TIGULLIO 2024 II Congresso Nazionale di ARITMOLOGIA

16-17 Aprile Sestri Levante (GE)

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Guido Parodi, Lavagna

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Roberto Maggi, Lavagna

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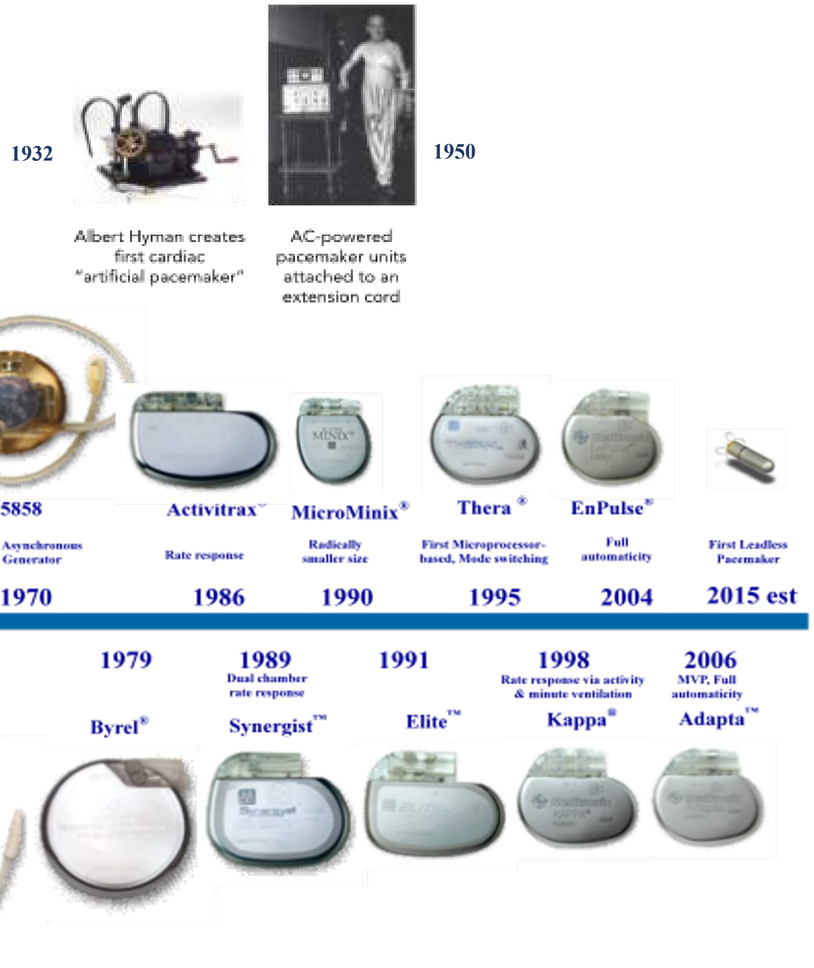
Sestri Levante

La stimolazione Leadless: dal VVI al DDD

Dr. Luca Paperini
Cardiologia 2, Azienda Ospedaliera Universitaria Pisana



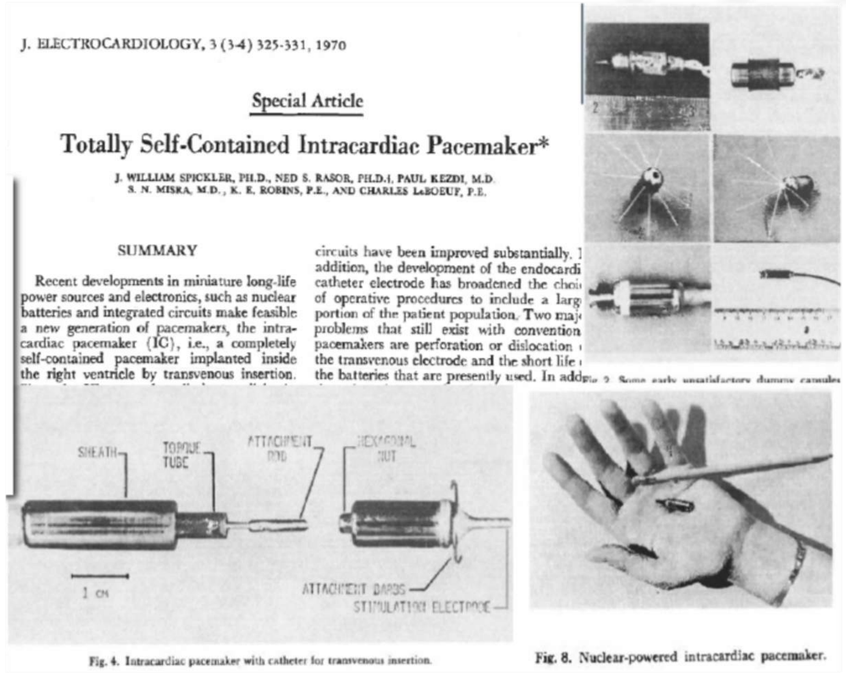
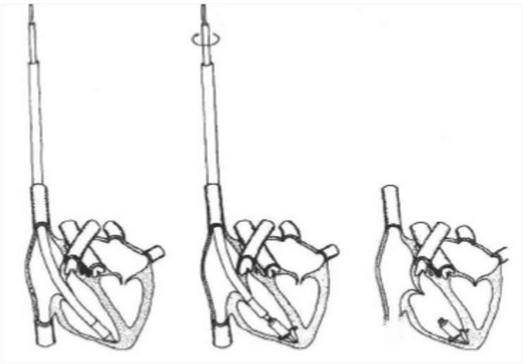


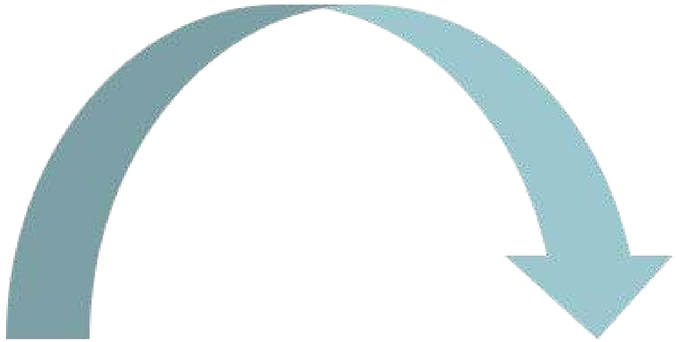
Fig. 4. Intracardiac pacemaker with catheter for transvenous insertion.

Fig. 8. Nuclear-powered intracardiac pacemaker.



QUALCHE NUMERO

- Epidemiologia



ESC European Society of Cardiology
European Heart Journal (2021) **42**, 3427–3520
doi:10.1093/eurheartj/ehab364

ESC GUIDELINES

2021 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy

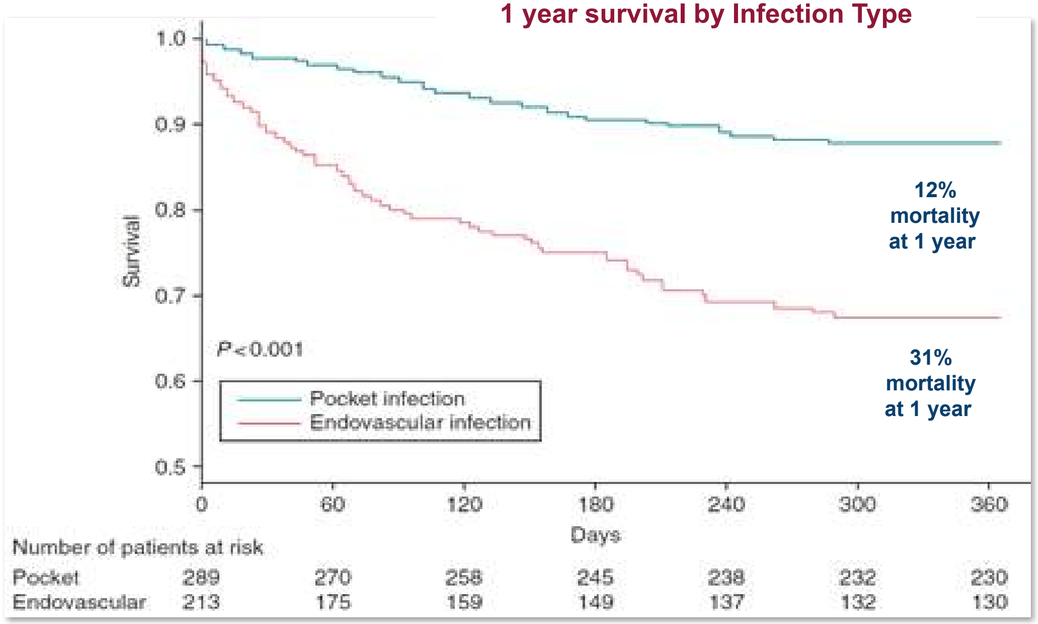
Developed by the Task Force on cardiac pacing and cardiac resynchronization therapy of the European Society of Cardiology (ESC)

With the special contribution of the European Heart Rhythm Association (EHRA)

and pathological conditions. There is a continuous growth in the use of pacemakers due to the increasing life expectancy and ageing of populations.[2–8] The estimated number of patients globally undergoing pacemaker implantation has increased steadily up to an annual implant rate of ~1 million devices.[2] Degeneration of the cardiac conduction system and changes in intercellular conduction can be manifestations of cardiac pathology or non-cardiac disease, and are most prevalent in older patients. Therefore, most bradycardias requiring cardiac pacing are observed in the elderly, with >80% of pacemakers being implanted in patients above the age of 65 years.

QUALCHE NUMERO

- le complicanze



Tarakji,et al; *Europace*, 2014;16:1490–1499

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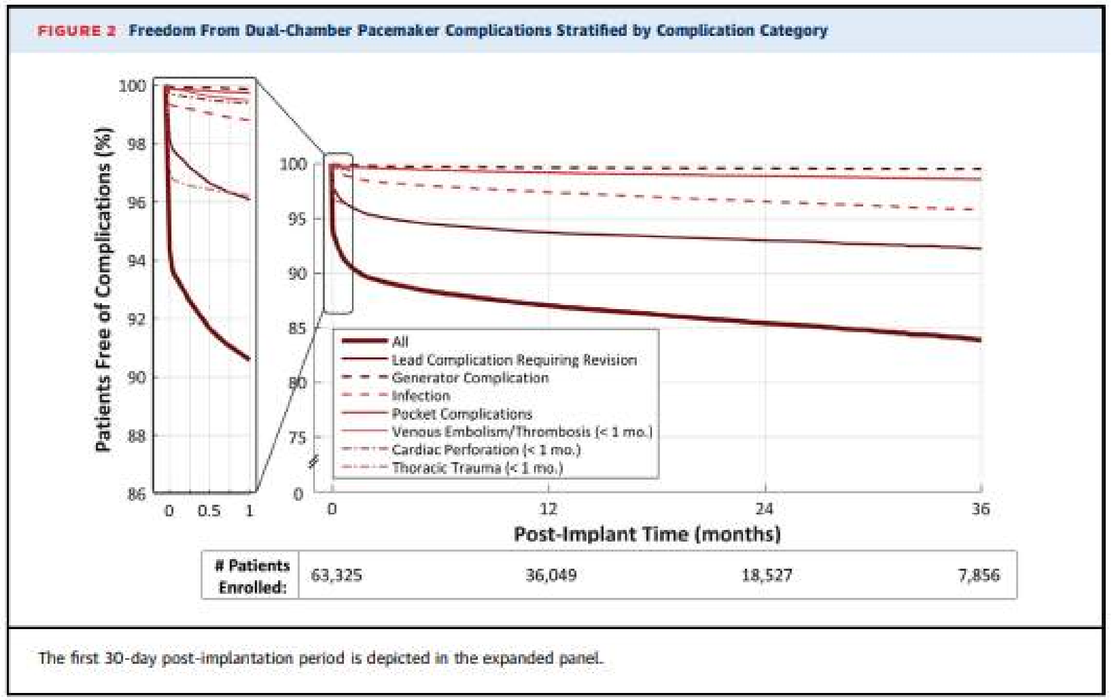
Complications and Health Care Costs Associated With Transvenous Cardiac Pacemakers in a Nationwide Assessment

Daniel J. Cantillon, MD,[a] Derek V. Exner, MD, MPH,[b] Nima Badie, PhD,[c] Kevin Davis, BS,[c] Ning Yan Gu, PhD,[c] Yelena Nabutovsky, MS,[c] Rahul Doshi, MD[d]

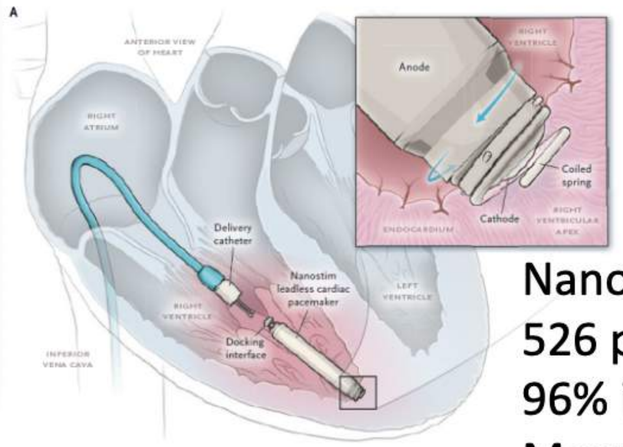


ORIGINAL ARTICLE

Percutaneous Implantation of an Entirely Intracardiac Leadless Pacemaker

Vivek Y. Reddy, M.D., Derek V. Exner, M.D., M.P.H., Daniel J. Cantillon, M.D., Rahul Doshi, M.D., T. Jared Bunch, M.D., Gery F. Tomassoni, M.D., Paul A. Friedman, M.D., N.A. Mark Estes III, M.D., John Ip, M.D., Imran Niazi, M.D., Kenneth Plunkitt, M.D., Rajesh Banker, M.D., James Porterfield, M.D., James E. Ip, M.D., and Srinivas R. Dukkipati, M.D., for the LEADLESS II Study Investigators*

August 30, 2015



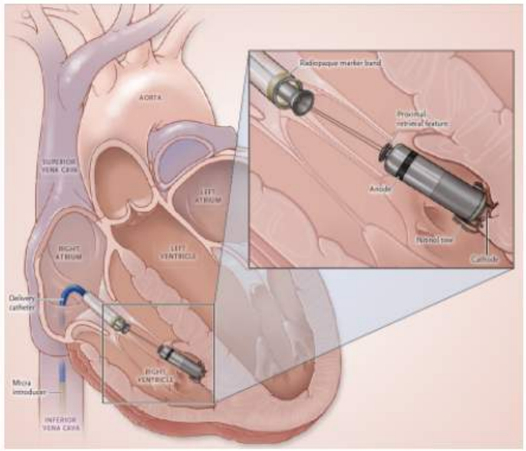
Nanostim
526 pts
96% implant success
Mean FU 6.9 months

ORIGINAL ARTICLE

A Leadless Intracardiac Transcatheter Pacing System

Dwight Reynolds, M.D., Gabor Z. Duray, M.D., Ph.D., Razali Omar, M.D., Kyoko Soejima, M.D., Petr Neuzil, M.D., Shu Zhang, M.D., Calambur Narasimhan, M.D., Clemens Steinwender, M.D., Josep Brugada, M.D., Ph.D., Michael Lloyd, M.D., Paul R. Roberts, M.D., Venkata Sagi, M.D., John Hummel, M.D., Maria Grazia Bongiorni, M.D., Reinoud E. Knops, M.D., Christopher R. Ellis, M.D., Charles C. Gornick, M.D., Matthew A. Bernabei, M.D., Verla Laager, M.A., Kurt Stromberg, M.S., Eric R. Williams, B.S., J. Harrison Hudnall, B.S., and Philippe Ritter, M.D., for the Micra Transcatheter Pacing Study Group*

November 9, 2015



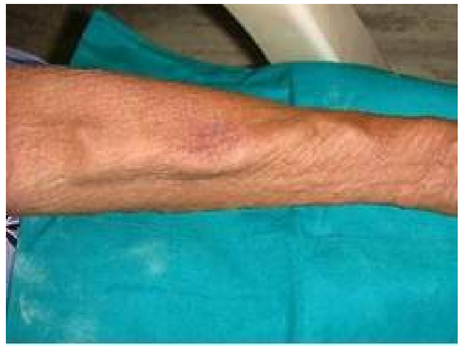
Micra
725 pts
99% implant success
Mean FU 4 months

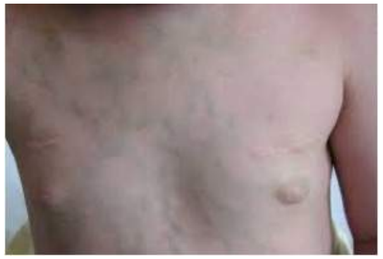
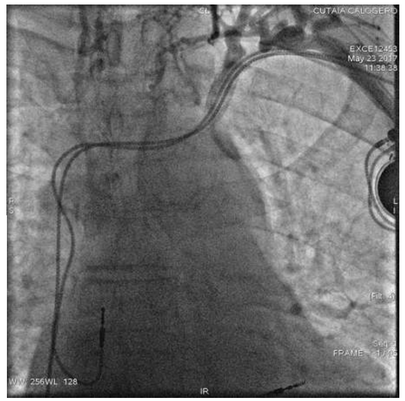
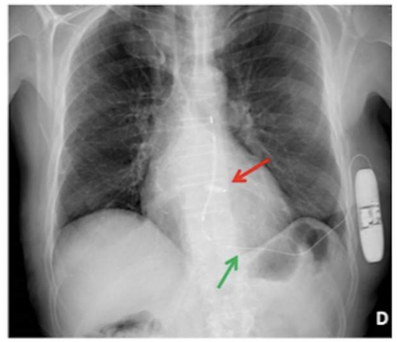
CE approval:	Nanostim	2013
	Micra	2015
	Micra VDD	2020

DATI CLINICI – real world

- **L'esperienza pisana (Maggio 2014 – Aprile 2023)**

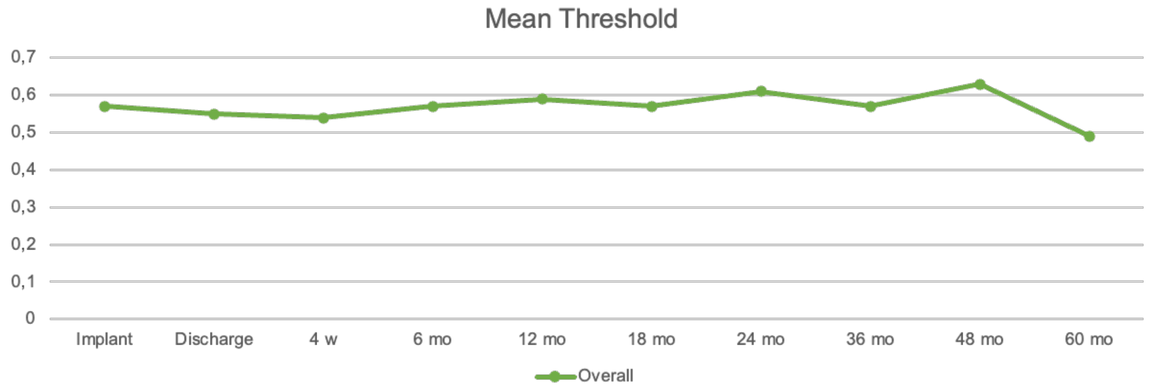
Population and characteristics	N = 203
Age, y	78 ± 9
Male, n (%)	162 (80)
Symptomatic AF with low HR and/or pauses, n (%)	111 (55)
Parox 2nd and 3rd degree AV block, n (%)	62 (30)
Parox symptomatic sinus node dysfunction, n (%)	22 (11)
Previous lead extraction, n (%)	60 (30)
Previous device infection, n (%)	35 (21)
High risk of infection, n (%)	53 (35)
Unsuitable venous anatomy, n (%)	19 (12)

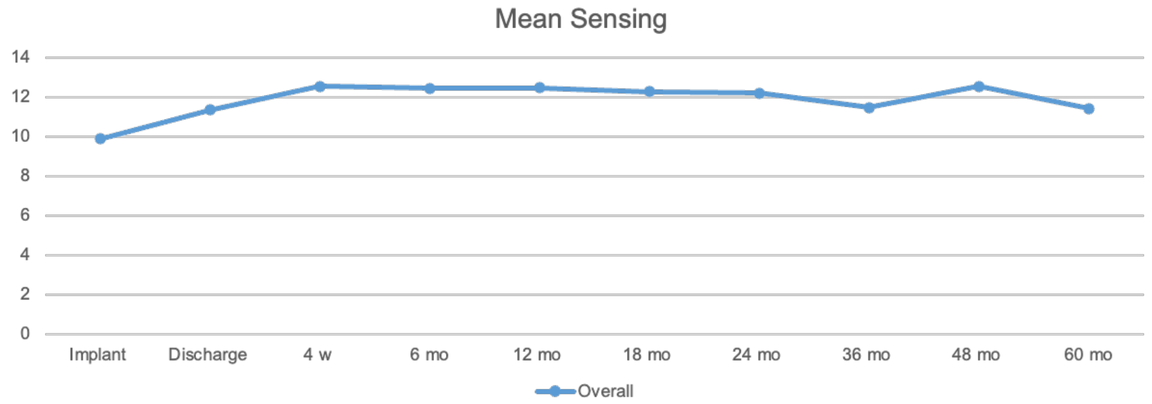


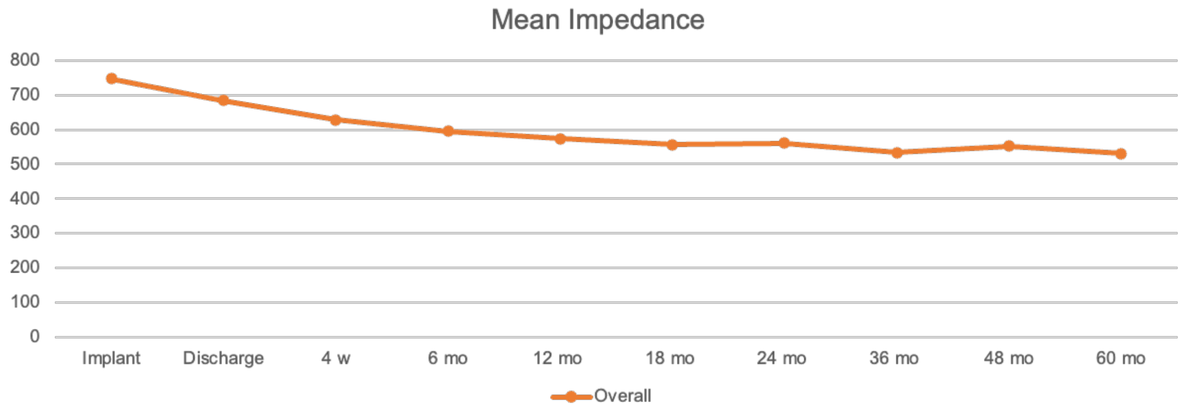




DATI CLINICI – real world

- **L'esperienza pisana (Maggio 2014 – Aprile 2023)**







DATI CLINICI – real world

- **L'esperienza pisana**

Published: 25 July 2020

Comparison between leadless and transvenous single-chamber pacemaker therapy in a referral centre for lead extraction

Giulio Zucchelli, Silvio Tolve, Valentina Barletta, Andrea Di Cori, Matteo Parollo, Raffaele De Lucia, Veronica Della Tommasina, Mario Giannotti Santoro, Stefano Viani, Tea Cellamaro, Luca Segreti, Luca Paperini, Ezio Soldati & Maria Grazia Bongiorni

Journal of Interventional Cardiac Electrophysiology **61**, 395–404 (2021) | Cite this article

100 pts vs 100 pts

FASTER PROCEDURES

0% COMPLICATIONS

matched with 100 patients undergoing TV-VVI PM implant (group 2) by age, sex, left ventricular systolic ejection fraction and previous TLE.

LOW FLUORO

7% COMPLICATIONS
6% SYSTEM REVISIONS
1% SYSTEMIC INFECTION

The implant procedure was successful in all patients.

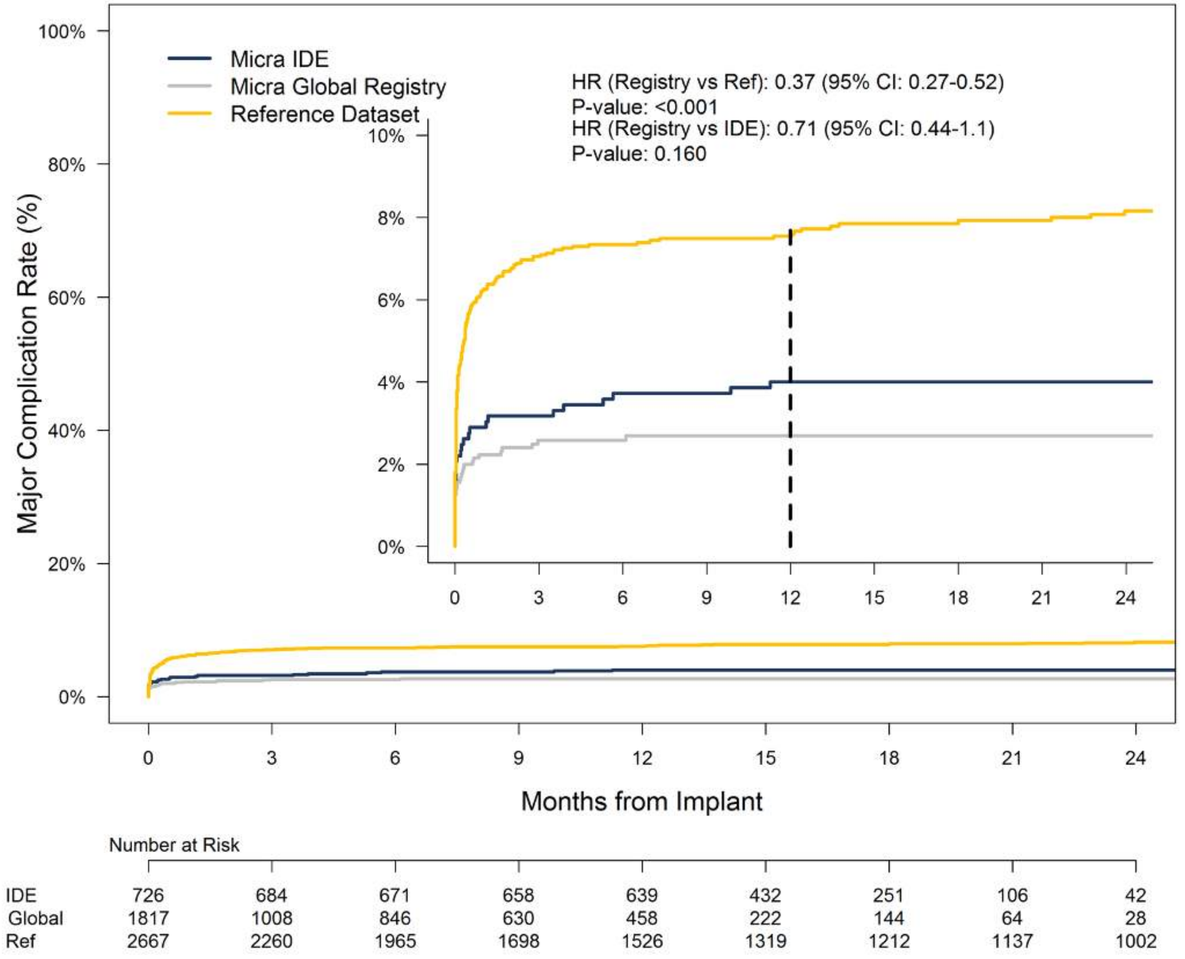
There was no difference about the rate of septal implant at the right ventricle (76% vs 86%, p = 0.10).

Electrical measurements were stable during follow-up in both groups, with a longer estimated battery life in MICRA GROUP (mean delivered energy at threshold at discharge: 0.14 ± 0.21 vs 0.26 ± 0.22 μJ, p < 0.001).

DATI CLINICI – real world

- **Confronto con PM transvenosi**

63% meno di complicanze maggiori rispetto a PM VVI tradizionali

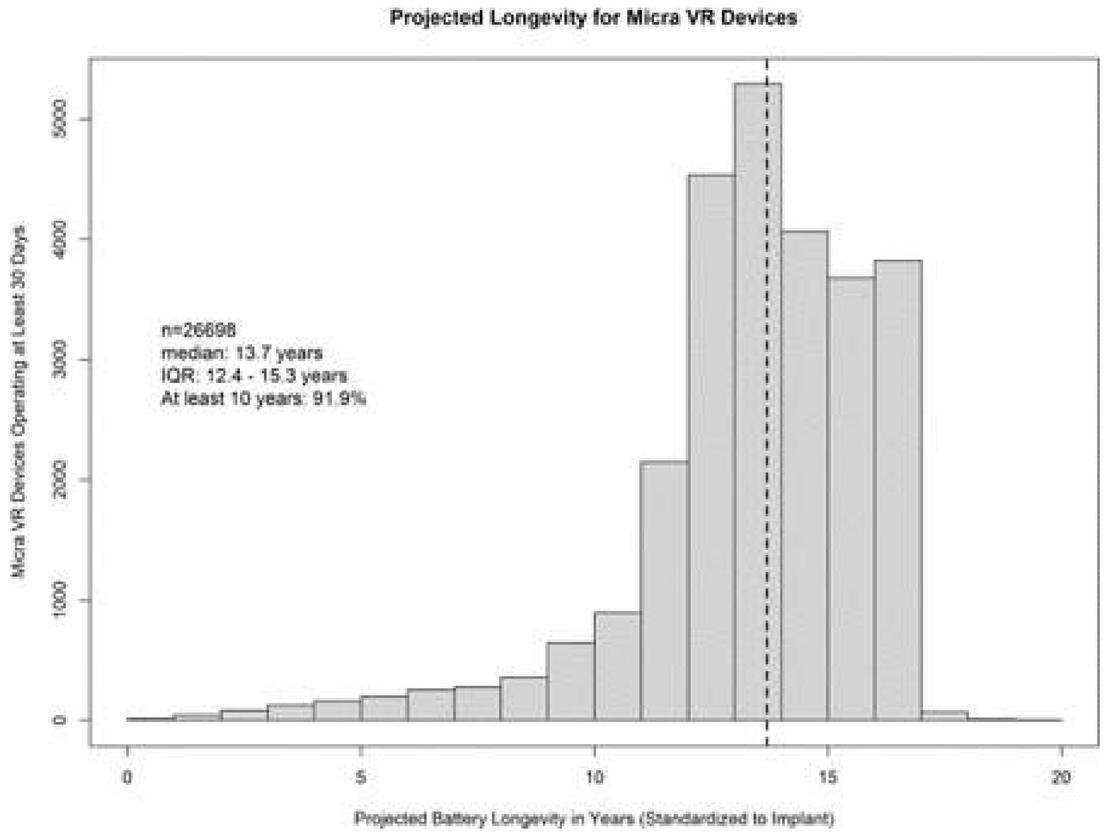


[1]El-Chami, MF, et al. Leadless Pacemaker Implant in Patients with Pre-Existing Infections: Results from the Micra Post-Approval Registry. Presented at: HRS 2018; May 10, 2018; Boston, MA.

ELECTROPHYSIOLOGY AND ARRHYTHMIAS
SESSION TITLE: AVOIDING TRANSVENOUS LEADS: LEADLESS AND SUBCUTANEOUS DEVICES

Abstract 13220:
Real-World Analysis of the Electrical Performance and Projected Longevity of Leadless Ventricular Pacemakers

Mikhael F El-Chami, Rand Ibrahim, Kurt Stromberg, Dedra H Fagan and Jonathan P Piccini



Among patients with >90% pacing burden (N=11,717), median projected battery longevity was 12.6 years (IQR: 11.6-13.4) with 87.2% of devices exceeding 10 years.

Originally published 30 Oct 2022 Circulation. 2022;146:A13220

ESC European Society of Cardiology
Europace (2022) **0**, 1–18
https://doi.org/10.1093/europace/euac066

POSITION PAPER

Practical considerations, indications, and future perspectives for leadless and extravascular cardiac implantable electronic devices: a position paper by EHRA/HRS/LAHRS/APHRS

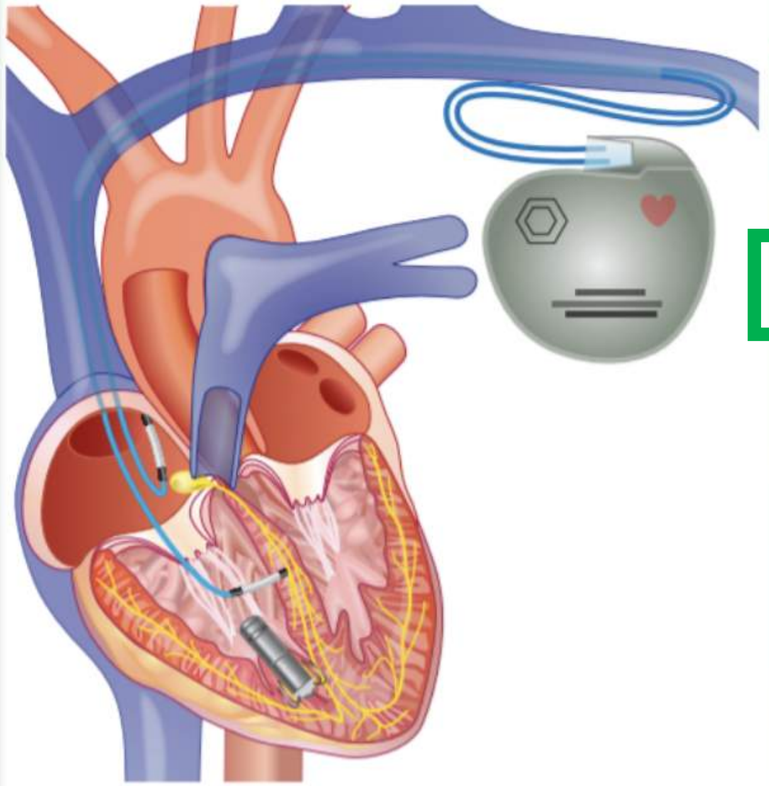
Lucas V. Boersma [1,2]*, Mikhael El-Chami[3], Clemens Steinwender[4], Pier Lambiase[5], Francis Murgatroyd[6], Theofania Mela[7], Dominic A. M. J. Theuns[8], Surinder Kaur Khelae[9], Carlos Kalil[10], Federico Zabala[11], Markus Stuehlinger[12], Radoslaw Lenarczyk[13], Nicolas Clementy[14], Kamala P. Tamirisa[15], Christopher A. Rinaldi[16], Reinoud Knops [2], Chu-Pak Lau [17], and Ian Crozier[18]

Table 8 LCPM position statements based on the underlying arrhythmia and clinical circumstances based on expert opinion

Pacing indication clinical condition	Transient SA or AVB with need of backup pacing and low anticipated ventricular pacing burden	Recurrent cardioinhibitory syncope and low anticipated ventricular pacing burden[a]	SR with complete AVB with no need for a high tracking rate	Permanent AF and AVB/slow ventricular response with increased anticipated ventricular pacing rate	SR and AVB with increased anticipated ventricular pacing burden[b]	SSS with increased anticipated ventricular pacing burden[b]
Missing or difficult superior venous access (V. subclavia, V. cava sup., congenital heart disease)	♥	♥	♥	♥	♥	♥
History or elevated risk of CIED infection (diabetes mellitus, dialysis, chronic use of corticosteroids, history of recurrent infections, and immunosuppressive therapy, frailty)	♥	♥	♥	♥	♡	♡
Tricuspid valve dysfunction risk (bio-valve replacement or repair)	♥	♥	♥	♥	♡	♡
Mechanical tricuspid valve	♥	♥	♥	♥	♥	♥
Heart failure and moderate to severe LV dysfunction (LVEF ≤35%) refusing ICD therapy	♡	♡	♥	♥	♥	♥
Age <65 years including young patients <20 years of age	♡	♡	♡	♡	♡	♡
Professional/avocational reasons	♡	♡	♡	♡	♡	♡

Pros and cons of leadless pacing compared to transvenous pacing

Pros
No generator pocket issues
No lead-related complications
Useful in case of venous access issues
Probably lower risk of device infection
Patient comfort and esthetics
Lower incidence of mid/long-term complications



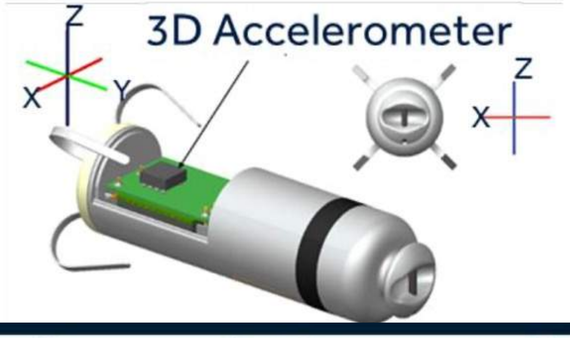
Cons
Requirement for high-resolution fluoroscopy at implantation
No atrial pacing
Imperfect AV synchrony (Micra AV)
Limited diagnostic features
No conduction system pacing
No wireless remote monitoring
Higher cost
Limited retrievability
Higher incidence of short-term complications

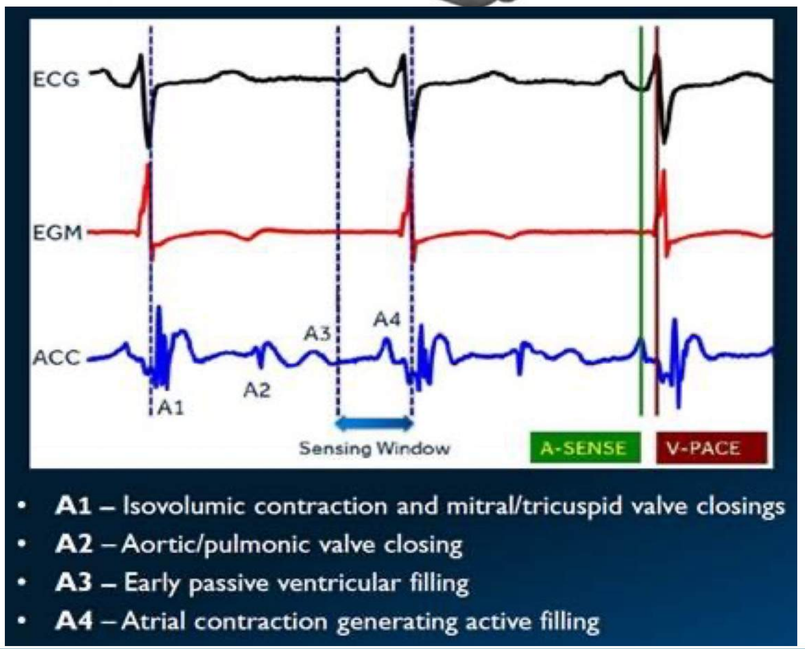
Burri, Eur Heart J, 2022 Mar 21;43(12):1216–1218

Leadless VDD: Micra AV

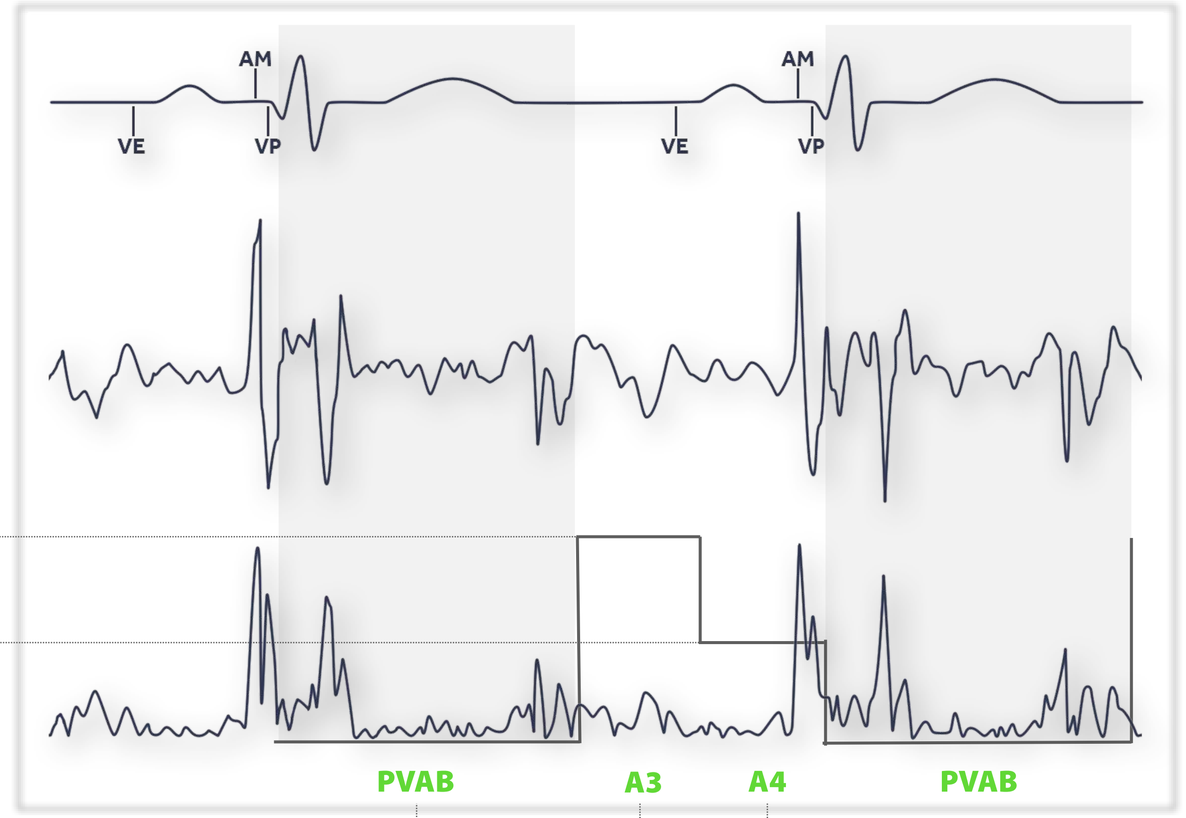
Population and characteristics	N = 203
Age, y	78 ± 9
Male, n (%)	162 (80)
Symptomatic AF with low HR and/or pauses, n (%)	111 (55)
Parox 2nd and 3rd degree AV block, n (%)	62 (30)
Parox symptomatic sinus node dysfunction, n (%)	22 (11)
Previous lead extraction, n (%)	60 (30)
Previous device infection, n (%)	35 (21)
High risk of infection, n (%)	53 (35)
Unsuitable venous anatomy, n (%)	19 (12)

AV Synchronous Pacing With a Ventricular Leadless Pacemaker:
Primary Results from the MARVEL Study





- **A1** – Isovolumic contraction and mitral/tricuspid valve closings
- **A2** – Aortic/pulmonic valve closing
- **A3** – Early passive ventricular filling
- **A4** – Atrial contraction generating active filling



A3 threshold
Needs to be set higher than the A3 signal.

A4 threshold
Needs to be set lower than the A4 signal but higher than the noise floor.

Post-ventricular atrial blanking (PVAB) period
The A1 and A2 signals are blanked. No atrial sensing occurs during PVAB.

A3 detection window
A less-sensitive setting where only large accelerometer signals will trigger a detection. It is designed to avoid detecting the A3 signal.

A4 detection window
Used to detect the A4 signal after ventricular diastole has completed.

The MARVEL study

Chinitz LA et al, Heart Rhythm 2018

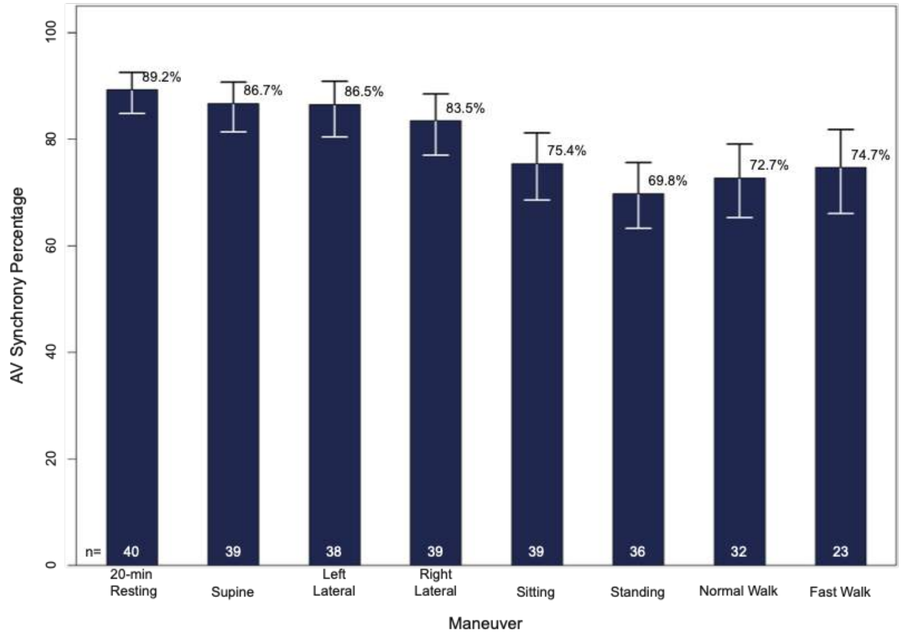
- AV synchrony during a period of rest in 64 patients was **87%**
- Sinus arrhythmia, low A4 amplitude, and PVCs contributed to lack of AV synchrony
  - no association between time of implant and AV synchrony
  - **no pauses**, no instances of PM-mediated tachycardia
  - **no adverse event** related to the device or algorithm were reported

Atrioventricular Synchronous Pacing Using a Leadless Ventricular Pacemaker

Results From the MARVEL 2 Study

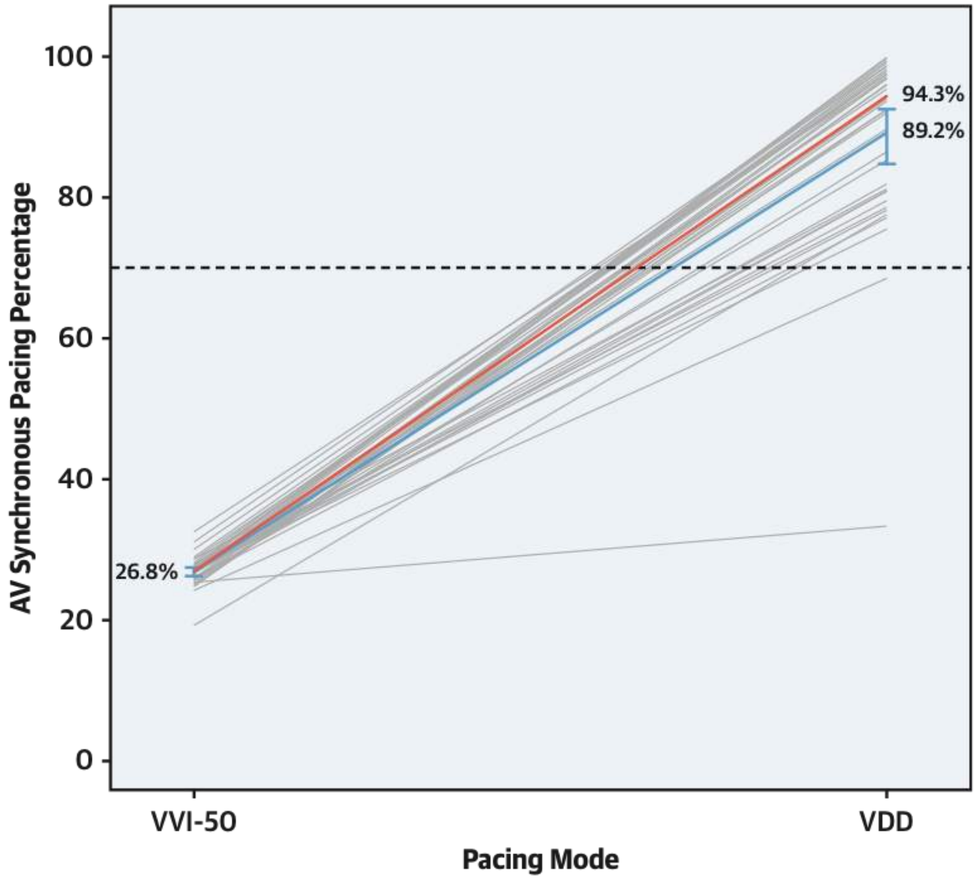
Clemens Steinwender, MD,[a,b] Surinder Kaur Khelae, MD,[c] Christophe Garweg, MD,[d] Joseph Yat Sun Chan, MD,[e] Philippe Ritter, MD,[f] Jens Brock Johansen, MD, PhD,[g] Venkata Sagi, MD,[h] Laurence M. Epstein, MD,[i] Jonathan P. Piccini, MD, MHS,[j] Mario Pascual, MD,[k] Lluis Mont, MD,[l] Todd Sheldon, MS,[m] Vincent Splett, MS,[m] Kurt Stromberg, MS,[m] Nicole Wood, BS,[m] Larry Chinitz, MD[n]

FIGURE 2 AV Synchrony Percentage by Maneuver



AV synchrony percentage by maneuver for patients with complete AV block and normal sinus function. Error bars represent 95% confidence intervals. Abbreviation as in Figure 1.

CENTRAL ILLUSTRATION AV Synchronous Pacing Percentage

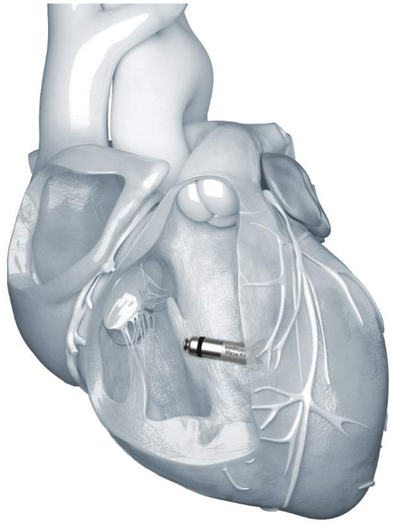


Steinwender, C. et al. J Am Coll Cardiol EP. 2020;6(1):94–106.

Atrioventricular (AV) synchronous pacing percentage during auto-setup (VVI-50 mode) and resting (VDD mode) in 40 patients with complete AV block and normal sinus rhythm. **Gray lines** indicate individual patients. **Blue line** connects average AV synchrony percentage and the **red line** connects medians. Error bars are 95% confidence intervals. **Black dashed line** is the primary objective of 70%. During VVI-50 pacing, 0% of patients had ≥70% AV synchrony, during VDD pacing 95% had ≥70% AV synchrony ($p < 0.001$).

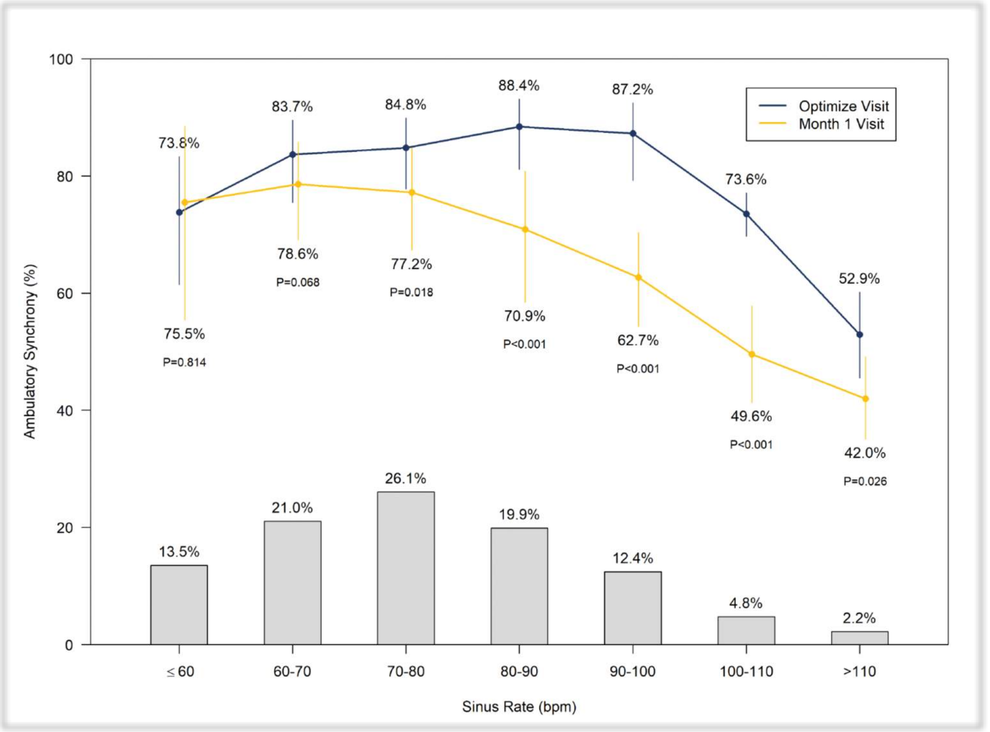
Ambulatory atrioventricular synchronous pacing over time using a leadless ventricular pacemaker: Primary results from the AccelAV study

Larry A. Chinitz, MD, FHRS,* Mikhael F. El-Chami, MD, FHRS,† Venkata Sagi, MD, FHRS,‡ Hector Garcia, MD,§ F. Kevin Hackett, MD,¶ Miguel Leal, MD, FHRS,†‖ Patrick Whalen, MD, FHRS,** Charles A. Henrikson, MD, MPH, FHRS,†† Arnold J. Greenspon, MD,‡‡ Todd Sheldon, MS,§§ Kurt Stromberg, MS,§§ Nicole Wood, BS,§§ Dedra H. Fagan, PhD,§§ Joseph Yat Sun Chan, MBBS¶¶



Improvement from optimized programming is most pronounced at elevated rates

- Micra™ AccelAV study



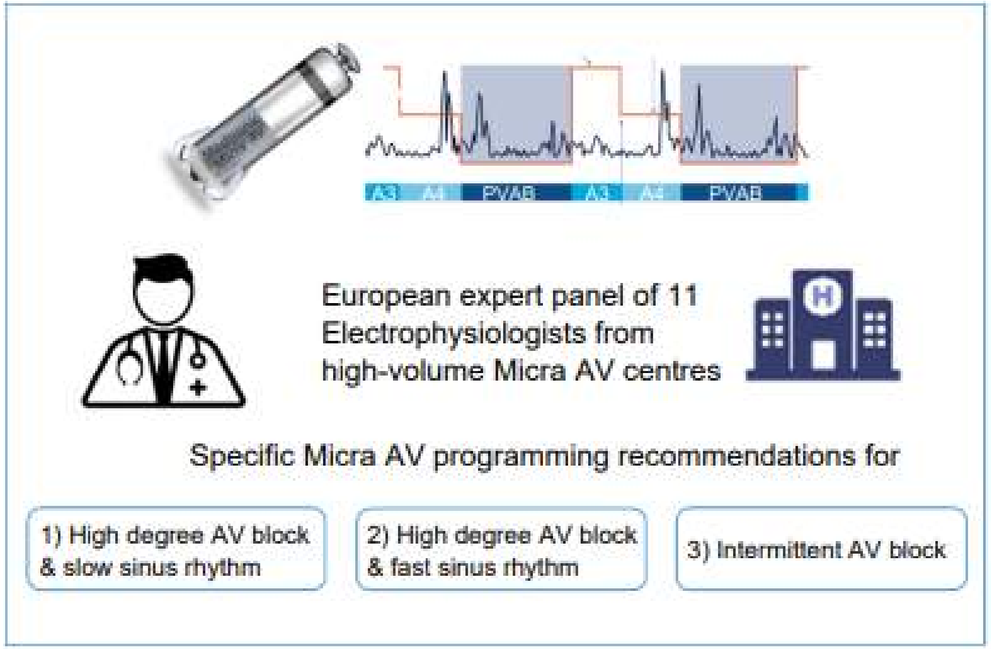
Optimized sub-study cohort: 20 subjects with complete AV block, normal sinus function, and optimized programming

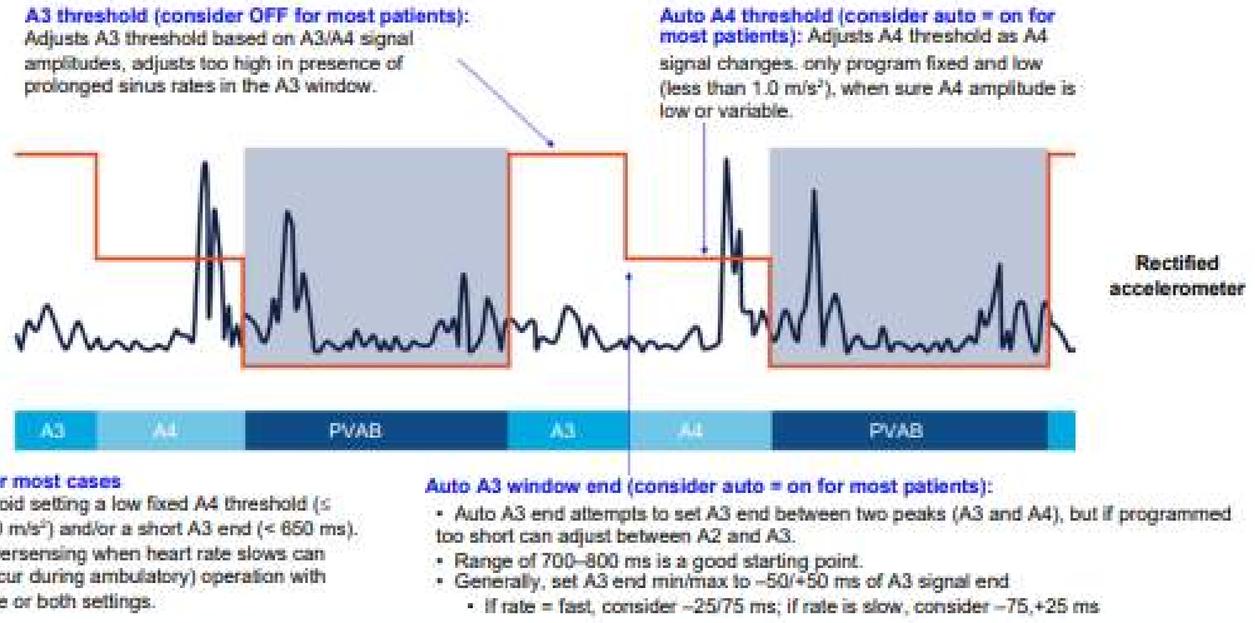
Strategies to improve atrioventricular synchrony in patients with a Micra AV leadless pacemaker

Christophe Garweg [1]*, Alexander Breitenstein [2], Nicolas Clémenty [3], Carlo De Asmundis [4], Saverio Iacopino [5], Jens Brock Johansen [6], David Sharman[7], Cathrin Theis [8], Xavier Viñolas Prat [9], Stefan Winter[10], and Tobias Reichlin [11]

Echocardiography

Strongly recommended collection of echo markers (e.g.: E/A, e'/a') to identify patients who may benefit from Micra AV implantation





Strategies to improve atrioventricular synchrony in patients with a Micra AV leadless pacemaker

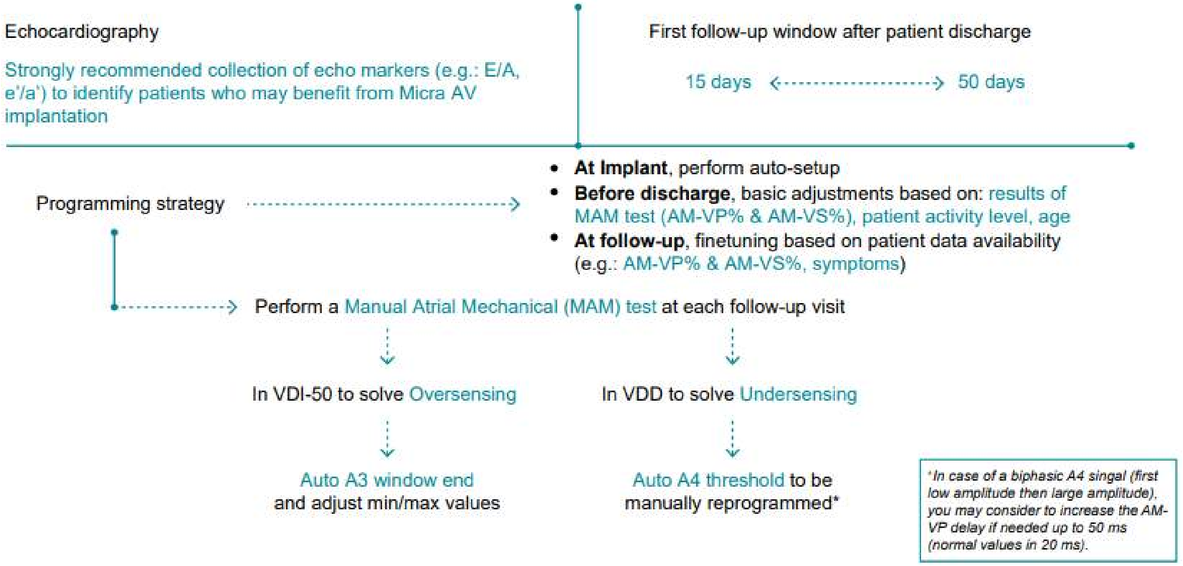


Table 1 Programming recommendations by patient profile

Programmable parameter	Patient profile: Slow sinus rhythm and high degree AV block	Fast sinus rhythm and high degree AV block	Intermittent AV block
Auto A3 Window End	ON A3 Window End range of 700–800 ms as a good starting point. Set A3 Window End Min/Max to −50/+50 ms of A3 signal end. If rate = fast, consider −25/75 ms; if rate is slow, consider −75,+25 ms.		
Auto A3 Threshold	OFF Adjusts A3 Threshold based on A3/A4 signal amplitudes, adjusts too high in presence of prolonged periods of high sinus rates in the A3 window. Program the A3 Threshold to a fixed value 1.0–1.5 m/s^2 greater than an isolated A3 signal.		
Auto A4 Threshold	ON Adjusts A4 Threshold as A4 signal changes. Only program fixed and low (<1.0 m/s^2), when sure A4 amplitude is low (<1.2 m/s^2) or variable.		
PVAB/upper tracking	The nominal of 550 ms works for most patients. A shorter value can be programmed in patients with small or early A2 signals. If 500 ms is programmed, an upper tracking rate of 115 bpm can be programmed.		
Auto PVARP	The nominal max PVARP of 600 ms works for most patients. This parameter guards against A2 oversensing if A2 signal occurs later at slow rates.		
Rate smoothing	Nominal = 100 ms It can be programmed longer if high sinus variability is observed at low rates.	Consider programming to 50 ms in patients with elevated sinus rates.	
AV conduction mode switch	Patient has AVB, no need to enable feature.		Program ON unless patient has idioventricular rhythm or 2:1 AVB with ventricular rates > 40 bpm.
Activity mode switch	ON It can provide rate support during patient activities that are not tracked by the device.		Consider programming OFF, if patient has intrinsic conduction and normal sinus function most of the time.
Tracking Check	OFF It may disrupt tracking at high sinus rates.		
Lower rate programming	50 bpm works for most patients. Measure sinus rate at rest. If sinus rate < 60 bpm, consider programming lower rate to 45 or 40 bpm.	Sinus rate > 60 and <100 bpm And if sinus rate is not anticipated to drop below 60 bpm at night, a lower rate of 60 bpm can be programmed.	If sinus rate > 60 bpm

Leadless VDD

Position statement	Symbol	Evidence
An LCPM with AV synchronous capability should be considered for all patients with sinus rhythm that may benefit from AV synchrony		EO

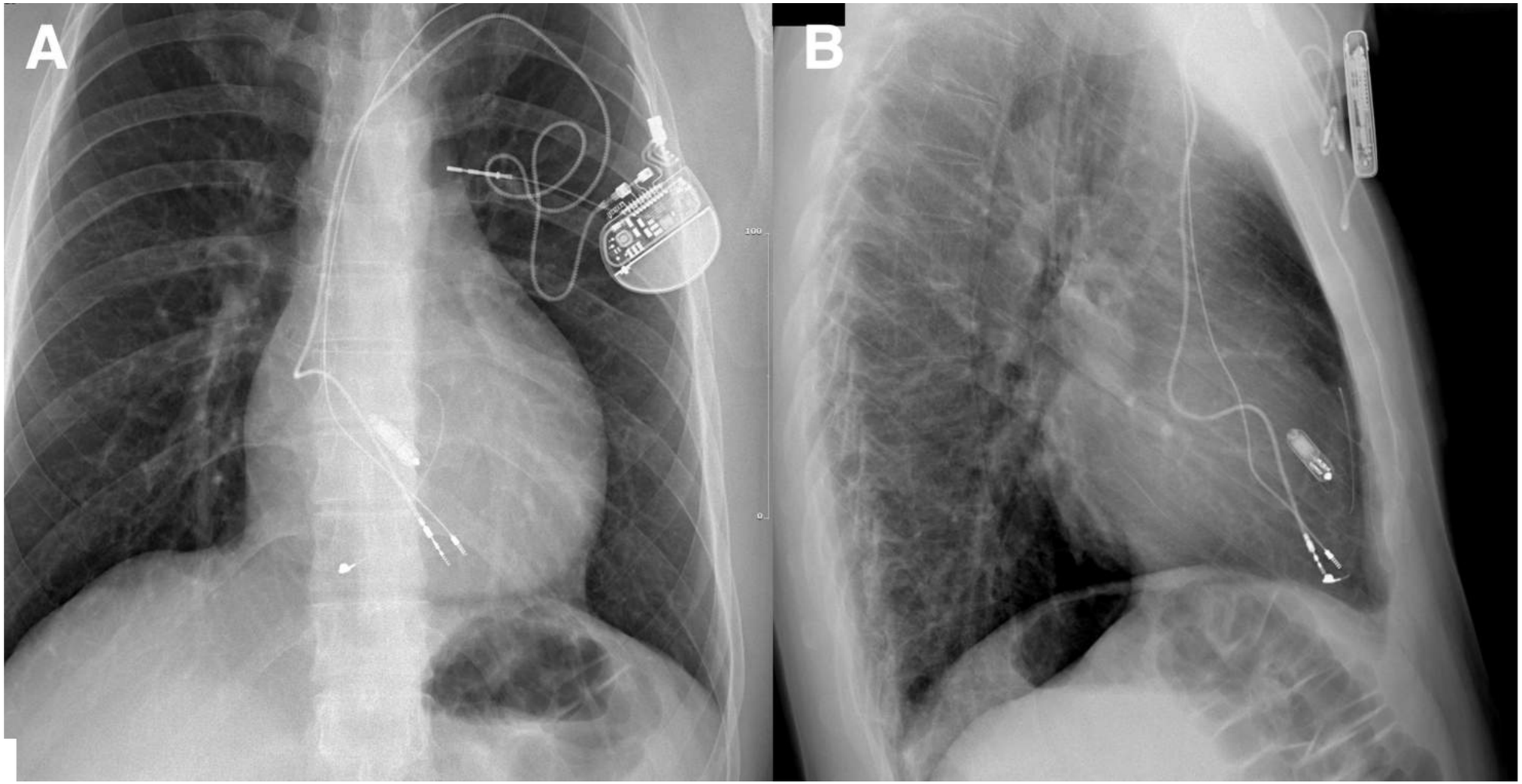
ESC European Society of Cardiology
Europace (2022) **0**, 1–18
https://doi.org/10.1093/europace/euac066

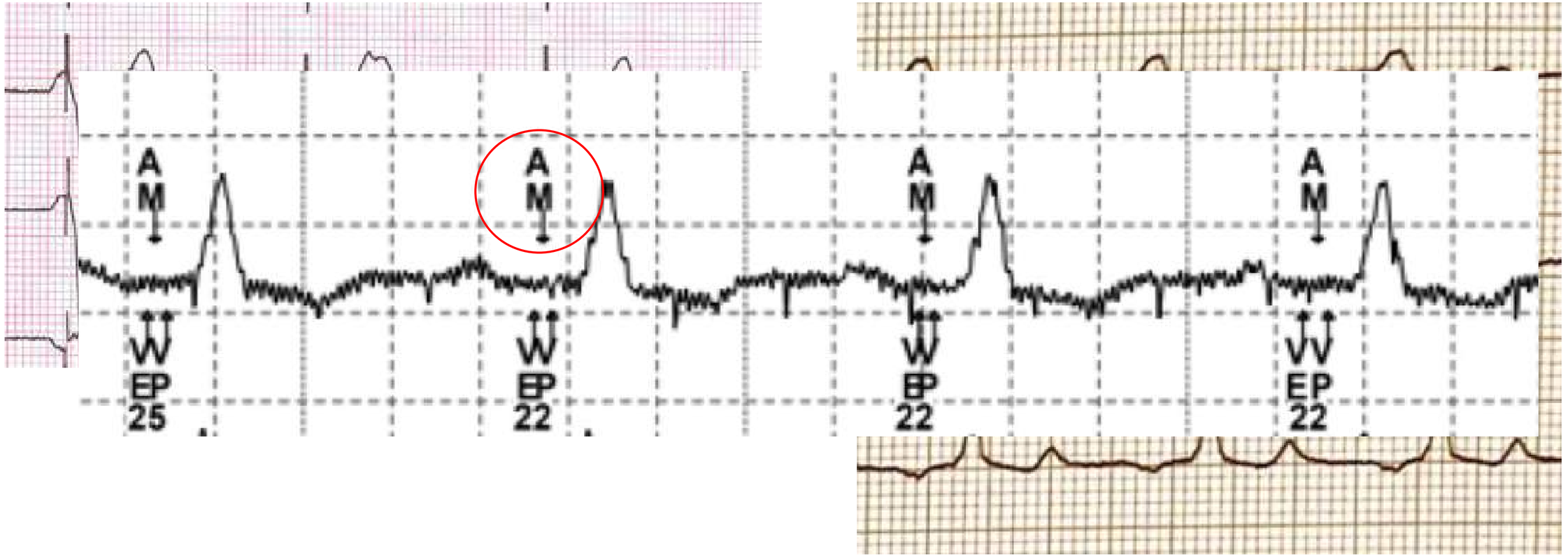
POSITION PAPER

Practical considerations, indications, and future perspectives for leadless and extravascular cardiac implantable electronic devices: a position paper by EHRA/HRS/LAHRS/APHRS

Lucas V. Boersma [1,2]*, Mikhael El-Chami[3], Clemens Steinwender[4], Pier Lambiase[5], Francis Murgatroyd[6], Theofania Mela[7], Dominic A. M. J. Theuns[8], Surinder Kaur Khelae[9], Carlos Kalil[10], Federico Zabala[11], Markus Stuehlinger[12], Radoslaw Lenarczyk[13], Nicolas Clementy[14], Kamala P. Tamirisa[15], Christopher A. Rinaldi[16], Reinoud Knops [2], Chu-Pak Lau [17], and Ian Crozier[18]

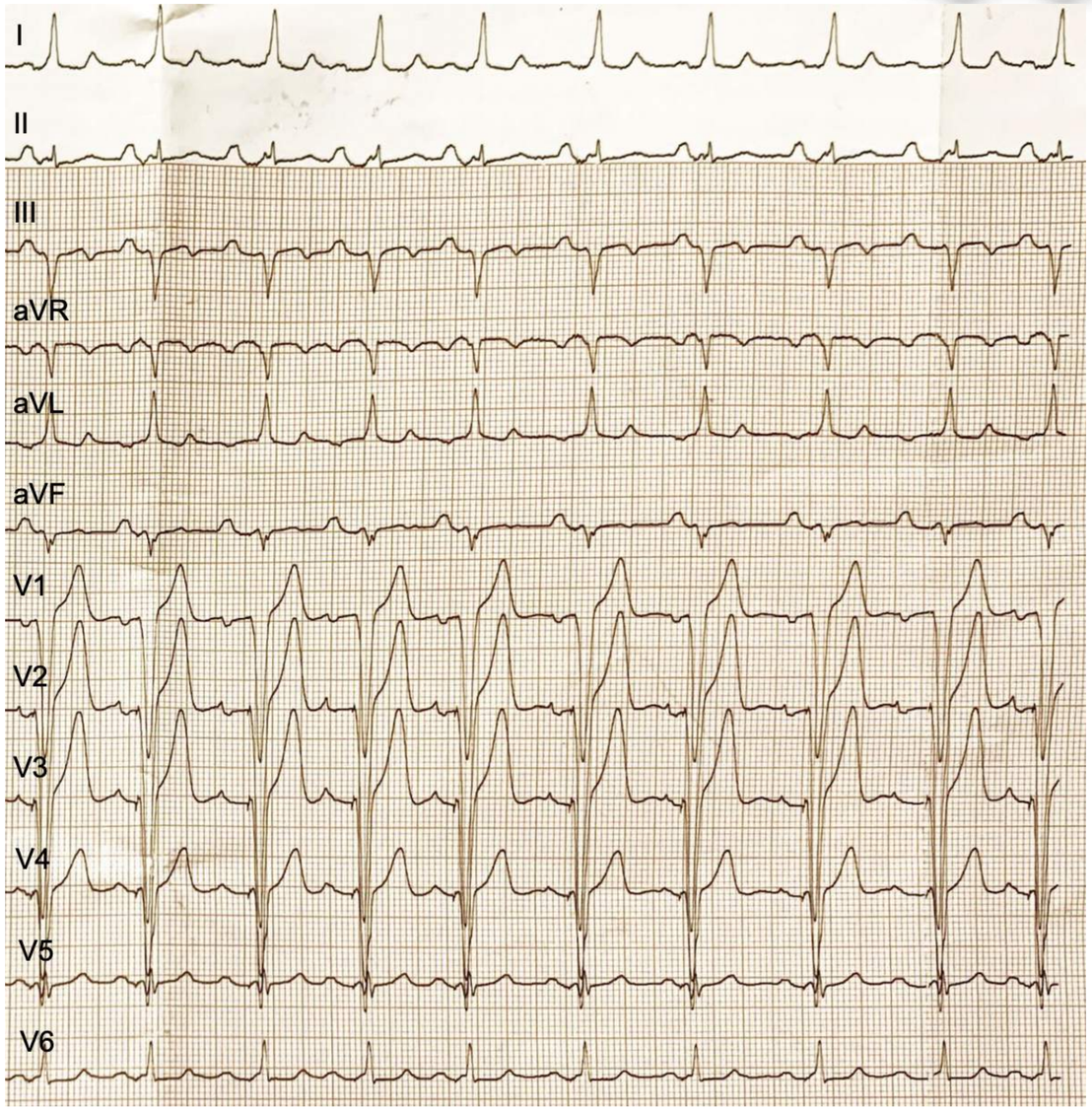
- Older patients
- Rather sedentary than sportive life-style (AV-synchrony at higher heart rates)
- Preserved LV function (no upgrade to CRT possible)
- Echo parameters (E/A ratio < 0.94)


A
B



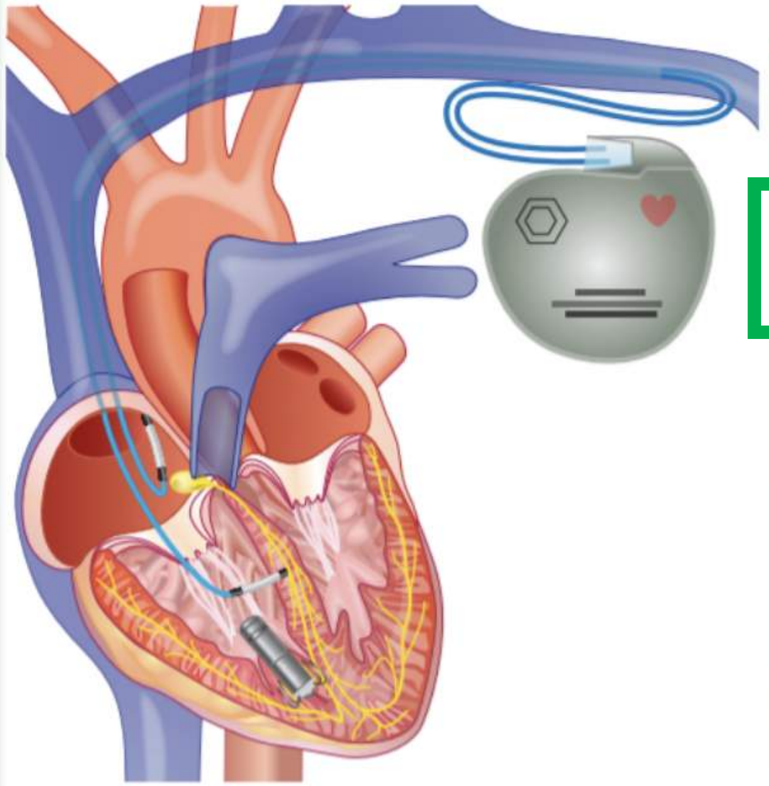
SINCRONIA AV… PER LA PRIMA VOLTA

- Soglia 0,75V/0,24 ms
- Impedenza: 590 Ohm
- Sensing: 9,2 mV



Pros and cons of leadless pacing compared to transvenous pacing

Pros
No generator pocket issues
No lead-related complications
Useful in case of venous access issues
Probably lower risk of device infection
Patient comfort and esthetics
Lower incidence of mid/long-term complications



Cons
Requirement for high-resolution fluoroscopy at implantation
No atrial pacing
Imperfect AV synchrony (Micra AV)
Limited diagnostic features
No conduction system pacing
No wireless remote monitoring
Higher cost
Limited retrievability
Higher incidence of short-term complications

Burri, Eur Heart J, 2022 Mar 21;43(12):1216–1218

AVEIR VR LEADLESS PACEMAKER

AVEIR DELIVERY AND RETRIEVAL CATHETERS

- Designed for ergonomic, single operator use
- Steerable delivery catheter with deflection mechanism[1,2]
- Hydrophilic coating on introducer sheath and a choice of 30cm and 50cm lengths[3]
- Protective sleeve fully covers the AVEIR VR Leadless Pacemaker's helix during catheter navigation in order to reduce the risk of damaging the helix or an injury to cardiovascular structures[1,2]

RESEARCH CORRESPONDENCE

Primary Results on Safety and Efficacy From the LEADLESS II–Phase 2 Worldwide Clinical Trial

JACC: CLINICAL ELECTROPHYSIOLOGY VOL. 8, NO. 1, 2022
ISSN 2405-500X

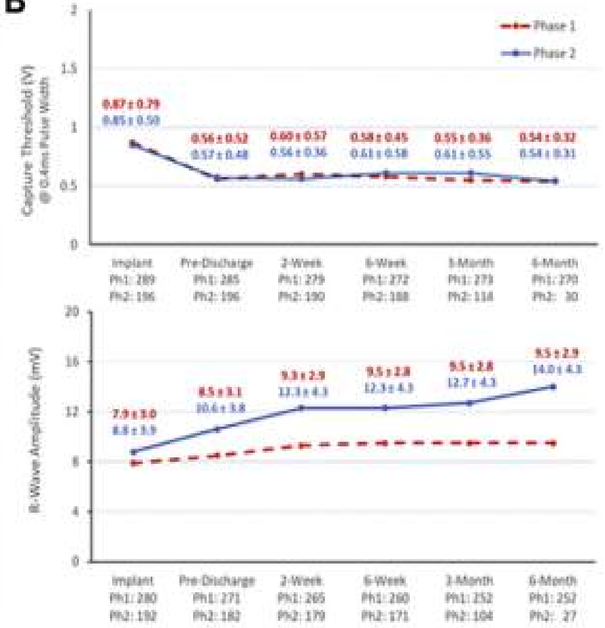
(A) Aveir leadless pacemaker
(B) Device electrical performance
(C) Implant procedure characteristics
(D) Serious Adverse Device Effects (SADEs)

A

Key Design Improvements:

- Standard transvenous pacemaker battery chemistry (Lithium Carbon-Monofluoride, CFx) & 12% improved battery life (1.1 years longer to 10.4 years @ISO standard settings)
- Altered form factor (10% shorter, 1.5Fr wider to 19.5Fr)
- Modified docking button enabling retrievability
- Modified delivery system with an ergonomic design
- Extension length of the active fixation helix is 1.6 mm
- New ASIC chip designed to provide an expandable platform to later support a dual chamber pacing system once approved.

B



C

Procedural Characteristics	Phase 1 Primary Cohort (n = 289)	Phase 2 Primary Cohort (n = 196)
Implant Success - % [no. success/no. attempt]	96% (289/300)	98% (196/200)[1]
Duration of implantation – min		
Total: sheath insertion to removal	50.0 ± 27.3	39.9 ± 21.6
Procedure: insertion of delivery catheter to removal	30.4 ± 18.2	28.7 ± 19.6
Duration of fluoroscopy – min	14.9 ± 9.4	9.4 ± 8.5
Device repositioning – % (no.)		
None	68.9% (199)	83.2% (163)
1	18.3% (53)	13.3% (26)
2	8.3% (24)	2.6% (5)
>2	4.5% (13)	1.0% (2)
Final device position in right ventricle - % (no.)		
Apex	48.4% (140)	3.6% (7)
Apical septum	1.7% (5)	68.4% (134)
Mid septum	NA[2]	28.1% (55)
Outflow, septum, or other	49.8% (144)	0% (0)
Access site closure technique[3]		
Figure-of-8 stitch	NA	82% (160)
Manual pressure	NA	26% (51)
Mechanical compression device	NA	2% (3)
Other (tobacco-pouch suture, Z-stitch, Perclose™)	NA	18% (36)

[1] Of the 4 unsuccessful implants, 3 were due to complications during the procedure (2 cardiac perforations and 1 premature LP deployment), and 1 was due to an inability to access the right ventricle due to patient anatomy.
[2] Phase 1 data collection did not include an option to specify mid septum
[3] More than one closure technique was used in some cases. Data not collected during Phase 1.

D

Event	Phase 1 Primary Cohort (n = 300) No. of Events	No. of Patients	Event Rate, %	Phase 2 Primary Cohort (n = 200) No. of Events	No. of Patients	Event Rate, %
Total	**22**	**20[1]**	**6.7%**	**9**	**8[1]**	**4.0%**
Cardiac perforation/tamponade/pericardial effusion	4	4	1.3%	3	3	1.5%[2]
Premature deployment with device migration	0	0	0.0%	2	2	1.0%[3]
Premature deployment without device migration	0	0	0.0%	1	1	0.5%[4]
Access site bleeding event	2	2	0.7%	1	1	0.5%
Pulmonary embolism	1	1	0.3%	1	1	0.5%
Deep vein thrombosis	0	0	0.0%	1	1	0.5%
Device dislodgement	5	5	1.7%	0	0	0.0%
Threshold elevation resulting in LP retrieval	4	4	1.3%	0	0	0.0%
Arteriovenous fistula	1	1	0.3%	0	0	0.0%
Pseudoaneurysm	1	1	0.3%	0	0	0.0%
Asystole during implant procedure	1	1	0.3%	0	0	0.0%
Ventricular tachycardia or ventricular fibrillation during implant procedure	1	1	0.3%	0	0	0.0%
Pericarditis	1	1	0.3%	0	0	0.0%
Orthostatic hypotension with weakness	1	1	0.3%	0	0	0.0%

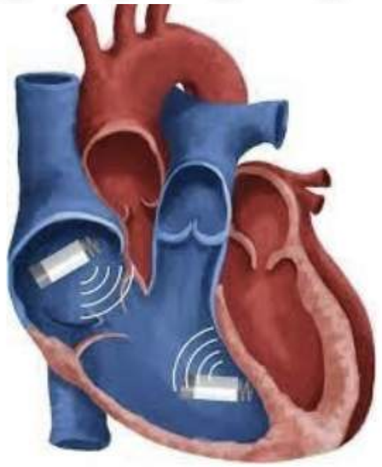
[1] Some patients had more than one event, and therefore the number of patients is less than the number of events
[2] All 3 cases resulted in cardiac tamponade of which 1 resolved with drainage and 2 resolved with subsequent sternotomy
[3] In both cases, the device migrated to the left pulmonary artery and was extracted without complication and successfully replaced with another Aveir LP in one case and a transvenous pacemaker in another case
[4] The device did not migrate, as it was fixated, and was electively replaced with another Aveir LP successfully

The Abbott Aveir™ Leadless Pacemaker System

- The Aveir™ leadless pacemaker system is specifically designed to be retrieved when the device needs to be replaced or if a patient's therapy needs change.

- Additional benefits include a small profile and is designed with the unique capability to communicate directly with another Aveir™ pacemaker in the future, which would allow for a true dual-chamber leadless pacing system.

The Abbott Aveir™ Leadless Pacemaker System



i2i (implant to implant) communication

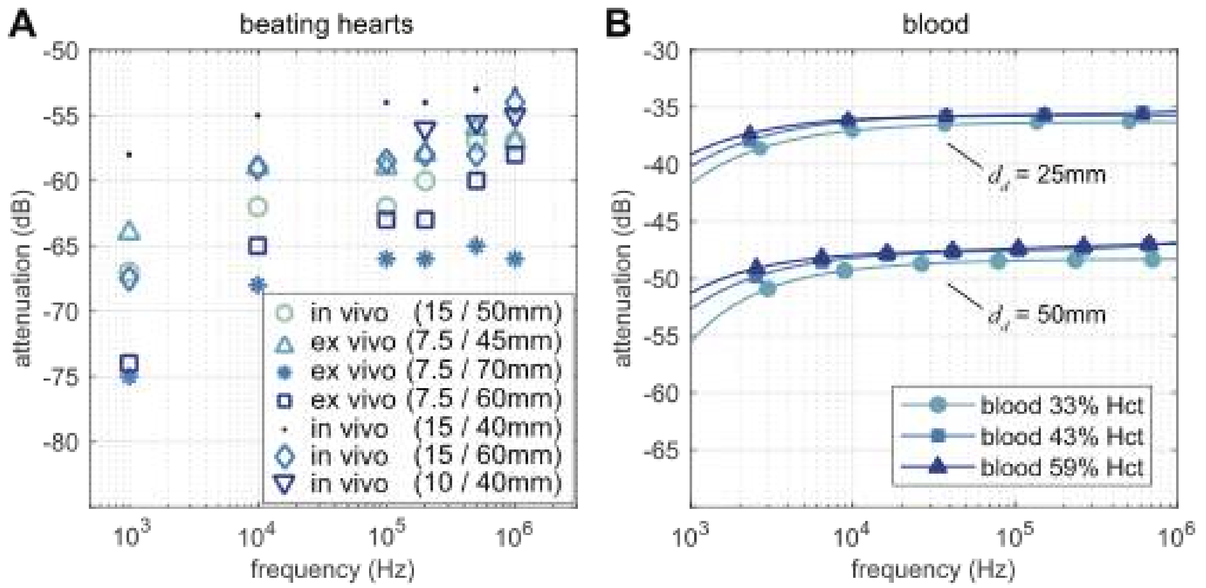
Leadless Dual-Chamber Pacing

A Novel Communication Method for Wireless Pacemaker Synchronization

Lukas Bereuter, MSc,[a,b] Mirco Gysin, MSc,[b] Thomas Kueffer, MSc,[a,b] Martin Kucera, MSc,[c] Thomas Niederhauser, PhD,[c] Jürg Fuhrer, MD,[a] Paul Heinisch, MD,[d] Adrian Zurbuchen, PhD,[e] Dominik Obrist, PhD,[b] Hildegard Tanner, MD,[a] Andreas Haeberlin, MD, PhD[a,b]

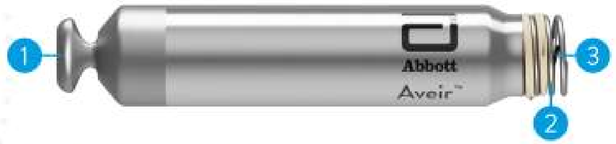
Inside the body, these requirements can typically not be met with wireless data communications based on radiofrequency telemetry and inductive coupling (as used by conventional cardiac implantable devices) (10,11). In contrast, galvanic coupled intrabody communication (12) is a promising approach for wireless data transfer between implanted devices. It uses the tissue as a transmission medium for electrical signals: the data from one device are modulated and applied as a small alternating current signal to the tissue via electrodes. This current will propagate in the tissue and can be registered almost simultaneously by another device.

FIGURE 5 Signal Attenuation in the Heart and in Blood



(A) Measured transfer function between the right atrium and the right ventricle. The dimensions in parentheses indicate the electrode distance and the device distance, respectively (d_e/d_d). **(B)** Transfer function of blood with different hematocrit (Hct) levels measured at 2 device distances.

THE WORLD'S FIRST AND ONLY ATRIAL DEVICE[1]



AVEIR™ AR Atrial LP

1. Docking button
2. Outer fixation helix
3. Inner helix tip electrode

Length: 32.2 mm **Diameter:** 6.5 mm

The atrial device has an additional inner-helix that acts as an electrode for pacing and sensing while also designed to provide extra anchoring and stability in the atrium.[2]

THE VENTRICULAR DEVICE

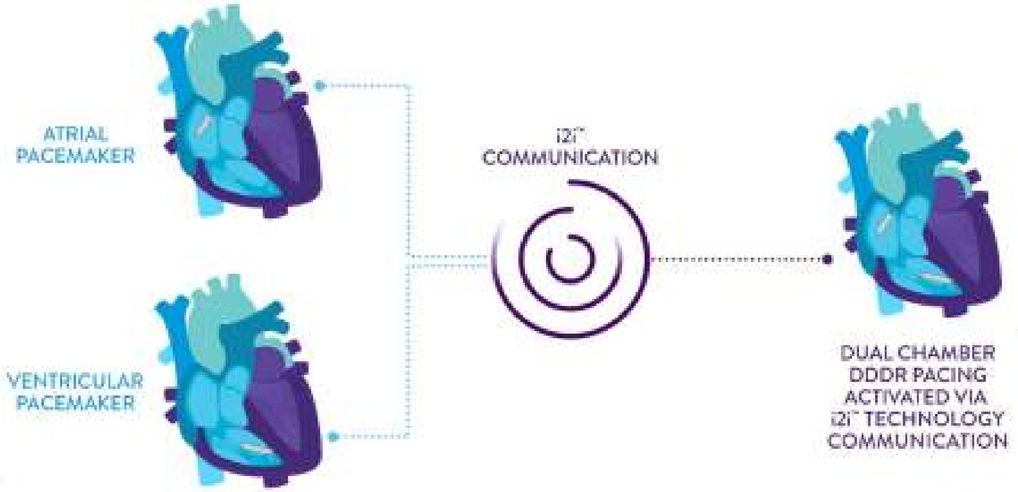
AVEIR™ VR Ventricular LP

1. Docking button
2. Fixation helix and distal dome tip electrode *(not pictured)*

Length: 38.0 mm
Diameter: 6.5 mm

i2i™ TECHNOLOGY

To support the dual chamber therapy, each implant communicates beat-to-beat with a paired, co-implanted device. This novel technology employs low-energy, subthreshold pulses between implanted devices using the conductive nature of the body's blood pool and myocardial tissue. These high frequency pulses of data are delivered concurrently with each locally paced or sensed event without impact on pacing or intrinsic sensing.



Servizio Sanitario della Toscana

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

A Dual-Chamber Leadless Pacemaker

Reinoud E. Knops, M.D., Ph.D., Vivek Y. Reddy, M.D., James E. Ip, M.D., Rahul Doshi, M.D., Derek V. Exner, M.D., M.P.H., Pascal Defaye, M.D., Robert Canby, M.D., Maria Grazia Bongiorni, M.D., Morio Shoda, M.D., Gerhard Hindricks, M.D., Petr Neužil, M.D., Mayer Rashtian, M.D., Karel T.N. Breeman, M.D., Jordan R. Nevo, M.S., Leonard Ganz, M.D., Chris Hubbard, M.B.A., and Daniel J. Cantillon, M.D., for the Aveir DR i2i Study Investigators*

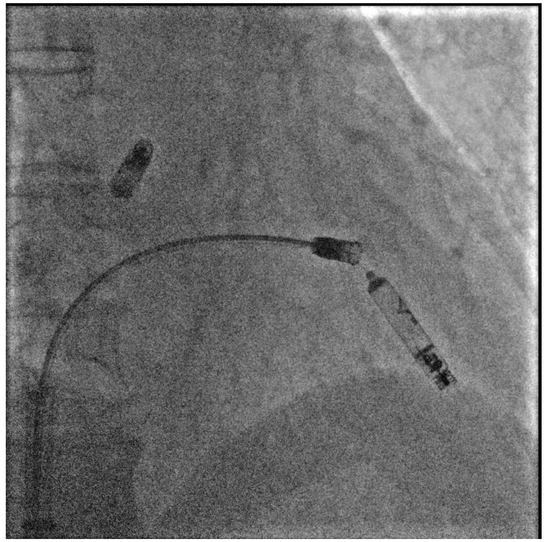


Table 1. Characteristics of the Patients at Baseline.*

Characteristic	Full Analysis Population (N=300)
Sex — no. (%)	
Male	187 (62.3)
Female	113 (37.7)
Age — yr	69.2±13.5
Height — cm	171.6±10.1
Weight — kg	82.9±19.1
Body-mass index†	28.1±5.6
Race or ethnic group — no. (%)‡	
American Indian or Alaska Native	1 (0.3)
Asian	5 (1.7)
Black	6 (2.0)
White	200 (66.7)
Declined or unable to disclose	89 (29.7)
Geographic region of enrolling center — no. (%)	
United States	184 (61.3)
Europe	89 (29.7)
Canada	27 (9.0)
Primary pacemaker indication — no. (%)	
Sinus-node dysfunction	190 (63.3)
Atrioventricular block	100 (33.3)
Conduction disorder with 1:1 atrioventricular conduction	4 (1.3)
Vasovagal (reflex) syncope	6 (2.0)
Previous ablation — no. (%)	60 (20.0)
Tricuspid-valve disease — no. (%)	
Insufficiency, prolapse, or regurgitation	72 (24.0)
Repair or replacement	3 (1.0)
Arrhythmia history — no. (%)	
Ventricular	13 (4.3)
Nonventricular or supraventricular	135 (45.0)
Previous extractions — no. (%)	
Transvenous lead extraction	24 (8.0)
Leadless pacemaker extraction	2 (0.7)

Table 2. Procedural Characteristics.*

Characteristic	Population with Pacemakers Implanted (N=298)†
Time from sheath insertion to removal — min	86.3±36.5
Time from delivery catheter insertion to removal — min	70.9±30.5
Ventricular leadless pacemaker	24.0±16.2
Atrial leadless pacemaker	40.2±22.6
Total fluoroscopic duration — min‡	18.3±10.7
Length of hospital stay — days	1.0±1.2
Atrial leadless pacemaker repositioning — no. (%)	
None	226 (75.8)
1	41 (13.8)
>1	31 (10.4)
Ventricular leadless pacemaker repositioning — no. (%)	
None	258 (86.6)
1	34 (11.4)
>1	6 (2.0)
Final leadless pacemaker placement in the right atrium — no. (%)	
RAA medial antral	140 (47.0)
RAA saccular	54 (18.1)
RAA lateral antral	42 (14.1)
RA lateral wall	32 (10.7)
RAA distal saccular	14 (4.7)
RA posterior wall	5 (1.7)
RA septum	2 (0.7)
Other	9 (3.0)
Final leadless pacemaker placement in the right ventricle — no. (%)	
RV apical septum	165 (55.4)
RV mid septum	101 (33.9)
RV apex	21 (7.0)
RV anterolateral free wall	3 (1.0)
RV inferior or diaphragmatic wall	1 (0.3)
Other	7 (2.3)

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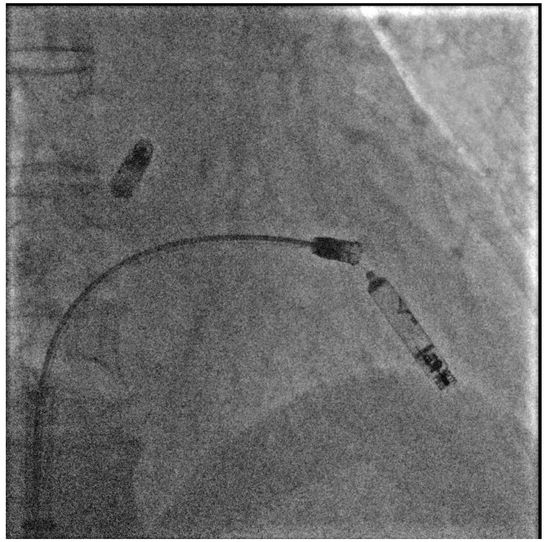
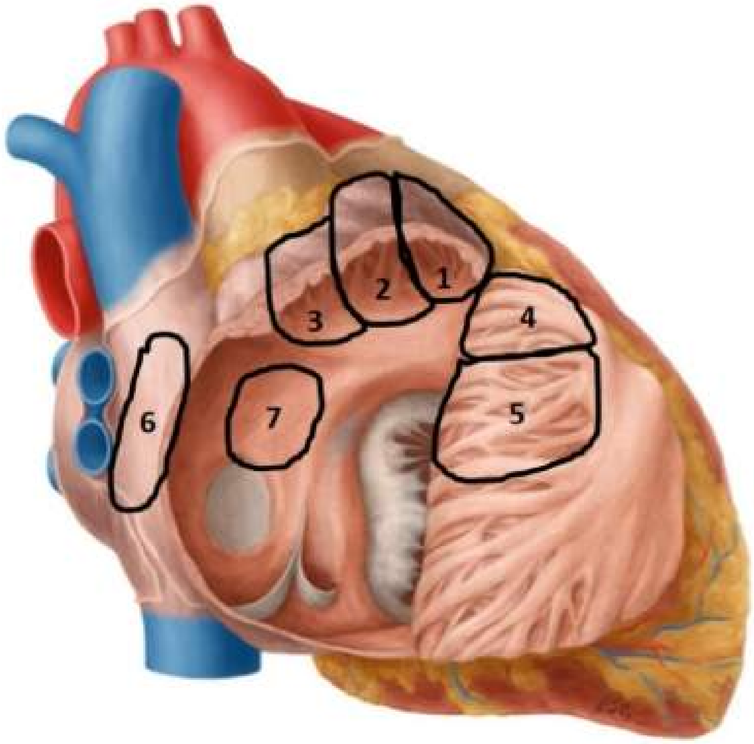


Mid-to-Deep Right Atrial Appendage	
1 – RAA Distal Saccular	2 – RAA Saccular
Base of Right Atrial Appendage	
3 – RAA Medial Antral	4 – RAA Lateral Antral
5 – RA Lateral Wall	6 – RA Posterior Wall
7 – RA Septum	



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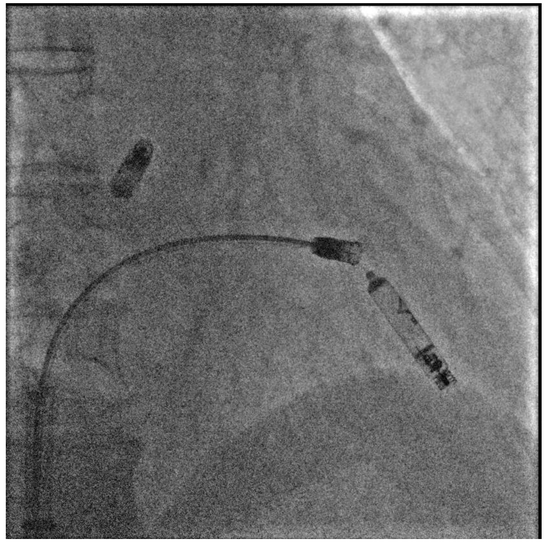

Table 3. Complications within 90 Days.*

Event†	Population with Attempted Implantation (N=300)‡	
	No. of Events	No. of Patients with an Event (%)
Cardiac arrhythmia	10	10 (3.3)
Atrial fibrillation	9	9 (3.0)
Transient complete atrioventricular block	1	1 (0.3)
Intermittent or complete loss of implant-to-implant communication	1	1 (0.3)
Intraprocedural dislodgement	6	5 (1.7)
Due to inadequate fixation	5	4 (1.3)
Due to mechanical dislodgement§	1	1 (0.3)
Postprocedural dislodgement¶	5	5 (1.7)
Urinary retention	3	3 (1.0)
Pericardial effusion	2	2 (0.7)
Treated with percutaneous pericardiocentesis	1	1 (0.3)
Managed conservatively	1	1 (0.3)
Capture threshold issues	2	2 (0.7)
Threshold elevation in the atrial leadless pacemaker	1	1 (0.3)
Intermittent capture in the ventricular leadless pacemaker	1	1 (0.3)
Access site bleeding	1	1 (0.3)
Retroperitoneal hematoma	1	1 (0.3)
Syncope‖	1	1 (0.3)
Heart failure	1	1 (0.3)
Oral pain**	1	1 (0.3)
Pleural effusion	1	1 (0.3)
Total	35	29 (9.7)

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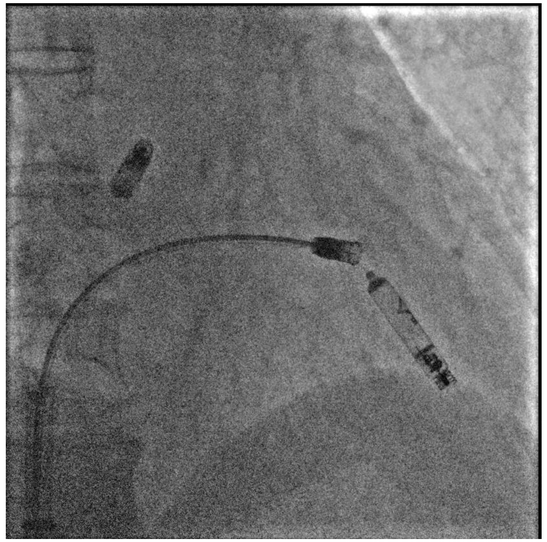

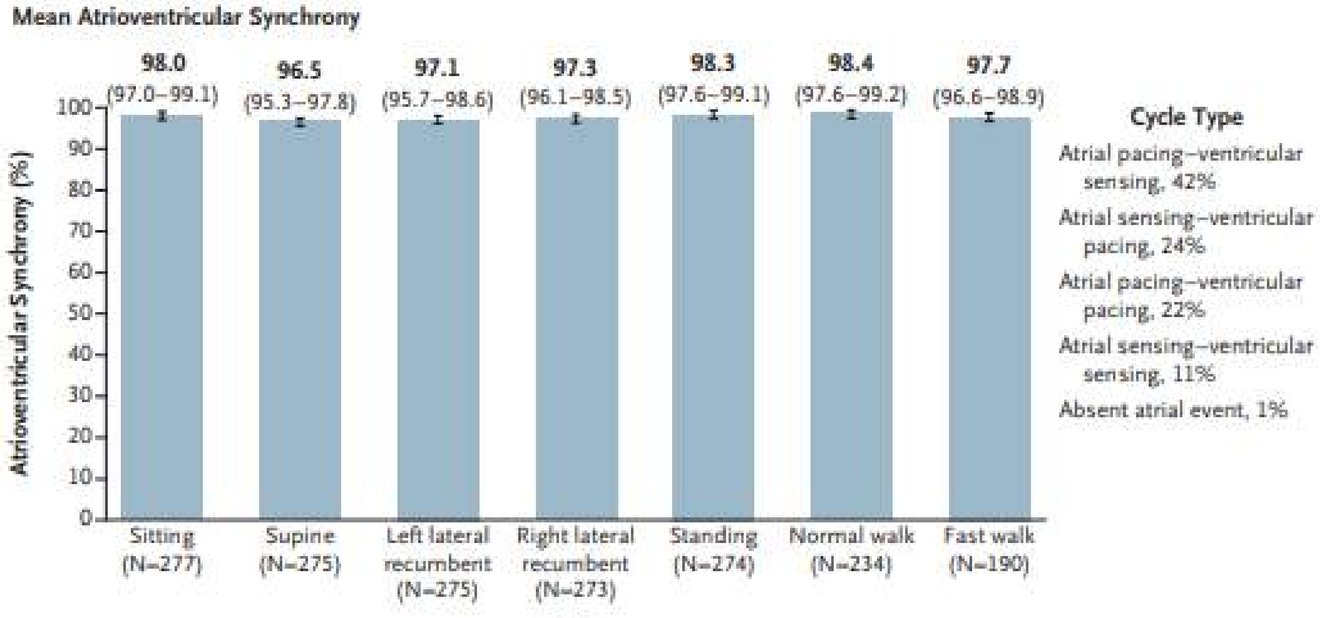

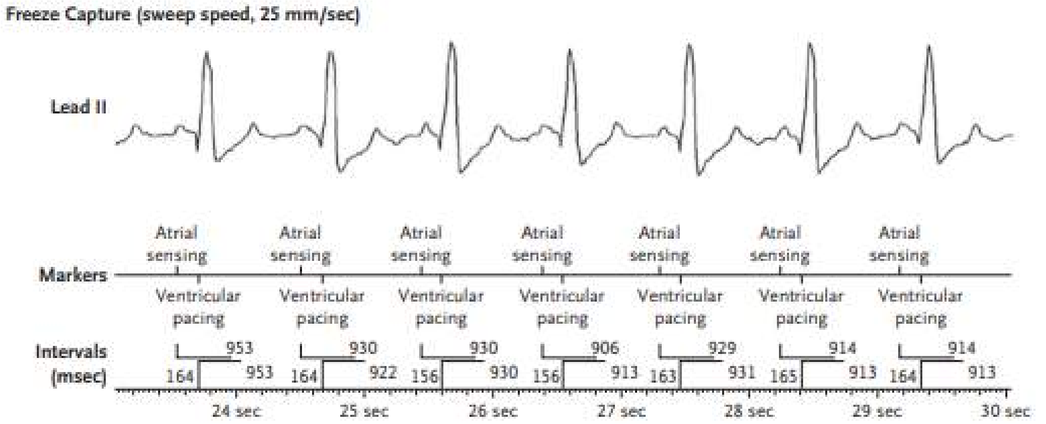

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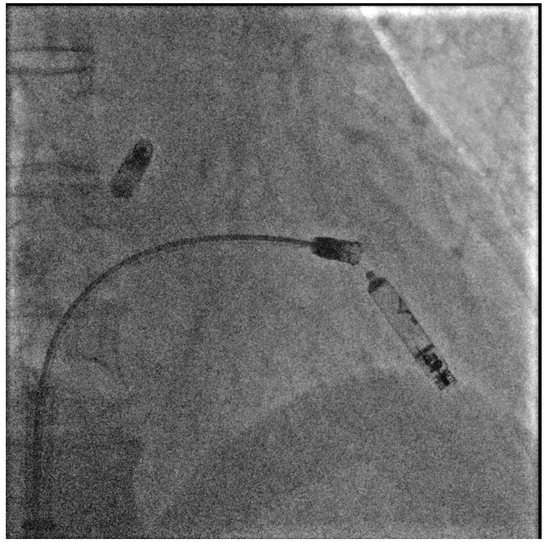
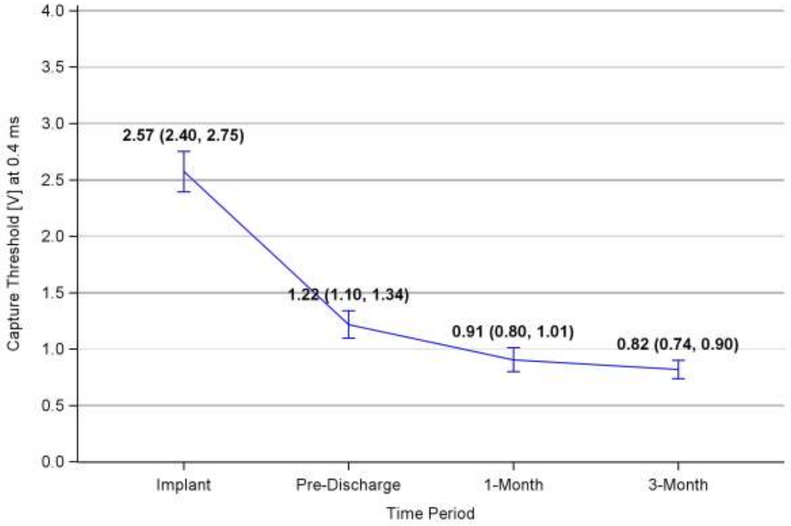


Atrial Leadless Pacemaker Capture Threshold

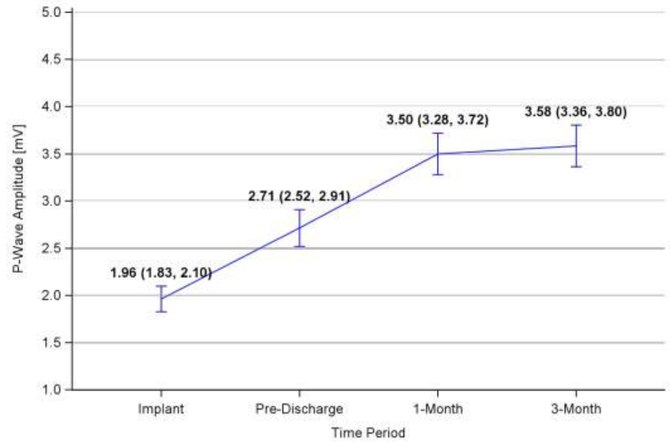


Mean (95% CI) is shown

CONCLUSIONS

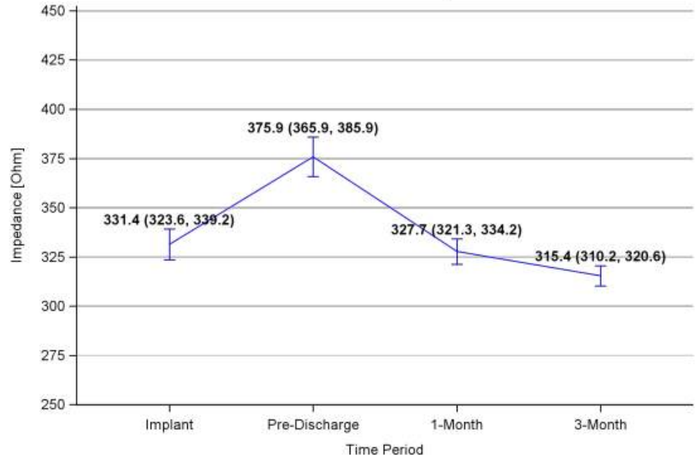
The dual-chamber leadless pacemaker system met the primary safety end point and provided atrial pacing and reliable atrioventricular synchrony for 3 months after implantation. (Funded by Abbott Medical; Aveir DR i2i ClinicalTrials.gov number, NCT05252702.)

Atrial Leadless Pacemaker P-Wave Amplitude



Mean (95% CI) is shown

Atrial Leadless Pacemaker Impedance

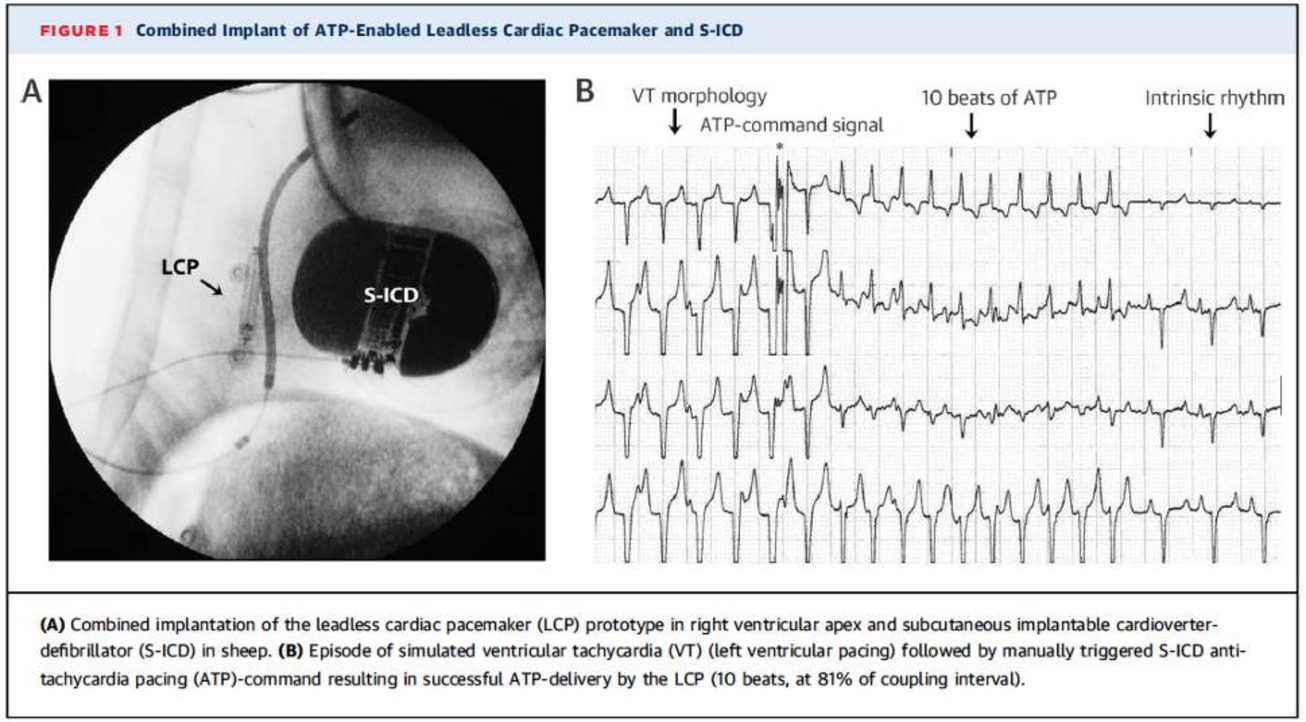


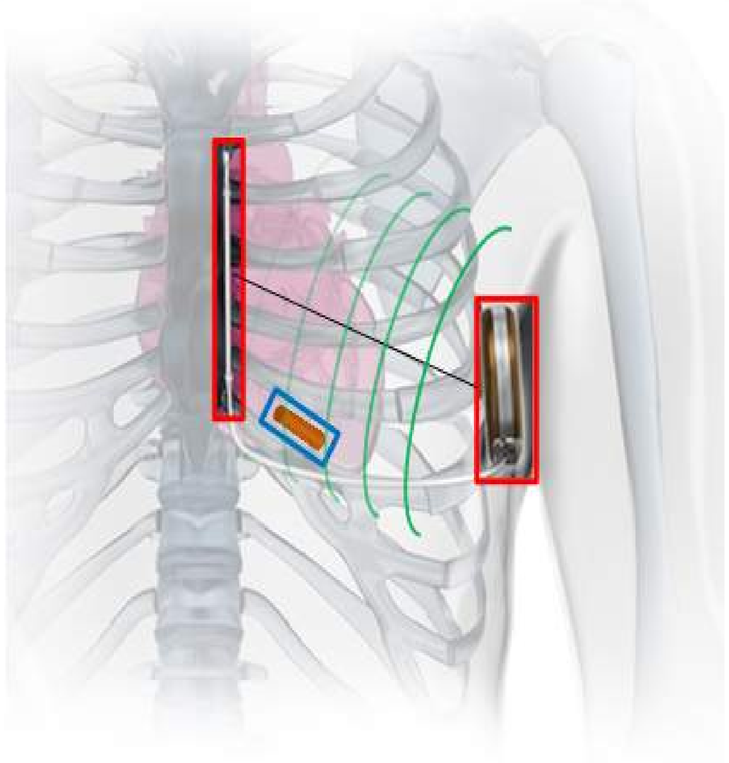
Mean (95% CI) is shown

…E IL FUTURO?

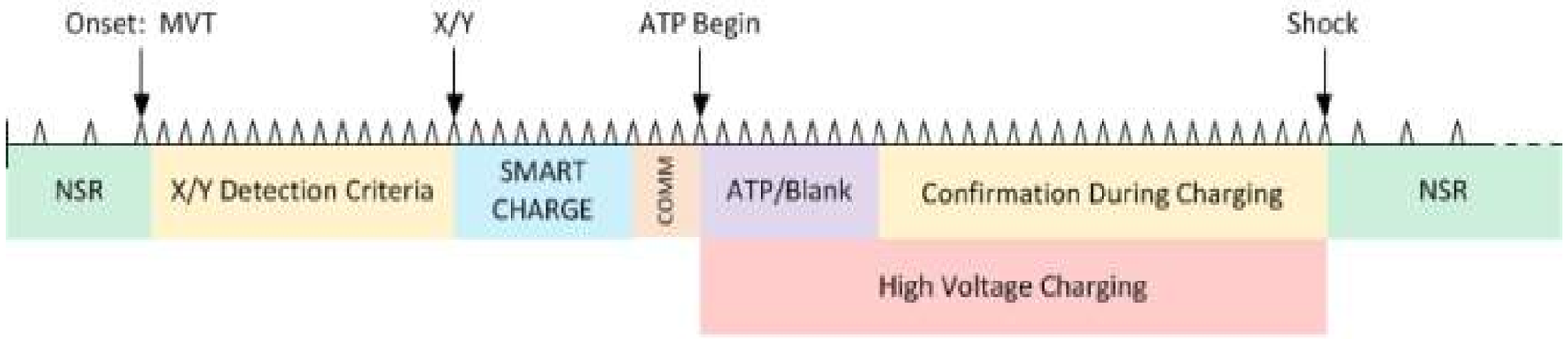
modular cardiac rhythm management system

In the next future S-ICD and leadless (A/RV/LV) PM would probably work together for the best care of our patients





1. Leadless pacemaker designed to sense and treat bradycardia independently from the S-ICD
2. ATP schemes will be built into the leadless pacemaker, but can be activated only by the S-ICD or the programmer
3. S-ICD will continue to sense tachycardia, following which it is designed to command ATP in the leadless pacemaker prior to a shock



CONCLUSIONI

- LE INDICAZONI ALLA STIMOLAZIONE LEADLESS SI STANNO EVOLVENDO (VVI, VDD, DDD, AAI?, ATP?)
- I DATI SULLE COMPLICANZE DEI SISTEMI LEADLESS SONO OTTIMI SE CONFRENTATI CON QUELLI DEI PACEMAKER TRANSVENOSI ANCHE SE RIMANE QUALCHE “DUBBIO” SULLA PERCENTUALE DI PERFORAZIONI
- IN TERMINI DI ESTRAIBILITA’ POTREBBERO ESSERE FAVORITI I SISTEMI A VITE ANCHE SE L’AUMENTO DELLA DURATA DELLA BATTERIA E LA POSSIBILITA’ DI INSERIRE PIU’ DI 1 DEVICE STANNO COMUNQUE SPOSTANDO LE INDICAZIONI VERSO PAZIENTI PIU’ GIOVANI

CONCLUSIONI

- E' DA ATTENDERSI UN BENEFICIO NETTO NEL FOLLOW-UP DEI SISTEMI LEADLESS IN TERMINI DI RIDUZIONE DELLA COMPLICANZE LEADS LEGATE O DELLE COMPLICANZE INFETTIVE

- I DATI INIZIALI ATTUALMENTE DISPONIBILI SUL SISTEMA COMBINATO ATRIAL LP-VENTRICULAR LP CONFERMANO LE OTTIME PERFORMANCE (ANCHE DEGLI IMPIANTI IN SEDE ATRIALE) SENZA SIGNIFICATIVO INCREMENTO DELLE COMPLICANZE

Ciao Ezio
Grazie
Ci mancherai……

DE
LI
VE
RY

AVEIR VR LEADLESS PACEMAKER

AVEIR DELIVERY AND RETRIEVAL CATHETERS

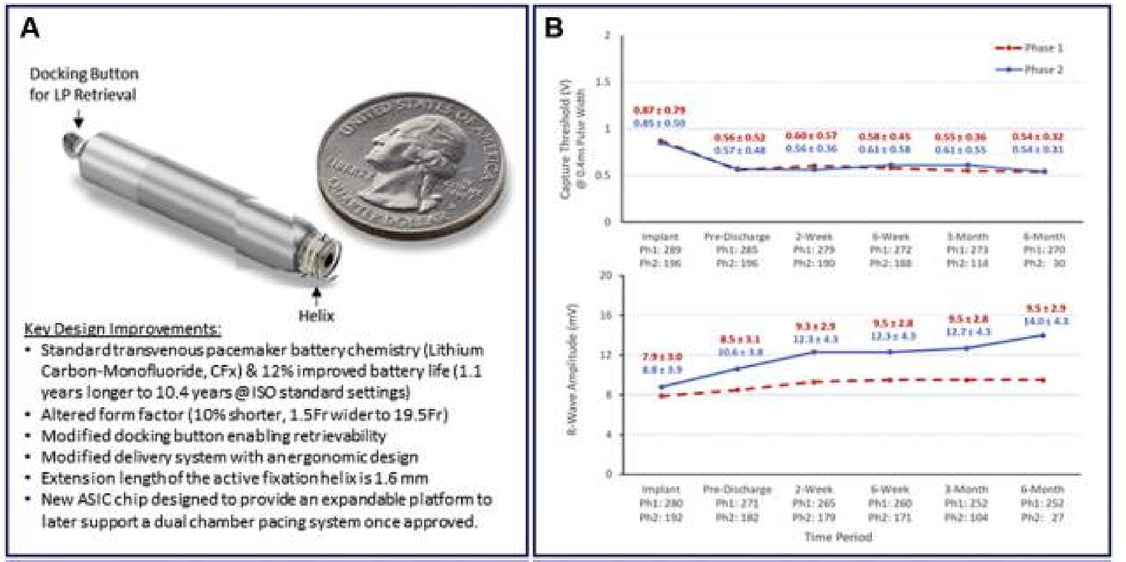
- Designed for ergonomic, single operator use
- Steerable delivery catheter with deflection mechanism[1,2]
- Hydrophilic coating on introducer sheath and a choice of 30cm and 50cm lengths[3]
- Protective sleeve fully covers the AVEIR VR Leadless Pacemaker's helix during catheter navigation in order to reduce the risk of damaging the helix or an injury to cardiovascular structures[1,2]

Letters

RESEARCH CORRESPONDENCE

Primary Results on Safety and Efficacy From the LEADLESS II–Phase 2 Worldwide Clinical Trial

FIGURE 1 Safety and Effectiveness Outcomes



C

Procedural Characteristics	Phase 1 Primary Cohort (n = 289)	Phase 2 Primary Cohort (n = 196)
Implant Success - % (no. success/no. attempt)	96% (289/300)	98% (196/200)[1]
Duration of implantation – min		
Total: sheath insertion to removal	50.0 ± 27.3	39.9 ± 21.6
Procedure: insertion of delivery catheter to removal	30.4 ± 18.2	28.7 ± 19.6
Duration of fluoroscopy – min	14.9 ± 9.4	9.4 ± 8.5
Device repositioning – % (no.)		
None	68.9% (199)	83.2% (163)
1	18.3% (53)	13.3% (26)
2	8.3% (24)	2.6% (5)
>2	4.5% (13)	1.0% (2)
Final device position in right ventricle - % (no.)		
Apex	48.4% (140)	3.6% (7)
Apical septum	1.7% (5)	68.4% (134)
Mid septum	NA[2]	28.1% (55)
Outflow, septum, or other	49.8% (144)	0% (0)
Access site closure technique[3]		
Figure-of-8 stitch	NA	82% (160)
Manual pressure	NA	26% (51)
Mechanical compression device	NA	2% (3)
Other (tobacco pouch suture, 2-stitch, Perclose™)	NA	18% (36)

[1] Of the 4 unsuccessful implants, 3 were due to complications during the procedure (2 cardiac perforations and 1 premature LP deployment), and 1 was due to an inability to access the right ventricle due to patient anatomy.
[2] Phase 1 data collection did not include an option to specify mid septum
[3] More than one closure technique was used in some cases. Data not collected during Phase 1.

D

Event	Phase 1 Primary Cohort (n = 300) No. of Events	No. of Patients	Event Rate, %	Phase 2 Primary Cohort (n = 200) No. of Events	No. of Patients	Event Rate, %
Total	22	20[1]	6.7%	9	8[1]	4.0%
Cardiac perforation/tamponade/pericardial effusion	4	4	1.3%	3	3	1.5%[2]
Premature deployment with device migration	0	0	0.0%	2	2	1.0%[3]
Premature deployment without device migration	0	0	0.0%	1	1	0.5%[4]
Access site bleeding event	2	2	0.7%	1	1	0.5%
Pulmonary embolism	1	1	0.3%	1	1	0.5%
Deep vein thrombosis	0	0	0.0%	1	1	0.5%
Device dislodgement	5	5	1.7%	0	0	0.0%
Threshold elevation resulting in LP retrieval	4	4	1.3%	0	0	0.0%
Arteriovenous fistula	1	1	0.3%	0	0	0.0%
Pseudoaneurysm	1	1	0.3%	0	0	0.0%
Asystole during implant procedure	1	1	0.3%	0	0	0.0%
Ventricular tachycardia or ventricular fibrillation during implant procedure	1	1	0.3%	0	0	0.0%
Pericarditis	1	1	0.3%	0	0	0.0%
Orthostatic hypotension with weakness	1	1	0.3%	0	0	0.0%

[1] Some patients had more than one event, and therefore the number of patients is less than the number of events
[2] All 3 cases resulted in cardiac tamponade of which 1 resolved with drainage and 2 resolved with subsequent sternotomy
[3] In both cases, the device migrated to the left pulmonary artery and was extracted without complication and successfully replaced with another Aveir LP in one case and a transvenous pacemaker in another case
[4] The device did not migrate, as it was fixated, and was electively replaced with another Aveir LP successfully

(A) Aveir leadless pacemaker
(B) Device electrical performance
(C) Implant procedure characteristics
(D) Serious Adverse Device Effects (SADEs)

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The Abbott Aveir™ Leadless Pacemaker System

- The Aveir™ leadless pacemaker system is specifically designed to be retrieved when the device needs to be replaced or if a patient's therapy needs change.

- Additional benefits include a small profile and is designed with the unique capability to communicate directly with another Aveir™ pacemaker in the future, which would allow for a true dual-chamber leadless pacing system.

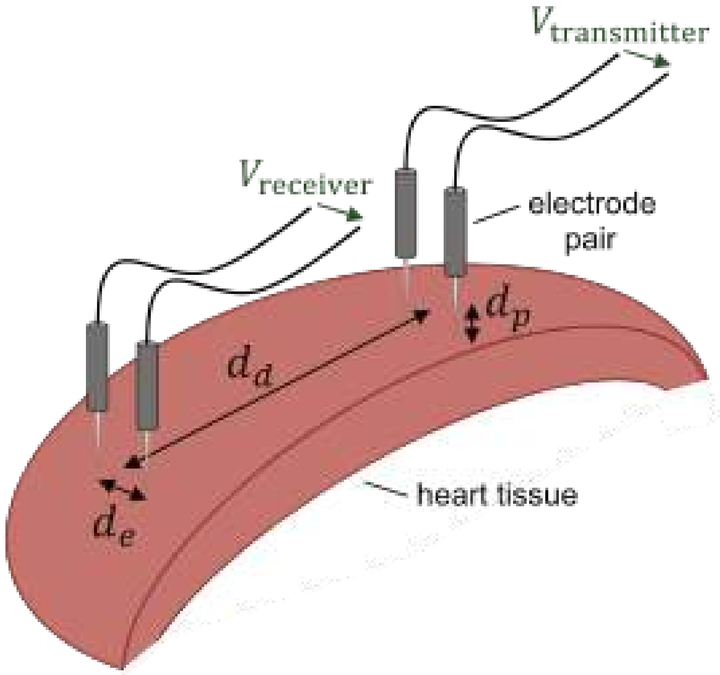
The Abbott Aveir™ Leadless Pacemaker System

Leadless Dual-Chamber Pacing

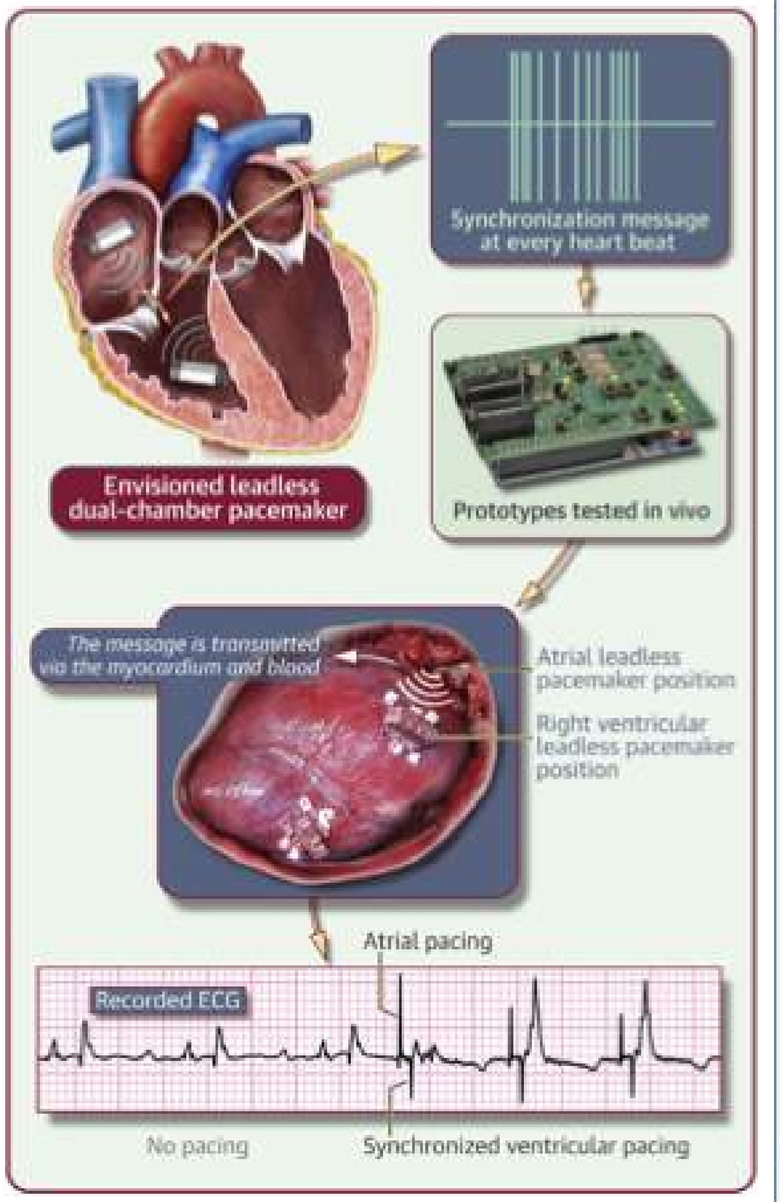
A Novel Communication Method for Wireless Pacemaker Synchronization

Lukas Bereuter, MSc,[a,b] Mirco Gysin, MSc,[b] Thomas Kueffer, MSc,[a,b] Martin Kucera, MSc,[c] Thomas Niederhauser, PhD,[c] Jürg Fuhrer, MD,[a] Paul Heinisch, MD,[d] Adrian Zurbuchen, PhD,[e] Dominik Obrist, PhD,[b] Hildegard Tanner, MD,[a] Andreas Haeberlin, MD, PhD[a,b]

FIGURE 2 Schematic Setup of Ex Vivo and In Vivo Measurements and Representation of Introduced Parameters



VISUAL ABSTRACT



Bereuter, L. et al. J Am Coll Cardiol Basic Trans Science. 2018;3(6):813-23.

Leadless Dual-Chamber Pacing

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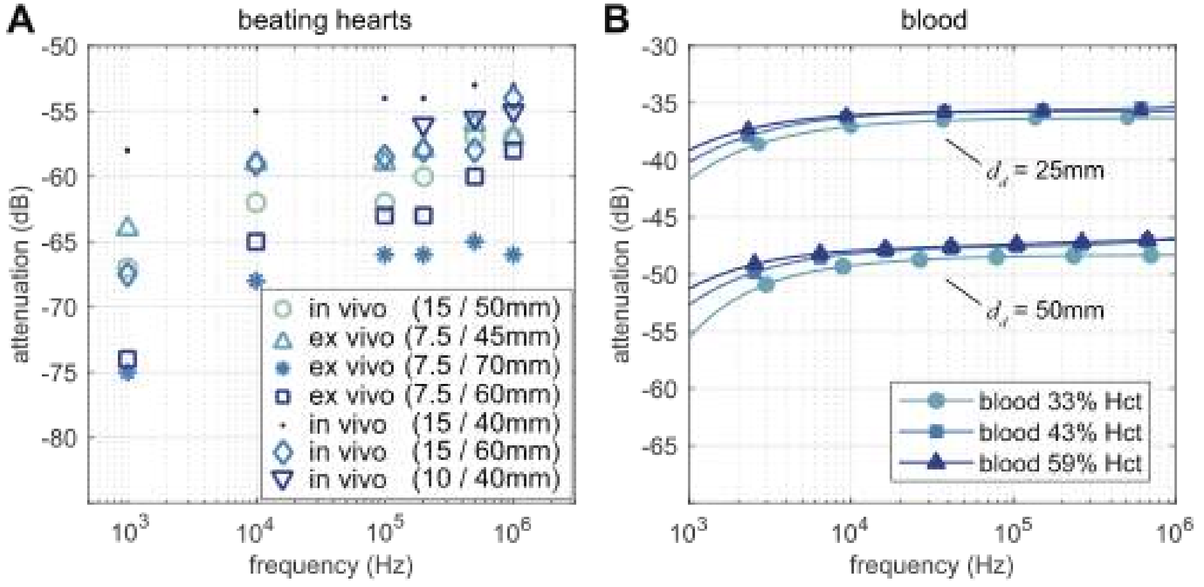
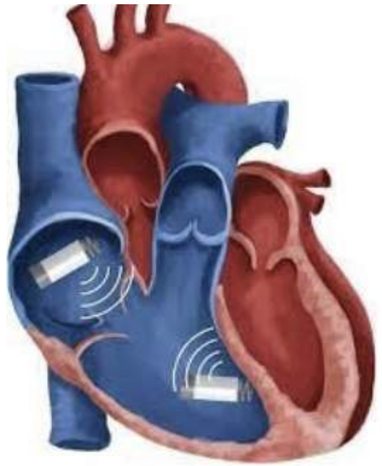
Inside the body, these requirements can typically not be met with wireless data communications based on radiofrequency telemetry and inductive coupling (as used by conventional cardiac implantable devices) (10,11). In contrast, galvanic coupled intrabody communication (12) is a promising approach for wireless data transfer between implanted devices. It uses the tissue as a transmission medium for electrical signals: the data from one device are modulated and applied as a small alternating current signal to the tissue via electrodes. This current will propagate in the tissue and can be registered almost simultaneously by another device.

FIGURE 5 Signal Attenuation in the Heart and in Blood

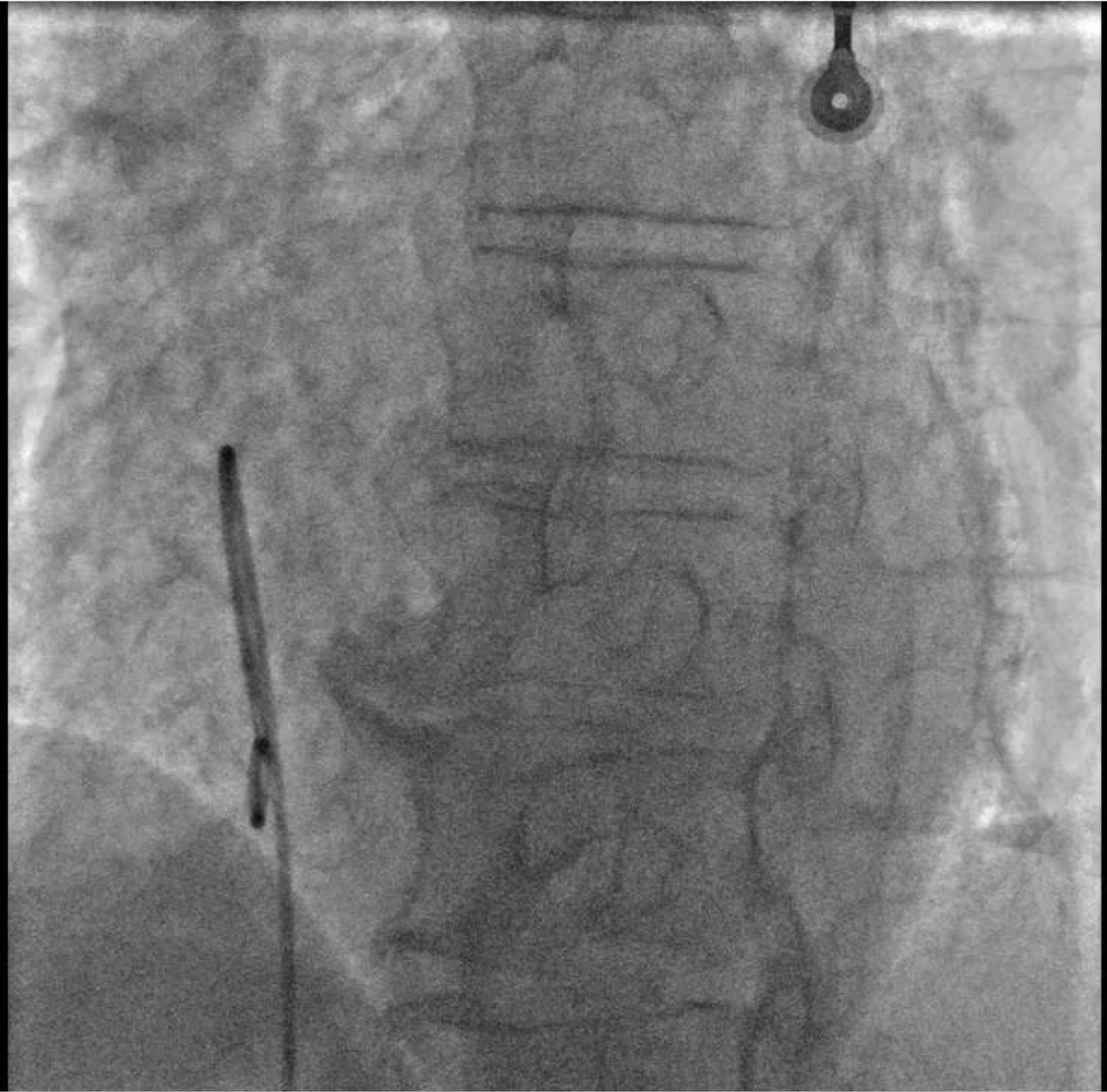


(A) Measured transfer function between the right atrium and the right ventricle. The dimensions in parentheses indicate the electrode distance and the device distance, respectively (d_e/d_d). **(B)** Transfer function of blood with different hematocrit (Hct) levels measured at 2 device distances.

Ongoing AVEIR DR i2i STUDY
Up to 550 patients



i2i (implant to implant) communication



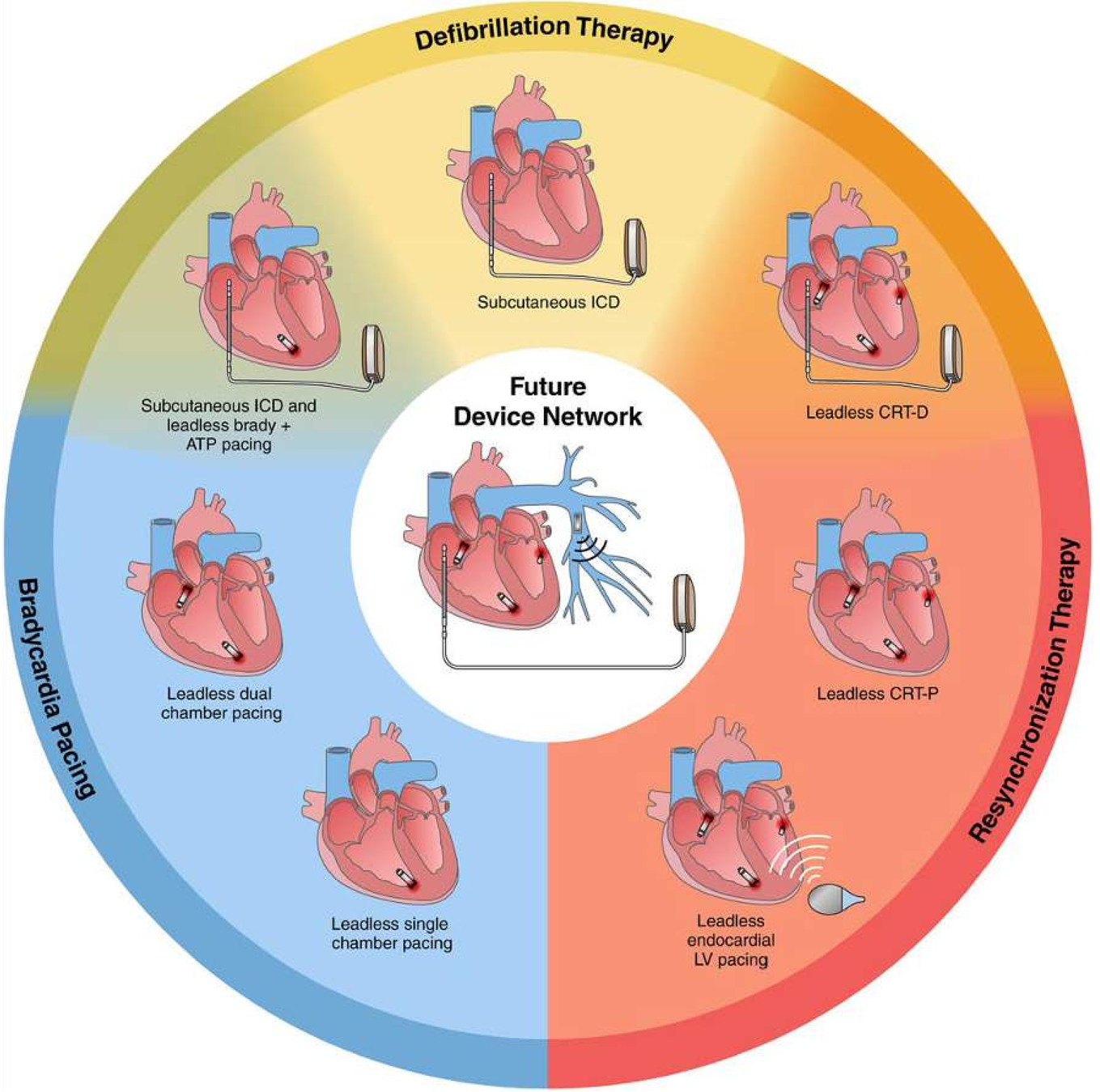
12 April 2023

RE: Aveir DR i2i IDE Study – Global Enrollment Closure Notification

Dear Aveir DR Investigators and Research Coordinators,

We are pleased to announce that enrollment for the Aveir DR i2i IDE study has ended as of the date of this letter. As of March 15, 2023, Aveir DR i2i IDE study has enrolled 319 subjects in the US, 105 subjects in EMEA, 35 in Canada and 41 in APAC subjects in the study. On behalf of the Steering Committee and Aveir DR i2i IDE study team, we would like to extend our gratitude for helping us achieve this milestone.

…E IL FUTURO?

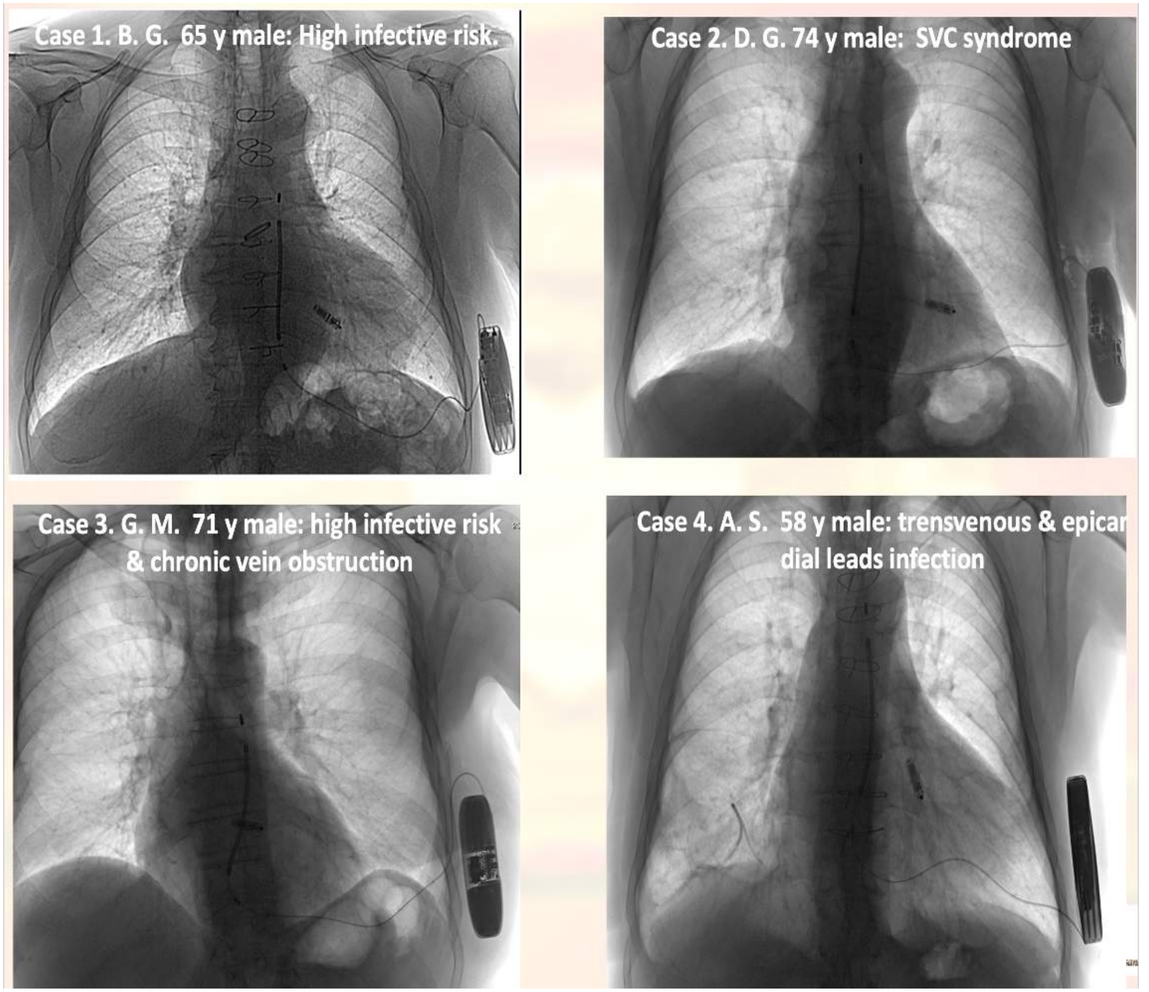


Modified from Tjong, Reddy, Jacc 2017

DATI CLINICI - real life

S-ICD + Micra VR

Population and characteristics	N = 213
Age, y (range)	46 ± 13 (14 -81)
Male, n (%)	163 (77)
Mean EF	46.4 ± 13
EF ≤ 35%	37%
Primary prevention	66%
Secondary prevention, n (%)	34%
De novo implant	57%
Previous lead extraction, n (%)	43%
Inter-muscolar position, n (%)	89% (100% from 2015)
2 incisions technique	78% (98% from 2015)
Hybrid implant (S-ICD + LPM MDT MICRA) n (%)	**8 (3.7)**



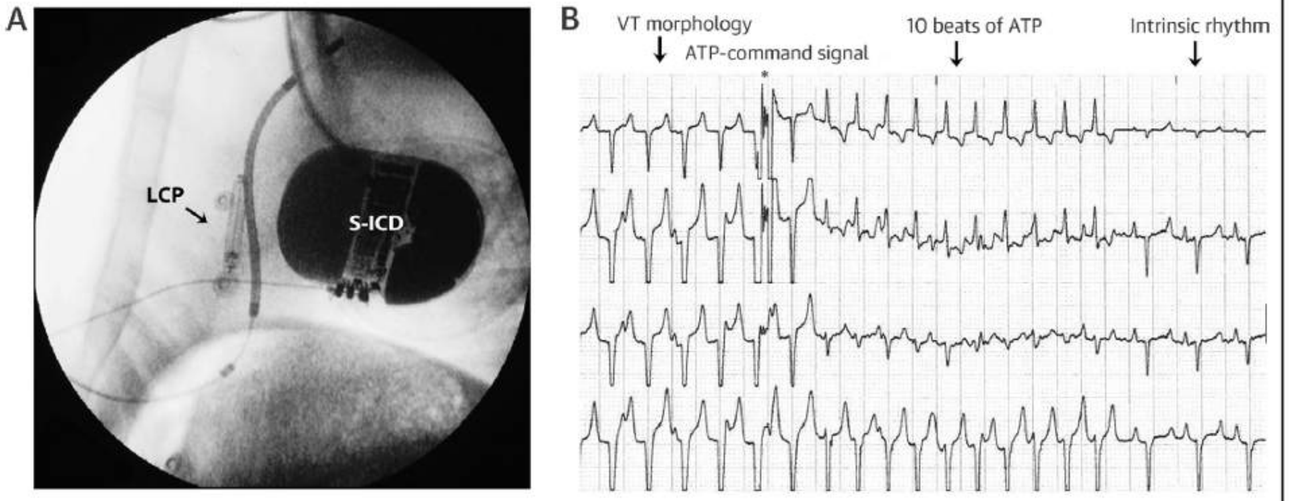
…E IL FUTURO?

modular cardiac rhythm management system

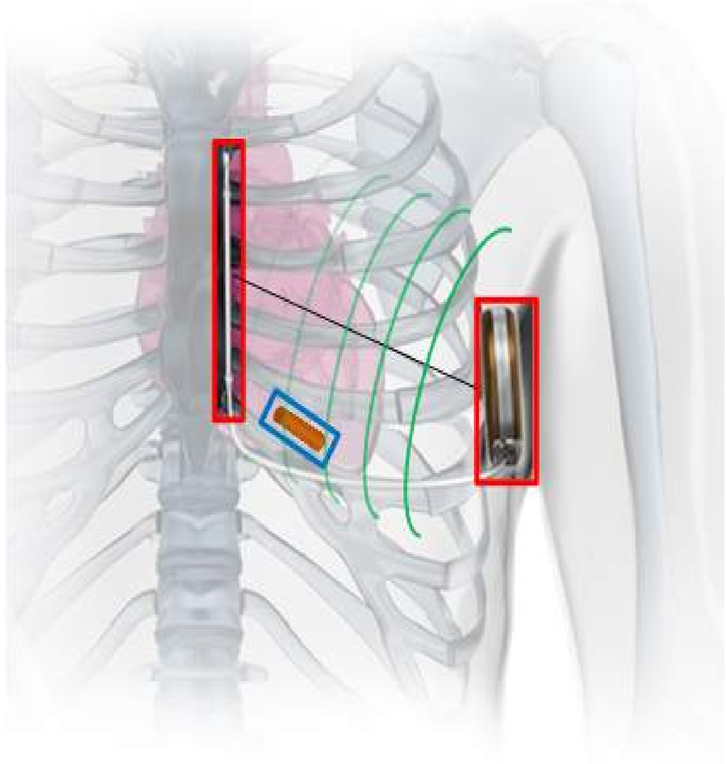
In the next future S-ICD and leadless (A/RV/LV) PM would probably work together for the best care of our patients

Tjong FVY et al; JACC 2016

FIGURE 1 Combined Implant of ATP-Enabled Leadless Cardiac Pacemaker and S-ICD

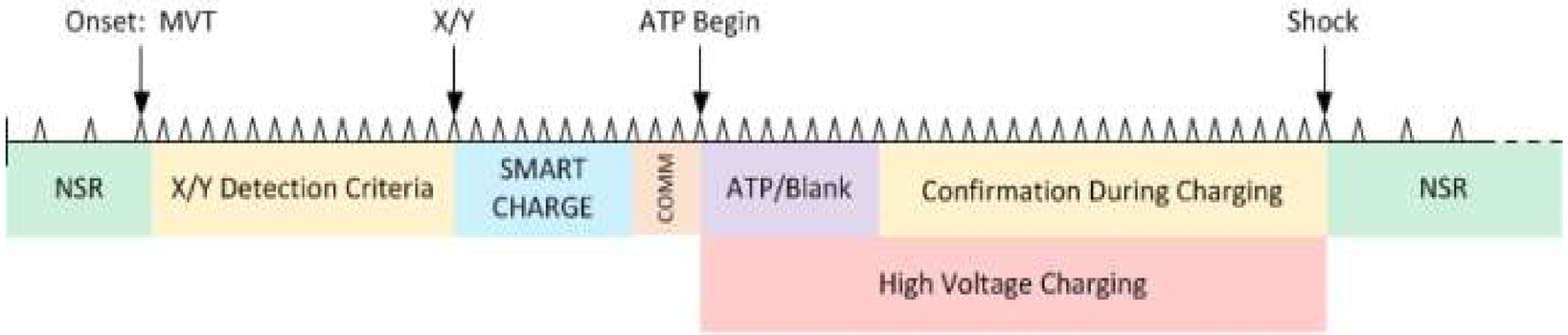


(A) Combined implantation of the leadless cardiac pacemaker (LCP) prototype in right ventricular apex and subcutaneous implantable cardioverter-defibrillator (S-ICD) in sheep. **(B)** Episode of simulated ventricular tachycardia (VT) (left ventricular pacing) followed by manually triggered S-ICD anti-tachycardia pacing (ATP)-command resulting in successful ATP-delivery by the LCP (10 beats, at 81% of coupling interval).



1. Leadless pacemaker designed to sense and treat bradycardia independently from the S-ICD
2. ATP schemes will be built into the leadless pacemaker, but can be activated only by the S-ICD or the programmer
3. S-ICD will continue to sense tachycardia, following which it is designed to command ATP in the leadless pacemaker prior to a shock

Example of ATP during charge in the Shock Zone



…E IL FUTURO?

CENTRAL ILLUSTRATION: An Overview of the History of Cardiac Pacing

Paradigm Shifts in Cardiac Pacemakers

1950s	1950s	1958	2015	2016	Future
AC-powered pacemakers tethered to an extension cord (Furman)	Battery-powered transistorized "wearable" pacemakers (Lillehei/Bakken)	First fully implantable pacemaker (Elmqvist/ Senning)	Implantable pacemaker—basic system had not evolved significantly	Leadless pacemaker—the entire device is placed within cardiac chambers	Batteryless devices, which harvest cardiac motion to power pacing circuits
					

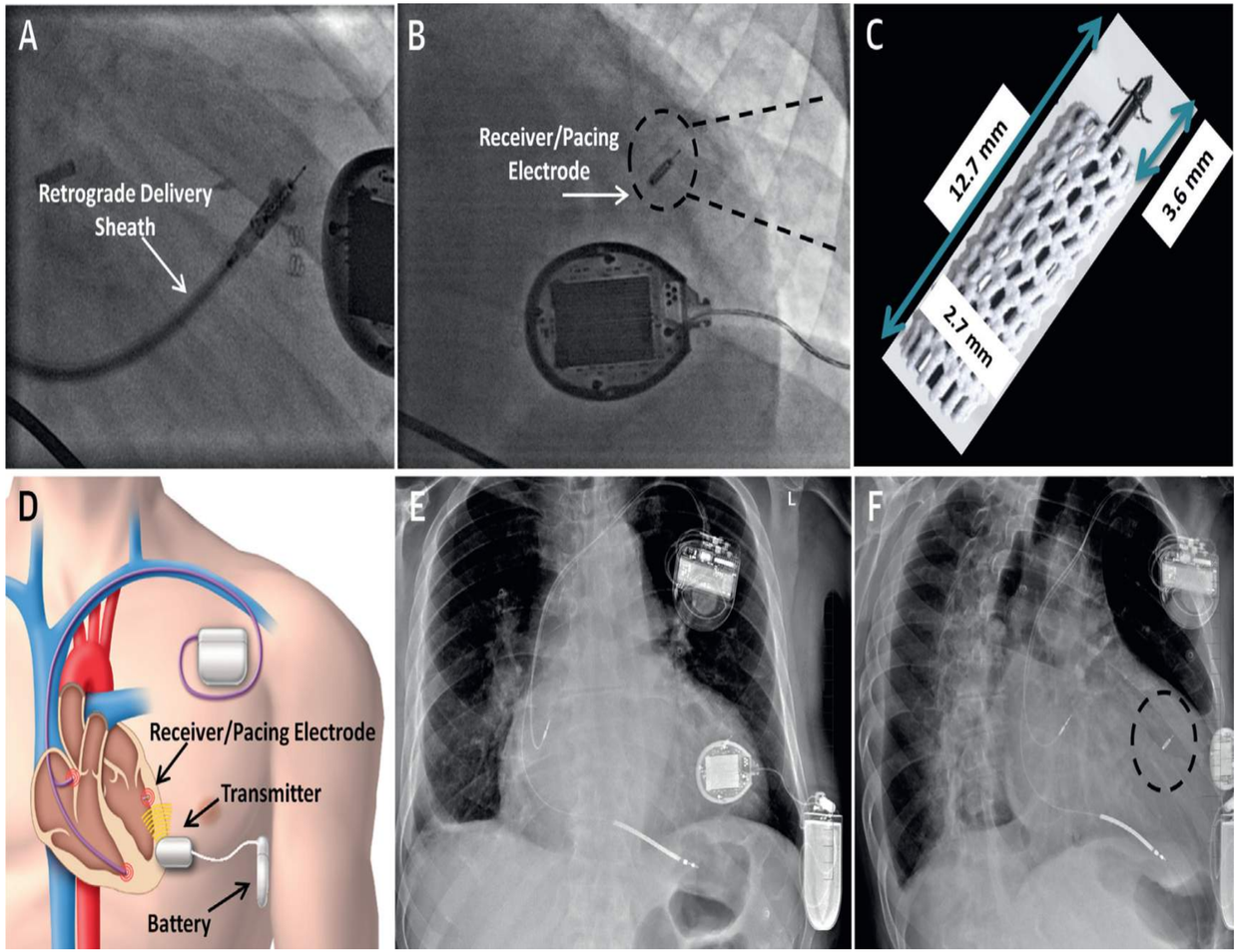
Mulpuru, S.K. et al. J Am Coll Cardiol. 2017;69(2):189-210.

CONCLUSIONI

- LE INDICAZONI ALLA STIMOLAZIONE SENZA FILI SI STANNO EVOLVENDO (vvi, vdd, ddd?, atp?)
- I DATI SULLE COMPLICANZE SONO OTTIMI IN CONFRONTO CON I PM TV ANCHE SE RIMANE QULACHE DUBBIO SULLA % PERFORAZIONI
- L'ESTRAIBILITA' POTREBBE FAVORIRE I SISTEMI A VITE ANCHE SE L'AUMENTO DELLA DURATA DELLA BATTERIA E LA POSSIBILITA' DI INSERIRE PIU' DI 1 DEVICE SEMBRA LA CHIAVE DI VOLTA NELLA SCELTA DI SPOSTARE L'INDICAZIONE VERSO ETA' PIU' GIOVANI

Cardiac Resynchronization Therapy With Wireless Left Ventricular Endocardial Pacing

The SELECT-LV Study



Reddy et al. J Am Coll Cardiol 2017;69:2119–29

The MARVEL study

Chinitz LA et al, Heart Rhythm 2018

- Accelerometer based atrial sensing is both feasible and significantly improves AV synchrony in patients with AV block and a single-chamber leadless pacemaker implanted in the RV
  - **improvements in AV synchrony led to improvements in stroke volume in AV block patients**
  - **AV synchrony was similar during postural maneuvers**
- AV synchrony was not compromised in patients with intrinsic AV conduction

The MARVEL 2 study

- To demonstrate the superiority of the algorithm to provide AV synchronous (VDD) pacing versus VVI 50 pacing in patients with sinus rhythm and complete AV block
- The primary safety objective was to demonstrate that the algorithm did not result in pauses or heart rate > 100 bpm

Steinwnder C et al. JACC Clin Electroph 2019

The MARVEL 2 study

- Improved median AV synchrony from 27% with VVI pacing to 94% in VDD pacing mode, with 95% of the cohort achieving **>70% AV synchrony pacing**.

- The VDD pacing algorithm improved ventricular performance 9% as measured by the **LVOT-VTI**

Steinwnder C et al. JACC Clin Electroph 2019

CENTRAL ILLUSTRATION: An Overview of the History of Cardiac Pacing

Paradigm Shifts in Cardiac Pacemakers

1950s
AC-powered pacemakers tethered to an extension cord (Furman)

1950s
Battery-powered transistorized "wearable" pacemakers (Lillehei/Bakken)

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First fully implantable pacemaker (Elmqvist/ Senning)

2015
Implantable pacemaker—basic system had not evolved significantly

2016
Leadless pacemaker—the entire device is placed within cardiac chambers

Future
Batteryless devices, which harvest cardiac motion to power pacing circuits

Mulpuru, S.K. et al. J Am Coll Cardiol. 2017;69(2):189-210.

The LEADLESS II IDE Study (Phase II): A Safety and Effectiveness Trial for a Leadless Pacemaker System

ClinicalTrials.gov Identifier: NCT04559945

Recruitment Status : Recruiting
First Posted : September 23, 2020
Last Update Posted : June 22, 2021

See Contacts and Locations

Sponsor:
Abbott Medical Devices

Italy

Centro Cardiologico Monzino
Milano, Italy
Contact: Claudio Tondo
Recruiting

Trial Details

The primary objective of the Leadless II IDE clinical study is to demonstrate that the Aveir™ leadless pacemaker is safe and effective for people who experience slower-than-normal heart rate and may receive a pacemaker to help restore a more normal heart rate.

The Leadless II IDE phase 2 study is a global prospective, multi-center, single arm study. The study will enroll 200 patients who need a VVI (R) pacemaker at up to 80 sites.

Primary Endpoints

The primary endpoints are to test the complication free rate and the composite success rate at 6 weeks post-implant.

Secondary Endpoints

The secondary endpoints include measuring an appropriate and proportional rate response during graded exercise testing (CAEP, or Chronotropic Assessment Exercise Protocol) and 6-minute walk test (MWT).

E GLI ALTRI?

LLPM VVI… when?

- LLPM are offered in first intention in case of:

(1) anticipated difficult vascular access,

(2) a history of complicated trans-venous PM,

(3) a pacing indication in a patient with permanent AF,

(4) an anticipated high risk of infection

But LLPM are more and more considered in patients with otherwise standard indications for single (and dual) chamber pacemaker implant

STORIA DELL'ELETTROSTIMOLAZIONE

1932

Albert Hyman creates first cardiac "artificial pacemaker"

AC-powered pacemaker units attached to an extension cord

1950

5800

First External Pacemaker

1958

5858

Pediatric Asynchronous Pulse Generator

1970

Activitrax™

Rate response

1986

MicroMinix®

Radically smaller size

1990

Thera ®

First Microprocessor-based, Mode switching

1995

EnPulse®

Full automaticity

2004

First Leadless Pacemaker

2015 est

1960

First Implantable Pacemaker

Chardack-Greatbatch

1979

Byrel®

1989

Dual chamber rate response

Synergist™

1991

Elite™

1998

Rate response via activity & minute ventilation

Kappa®

2006

MVP, Full automaticity

Adapta™

J. ELECTROCARDIOLOGY, 3 (3-4) 325-331, 1970

Special Article

Totally Self-Contained Intracardiac Pacemaker*

J. WILLIAM SPICKLER, PH.D., NED S. RASOR, PH.D.†, PAUL KEZDI, M.D.
S. N. MISRA, M.D., K. E. ROBINS, P.E., AND CHARLES LeBOEUF, P.E.

SUMMARY

Recent developments in miniature long-life power sources and electronics, such as nuclear batteries and integrated circuits make feasible a new generation of pacemakers, the intracardiac pacemaker (IC), i.e., a completely self-contained pacemaker implanted inside the right ventricle by transvenous insertion.

circuits have been improved substantially. I addition, the development of the endocardi catheter electrode has broadened the choi of operative procedures to include a larg portion of the patient population. Two maj problems that still exist with convention pacemakers are perforation or dislocation the transvenous electrode and the short life the batteries that are presently used. In addi

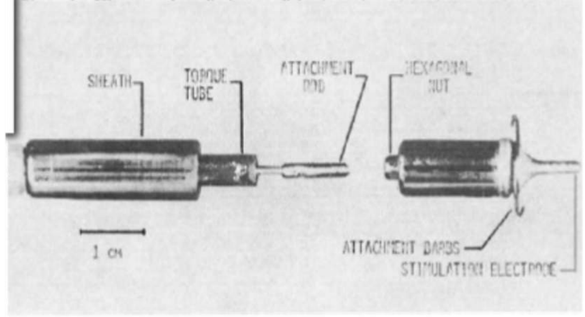


Fig. 4. Intracardiac pacemaker with catheter for transvenous insertion.

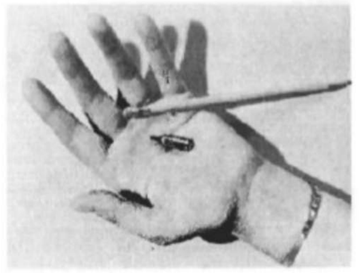
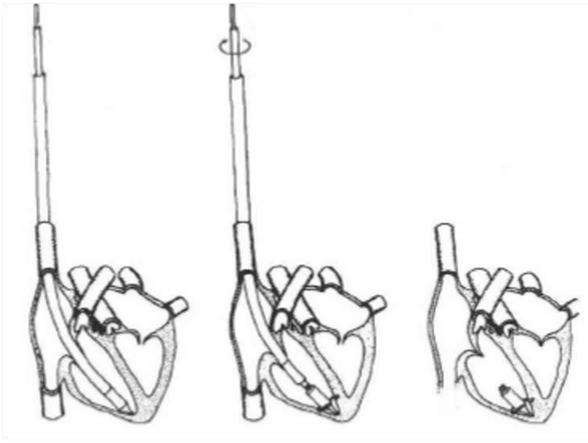
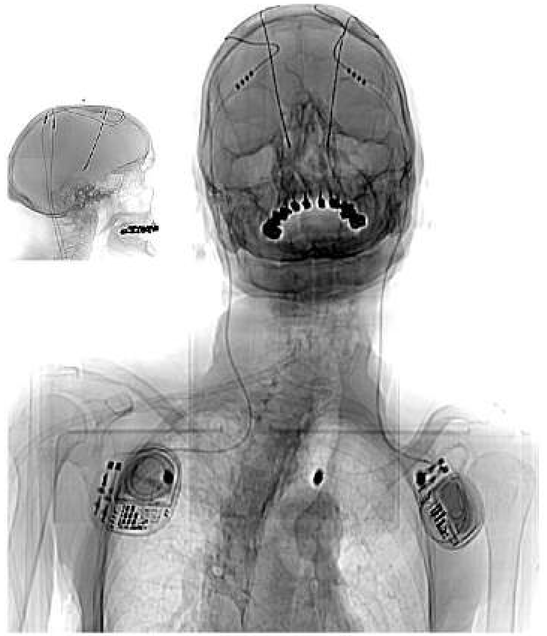


Fig. 8. Nuclear-powered intracardiac pacemaker.



DATI CLINICI - real life

L'esperienza pisana: pazienti speciali



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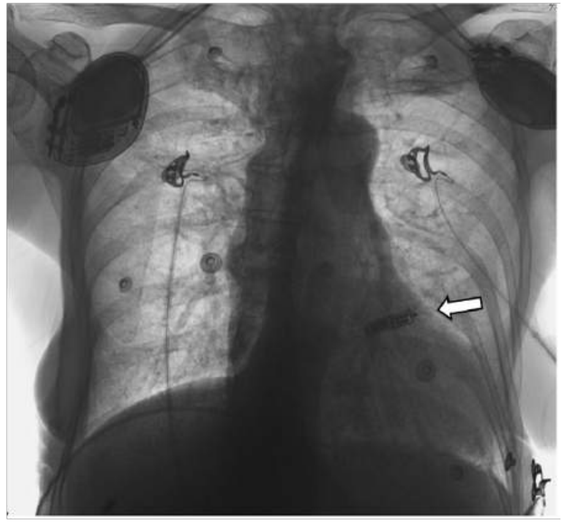
Correspondence

Leadless cardiac pacemaker implant in a patient with two deep brain stimulators: A peaceful cohabitation beyond prejudices

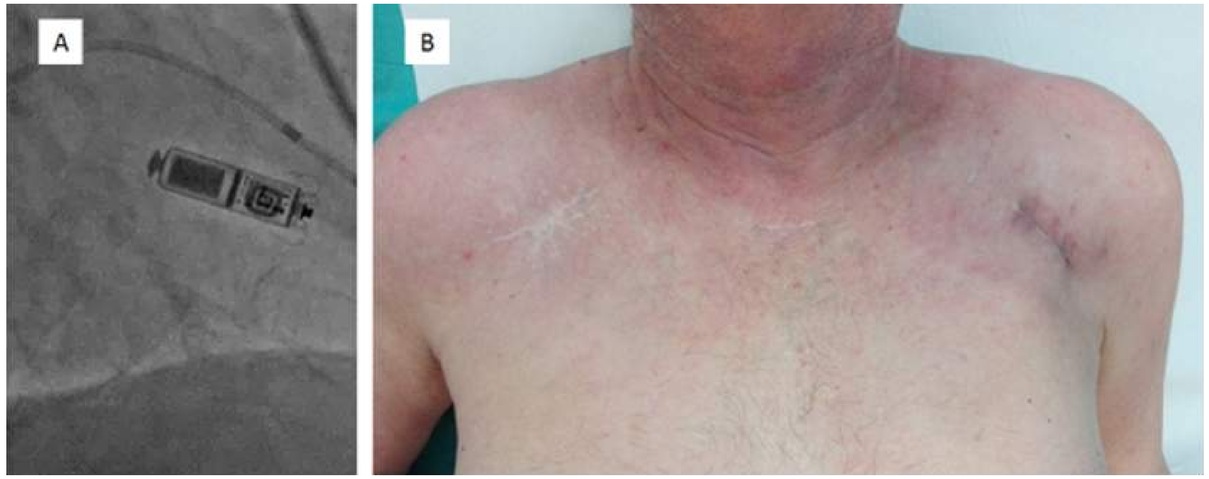
Maria Grazia Bongiorni [a,1], Giulio Zucchelli [a,1], Giovanni Coluccia [a,*,1], Ezio Soldati [a,1], Valentina Barletta [a,1], Luca Paperini [a,1], Francesca Menichetti [a,1], Andrea Di Cori [a,1], Luca Segreti [a,1], Eleonora Del Prete [b,1], Roberto Ceravolo [b,1]

[a] Cardiothoracic and Vascular Department, University Hospital of Pisa, Italy
[b] Department of Clinical and Experimental Medicine, Division of Neuroscience, University Hospital of Pisa, Italy



DATI CLINICI - real life

L'esperienza pisana: pazienti speciali



- uomo di 78 anni
- portatore di PM DDD per BAV
- espianto + reimpianto controlaterale
- sindrome della vena cava superiore

Contents lists available at ScienceDirect

Journal of Cardiology Cases

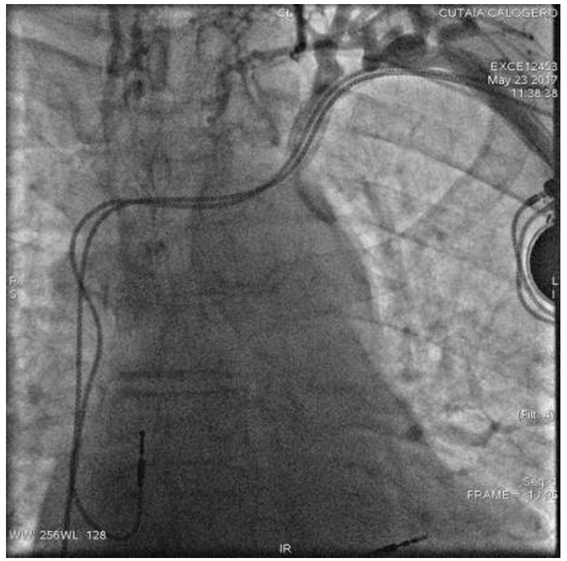
journal homepage: www.elsevier.com/locate/jccase

Case Report

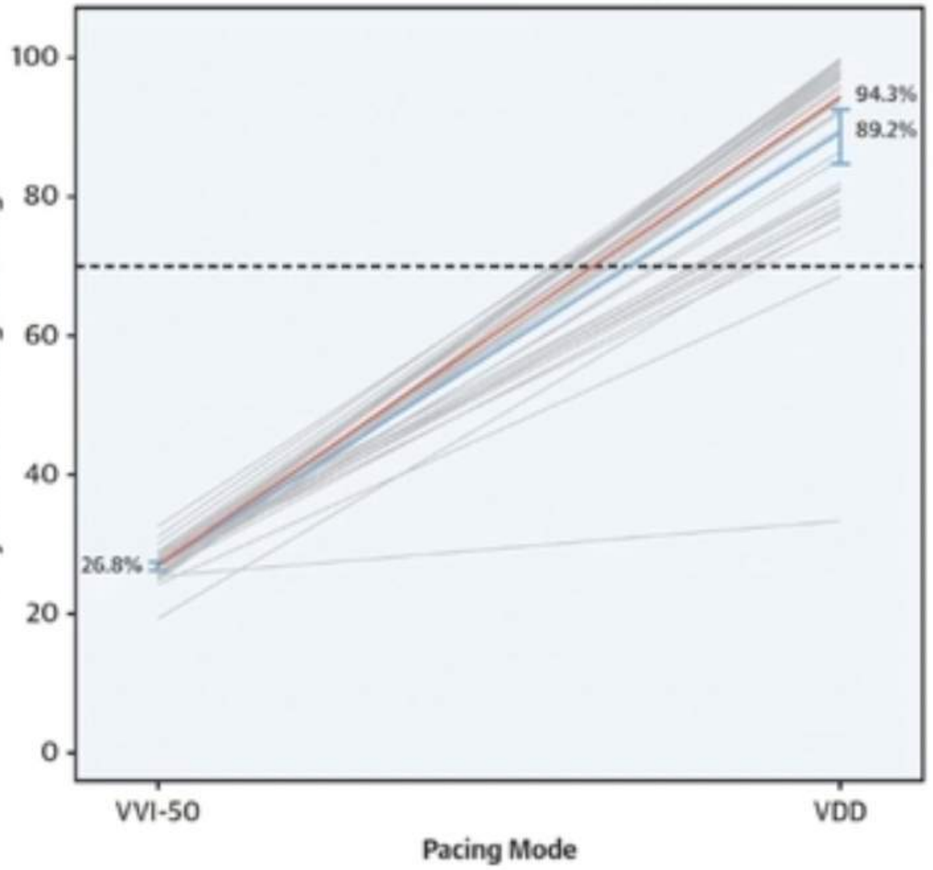
Leadless pacing in a patient with superior vena cava syndrome undergoing lead extraction and percutaneous angioplasty

Giulio Zucchelli (MD PhD), Elena Favilli (MD)*, Stefano Viani (MD), Valentina Barletta (MD), Andrea Di Cori (MD), Luca Segreti (MD), Maria Grazia Bongiorni (MD)

Cardiac Thoracic and Vascular Department – AOUP, Santa Chiara University Hospital, Pisa, Italy



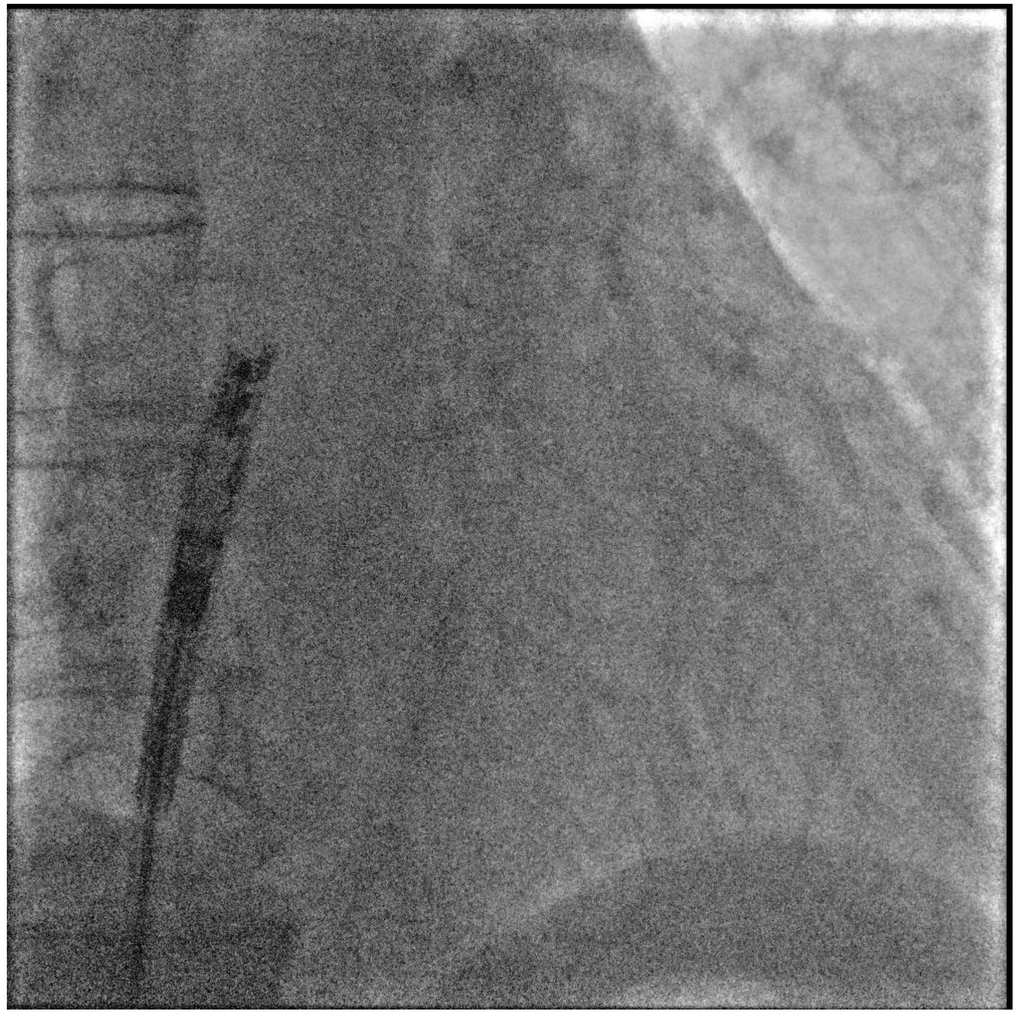
VVD leadless pacemaker leads to keep AV synchrony

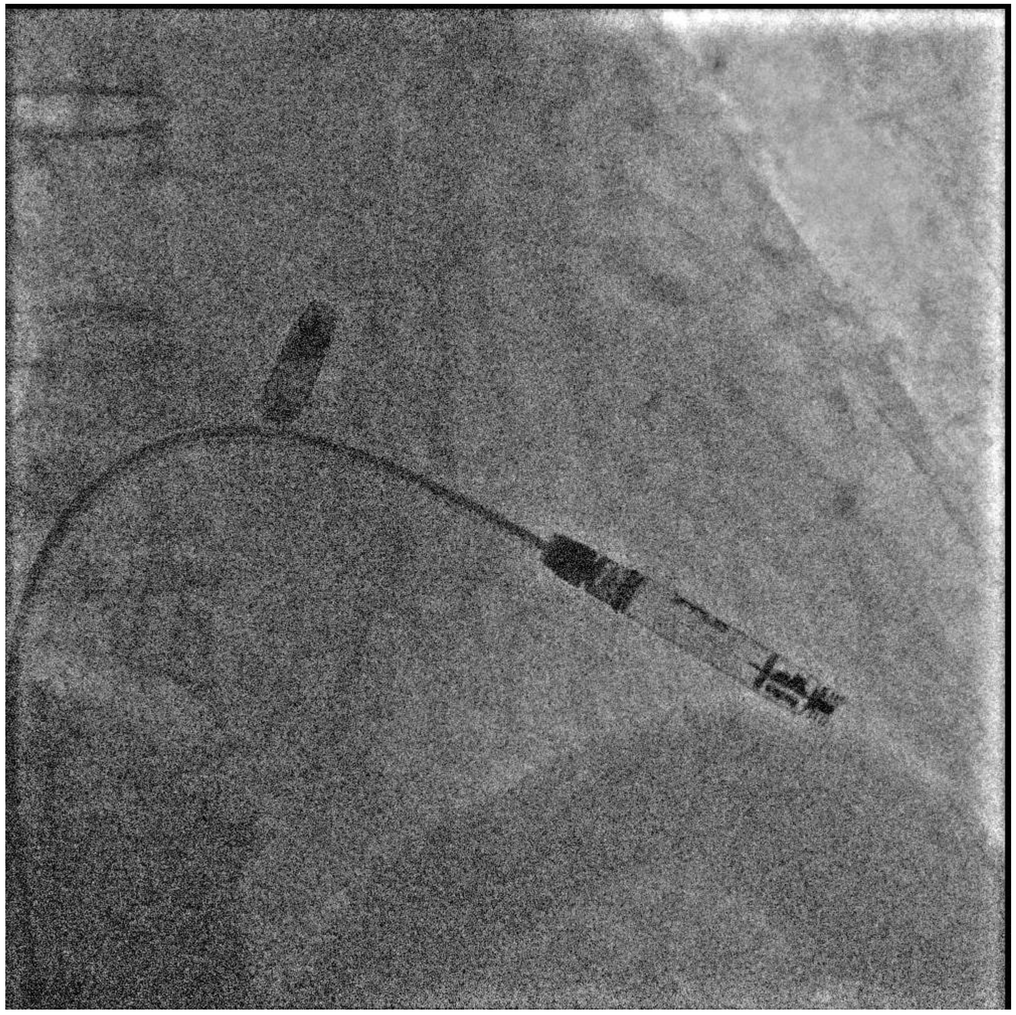


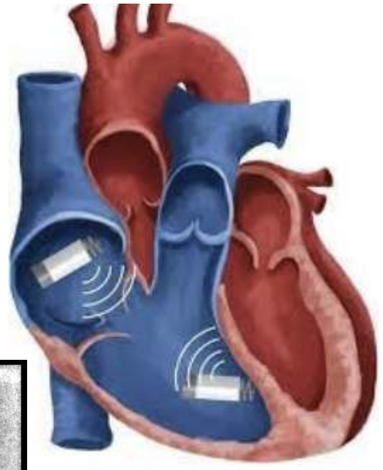
AV synchrony is increased from 27% using VVI mode to 89% using VDD mode

C.Steinwender et al., JACC EP, 2012

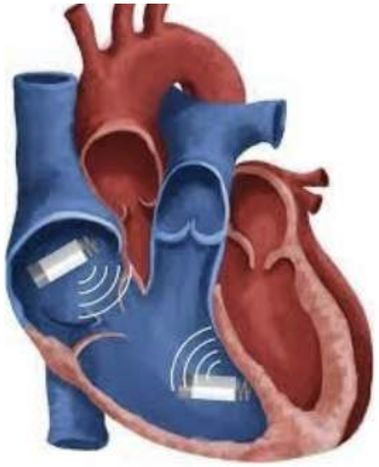
Ongoing AVEIR DR i2i STUDY
Up to 550 patients

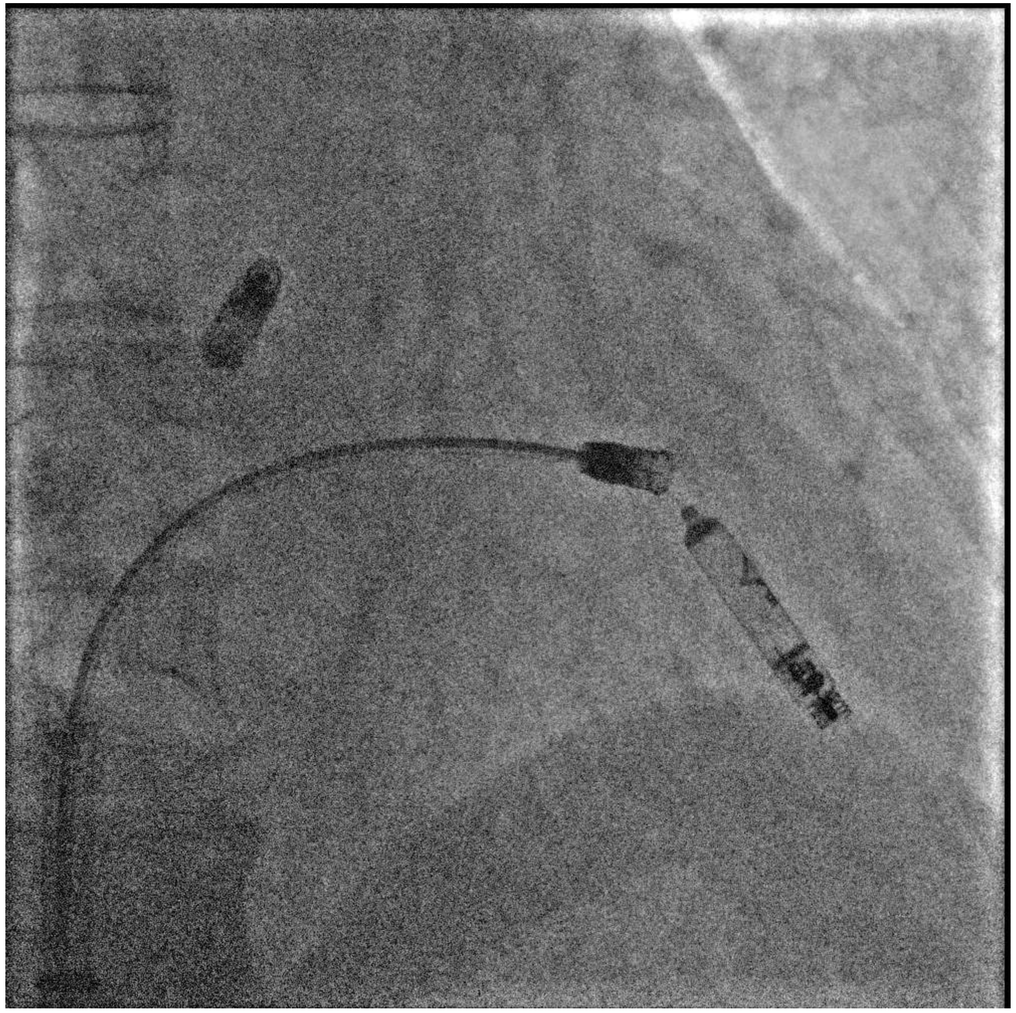






Ongoing AVEIR DR i2i STUDY
Up to 550 patients





The clinical journey of Micra™ AV leadless pacing

2018–2020

MARVEL

Demonstrate the ability to sense atrial contractions using the device accelerometer and provide AV synchronous pacing (download study with Micra VR).

MARVEL II

Determine the feasibility of an enhanced accelerometer-based algorithm to provide AV synchronous pacing (download study with Micra VR).

2022

AccelAV + Optimize Sub-Study

Report on the performance of an accelerometer-based algorithm that provides AV synchronous pacing.

2023+

Post-Approval Registry (PAR)

Evaluate performance in a global, real-world population; interim results through first 12 months; study will follow patients through 3 years.

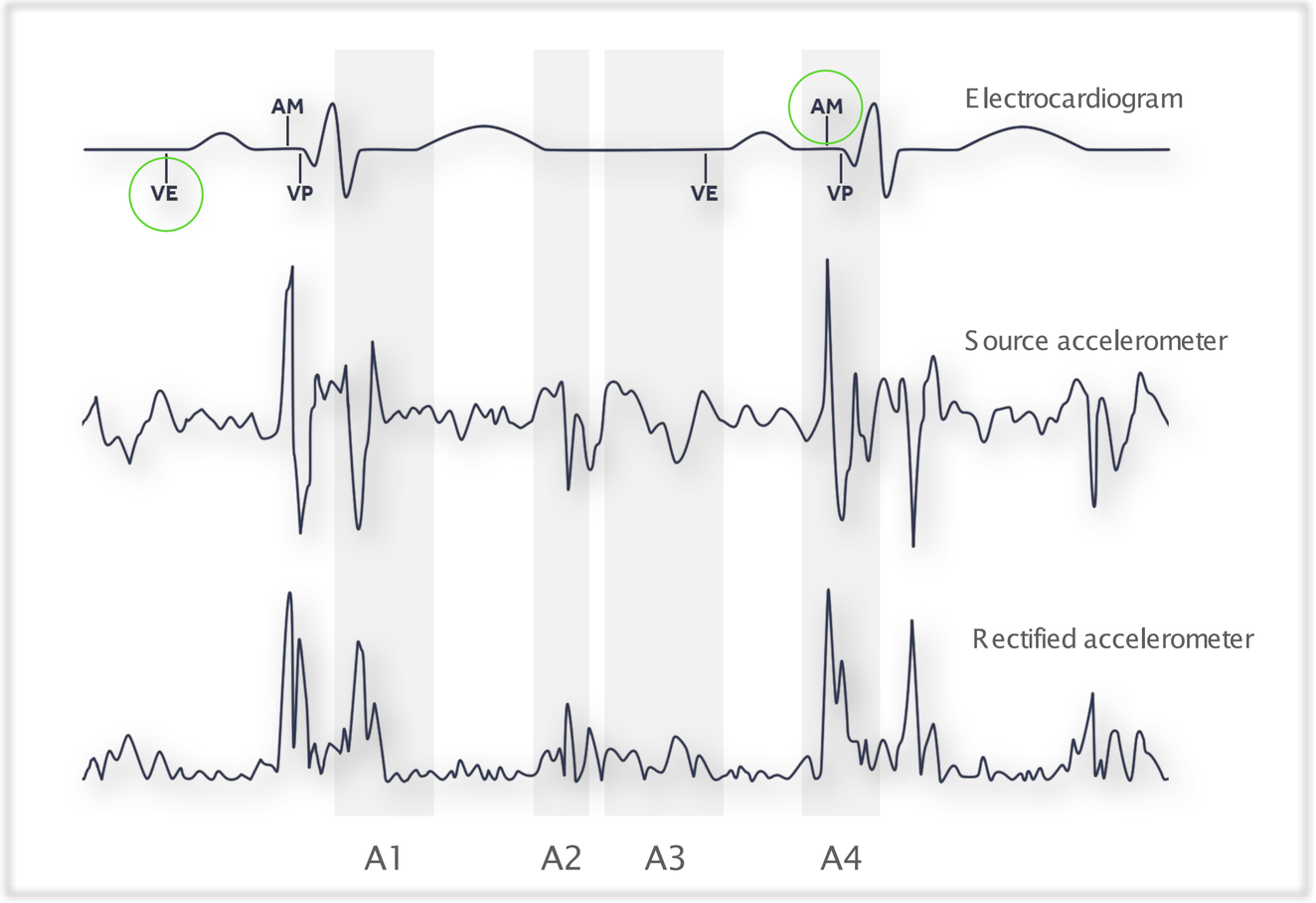
Coverage with Evidence Development (CED) **Evaluate performance in US Medicare population** via observational claims analyses.

Feasibility → Performance → Real-world

- **Micra™ VR and AV leadless pacemakers**

7,600+ physicians trained, 200+ manuscripts published, and 17,000+ patients followed in research activities[5]

Micra™ AV's accelerometer detects mechanical atrial activity and uses this information to deliver AV synchronous ventricular pacing.



Ventricular end (VE) marker
End of the A1–A3 ventricular-event signals

Atrial mechanical (AM) marker
Marker that indicates the device detected the atrial mechanical contraction or A4

A1
Start of ventricular systole, mitral and tricuspid valves close

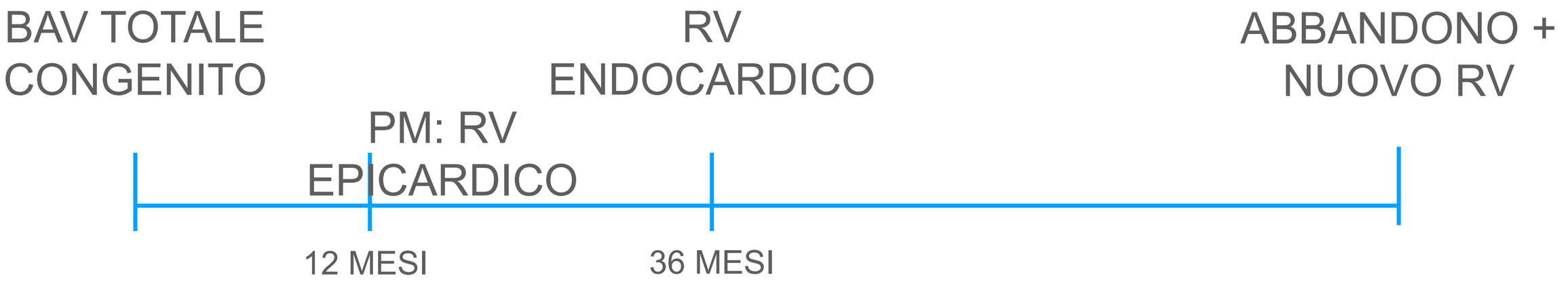
A2
End of ventricular systole, aortic and pulmonic valves close

A3
Diastole, passive blood flow from A to V, corresponds to E-wave on Doppler echo

A4
Atrial systole, blood pushed into ventricles,100ms electromechanical delay, corresponds to A-wave on Doppler echo

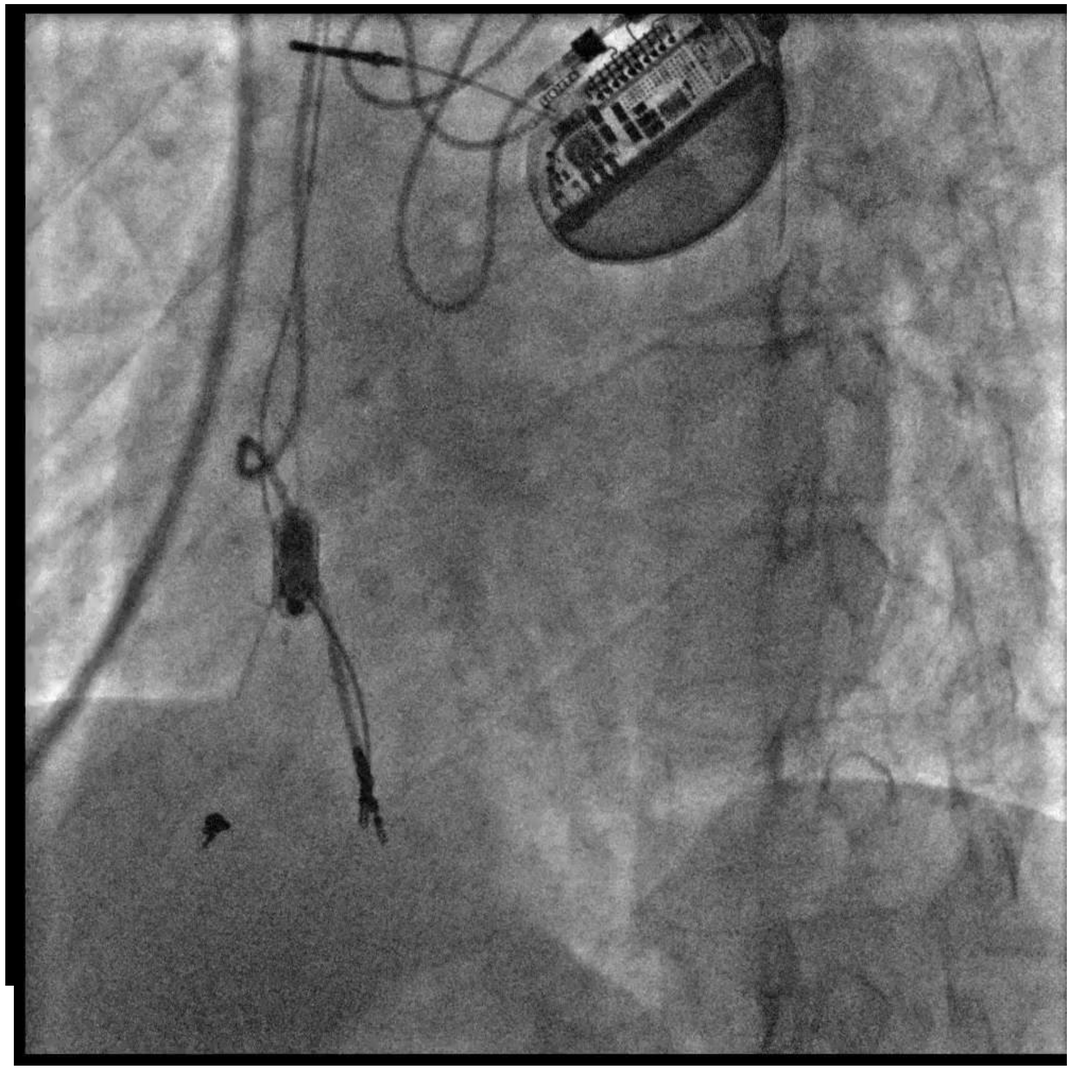
- L. D. ♂ 28 anni

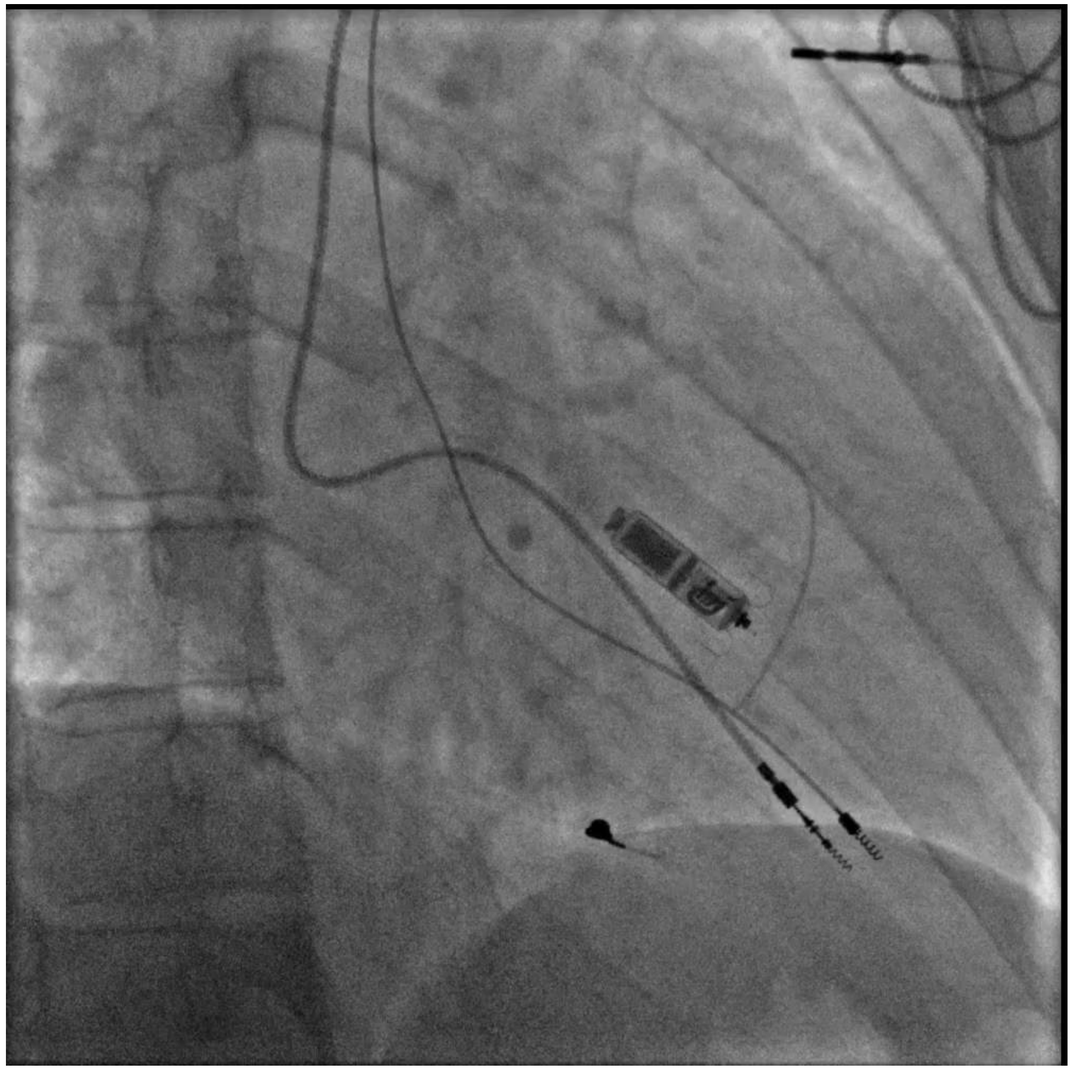
- ccTGA
- Blocco atrioventricolare completo congenito



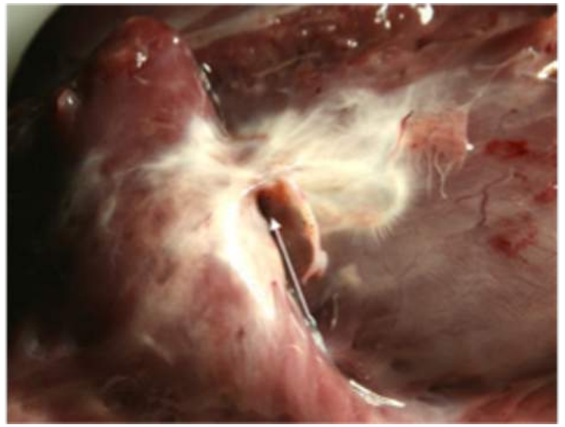
- Controllo PM:
  - Soglia RV: 2,5V/0,24 ms
  - Impedenza RV: 400 Ohm

  - Contrazioni m. pettorale riproducibili (bipolare)
  - Riferito c/o ns. centro

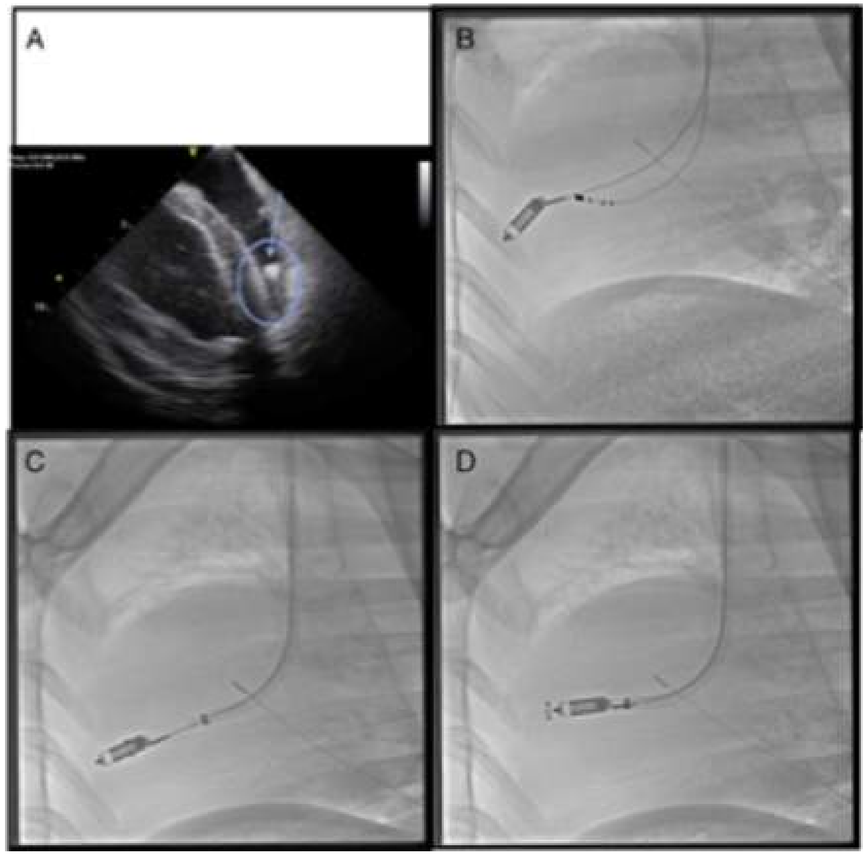




ESTRAIBILITA'



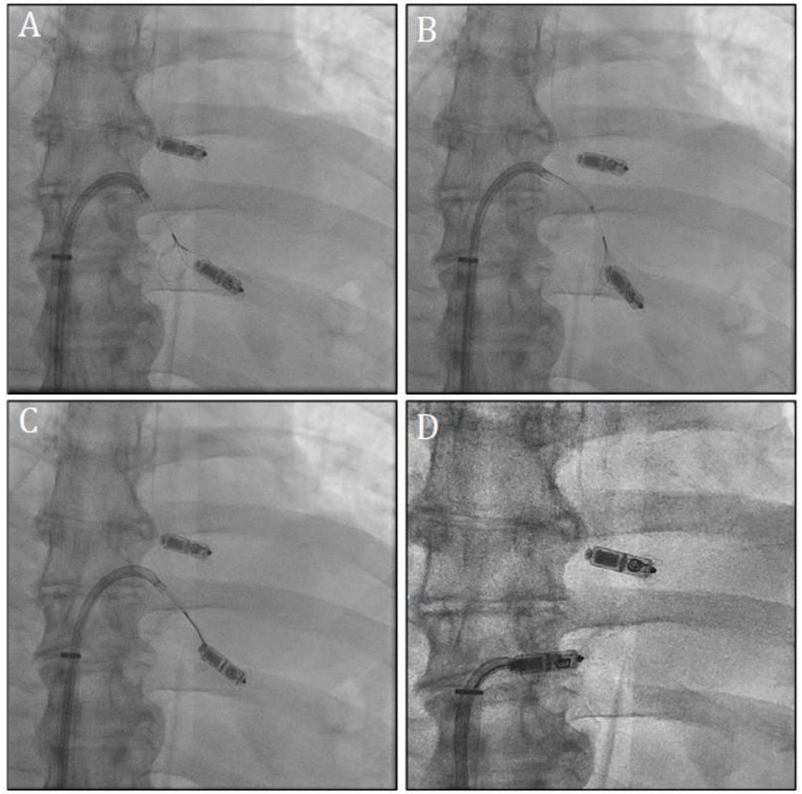
'YOU GET OUT WHAT YOU PUT IN'



Micra device has been successfully retrieved after 28 months in chronic animal models using a custom sheath combined with market-released tools

Bongiorni MG et al. Heart Ryhthm Case Report 2016

ESTRAIBILITA’



Afzal et al. Heart Rhythm 2018

“The most common reason for immediate retrieval was elevated pacing threshold after tether removal.

The most common reason for delayed retrieval included elevated pacing threshold at follow-up, endovascular infection, and need for transvenous device”

ELSEVIER

Heart Rhythm

Volume 15, Issue 6, June 2018, Pages 841-846

Clinical
Devices

Techniques for successful early retrieval of the Micra transcatheter pacing system: A worldwide experience

Muhammad R. Afzal MD *, Emile G. Daoud MD, FHRS *, Ryan Cunnane MD †, Shiva K. Mulpuru MD ‡, Alan Koay MD §, Azlan Hussain MD §, Razali Omar MD, FHRS §, Koh Kok Wei MD §, Anish Amin MD ¶, Gregory Kidwell MD ¶, Nirav Patel MS ||, Charles Love MD, FHRS **, Michael Lloyd MD, FHRS ††, Maciej Sterliński MD ‡‡, Seth Goldbarg MD, FHRS §§, Miguel A. Leal MD, FHRS ¶¶, James Gabriels MD ||||, Apoor Patel MD |||| … Ralph S. Augostini MD, FHRS *

Show more

https://doi.org/10.1016/j.hrthm.2018.02.008

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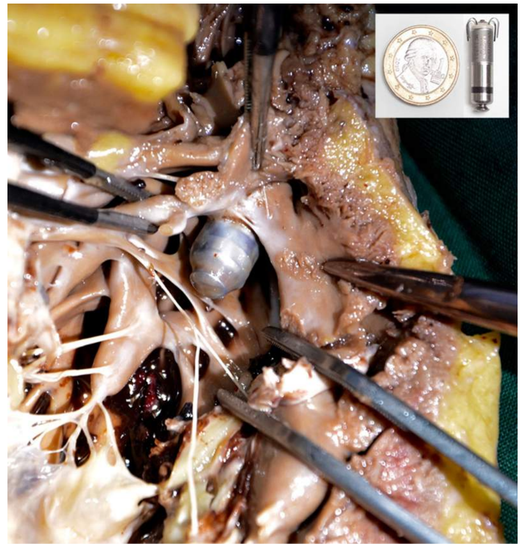
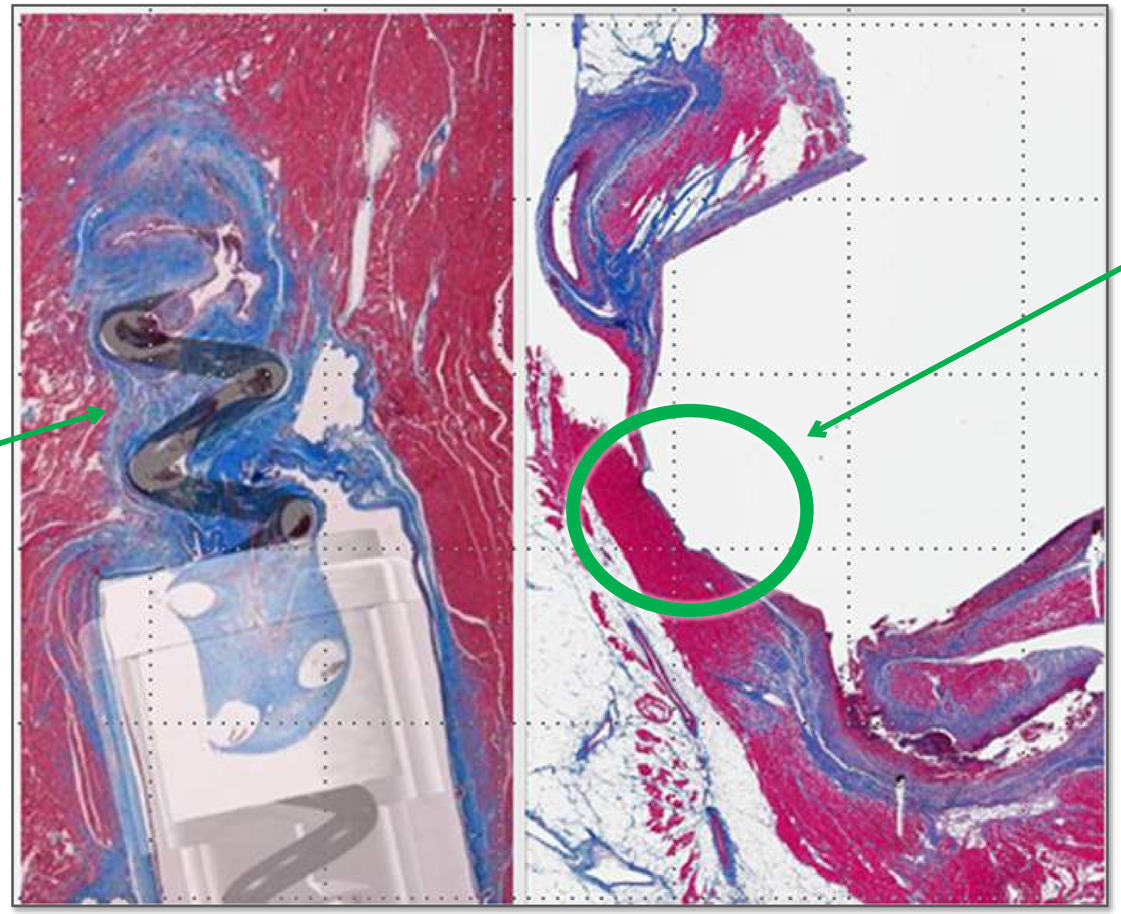


DATI CLINICI - Istologia

Meccanismo di fissaggio separato dall'elettrodo

Fibrosi



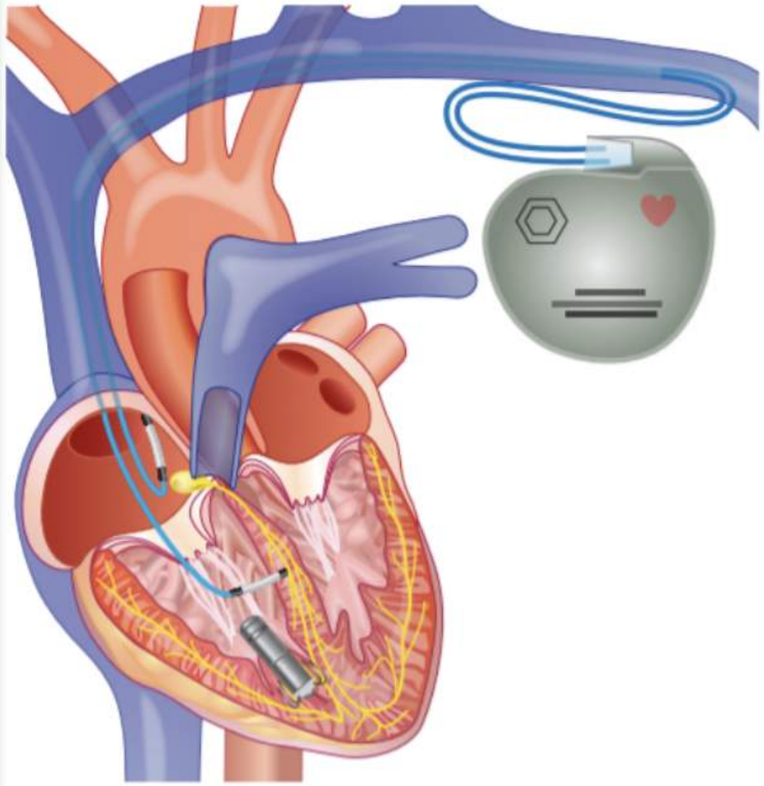
Histology of lead helix

Histology of Micra

Pros and cons of leadless pacing compared to transvenous pacing

Pros

- No generator pocket issues
- No lead-related complications
- Useful in case of venous access issues
- Probably lower risk of device infection
- Patient comfort and esthetics
- Lower incidence of mid/long-term complications



Cons

- Requirement for high-resolution fluoroscopy at implantation
- No atrial pacing
- Imperfect AV synchrony (Micra AV)
- Limited diagnostic features
- No conduction system pacing
- No wireless remote monitoring
- Higher cost
- Limited retrievability
- Higher incidence of short-term complications

Burri, Eur Heart J, 2022 Mar 21;43(12):1216-1218