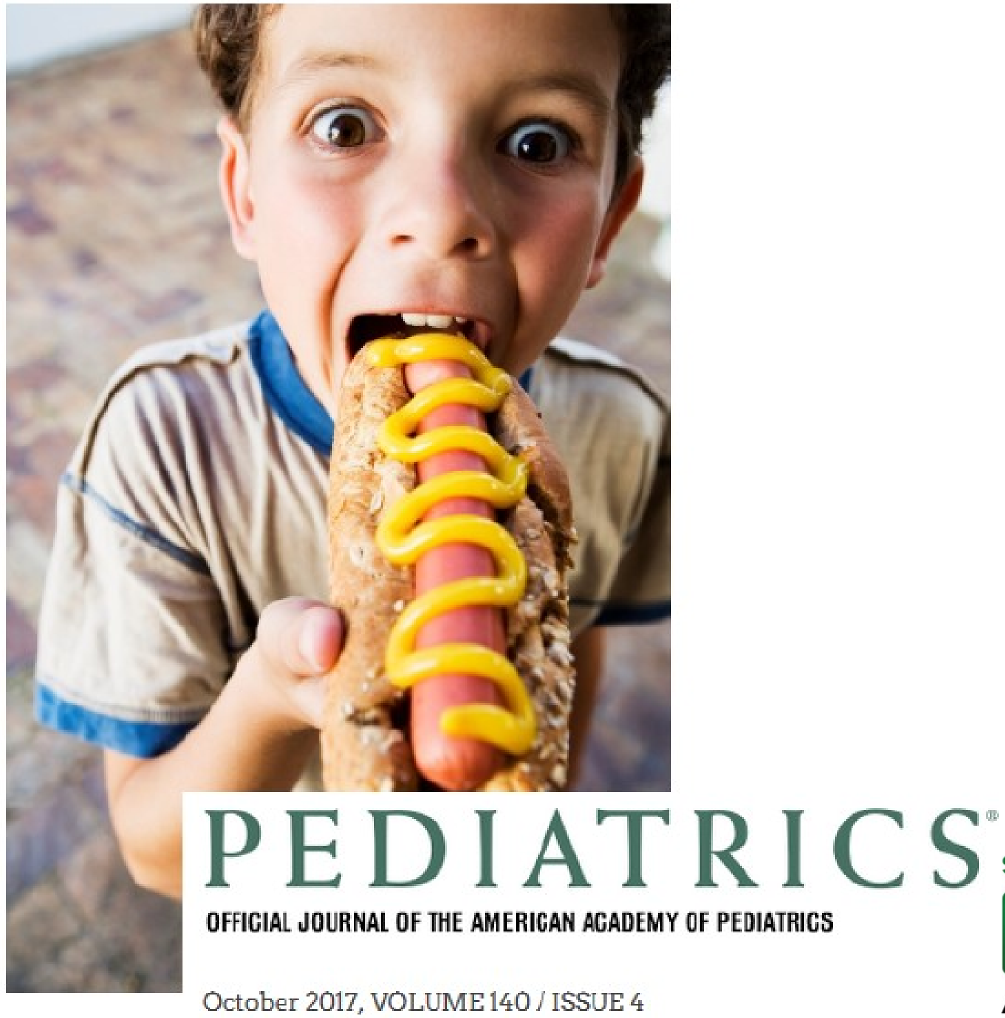
Pediatric population

Children are different

Sudden Cardiac Arrest While Eating a Hot Dog: A Rare Presentation of Brugada Syndrome in a Child

Isa Ozyilmaz, MD,[a] Bedir Akyol, MD,[b] Yakup Ergul, MD[a]





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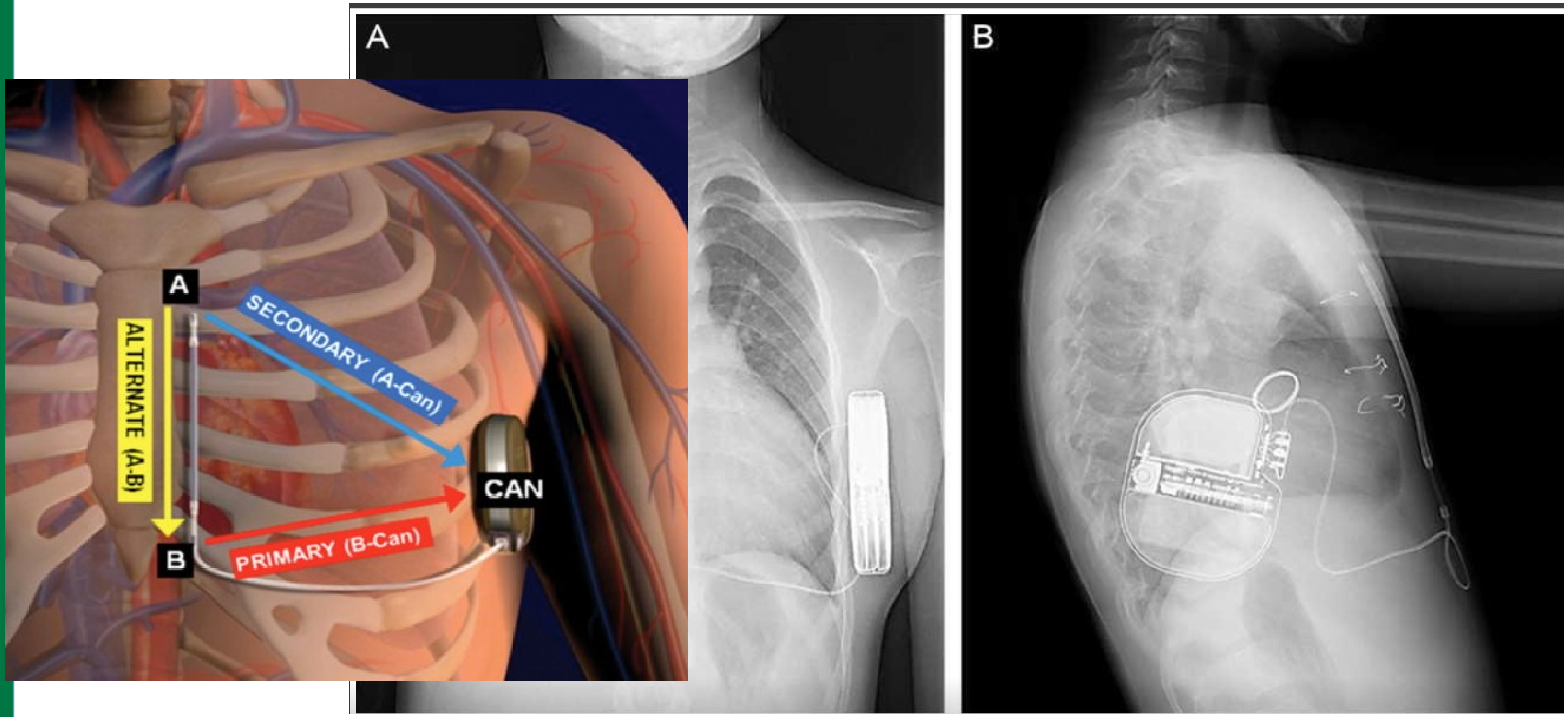
Issues to consider

- Pediatric indications
- Technical considerations
  - Transvenous system vs. epicardial system
  - Newer subcutaneous coils and arrays
  - Subcutaneous ICD systems
  - MRI Conditional devices
- Current results of pediatric ICDs
- Emotional/behavioural considerations

S-ICD : subcutaneous defibrillators Valid alternative for pediatric patients



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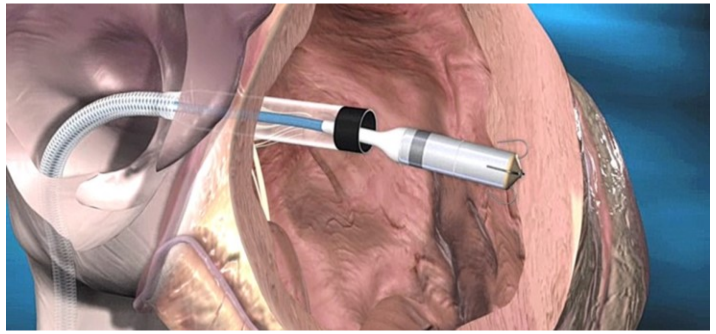
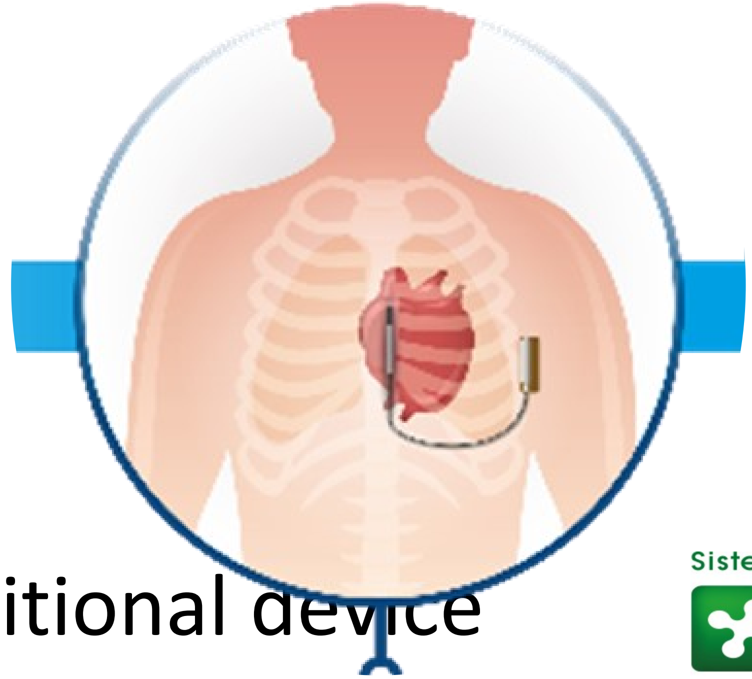
New technology
in pacing and defibrillation devices

- LEADLESS PACEMAKERS :
  - PTS VVI /VDD pacing indications (no pocket, no lead)



- SUBCUTANEOUS ICD :
  - Pts no pacing indications
  - No endovascular components
  - Similar poket infection risk of traditional device



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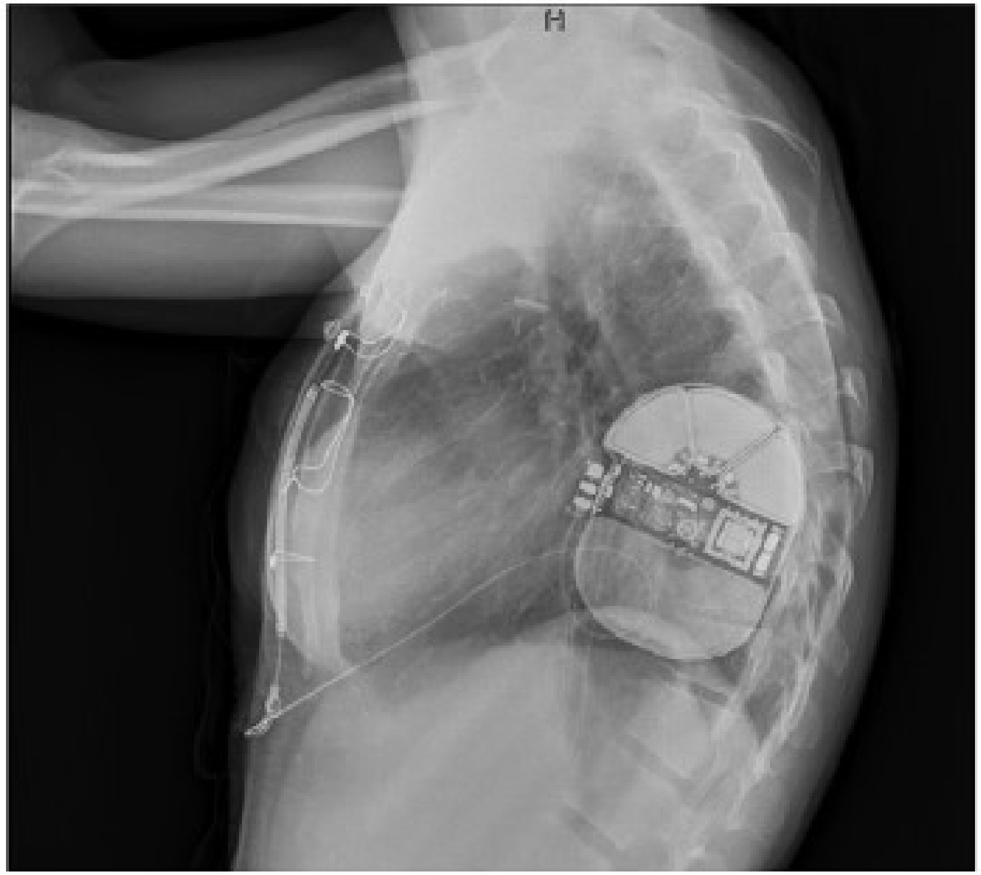

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Special Considerations for Specific ICD Patient Populations

Fig. 3. Postimplant chest x rays (AP/LL). Patient #12 (41 years old/M): Transposition of great arteries-Ventricular septal defect. Pulmonary outflow tract obstruction s/p Senning procedure. s/p VVI PMK implant.

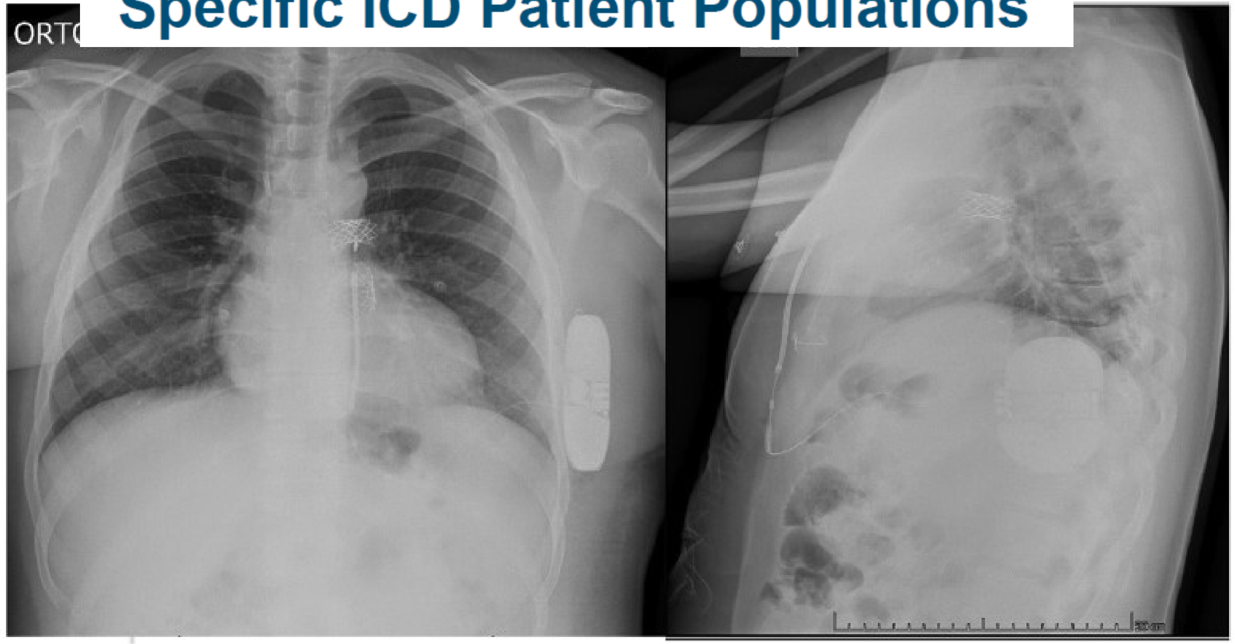
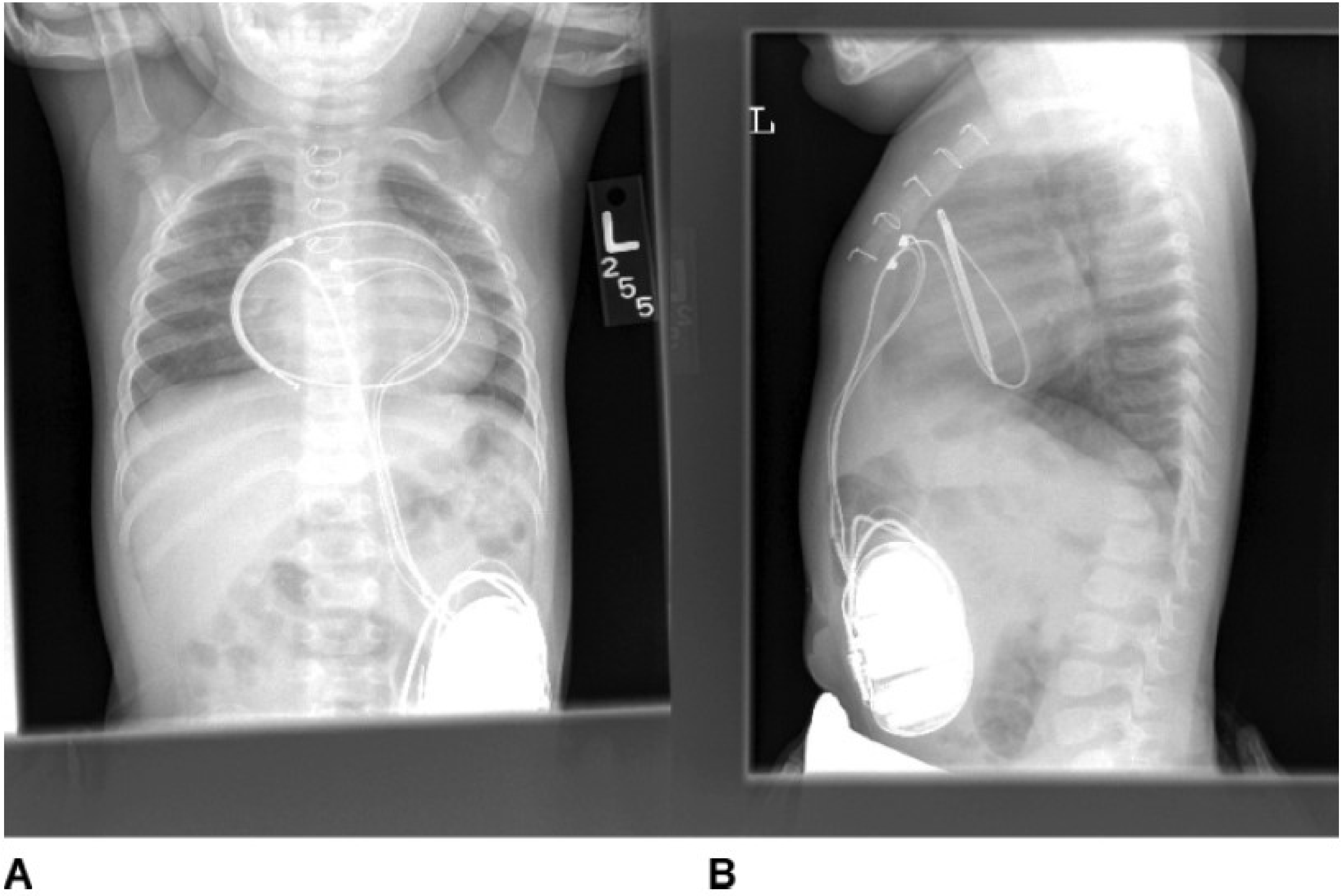


Fig. 4. Postimplant chest x rays (AP/LL). Patient #13 (37 years old/M): Tetralogy of Fallot s/p surgical correction s/p repeated pulmonary branches stenting s/p Edward Sapien pulmonary valve implant.



Direct pericardial approach: Single coil (infant)

- Cannon et al. PACE 2006

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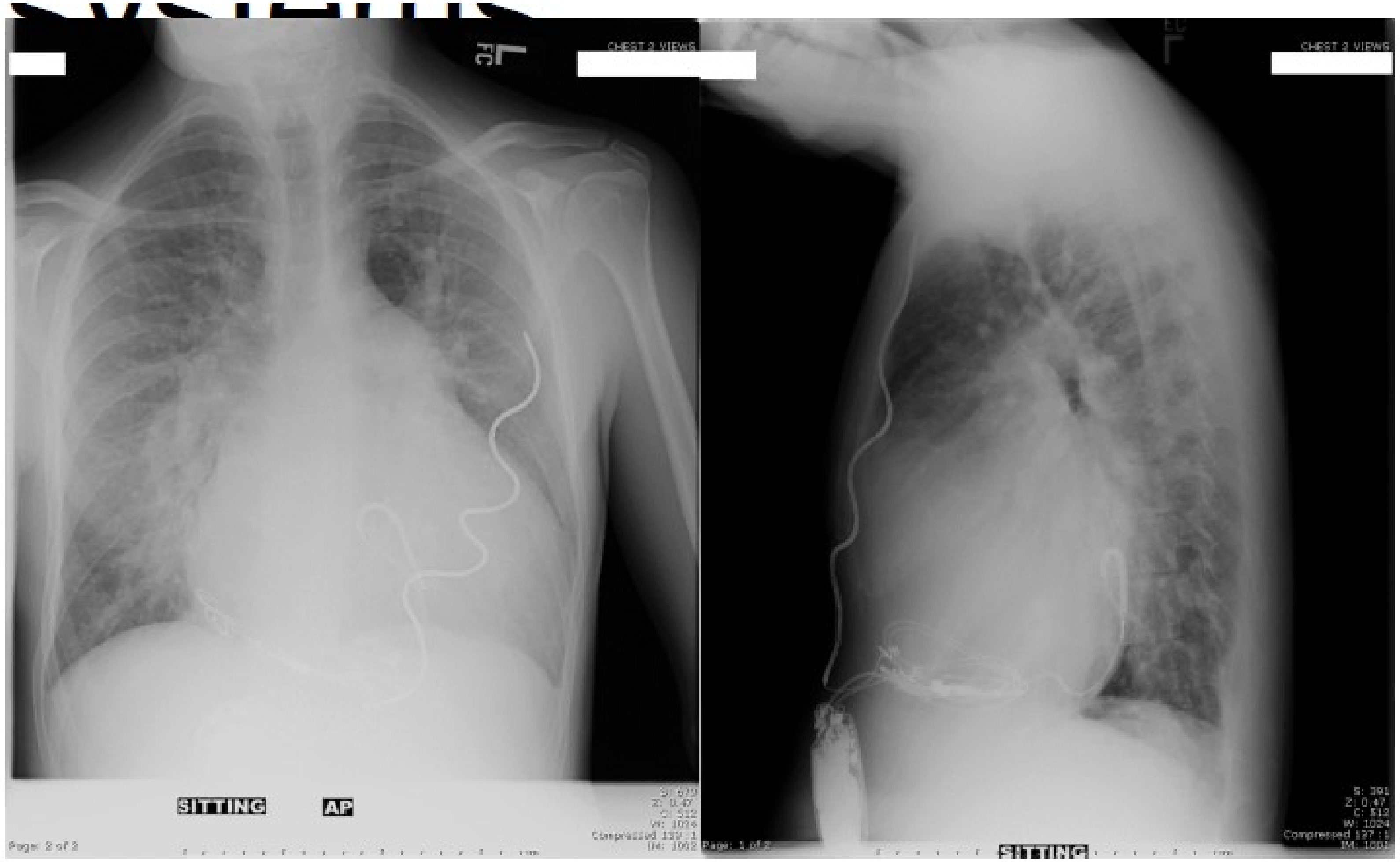
OTHER EPICARDIAL SYSTEM

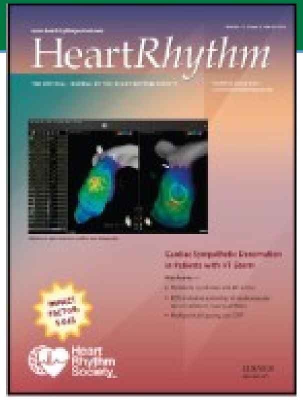
- Epicardial pace-sense lead
- Coil on epicardium posteriorly
- Subcutaneous anterior array
- Abdominal generator



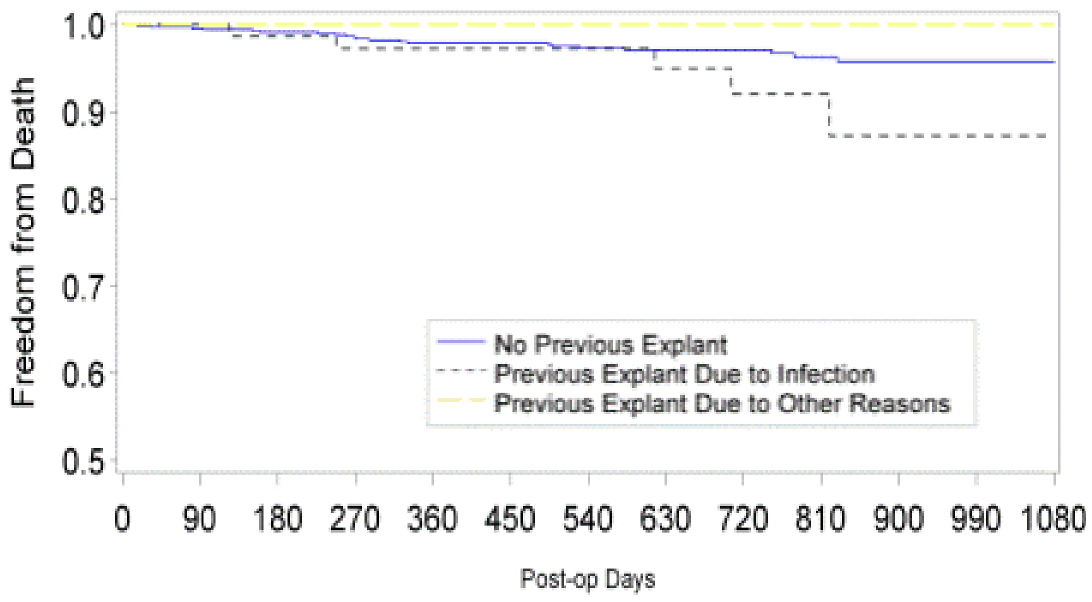
Stephenson et al JCE 2005

Infection and mortality after implantation of a subcutaneous ICD after transvenous ICD extraction

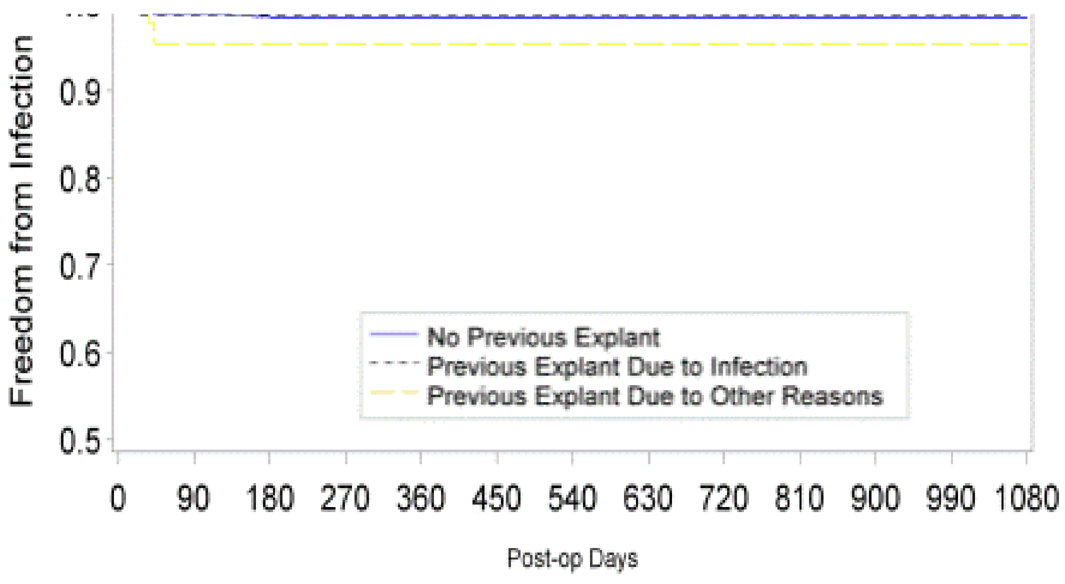
Lucas Boersma, MD, PhD,[*] Martin C. Burke, DO,[†] Petr Neuzil, MD, PhD,[‡] Pier Lambiase, MD, PhD,[§] Ted Friehling, MD,[||] Dominic A. Theuns, PhD,[¶] Fermin Garcia, MD,[#] Nathan Carter,[**] Timothy Stivland,[**] Raul Weiss, MD,[††] on behalf of the EFFORTLESS and IDE Study Investigators



Low mortality rates in patients re-implanted with an S-ICD following explant of a TV-ICD



S-ICD implant following TV-ICD extraction did not result in higher risk of re-infection



Re-implantation with S-ICD following explant of a TV-ICD results in low rates of major complications and mortality compared to published data for TV-devices[2], suggesting that the S-ICD is a suitable alternative for TV-ICD replacement

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1.Heart Rhythm 2016;13:157–164)

2. . Maytin M et al. Circ Arrhythm Electrophysiol. 2012; Tarakji et al; Europace, 2014;16:1490-1495

S-ICD LEAVES THE HEART UNTOUCHED

In the EFFORTLESS registry of almost

1000 PATIENTS OVER 3 YEARS,

there were:

ZerO ENDOVASCULAR INFECTIONS[1]

25

ZerO SYSTEMIC INFECTIONS[1]

25

ZerO ELECTRODE FAILURES[1]

25

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S-ICD Integration with Leadless PM

S-ICD Integration with Leadless PM

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Regione Lombardia
ASST Bergamo Est

1'st Animal&Human Experience S-ICD combined with LP

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EUROPEAN SOCIETY OF CARDIOLOGY®

BASIC SCIENCE

Combined leadless pacemaker and subcutaneous implantable defibrillator therapy: feasibility, safety, and performance

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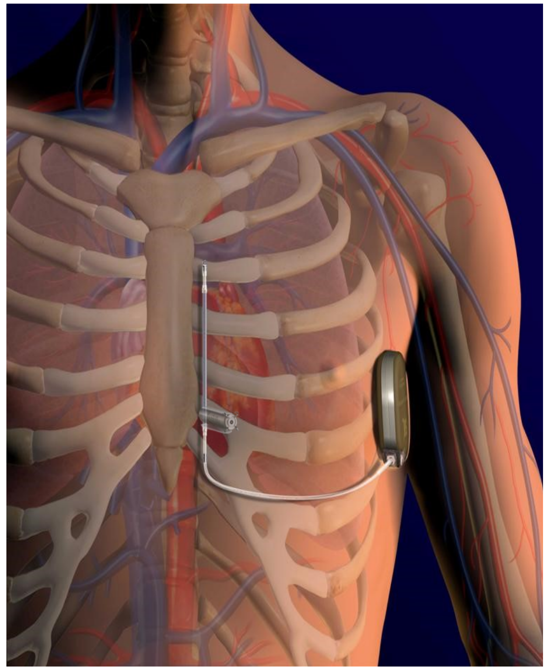

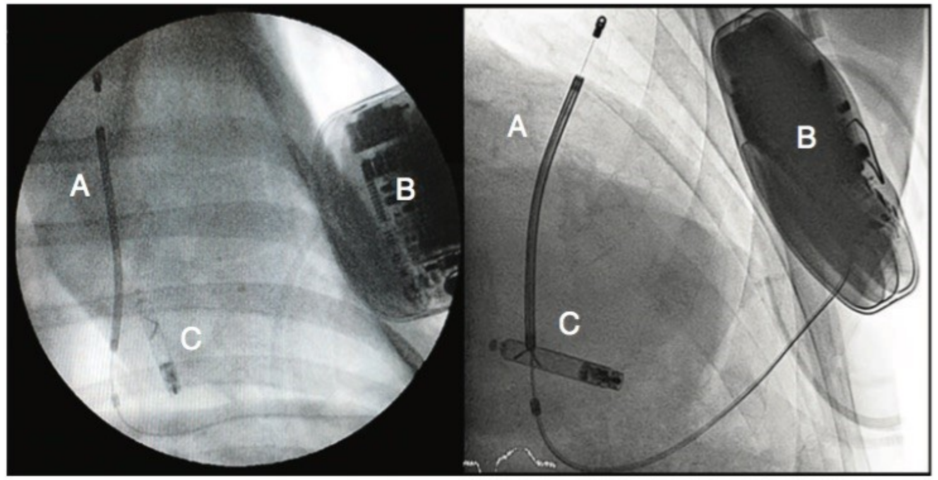

Figure 3 Fluoroscopy image of combined LP and S-ICD implant. (*Left panel*) Fluoroscopy image of combined LP and S-ICD implant in a sheep. (*Right panel*) Fluoroscopy image of combined LP and S-ICD implant in 72-year-old patient. (A) S-ICD shock lead, (B) S-ICD pulse generator, and (C) LP projected over right ventricular apex.

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CLINICAL RESEARCH

The SIDECAR project: S-IcD registry in European paediatriC and young Adult patients with congenital heaRt defects

Massimo Stefano Silvetti[1*], Luc Bruyndonckx[2,3], Alice Maltret[4,5], Roman Gebauer[6], Joanna Kwiatkowska[7], László Környei[8], Sonia Albanese[9], Cristina Raimondo[1,4], Christian Paech[6], Maciej Kempa[10], Gábor Fésüs[8], Reinoud E. Knops[2,11], Nico Andreas Blom[2,12], and Fabrizio Drago[1]

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Conclusion

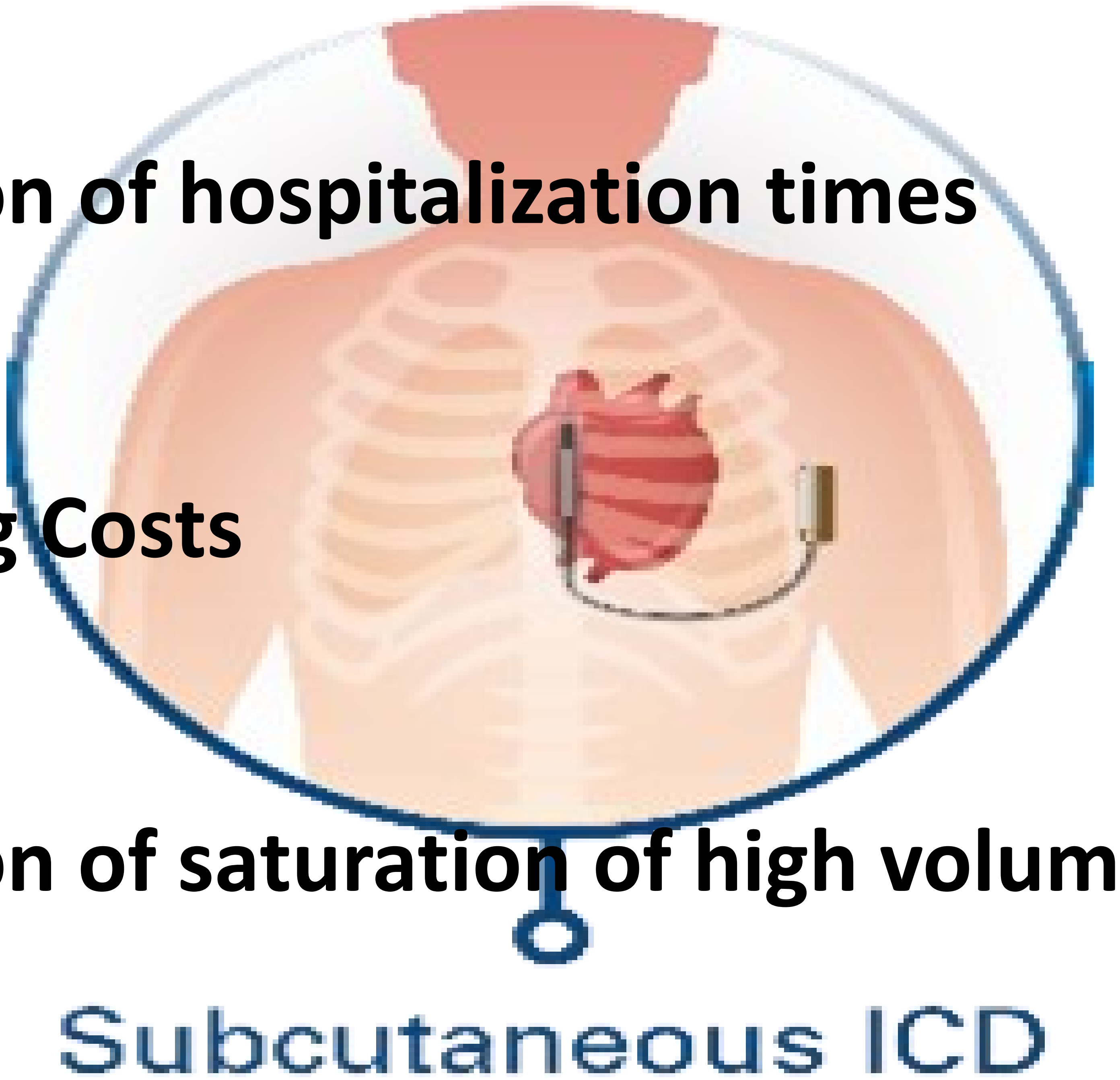
- S-ICD is recommended in AHA/ACC/HRS guidelines with a Class I and a Class IIa recommendation, and a Class IIa in ESC guidelines
- S-ICD is a suitable solution for the majority of the patients at risk for SCD any endovascular and systemic infection are reported studies
- Studies showed that implant an S-ICD after removal of an infected TV-ICD did not result in higher risk of re-infection

Conclusion

- **Reduction of hospitalization times**

- **Reducing Costs**

- **Reduction of saturation of high volume centres**



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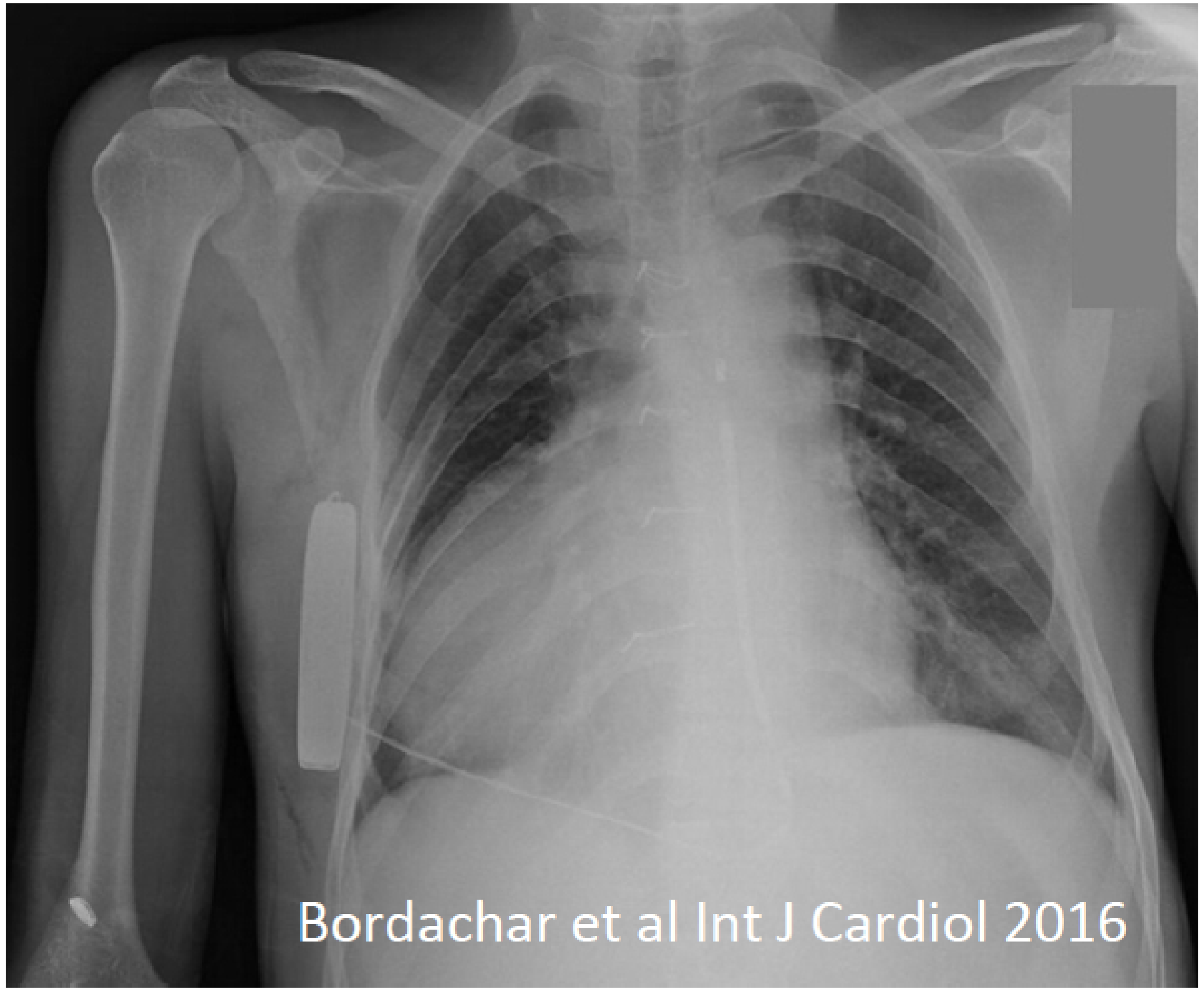
S-ICDs in children

- Generator is large
- Teenagers hate them
- 25% of pediatric patients fail ECG screening for S-ICD
  - Campbell et al. Heart Rhythm 2018
- However, avoids transvenous access



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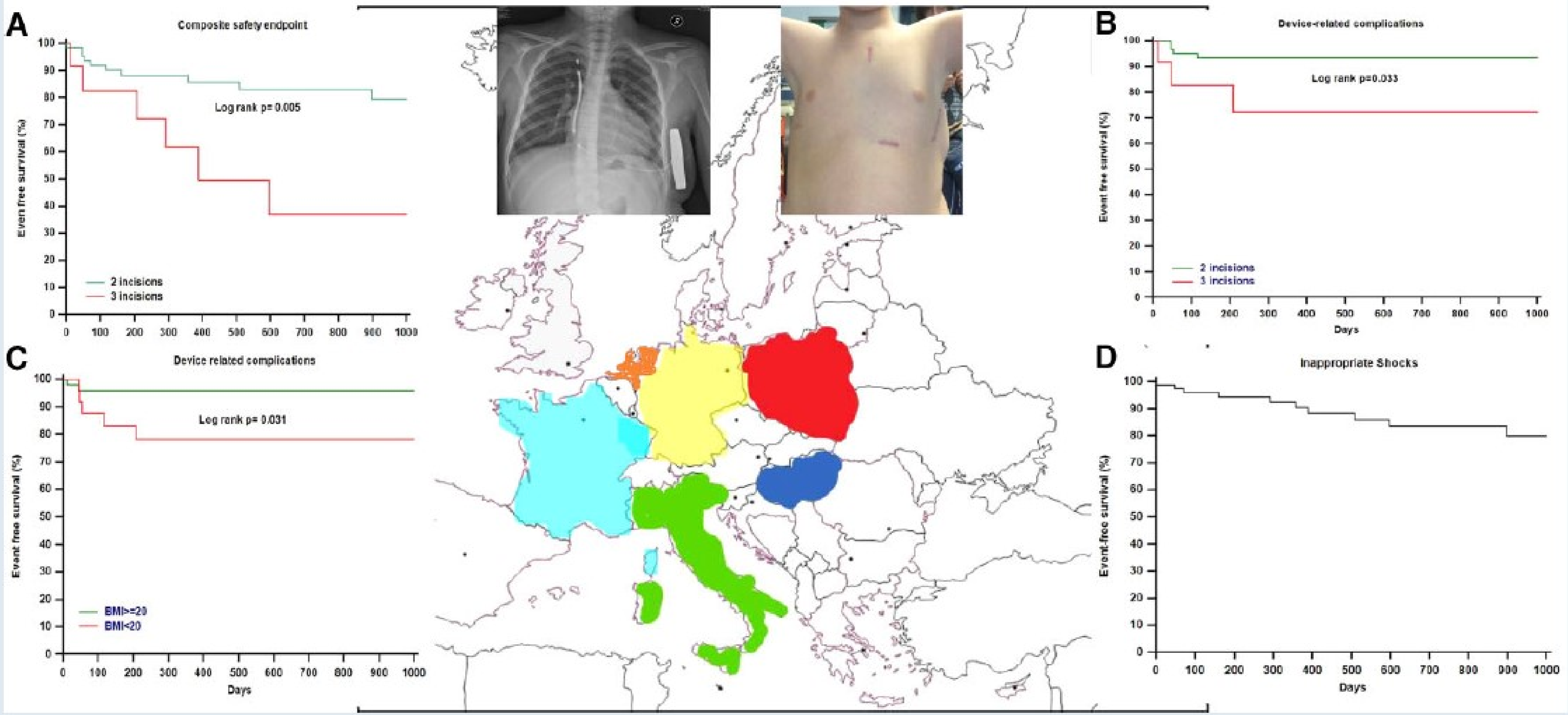
Results of the **SIDECAR** (**S-IcD** registry in **E**uropean paediatri**C** and young **A**dult patients with congenital hea**R**t defects) project.



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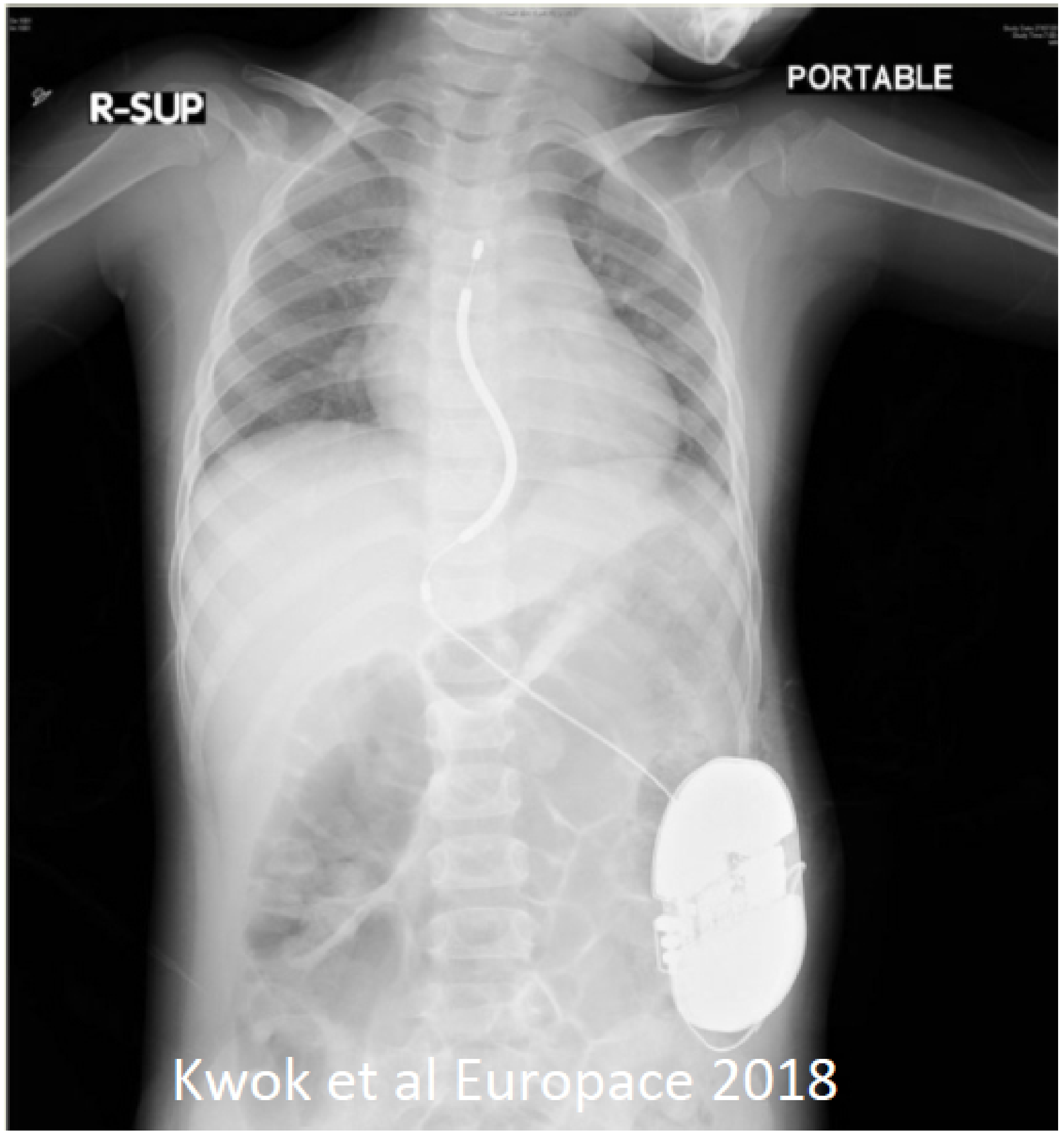

Subcutaneous ICD placed abdominally

- 4 year old, 20 kg, idiopathic VF (Hong Kong)
- No pacing indication
- Lead is parasternal w/slack
- Generator is intramuscular
- DFT successful at 65J

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Conclusions

The a novel pacing – icd system

- Minimizing the risks of infection and other complications associated with a lead and/or device pocket (pneumothorax, dislodgement, long-term infection,malfunction)
- Improving patient comfort
- Useful in PEDIATRIC patients IS STILL debate

CONCLUSIONS